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Run Your Lab Like a Business

January / February 2012 Volume 7 • Number 1

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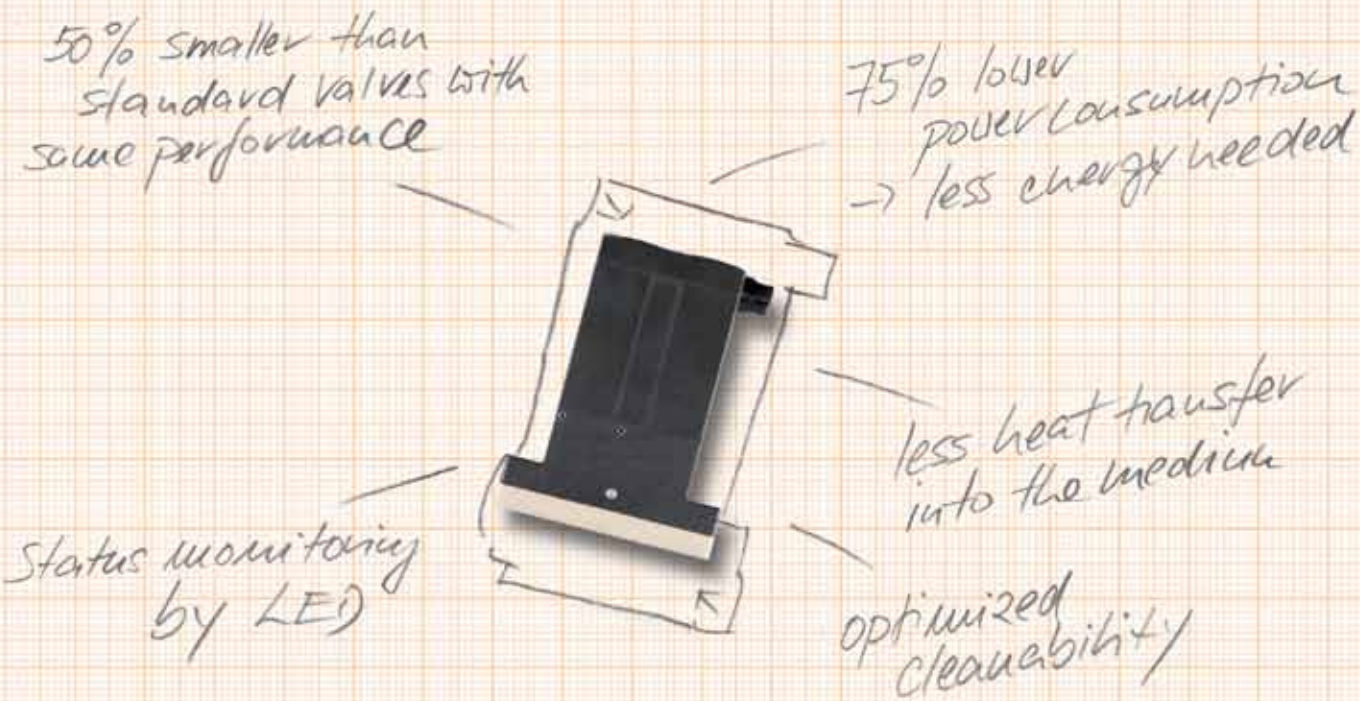

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CONTENTS

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Get New Insights into HPLC, UHPLC and LC systems

The first issue of our new supplement, INSIGHTS, can be found in this month's premier 2012 issue of *Lab Manager Magazine*. This new companion to our magazine features detailed reports on developments in UHPLC, LC, and HPLC systems, giving readers valuable information on the latest product offerings and trends as well as what expert end users have to say about these systems. Readers will also find out how to properly run and maintain their UHPLC/HPLC systems, some of the arguments for and against upgrading from HPLC to UHPLC, along with the results of our latest survey on HPLC purchasing practices. If HPLC, UHPLC, or LC systems are important in your laboratory, or if you're looking to add or upgrade to any of these instruments, this first issue of INSIGHTS will offer guidance in your decision-making process and help you get 2012 off to a well-informed start.

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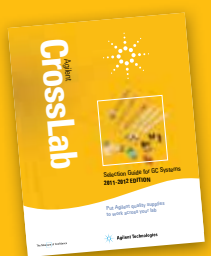

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Frugal Resolutions

On January 1st, 2012, the front page of The *New York Times* Sunday Business section featured a large, squalling New Year's Day baby. The headline read: "I Just Got Here, But I Know Trouble When I See It." The sentiment—echoed almost everywhere—is that the U.S. economic forecast remains gloomy and recovery is not expected any time soon.

Apropos of these restrained economic times, this month's cover story examines the budgeting process and how managers can design and work most effectively within their research budgets which, as our recent survey revealed, have been essentially flat since 2009. Software tools, project management techniques, and ideas for maximizing research dollars are all covered. One idea the author puts forth is outsourcing. "Outsourcing of various lab activities, particularly capital- and staff-intensive ones, can also provide cost savings, thereby freeing funds to be spent elsewhere." As the author points out, "No one enjoys the budgeting process, but it's something that must be done." And, done well, is worth the effort.

Echoing the same need for frugality, this month's Laboratory Management article, "To Own or Not to Own," looks at the financial advantages of and options for leasing capital equipment. "Leasing allows laboratories to use the most up-to-date technology without having to fork over the huge initial amount of capital necessary to purchase the instruments." Turn to page 20 to find out whether a leasing program is right for your lab and if so, what sort of agreement would be best.

Our second management article, "An Enterprise Approach to R&D Informatics," opens with the economy: "The ongoing economic recession means that businesses everywhere need to rein in spending and do more with less." Author Michael Doyle makes the argument that "closing cost and efficiency gaps between the research lab and final product requires a new approach to informatics, one that focuses on "e-enabling" data visibility, integration and sharing across the end-to-end innovation cycle." Something else you might consider in your belt-tightening, productivity-improving resolutions for 2012.

And finally, this month's Technology & Operations article, "The Evolving Service Model," repeats the same theme: "As capital budgets became constrained due to the economic downturn, companies look to save costs in as many areas as possible. So as they try to eke out more mechanical life from their existing base of installed laboratory equipment, they will turn more frequently to service agreements." Author Bernard Tulsi then describes various manufacturers' equipment service and maintenance offerings and developments in this important category.

On another note, beginning with this first issue of 2012, we are pleased to introduce a new editorial section to the magazine devoted to developments in laboratory automation. Turn to page 26 for Joe Liscouski's piece, "Integrated Systems." It's not surprising to hear that the dream of integrated automation systems remains just that—a dream. However, Liscouski provides some ideas for getting around system juggernauts and making the most of what's currently available. "The bottom line is planning. Labs have to develop rational lab-wide plans for the specification, purchase and use of laboratory technologies. You have to purchase from the selection of products that exist, but you can make informed choices," he says.

Hope you enjoy these timely pieces along with everything else we offer in *Lab Manager Magazine*'s first issue of 2012.

Happy New Year!

