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June 2012 Volume 7 • Number 5

HAZCOM 2012

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Summer is almost upon us and that means *Lab Manager Magazine's* August 2012 Product Resource Guide isn't far off either. Our summer guide will feature an all-new design to help you quickly and easily find all you need to know about the roughly 60 product categories set to appear in the publication. Also, instead of technical articles, you'll get easy-to-grasp blocks of key information necessary for making the best buying decisions, including the right questions to ask when shopping for particular technology. We'll also including our most up-to-date manufacturer lists as well as a selection of recently released products in each category to give you a taste of what's new and where you can get it. Our goal with the new layout is to provide you with a quick reference tool to help you make the best decisions on new equipment for your lab. Look forward to getting your hands on this resource in early August!

MAGAZINE

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Managing Projects

According to PMI (the Project Management Institute), project management is the application of knowledge, skills and techniques to execute projects effectively and efficiently. It is a strategic competency for organizations, enabling them to tie project results to business goals—and thus, better compete in their markets." While it might not be a lab manager's distinct profession, basic project management skills and techniques certainly find application in most modern research facilities. If you manage one of those facilities, turn to page 22 for John Borchardt's five rules for successful project management. As with so many other management tasks, it is no surprise that communication is the critical component.

The importance of sound project management practices in the lab is echoed in this month's "Science Matters" column (page 20), in which Alan Edwards tells us, "When a lab can effectively adopt a work project model, it is embracing a spirit of teamwork and already a step ahead in adapting to the new business reality of the sciences."

In addition to management skills, making the right buying decisions is equally important in running a lab. For that we provide product focus reports this month on centrifuges, PCR reagents, freeze dryers and electronic lab notebooks. Complementing the ELN report is this month's "Ask the Expert" column (page 40), in which Tanuja Koppal talks to two scientists—one from pharma and the other from academia—about their experiences transitioning from paper to ELNs. Issues such as ease of use, customization, integration, and security are all discussed by these steely-eyed end users. In addition, this month's Technology & Operations piece, "Building Transparency—A Top-Down View" (page 36), discusses a real-world project designed to gain efficiencies through the integration of electronic laboratory notebook (ELN) systems.

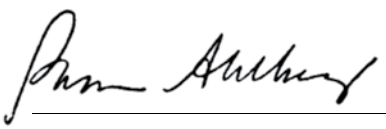
Another important technology that is having or will have an impact on scientific efficiency and productivity is cloud computing. In this month's feature, "Concerning the Cloud," author Mike Weaver says that the true disruptive technology that is emerging from the cloud is data—lots of it and that this Big Data is the offspring of the cloud's main advantage: collaboration. "The collaborative potential in the cloud has woven together relationships like nothing the world has ever seen, expelling an hourly exhaust of terabits of data. Big Data may be defined as the analytical crunching of this massive amount of data into meaningful business productivity. The result: a true competitive edge," says Weaver.

Integrated ELNs, cloud computing, ERP (Enterprise Resource Planning), Big Data, and high performance computing are the kinds of topics we plan to cover more thoroughly for the remainder of this year and next, when we launch an editorial section devoted exclusively to important scientific computing and lab automation topics.

Speaking of future editorial topics, we are currently at work on our 2013 editorial calendar and are very grateful to those of you who recently participated in our Readership Survey. Your comments and suggestions will help us identify topics of interest that matter most to readers. So thank you very much for that important feedback. For those who did not participate in the survey, feel free to send any and all suggestions to me directly (pam@labmanager.com).

We hope you find this month's cover story about OSHA's new Hazard Communication standard timely and useful as you set about to prepare your lab accordingly. Fortunately, you have some time, but best not to procrastinate too long.

Cheers,



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WHAT LAB MANAGERS NEED TO KNOW ABOUT NEW LABELING, COMPLIANCE DATES, MSDS, TRAINING AND MORE

by Vince McLeod

Working in the safety and health field, I knew that OSHA rules took a long time to develop and perhaps longer to change. I did not really think about how long it took or why. I just knew that in my thirty-plus years of protecting workers and watching OSHA that developing new rules or strengthening/updating existing ones was a long process. Then I came upon Leo Gerard's article about how these delays in rule making are costing lives.[1] At least a dozen lives per day! And, as Mr. Gerard points out, these are lives taken, not given, because, and I love this quote, "no one volunteers to sacrifice their life for corporate profit."

> "The new Globally Harmonized System aims to reduce confusion about chemical hazards in the workplace, improve the understanding of hazards, & help with safety training."

So, how long does it take OSHA to develop and issue safety and health standards? The Government Accountability Office (GAO) found a wide range of rule-making timelines, the shortest being 15 months and the longest 19 years.[2] On average, it took OSHA seven years and nine months to issue a final standard! But perhaps more important, it is getting worse. The time it took to finalize standards in the 1990s was 70 percent longer than in the 1980s. And it was another 30 percent longer in the 2000s.

Why does it take so long for OSHA to issue a new standard, and why has it been getting harder in recent times? Agency officials at the GAO and outside experts cite several key factors. The major ones are the increased number of procedural requirements put in place since 1980 and the high standard of judicial review that is needed. The main components of necessary procedures encompass the significant data challenges and complex requirements for OSHA to demonstrate the need for the new regulations. Data challenges range from a lack of available scientific data for some hazards to having to review and evaluate many scientific studies. Where available data is scarce, OSHA has limited access to worksites to collect the necessary information to demonstrate the need for a new standard. Perhaps the biggest hurdle of all is having to show economic feasibility, where OSHA must demonstrate that affected industries will be able to maintain long-term profitability and competitiveness.

But the GAO report points out that OSHA standards save lives, citing a 55 percent reduction in machine-related deaths between 1990 and 1997 due to OSHA's lockout/tagout standard as one example. Another example is OSHA's revision of the Hazard Communication standard, which is the subject of this article. The revised standard incorporates the United Nations Globally Harmonized System (GHS) for hazardous chemicals and will protect workers from dangerous chemicals while also helping American businesses compete worldwide. OSHA estimates that the revised standard, now aligned with the UN's global chemical labeling system, will save an additional 43 lives annually. In addition, American businesses will save an estimated $475.2 million due to enhanced productivity.[3]

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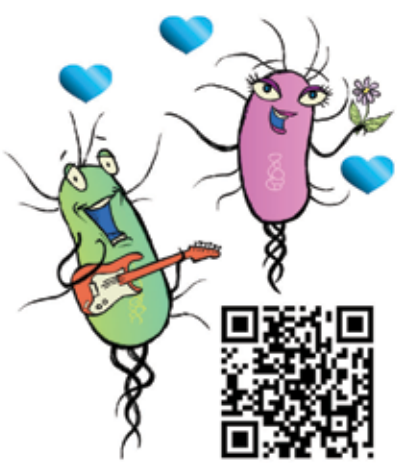

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A new Hazard Communication standard—with GHS

The goal of the revised Haz Comm, as it is affectionately known, is to better protect workers from hazardous chemicals. According to Secretary of Labor Hilda L. Solis, "Revising OSHA's Hazard Communication standard will improve the quality, consistency, and clarity of hazard information that workers receive, making it safer for workers to do their jobs and easier for employers to stay competitive in the global marketplace."[3] The changes were made to incorporate the best from the United Nations' Globally Harmonized System of Classification and Labelling of Chemicals, also known as GHS. The new Globally Harmonized System aims to reduce confusion about chemical hazards in the workplace, improve the understanding of hazards, and help with safety training. The changes were long overdue as the existing standard approaches its thirtieth birthday. Assistant Secretary of Labor for Occupational Safety and Health Dr. David Michaels said it well: "OSHA's 1983 Hazard Communication standard gave workers the right to know. As one participant expressed during our rule-making process, this update will give them the right to understand as well." [3]

Definition of GHS and its history

The Globally Harmonized System is not a regulation or a mandatory standard. It is a system for standardizing or harmonizing information on dangerous chemicals *internationally*. The purpose of GHS is to create a logical, comprehensive, and standardized system to communicate information about chemical hazards to workers, employers, consumers, emergency responders, transporters, and anyone who might come in contact with these materials worldwide.

The Globally Harmonized System was needed because from country to country and even just in the United States confusion exists in communicating about chemical hazards. The confusion stems from many different classification systems, using many different symbols, colors, shapes, and pictograms. In the US (and throughout the world) there are many different material safety data sheets. It is not hard to understand the need.

The birth of the Globally Harmonized System was in 1992 at the United Nations Conference on Environment and Development. Called the "Earth Summit," UNCED adopted an international mandate calling for "a globally harmonized hazard classification and compatible labeling system, including material safety data sheets and easily understandable symbols … by the year 2000."[4] The International Labor Organization studied the tasks needed to achieve harmonization and identified four major systems that would form the basis for a GHS: United Nations Transport Recommendations; United States Requirements for Workplace, Consumer, and Pesticides; European Union Dangerous Substance and Preparations Directives; and Canadian Requirements for Workplace, Consumers, and Pesticides. A coordinating group was created to manage development of the system. This working group was the Inter-Organization Program for the Sound Management of Chemicals, or IOMC. Work on GHS chugged along for about ten years until September 2002, when the World Summit on Sustainable Development encouraged countries to begin using the new GHS with a goal of full implementation by 2008. The IOMC presented the GHS to the United Nations GHS Subcommittee, which formally adopted the system in December 2002. It was published as the *Globally Harmonized System of Classification and Labelling of Chemicals* and became known as the "Purple Book."[4] Its fourth revision was just completed at the end of 2011.

OSHA actions

Looking at the development of the Haz Comm revisions to align with the new Globally Harmonized System, OSHA beat its average. Where the GAO found that it took OSHA an average of seven years and nine months to produce a final rule, changes to the Hazard Communication standard required just nine actions stretching between September 2006 and February 2012 to become law.[5] A relatively short five years and five months.

In brief, the process looks like this:

- OSHA issues Advanced Notice of Proposed Rulemaking in September 2006.
- After receiving and considering more than 100 comments, OSHA issues a Notice of Proposed Rulemaking in September 2009.
- Following another comment period, public hearings are held and completed in May 2010.
- Final Rule is published in the Federal Register in March 2012.
- Final Rule provisions took effect in May 2012.

According to the preamble and introduction in the Federal Register, OSHA says, "The adoption of the GHS will improve OSHA's current HCS by providing consistent, standardized hazard communication to downstream users."[5] OSHA does recognize that the GHS is evolving

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and will continue to be updated in the future to reflect new technological and scientific developments. Unfortunately, OSHA clearly points out that "Any future changes to the HCS to adopt subsequent changes to the GHS would require OSHA's rule-making procedures." [5] Thus keeping up with change will be tedious.

What has changed?

Before we discuss the revisions to OSHA's Hazard Communication standard, let us briefly review what Haz Comm is. There are three main components to this "information" standard: labels, material safety data sheets, and employee training. Chemical labels provide an immediate and conspicuous summary of the substance's hazards. When you pick up the container you can readily see what dangers are present. The material safety data sheets provide more detailed technical information on hazardous ingredients, chemical properties, precautions for use, disposal, and so on. The MSDS are an important reference for exposed employees, safety professionals, industrial hygienists, emergency responders, and health care professionals. Finally, training is required to ensure that employees understand the hazards and know the protective steps to take to avoid exposure, illness, and injury.

As the title of the Purple Book says, the GHS is simply a system for classification and labeling of hazardous chemicals. It provides comprehensive lists of hazard classes for physical and health hazards. Each class is further defined with categories, ranks, types, or divisions with very specific criteria. There are 16 physical hazard classes (see Figure 1) and ten health hazard classes (see Figure 2) plus an environmental hazard class. OSHA expects that all existing hazard communication systems will change to be consistent with the harmonized elements of the GHS.[6]

Figure 1. Physical Hazards

- Explosives
- Flammable Gases
- Flammable Aerosols
- Oxidizing Gases
- Gases Under Pressure
- Flammable Liquids
- Flammable Solids
- Self-Reactive Substances
- Pyrophoric Liquids
- Pyrophoric Solids
- Self-Heating Substances
- Substances which, in contact with water emit flammable gases
- Oxidizing Liquids
- Oxidizing Solids
- Organic Peroxides
- Corrosive to Metals

Figure 2. Health Hazards

- Acute Toxicity
- Skin Corrosion/Irritation
- Serious Eye Damage/Eye Irritation
- Respiratory or Skin Sensitization
- Germ Cell Mutagenicity
- Carcinogenicity
- Reproductive Toxicology
- Target Organ Systemic Toxicity - Single Exposure
- Target Organ Systemic Toxicity - Repeated Exposure
- Aspiration Toxicity

Figure 4. GHS Pictograms and Hazard Classes

- Oxidizers

- Acute toxicity (severe)

- Carcinogen
- Respiratory Sensitizer
- Reproductive Toxicity
- Target Organ Toxicity
- Mutagenicity
- Aspiration Toxicity

- Flammables
- Self Reactives
- Pyrophorics
- Self-Heating
- Emits Flammable Gas
- Organic Peroxides

- Corrosives

- Environmental Toxicity

- Explosives
- Self Reactives
- Organic Peroxides

- Gases Under Pressure

- Irritant
- Dermal Sensitizer
- Acute toxicity (harmful)
- Narcotic Effects
- Respiratory Tract
- Irritation

The revised Haz Comm mandates changes to three main elements: hazard classification, product labels, and material safety data sheets. All requirements within existing regulations must be modified to align with the GHS. Current hazard determinations are performance-based. Under the revised Haz Comm, hazard classification will follow the specific criteria of the GHS. Chemical producers, manufacturers, and importers must change their labels to include the harmonized signal word ("danger" or "warning"), pictograms, and hazard statements for each hazard class. For an example of the new label format, see Figure 3. The nine pictograms relating to the hazard classes are seen in Figure 4. The third major change required by the new Haz Comm is that MSDS must follow the new sixteen-section safety data sheet (SDS) format. The Globally Harmonized System SDS format is very similar to the American National Standards Institute (ANSI) format discussed in a previous article on MSDS.[7]

Figure 3.

How long do we have to comply?

The revised Hazard Communication standard has an effective date of May 25, 2012. But although the rule is in effect, changes do not occur overnight, and OSHA has built in adequate time for completing each task. Employers have until December 2013 to train employees on the new label elements and safety data sheet format. And they have until June 2016 to fully implement all aspects of the new Haz Comm, including hazard classification, new labeling, and training. Chemical producers, manufacturers, importers, and distributors have until June 2015 to fully comply with modifications required by the GHS, with one exception. They may continue to ship products with the current labels until December 2015.

So, embrace change. These are for the best and should have a positive effect both on worker safety and company bottom lines. Get moving, but remember—stay safe!

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***Vince McLeod** is an industrial hygienist certified by the American Board of Industrial Hygiene and the senior industrial hygienist in the University of Florida's Environmental Health and Safety Division. He has 22 years of occupational health and safety experience at the University of Florida, and he specializes in conducting exposure assessments and health-hazard evaluations for the university's 2,200-plus research laboratories.*

STREAMLINING THE CHEMICAL INVENTORY PROCESS

A COST-BENEFIT CASE STUDY EXPLAINS THE BENEFITS OF IMPLEMENTING MATERIAL TRACKING SOFTWARE USING BAR CODE TECHNOLOGY

by Darryl Braaksma

Darryl Braaksma is a senior business and financial consultant for ChemSW. He has more than 25 years of experience serving a major corporation in research and analytical laboratory, environmental management and financial comptroller roles. Braaksma has implemented and managed financial programs for global service cost distribution and recovery, served as the IT project manager to manage environmental liabilities and reserve forecasts for Superfund and RCRA programs, and served as a lead project chemist for establishing a state-certified testing and analytical laboratory for the testing of hazardous waste and wastewater in California. He has a postgraduate degree in pharmacology from the University of California, Santa Barbara, and an MBA from Saint Mary's College of California.

In March 2012, *Lab Manager Magazine* along with ChemSW, Inc. hosted a "Product Spotlight" webinar—"How to Calculate the Costs and Quantify the Financial Benefits of Chemical Inventory Management." Darryl Braaksma, senior financial analyst at ChemSW, gave a presentation on ways in which laboratories can streamline their processes and manage chemical inventory more efficiently. He presented the results of an in-depth survey of customers using ChemSW's CISPro™ chemical inventory system and discussed a cost-benefit case study that explained how laboratories can calculate their own return on investment (ROI). The live webinar was attended by an international audience from diverse industries. Following the presentation, attendees were able to ask questions and voice their concerns. This event provided them with a unique opportunity to interact with ChemSW's expert and to seek his guidance and advice on various issues related to chemical inventory management. The event was moderated by Tanuja Koppal, Ph.D., contributing editor for *Lab Manager Magazine*.

Q: What are some of the key challenges of chemical inventory management?

A: Many organizations are tracking their chemical inventories on paper or with basic spreadsheet programs or with legacy in-house solutions. Unfortunately, these solutions are often inefficient and typically cannot provide accurate, real-time information. When a researcher needs materials and the inventory data is incorrect or the material is not available, the lab's workflows are compromised. Lack of accurate information concerning chemical inventory also affects the organization's ability to manage chemical costs efficiently, which can lead to underestimating or overestimating the resources required. Getting chemical inventory under control enables the organization to become much more efficient.

Q: What can be done to tackle some of those challenges and make processes more streamlined and efficient?

A: Simply knowing what chemical inventory is on hand and where it is eliminates a lot of management headaches and regulatory scrutiny. This can be accomplished with a best-practices chemical inventory management system, such as CISPro, that employs bar code technology to provide accurate, real-time chemical container data that is integrated with material safety data sheet (MSDS) management and addresses regulatory requirements for chemical management and reporting.

Q: Can you share with us some of the details and key findings of the recent survey that you conducted?

A: Our survey of CISPro users examined the changes in operational and inventory management efficiencies that resulted from CISPro implementation. Quantitative questions were asked about management processes to measure the changes before and after the implementation of CISPro.

The results revealed efficiencies of 14 value metrics in the areas of chemical inventory reporting, chemical inventory management, MSDS management, chemical procurement and disposal, and laboratory operating practices. The study found that CISPro streamlined processes and enabled the organizations to realize savings in labor and resources for using and managing chemical inventories. While all areas examined showed improvement, the most significant benefit was associated with laboratory operations and the time-saving efficiencies gained by the staff.

Q: You mention that two key value areas emerged from your survey. Can you elaborate further on those areas?

A: The survey results are divided into two key value areas: laboratory operations and chemical inventory support. Laboratory operations focused on labor activities, while chemical inventory support focused on management and resource costs.

Labor costs are known to be the largest expense line item for operating a lab. Thus laboratory processes were scrutinized to determine the time personnel spent on lab operations associated with chemical inventory and information. Our activities were examined: workflow delays attributed to missing inventory, searching for chemicals in the inventory, researching chemical information and properties, and generating chemical order requests.

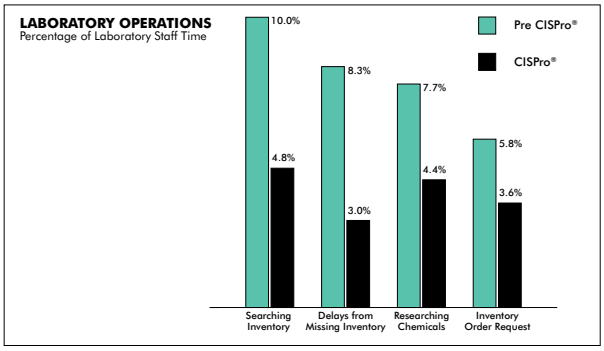

Figure 1: Lab operations man hour percentages before and after CISPro implementation. The above four activities, when added together, represent an average of 31.8% of the time spent per person on chemical management activities. That amount dropped to 15.8% after CISPro implementation, delivering a time-savings of approximately 15% per person.

The chemical inventory support value area was broken down into two subgroups: nonlabor-related cost reductions and labor-related efficiencies. Nonlabor-related cost reductions focused on container quantities, storage space utilization, purchase order quantity, chemical purchasing and waste drum management as affected by the implementation of CISPro. Labor-related cost reductions for chemical inventory support focused on changes in the amount of time needed to perform certain tasks; for example, physical inventory before and after the implementation of CISPro.

Financial benefits were achieved in both areas.

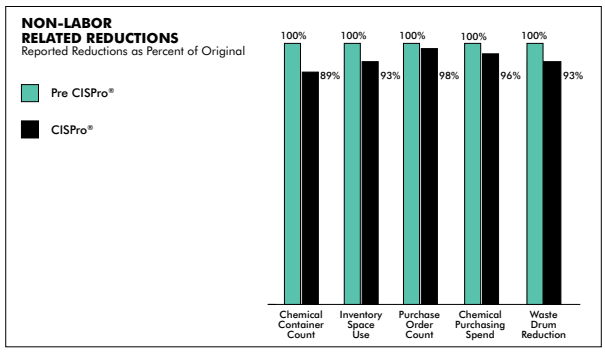

Figure 2: Survey participants were asked to estimate changes in total quantity of chemical containers after CISPro implementation. Typically, organizations will clean house of all chemical containers that have expired and foresee no future use. Though a few organizations reported as much as 50% reduction in chemical containers, the average container count reduction was measured to be 11%.

Q: What were some of the parameters and variables included in your financial benefit analysis for implementing a chemical inventory management system?

A: For a study of this kind, a number of financial assumptions are made. Fully loaded labor rates were applied to the efficiencies as they related to each discipline studied. Nonlabor-related reductions such as costs for storage area, purchase orders and waste drum disposal were also calculated as they related to the study. The parameters and the specifics are disclosed in my white paper. *(See link to white paper below.)*

Q: Can you go over some details of how lab managers can calculate cost savings and determine return on investment?

A: The survey data provided two correlations to calculate financial benefit: the number of CISPro users as related to the laboratory operations and the chemical container count as related to the resources for inventory management. Based upon the survey results, we discovered that organizations using CISPro are able to enjoy on average an annual financial benefit of $12,900 per laboratory staff user plus $12.50 per container for inventory support.

For example, assume XYZ organization implements CISPro Live, a web-based application, with five concurrent users. The organization fully deploys the application to its 50 chemists and manages 10,000 chemical containers.

Based upon the study, the estimated annual financial benefit to XYZ of fully using CISPro features is approximately $770,000 ($645,000 from laboratory operations and $125,000 from inventory support management).

Financial metrics for a five-year period calculate a ROI of 1,300 percent with a net present value of $1,370,000 and a payback period of eight months. The opportunity loss for XYZ is approximately $36,000 monthly.

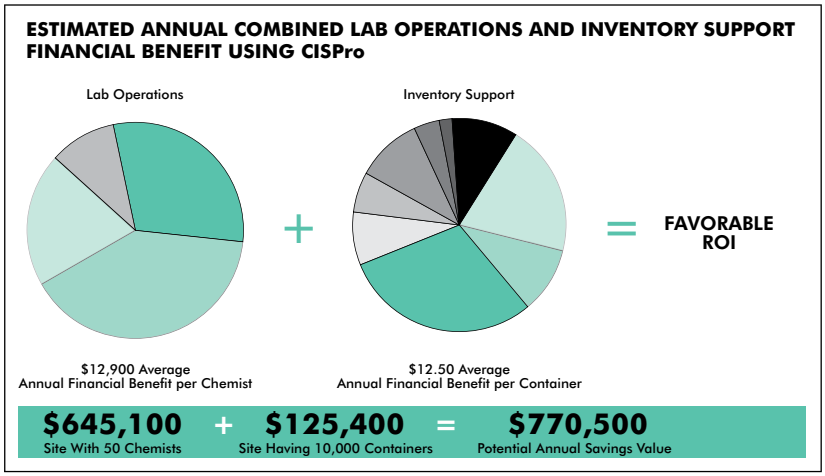

Figure 3: Based upon the study findings, the annual financial benefits for a company fully using CISPro is approximately $770K ($645K Lab Staff / $125K Inventory Management) with a five-year accumulative After Tax Present Value of $1,470K (3% Inflation/15% Cost of Capital/36% Tax Rate).