Pamela Ahlberg - Editor-in-Chief

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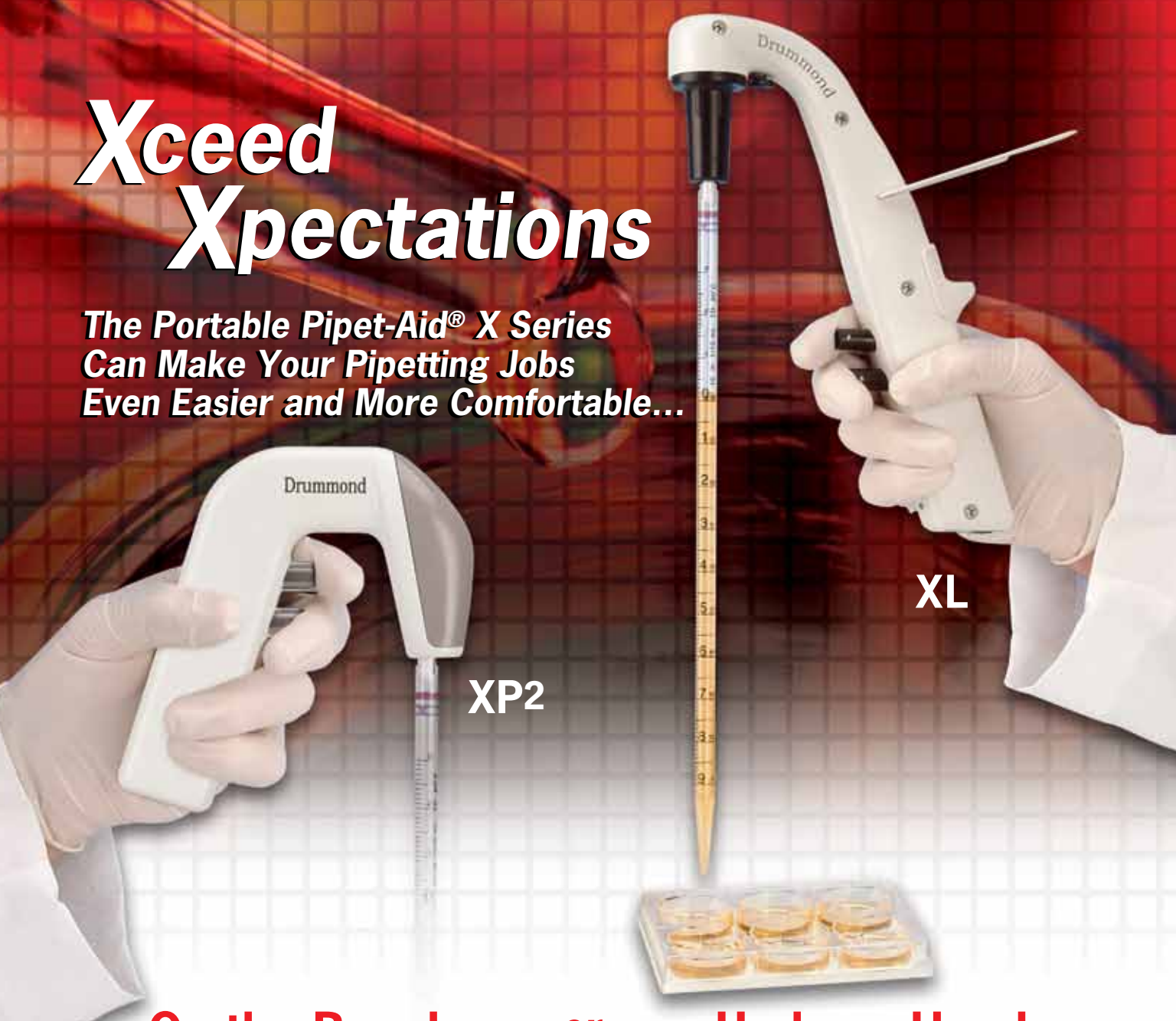

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BUDGETING 101

TIPS FOR MANAGING YOUR LABORATORY RESEARCH DOLLARS

by John K. Borchardt

"Budgets are like making sausages; it is better not to see them made," noted Otto von Bismarck, the Iron Chancellor. (As the man who combined the many German principalities into a unified nation, he was an effective manager if ever there was one.) No one enjoys the budgeting process, but it's something that must be done. If done well, it's worth the effort.

In October 2011, *Lab Manager Magazine* conducted a survey of managers to learn about some of the details of their laboratory budget processes. Slightly more than 95 percent of the respondents were responsible for the budgets in their laboratory.

> "Modern software can allow staff scientists & engineers to propose budgets for their own activities."

Budget basics

The budget is a short-term plan for the future. To get down to the basics, the purpose of a budget is to establish a forecast of revenues and expenditures to guide one's efforts during the next fiscal period (either a calendar year or a fiscal year, which often begins July 1). For example, according to Harry Baguma, director, Biomedics Products, Ltd., his firm's budgeting process begins with a SWOT (Strengths, Weaknesses, Opportunities and Threats) analysis of the company and its product lines by managers of Biomedics' various departments. This is the basis of determining the funding needs of Biomedics' product lines. Consultations are held with accounting personnel and management to make sure that all cross-cutting issues are addressed in the budget.

Survey results indicate that the extent of laboratory managers' budget discussions with senior managers varies. For example, Dennis Busiere of the Monroe County Environmental Lab (Rochester, NY) commented, "Prior to creating the budget, I meet with the senior management and highlight possible constraint issues and funding requirements."

Discussions with laboratory staff members to determine budget needs are also important. For instance, Patty Eschliman, laboratory manager at Madonna Rehabilitation Hospital, notes, "I prepare the budget for my lab based on discussions with my staff and submit it to accounting/management for review and approval."

Modern software can allow staff scientists and engineers to propose budgets for their own activities. Free software to do this is widely available and can be found by using an online search engine such as Google or Bing.

Once the laboratory budget is established and approved, the spending performance of the organization—and of the organization's managers—is measured against this budget. Survey results indicate that laboratory managers usually monitor this spending on a monthly basis.

Having the actual spending come close to the budgeted amount suggests that the managers understand their business and its spending requirements. If their actual spending is dramatically above or below that budgeted, this suggests they aren't controlling the R&D process. Their performance evaluations and salary raises could suffer as a result. Some people, including novice managers, think their superiors will be pleased if the actual spending of their group is substantially under-budget. However, spend-

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ing drastically under one's budget can result in understaffing, low morale and poor productivity from overworked staff members. Understaffing of your department often results in missed deadlines and opportunities.

For example, I once worked for a manager whose budget allowed him to hire one new chemist and two additional technicians to handle his department's workload. However, he did not do so. Within six months, his department faced the low morale and poor productivity mentioned above. Another former manager of mine decided to limit travel costs by reducing the frequency with which his technical service specialists traveled with company sales personnel to visit customers. The result was dissatisfied customers, less effective customer service, and a slowdown in sales growth.

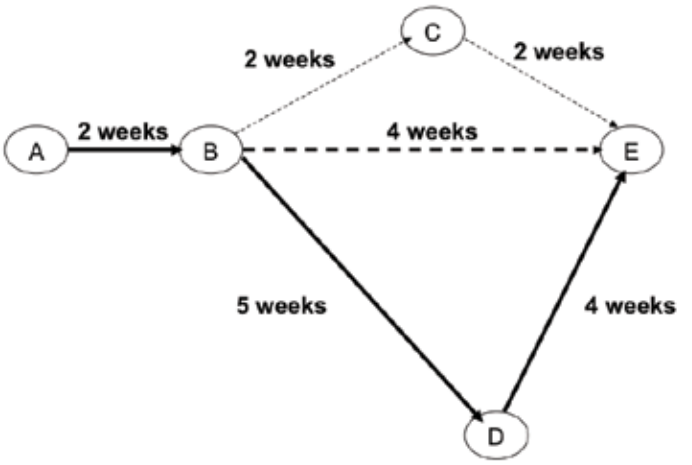

Figure 1. A representative budget process illustrating that some budget steps can be accomplished more quickly in parallel than sequentially.

Of course, one has to be aware of the opposite effect: throwing money at an R&D problem to solve it. That doesn't always work.

Where does the money go?

It helps to understand where the money has gone in the past (see sidebar). Your lab's previous budgets can help in this regard. Understanding how money is spent by similar laboratories operated by other companies can also be useful. The Frost & Sullivan annual survey of laboratory spending[1] can be helpful here. Some of the results are summarized in Tables 1 and 2 of the sidebar. Survey results indicate that most laboratory budgets have been essentially flat since 2009.

The biggest single item in laboratory budgets, staff costs, isn't discussed in the Frost & Sullivan survey but is included in the *Lab Manager Magazine* survey. Items included in budgeting were total personnel costs, incorporating salary and benefits; and capital equipment, materials, supplies and consumables. Additional budgeted items were conferences and trade show attendance, and literature.

Getting started

The SWOT analysis described earlier by Harry Baguma can result in a prioritized list of projects to work on in the coming fiscal year. Customers, suppliers, sales representatives, marketing executives and plant managers may all have useful input for this list. For instance, sales personnel can report new product needs requested by the company's customers. Plant managers may request projects that will improve operations of the production plants for which they are responsible. It is important for lab managers to seek input from these stakeholders. Once all input has been received and studied, a budget needs to be determined for each project on this list.

The next step in the budget process is to consider outsourcing. A laboratory manager can obtain cost estimates from outside firms and compare these costs to the costs of doing the work in-house. This sort of activity has led to outsourcing of support functions such as building and grounds maintenance, janitorial services, security, and operation of the company cafeteria. Outsourcing of various lab activities, particularly capital- and staff-intensive ones, can also provide cost savings, thereby freeing funds to be spent elsewhere.

Time is required to assemble the project list, estimate the cost of each item and set the relative priority of each item. This process, particularly the setting of priorities, can lead to extended debates that delay the budget's establishment and approval.

One way to prevent this delay is to borrow from the principles of project management. Lab managers know the date on which the budget must be submitted to upper management for approval. Working backward from this date, one can set a timetable for completing each step of the budget process. In essence, completion of each step becomes a project milestone. A delay in achieving one

milestone immediately alerts lab managers to the fact that they must adjust the timing of the remaining steps of the budget process to achieve the required overall budget completion date.

Another principle of project management is that some project steps can be accomplished more quickly in parallel than in a series one after the other (Figure 1). By adopting the project management mindset when working on budgets and by working on some aspects of setting a budget in parallel rather than sequentially, lab managers may be able to reduce the length of the budgeting process or respond more quickly to delays in the process.

Staff members' perspectives

It is usually helpful to include staff members in the budgeting process or at least to make them aware of its progress. They might have useful ideas on the need for new equipment or additional staffing. They could perform some of the work associated with budgeting, such as pricing equipment being considered for purchase and determining the need for various optional instrument features. Inclusion in the budgeting process can make them feel part of the team and may improve morale.

Sales representatives and members of lab service groups can ask customers to describe problems they need solved and to estimate their tech service needs for the coming year. Feedback can be used to help determine needed funding for the coming year.

Internal customers of the laboratory often make recommendations concerning the laboratory spending required to meet their goals, and then review the budget. These customers include operating divisions of the company, such as sales and marketing groups, developmental products groups, and production plant personnel.

The final stages

Once all the required input is collected, all the proposed projects—research, development, plant support and technical support—can be grouped into three categories: essential, nice to do, and do only after the first two categories are budgeted. Then, based on these work estimates, lab managers can draw up and submit a budget. This approach is effective in funding an RD&T (Research, Development & Technology Transfer) program

focused on customer needs. It also helps lab managers develop fallback positions. Should higher-level managers require budget cuts, lab managers can delete some of the third-category projects (to be funded only after the first two categories are funded) from the budget. This can eliminate tedious, sometimes acrimonious budget disagreements with higher-level managers.

Typically budgets are then reviewed by higher-level managers. Committees of senior managers at a laboratory may review the overall laboratory budget before it is sent to high-level research managers and personnel in the office of the organization's chief financial officer (CFO). The CFO's office in large companies typically includes financial analysts who specialize in creating and managing budgets.

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1. J. Witonsky, "Laboratory Spending Trends," *Lab Manager 2012 Product Resource Guide*, pp. 8-12 (November 2011).

***Dr. John K. Borchardt** is a consultant and technical writer. He is the author of* Career Management for Scientists and Engineers *and often writes on career-related subjects. He can be reached at jkborchardt@hotmail.com.*

FLUCTUATIONS IN LABORATORY SPENDING

By John K. Borchardt

To better understand the spending trends among laboratories, the editors of *Lab Manager Magazine* and business and research consulting firm Frost & Sullivan, Inc., conducted a survey of 146 *Lab Manager Magazine* readers qualified as decision makers who either influence or approve their laboratory purchasing policies[1]. Jonathan Witonsky, a Frost & Sullivan industry manager, reported on the results. Respondents to the September 2011 survey were primarily laboratory managers, department managers, laboratory directors, laboratory technicians and principal investigators at academic institutions, hospitals or clinical laboratories, biotechnology companies, and chemical or petrochemical companies globally.

Table 1. Types of Organizations Surveyed

Organization Type	Percentage of Respondents
Industrial	24
Academic	23
Biopharmaceutical	23
Patient care	23
Government	5
Other/not available	2

As Table 1 indicates, with the exception of respondents from government and miscellaneous other laboratories, respondents almost equally represented industrial, academic, biopharmaceutical and patient care laboratories. The average total budget of these laboratories was stable in 2010 and 2011 and is forecast to increase by 1% in 2012. During these years, the average budget for the laboratories surveyed was US$313,200 to $316,000.

The percentage of the budget spent on various types of laboratory equipment and supplies is summarized in Table 2.

Table 2. Budget Spending on Equipment and Supplies

Item	Percentage of Spending	
	2011	2012
Instruments	26	27
Equipment	13	13
Chemicals	15	16
Life science reagents & kits	16	16
Glass labware	5	5
Plastic labware	6	6
lab supplies	19	18

The actual category representing the largest amount of spending and the biggest percentage of the laboratory budget isn't mentioned in the above spending breakdown: the salary and other costs of the laboratory staff. Nor are other items such as building and grounds maintenance and security.

THREE REASONS YOU'RE FAILING GEN Y

By Mike Domitrz

Do you get frustrated with the Gen Y'ers in your lab? Do you find them to be lazy, apathetic and self-absorbed? Do you sometimes say to yourself, "Where did this generation's parents go wrong?"

Good news! Gen Y is as hard working as any generation before. Many managers (maybe even you) are simply failing to understand Gen Y. When you fully grasp how a Gen Y'er views the workplace, you are much more likely to draw incredible results from this generation.