For more information, check out:

-ChemSW's white paper: *Quantifying the Financial Benefits of Chemical Inventory Management Using CISPro.* (http://www.chemsw.com/White-Papers/Financial-Benefits.aspx)

-An archive of the webinar can be found at www.labmanager.com/chem-managementspotlight

Q: If you were to give some advice and share some best practices, what would those be?

A: Effective inventory management of any kind involves getting the right inventory in the right place at the right time in the right quantity. Chemical inventory management focuses specifically on controlling the activities involved with chemicals used by an organization. A proven way to ensure real-time chemical inventory accuracy is to adopt and implement best-practices software using bar code technology. Procedures for material receiving, moving and closeout are critical steps to ensure that a chemical inventory system is accurate and user adoption is maximized. Research the different solutions available. Learn the industry best practices. Ask for demonstrations. Discuss your specific needs with the vendors. Make a choice based upon the solution that offers the functionality you'll need today and the sustainability you'll want in the future.

GETTING THE PROJECT METHOD RIGHT

By Alan Edwards

Business has changed across virtually every industry in this post-recession era. Companies must simply do more with less, and this is especially true in the sciences where, among many other factors, the expiration of valuable drug patents and the dawn of personalized medicine are impacting the way things get done on a daily basis in labs around the world. There are still so many unknowns as the industry continues to transform, but what's clear is that these transformations will have a very real impact on everyone's bottom line.

Despite these challenges, I believe we'll soon see these business changes become second nature, like so many past innovations in the scientific industry. One of the best outcomes is that the scientific workforce will become smarter and more efficient. And we'll all realize that the new way is ultimately a better model for achieving our most ambitious goals, such as personalized medicine.

However, labs will need to embrace the changing business model in order to remain competitive and reach their goals, whatever they may be. Project and work management is perhaps one of the most critical areas that labs will need to get right in order to begin this journey.

Why? As I've discussed before in this column, scientists are no longer stuck in the ivory tower. They are no longer guarding their work because they know that others' knowledge, research, and input are valuable tools in helping them to reach their own goals. Studies prove that all scientific fields are increasingly relying on teamwork to meet modern business objectives.

When a lab can effectively adopt a work project model, it is embracing that spirit of teamwork and already a step ahead in adapting to the new business reality of the sciences. Labs today are still somewhat structured when it comes to a menu of basic services, but labs must also be able to offer diversified and custom services to their clients in order to remain relevant and continue to attract new business.

> "Labs will need to embrace the changing business model in order to remain competitive."

Conducting specialized services on a project basis allows labs to easily take advantage of the global knowledge and resources available today; it's also the way many scientists want to work.

Because of the free-agency phenomenon, scientists are acquiring valuable and varied skills as they take on the challenges of each organization they work for. These contingent workers are no longer seen as "low level," but rather as elite professionals who have chosen to carve out their careers outside the bounds of traditional employment. That means there is a whole host of highly skilled talent around the globe that will likely have the expertise you need for your specific goals. And it's easier to find and employ this talent because of how attractive free-agent work is to so many of these professionals in terms of work-life balance.

The project-model phenomenon itself has also led to some interesting developments within the sciences in which high-level talent is being concentrated in certain places. It is now easier than ever for labs to call up an entire "synchronized workforce" to perform either an entire project or perhaps just a part of a project. These workforces are easily engaged—often through a workforce solutions company that has a pulse on where to find the best talent—and then disengaged when the work is finished. This can be an incredibly efficient way to conduct lab work, especially when the work does not necessarily fall within the realm of a lab's core capabilities.

Once you embrace the project model of conducting valuable work within your lab, you might find that the quality of your product is soaring and that the talent available to you is really only limited by the goals you want to achieve.

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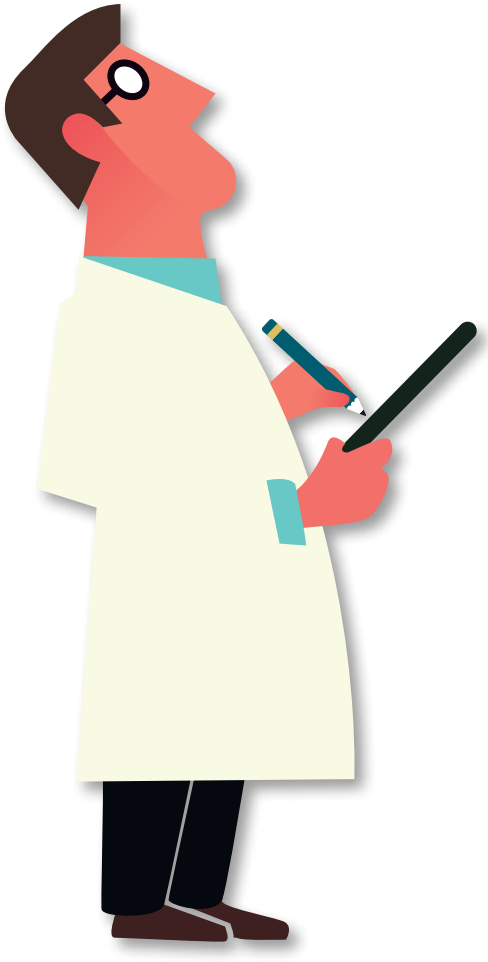
SMART PROJECT MANAGEMENT

FIVE RULES FOR MAINTAINING STAKEHOLDER SUPPORT, MANAGING COSTS AND ACHIEVING GOALS

by John K. Borchardt



"The project manager [needs] to establish the outlines of the plan and then fill in the details with stakeholders."

Work, particularly R&D, in organizations is increasingly done through projects. In the words of Eric Verzuh, project manager, consultant, and author of the book *The Fast Forward MBA in Project Management*,[1] "Most managers would do well to learn project management skills." Effective management is needed from the very beginning of a project. This begins with establishing project rules to define what the project is all about so that the participants and stakeholders understand and agree upon the project and the definition of its success.

The five rules for a successful project are:

1. Agreement on goals among all project participants (those doing the actual hands-on work), stakeholders, and management
2. A good project plan to accomplish these goals
3. Effective communication
4. Scope control
5. R&D management and business management support

These goals are interdependent, but let's look at each one separately.

Obtaining agreement on goals

Working on a project without agreeing on goals is fraught with danger. This author has seen this happen at least three times; the results were wasted time, effort, and money. Even if the needed agreement was later obtained, initial disagreement about goals can result in lingering resentment and morale problems.

Rule 1 can be difficult to achieve because of the different perspectives of the various project stakeholders and team members. For example, top priorities of R&D management include staff availability for the project, hiring of new staff members if required, and meeting intellectual property protection requirements. Top priorities

of the plant engineers on the project team are likely to be low manufacturing costs, low capital investment requirements, and minimum disruption of existing plant operations when manufacturing the new product. Business management will be most concerned with achieving the profit margin and production volumes, identifying potential customers, and beginning the sales effort at the appropriate time. (This often is before project completion. For example, Boeing was selling its 787 Dreamliner passenger aircraft long before the first one rolled off the assembly line.)

Cost goals are related to stakeholders' expectations for profitability. Project timetables are related to the business case. For example, late delivery of the project's commercial result may result in lost profits and sales as potential customers take their business to your firm's competitors.

Product performance can affect its value to the customer and thus the price your firm can charge and the resulting profitability.

Establishing a good project plan

The project manager's most important responsibility is planning. Planning should involve the participation of project stakeholders and participants. The best approach for Rule 2 is for the project manager to establish the outlines of the plan and then fill in the details with stakeholders. The plan must indicate a clear path to intermediate goals (project milestones) and to the final project goal. The plan must include time estimates for achievement of each milestone. Comparing target milestone completion dates with the actual completion dates permits the rate of progress to be assessed. Thus the project plan can provide early indications the project is falling behind, so the project manager can take timely steps to put the project back on schedule.

A good project plan also shows who is responsible for what. It provides the details needed for estimating the people, equipment, materials, and time needed to get the job done. Good estimates for these four factors enable a good forecast of the project cost. Mind maps can put all this information on a single page.[2]

Plans may change and priorities alter as the project proceeds and situations change. So the project manager must often replan. If changes become necessary, the project manager should take responsibility, learn about the situation, and take steps to prevent the problems from recurring. The project team and stakeholders must be involved in this replanning process.

One requirement for effectively modifying project plans in a timely manner is risk assessment. Team members should be responsible for identifying potential risk issues. One team member should be responsible for tracking all issues and their resolutions. The lessons from this exercise may be transferrable to other projects, so they should be shared with all team members and stakeholders.

Establish rules for communication

As the project proceeds, Rule 3 is essential. Success depends on project participants and stakeholders being able to come to agreement, identify and solve problems, and coordinate their efforts. This requires effective communication. Effective communication in turn requires that guidelines be set on how project participants will communicate among themselves—often not a simple matter if the project team is a global one. Guidelines also need to be set on how and how frequently to provide progress reports to stakeholders.

Effective communication is necessary because the project manager may not have the independence and authority to make all the decisions needed during the course of a project. The project manager must have the authority to direct the project team members and the workflow to achieve the intended results. However, some decisions will be made by project stakeholders. Project managers also may have to depend on managers in traditional roles such as R&D, manufacturing, and sales and marketing. They may also have to rely on managers in other organizations, such as customers and suppliers, to provide resources including project team members, funding, and facilities in which to do the work.

During the course of a project, team members may have access to proprietary information belonging to stakeholders. The project manager should take responsibility for having all team members respect the confidentiality of this information.

Another reason for effective communication is that the concerns and priorities of stakeholders and potential customers for the project team's work results can change over time. Frequent communication is needed for project managers to adjust what they are doing to take these changes into account. Moreover, one must guard against unnecessary project scope creep and the problems that can cause.

Control project scope

The project plan defines the scope of the project. Scope creep, the inclusion of additional requirements later in the process, can greatly increase project costs while delaying achievement of goals. So Rule 4, scope control, is essential. The costs and benefits of any changes in project scope must be clearly understood before the scope is expanded.

Controlling costs and maintaining an acceptable rate of progress may sometimes require reducing the project scope. Should this be necessary, it also becomes necessary to manage stakeholders' expectations. For example, if it is impossible to meet the targeted product cost in the development of a new laboratory instrument, stakeholders must be informed in a timely way. Then the news that the instrument will cost 10 percent more than originally planned will not come as a major shock that might cause some stakeholders to lose faith in the project and reduce or withdraw their support.

Project participants and stakeholders need to understand the tradeoffs between project costs, maintaining the project schedule, and any changes in project scope. This requires timely communication—first between project participants and then with project stakeholders.

Obtain and maintain high-level management support

Rule 5, obtaining strong R&D management and business management support, is essential if work is to be done at the desired pace and milestones are to be achieved on schedule. This support must be maintained in the face of competing priorities of other projects and budget changes caused by poor business conditions.

The project manager is the person responsible for delivering the overall project results. However, this may not be the same as delivering the project's complete business case. The project may require organizational changes the project manager may not have the authority to make. For example, once the results of the R&D project are achieved, commercialization of these results may require installing a new production line in an existing plant or the construction of a new production facility. Project managers may recommend this but often do not have the authority to commission the necessary work. Marketing

Killing the Project by John K. Borchardt

The traditional view is that the project manager is the project champion who defends the project against budget cuts and maintains the support of project team members and stakeholders. However, sometimes the right decision is not to continue the project but to terminate it. The project manager may have to go to project stakeholders and explain that the project results will not be achievable with the resources available to the organization. In this situation, the project manager may recommend that the project be killed.

However, there are possible alternatives to this draconian situation. The project manager should consider them before recommending that the project be terminated. For example, should the problem be that the organization does not have the trained staff or laboratory supplies and equipment needed to do some of the work required to achieve project results, outsourcing to obtain access to these resources is a possibility.

If the knowledge and technology needed to accomplish some project milestones do not exist within the project manager's organization, the project manager may be able to take steps to access this knowledge or acquire this technology from an outside organization—other companies, research institutes, universities, government laboratories. Options include licensing technology or hiring new staff members (or temporary employees) to obtain access to this knowledge. Outsourcing or taking on outside organizations as project stakeholders may enable project managers to access the required technology not available within their own organizations. The project manager may also acquire this technology through the mechanism of open innovation.[3] Project managers may not have the authority to do this on their own and may need the support of other managers within their own organizations or the support of outside stakeholders to accomplish this.

the newly developed product may require hiring and training new sales personnel or additional training for current salespeople. Making organizational changes such as these requires the participation of project stakeholders such as production and sales managers.

The appropriate stakeholders must be willing to make the needed organizational changes. Otherwise the project will be just an academic exercise whether or not project goals have been met. Maintaining stakeholders' financial support and their willingness to make timely organizational changes requires the effective communication discussed above and persuasive skills on the part of the manager to gain the benefits of commercializing the project results.

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EVOLVING TRAINING PROGRAMS

WHETHER YOUR LAB IS GROWING OR SHRINKING, TRAINING PROGRAMS NEED TO STAY IN SYNC WITH YOUR CHANGING REQUIREMENTS by Ben Culp

Mergers, acquisitions, downsizing and organic growth can dramatically affect the efficient functionality of your organization's current training program. While organic growth is often a slow and measured process, the addition of a new department or product group can cause a sudden increase in headcount. Most often the increase in headcount results in trying to fit a larger organization into a system developed for a smaller number of trainees. The training program that worked well when your organization had 10 employees might be strained by 50 employees and even become dysfunctional with 100 employees. Similarly, an organization that grew from 500 to 1,500 employees might also find its original training concept has become inefficient or even too unrealistic to be effective. Conversely, an organization that has experienced a staff reduction through a spin-off or downsizing may find its training program, designed for a large number of trainees, bloated. Five people training one person simply does not enable the trainee to learn five times faster. Not adapting to a growing organizational landscape may result in delayed deployment of trainees, incomplete training and the dilution of available training resources.

Your organization has added to the headcount to meet a specific need with an expected implementation timeline. If the individuals have not progressed through the training program in the allotted amount of time, the downstream effects may negatively impact the organization's goals. Therefore it is critical that your training program be tailored to fit the needs of the organization. Training is not exclusively for new hires, as it will also include refresher training for current staff as well as training required on new or modified procedures. Some organizations have specifically determined refresher training timelines, and these must be factored into the size of the training structure. Which of these training scenarios best describes your current situation?

Start-ups, mom and pops, and independent departments

Very small organizations often do not have a training "program" and they take an "as needed" training approach. The trainee is instructed by another person who routinely performs the procedure. The trainer's talent for teaching is often trumped by his or her availability and knowledge of the process to be taught. An informal mentor relationship is formed, and the trainer generally is available to assist when questions arise, as the trainer often works side by side with the trainee. In these smaller organizations the subject matter expert (SME) who developed the procedure may instruct the trainee directly. In this ideal situation the SME is able to relay the history and evolution of the procedure to the trainee. This creates a more formal mentor relationship, and the SME experiences a greater level of comfort with the trainee's ability to perform the procedure. Documentation of training is often similarly informal in these smaller organizations and might not withstand a robust audit by external groups or stakeholders.

Midsize organizations and the designated trainer

Midsize organizations often have a more formal training program for all employees. These programs often begin in the Human Resources Department, where organizational history, policies and new-hire orientation are relayed to the trainee. The trainee is assigned to a designated trainer in the receiving or home department. The designated trainer is often chosen for his or her expertise in most of the department's procedures, teaching skills and a history of training successes. This trainer is often a department member who is not routinely included on production throughput. It would be unreasonable to expect the trainer to succeed at two full-time jobs (training and production) in a single day. Once training is complete, ideally the

trainee is coupled with another seasoned employee who will serve as a mentor. This is often an informal relationship that is created through proximity. It is unlikely that one would trust a room full of novices without some level of seasoned guides present. Documentation of training is often thorough and consistent when a single person is responsible for the training. This level of training is near the tipping point of an organization's being ready to use an electronic training record or learning management system.

Large organizations and the designated training group

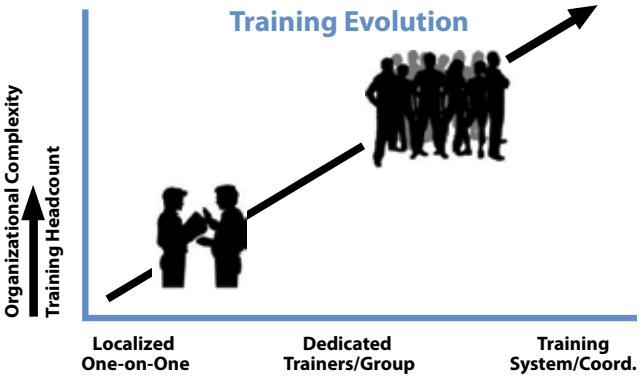
Organizations that have a regular stream of trainees often find it most efficient to establish a designated training group to handle training for the most routine procedures. The clear advantages to this are in consistency across the larger organization and the ability to disperse new information rapidly. However, in every organization there are going to be pockets of specialty groups with a finite number of employees who will behave like a small company. It is important in that situation to retain the special training relationship that exists between the SME and the trainee. The larger training group must adapt and provide à la carte training and flexibility. Not doing so can promote the development of silos.

> "The training program that worked well when your organization had 10 employees might be strained by 50 employees."

Mergers and acquisitions eventually result in the marriage of two diverse training programs. Often each of the two organizations continues to operate within their as-is training configuration until an external audit forces a change. While the level of subject matter training will likely not be disputed, the mechanisms for what triggers training and how training is documented will cause the most consternation. Documentation of training practices often intensifies as the organization grows larger and the number of external stakeholders increases. External stakeholders include regulatory agencies, clients and final product users.

Coordination of organization-wide training

Large organizations manifest themselves in multiple configurations. There may be one site with a large number of employees across a variety of medium/small departments, multiple sites that perform similar functions, or academic settings with a large array of small units spread geographically *and philosophically*. When these configurations are present, it is beneficial to have a single point person or unit. The point person is responsible for coordinating the variety of training approaches performed across the organization. The titles of these point people are often training coordinator or training manager/director. While this function may be akin to herding cats, the benefits are that the *wheel* needs to be invented only once, no one group is left out of either critical information sharing or new process developments, and the documentation of training completion *eventually* becomes similar. Few things are as frustrating, from an outside auditor's perspective, as having department A's training documentation be configured in one manner and depart-



ment B's training documentation be the opposite or even nonexistent. These differences will undoubtedly be outlined as a critical deficiency in an audit or inspection report.

Why vs. how approach

Bigger is not necessarily better, and the benefits of having the scientist provide direct training to the trainee can be lost as the training organization expands. The scientist (or SME) who used to handle the one-on-one training may be required to delegate those duties to a designated trainer. The risk is that the trainer might not adequately explain the evolution and decision points of a given procedure. In these cases *how* the procedure is performed may win out over *why* it is being performed, and critical thinking may not be engaged when the activity is performed. When the trainee knows why a procedure is performed in a certain way, it is inevitable that potential problems will be identified earlier in the process. Here is a simplified example of where HOW wins out over WHY. A three-step process involves three people—the first person digs the hole, the second person plants the tree in the hole and the third person fills the hole. If the person who is to plant the tree fails to put the tree into the hole, then the third person should not put dirt back into the hole. Critical thinking would trigger the third person's raising a red flag and addressing the deficiency rather than just refilling an empty hole. This simple example can be expanded to fit any of the processes that your organization performs. Training the *why* is an essential component, and care to do so must be exercised when your training program evolves to a larger size.

When the trainee knows why a procedure is performed in a certain way, it is inevitable that potential problems will be identified earlier in the process."

Triggers for change

How do you know when it's time to migrate to a more developed, structured training program or to reduce the depth and/or scope of the one that you have in place? Hockey legend Wayne Gretzky said, *"A good hockey player plays where the puck is. A great hockey*

player plays where the puck is going to be." The same can be said for training programs. Recognizing the need for an increase in training before the need arises is essential. It is critical for your organization's administration to keep you informed of potential headcount changes. Further, it is important that you develop a game plan for scaling up your training organization in the event that occurs. If there are others in your organization who are also involved in training, you want to meet with them to discuss the "what ifs?" When the organization grows it will be to your benefit to be ready with your plan.

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"Nothing will get management's attention faster than disproportionate training labor costs."

In the event of a 10 percent to 15 percent reduction in workflow, it is likely that the benefits of the larger organization's training structure will be supported; however, in these situations it is important to keep an eye on the labor costs. Nothing will get management's attention faster than disproportionate training labor costs. *"Headcount is down, but training labor has stayed the same."* Hence, adjustments to the ratio of trainers to trainees become inevitable. Due to their technical value and broad skill set, trainers tend to weather business downturns well.

An evolved program

Your training program must evolve to stay in sync with the needs and size of the growing/shrinking organization. It is critical that the benefits of ground floor scientist-based training that includes the *why* of a procedure is not lost as the organization grows. It is equally important, for example, that the sophistication of documentation developed by large training organizations not be lost when reductions in structure without disproportionate labor and other costs are necessary. Appropriately evolved training programs will be viewed by their parent organization as a component of its success and a positive contributor to the bottom line.

GETTING EMPLOYEES TO GIVE THEIR ALL

By Edie Raether, M.S., CSP

Do your employees simply show up for work or are they committed to making a difference? Your employees' passion, ideas, feedback and enthusiasm are your lab's greatest asset. Focusing on numbers does not increase your profitability, but learning to motivate, monitor, measure and manage productivity and change does.

Research reveals that only 17 to 29 percent of the U.S. workforce is engaged, a fact that can devastate a lab's bottom line. Just getting the job done to collect a paycheck is not the level of commitment necessary for a high performance work team.

While performance reviews can be effective, the feedback must be more immediate than a quarterly evaluation. Giving feedback months after the fact is like expecting your dog to stop piddling on the carpet when you reprimand him a week after the incident. There is no value to delayed feedback for either dogs or humans, nor will it correct or change their behavior.

"Research reveals that only 17 to 29 percent of the U.S. workforce is engaged, a fact that can devastate a lab's bottom line."

It is essential to unleash the other 93 percent of your workers' untapped potential. Research reports that organizations with highly engaged employees outperform those with a less engaged workforce in their innovation, productivity, and profitability.

Southwest Airlines, one of the more profitable airlines, hires people with a positive attitude and trains for the necessary skills. Trying to change a Negative Nellie into a Positive Polly may be like trying to push a river.

People who are passionate about research and the discovery process are not in the lab doing their best to wear the "employee of the month" button. They are in sync with their instincts and are clear on their purpose and mission in life and are unstoppable. They are driven from within and compelled to express their inner genius and vision just as Michelangelo was when he confessed: "In every rock of marble I see a statue; I merely chisel away so others can see what I already know."

You probably have been given lists on what motivates a workforce, such as celebrating their wins with

LABCAST

Be sure to attend Edie Raether's Lab Manager Academy webinar, "Getting Employees to Give Their All… How to Create an Engaged Workforce in Your Lab," on Wednesday, July 11th, or afterwards at:

www.labmanager.com/engaged to watch the archived video.

bells, balloons and bravos. However, we need to get beyond both the carrot and the stick. Yes, external rewards and clever, creative treats will work for many, but those for whom it does will never be your top producers.