Let's first examine the three reasons why many mangers fail in working with Gen Y:

1. Perceived apathy and laziness, thus perceived lack of work ethic.
2. Inability to focus.
3. Lack of respect.

Perceived apathy and laziness, thus perceived lack of work ethic

Absolute MYTH! When Gen Y is inspired and loves what he/she is doing, Gen Y is determined, hard working and strong problem solvers. The key wording is "inspired and loves what he/she is doing." Get to know the Gen Y better so that you fully grasp what aspects of the job he/she finds most fulfilling. Next, emphasize the parts of the job the Gen Y LOVES the most. By doing so, you will be a better manager.

Did you know Gen Y'ers appreciate caring relationships and being valued? Family is much more important to Gen Y than the past few generations before. Create a family atmosphere at work. The tighter the work family, the more a Gen Y will want to work harder.

You are not in a factory of the past where people thought, "Come to your place of work and focus solely on your job." Personal connections count today. Gen Y connects tightly with those who CARE about the WHOLE person. In addition to what happens during work, show interest and appreciation for what Gen Y does in his/her personal life. Remember they love Facebook because it keeps them in touch with their family and friends. Bonding counts!

Inability to focus

Can you text, hold a conversation and solve a problem on your computer all at one time? Gen Y can! Your Gen Y colleague has the ultimate concept of focus—being able to be so skilled at utilizing tools that he/she can multi-task—which clearly requires an ability to focus quickly in multiple directions. Instead of thinking, "Gen Y doesn't focus," what about asking yourself, "How can I best utilize this colleague's ability to multi-task?"

Lack of respect

Who is disrespecting who? Anytime a leader says to me, "My people don't respect me," I instantly want to ask, "Why should they?" How are you role modeling respect? Are you seeing the Gen Y for all the gifts he/she currently brings to your lab? Are you voicing your gratitude for their talents? If someone doesn't feel respected, what are the odds the person is going be in the mood to be GIVING respect?

When you decide to no longer be frustrated with Gen Y but instead take the time to learn about Gen Y, you may be surprised by how much better of a leader Gen Y is going to teach you to become now and in the future. Just like parents of 20 years ago, "because I said so" doesn't work today. YOU need to be better!

***Mike Domitrz** has been working for two decades with the latest generations as they go from middle school through their university education. As the founder of The Date Safe Project Inc., he is known for his unique ability to connect with Gen Y AND to get Gen Y to take action others couldn't. How? He discovered what Gen Y wants and needs in their relationships to be most productive. Today, he is sharing how to draw the passion out of you and your colleagues to achieve incredible goals at www.AskingInc.com.*

AN ENTERPRISE APPROACH TO R&D INFORMATICS

PROVIDES WIDER CONNECTIVITY ACROSS THE R&D, PLM AND CORPORATE DECISION-MAKING LANDSCAPE

by Michael Doyle

Whether they are developing a new drug, dish detergent, airplane parts or computer chips, companies with heavy R&D requirements face a number of tough challenges. The ongoing economic recession means that businesses everywhere need to rein in spending and do more with less. Global competition (and in the pharmaceutical industry, patent expirations) are undercutting many of their "bread and butter" products—those that are easy and cheap to produce are now even easier and cheaper for someone else to make in places like China or India. To retain a competitive advantage, companies need to up the ante on innovation by designing and developing better, safer and more effective products than their competitors. And they need to get these products to market both fast and cost-effectively.

As if all the above weren't challenging enough, product complexity has also reached an all-time high. Chemistry, materials science, formulations, lab experiments, virtual experiments, QA/QC test results and more form the basis of an ever-growing data pyramid that leads to a new product, and this data is just as critical for the manufacturing and business sides of the house to have access to as it is for R&D. For example, a single change to a formulation ingredient can have a big impact on later-stage activities such as processing, the selection and calibration of plant equipment, or even the design of package labels, so it's important that organizations ensure broad data access and collaboration up and down the design-test-manufacture pipeline. The problem is this is much easier said than done. Closing cost and efficiency gaps between the research lab and final product requires a new approach to informatics, one that focuses on "e-enabling" data visibility, integration and sharing across the end-to-end innovation cycle.

> "Closing cost and efficiency gaps between the research lab and final product requires a new approach to informatics."

Rethinking R&D informatics

It's no secret that R&D activities involve massive amounts of data from a variety of sources. In addition to output generated from lab experiments, product testing and virtual science like modeling and simulation, organizations also need to capture and share information from previous projects, from publicly available databases and from production and scale-up systems, as well as from contract research, sourcing and distribution partners. The global reach of today's corporate enterprise means that critical knowledge can easily get trapped in departmental, system and geographic silos. The research scientists don't end up sharing data with processing engineers, the processing engineers aren't communicating enough with procurement specialists, regulatory experts aren't brought into design planning early enough and so on. Project collaborators often turn to manual approaches to leverage multiple information sources—spending hours searching files, reformatting, and cutting and pasting reports together, or they enlist IT resources to hand code customized "point-to-point" connections to move data between systems and applications. But these ad hoc attempts at data and process integration are too time-consuming and expensive to make sense on a global scale.

In the mold of solutions for PLM (Product Lifecycle Management) and ERP, (Enterprise Resource Planning) Innovation Lifecycle Management demands an underlying, open, enterprise-level informatics framework that allows organizations to electronically integrate diverse information silos, make data more visible and accessible to multiple stakeholders, and move it more efficiently through the design-test-manufacture pipeline.

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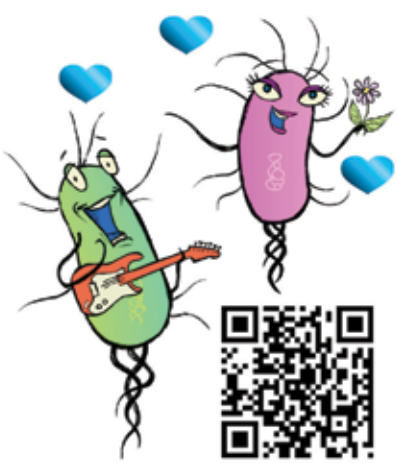

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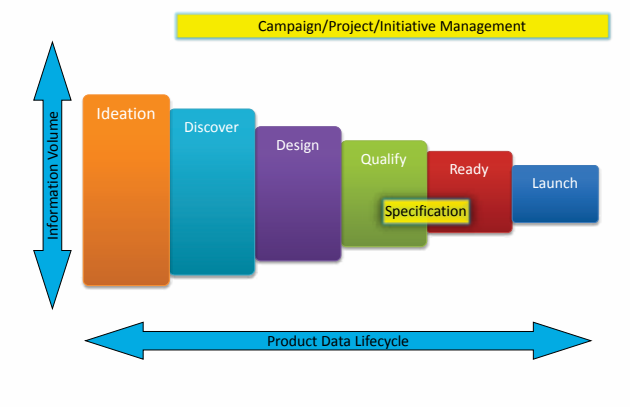


▲ *Current State of New Product Introduction Cycle.*

Accelerating innovation through e-discovery, e-design and e-development

Thanks to the advent of cloud computing, service-oriented architecture, the use of web services and of technologies that support advanced search and data mining, more streamlined "e-innovation" is now a real possibility. Web services can, for example, be used to support "plug and play" integration of multiple data types and formats without requiring customized (and expensive) IT intervention. As data previously scattered throughout the organization is made accessible through a single informatics framework, a number of time, cost and efficiency benefits can be realized.

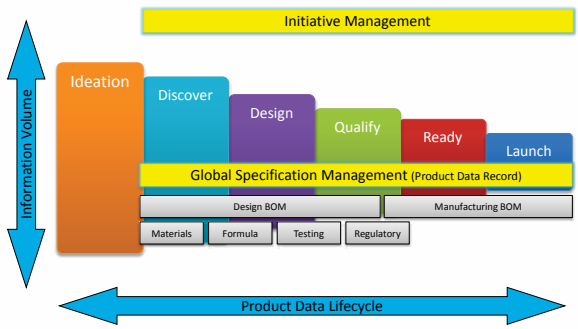
First, information, no matter where or how it was generated, can be utilized by numerous contributors up and down the product development value chain, enhancing collaboration. Toxicologists can make their history of assay results available to formulators developing recipes for a new cosmetic, for example, or chemists can work more closely with sourcing experts to ensure that the compounds they are developing in the lab are actually viable candidates for large-scale production. Second, processes such as specification management that were previously disjointed due to critical data being locked within isolated databases and proprietary systems can be streamlined and automated, speeding cycle times. And third, institutional knowledge can be captured and archived, promoting re-use and reducing unnecessary rework.

Openness, flexibility and simplicity are key to making e-innovation work, however. Your informatics framework can't be proprietary or at some point it just won't be able to use information from some small, yet critical, system or application without IT intervention. It also can't force scientists and other specialists into a rigid way of doing things. Individuals should still be able to use the tools that are most suitable to their work (for instance, advanced modeling software or high-throughput testing equipment) while being able to more easily share their knowledge and results with the rest of the organization. And finally, the reporting of complex data should be simple enough that it can be leveraged by a number of different users, whether a PhD chemist working on the discovery of lead compounds, a processing engineer getting a product ready for scale up, or a business executive making decisions related to marketing and distribution.

Here's a good example that illustrates the benefit of using an underlying informatics framework for e-discovery: extending the reach and value of virtual science. Sophisticated modeling and simulation software can be very helpful in augmenting standard wet chemistry. By allowing researchers to design and test compounds, formulations, mixtures and more *in silico*, organizations can speed time-to-innovation and reduce lab costs. They can look at, for instance, how a new ingredient will impact the viscosity of a shampoo or identify molecules that are cheaper to use in a drug and narrow down the options before doing a series of far more costly and time-consuming live experiments. Now imagine the additional value that could be realized if this discovery research data were captured and made available *much earlier* to product development and production stakeholders further up the innovation chain. Once the potential new ingredient is identified, plant engineers could use the information to make sure they have the right specs for large-scale production, procurement specialists could start sourcing from suppliers, or maybe even the person in charge of product packaging can begin working on new labels that list the additional ingredient—increasing efficiencies that translate directly into faster time-to-market.

E-enabling development is also much simpler with integrated informatics. Consider all the processes that go into clearing a new ingredient compound out of discovery and into development. At a big consumer packaged goods company, this may involve multiple steps that touch numerous information sources and applications. Product safety and efficacy tests need to be reviewed, which includes data from three to four different systems. The new formulation needs to be compared with historical data and scenarios. Conclusions and recommendations are written up and formatted so the next contributor to interact with the information can actually use it. Without an integrated informatics framework in place, a reviewer will likely have to jump back and forth between several different screens and information systems to get through the process, with each step taking several

minutes. Multiply the number of steps in the process, the number of systems involved and the number of times the process needs to be completed (sometimes for each of the 30 to 40 ingredients making up a formulation) and it's easy to see how just this one activity alone can eat up an enormous amount of time and resources.



▲ *Design BoM contains Material, Formula, Testing & Regulatory.*

An enterprise informatics platform, on the other hand, can compress process cycle time by freeing participants from tedious manual tasks such as searching for data, prepping information for analysis, formatting reports for different users and bouncing around between multiple applications and systems. When all the data related to product discovery, design and development is captured within a single information framework, processes can be automated across disciplines, applications, systems and departments, which in turn speeds the flow of information along the product innovation value chain.

The last mile: Marrying R&D with systems supporting PLM and ERP

In a climate where budgets are tight, competition is fierce and time-to-market timelines are continually shrinking, product innovation must be more closely aligned with the nuts-and bolts activities that are involved in bringing a great idea to life. In addition to accelerating innovation processes and enhancing collaboration from product ideation through production scale-up, an enterprise approach to R&D informatics must finally be able to hand off critical data, in a usable, structured format, to PLM and ERP systems that govern product manufacturing, supply chain management and distribution. When complex research information can be pulled into these more structured practices (and vice versa) product specification will become more complete, consistent, global and streamlined. For example, if an organization can consider chemistry-level details during product development and deployment activities, activities like claims support, regulatory compliance, sourcing and more can be made more efficient and accurate.

Rather than looking at the innovation cycle as something separate from the product life cycle, organizations are beginning to find ways to ensure wider connectivity and deeper, more integrated informatics across the R&D, PLM and corporate decision-making landscape. The critical layer is a scientifically aware informatics and data-pipelining platform that shepherds the knowledge that drives innovation all the way from the research lab to the final product.

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TO OWN OR NOT TO OWN?

UNDERSTANDING THE PROS, CONS AND OPTIONS OF LABORATORY EQUIPMENT LEASING by Rachel Muenz

With the current tough economy, leasing laboratory equipment could be the way to go for many labs that must now work with very tight budgets.

Though leasing does carry some risk, it also has many advantages.

"An equipment lease is one of the best ways for businesses to stay ahead of the development curve," said account specialist Brad Harmon of First Star Capital (Walnut Creek, CA), an independent direct lender whose focus is equipment leasing, including lab instruments.

He added that leasing allows laboratories to use the most up-to-date technology without having to fork over the huge initial amount of capital necessary to purchase the instruments.

"Running a lab entails making sound financial decisions that improve the condition, quality and overall competitiveness of the business as a whole," he said, adding that leasing offers a number of other advantages, including:

- Flexibility with terms and equipment
- Conservation of working capital and credit lines
- Increased opportunities from not tying up working capital resources
- Tax benefits, such as enhanced depreciation/accelerated write-offs
- Improved financial ratios (balance sheet) with operating expense vs. liability
- Fast turnaround time compared to other forms of financing
- 100% financing typically available for established companies

As with any type of lease, however, laboratory equipment leasing does have its risks and disadvantages.

What you should be aware of

Mike Bartlett, director of global financial services at Thermo Fisher Scientific (Waltham, MA), which has its own leasing program, says there are two main risks in leasing laboratory equipment. The first is that interest rates could change after a customer has signed a lease.

Since Thermo Fisher's leases are at a fixed rate for the life of the lease, a customer could end up paying more than necessary if interest rates drop during the term of the lease. On the other hand, Mr. Bartlett added, if interest rates rise during the lease term, the customer ends up getting a better deal with the cheaper rate they locked into at the beginning of the lease.

The second risk with leasing is that a customer could commit to the wrong type of lease, he said, meaning it's definitely worth your while to research the various types of leases before committing.