There is a unique change management method, however, that will engage all employees, both the internally or externally motivated. Since people drop out and lose interest in any task if they are bored, you must implement the psychology of "flow." It worked for Michael Jordan, and it will work for you as well. Optimal performance occurs when people are between a state of boredom and anxiety, as both of those extremes are dysfunctional. With high anxiety, your employees are so stressed out that mistakes prevail and decision making is seriously impaired by bad judgment. Oxygen to the brain is cut off and, like a car, humans cannot run well without a fuel supply.

However, when people are bored because of being overqualified or simply not interested, they slip into a state of apathy. They know the routine so well, they go on autopilot. Innovation and creativity do not occur in this disengaged state of mind, body and spirit. The natural and inevitable side effect of mastery is apathy. Thus, your most competent, experienced employee may have mastered all skills and checked out mentally years ago.

Beyond perks, parties and picnics, the true key to engagement and motivation results from managing the tension level of your employees. Too little tension and challenge can be just as counterproductive as too much tension. Doing more with less can be a stimulant and ignite a fire in the bellies of those who have been mentally snoozing.

To determine your group's level of productive tension, intention and engagement regarding a specific task important to them, please contact me for a complimentary ChangeGrid assessment. It will predict if an employee will follow through on a task or activity and guide you in how to minimize negative possibilities and maximize positive outcomes. You will understand the choices they make and the actions they take from a new perspective. Performance, productivity, and progress can thus be more efficiently and effectively executed by engaging employees to give their all.

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CONCERNING THE CLOUD

THIS DISRUPTIVE TECHNOLOGY REQUIRES LABS TO LEVERAGE THEIR KEY COMPETITIVE ASSET – DATA

by Mike Weaver

While cloud computing is merely a metaphor to signify the abstraction of technology, resources and locations, the possibility of your laboratory missing out on the biggest technological leap ever is real.

There has been a lot of hype over the last few years concerning the cloud. In the consulting world, it was interesting to watch how clients would respond with awe to cloud-speak (discussions centered around cloud technology). Scott Adams captured the atmosphere with a soon-to-be classic Dilbert strip that read, slightly paraphrased, "[Manager] I hired a consultant to help us evolve our products to cloud computing. [Consultant] Blah blah cloud, blah blah cloud, blah blah platform. [Manager] It's as if you're a technologist and a philosopher all in one!"[1] The comic was funny, but it was also true. Until recently, companies were amazed by a relatively old idea of mainframe computing. Mainframe technology peaked between 1959 and 1973, carrying out critical operations for government and large corporations. This is where massive computing power was centralized to handle tasks like census statistics and ERP. This phase was followed by the advent of the personal computer, where the landscape shifted to a data-local paradigm until 1995.

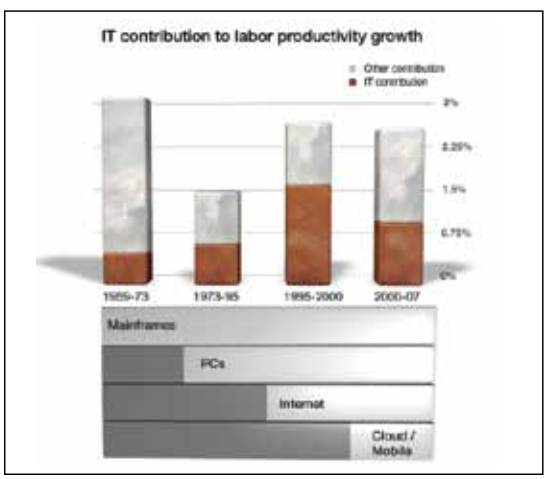
From the mid-90s on, we transitioned into a web 2.0, mobile and cloud environment. With history repeating itself, we now have centralized data storage and massive computing power with the ability to access information anywhere. The "dumb terminal" access points have been replaced by 4G and Wi-Fi connected to phones, tablets and laptops. A few key aspects have been optimized for redundancy, security and speed, but under the covers it is still a mainframe-to-terminal concept.

So why, if not leveraged, will this cyclical idea of the cloud have the power to greatly disadvantage your laboratory? The answer is data. The true disruptive technology that is beginning to emerge from the cloud is data—lots of it—coined as Big Data. Big Data is the offspring of the cloud's main advantage: collaboration. The collaborative potential in the cloud has woven together relationships like nothing the world has ever seen, expelling an hourly exhaust of terabits of data. Big Data may be defined as the analytical crunching of this massive amount of data into meaningful business productivity. The result: a true competitive edge.

Even the slightest change in business habits, from safety to customer service policies, can have enormous effects on productivity and profitability. There are many examples of impact occurring when slight changes were made in precisely the right direction, as seen here: An untested CEO took over one of the largest companies in America. His first order of business was to attack a single pattern among his employees—how they approach work safety—and soon the firm, Alcoa, became the top performer in the Dow Jones. Procter & Gamble was close to canning the blockbuster product Febreze until a small pattern emerged in the consumer data that prompted them to make a change in its marketing. Habits can be changed if we understand how they work.[2] Thus for the first time, the answers that are needed to explain habits and advance productivity, product quality and profitability now exist. Big Data will drive the new era.

Data has become a torrent flowing into every area of the global economy.[3] The relationship between productivity and IT investments is well established; however, exploration of the link between productivity and data is just beginning. The use of Big Data will become a key basis of competition and growth for laboratories. From the standpoint of competitiveness and the potential capture of value, laboratories need to take Big Data seriously. In most industries, established competitors and new entrants alike will leverage data-driven strategies to innovate and capture value from deep and real-time information.

In order to weather the cloud storm and leverage the truths hidden in Big Data, we should draw upon what history has taught us about IT and its relationship to productivity gains, while understanding that there are two essential preconditions. The first condition is capital deepening—in other words, IT investments gave workers better and faster tools to do their jobs. The second condition is investment in organizational change—i.e., managerial innovations that complemented the IT investments in order to drive true productivity gains. The same preconditions that explain IT's impact in enabling historical productivity growth currently exist for Big Data.[4]



Let's review a few early examples of success that Big Data has yielded, then list a few tools and some potential areas of application for your laboratory.

The Italian Medicines Agency collects and analyzes clinical data on the experience of expensive new drugs as part of a national cost-effectiveness program. The agency can impose "conditional reimbursement" status on new

drugs and then reevaluate prices and market-access conditions in light of the results of its clinical data studies.

The California-based integrated managed-care consortium Kaiser Permanente connected clinical and cost data early on, thus providing the crucial data set that led to the discovery of Vioxx's adverse drug effects and the subsequent withdrawal of the drug from the market.[5]

In order to handle Big Data analysis, aggregation and management, there are a growing number of tools and general technologies available. Here are a few key tools that have shaped the landscape thus far:

- Big Table — Proprietary distributed database built on the Google File System
- Business Intelligence (BI) — A type of application software designed to report, analyze and present data. BI tools are often used to read data that have been previously stored in a data warehouse or data mart. BI tools can also be used to create standard reports that are generated on a periodic basis, or to display information on real-time management dashboards like a GC or HPLC operational status grid.
- Cassandra — An open-source (free) database-management system designed to handle large amounts of data on a distributed system. Developed originally at Facebook, it is now managed as part of the Apache Software foundation.
- Cloud computing — A computing paradigm in which highly scalable computing resources, often configured as a distributed system, are provided as a service through an app or Web browser network. There are many organizations offering B2B collaborative functionality, from remote sample scheduling to global inventory management.
- Dynamo — Proprietary distributed data storage system developed by Amazon.
- Mashup — An application that uses and combines data presentation or functionality from two or more sources to create new services. These applications are often made available on the Web and frequently use data accessed through open application programming interfaces or from open data sources.
- Google File System — Proprietary distributed file system developed by Google.[6]
- Visualization — Technologies used for creating images, diagrams or 3D charting to highlight trends in massive amounts of data not easily identified in tabular data formats.

In addition to Big Data tools, there are key techniques that laboratories should consider to increase business and improve client satisfaction for the future:

Association rule learning — A set of techniques for discovering interesting relationships, i.e., "association rules," among variables in large databases. These techniques consist of a variety of algorithms to generate and test possible rules. One application is market basket analysis, in which a laboratory can determine which test outcomes frequently occur together. The laboratory can use this information to help the client in predictive modeling, and also within internal marketing campaigns, to garner more business.

Natural language processing (NLP) — A set of techniques from a subspecialty of computer science (within a field historically called "artificial intelligence") and linguistics that uses computer algorithms to analyze human (natural) language. Many NLP techniques are types of machine learning. One application of NLP is using sentiment analysis on social media to determine how prospective clients are reacting to a new product marketing campaign or function within customer service.

Optimization — A portfolio of numerical techniques used to redesign complex systems and processes to improve performance according to one or more objective measures (e.g., cost, speed or reliability). Examples of applications include improving operational processes such as scheduling, test routing and laboratory floor layout, and making strategic decisions such as product range strategy and linked client analysis. Another great example is in inventory management, where there is full transparency at the SKU level while bar code systems linked to automated replenishment processes reduce the incidents of running out of stock.

Regression — A set of statistical techniques to determine how the value of the dependent variable changes when one or more independent variables are modified. Regression is often used for forecasting or prediction. Examples of applications include forecasting test volumes based on various market and economic variables and determining what measurable manufacturing parameters most influence customer satisfaction.

Time series analysis — A set of techniques from both statistics and signal processing for analyzing sequences of data points to extract meaningful characteristics from the data.

Examples of time series analysis include the hourly value of an in-process test to chemical completion and the trending of a result component for a given condition every day. One aspect is to decompose a series into trend,

seasonal and residual components, which can be useful for identifying cyclical patterns in the data. An example includes forecasting production control limits and alerting stakeholders when something is going the wrong way.

Last, simply making Big Data more easily accessible to relevant stakeholders in a timely manner can create tremendous value. In the public sector, for example, making relevant data more accessible across otherwise separated departments can sharply reduce search and processing time. In manufacturing, integrating data from R&D, engineering and manufacturing units to enable concurrent engineering can significantly cut time to market and improve quality.

In summary, data is becoming a key competitive asset, thus laboratory leaders must understand their data assets with the right tools and identify data gaps that exist. Laboratories should conduct an inventory of their own proprietary data and also systematically catalog other data to which they could potentially gain access, including publicly available data (e.g., government data, other data that are released into the public domain) and data that can be purchased from data aggregators, or other tools and techniques in a data value chain.

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BUILDING TRANSPARENCY—A TOP-DOWN VIEW

HOW STRATEGICALLY INTEGRATING INFORMATICS TOOLS ACROSS A DRUG DISCOVERY WORKFLOW CAN IMPROVE TRANSPARENCY, TRUST AND PRODUCTIVITY

by Mark J. Hayward, Chi Zhang, Romel Campbell, and Qing Ping Han

(This is Part I of a two-Part series.)

Drug discovery is an inherently collaborative venture that necessitates the interaction and integration of people, processes, laboratories, and technology. This is easier said than done, however, and the ability to achieve optimal communication and coordination of effort; exploit potential synergies; and maximize the quality, reliability, and reproducibility of results begins with a foundation built on transparency and trust.[1] In a drug discovery organization where there is transparency and trust, researchers are better able to share and compare data, rely on or openly question results, and support each other's efforts in a truly collaborative environment. The willingness to embrace transparency is a significant statement by individuals and organizations, saying, "I want to do it right."[1,2] In an open environment where data are readily shared, time otherwise spent debating the accuracy of the data can instead be applied to moving projects forward.[2]

Building transparency into the research setting depends on several key factors: high-quality raw data; shared analytical tools; curated datasets; and clear documentation, audit trails, and reports. The strategic integration of informatics tools across a drug discovery workflow can foster transparency and improve the quality and standardization of data reporting and interpretation. Although a move toward greater openness may encounter some resistance in an organization, the potential gains far outweigh the challenges.[2]

Part I of this two-part article presents the principles and foundations for implementing informatics as an integrative tool for achieving these organizational goals. It provides recommendations based on real-world experience and the results of a project carried out in the drug discovery analytical group at Lundbeck Research. The project was designed and intended to gain efficiencies through the integration of electronic laboratory notebook (ELN) systems. Part II, to be published in the September issue, will provide a detailed description of the case study in which Lundbeck integrated multiple informatics tools and software packages to improve data quality and transparency across analytical methods used to determine the composition, structure, and purity of drug compounds in development; make physic-chemical/ADME measurements; perform complex bioanalyses; and evaluate the solubility, stability, and other critical characteristics of experimental drug compounds in various formulations.

Building transparency and trust

A willingness to invest the time, effort, and resources to develop and implement an organizationwide informatics strategy can yield significant gains in productivity and accelerate the path to a marketable product. Several key factors can contribute to the ultimate success and timetable for accomplishing this type of ambitious project. One is the need for a clear understanding at the outset of what you want to achieve. It is critical to define your vision and outline a path forward, recognizing that there will undoubtedly be bumps and detours along the way and maybe even some backtracking and rethinking. Set realistic expectations. Then identify the resources and people—scientists, information technology (IT) specialists, and project managers—needed to move forward, drawing both from within the organization and on expertise from outside as needed, including vendors and independent consultants.

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Identify and anticipate the challenges and potential obstacles, both generic and specific, to your organization. Recognize that every work environment is different, and a vendor cannot know how you want an instrument, analytical device, or algorithm to work in your laboratory. Some degree of customization will always be needed, and this should be viewed as an opportunity to optimize your workflow. It is unrealistic to assume that any analytical instrument will arrive ready to use. Unpacking a device and plugging it in is only the first step. Maximizing the usefulness of a new tool or software program and integrating it into your workflow requires customization, training, and the necessary links to other platforms—including ELN systems, the organization's data collection and storage system to ensure open access to data—and to external networks, interfaces, and data stores as needed.

No single informatics approach will be sufficient or optimal for every process, research group, or workflow. Furthermore, each approach is unlikely to be a simple, works-right-out-of-the-box software solution. While every device and analytical instrument may have its own dedicated software platform, the key to encouraging and enabling transparency lies in the customization of the software to optimize its functions for a particular application or workflow and the integration of distinct software systems into a unified informatics network. This strategy will allow for organizationwide access to and use of critical resources, experimental results, and proprietary knowledge.

Informatics cannot change the quality of the science, which must always be a top priority, but it can add significant value to the scientific output. It can make it easier for scientists to view, mine, and transfer data; utilize the data in multiple distinct operations or analyses; and extract valuable information and conclusions from the data. The result will be streamlined, more efficient processes. Informatics can even make it possible for the data to find the scientist.

Several missteps can cause informatics initiatives to fail. First and foremost, informatics needs to be clearly enabling and not create more work or increase the chances for generating false metrics. Too often, the implementation of informatics tools introduces barriers instead of removing them. For example, the need to input large amounts of information manually can create a data input barrier. To the extent possible, data should load automatically from an instrument to the software platform and download to visualization and data reporting tools as well as ELNs and servers. Another common mistake is expecting informatics to be able to substitute for face-to-face communication. Overestimating or underutilizing your in-house informatics capabilities and expertise and not taking advantage of outside guidance and advice can also introduce barriers to successful implementation.[2]

Overall, it is important to build and implement an informatics system with foresight and flexibility as the cornerstones of the design. At first, it is crucial to focus on delivering the core needs of the organization. However, the design of an informatics network must also take into account the possibility and implications of adding instruments or new software platforms a year or two down the road, and it must plan for such eventualities. Realistically, it is not possible to anticipate all future needs.

Furthermore, there is not likely to be sufficient time to implement every idea envisioned as a single package. From an organizational perspective, the design of an informatics system and integration of individual instruments and software platforms should be based on a vision driven by overall organizational goals. Meeting these goals, while also building in the flexibility and capacity for reorganization and expansion, should be primary considerations for core informatics technology selection. Once these goals have been delivered, it is often surprisingly easy to identify opportunities for further productivity gains in the work environment. These can be further enhanced by applying Lean Six Sigma approaches to internal workflows, perhaps best performed as separate small projects. Implementation of an informatics strategy as several smaller projects, with some pursued in parallel and others sequentially, is a prudent choice. It has the advantage of more predictable time lines. This can help to engender trust among the senior management as progress is more readily evident, there is less financial exposure, and you are better able to optimize the informatics to match the actual workflow for even greater productivity gains.

Real-world implementation

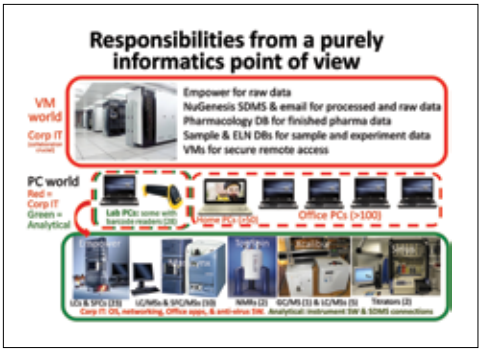
The concepts and principles described above were the basis for a real-world project implemented at Lundbeck, in which informatics integration resulted in improved data quality and transparency and, ultimately, a higher level of trust and enhanced productivity across a highly collaborative drug discovery organization. The analytical workflow in place at Lundbeck incorporated three main software platforms—Empower, MassLynx (including OpenLynx and FractionLynx), and NuGen-

esis® Scientific Data Management System—as well as independent detectors and instruments from other vendors, each with its own data management and reporting software. The goal was to utilize ELNs to develop an integrated informatics network that would capitalize on the strengths of each platform, generate high-quality data, and establish a high level of trust in the accuracy, reliability, and interpretation of the results. This vision included built-in, data-driven checks and balances that ensured ongoing monitoring and quality control and incorporated mechanisms for making the information available and understandable to a diverse group of scientists working on common projects.

> "Informatics needs to be clearly enabling and not create more work or increase the chances for generating false metrics."

A key consideration in designing an informatics workflow is how the data are going to get from the data collection mechanism built into a detector or analytical system to the higher level data storage, analysis, and reporting system maintained by the analytical group and, ultimately, into the corporate IT network, thereby making it accessible to the entire community. One solution is to establish a virtual machine (VM) system. A VM is similar in concept to cloud computing, but differs in that the "cloud" remains within the organization and the data and functions are not distributed among computers in the public domain.

Lundbeck installed a bank of CPUs to manage a variety of centralized computational needs, including database access, communications, and remote access in the VM space. This VM capacity was also employed to process, store, and distribute analytical data and to provide remote access for data viewing and instrument operation during nights and weekends, as depicted in Figure 1. All the data have a duplicate audit trail—one maintained within an individual instrument's software and one in an organization-level system managed by the IT group that is automatically backed up daily to an off-site, secure location and is accessible (in read-only mode) to anyone with appropriate clearance from within or outside the company.



Data, outcomes, and lessons learned from this project are presented in Part II—A Bottom-Up View. Overall, the project was a success, resulting in greater access to data across the organization, improved data transparency, and lower barriers for data entry and utilization. Informatics can and should be enabling and empowering. This case study demonstrates that if conceptualized, designed, and implemented in a thoughtful way that takes into consideration the current and future capabilities and needs of individual laboratories, research groups, and the organization as a whole, informatics tools can enhance efficiency and improve productivity across disciplines and workflows. Building transparency and trust takes time, but the benefits can be dramatic and the gains in productivity well worth the investment in time and resources. The results achieved in this project indicate that over the course of a year of total transparency, in addition to consistent and efficient delivery of high-quality results, output from the same full-time employees—including both providers *and* customers—can be increased greater than threefold.

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Cecilia Björkdahl, Ph.D.

Stan Piper

ASK THE EXPERT

CHOOSING THE RIGHT ELN FOR THE RIGHT APPLICATION

by Tanuja Koppal, Ph.D.

Contributing editor Tanuja Koppal, Ph.D., talks to two scientists—one from a large pharmaceutical company and the other from a large academic institution—about their experiences with transitioning from paper to electronic lab notebooks (ELNs). Cecilia Björkdahl, Ph.D., manages the across-the-board research documentation project commissioned by the Board of Research at Karolinska Institutet Medical University. She discusses the challenges of adopting ELNs in a diverse academic setting and offers some recommendations and improvements that can make the transition easier. Stan Piper, formerly principal scientist specializing in informatics projects in Pfizer's Pharmaceutical Sciences division, outlines the process for evaluating and implementing the right ELN that meets the needs of both the organization and the individual user. He advises managers not only to consider the present use for ELNs but also to keep an eye out for future applications and growth.

Interview with Cecilia Björkdahl:

Q: Can you share your experiences transitioning from a paper to an electronic lab notebook?

A: For us the ELN has been very easy to use. You just need an hour's introduction to the system, and you're up and running. It's quite simple in a good way, without any kind of sophisticated configuration necessary. The ELN we use is completely off the shelf, unlike our laboratory information management system (LIMS), where we did a lot more customization. I would say it's worked probably better than the LIMS, to date at least, when it comes to getting new users to use the system quickly. Customization is good, but it's also extremely time-consuming. And in the end, you don't always get what you thought you wanted anyway.

Q: Do you find that there are some limitations or disadvantages to using ELNs?

A: I think some of the functionality may be too simple. It's a balance in terms of making it easy to use and not too complicated to maintain, while supporting a lot of what our researchers do. Some of our users have their protocols in Microsoft Word or Excel, and when they wanted to transfer that information into the ELN system, we ran into some difficulties. You have more options to change the layout and format with Word than with the ELN. But I think the main limitations of ELN are related to size. We have a lot of researchers who handle really large data files, in terabytes and petabytes, because they have a lot of genotype data or large image files. We currently have a size limitation of 15 megabytes per attachment or insertion, although there's no limitation per person or group. Currently the data is stored locally on servers, and the ELN can connect to that. But I think that's something that we need to address, how we handle the data, ensuring that we have a good reference system for where that data is kept. We have around 1,000 users at the university, and we have the potential to include probably 4,000 to 5,000 users. In that sense, we still have a long way to go.

Q: Have you run into any kind of problems with integration or security?

A: With regard to security, it has to do with accessibility and making sure that the communication with the ELN system and also to the server is encrypted. We have a very diverse environment, and here academia will differ from a company, where it's a bit more regulated as to the kind of computers and programs people are using. We have 22 different departments and around 2,000 Ph.D. students and 3,000 researchers, and then we have undergraduates too. People have different types of computers, and they have different versions of the systems on their computers. We have had users contacting us with some problems and issues that have come up in their local environments that we didn't anticipate before we started, and we think a lot of that has to do with the diversity we have.

Q: As the project manager, what are some of your biggest concerns with using ELNs?

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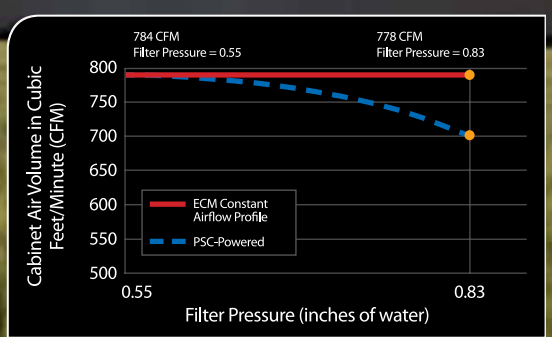

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Cecilia Björkdahl manages the across-the-board research documentation project commissioned by the Board of Research at Karolinska Institutet Medical University. She has been at Karolinska Institutet since 2002, starting as an Alzheimer's disease researcher and earning her Ph.D. in neuroscience. She then moved to the Karolinska Institutet Biobank in 2008, where she has been in charge of internal audits and ensuring traceability for sample collections at different departments. This work has included taking part in implementing a laboratory information management system. Since 2009 she has managed the improvement of the research documentation process, and part of this work has been the procurement, evaluation, and implementation of an ELN throughout Karolinska Institutet.