For example, a customer might sign a five-year lease-to-own agreement, where they'll end up owning the instrument after five years, but the technology changes two years into the agreement.

"They've decided they'd like to have the latest and greatest technology, but they're locked into ownership of [an older model of] that particular instrument," Mr. Bartlett said.

Thermo Fisher does a number of things to prevent customers from choosing a lease that may not be the best fit for their company.

"We counteract that through different types of structures," Mr. Bartlett said. "We have operating leases, and we have technology refresh-type offerings that are certainly available for most instruments that we sell. We try and work very closely with the customers if they do decide that they want to upgrade to that [newer] technology."

Mr. Harmon of First Star Capital added that acquiring laboratory equipment always involves risks—such as acquiring an instrument that is inadequate or inappropriate for the lab's needs—no matter how that equipment is funded.

"Investing in lab equipment can entail risks, all of which will be prevalent regardless of whether the equipment is leased, purchased outright with cash or acquired with any other funding option," he said.

He suggested that lab managers who are considering leasing equipment should first think about why the equipment is needed and what the economic justification is.

"If the equipment will pay for itself through cost savings/efficiencies or by creating an additional revenue stream, it will likely strengthen the case for approval," Mr. Harmon said.

Lab managers should also make sure they have all the relevant credit and financial information organized and ready to submit along with their application for lease approval and have at least an approximate monthly budget in mind, he said.

"This [having a monthly budget handy] will allow the lessor to try and put forth the most affordable lease structure (term, payment, etc.)," Mr. Harmon said.

So many options

Anyone looking to lease laboratory equipment has a lot of choices because just about any instrument can be leased, along with laboratory furniture.

Along with constantly evolving technology, the most expensive instruments also tend to be the most popular to lease, Mr. Bartlett said.

"Probably the most common types of equipment are the higher-ticket items," he said. "The more expensive the equipment, the more likely it's going to be leased or financed."

Such instruments include mass spectrometers, chromatography instruments and diagnostic/health equipment, Mr. Bartlett said.

Mr. Harmon added that analyzers and autosamplers are also common choices for many lessees, and some larger labs sometimes acquire a LIMS through a lease.

"Oftentimes, labs use leasing to secure less specialized equipment as well—assets such as computer systems, phone systems, office furniture, storage cabinets and even HVAC systems are all common," Mr. Harmon said.

The popularity of leasing lab equipment itself also varies among customers.

"It's oftentimes a function of the customer and industry, so if you look at our healthcare customers, leasing is more prevalent than it would be with large pharmaceutical customers," Mr. Bartlett said, adding that small labs in the environmental and biotech industries or emerging companies also tend to lease more often at Thermo.

First Star's clients are mostly made up of established companies with stable cash flow, clientele and ownership, rather than emerging labs, Mr. Harmon said.

"Young companies, such as start-ups, typically don't have a track record of commercial credit, thereby making it difficult to qualify for lease funding approval," he explained. "Furthermore, labs with established clientele and stable cash flow are typically better positioned to forecast equipment needs, asset life cycles and manageable monthly payment obligations."

Mr. Harmon said that, in general, lease contracts are usually around 24 to 60 months at First Star, and end-of-term lease options vary depending on whether the lab has a capital lease or a true lease.

"A capital lease allows for a 'bargain purchase option' at the end of the term, such as $1 or a fixed percentage of the original acquisition cost (oftentimes 10 percent), while a true lease allows more flexibility, including the option to return the equipment and walk away, renew the lease for 12 additional months at a discounted rate or purchase the equipment for the depreciated fair market value," he said.

"An equipment lease is one of the best ways for businesses to stay ahead of the development curve."

Thermo Fisher also offers $1 and fair-market-value purchase options with payment structures of 12 to 60 months and a variety of other payment options. The leasing division also offers master lease line of credit, reagent agreement, future funds and emerging-credit lease options for development stage companies—all of which are explained further on their website.

Mr. Bartlett said, however, that the traditional capital lease remains the most popular leasing program at Thermo Fisher and most of their customers' leases are three-to-four-year terms, while about 75 percent of those customers look to own the instruments at the end of the lease.

Customers who deal with changing technology prefer the operating lease structure, he added, explaining that operating leases have a shorter two-to-three-year term and customers don't own the instrument at the end but have the options to purchase, continue to lease or upgrade to the newest version of that instrument.

"We see cases where technology changes every 18 to 24 months, and so for those customers—such as pharmaceutical customers and some of the top academic research institutions—they always want to maintain the latest technology in their labs, so they would look for that [operating lease] program," Mr. Bartlett said.

Laboratory equipment leases can also include a maintenance/service option if the customer wishes it. Because Thermo is also an equipment manufacturer, what is known as a *captive leasing company*, it also provides maintenance for its leased equipment, Mr. Bartlett said.

"If customers want to add an extended service contract, then we're happy to include that on the lease," he said, adding that most of the equipment Thermo sells comes with a one-year warranty.

For those who decide to add service to their lease, it's simply added to their payment at the end of the month, Mr. Bartlett said, and Thermo also has a reagent rental program that bundles consumables/reagents, equipment and service into one payment per month.

While First Star is not an equipment manufacturer, it can also include service/maintenance agreements in its leases if customers ask for them, Mr. Harmon said, adding that "soft costs," such as service and maintenance, should be less than 20 percent of the total transaction size.

He added that while the lease is done through First Star, the maintenance aspect would be handled by the original manufacturer.

"The equipment manufacturer/supplier would simply include this as a line item on the invoice so that it is paid for in conjunction with the equipment acquisition," he explained. "The service/maintenance agreement is then paid for and subsequently administered by the manufacturer or an authorized technician of some sort—the logistics of this are handled by the equipment supplier and the lesee/end user of the equipment."

Current leasing trends

Despite the cost savings leasing can provide, the recession has made it tough for smaller laboratories to get loans from banks and other traditional lending agencies because they have been forced to do some belt tightening, according to both Mr. Harmon and Mr. Bartlett.

That's meant a drop in demand over the past few years at lending companies such as First Star, Mr. Harmon said.

"On the lending/extension of credit side, there was a flight to quality combined with a sometimes pronounced tightening of credit approval criteria," Mr. Harmon said. "This, combined with an overall deterioration in credit quality, contributed to the environment of lower equipment investment/lease volume."

However, he said things have been looking up recently.

"In general, the demand for and extension of credit have decreased during the recession, although a clear recovery is under way with the trends pointing upward in 2011 and going into 2012," he said.

On the other hand, laboratories' difficulty in getting loans at banks and other leasing companies due to new restrictions has meant a recent increase in business for Thermo Fisher's leasing division, Mr. Bartlett said.

"Our business this year on the finance side is up, I would say, approximately 35 percent over the last year," he said, adding that concern about the economy has also driven that increase.

The company's reagent renewal program and its technology refresh program, which was just rolled out in 2011, along with various payment structures have also helped grow Thermo's leasing business, Mr. Bartlett added.

"We try and really look at the customer's needs, understand the challenges they're facing today and put the right program in place," he said. "Through the efforts of the team here, [we've] done a very good job in understanding what those challenges are and making sure that we have the right program to offer."

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IT'S A CORE VS. TRANSACTIONAL THING

By Alan Edwards

As the prospect of personalized medicine transitions from concept to reality and begins to truly impact the pharmaceutical industry, almost everyone who works in the sciences could be affected.