A: I think it's associated with getting a stable system that we can trust and getting it up and running. Once you have that in place, you can always work from that. Also with ELN implementation, don't make it into an information technology issue but make it a research issue. Here we have managed to include researchers early in the planning, with me functioning as a go-between for the researchers and the IT staff. So an ELN is not just something that IT decides on, gives you, and forces you to use. The researchers should be the ones driving the process.

Interview with Stan Piper:

Q: What factors did you consider when you started your search for the right ELN?

A: There were two things—the drivers that led us to look for an ELN and the key criteria for selection that we were looking for. In terms of drivers, we wanted to move from the paper-based system and increase efficiencies in the laboratory as well as increase quality and compliance. For selection approaches, you can either take an application and try to customize it to what your users expect, or you can pick a partner that can deliver an application that's very close to your requirements and then do small tweaks and configurations for your users' needs. We were really looking for the latter, and the key in that case was really asking our users what they were looking for and getting early user engagement.

Q: What kind of feedback did you get from the users?

A: The users were really looking for a few different things. One was usability, obviously. If we put an electronic system in, it had to be usable and couldn't be overly complex. It needed to be just as portable and just as accessible as a paper notebook. It needed to be searchable. And finally, the users wanted an electronic system to be more collaborative than the current paper system.

When we went through the choice of vendors, there were four high-level categories considered—operation, quality, interface and integration, and other. The category called *operation* included experiment setup, ordering, the ability to handle chemical reactions and structures, the ability to apply workflows to things in the system, and being able to get metrics from the system. The *quality* category included things such as signature and reviews; approvals; and some way to address archiving, reviewing, witnessing, and reporting. The third area that we were looking to evaluate was what we called *interfaces and integration.* The user interface, the look and feel of the product—do they seem right? Is it something that's very foreign to your environment within your company? What did the base configuration look like? Is it easy for users to make changes that they need? And then on the integration side, what are the available instrument connections? If we want to do direct instrument connection, is it available to us? And then, the last large category called "other" included the relationship with that vendor as a company and their size of scale and support, etc. What kind of relationship would you have with this company moving forward? Are they scaled to the size that could support your organization? Do they have appropriate training, organization, and staff to support your enterprise? Could they help with implementation as well as with maintenance and upgrades?

Q: Do you think that lab managers, although they are looking at the present when they buy an ELN, should really be thinking more futuristically when they actually go about implementing it?

A: That's correct. It is important to consider "the ultimate total cost of ownership" because you're really looking at ELN as a long-term tool. You have to look very far into the future to see whether ELN is going to be a key piece of your knowledge management puzzle. Could this system grow to a point where you really need to think about the total cost of ownership over a decade or two before you'd be moving on to some change in technology? Think downstream in your process and in time to see how other systems or users are going to want to consume information in the ELN. You may want to rethink how you implement your ELN, because you may want the data in the ELN to be structured in a way so that you can access it long term. So if you see ELNs as a key

Stan Piper is a Principal Scientist specializing in informatics projects in Pfizer's pharmaceutical sciences division. Stan has been with Pfizer since 1998. He began as an analytical lab scientist, and for the past 10 years Stan has worked as a member of several business systems and integration teams, evaluating and implementing laboratory solutions including: Laboratory Information Management System (LIMS), Chromatography Data Systems (CDS), Electronic Lab Notebook (ELN), and Lab Data Archive applications. He is currently serving as business lead for several global informatics programs including a division-wide knowledge management initiative.

Stan received his B.Sc. in chemical biology from Stevens Institute of Technology in 1998, and his MBA from Rensselaer Polytechnic Institute in 2006. He has published several articles and presented several talks on the implementation of lab informatics solutions and their effect on laboratory business practices.

piece of your knowledge management strategy, then that should be part of your evaluation.

Q: If you were to recommend some improvements in the ELNs, what would those be?

A: We need to look at things like extraction tools and business intelligence tools that can extract real scientific information from the ELN and apply some sort of context to it so that we can begin to build predictive control to improve our processes. I have a colleague who says that if we put in an ELN but don't build new efficiencies, the only thing we've done is put paper on glass. It should be adding benefits, particularly around knowledge management, to improve our decision making and our processes. We continually need to improve ELNs, driving toward that goal. This depends partly on how the vendors build the product, how they structure the data moving forward, but it also depends on the customers. It's the customer's long-term vision of how they want to extract data, what kind of context they want to apply to it, how they want to feed it back into their systems and send that information back to the vendors; that plays just as important a role.

THIS FACILITY'S SUCCESS IS BASED ON BALANCE

by Rachel Muenz

Headquartered in the Livermore Valley in Northern California, the National Food Lab (NFL) is more than just a food and beverage testing facility.

"We really are a full-service research and consulting company for the food industry, starting with developing new ideas through marketing [and] with our product development group," says Julie Hill, vice president of the NFL's chemistry division.

She adds that the facilities include a chef to bring in culinary ideas, a sensory group to evaluate the sensory properties of the product, and a consumer group to evaluate the consumer acceptability of a product.

The facility also includes food safety, microbiology, and chemistry divisions. "I head up the chemistry group and handle things that shouldn't be in food, [such as] pesticide residues, and also things that should be in food," Ms. Hill says, adding the facility is focused on food manufacturers rather than on individuals.

> "The biggest challenge is ... making sure that we're challenging the lab and the staff but not getting so over our heads that we're doomed to fail."

"We're so food company-focused … that often we [do] the testing for them, [so] if it ever went to a dispute, there would be conflict-of-interest issues if we did work for consumer groups or individuals," she explains. "So we kind of shy away from that."

That was a good thing in the case of a strange request from one individual.

"We didn't take this one, but we do get individuals calling us on occasion, and the strangest request was to test someone's food because it was making [the person] sing like Elvis," Ms. Hill says, adding with a laugh, "I couldn't make up that one."

Inside the chemistry division

There are 155 employees in the NFL—some of whom are part-time staff— and about 35 of the

employees belong to the chemistry division. All those staff have college degrees, most in either chemistry or food science or some aspect of microchemistry or biochemistry, Ms. Hill says. The NFL also has a full training program for new staff.

▲ *The NFL's main instrument lab where chemists can easily collaborate on method development and problem solving.*

"It's more of a co-worker training program—'see one, do one, teach one,'" Ms. Hill explains. "There is [also] some opportunity to go outside and do some vendor training and go to events like [the IFT's (Institute of Food Technologists') Annual Meeting & Food Expo] or other meetings. We're trying to do more of that now than we have in the past."

Those 35 employees are kept busy analyzing an average of 50,000 to 75,000 samples a year while usually handling about 500 client projects from the 5,000 customers the NFL has in its database at any one time, she explains.

That large amount of work is kept manageable through the organization of the chemistry division, with specific employees focused on specific tasks—the sample control group, for example, is responsible for and handles all incoming samples.

"They make sure the paperwork that's sent with the samples is correct, tests have been identified, and products' sample codes are identified correctly," Ms. Hill says, adding the group also deals with clients on any issues that might come up as samples arrive at the facility.

If the sample control group is uncertain about how to handle an item, it is sent to the project leader, who also handles any technical issues that arise. After the sample control group is through with them, samples are sent to the individual chemist to run tests; the results are compiled and then sent to the client service group, who are responsible for getting the

final report to the client and handling any requests clients have.

"Everybody handles his or her piece of the stream, so it just makes it easier if you really know your piece and handle that well," Ms. Hill says.

"When we get it right, it's a reward for everyone; it means we're doing our job correctly."

A typical two weeks

That whole process begins with the samples arriving every day at 10:00 a.m. by FedEx or UPS. All the boxes are opened, and the samples and paperwork are inspected. The samples are logged into the lab's PerkinElmer Labworks LIMS program, and the paperwork is distributed to the chemists. The LIMS program is also used for test data and final reports.

While the NFL's microbiology department starts testing each sample they get that same day, because the chemistry department might get only one kind of a sample a day, they have to batch their samples over a longer time, Ms. Hill explains.

"It's just not cost-effective to run just one vitamin C, [for example]," she says. "We take in a bunch over a [longer] time period and batch [the samples] over a one- or two-week time period, depending on the turnaround time needs."

The analysts prioritize which samples need to be done first, and batched samples are then run all at once, with the testing broken up into sample preparation and analysis stages. Technicians prepare the samples, and then it's up to the chemists to run them on the instruments.

"Those [samples] are usually prepared midday and then put on the instruments at night," Ms. Hill says. "The next morning, the analysts will pull them off the instruments, interpret the results, do all the calculations, and do all the quality control charts. Then, if the data passes all the QC requirements, it goes to second review."

▲ *A typical day extracting pesticide out of food samples.*

Once that stage is complete, the results go to the client service group, who compile all the data into a report that is passed to the project leader for final approval of the entire project and finally emailed to the client.

"And we do that over and over and over," Ms. Hill laughs.

As for instrumentation, the chemistry department uses HPLC, autotitrators, protein analyzers, and moisture ovens to do its food chemistry tests, which determine components such as vitamin C that are found naturally in foods.

For testing for things that shouldn't be in food (pesticides, heavy metals, etc.), the chemistry division uses more

advanced equipment such as LC-MS-MS, GC-MS-MS, and ICP-MS, with Thermo Fisher Scientific, Agilent, and PerkinElmer making up the three main brands they use in the whole division.

The tough stuff

For Ms. Hill, balance is one of the major challenges in the chemistry division.

"The biggest challenge is assessing the capability of the lab, making sure that we're challenging the lab and the staff but not getting so over our heads that we're doomed to fail," she says.

She adds that her 25 years of experience in the industry—24 of them with the NFL—have helped her better understand which projects her division can handle and which it can't.

> "If a new regulation goes into effect, it just ups the awareness of doing testing. For example, the Food Safety Modernization Act is playing a big role."

"I've been doing this for a long time, so I know what project is going to be too much," Ms. Hill says. "I've been burned a few times and lost sleep over projects, and I don't like to do that."

The greater awareness of food safety in recent years, with food safety problems getting into the press and to the public much faster than before, has created another tough challenge for the NFL, as it has also sped up the turnaround time for results, she adds.

▲ *Technician extracting fat for food using the traditional soxlet method.*

"Twenty years ago, when I started, that didn't happen," Ms. Hill says. "It wasn't blasted out as fast. It's good for [our] business, but I think that's been a big change even in the last five years."

She adds that new government regulations have contributed to that greater awareness of food safety.

"It has a big impact on the testing industry; if a new regulation goes into effect, it just ups the awareness of doing testing," Ms. Hill explains. "For example, the Food Safety Modernization Act (FSMA) is playing a big role."

Despite her involvement with food in her work, she says she doesn't really have a favorite food.

"I'm a believer in a little bit of everything and not a lot of any one thing," Ms. Hill says. "I think you get into trouble when you eat a lot of one product, because if it is contaminated, then you are exposing yourself."

However, she adds she does have a least favorite food after a certain test in the lab.

"We tested fried chicken for fat one time, and it was over 25 percent fat," she says. "I just saw the amount of fat that was in the beaker—I haven't really eaten fried chicken since."

Varian Triple Quad 320 Gas Chromatograph Mass Spectrometer/Mass Spectrometer, the NFL chemistry department's work horse.

Staying motivated

As for the best part of her job, Ms. Hill says the successes are what make the challenges worthwhile.

"When we get it right, whatever that 'right' is—whether we win a project … or if we pass our proficiency samples so we get the same results as another laboratory," she says are what she enjoys most about her job. "When we get it right, it's a reward for everyone; it means we're doing our job correctly."

She adds that her staff also seems to be motivated by the "wins" as well, so she makes sure they get to hear that they won a project or that test results were what were expected. Putting family first is another benefit of working at the NFL.

"We're a very family-oriented business where we have flexible hours." Ms. Hill says. "I think between those two [the wins and flexible hours], they seem to be a pretty happy staff. But I think we need to do more; there's definitely more investigation [needed] into what really does motivate them instead of just assuming."

The lab's future

Currently, the lab is in the final stages of getting its ISO accreditation, something it has been working on for the past 18 years, Ms. Hill says.

"It's always been in the back of my mind; every time we've [developed] any kind of quality program in place at the lab, we've always based it on ISO, so [we've been] pointing in that direction all along," she says. "[It has finally become] a financial incentive to be an ISO lab. Our clients were starting to ask for it, but the basis of our quality program has always been ISO."

The NFL had its audit on April 9, and Ms. Hill expects the whole process to be complete around September.

Further into the future, she says the lab doesn't expect to change too much but is hoping to do more consulting work versus the straight testing of samples, though those possible changes are still just in the strategic planning stage.

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"We like to work with food manufacturers in helping them develop their programs, doing validation of their processes, [such as how, for example, they should cook their] rice crackers to make sure there's no *Salmonella* in the rice that will eventually [get] in the final product."

Rachel Muenz, *assistant editor for* Lab Manager Magazine, *can be reached at rachelm@labmanager.com or by phone at 888-781-0328 x233.*

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THE RIGHT CHOICE FOR

CENTRIFUGES

by Rachel Muenz

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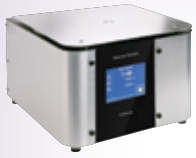

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HETTICH INSTRUMENTS CELL CULTURE VALUE PACKAGE

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➤Hettich recently announced the launch of its Cell Culture Value Package. The Cell Culture Value Package provides laboratories a robust, economical centrifuge package for spinning 15 mL and 50 mL conical tubes. The package features the ROTOFIX 32A benchtop centrifuge—an all-steel-constructed centrifuge that is quiet, reliable and safe.

- Boasts a five-year total warranty and is guaranteed to ship in 24 hours
- Centrifuge features a wide variety of swing-out and fixed angle rotors
- A wide range of other accessories is also available
- Exchangeable rotors also offered
- ROTOFIX 32A has dimensions of 257 x 366 x 430 mm (10" x 14.5" x 17")

BECKMAN COULTER OPTIMA X SERIES ULTRACENTRIFUGES

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➤Optima X Series preparative ultracentrifuges from Beckman Coulter Life Sciences incorporate an array of contemporary technical features to enhance the user experience, increase productivity and reduce costs. These centrifuges are available in two models—the XE, which delivers all of the basic features required to quickly set up and complete a run, and the more advanced XPN.

- Large touchscreen display offers a selection of nine languages
- Feature clean, intuitive design and on-screen help
- Reach a maximum speed of 100,000 rpm and generate forces up to 802,000 *x g*
- New Optima XPN iOS app (for XPN models only) allows remote monitoring and control of up to 16 instruments; can be used on iPhone, iPad or iPod Touch devices

An essential piece of basic laboratory equipment, the centrifuge applies thousands of gravitational force equivalents to a sample while spinning in order to separate structures and particles suspended in a liquid. Centrifuges are used for many applications in the lab, such as for performing density measurements, isolating suspended particles, separating liquids, and to clarify suspensions. A key consideration when you are looking at buying a centrifuge is the relative centrifugal force (RCF)— a function of rotor radius and the square of the instrument's rotational speed. Centrifuges which have the same RCF will supply the user with comparable resolving power and RCF is also important to know if you are transferring methods between centrifuges. Centrifuges fall into two general categories: Less costly instruments that feature basic capacity and speed, and "eco-friendly," ergonomic instruments. When deciding between these two types, you should consider the accessibility of the instrument and noise. Depending on the size and setup of your lab, certain centrifuges may not work if there is not enough room, and you also don't want an extremely loud centrifuge right next to where staff work. Discussing your needs with your vendor will help you determine the best centrifuge for your lab.

APPLICATIONS

- Performing density measurements
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ELECTRONIC LABORATORY NOTEBOOKS

CONVERGENCE OF DATA, INSTRUMENT SYSTEMS

by Angelo DePalma, Ph.D.

The consulting group Atrium Research defines an electronic laboratory notebook (ELN) as "a secure system that assembles content from multiple sources that are related to each other, allows for contextual annotation, and packages in a legally acceptable document [that] can be searched, mined, and collaborated."

As a component of a lab's information infrastructure, ELNs help laboratories capture and manage knowledge, streamline data management, protect intellectual property (IP), and, as a central repository, foster collaboration between and among groups and locations.

ELNs are *not* simply replacements for paper notebooks or the "savior" for every data management woe. Nor are they repositories for all data or even the final resting place for unstructured data such as emails. Atrium concludes that an ELN is not "going to make you more 'productive' all by itself."

Non-specific or generic ELNs provide most of the benefits of electronic data capture and storage and work more or less efficiently in any lab environment. But "no vendor has best-in-class functionality across multiple domains," according to Atrium CEO Michael Elliot.

Application- or task-specific ELNs, however, are experiencing the strongest growth. Atrium believes their popularity is due to higher user acceptance, more easily demonstrated return on investment, and their "disruptive" effect on lab operations; while generic ELNs compete directly against paper notebooks, specific ELNs do a lot more.

Both ELN types have their fans. As IT budgets are squeezed, companies comprising several laboratory types may decide on a one-stop solution to electronic record keeping. Specificity and some functionality are lost, but one product may perform well enough. Aside from cost, generic ELNs' scalability offers installation and deployment advantages: one product, many labs or disciplines, and multiple functions. Benefits are more accessible if the ELN product integrates easily with existing instrumentation and information backbones.

Trends

In a recently completed *Lab Manager Magazine* survey, respondents indicated that web-based and client-server ELNs comprised nearly 70 percent of installations, and more than 60 percent of deployments served fewer than 25 lab workers. The three most cited benefits of ELNs were protecting IP (26 percent), streamlining documentation and reporting (21 percent), and having a centralized repository for data (16 percent). Interestingly, just 5 percent of respondents mentioned improved communication and workflow coordination as significant benefits.

That adopting electronic records involves a shift in how labs operate and interact with data is well known. Indeed training, buy-in from rank-and-file workers, integration with existing systems, and fear of obsolescence accounted for 60 percent of challenges cited by respondents. At the other end of the desirability spectrum, 29 percent of end users believed that an ELN package's ability to provide remote or web access was "unimportant." Similarly, a quarter of those surveyed were not concerned with technical considerations such as ease of installation, multiple platforms, or scalability.

Convergence of data and instrument systems has become the key trend in ELNs. Readers are aware of environments in which ELNs and laboratory information management systems "communicate." But that's not the limit of convergence, according to Michael Price, VP of sales at KineMatik (Princeton, NJ). "Linking ELNs with lab equipment for data pull/push and creating synergies between other 'technology solutions' like quality management and clinical document management and enterprise resource

planning systems will allow better decision-making about investment and disinvestment."

"ELNs are *not* simply replacements for paper notebooks or the "savior" for every data management woe."

ELNs built on potent collaboration platforms such as Sharepoint can enhance efficiency, productivity, and collaboration while providing inherent capabilities critical to regulated industries; for example, supporting secure capture, exchange, and management of data efficiently and cost-effectively.

"Any company invested in R&D will benefit from an ELN, particularly with implementation across a broad set of verticals," Price says.

ELNs have passed the stage where users simply replace paper notebooks with a completely analogous electronic counterpart. "ELNs are more than just 'sticker books,'" says Stuart Ward, Ph.D., product manager for E-WorkBook Suite at IDBS (Surrey, UK). Organizations are adopting ELNs through recognition of deliverables such as asset/sample management, data capture, graphing, and reporting. ELNs serve as researchers' "single points of truth" and "essential collaboration hubs," notes Ward. Within this context, ELNs provide a means of capturing and sharing diverse instrumentation data from, for example, chromatographs and weighing stations.

Within the collaboration model, ELNs also provide granular security that allows sharing some data within an organization or even outside the company, while protecting sensitive data within a group or company.

Not surprisingly, the most cited benefit of ELNs in our survey was the protection of IP. The America Invents Act of 2011 moves the United States to a "first to file" model that places a premium on data integration and reporting, a function well suited to ELNs. "It's no longer sufficient to have a time stamp," Dr. Ward observes. "You need to find and pull together useful information suitable for patent filing quicker than your competitors. That means you need a data *system*, not a sticker book."

Purchase decisions

"Consolidation of IT software and a harmonization of processes to improve productivity tend to be the main drivers for ELN acquisition," Dr. Ward tells *Lab Manager Magazine*. In today's data-rich laboratories, no rationale exists for asking researchers to capture and consume scientific data in ways less sophisticated than those they use to consume music or social media. In addition to saving time, the aggregative power of an ELN should also reduce decision-making time.

But the key, Dr. Ward says, is software that does much more than simply capture documents or time stamp experiments. Researchers require a combination of simplicity and sophistication. Any modern ELN should allow capture and computation of a wide range of data, offer rapid search capabilities, and be able to serve multiple software platforms.

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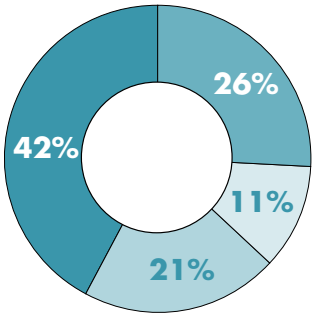
THE TYPES OF ELN INSTALLATIONS OUR READERS USE IN THEIR LABS:



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CENTRIFUGES

ADDING SAFETY AND VERSATILITY TO HIGH-SPEED SEPARATIONS

by Mike May, Ph.D.

When it comes to common technology in a laboratory, centrifuges rise toward the top of the list. If a scientist wants the liquid at the bottom of the tube, but it's distributed along the sides in droplets, centrifuge it. Need to separate the cells from a suspension? Centrifuge it. This tool also comes into play in a wide range of other workflows, including purifying DNA, RNA, or proteins. As Dr. Lars Borrmann, group marketing manager at Eppendorf (Hauppauge, NY), says, "It's very common technology."

To meet so many applications, centrifuges come in many forms. Microcentrifuges can spin 1.5- to 2-milliliter tubes at speeds that provide 20,000 times the force of gravity (*g*). Molecular biologists use this kind of centrifuge when purifying nucleic acids or proteins. Many researchers use a multipurpose centrifuge. These come in benchtop or floor models and provide considerable versatility. For example, it might spin tubes that range in volume from 1.5 milliliters to 1 liter. These can even spin multiwell plates. For faster spinning, researchers use an ultracentrifuge, which can spin tubes at speeds that generate 100,000 to 1,000,000 x *g*. "This could be used to separate proteins based on their mass," says Borrmann. So-called flow-through centrifuges provide nonstop spinning, which comes in handy when someone needs to spin down large volumes—up to a few thousand liters—from a bioprocessing fermenter or tank. "You can spin the entire liquid through," says Borrmann, "and it separates the cells from the liquid in a continuous flow."

Increasing comfort

Anyone who ever used an ultracentrifuge years ago knows that "easy to use" did not describe that device. After loading tubes in the rotor, you screwed down the top; it felt like reaching into the bottom of a washing machine to get the rotor in place. The process is a little easier now.

"There are lots of factors you can improve," says Borrmann. For example, giving the device a lower profile provides easier access. Instead of using a screw that requires several turns to tighten, Borrmann says they have a QuickLock rotor that "closes in a quarter turn and is safely closed."

These features also play a part in what Borrmann calls an overall trend toward making centrifuges more user-friendly. His company even makes sure that the lid closes easily. "It's like a door on a Cadillac closing," he says. "It's a soft-touch approach that gently closes and locks automatically."

More from less

As labs require more equipment, space grows increasingly valuable. That impacts the design of centrifuges. "Size is important," says Borrmann. "Today's centrifuges save space."

Also, researchers prefer platforms that perform multiple functions when possible. Thinking along those lines, Eppendorf developed its crossover centrifuge 5430. "It's between a micro centrifuge and a multipurpose one," says Borrmann. "It has the size of a micro centrifuge but can do some of what a multipurpose centrifuge can do, like spinning plates."

Other centrifuges also include new features. For example, Borrmann points out a trend toward refrigerated centrifuges. "They protect samples better from the heat generated during spinning, and they ensure a more consistent environment during the process," he says.

Safer spinning

Some of the enhanced safety features of modern centrifuges can be heard but not seen. For example, quieter devices make life in the lab more pleasant while the centrifuge runs.

Noise, however, does not generate a centrifuge's biggest danger. If work is being done on biological agents and a tube breaks during spinning, the agent can be released

into the air. That's just what happened at a biosafety level 3 (BSL-3) laboratory at Yale University in 1994, and a scientist contracted the Sabia virus, which can cause internal bleeding. Although the Yale scientist recovered, today's centrifuges guard against such an accident.

"It's like a door on a Cadillac closing. It's a soft-touch approach that gently closes and locks automatically."

For example, some centrifuges provide aerosol-tight containment. So if a researcher is spinning bacterial cells, a virus, or radioactive samples and a tube leaks, the material cannot escape the rotor.

Nonetheless, Brandy J. Nelson, biological safety officer at the University of Kentucky, points out that researchers might buy a centrifuge without the aerosol-tight feature because they plan to use the device in a BSL-1 or -2 lab. "Then they might move to working with viral vectors and need that containment." She says that some manufacturers offer an upgrade to an aerosol-tight rotor, but some don't. "Manufacturers could do better at that," she says.

In addition, after a broken tube, the rotor traps just the potentially infectious or hazardous substance. It's safe only if a researcher opens the rotor in a biosafety cabinet. Nelson would like to see a sensor that tells you ahead of time that a tube leaked. Maybe the sensor could just detect liquid in the rotor.

Rather than place all of the safety responsibility on the manufacturers, Nelson adds that training could be improved in labs that use centrifuges. "They're very common equipment in labs, and people don't always get training and information on hazards," she says.

Managing maintenance

Nelson's other top requests involve maintenance. First, she'd like to see easy-to-clean rotors and buckets. "It's very hard to decontaminate them after a spill," she says. "In microcentrifuges, for example, it's really hard to clean where you put the 1.5-milliliter tubes."

Nelson's second request involves ordinary wear. "In some centrifuges, the rotor is exposed to such high force that it wears down over time, and you have to change the speed rating." She says that some centrifuges digitally track the usage of rotors so you know when to set back the speed rating on them. "It would be nice if they all did that," Nelson says.

With the advances in centrifuges since the hand-cranked ones in the 19th century, we can surely expect an increasing array of capabilities and applications. Likewise, tomorrow's centrifuges should be even safer than today's.

Mike May *is a freelance writer and editor living in Austin, TX. You can reach him at mike@techtyper.com.*

FOR ADDITIONAL RESOURCES ON CENTRIFUGES, INCLUDING USEFUL ARTICLES AND A LIST OF MANUFACTURERS, VISIT WWW.LABMANAGER.COM/CENTRIFUGES

FREEZE DRYERS

MORE WAYS TO LYOPHILIZE SAMPLES

by Mike May, Ph.D

The use of freeze dryers extends from applications in academic labs to zoos. Moreover, this technology contributes to basic research and manufacturing. For example, scientists at a zoo might use a freeze dryer to increase the concentration of a tranquilizer so that it works for larger animals such as bears or even elephants. Likewise, researchers use freeze-drying techniques to study animal nutrition, including freeze-drying excrement as part of the process of determining the amount of calories an animal captures from the food it eats. These examples, though, provide only a glimpse of the many workflows that depend on freeze-drying.

In brief, the freeze-drying process, or lyophilization, dehydrates a sample to preserve it. For instance, pharmaceutical companies might lyophilize a drug solution, making a preserved freeze-dried powder. This can be put in a two-sided syringe—with the powder in one side and saline in the other—that combines the ingredients only before injection, thus increasing the shelf life of a product.

In fact, some of the first large-scale freeze-drying started in World War II. Getting enough plasma to Europe to treat soldiers who were injured in combat required extensive refrigeration. Often, a lack of resources prevented the plasma from staying frozen and some of it spoiled, which created a life-or-death situation in field hospitals. To make it possible to ship the plasma at room temperature, the United States Army started freeze-drying the plasma. Preserved through lyophilization, the plasma gained the shelf life that military medical units needed.

Explaining the process behind freeze-drying, Jenny Sprung, product manager at Labconco (Kansas City, MO), says, "It takes a solid frozen sample and removes the moisture from it, without passing through the liquid phase." In that way, this sublimation-based process maintains the biological integrity of the sample and preserves it for storage.

The lack of heating in this process makes it particularly useful for heat-sensitive materials. For example, researchers use lyophilization in many processes that involve nucleic acids—DNA and RNA—such as sequencing.

Diverse devices

Researchers can choose between freeze dryers that handle anywhere from half a liter to 100 liters. Manufacturing facilities, such as drug-making facilities, use the larger devices.

How a freeze dryer works, though, depends in part on the solution being lyophilized. "We've seen a move from aqueous-based samples to more solvent-based ones," says Sprung. The solvent matters because freeze-drying requires the right collector temperature to ensure that the sample won't melt back on the freeze dryer. For example, Sprung says, "We're seeing more [high-pressure liquid chromatography] samples." These use acetonitrile as the solvent, and it melts at –45 degrees Celsius. To lyophilize such samples, a freeze dryer needs a lower collection temperature.

Given the pace of changes in research, scientists often adjust protocols. Consequently, Sprung says, "My recommendation is that if you're going to purchase a freeze dryer, think long term." She points out, for example, that alcohols did not freeze-dry very well in the past because of their low freezing points, but Labconco makes freeze dryers that go down as far as –105 degrees Celsius, which works with some alcohols.

Beyond freeze-drying at lower temperatures, the newest models include some additional features, such as allowing users to program the temperature to ramp up during a run. For example, the SMART freeze-drying technology from SP Scientific (Stone Ridge, NY) helps researchers develop new freeze-drying protocols. Some of today's freeze dryers even include a freezing step on the front end.

Consultation counts

For anyone in the market for a new freeze dryer, Sprung says, "I recommend talking to a manufacturer first." She adds that some customers just order a freeze dryer without talking to anyone, which doesn't always work so well. "Many people who do that have had to exchange them," Sprung says.

> **"We've seen a move from aqueous-based samples to more solvent-based ones."**

It's worth taking the extra time at the start to get the best product because freeze dryers tend to last a long time. "We started manufacturing them in 1974," Sprung says, "and we still have some of our first freeze dryers out there." She adds that people still call for parts and service on her company's earliest models. That brings up another consideration: a customer should select a company that looks strong enough to be around a few decades down the road, in case today's newest freeze dryer needs parts and service many tomorrows from now.

In fact, scientists never know when they'll need parts or service. From a user's standpoint, Jordan J. Green, Ph.D., professor of biomedical engineering at Johns Hopkins University in Baltimore, Maryland, says, "I am mostly satisfied with the current products overall." He adds, "The biggest improvement that matters to me is reliability. For example, my lab's lyophilizer is currently being repaired due to a problem with the pump."

Also, Thomas Anchordoquy, Ph.D., professor at the University of Colorado's Skaggs School of Pharmacy and Pharmaceutical Sciences, would like to see a temporary power source with a surge protector as part of a freeze dryer. He says, "Currently, when we have a power spike, the lyophilizer program often shuts down."

So both new and old freeze dryers will probably end up needing service at some point. This arises in part from the extensive use of these instruments in a lab, plus the fact that researchers tend to keep a freeze dryer in service for a long time—usually decades. That makes all the more reason for a researcher to carefully explore how a freeze dryer will be used and to talk to an expert about options before making a purchase. Likewise, finding the most versatile unit now could make a freeze dryer more likely to be useful in future protocols. This workhorse technology will probably stay around—in research and manufacturing—for many decades in the future.

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FOR ADDITIONAL RESOURCES ON FREEZE DRYERS, INCLUDING USEFUL ARTICLES AND A LIST OF MANUFACTURERS, VISIT **WWW.LABWRENCH.COM/FREEZE-DRYERS**

PCR REAGENTS

MAKING IT POSSIBLE TO AMPLIFY MORE ACCURATELY, EVEN WITH PROBLEMATIC SEQUENCES

by Mike May, Ph.D.

To get enough DNA for processing, such as sequencing the chain of nucleotides, researchers turn to the polymerase chain reaction (PCR). A series of reagents drive this process, and that includes polymerase, buffers, and so on. To make it easier for scientists to use this technique, vendors make kits of PCR reagents. As PCR moves forward, taking on more difficult stretches of DNA to amplify, the reagents must advance in lockstep. In fact, every advance in PCR platforms demands concomitant improvements in the PCR reagents to get the most from the advancing technology.

"Robustness is a recurring theme with PCR reagents, and it has been for many years," says Fiona Stewart, Ph.D., PCR product manager at New England Biolabs (Ipswich, MA). For the most part, robustness describes reliability and consistency of the reagents. For example, forensic labs apply PCR to many materials from crime scenes to analyze DNA samples, and those processes must produce reliable results. In these cases, lives literally hang in the balance, in part determined by the consistency of the PCR reagents.

Pushing ahead with the platform

"Trends in PCR reagents tend to go hand in hand with advances in instrumentation," says Rod Pennington, Ph.D. senior research scientist at Promega (Madison, WI). "For instance, we see a trend toward reagents containing brighter, less-inhibitory (double-stranded) DNA binding dyes. This enables users to utilize the full HRM (high-resolution melt) potential of current thermocyclers that feature finer temperature control." He adds that today's PCR platforms often provide faster cycling with high throughput, and reagents must be designed for that.

Today's reagents can also help scientists find specific targets in samples. As Pennington says, "In some cases, researchers need reagents that are custom produced and/or preloaded with primers and probes for detection of specific targets."

The need for speed

At the real-time PCR research and diagnostic core facility of the School of Veterinary Medicine at the University of California, Davis, director Emir Hodzic, D.V.M., Ph.D., often gets requests for fast turnarounds on samples. "Sometimes our clients ask for results within a couple of hours," he says. "To go that fast, we need to change the thermal cycler's block. That's an obstacle to speed, and then you need to do some optimization."

Trisha Dowling, director of product management for PCR at Life Technologies (Carlsbad, CA), points out that "there are differences in thermal cyclers that are optimized for faster PCR reactions." For example, she says, "Our Veriti thermal cycler is optimized to run both standard and fast PCR protocols at a range of volumes. Our GeneAmp PCR System 9700 offers multiple block choices of different alloys for faster sample ramp rates." To run the process faster, the thermal-cycler block needs to accommodate faster temperature changes and the enzyme must also work at the new rate. By using a smaller volume, the sample's heat can be changed faster and the enzymatic reaction works faster across the sample, too. "All those components must work together," she says.

Another key factor to faster reactions is ease of setup and programming. As Dowling says, "Our Veriti thermal cycler has an intuitive touchscreen that makes it very easy to input and quickly start your PCR protocol, or to easily access one of the many pre-programmed methods."

Out-of-the-box excellence

Scientists also expect today's PCR reagents to work more or less upon delivery. "They want good results with minimal optimization, regardless of the template," says Stewart.

In the past, different DNA templates required different polymerases for amplification. "Now, there's no reason to have a bunch of polymerases in your freezer,"

says Stewart. "In fact, researchers want to see good results for all of their PCR reactions using a single polymerase and—as often as possible—a single buffer."

Pennington also notes the trend toward simplification of the PCR workflow. He says, "For instance, inhibitor-resistant PCR enzymes and buffer formulations can allow the user to avoid certain time-consuming steps in their sample preparation."

Charles Nicolet, Ph.D. director of sequencing technology at the University of Southern California's Epigenome Center Data Production Facility, says, "We have been using a 2X master mix from Kapa Biosystems for our PCR. It is stable, easy to use, and robust. It amplifies regions with little to no apparent bias. Technically we would not change anything." He adds, "I suppose economics are always an issue. The Kapa enzyme is very competitively priced, but if anything could be changed, then making it cheaper is always appreciated." As researchers apply PCR to even more research questions and use it increasingly as part of the sample preparation for other processes, such as next-generation sequencing, price could turn into an even bigger issue.

As expected, speed

For most any trend related to lab work, people want things to work faster, and PCR is no exception. In fact, researchers tend to want more and faster. With PCR reagents, that means researchers want the process to run faster and work with, as Stewart says, "more difficult amplicons." For example, she says, "GC-rich amplicons have always been difficult to amplify, but we're making significant headway there."

On the speed side, the reagents really stretch the possibilities. "We're pushing the limits of speed," Stewart says.

In addition, researchers want to set up their PCR reactions at room temperature. "So they want to use hot-start reagents, whose polymerase is inhibited at lower temperatures and activated during PCR cycling," Stewart says.

Enhanced accuracy

Fidelity of amplification—getting the nucleotides right—also keeps increasing with advances in PCR reagents. In some cases, researchers simply use PCR for a yes-no assay—one that just looks to see if a sequence exists in a sample. In such cases, there's no reason to pay the higher price for increased fidelity. On the other hand, if a researcher uses PCR to make libraries for next-generation sequencing, higher fidelity from the PCR impacts the accuracy of the end result from the sequencing. In those cases, a researcher wants as much fidelity as possible from the PCR reagents.

Some applications of PCR raise the accuracy bar higher than ever. As Pennington says, "With PCR being increasingly popular in forensics and environmental testing, there is a need for reagents that function well in the presence of inhibitors and with less-than-pristine samples in general."

In the future, PCR will continue to expand to new areas, with the reagents driving that in part. "High-throughput reagents are particularly well-suited for assays run repeatedly on large numbers of samples, as might be seen in a diagnostic setting," says Pennington. He also notes the potential of digital PCR, which provides more precision than traditional PCR. He says, "Digital PCR opens up new and better options for quantification of low-copy targets." He adds, "Improved reagents and technologies for HRM allow this technique to be applied to analyses of difficult SNPs (single nucleotide polymorphisms) that weren't amenable to HRM analysis before the advent of these improvements."

So the advances in PCR reagents push this technology into more applications. The more sophisticated reagents also make it easier for scientists to use this technology, all while getting more accurate answers in less time.

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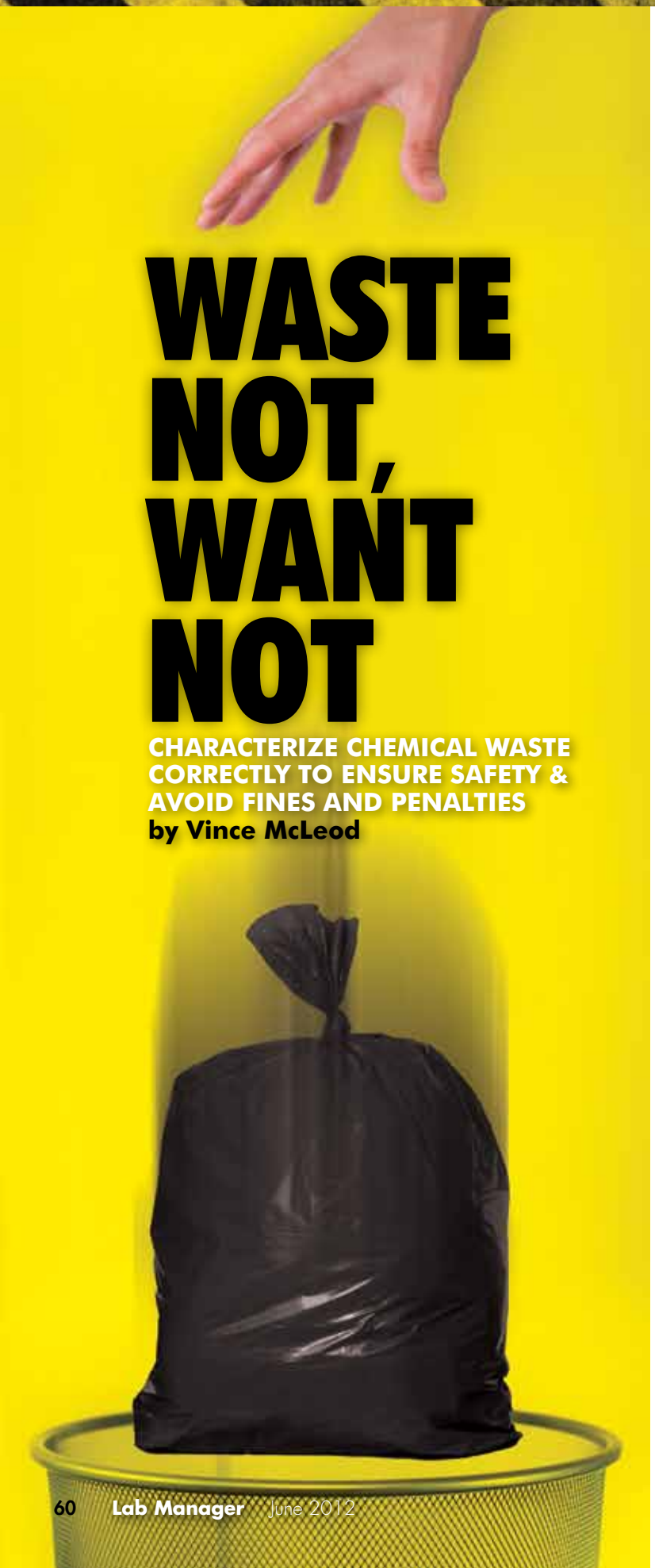

WASTE NOT, WANT NOT

CHARACTERIZE CHEMICAL WASTE CORRECTLY TO ENSURE SAFETY & AVOID FINES AND PENALTIES

by Vince McLeod

A recent visit by state and federal inspectors brought to light the importance of knowing all your waste streams intimately. Working in a large academic research institution, with all its diverse classroom laboratories, research laboratories and support shops, is quite the challenge. And, sure enough, a few things slipped through the cracks. Sharp-eyed, experienced inspectors were able to uncover these transgressions without much effort, and the resulting fines were not insignificant. A reoccurring problem, though mostly concerning shop waste streams, was the failure to fully determine the hazardous characteristics of all wastes.

"Some states and local jurisdictions have waste or chemical management requirements that go "beyond the EPA."

This month, we will provide an introduction and overview of waste characterization. Our focus will be on laboratory chemical wastes, since these are the main culprits when it comes to waste streams in research and production facilities, and determining whether they should be considered hazardous. Proper management of chemical waste is not only important for safety but also for economic health, as we found out given the serious fines and penalties possible if they are not handled according to regulations. We will zero in on the federal regulations dealing with hazardous waste characteristics.

Getting started — Know the rules

The Environmental Protection Agency (EPA) developed regulations, outlined in the Resource Conservation and Recovery Act (RCRA), for the treatment, storage and disposal of all hazardous wastes. RCRA defines those wastes that are hazardous, i.e., those that must be disposed of as hazardous wastes. The details are contained in the Code of Federal Regulations, Title 40: Protection

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SAFETY TIP

PROVIDE SECURE, ADEQUATELY SPACED, WELL VENTILATED STORAGE OF CHEMICALS By James. A. Kaufman

In academic institutions, the most serious issue is the restriction of access to hazardous chemicals to appropriate personnel. Students and others will steal chemicals. Keep the door to the storeroom locked and only allow authorized people to get at these materials. Today, we are even more concerned about the misuse of lab chemicals. Keep the door locked.

The space provided for chemical storage should be sufficient to permit containers to be no more than two deep on a shelf. There should be enough room between containers to permit a hand to reach in and remove a bottle without knocking something off the shelf.

Put a supply of colored, adhesive dots in the storeroom. Have everyone mark the cap of everything used for the next year. At the end of the year, make up a list of the unmarked containers. Send the list to waste disposers for a bid in removal.

Chemical store room ventilation is recommended to be one cubic foot per minute per square foot of floor space. The minimum recommended level is 150 cubic feet per minute.

The use of lips on shelves is recommended in locations where earthquakes, hurricanes, or tornadoes are likely. In this case, a removable wire insert type is suggested.

Source: Kaufman, James A., Laboratory Safety Guidelines - Expanded Edition, The Laboratory Safety Institute, www.labsafetyinstitute.org

of Environment, parts 260 to 265.[1] We believe that most lab managers are well aware of the U-list and the P-list, specific lists of hazardous chemicals that, when disposed of, become hazardous chemical wastes. The U-list covers discarded chemical products, off-specification chemicals, container residues, and spill residues that have been identified as toxic wastes and receive a corresponding U-code. The P-list refers to a special sub-list of compounds identified as acutely toxic and subject to smaller quantity exclusions. These lists are found in 40 CFR 261.33.

In addition, there are smaller lists for chemicals from nonspecific sources, mixtures of spent solvents, wastewater sludge and distillation bottoms that fall under the F-codes (found in 40 CFR 261.31). Wastes from specific procedures such as wastewater treatment sludge and distillation wastes from certain chemical production processes receive a K-code (found in 40 CFR 261.32).

Although federal regulation establishes a baseline, we must emphasize that some states and local jurisdictions have waste or chemical management requirements that go beyond the EPA. Therefore, it is critical to check with state and local entities regarding any additional requirements.

Next step — Identification

As a lab manager, the burden is on you, the generator, to characterize all wastes produced by the lab or facility. For the average laboratory, a waste is considered hazardous if any components are on one of the two lists of hazardous chemicals (P-list for acutely hazardous or U-list for general toxic chemicals). But what if your lab generates a waste stream that does not contain any U-listed or P-listed material and does not fall into one of the F- or K-listed categories? How do you make a determination of whether the waste is hazardous or not? Very simply, it must meet one of the hazardous characteristics: ignitability, corrosivity, reactivity or toxicity, as defined in 40CFR 261.20. In these cases, we would encourage you to contact an experienced consultant to assist in sampling and testing in order to determine whether the waste meets any hazardous characteristics. If the waste is not hazardous, then disposal via the sewer system or the general refuse collection might be an alternative. However, we caution you again to confirm with the local providers and authorities to ensure that all local codes and ordinances are followed.

"As a lab manager, the burden is on you, the generator, to characterize all wastes produced by the lab or facility."

The hazardous characteristics

Unconventional, temporary or short-term wastes must be fully characterized for proper disposal. Again, the four hazardous characteristics are ignitability, corrosivity, reactivity and toxicity. Actual testing is sometimes avoided with sufficient general knowledge, i.e., knowledge of the specific constituents used and the process by which the waste is generated. In most cases, however, representative samples are collected and tested to make the determination.