After all, it could be argued that personalized medicine is one of the biggest challenges facing biotechnology and big pharmaceutical companies in the 21st century. And once the challenge is met, big pharma's way of doing business will be dramatically changed.

For example, blockbuster drugs—which are developed for the masses and have always been a source of huge profits for the world's largest pharmaceutical companies—will be a thing of the past. New, smaller players in biotechnology, with their niche drugs and the opportunity to grow within the market, will become significant competition as they develop therapies that target specific biological subgroups. To keep up, all organizations will have to find ways to deliver drugs that are "personalized" and help only small populations.

The benefits to patients are obvious. Personalized therapies are designed in recognition of the fact that every ailment is, in theory, as unique as the individual. In other words, one disease doesn't fit all. With that in mind, personalized medicine could lead to dramatically better results for patients. Without a large population of consumers, however, drug companies almost certainly will experience less profit from any one drug, forcing them to rethink traditional approaches to research and development, marketing, and the way medicines are prescribed.

Personalized medicine is just one high-profile example of how the science industry will continue to transform in the 21st century. The scenario isn't all doom and gloom from a profit perspective, but rather a powerful argument for the need for large and small labs alike to embrace versatilability™—or the ability to maintain a high level of versatility—in all aspects of their business.

> "All organizations will have to find ways to deliver drugs that are 'personalized'."

Doing this in the area of research and development is particularly critical, since it is usually the most costly step in the process of sending a product to market. And in the age of personalized medicine, while it still might cost $1 billion to develop a particular drug or product, the revenue potential over 20 years has the potential to be cut in half.

Optimization of research dollars, then, should be an important step for labs in the quest to achieve versatilability. A secondary goal should be to decrease the cost of R&D without sacrificing quality; time and time again it has been shown that one of the most effective ways to do this is to learn how to utilize the modern scientific workforce more effectively. That should start with figuring out which of your lab's functions are strategic and which are transactional.

"Drug companies almost certainly will experience less profit from any one drug."

The strategic functions of your lab should be at the core of what you do—the types of research that directly affect your lab's bottom line. It makes sense that you would allocate more dollars to the directional and proprietary functions of your lab. Transactional work, on the other hand, should be seen as tasks that are important and necessary, but not at the core or with the ability to absorb the strategic impact of your lab's expertise. Special projects, programs, or clinical trials could also be considered transactional work if they are needed only for a certain time frame and fit within the larger context of your lab's core capabilities.

Once you've identified core versus transactional capabilities, you can analyze your workforce and use it according to whichever capabilities are important at the time. It makes sense to hire people permanently for core capabilities, since their expertise will be needed on an ongoing basis. For transactional work, however, hiring highly skilled contingent labor is a smart move that allows you to engage them for a specific period.

You can then easily disengage contingent talent when the project is done, allowing you to more efficiently allocate research dollars. And as more and more scientists seek out contingent opportunities because of their flexibility, the pool of talent will only become larger and make it easier for you to source specialized talent when you need it.

Find creative ways to utilize the scientific workforce, and you will always be one step ahead as the science industry continues to transform.

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INTEGRATING SYSTEMS

WITH THE ARCHITECTURAL BASIS FOR INTEGRATION STILL UNDEVELOPED, USERS MUST FOCUS ON THEIR OWN REQUIREMENTS

by Joe Liscouski

"Integration" within lab automation is a bit like the word "free" in a store window: It gets your attention and you want to find out more; sometimes you're glad you did and other times not. The reason it grabs our attention is that an integrated lab system can yield highly desirable benefits. It implies:

- **Ease of use** - integrated systems are expected to require less effort to get things done
- **Improved productivity, streamlined operations** - we expect the number of steps needed to accomplish a task to be reduced
- **Less duplicate data** - you shouldn't have to look in multiple places to find what you need
- **Fewer transcription errors** - integration will result in electronic transfers that should be accurate, and this means there's no need to manually enter and verify data transfers
- **Improved workflow and movement of lab data** - this will reduce the need for people to make connections between systems because *integration facilitates workflow*
- **More cost-effective and efficient lab operations**

Integration also brings us closer to another highly marketed goal: the paperless workplace. Integration is a necessary step toward that objective.

The examples we have of integrated software environments bear that out. Office productivity suites from Microsoft, Apple, Google and OpenOffice that combine word processing, spreadsheets, email, calendars and other functions are good examples. If I wanted to insert a chart right <here>, the word processor would bring up the appropriate application, create the chart and insert it. If I wanted to edit that chart, I'd click on it and the application would open automatically. An invitation sent via email can be clicked on and added to my calendar with the option to accept or decline.

There are examples in hardware as well. Your laptop has USB and/or Firewire connections. Plug the cables in and things work. The telephone is another. Modular connectors and tone dialing standards allow fax machines, computers and point-of-sale components to work without a lot of effort. Networks with modular connectors or wireless components also make the assembly of integrated computer or entertainment systems less difficult. When we think about integration, the models we have in mind are things like those, or perhaps Lego blocks.

> "Integration doesn't 'happen,' and it isn't just a matter of plugs that fit together."

All of these examples, as well as others, have something in common: *They were designed to work together, and there is an architectural basis for integration.* There are rules for how things should work in an integrated environment and standards (hardware and software) that dictate how connections are made, how information and signals move, and what the operational priorities and rules are, etc. Integration doesn't "happen," and it isn't just a matter of plugs that fit together. It is the result of a complete engineered system with all parts designed to work together. And that systems engineering is what we are missing in lab applications (both hardware and software).

The examples noted have something else in common: *Their development and behavior are controlled by single vendors or organizations that carefully control the critical elements that*

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keep things working. Working with a given vendor's application environment offers a lot of flexibility. Working between vendor environments reduces that flexibility to data exchanges with reduced capability common-data formats (those warning messages telling you that saving in a .txt format will result in loss of access to features). An integration architecture includes the rules interacting, and components need to function in the form of standards and programming interfaces. An organization exists to manage those elements and alter them in a controlled manner. One reason the Internet works is because the World Wide Web *Consortium* (www.w3.org) manages the underlying architecture.

"If either of the systems you are connecting changes, the code you developed may have to change."

What does this mean for laboratory systems?

We are a long way from having the integrated environment we'd like to have, one where we can connect the outputs and inputs of various elements—regardless of who the vendors are—and have them function. That is a bit of a simplification, but if you boil it all down, that is what people are looking for; we've seen it work in other environments and want the same level of flexibility in our labs. We're missing the overall architectural plan that enables integration between systems, regardless of what industry you work in. This isn't a life science or petrochemical problem—this is a fundamental issue that cuts across *all* industries that engage in scientific and laboratory work.

Today, integration is a function of individual vendor efforts. Those efforts result in the following:

- **Connections between specific sets of instruments and software packages that are supported by the vendor**
- **Facilities that a programmer can use to make connections**
- **Partnerships between vendors to link specific products or product sets**
- **Integration performed by third-party systems integrators and consultants**

In the first case, the vendor provides support for certain models of instruments (balances, etc.) or software systems. The level of support is uneven. A balance may be electronically supported for data access and control (you tell the system when you are ready to make a measurement and the software takes the reading and enters it into its data structure; then it may tare the balance automatically). In other cases the interface is one-way; the instrument or software system sends a data stream to the vendor's software, which extracts the information it needs. You may be faced with being able to use only equipment the vendor has supported or working with the vendor to support the devices you currently have.