Ignitable wastes are given the code D001 and exhibit any of the following properties:

- A liquid that has a flash point less than 60°C (140°F), determined by the Pensky-Martin Closed-Cup Tester or the Setaflash Closed-Cup Tester
- A non liquid that is capable of causing fire through friction, adsorption of moisture or spontaneous chemical changes
- Is an ignitable compressed gas as defined in 49 CFR 173.300
- Is an oxidizer as defined in 49 CFR 173.151

Corrosive wastes are given the code D002 and exhibit any of the following properties:

- Aqueous liquid with a pH less than 2 or greater than 12.5
- A liquid that corrodes steel at a rate greater than ¼ inch (6.35mm) per year at a test temperature of 55°C (130°F)

Reactive wastes are given the code D003 and exhibit any of the following properties:

- Is normally unstable and undergoes violent change without detonating
- Reacts violently with water
- Forms potentially explosive mixtures with water
- Generates toxic gases or vapors when mixed with water
- Is a cyanide- or sulfide-containing waste that can generate toxic gases or vapors
- Is capable of detonation or explosion if subjected to a shock or heat
- Is an explosive as defined in 49 CFR 173

Toxic wastes are given a D-code, according to Table 1 (below), if any of the toxic compounds present are equal to or above the respective limits as determined by the Toxicity Characteristic Leaching Procedure (TCLP). This is basically a water-extraction procedure for determining if toxic compounds can leach out of the waste. TCLP is defined in Test Method 1311.[2]

Summary

To operate safely and to avoid potential expensive regulatory fines, proper management of hazardous chemical waste is paramount. If you are new to handling laboratory wastes, this article should get you moving down the right path. If you are an experienced lab manager, then hopefully there is some useful information here to help you review your current operations. We look forward to lots of reader feedback. Stay safe!

Maximum Concentration of Contaminants for the Toxicity Characteristic

EPA HW No.[1]	Contaminant	CAS No.[2]	Regulatory Level (mg/L)
D004	Arsenic	7440-38-2	5.0
D005	Barium	7440-39-3	100.0
D018	Benzene	71-43-2	0.5
D006	Cadmium	7440-43-9	1.0
D019	Carbon tetrachloride	56-23-5	0.5
D020	Chlordane	57-74-9	0.03
D021	Chlorobenzene	108-90-7	100.0
D022	Chloroform	67-66-3	6.0
D007	Chromium	7440-47-3	5.0
D023	o-Cresol	95-48-7	200.0
D024	m-Cresol	108-39-4	200.0
D025	p-Cresol	106-44-5	200.0
D026	Cresol	.....	200.0
D016	2,4-D	94-75-7	10.0
D027	1,4-Dichlorobenzene	106-46-7	7.5
D028	1,2-Dichloroethane	107-06-2	0.5
D029	1,1-Dichloroethylene	75-35-4	0.7
D030	2,4-Dinitrotoluene	121-14-2	0.13
D012	Endrin	72-20-8	0.02
D031	Heptachlor (and its epoxide)	76-44-8	0.008
D032	Hexachlorobenzene	118-74-1	0.13
D033	Hexachlorobutadiene	87-68-3	0.5
D034	Hexachloroethane	67-72-1	3.0
D008	Lead	7439-92-1	5.0
D013	Lindane	58-89-9	0.4
D009	Mercury	7439-97-6	0.2
D014	Methoxychlor	72-43-5	10.0
D035	Methyl ethyl ketone	78-93-3	200.0
D036	Nitrobenzene	98-95-3	2.0
D037	Pentrachlorophenol	87-86-5	100.0
D038	Pyridine	110-86-1	5.0
D010	Selenium	7782-49-2	1.0
D011	Silver	7440-22-4	5.0
D039	Tetrachloroethylene	127-18-4	0.7
D015	Toxaphene	8001-35-2	0.5
D040	Trichloroethylene	79-01-6	0.5
D041	2,4,5-Trichlorophenol	95-95-4	400.0
D042	2,4,6-Trichlorophenol	88-06-2	2.0
D017	2,4,5-TP (Silvex)	93-72-1	1.0
D043	Vinyl chloride	75-01-4	0.2

1. Hazardous waste number.
2. Chemical abstracts service number.

References:

1. *Protection of Environment.* Environmental Protection Agency, 40 CFR, Subchapter I — Solid Wastes, Parts 260–265. http://www.gpo.gov/fdsys/search/pagedetails.action?collectionCode=CFR&searchPath=Title+40%2FChapter+I%2FSubchapter+I%2FPart+261&granuleId=&packageId=CFR-2000-title40-vol1&oldPath=Title+40%2FChapter+I%2FSubchapter+I&fromPageDetails=true&collapse=true&ycord=157
2. *Test Methods for Evaluating Solid Waste, Physical/Chemical Methods.* EPA Publication SW-846. Environmental Protection Agency, Washington, DC. Latest edition. From 40 CFR 261.24 (page 55 in the PDF referenced above).

***Vince McLeod** is an industrial hygienist certified by the American Board of Industrial Hygiene and the senior industrial hygienist in the University of Florida's Environmental Health and Safety Division. He has 22 years of occupational health and safety experience at the University of Florida, and he specializes in conducting exposure assessments and health-hazard evaluations for the university's 2,200-plus research laboratories.*

THE THIRD ANNUAL LABORATORY SAFETY SURVEY

SMALL BUT STEADY IMPROVEMENT ACROSS MOST LAB SAFETY CATEGORIES

by Pam Ahlberg

Three years ago we began surveying our readers to find out about their lab safety practices and to track how those practices change moving forward. Last year's survey indicated fairly substantial improvement over 2010 despite the continuing economic pressures that might have made lab health and safety a "nice to have" and not a "must have." But that was not the case last year, nor was it the case this year, when we found modest but steady improvement across nearly all lab health and safety categories.

Demographics

This year 464 lab professionals participated in the survey. Most of the respondents (just under half) were again from the supervisor, director, or manager levels. The largest areas of work were fairly evenly distributed among the biotechnology, chemical, clinical, environmental, and microbiology industries. A slightly smaller percentage were involved in the food and beverage and pharmaceutical industries, while the balance worked in cancer/oncology, cell biology, drug discovery, forensics, genetics, immunology, neuroscience, and "other."

When it came to the types of research organizations respondents worked in, the majority were university or college (28 percent), clinical or medical (26 percent), industry (18 percent), and government (11 percent). The balance, at much smaller percentages, worked in contract labs, private research, and manufacturing. These numbers were nearly identical to last year's. Also similar to last year's results was the size of respondents' labs, with almost half (42 percent) working in labs with ten or fewer people. Only 10 percent worked in labs with 101 or more people.

Safety and hygiene

This year we found that the differences in laboratory safety and hygiene practices from 2011 to 2012, while rather small, were moving in the right direction. For example, 75 percent of respondents said their labs have designated hygiene officers, up three percentage points from last year. And 20 percent of respondents reported that their labs do *not* have designated hygiene officers, down four points from last year (24 percent vs. 20 percent). For designated safety officers, the percentage greater was even smaller but positive just the same, with 81 percent having designated safety officers compared with 80 percent last year and one percent fewer *not* having designated safety officers in their labs. While the numbers aren't dramatic, the trend is promising.

Equally positive were improvements in all kinds of laboratory record-keeping practices. This year's survey reports a nine percent increase in the number of labs having a copy of the UF Laboratory Safety Manual (56 percent vs. 47 percent), a six percent improvement in being current in their annual chemical and hygiene planning and training (86 percent vs. 80 percent), and a five percent increase in those having a biological safety manual (73 percent vs. 68 percent). As for materials safety data sheets and chemical inventories, both of those remained constant year over year at 99 percent and 91 percent, respectively.

"[Seventy five] percent of respondents said their labs have designated hygiene officers, up three percentage points from last year."

Health and safety

In basic laboratory health and safety management practices, we also saw small and consistent improvement, with minor exceptions. Four percent more labs reported that their chemical and lab safety manuals were current and accessible to every worker (96 percent vs. 92 percent). One percent reported that those workers using biohazards, toxins, and regulated carcinogens had received special training (90 percent vs. 89 percent). Another one percent more respondents said that all workers were instructed in emergency action/fire prevention plan procedures (97 percent vs. 96 percent) and that all hazards identified by previous safety audits had been abated (92 percent vs. 91 percent). Two percent more respondents said that workers had been trained in how to respond in the event of an accident such as a chemical spill (96 percent vs. 94 percent).

However, there were a few downturns in this category, which included a one percent decline in the number of labs that said workers were properly trained in chemical safety, physical hazards, and laboratory safety (94 percent vs. 95 percent). Another one percent fewer labs reported that periodic laboratory safety inspections were performed by lab workers (88 percent vs. 89 percent). Fortunately, these small percentage decreases were outweighed by greater increases.

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When it came to safety inspections, about a third of respondents (32 percent) said that their labs conducted those annually, followed closely by those who hold inspections monthly (30 percent), quarterly (17 percent), and twice a year (12 percent). Compared with 2011, these new numbers represent a general increase in the frequency of safety inspections, with a three-point increase in those doing inspections every six months and every month. Decreases were reported in longer inspection intervals: every two years—down four points and annually—down one point, which all in all is an improvement in the frequency of safety inspections.

When asked 18 questions concerning general safety management practices, such as labeling, clutter, lighting, first aid kits, and protective clothing, the answers also indicated a positive trend. Of those 18 categories, 11 showed improvements from last year, four showed lack of improvement, and three remained the same as in 2011. The greatest jump in improvement was to the statement "Sinks are labeled 'Industrial Water - Do Not Drink'"—with yes answers up nine points, from 41 to 50 percent. Another response indicating considerable improvement was to the statement "All shelves have lips, wires, or other restraints to prevent items from falling"—with yes answers up five points, from 60 to 65 percent. The most notable *decreases* in improvement were responses to the statement "There is adequate noise control to allow workers to focus on their work"—with yes answers down three points from 90 to 87 percent, and to "All employees know the location of the first aid kit and it is accessible"—down two points, from 95 to 93 percent.

Hazardous materials

Of the 12 statements concerning hazardous materials management in the lab, improvements over 2011 numbered nine, no change was indicated for three, and only one statement—"Chemicals are properly labeled to identify contents and hazards"—dropped one point, from 98 to 97 percent. Those statements that had the greatest jump in yes answers were "Hazard evaluations and exposure assessments have been conducted for high-hazard/low-PEL material use in the lab (e.g., formaldehyde, methylene chloride, etc.)," moving up four points, from 79 to 83 percent, and "There is a designated chemical hygiene officer for the lab," moving up three points, from 72 to 75 percent. The highest percentage of yeses were to the statements "All regulated carcinogens are handled safely to reduce employee exposure" and "All sharp objects are stored in puncture-proof containers and labeled appropriately (medical or hazardous waste)," both at 96 percent, followed by "Chemicals are separated by hazard class (acids, bases, oxidizers, flammables, etc.) and stored to prevent spills" and "A plumbed emergency shower is available within 100 feet of all areas where chemicals may splash onto an employee's body," both at 95 percent yes.

> "Equally positive were improvements in all kinds of laboratory record-keeping practices."

Fire and electrical

In the category of fire and electrical safety, nearly the exact pattern was repeated. Of the eight statements, improvements in yes answers numbered six, lack of improvement numbered two, and one statement, "Fire doors are unobstructed and easily closed," remained the same as last year at 96 percent yes. The greatest improvement in this category—with a three-point increase in yeses over last year—was to the statement "All flammable liquids are stored in flammable-proof storage cabinets."

Laboratory equipment

The only category in which improvement and lack of improvement negated each other was safety of laboratory equipment. And as you can see in the chart below, the number of statements to which the yes answers rose was the same as the number that did not—with five percent each. Two statements retained the same number of yeses as the year before. Notable here was the six-point increase in improvement to the statement "Non-spark-proof refrigerators (household types) are labeled 'Unsafe for flammable storage,'" and two with three-point gains: "All biological safety cabinets and chemical

fume hoods have been tested within the past year" and "Test labels are properly affixed to the fume hoods and biological fume cabinets tested." A bit distressing was that three percent fewer respondents answered yes to the statement "All gas cylinders are chained to an immovable object to prevent tipping or falling," especially compared with 2011, which reported a seven percent increase in yes answers to this same statement.

So as this year's lab safety survey reveals, lab safety practices continue to improve for the most part, though not to the same degree as was reported from 2010 to 2011. We can only hope that the upward trend continues, no matter how small the percentage increases.

"New numbers represent a general increase in the frequency of safety inspections."

Changes in Lab Safety Practices from 2011 to 2012

	2012			2011		
Please respond to the following Laboratory Equipment safety statements.	Yes	No	Don't know	Yes	No	Don't know
All biological safety cabinets and chemical fume hoods have been tested within the past year.	**92%**	**4%**	**4%**	**89%**	**7%**	**4%**
Test labels are properly affixed to the fume hoods and biological fume cabinets tested.	**93%**	**4%**	**3%**	**90%**	**9%**	**1%**
Storage in fume hoods and biological safety cabinets is kept to a minimum and is placed so as to not impede proper airflow.	**93%**	**5%**	**2%**	**93%**	**6%**	**1%**
All rotating or movable parts and belts are properly guarded with screens.	**90%**	**2%**	**8%**	**89%**	**5%**	**6%**
All refrigerators/freezers used for storage of flammables (non-sparking/laboratory safe) are properly labeled.	**90%**	**4%**	**6%**	**92%**	**5%**	**3%**
Non-spark-proof refrigerators (household types) are labeled "Unsafe for Flammable Storage."	**72%**	**22%**	**6%**	**66%**	**28%**	**6%**
All gas cylinders are chained to an immovable object to prevent tipping or falling.	**93%**	**2%**	**5%**	**96%**	**3%**	**2%**
Valves of gas cylinders are capped when not in use.	**91%**	**4%**	**5%**	**94%**	**4%**	**2%**
Gas cylinders are stored with other compatible gases.	**93%**	**2%**	**5%**	**95%**	**2%**	**3%**
Gas cylinders are not emptied completely, but left with 25 psi to prevent backflow.	**73%**	**10%**	**17%**	**73%**	**10%**	**17%**
Empty cylinders are marked "MT" or "EMPTY" and stored separately	**86%**	**6%**	**8%**	**87%**	**8%**	**5%**
Rooms containing compressed gases have a sign outside the room stating COMPRESSED GAS and the name of the gas and hazard class.	**69%**	**22%**	**9%**	**67%**	**26%**	**7%**

SURVEY SAYS: ARE YOU IN THE MARKET FOR A TITRATOR?

Titration is a common laboratory operation for quantifying chemicals or reagents, usually in aqueous solution. In a typical setup, the *titrand*—the solution containing the unknown—is treated with precise volumes of a standard solution of the *titrant*—the reagent of known strength. The titration end point is reached when a chemical balance is achieved between the titrant and titrand. The concentration of the unknown in the original sample is calculated through simple equations related to the applicable chemical stoichiometry and any dilutions that may have occurred during sample preparation. Titrators are specialized instruments that perform titrations with minimal operator intervention and can thus minimize errors, improve throughput, and facilitate documentation. There are two major titrator types: potentiometric acid-based designs and Karl Fischer titrators. Those in the first group, which use a pH or redox probe, resemble pH meters in their ability to derive acid strength and total acidity; Karl Fischer titrators measure water content in foods, materials, biofuels, etc. Most titration work occurs in quality control laboratories. The latest trends and developments in titration are flexibility and versatility. Different industries have different titration needs, ranging from low-cost, easy-to-use, single-type titrations to complex, multi-chemistry, multielectrode, multi-sample, and multireagent analysis. To ensure a consistent high level of accuracy and precise volumes of titrant, many labs are automating their titration work.

The types of titrators our readers use in their labs:

Potentiometric	**47%**
Karl Fischer Coulometric	**22%**
Karl Fischer Volumetric	**27%**
Other	**4%**

The titration methods our readers are currently using in their labs:

Manual titration	**44%**
Automated titration	**56%**

The main hardware-related errors our readers experience with their titrators include:

Measurement of the titrant aliquot	**11%**
Indicator variability	**11%**
Operator fatigue and computation error	**15%**
Anomalies in composition of the standard solution	**10%**
Accuracy of the delivery system	**20%**
Systemic and non-systemic errors	**24%**
Other	**10%**

The top 10 factors and features our readers look for when buying a titrator:

	Important	Not Important	Don't Know
Accuracy	**98%**	**2%**	**0%**
Reliability	**98%**	**2%**	**0%**
Ease of use	**94%**	**6%**	**0%**
Service and support	**91%**	**9%**	**0%**
Low maintenance	**85%**	**12%**	**4%**
Operating cost	**85%**	**12%**	**4%**
Warranty	**85%**	**15%**	**0%**
Price	**79%**	**17%**	**4%**
Data management	**73%**	**25%**	**2%**
Ease of installation	**73%**	**23%**	**4%**

For more information on titrators, visit www.labmanager.com/titrators

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SURVEY SAYS: ARE YOU IN THE MARKET FOR A UV-VIS SPECTROPHOTOMETER?

UV-Vis spectrophotometers are indispensable for measuring analyte concentrations—in scientific research, academic teaching, and QA/QC laboratories. UV-Vis spectrometers come in four basic models: low-cost single-beam, dual-beam, array-based, and handheld. Single-beam techniques must apply a correction for the loss of light intensity as the beam passes through the solvent. Dual-beam spectrometers use a second solvent reference cell and perform the correction automatically. Single- and dual-beam benchtop instruments use a broad spectrum lamp as the light source, and most use a photomultiplier tube as the detector. Future improvements in UV-Vis spectrophotometers will focus on ease of use, portability, and application-specific instruments. UV-Vis analysis of solid samples and materials continues to grow in areas such as solar cell research, semiconductor products, and coating materials. Advances in light sources will provide new developments in conventional spectrophotometers and handheld UV-Vis instruments. Further development in remote sensors will enable more types of samples to be measured outside the laboratory. UV-Vis instruments have become smaller as a result of microelectronics miniaturization, but were always limited by the instrument's components and pathways used for delivering radiation and measuring absorbance or transmittance.

The types of UV-Vis spectrophotometers our readers are using in their research.

Single Beam	43%
Dual Beam	43%
Array-based	11%
Handheld	3%

How often our readers use their UV-Vis spectrophotometers in their labs:

Several times daily	32%
Once a day	6%
Several times each week	37%
Once a week	8%
Two to three times a month	8%
Once a month	3%
Less than once a month	5%

We asked our readers how often they use performance verification tests for wavelength accuracy, stray light, resolution and photometric accuracy. Here's how they responded:

Annually	31%
Every six months	11%
Quarterly	13%
Monthly	12%
After every use	3%
We don't do performance verification tests	24%
Not applicable	2%
Don't know	4%

The top 10 factors/features our readers look for when buying a UV-Vis spectrophotometer:

	Important	Not Important	Don't Know
Ease of maintenance/ low operating costs	90%	3%	7%
Excellent reproducibility	90%	6%	4%
Ease of use	86%	9%	5%
Wavelength accuracy	84%	12%	4%
Better sensitivity and resolution	85%	12%	4%
Price	85%	12%	4%
Warranties	85%	15%	0%
Faster acquisition and analysis of data	65%	32%	3%
Service/support in general	64%	29%	7%
Safety	60%	32%	8%

For more information on UV-Vis spectrophotometers, visit www.labmanager.com/spectrophotometers

COMPLETED SURVEYS: 297

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SURVEY SAYS: ARE YOU IN THE MARKET FOR A GAS GENERATOR?

If you've had to lug a tank of gas to an experiment station and secure it in place, you know the hassle and danger involved. Many lab managers are turning to generators for convenience; cost also plays a part with labs needing to pay for the delivery of gas while the time required to change the tanks and the managerial costs of maintaining the necessary supply of tanks also hurt the bottom line. Most generators pay for themselves in two years on the hard costs alone and can also make a better product. When you generate gas at a plant, the second you start doing anything with it, the gas starts to degrade, even as the producer starts to fill a tank from a big supply. If users decide to go the gas generator route, they have plenty of options to choose from. One class, the zero air gas generator, makes air that is free of hydrocarbons, which is the kind of gas needed for many processes, including gas chromatography. Labs can also buy generators that make a specific gas, such as hydrogen or nitrogen.

The type(s) of gas generator(s) our readers are looking to purchase for their labs include:

Calibration	5%
Hydrogen	26%
Nitrogen	34%
Purge	6%
TOC	2%
Zero Air	21%
Other	6%

The reasons our readers are purchasing/considering purchasing a gas generator:

Switching from helium to hydrogen	11%
Cheaper than gas cylinders	25%
Increase safety	19%
Building/renovating lab	7%
Upgrading old system	17%
Starting a new lab process	15%
QA/QC	2%
Other	3%

Applications our readers are using or planning to use their gas generators for:

TOC analysis	3%
Gas chromatography with flame ionization detection	31%
High-performance liquid chromatography	18%
Gas chromatography with mass spectrometric detection	20%
Fourier transform infrared spectroscopy	6%
Inductively coupled plasma systems	5%
Nuclear resonance spectroscopy	3%
Other	12%

The 10 most important features/factors in our readers' decisions to purchase a gas generator:

	Important	Not Important	Don't Know
Value for price paid	96%	4%	0%
Durability of product	93%	3%	3%
Performance of product	93%	7%	0%
Low maintenance/easy to clean	91%	2%	7%
Total cost of ownership	89%	5%	5%
Low operating costs	89%	9%	2%
Service and support	84%	15%	2%
Availability of supplies and accessories	83%	10%	7%
Ease of use	82%	12%	5%
Warranties	79%	14%	7%

For more information on gas generators, visit www.labmanager.com/gas-generators

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ABSTRACT: Increasing the sensitivity and resolution of LC/MS instruments has been an ongoing focus for instrument manufacturers. As a result of this increased sensitivity of today's analytical instrumentation, the choice of high purity solvents can greatly influence the test results that are achieved.

INTRODUCTION: To meet the needs of the most demanding ultra-high pressure liquid chromatography (UHPLC) and mass spectrometry research and analytical testing applications, such as proteomics, drug discovery, pharmacokinetics, and clinical research, instrumentation is not the only parameter to be considered. Solvent design and selection is also very important. Performance of three specific solvents, (1) **Acetonitrile**, (2) **Methanol**, and (3) **Water** was examined in detail and the solvents were assessed for their suitability in selected LC/MS applications. In particular, the impact of packaging materials on the quality of LC/MS solvents was evaluated. The performance of LC/MS grade solvents was compared using LC/UV/MS gradient, MS infusion, and trace metals analysis. One way to ensure that high purity LC/MS grade solvents meet stringent purity requirements is by improving the packaging associated with the storage and delivery of these solvents. For example, certain containers can leach metal ions during storage, and lead to the formation of metal adducts, which can adversely impact test results.

EXPERIMENTAL CONDITIONS:

Materials:

- LC/MS grade Acetonitrile, Methanol, and Water from various suppliers
- J.T.Baker® ULTRA LC/MS™ solvents
- Standards **(Sulfadimethoxine, Chloraphenicol)**

Methods:

- LC/MS gradient **(Waters ACQUITY UPLC® System/LCT TOF mass spectrometer)**
- Positive/Negative ESI **(electrospray ionization)**
- Direct infusion to mass spectrometer **(Waters Quattro Micro)**
- Trace metals **(Perkin-Elmer ICP-MS)**

RESULTS: Results indicate that J.T.Baker® ULTRA LC/MS™ solvents and solvent packaging show better performance than other traditional LC/MS grade solvents. The J.T.Baker® ULTRA LC/MS™ water packaged in the borosilicate bottle maintained sodium levels < 9 ppb in two months while material packaged in amber glass bottles presented sodium levels > 150 ppb. Sodium metal adducts (m/z 333) were also reduced. The J.T.Baker® ULTRA LC/MS™ grade exhibited adducts of 40% compared to 150% for the material packed in amber glass bottles.

CONCLUSIONS:

Based on the data compiled for the study, the test results indicate that J.T.Baker® ULTRA LC/MS™ solvents are more suitable for use on UHPLC and high sensitivity mass spectrometry instrumentation. J.T.Baker® ULTRA LC/MS™ solvents also offer better performance than the other brands tested by delivering:

- Lower trace metals
- Reduced adduct formation
- Minimal suppression

REFERENCES / TRADEMARKS

ACQUITY UPLC System™ and Quattro Micro™ are trademarks of Waters Technologies Corporation.

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Figure 1: ULTRA LC/MS Water—Sodium level (Borosilicate vs Amber Bottle)

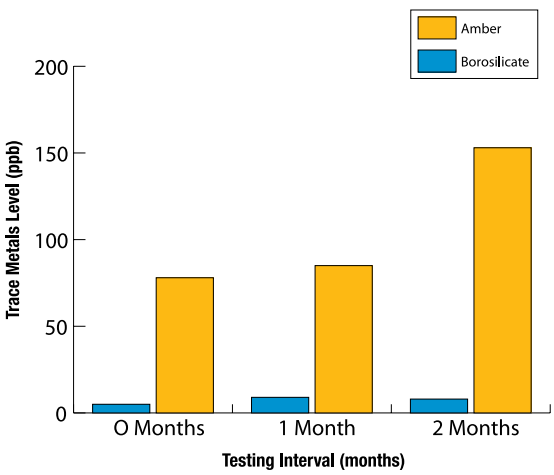

Figure 1a contrasts the sodium leaching for water packaged in amber bottles to borosilicate bottles over a two month time interval.

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• **Compact, quiet and stylish.** Streamlined design incorporates bottle, controls and pump (Control & Pro models), in a small footprint that fits nicely on a lab bench or next to a Biological Safety Cabinet; a clip is included to help secure the tubing out of your way. Smooth contours and touch panels rather than knobs mean "easy to keep clean" as well.

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Control. The BVC Control features a powerful whisper-quiet VACUUBRAND® chemistry-design vacuum pump, eliminating the need for, and isolating from central vacuum supply. Potentially Biohazardous materials can be contained in a local area. The pump is turned on and off automatically on demand when using the VacuuHandControl which further reduces the noise level. An easy to clean touch panel adjusts and indicates the vacuum level switchpoint. This provides exactly the aspiration power you need ,when you need it. Available with either a 4 liter polypropylene, or 2 liter bleach resistant glass bottle.

Professional. The top-of-the-line BVC Professional includes an external liquid level sensor, which operates without contacting, or being exposed to bottle contents. This lets you concentrate fully on your work without worrying about overflow. A special disinfection program allows the aspiration of disinfectant after the system is shut down to decontaminate the VacuuHandControl. The 4L polypropylene bottle version is supplied with quick connectors as standard; the 2 liter glass bottle "bleach proof" version includes hose barb connections; optional quick connectors are available. The contact free design of the level sensor simplifies container design and reduces costs when using multiple collection bottles.

EXTENDING HOMOGENEOUS ELISA SCREENING IN THE HIGH THROUGHPUT WORLD:

DEVELOPMENTS TO SUPPORT ALPHALISA DETECTION IN ARRAY TAPE™

ELISA is widely used for screening and quantification of substances in biological samples. While advances have been made in delivery of partial automation for ELISA applications through the use of workstations, the multiple wash steps inherent to the traditional ELISA process complicate adaption to a fully integrated automation environment.

The AlphaLISA®* chemistry available from PerkinElmer greatly simplifies the ELISA process by eliminating the repetitive wash steps. Although the standard protocol requires either a two or three step incubation process, additional work completed by Prasad et al suggests that a single incubation step will generate similar results for some assays[2]. The resulting streamlined process increases the opportunity for application and integration of fully automated, inline equipment platforms to achieve lower cost in high throughput screening applications.

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In response to the high throughput screening needs of protein chemistry, the Array Tape Platform from Douglas Scientific presents an effective and efficient inline automation solution for laboratory processes. Well proven for SNP genotyping, the platform's unique consumable, Array Tape, replaces microtiter plates with a flexible, continuous strip of embossed, low volume reaction wells (Figure 2).

In this article, results of AlphaLISA assays performed in Array Tape are described and compared with the published results from PerkinElmer[1].

MATERIALS AND METHODS

The AlphaLISA Process

The AlphaLISA chemistry is a bead-based assay. A biotinylated anti-analyte antibody binds to the streptavidin-coated donor beads while another anti-analyte antibody is conjugated to AlphaLISA acceptor beads. When exposed to an analyte of interest, the beads come into close proximity. Excitation of the donor beads then provokes the release of singlet oxygen molecules that triggers a cascade of energy transfer in the associated acceptor beads resulting in a sharp peak of light emission at 615 nm1 (Figure 1).

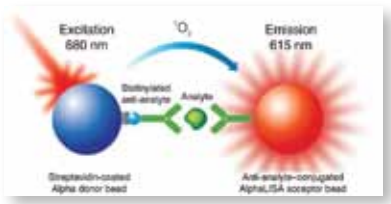

Figure 1: Excitation of donor beads results in a sharp peak of light emission

ARRAY TAPE

A specialized Array Tape was designed to accommodate the requirements of the AlphaLISA assay (Figure 2). Array Tape is a continuous polypropylene strip, serially embossed with 384-well arrays. A 7.5 µL reaction well volume was used in the testing; however, reaction well volumes of 2-20 µL are possible.

ARAYA® DETECTION SYSTEM FOR ALPHA CHEMISTRY

Chemistry excitation and signal detection in the Araya are accomplished through the use of a specialized optical reader designed to capture and detect the signals associated with the smaller volumes.

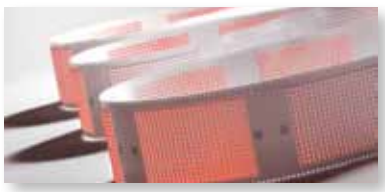

Figure 2: Array Tape™ is a thin and flexible microplate replacement, serially embossed with reaction wells.

EXPERIMENTAL PROTOCOL

AlphaLISA-based insulin assays were performed using commercially available samples (Human Insulin Kit AL 204 C) using a series dilution ranging from 1 – 345,000 pg/mL. Assays were performed in Array Tape using a final reaction volume of 5.0 µL with three concentrations of both acceptor and beads. The 5 µL reaction volume was achieved by adding 0.5 µL of analyte from the dilution series, 2.0 µL of acceptor beads and 2.5 µL of donor beads. The 5 µL reaction volume represents a deviation from the 10 µL minimum volume recommended in the PerkinElmer technical data sheet1. Donor and acceptor beads were used in three concentrations, including PerkinElmer's recommended 2.5X preparation1 (referred to as 1X in this paper) with additional dilutions of 0.6X and 0.3X of the recommended preparation. All other methods followed to published protocols1. After 90 minutes of incubation, signals were captured from assay mix using the Araya technology.

RESULTS AND DISCUSSION

The signal acquired was plotted against the standard concentration (Figure 3). The LDL was calculated using the standard curve and background mean + 3 SD. The dynamic range and limit of detection was compared with published report of an Insulin AlphaLISA assay using a dilution series of insulin standards. The Array Tape, in combination with Araya, delivers similar results reported by PerkinElmer using a microplate system for limit of detection and dynamic range of the assay, including the lower limit of detection of 3 pg/mL1 (Figure 3) .The dynamic range (Figure 3) demonstrates the relationship between insulin concentration and AlphaLISA signal captured from the Array Tape containing assay mix. The dynamic range was equal to the reported results from the kit provider.

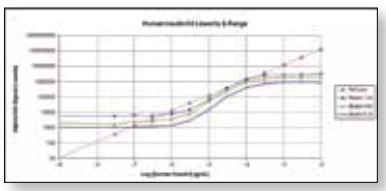

Figure 3: Insulin Dilution Curves at standard and reduced bead concentrations

SUMMARY

ELISA is the most widely used detection platform for analysis and quantification of analytes in biological samples. Array Tape offers unique opportunity to perform the assay at a miniaturized volume. Data quality generated from miniaturized reactions and Araya detection technology closely matches the dynamic range of published results. Detection of signal from assays using reduced bead concentrations of both donor and acceptor beads was achieved with. Dynamic range and sensitivity of the reduced bead concentrations was similar and comparable with PerkinElmer's reported results. These results clearly demonstrates that AlphaLISA assays can be performed with lower concentration of beads and miniaturized reaction volumes in Array Tape using Araya detection technology.

Combining a single incubation step[2] with an optimized Array Tape Platform for homogeneous AlphaLISA featuring in-line, modular liquid handling provided by the Nexar system combined with inline incubation and Araya detection is credible and can be expected to provide walk-away automation for miniaturized, HTP AlphaLISA assays. Furthermore, published literature by PerkinElmer[2], suggests that opportunities exist to shorten incubation times for selected assays, which allows for even greater opportunities in continuous systems such as Array Tape.

Literature Cited:

1. AlphaLISA Reagents Sheet. PerkinElmer. TDS-AL204-06.

2. Prasad, A. et al. A Comparison of AlphaLISA and TR FRET Homogenous Immunoassays in Serum-Containing Samples. Perkin Elmer Application Note. 2009.

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ACCELERATING 3D MICROTISSUE PRODUCTION

FAST AND EFFICIENT 3D MICROTISSUE PRODUCTION WITH THE VIAFLO 96 CHANNEL HAND-HELD ELECTRONIC PIPETTE

Preclinical drug development relies on advanced in vitro models with a high degree of standardization to achieve maximal predictivity for an efficient compound de-risking strategy. InSphero's scaffold-free organotypic three-dimensional (3D) microtissue spheroids fulfil these requirements as they can be produced and assayed by standard automated liquid handling systems. The Integra Viaflo 96 Channel Electronic Hand-Held Pipette is perfectly suited to produce 3D microtissues in InSphero's GravityPLUS™ hanging drop plate and to further culture and process them in the GravityTRAP™ platform. Ease of use, versatile programming, and highly accurate tip positioning are the key advantages of the Viaflo 96 pipette which guarantee to perform medium to high throughput screening campaigns with 3D microtissues successfully and with considerable time savings of up to 40% compared to manual pipetting with an 8-channel pipette.

INTEGRA

2 Wentworth Drive,
Hudson, NH 03051 USA
Tel: 1-603-578-5800
www.integra-biosciences.com

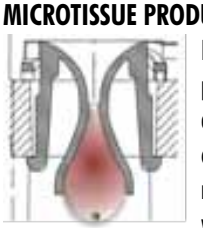
3D MICROTISSUES FOR THE ADVANCEMENT OF CELL-BASED ASSAYS

3D cell culture enables the investigation of cellular functions that are usually not observable in «petri-dish-based» culture formats. InSphero offers a variety of scaffold-free microtissues derived either from tumor cell lines, primary cells or iPSCs. Theses microtissues display a variety of organotypic features which underscores their biological relevance in predicting drug interaction far better than with commonly used cell monolayers:

- Enhanced formation of cell to cell contacts (tight junctions, desmosomes, etc.)
- Extracellular matrix formation
- Polarization of epithelial cells
- Organotypic cell arrangement in co-cultures of parenchymal and non-parenchymal cells
- Altered gene expression profile due to epigenetic regulation

Because of their more pronounced tissue-specific properties and functionality, 3D microtissues are perfectly suited for medium to large scale compound testing as required in the pharmaceutical, cosmetics and chemical industry.

INSPHERO'S HANGING DROP MICROTISSUE PRODUCTION PLATFORM



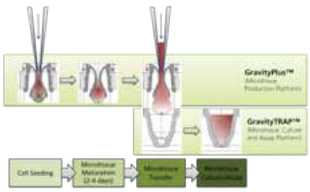
InSphero's microtissue production system relies on the hanging-drop cell culture technology, which minimizes the interaction with artificial surfaces and maximizes cell to cell contact mediated by gravity-enforced cellular self-assembly. InSphero's patent-pending hanging-drop platform GravityPLUS™ is designed to produce and maintain standardized microtissues in a highly reproducible fashion using standard liquid handling equipment. Each individual well is designed in the shape of two opposed funnel-like structures connected by a capillary, thus creating sufficient adhesive and capillary forces to keep a drop of 35-45 µl stably in place. Microtissues are produced in the GravityPLUS™ plate upon application of a cell suspension of defined cell density from the top. Microtissue formation and maturation in the hanging drop occurs within 2-4 days after seeding depending on cell types used.

GRAVITYTRAP™: 3D MICROTISSUE RECEIVER AND ASSAY PLATFORM

For extended culture periods and downstream processing (compound treatments, assays), the microtissues can be transferred into the GravityTRAP™ format, which is a specifically designed multi-well plate to accommodate microtissues produced in the GravityPLUS™ system. The GravityTRAP™ offers several key advantages for culturing, manipulating and assaying microtissues:

- No attachment to plastic due to non-adhesive coating
- Transparent clear bottom for visual inspection by inverted bright field or fluorescence microscopy
- Safe medium replacement without risk of microtissue loss

The transfer of microtissues from the GravityPLUS™ into the GravityTRAP™ platform can be achieved simply by supplying sufficient medium to the already existing hanging drop, which eventually falls into the well of the aligned GravityTRAP™ underneath carrying along the microtissue.



The above figure illustrates the sequence of 3D microtissue seeding, formation and maturation in the GravityPLUS™ plate with subsequent transfer into the GravityTRAP™ format for long term culture and experimental procedures.

VIAFLO ELECTRONIC 96 CHANNEL HAND HELD PIPETTE

Viaflo 96 is a 96-channel pipette, which was designed to resemble hand held pipetting and to increase productivity at the same time. The pipette is guided by hand but movements are assisted by motors for effortless and ergonomic working.

Viaflo 96 is used to transfer reagents and samples from a reagent reservoir to 96 and 384 well plates or from plate to plate. Up to 96 samples can be transferred at once.

To reformat 96 well plates to 384 well plates, the plate holder can be shifted to quickly accommodate all wells of a 384 well plate.

Viaflo 96 covers a large volume range of 0.5 µl to 1250 µl with four interchangeable pipetting heads. These heads are changed within seconds to optimally adapt Viaflo 96 to the application currently performed.

For delicate pipetting operations, such as the transfer of microtissues, several user-defined position settings can be used. This allows automatic guidance into the wells but also to set a specific z-height. The z-height sets a minimum height above a plate and assures that all subsequent transfers are performed at the same height to guarantee highly reproducible pipetting results.

For full application note go to...
labmanager.com/integra-appnote

SENSITIVE, HIGH-THROUGHPUT DNA MEASUREMENT WITH THE µMAX LOW VOLUME MICROPLATE

Molecular Devices

1311 Orleans Drive
Sunnyvale, CA 94089-1136 USA
Toll free: 1-800-635-5577
www.moleculardevices.com

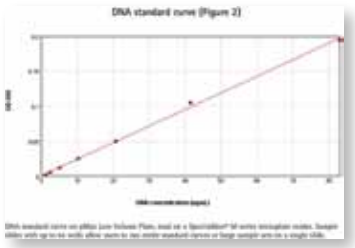
Quantitation of nucleic acids is commonly performed using UV absorbance. Molecular Devices' µMax Low Volume Microplate allows users to read up to 64 samples per plate on SpectraMax® Microplate Readers, with sample volumes as low as 2 µL. The µMax Microplate incorporates a specially designed adapter and a slide pair whose optical clarity allows measurements in UV/Vis absorbance and fluorescence modes to meet users' application needs. The µMax Microplate's slide design (Figure 1) eliminates the need for calibration and gives consistent well-to-well reads.

CLEANING THE µMAX SLIDES

For most sample measurements, simply wiping the slides with disposable lab wipes is sufficient. If minimal background noise is required due to low sample concentration, more careful cleaning is recommended. After cleaning slides with a lint-free wiper, inspect them for dust particles against a dark background. Remove any visible dust using a canned air duster in short, gentle bursts.

DNA STANDARD CURVE

To demonstrate sensitivity of DNA detection with the µMax Low Volume Microplate, DNA standards of known concentrations ranging from 1.9 to 190 ng/µL were pipetted onto the wells (spots) of the µMax Low Volume Plate, along with TE buffer blanks, in sets of three or six replicates using an 8-channel pipettor. Volume per spot was 2 µL using the µMax top slide with 0.5-mm spacers. The µMax plate was read on a SpectraMax M5e microplate reader, and data were analyzed and graphed with SoftMax® Pro 6 Software (Figure 2). The lower limit of detection for double-stranded DNA based on a calculation of three times standard deviation of the background was less than 2 ng/µL.



DNA QUANTITATION

DNA concentrations can be calculated directly from absorbance readings at 260 nm. This requires use of a pathlength value, which is either 0.5 mm or 1.0 mm for the µMax Low Volume Microplate, depending on which cover slide option is used. In SoftMax® Pro 6 software, preconfigured protocols simplify the calculation of DNA concentrations for samples read with the µMax Low Volume Microplate.

The µMax Low Volume Microplate enables sensitive measurement of small sample volumes without compromising accuracy. Its slides are easy to handle, and all optical surfaces are fully accessible for ease of cleaning. No calibration is required, as the spacer and slide design provide excellent well-to-well uniformity. 24- and 64-well sample slides, as well as cover slides with 0.5- or 1.0-mm spacers, are available to meet users' throughput and sample volume needs. The µMax Low Volume Microplate is compatible with all SpectraMax Readers including the SpectraMax Paradigm® Platform, as well as the StakMax® Microplate Stacker.

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Elemental Analyzer

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- Uses sample sizes of typically 2 - 20mg
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Cyanide Analyzer

CNSolution 3100

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- USEPA approval of ASTM D 7511-09e2 allows labs to analyze samples for total cyanide without a preliminary 2-hour acid distillation step

OI Analytical www.oico.com

Discrete Analyzer

AQ1

- Automatically tests multiple samples in discrete reaction vessels
- Supplied with standard methods to USEPA, ASTM, ISO and other internationally-recognized standards
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Thermo Fisher Scientific www.thermoscientific.com

ESTABLISHING GOOD ERGONOMIC WORK PRACTICES WHEN PIPETTING

PROBLEM

Ergonomic injuries are widely recognized as a major factor in work place health. About one-third of all occupational injuries and illnesses stem from over exertion and/or repetitive motion. Much of this can be prevented through appropriate changes in work habits.

VistaLab TECHNOLOGIES
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Brewster, NY 10509 USA
Toll free: 1-888-652-6520
www.vistalab.com

Proper posture is the most important element in establishing good ergonomic work practices. During repetitive tasks such as pipetting, maintaining body positions that provide a maximum of strength with the least amount of muscular stress is important to minimize the risk of injury. A number of common pipetting techniques have been identified as potentially hazardous due to biomechanical stress factors, coupled with the ergonomic deficiencies of many existing pipette designs which fail to shield users from cumulative injuries linked to long sessions of awkward repetitive motion.

SOLUTION

Technique: elevated, "winged elbow". The average human arm weighs approximately 6% of the total body weight. Holding a pipette with the elbow extended (winged elbow) in a static position places the weight of the arm onto the neck and shoulder muscles and reduces blood flow, thereby causing stress and fatigue. Muscle strength is also substantially reduced as arm flexion is increased.

Corrective action: Position elbows as close to the body as possible, with arms and wrists extended in straight, neutral positions (handshake posture). Keep work items within easy reach to limit extension and elevation of arm. Arm/hand elevation should not exceed 12" from the worksurface.

Technique: Over-rotated forearm and wrist. Rotation of the forearm in a supinated position (palm up) and/or wrist flexion increases the fluid pressure in the carpal tunnel. This increased pressure can result in compression of soft tissues like nerves, tendons and blood vessels, causing numbness in the thumb and fingers.

Corrective action: Forearm rotation angle near 45° pronation (palm down) should be maintained to minimize carpal tunnel pressure during repetitive activity.

Technique: Tight grip (clenched fist). Hand fatigue results from continuous contact between a hard object and sensitive tissues. This occurs when a firm grip is needed to hold a pipette, such as when jamming on a tip, and results in diminished hand strength.

Corrective action: Use pipettes with hooks or other attributes that allow a relaxed grip and/or alleviate need to constantly grip the pipette. This will reduce tension in the arm, wrist and hand.

Technique: Concentrated area of force (contact stress between a hard object and sensitive tissues). Some devices have plungers and buttons with limited surface areas, requiring a great deal of force to be expended by the thumb or other finger in a concentrated area.

Corrective action: Use pipettes with large contoured or rounded plungers and buttons. This will disperse the pressure used to operate the pipette across the entire surface of the thumb or finger, reducing contact pressure to acceptable levels.

THE OVATION SOLUTION

The Ovation BioNatural Pipette was specifically designed to address each of these posture-related concerns.

- the user's arm elevation remains low, minimizing stress to the elbow, shoulder and neck
- The user's elbow remains close to the body in a neutral posture to maximize available arm strength
- The user's wrist remains in a pronated position and neutral range of motion throughout all pipetting operations, eliminating repetitive twisting of the forearm and reducing pressure on the carpal tunnel
- Ovation's adjustable hook allows a custom fit and reduced holding effort for right and left-handed users
- The pipette's contoured shape provides maximum stability and minimal contact pressure for the hand. A loose, relaxed grip increases available strength in the hand, improving endurance and productivity during pipetting
- Rounded plunger and tip ejection buttons with reduced forces minimize contact stress

For more information about the Ovation pipette, visit www.vistalab.com

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Nichiryo Nichipet Premium

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- Features a non-corrosive and non-greased ceramic plunger and abrasion-resistant nozzle tip
- Also includes improved O-rings rated at 600,000 aspirate/dispense cycles, and a solvent-resistant high-impact polymer body
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Core Life Sciences www.CoreLifeSciences.com

Electronic Pipette

Xplorer plus®

- Specially designed for users working with complex or long pipetting series
- Provides exact setting of parameters, maximum reproducibility and low operating force
- Includes a history function that automatically saves the last parameters for faster handling
- Features password protection for users' programming and settings

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FT4

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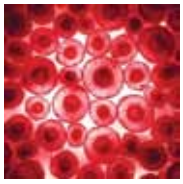

- Supplied in proprietary reagents that ensure high survival and recovery rates
- Derived from the peripheral blood of normal healthy human adult donors collected at IRB-approved blood banks
- Seven types are currently available
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- Weighs only 4 lbs. (1.8 kg); can be conveniently carried from place to place
- Saves space with compact dimensions of 8.75W x 10L x 4.5"H (22.2W x 25.4L x 11.4 cm H)
- Made of molded, high-impact plastic for rugged durability
- Features a contoured eyepiece with a built-in UV-absorbing window for safe viewing

Spectroline www.spectroline.com

Large Particle Flow Cytometers

Copas Plus

- For high-throughput analysis and sorting of human induced pluripotent stem cell (hiPS) clusters using large particle flow cytometry
- Allows the analysis and sorting of intact hiPS cell clusters from a complex mixture of varying sizes based on size, optical density and fluorescent parameters
- Does not influence the morphology or viability compared to manually sorted cell clusters

Union Biometrica www.unionbio.com

Image Analysis System

PXi

- Provides a one-click method for accurately imaging chemiluminescent and fluorescent blots, as well as 1-D gels (up to 10cm x 12 cm) stained with any type of fluorescent dye
- Features a high resolution 6.3 million pixel camera and large fixed aperture lens
- Can be rapidly set up to automatically select the best conditions

Syngene www.syngene.com

Monoclonal Antibodies

Ureaplasma parvum

- Possesses a small simple genome
- Ureaplasma parvum is the genus found in the human urogenital tract; its presence has been associated with several conditions including urethritis, pelvic inflammatory disease, congenital pneumonia and neonatal meningitis
- New monoclonal antibodies have applications in ELISA and IFA

ViroStat www.virostat-inc.com

3D Piezo Movement Micromanipulator

Ureaplasma parvum

- Penetration mode provides high acceleration steps for cell insertion
- Features 20 mm of travel in all axes
- Compact; allows multiple manipulators in a small space
- Provides precise electrode positioning and drift-free operation
- Operate up to 14 manipulators with the optional control unit Hub

Warner Instruments www.warnerinstruments.com

LIMS & SOFTWARE

PRODUCT SPOTLIGHT

ACHIEVE END-TO-END PRODUCTIVITY

NEW PLATFORM AIMS TO BOOST SUCCESS OF SCIENCE-DRIVEN COMPANIES

Earlier in April, Accelrys, Inc. issued an industry-wide call to close the productivity gap from innovation through commercialization that is slowing product development and time-to-market, thus hampering competitiveness for science-driven organizations.

Currently, only 25 percent of projects in industries ranging from pharmaceuticals to aerospace result in the commercialization of new products, according to IDC Manufacturing Insights. Of the 25 percent of products that make it to market, 66 percent fail to meet original design or consumer expectations.

"There is growing consensus that new product development is increasingly ineffective – especially for science-driven innovation," said Joe Barkai, research vice president of product lifecycles strategies at IDC. "Scientific-driven research and development organizations are at a critical juncture – their homegrown systems no longer meet the demands of today's fastest-to-market environment."

In order to deal with this problem, Accelrys has introduced the new Accelrys Enterprise Platform.

This platform offers the first scientifically aware, service-oriented architecture (SOA) that enables the integration and deployment of broad scientific solutions spanning data management and informatics, enterprise lab management, modeling and simulation, and workflow automation.

"Effective, efficient, end-to-end innovation is critical to the competitiveness of science-driven organizations," said Accelrys president and chief executive officer Max Carnecchia. "The Accelrys Enterprise Platform is a game-changer for organizations looking to deliver more competitive products, sooner and more cost-effectively to market."

The platform can manage structured and unstructured information encountered early in the innovation cycle, as well as highly structured, automated batch records required by lock-down production and can integrate with existing IT infrastructures.

For more information, visit www.accelrys.com.

Control Software

INSTINCT

- Redesigned control software for the MICROLAB NIMBUS automated liquid handling workstation
- Puts NIMBUS functionality into the hands of users at all experience levels, with short learning curves
- Supports a wide range of daily lab work with new tools
- Wizards quickly walk the user through method creation steps for common routines

Hamilton Robotics www.hamiltoncompany.com

Spectroscopy Software

GRAMS 9.1

- Now delivers enhanced capabilities to meet the needs of scientists engaged in a variety of spectroscopic experiments and disciplines
- Offers intuitive and simplified workflows
- Enables scientists to more easily and rapidly access their data and make more informed decisions about the results generated
- Supported on Microsoft Windows 7, 32 and 64 bit Operating Systems and adds compatibility with more than 30 new instrument data formats

Thermo Fisher Scientific www.thermoscientific.com

Software Update

CytoSure™ Interpret Software

- For array Comparative Genomic Hybridization (aCGH) analysis
- Features a new relational database design
- Now allows sample data to be stored and analyzed in accordance to its relationship with other data
- Also performs common analysis steps automatically via the "Accelerate Workflow" mode
- Speeds up analysis, especially when working with a large number of samples

Oxford Gene Technology www.ogt.co.uk

Online Center for Core-shell HPLC/ UHPLC Columns

Kinetex Experience

- Includes technical and application information and the latest Kinetex calculator for easy method transfers
- Also provides column selection tools, FAQs and online technical support
- Can be reached directly at www.phenomenex.com/kinetex
- New "Core Club," where chromatographers can access videos, view testimonials from other users, sign up for special promotions and link to related social media tools also available

Phenomenex www.phenomenex.com

DB Software

LabSolutions

- Integrates a data management function with LabSolutions LC/GC control and analysis software
- Optimally configured for PC-based laboratories
- Connects to up to four LC/GC instruments for simultaneous use
- Compliant with electronic records and electronic signature (ER/ES) regulations
- Database allows multi-data report creation using Microsoft Excel

Shimadzu www.ssi.shimadzu.com

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- For storage, freezing, and manipulation of biological solutions
- Injection blow molded in an ISO Class 5 (Class100) environment and radiation sterilized
- Available in sizes from 125ml to 20L
- Manufactured from resins approved for medical applications in PET or polycarbonate with HDPE closures

Cellon (Biofluid Focus Inc.) www.biofluidfocus.com

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- Include multiple CILS label shapes and sizes on a single roll/A4 sheet
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CILS International www.cils-international.com/usa

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- Features an absorbent white side that is non-flaking, non-skidding, and low-linting
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Current Technologies www.currtechinc.com

Black 1536-Well Cycloolefin Microplate

- Designed for fluorescence measurements and light protected compound storage
- Developed specifically for use in highly automated systems
- Has no alphanumerical coding and is ideal for automated sealing techniques using metal cover plates
- Cycloolefins feature quartz glass-like properties and a particularly low autofluorescence in the lower UV range

Greiner Bio-One www.greinerbioone.com

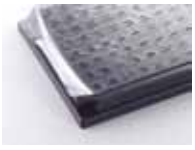
96-Well PTFE Sealing Film

- Seals samples in microplates during high throughput bioanalytical studies without exposing samples to the film's sealing adhesive
- Protects samples against cross contamination or evaporation
- PTFE film material is compatible with aqueous solutions and organic solvents and resistant to most laboratory chemicals
- Available in 2 mil and 5 mil thickness

J.G. Finneran Associates www.jgfinneran.com

Gas Permeable Adhesive Microplate Seals

500120 Series

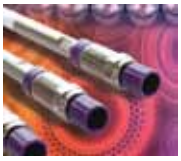


- Allow uniform air and carbon dioxide (CO_2) exchange
- Prevent moisture evaporation
- Available with 96 round windows for a 96-well plate, and 384 square windows for a 384-well plate
- Provide high integrity microplate closure from minus 20°C to 80°C
- Supplied sterile in packs of 50 (5x10 sheets)

Porvair Sciences www.porvair-sciences.com

C8 Phase Solid Core HPLC Column

Accucore™



- Feature a shorter alkyl length bonded phase, which provides lower hydrophobic retention than the equivalent C18 phase
- Enhances chromatographic performance without generating excessive operating pressure
- Enables laboratories to improve sample throughput and quality of results
- Compatible with any instrument from any manufacturer
- Recommended for analytes with medium hydrophobicity

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Sterilin Quick Start

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Thermo Fisher Scientific www.sterilin.co.uk

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- Include silicone o-ring seals, no grease required
- Provide easy assembly and disassembly
- Maximize the viewing area and provide optimal access for electrodes
- Available for use with 12, 15, 18, and 25 mm round coverslips
- Designed to be compatible with the Warner QE-1 Quick Exchange Platform, and the DH- 35i and DH-40i Culture Dish Incubators

Warner Instruments www.warnerinstruments.com

Screw Cap Sample Storage Tube

Octygen

- Externally threaded, 2D coded, 0.50ml
- Offers 475 microliters working volume and is 25.6mm tall
- Uses just 60% of the space typical 0.50ml 96-well screw cap tubes use to store the same volume
- Increased storage density helps save costs
- Can be stored in an automation-compatible Micronic rack

Octygen www.micronic.com

Parallel Protein Purification with Improved Yield and Concentration

Problem: Protein affinity purification is typically carried out in a miniaturized format using spin columns or gravity flow methods. Both techniques have limitations. Spin columns do not maximize the capacity of a given resin because the protein-containing solution passes through the resin bed too quickly. Due to this, the final protein yield is usually lower when compared with gravity flow or batch purification methods. The user of this technique might find that obtaining sufficient protein requires repeating the same protocol over and over.

Small-scale gravity flow protein purification better maximizes the capacity of a given resin due to the slow flow-rate of purification media over the resin bed. Gravity flow methods, however, are cumbersome because in order to maintain target protein activity, constant oversight is needed to ensure that the resin remains wet. Finally, the elution volumes for gravity flow columns are typically large, which dilutes the purified protein, and may compel the user to add an extra concentration step to obtain a sample of high enough concentration for their functional assay.

Solution: One product that may help is the PureSpeed Protein Purification System from Rainin Instrument, a subsidiary of Mettler Toledo. The PureSpeed system utilizes a resin bed in a pipette tip alongside a multichannel E4 XLS electronic pipette for parallel purification of up to 12 protein samples. This system is advantageous compared to spin column and gravity flow formats because it uses repetitive, automated up-and-down pipetting and a tightly packed resin volume to maximize protein binding to resin while reducing hands-on time and the required elution volume. The final protein yield is higher than that obtained for spin column purification while the final protein concentration is higher than that obtained for gravity flow methods. The result is the user will not have to repeat the same purification and will not have to carry out downstream concentration steps prior to assaying the protein sample. Finally, compared to gravity flow methods, the user does not have to worry about protein inactivation due to the resin drying.

The PureSpeed system has many accessories and features available to the user so they can easily customize and carry out their processes. For example, Rainin PureSpeed protein tips are available with three different types of resin: protein A and protein G resins are used to purify antibodies, while Ni-IMAC resin is used to purify 6 x His tagged proteins. With the E4 XLS pipette and PureSpeed Accessory Kit, PureSpeed tips can be used for semi-automated up-and-down pipetting in protein loading, washing, and eluting steps. The user, after setting up the PureSpeed system with the appropriate buffers and protein samples in a deepwell plate, can initiate the PureSpeed protocol on the E4 XLS pipette prior to stepping away from the purification system until the next step in the procedure. Following each step, the pipette is simply transferred from one row of wells in the deepwell plate to the next, and after completion of the protocol, purified protein is easily collected from the elution wells. The final protein yields and concentrations are highly reproducible using PureSpeed mode with the E4 XLS pipette. In addition, protein functionality is preserved throughout the purification process, making many downstream assays a reality.

For more information, visit: www.mt.com/purespeed

▲*The Rainin PureSpeed Protein Purification System: for automated parallel processing to obtain up to 12 protein samples of excellent purity, concentration, and yield.*

IR Spectroscopy for Protein Quantitation

Problem: Classical methods for protein quantitation rely on colorimetric assays, such as those involving protein-copper chelation (bicinchoninic acid (BCA) and Lowry assays) and dye-binding based detection (Bradford and "660 Assay") or ultraviolet (UV) spectroscopy. Each of these methods has limitations. In colorimetric assays, standard curve determinations differ considerably from assay to assay, affecting reproducibility of protein concentration estimations[1]. Similarly, the UV spectroscopy-based method relies on absorbance at 280 nm by a protein's aromatic amino acids, predominantly tryptophan and tyrosine. Therefore, those proteins, such as Protein A, that do not contain aromatic amino acids, cannot be quantified based on 280 nm absorbance. Amino acid analysis delivers possibly the most accurate protein quantitation; however, it is expensive and slow if samples are sent to a third party for analysis. If amino acid analysis is performed in-house, it requires time-consuming sample manipulation and specialized equipment. In all of these methods, sensitivity to buffer components and contaminating biomolecules can often render the assay unreliable[2].

Solution: The Direct Detect™ system (EMD Millipore), an infrared (IR)-based spectrometry system, represents an innovation in biomolecular quantitation. The key to this advance lies in a new membrane technology for preparing and presenting aqueous biological samples to make them compatible with infrared analysis. It employs a hydrophilic polytetrafluoroethylene (PTFE) membrane that is designed to be transparent in most of the infrared spectral region and enables application of biomolecule solutions directly onto the membrane. The system has been optimized for detection and quantitation of proteins. By measuring amide bonds in protein chains, the system accurately determines an intrinsic component of every protein without relying on amino acid composition, dye binding properties or redox potential.

IR-based protein quantitation using the Direct Detect™ system involves measuring the intensity of the Amide I signal in the protein's IR spectrum, and subtracting the signal contributed by buffer alone in that region. A sample spectrum (Figure 1) shows that the IR spectrum of SDS does not have a strong signal in the Amide I region that would significantly interfere with protein quantitation. As a result, IR-based quantitation retains accuracy and reproducibility in the presence of SDS. Similarly, the IR spectra of reducing agents such as DTT do not interfere with Amide I quantitation (spectra not shown). Also, IR-based quantitation of proteins is independent of time. Unlike colorimetric Bradford and micro BCA assays, which are based on indirect detection of a secondary reaction and whose signals continue to change over time, the IR signal of a protein is not affected by the time between sample preparation and data acquisition.

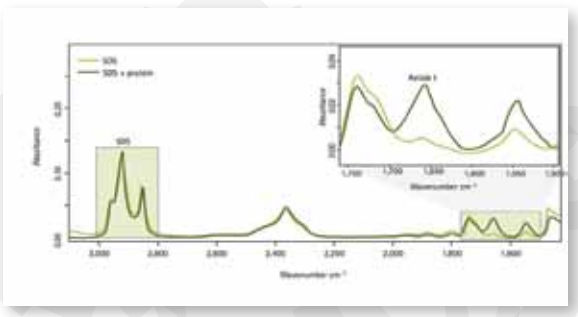
The stability of the IR signal over time, together with compatibility with detergents and reducing agents, make IR-based quantitation a more convenient, flexible, universal approach to measuring protein levels in complex mixtures, compared to the Bradford and BCA colorimetric assays. Also because assay-free, IR-based quantitation only requires a standard curve to be generated once (instead of for every experiment), quantitating single samples using the Direct Detect™ system is faster than quantitating single samples using colorimetric assays. Benchmarking every experiment to the same, robust standard curve also provides more reproducible results and facilitates intra-assay comparisons across multiple experiments referencing the same standard curve.

For more information on the Direct Detect™ system, please visit www.millipore.com/directdetect.

References

1. Manneberg, M., et al. (1992). Comparison of the Coomassie brilliant blue, bicinchoninic acid and Lowry quantitation assays, using non glycosylated and glycosylated proteins. J. Biochem Biophys Methods., Jun; 24(3-4):265-74

2. Kessler, R.J., Fanestil, D.D. (1986). Interference by Lipids in the Determination of Protein Using Bicinchoninic Acid. Analytical Biochemistry, 159:138-142.



▲*The characteristic peaks of the SDS IR spectrum are distinct from the Amide I region of the protein spectrum.*

Total Nitrogen/Total Sulfur Analysis in Low Value Crude Products Using Direct Spray Injection

Problem: With ever increasing regulatory requirements, the balance between the declining quality of incoming crude oil and the heavily regulated quality of outgoing products makes refining a very quality-conscious operation. For environmental reasons and its impact on quality, accurate measurement of sulfur content in hydrocarbons is critical during refinery processes as levels are rigorously controlled by both national and international regulations. In addition, as maximum levels for sulfur continue to be lowered, analytical instrumentation plays a pivotal role in complying with these regulations.

Low value, high molecular weight hydrocarbon fractions of crude oils are often converted to higher value blending stock, using catalytic cracking processes. These low value products typically contain high concentrations of nitrogen and sulfur, both of which are detrimental to catalytic performance. Knowledge of the sulfur and nitrogen content of low value distillates is therefore required prior to processing into higher value products.

Traditionally, the introduction apparatus used for combustion-based trace elemental analysis of crude products depends upon the boiling point of the sample. For light hydrocarbons, direct injection using a ceramic syringe or liquids module is most common, while for heavy hydrocarbons, boat inlet introduction is employed. As a result, two introduction modules are required by analysts to cover the range of sample boiling points analyzed. This need has meant that analyses take five minutes for light hydrocarbons and 12 minutes for heavy hydrocarbons per replicate, thus affecting productivity.

Solution: Total nitrogen/total sulfur analysis using direct spray injection provides the capacity to analyze both heavy and light hydrocarbons from ppb levels up to percent levels using a single introduction module such as the Thermo Scientific jetPRO™ direct spray injector. It operates by introducing the sample into the furnace as an aerosol of sample droplets. This aerosol process is created via high velocity oxygen jets impacting on the surface of the liquid sample as it exits the sample needle. The gas breaks small liquid droplets from the sample surface which produces both a fine mist of sample droplets and mixes the sample with oxygen. The entire sample plus oxygen is then carried into the furnace by a carrier gas. Once in the hot zone of the furnace, the following reactions take place; $RN + O_2 \rightarrow NO + H_2O + CO_2$ and $RS + O_2 \rightarrow SO_2 + H_2O + CO_2$. The jetPRO direct spray injector is permanently located inside the furnace in an environment with a temperature of approximately 1000°C. The spray head temperature, however, is maintained at a temperature below 100°C. If the temperature of the spray head was higher than this, low boiling point samples would not enter the spray head as a liquid and the injection process would be poorly controlled.

Active cooling of the jetPRO direct spray injector is achieved by advanced heat management. The minimum amount of radiative heat is transferred to the injector by coating it with chromium. The injector itself is made of solid copper and is in thermal contact with a large, fan-cooled heatsink. This heat management allows for the spray head to be maintained permanently in the furnace while being at a low temperature.

The jetPRO direct spray injector in the Thermo Scientific iPRO 5000™ Series Total Nitrogen/Total Sulfur (TN/TS) analyzer has overcome the requirement to use two introduction modules for the precise analysis of light and heavy hydrocarbons. This has been achieved by directly injecting both high and low boiling point liquids into the furnace using a single, universal injector. This new design of injector module has improved the precision and accuracy of results for the analysis of heavy hydrocarbons compared to the current boat inlet oxidation method, while maintaining ASTM compliance. In addition, the analysis time for heavy hydrocarbons is now one quarter of the boat method analysis time at just over three minutes. For light hydrocarbons, accuracy and precision are maintained while the typical analysis time is also three minutes.

For more information about the Thermo Scientific iPRO 5000 series analyzer, please call +1 800-532-4752, email analyze@thermofisher.com or visit www.thermoscientific.com/ipro

▲*The Thermo Scientific iPRO 5000 Series Total Nitrogen Total Sulfur (TNTS) analyzer.*

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PRE-OWNED EQUIPMENT MARKETPLACE

PARTING POINTS

Takeaways from this month's issue:

HAZCOM 2012 – ARE YOU PREPARED?

OSHA's revised Hazard Communication standard incorporates the United Nations Globally Harmonized System (GHS) for hazardous chemicals and will protect workers from dangerous chemicals while also helping American businesses compete worldwide. Changes aim to:

- Reduce confusion about chemical hazards in the workplace
- Improve the understanding of hazards
- Help with safety training
- Better protect workers from chemical hazards

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SMART PROJECT MANAGEMENT

Working on a project without agreeing on goals is fraught with danger. The results of such disputes are often wasted time, effort, and money. Some of the rules for a successful project include:

- Agreement on goals among all project participants
- A good project plan to accomplish these goals
- Effective communication
- Scope control

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CONCERNING THE CLOUD

While cloud computing is merely a metaphor to signify the abstraction of technology, resources and locations, the possibility of your laboratory missing out on the biggest technological leap ever is real. Some of the key techniques labs should consider:

- Association rule learning
- Natural language processing (NLP)
- Optimization
- Regression

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ASK THE EXPERT: CHOOSING THE RIGHT ELN FOR THE RIGHT APPLICATION

Ph.D. Cecilia Björkdahl of Karolinska Institutet Medical University, and Stan Piper, formerly principal scientist specializing in informatics projects in Pfizer's Pharmaceutical Sciences division, discuss how to choose and implement the right ELN in your lab:

- Make sure that the communication with the ELN system and also to the server is encrypted for security
- Don't make it into an information technology issue, but make it a research issue
- Consider your future needs when making an ELN purchase

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WASTE NOT, WANT NOT

Proper management of chemical waste is not only important for safety but also for economic health, given the serious fines and penalties possible if it is not handled according to regulations. Lab managers should:

- Familiarize themselves with the EPA's U and P-lists of hazardous chemicals
- Check with state and local entities regarding any additional requirements
- Contact an experienced consultant to ID any wastes not on the EPA lists
- Make sure they know the four characteristics of hazardous waste

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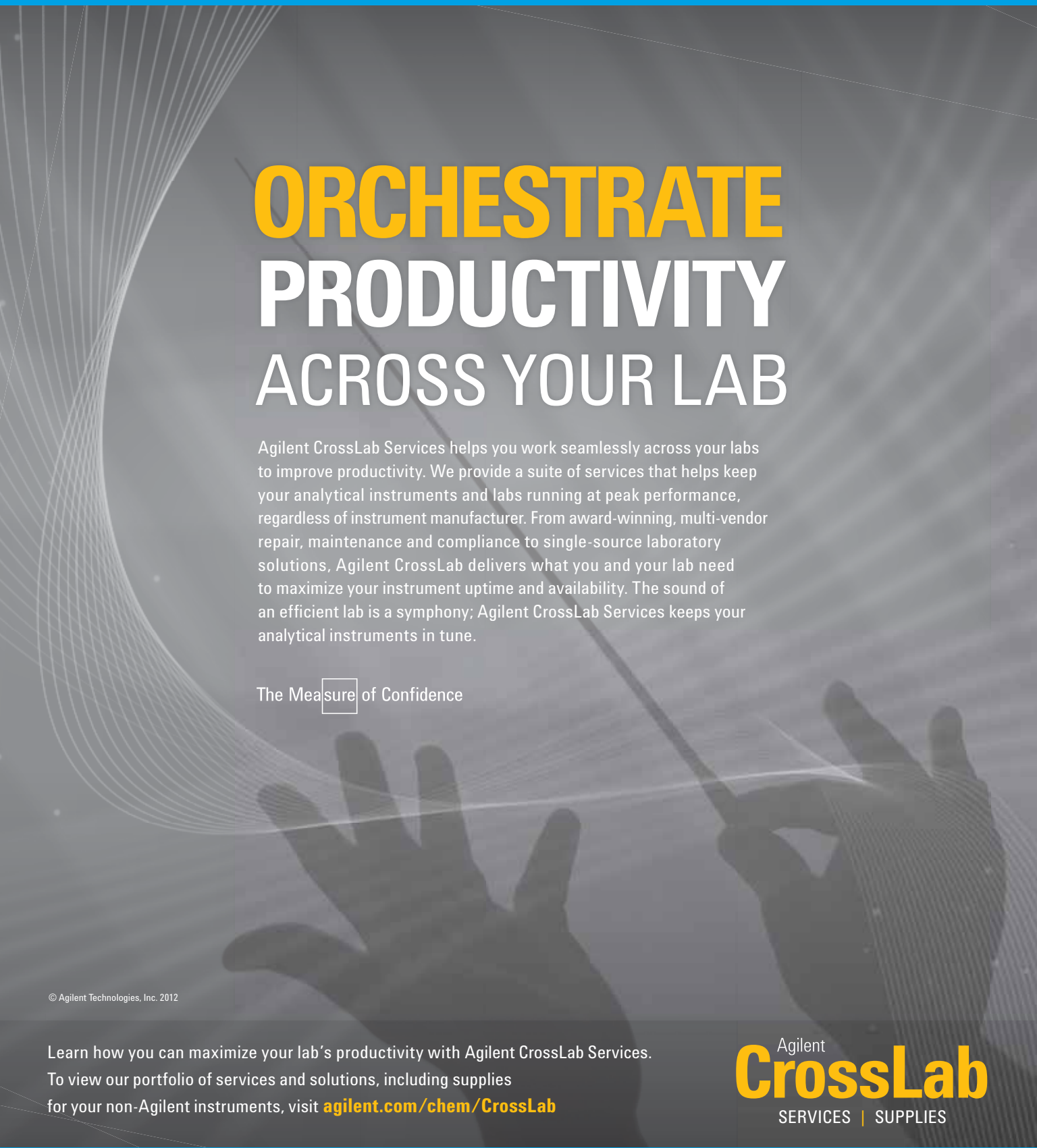

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