Programming interfaces—facilities designed by the vendor to allow controlled program access to database elements—give you more control over how things happen, but you have to do the development and support it. If either of the systems you are connecting changes, the code you developed may have to change. This can be a serious problem if you go beyond the facilities provided by the vendor and make changes to the underlying code. Upgrades to the vendor's products can compromise any modifications you've made—either to the connecting systems or the underlying components in database applications. This problem can exist even if the vendor has made the changes under contract with you (the contract should specify that programming will be supported or corrected if product upgrades cause it to fail).

Vendors will form partnerships to solve what they recognize as a mutual need. An instrument data system vendor may want to connect to another's LIMS or electronic lab notebook (ELN). The combination would offer a market advantage to both. The point the customer needs to examine is whether this connection is designed to facilitate a marketing relationship or if it is the result of a serious engineering investment to provide a robust supportable interface. Will it be supported in the current and subsequent versions of each product, particularly since products are going to be on asynchronous development cycles? Marketing partnerships come and go; but once you've invested in the products, you have a system you have to live with—so ask the right questions.

Finally, there are a number of companies that will offer integration services. These can be an effective solution to specific requirements. However, the final responsibility lies with lab management: An integrator has to be chosen carefully to ensure that the vendor is reliable and will be in a position to support the work over successive generations of upgrades (upgrade processes tend to cause things to break if not well-engineered). This is an outsourcing exercise, and all the rules and issues apply.

What can be done to change the situation?

The problems we are looking at are the result of a lack of maturity in the marketplace. Vendors are building products based on their perception of need, and if the customer base doesn't demand integration capability they won't invest the engineering resources to provide it. Before that investment can happen the architectural basis for integration has to be developed, and you can't ask the developers to provide a capability without defining the requirements and underlying structure to support it.

This problem has been faced by others and successfully addressed. Manufacturing industries have developed standards that permit integration. The same has been done in clinical chemistry. Clinical labs were faced with a fixed cost-per-test structure and variable costs. Increased efficiency and productivity were the means of addressing the situation, and those were enabled by the development of standards for integration and communications between lab systems under a program of Total Laboratory Automation—in other words, the architectural basis was planned.

The onus is on the customer base. This problem has been addressed in John Trigg's Integrated Lab[1] website and in a proposal on the website[2] of the Institute for Laboratory Automation. The latter reference describes a proposal for studying the work done in clinical laboratory systems to see how it can be applied to other environments, with the possibility of capitalizing on 20 years of standards development work. We need to work as a multi-industry community to address the issue. There are considerable benefits to the development of an industry-wide lab integration architecture. It moves labs away from having to address the problems and limitations noted above and gives them the ability to choose among best-of-breed solutions. This should foster competition between vendors to produce better products and help new vendors develop offerings that meet lab needs.

How do you address the issue of lab automation integration in your lab today?

The bottom line is planning. Labs have to develop rational lab-wide plans for the specification, purchase and use of laboratory technologies. You have to purchase from the selection of products that exist, but you can make informed choices.

1. Take a look at your lab, and decide how you want it to operate. What is the desired work flow, where is data generated and where does it need to go? That includes instruments, data systems, LIMS, ELNs, etc. Draw a map showing the flow of data and information.
2. Specify products that facilitate that map. Make conformity to your ideal data flow part of the functional requirements.
3. Make provision for flexibility. The most expensive products are those that are going to store data for the long term, the ones that you will go to for answers about samples and experiments. They may not be the most expensive on a dollar basis, but that point of view may change when you consider the cost of changing systems, training people and transferring data from one environment to another. These are the centerpieces of your plan. Choose wisely.
4. Purchase products that generate data (balances, instruments, etc.) that are compatible with the data storage/management systems.
5. Allow for change. When planning a project, particularly if software development is involved, design systems so that change is simple, and all instrument model-specific codes are localized in case replacement is necessary.

The ability to integrate laboratory systems isn't where it needs to be. That can change. It has been developed successfully in other industries.

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THE EVOLVING SERVICE MODEL

HOW THE RIGHT SERVICE AGREEMENT CAN EXTEND EQUIPMENT LIFE, PROTECT ASSETS, SIMPLIFY OPERATIONS AND DELIVER SAVINGS

by Bernard Tulsi

Faced with shrinking budgets, laboratory managers are constantly seeking more effective ways to service and maintain their equipment, which they must now keep operational over lengthening life spans. Providing much-needed respite in this challenge are multivendor support operations—several of which have been provided by prominent original equipment manufacturers (OEMs) such as Agilent, General Electric (GE), PerkinElmer (PE) and Thermo Fisher Scientific for at least a decade already.

A recent survey by Frost & Sullivan of 150 *Lab Manager Magazine* readers with decision-making roles in their laboratories assessed how the managers sourced their service and maintenance requirements. To maintain their instruments—tools associated with data and analytical output—59 percent of the managers relied on instrument manufacturers' service contracts. Around 30 percent used manufacturers' service contracts to maintain their equipment—tools that perform physical functions such as cooling, freezing, stirring, mixing and centrifuging, among others. Jonathan Witonsky, Industry Manager, Drug Discovery Technologies & Clinical Diagnostics at Frost & Sullivan, noted that most labs today have far less funds at their disposal, and now typically demand more resources from manufacturers both for their initial purchases and maintenance needs.

Lab managers typically assess and differentiate between activities that add or don't add value in their core functions. Those not adding value are outsourced, says Gary Grecsek, Vice President, OneSource Laboratory Services, PerkinElmer, who helped to develop PE's OneSource multivendor service program. He says that for labs using instruments from mostly one OEM, reliance on that vendor for repairs and maintenance makes sense. "Today, labs typically use many different technologies from multiple vendors, and multivendor maintenance services give managers much-needed simplicity," says Grecsek.

OEMs offering these services compete with each other, with in-house efforts at labs and a variety of other companies and niche vendors that offer equipment service and maintenance at different levels. Several companies offer an insurance-type model that enables laboratory customers to include several assets on one contract. They manage the OEMs on behalf of the laboratory customers, enabling them to save costs and shed some administrative burdens, although this approach is less common now. Customers typically include academic, pharmaceutical, biotechnology, industrial and government laboratories and fee-for-service contract operations. The OEMs have experienced considerable growth and advancement in the service sector during the past three to five years, and commonly have service engineers at multiple customers' locations to perform preventive and maintenance services on multiple suppliers' instruments and equipment, says Dan Young, Director, Service Operations for the Global Enterprise Group, Thermo Fisher Scientific.

Bob Moore, Director of North American Service Sales, General Electric Healthcare Life Sciences, says that service operations were a cost center in the late 1990s; they were considered a "necessary evil" to sell equipment and consumables and not necessarily a source of earnings. The biotech and pharmaceutical sectors were heavily focused on growth and new product devel-

opment at that time, and had access to substantially more financial resources. "Now, OEMs and the health science companies realize that they have to control spending and better manage their assets, which represent a lot of committed capital—and the focus has shifted to those issues." The prevailing model seeks to control costs better and to capture data to facilitate decision making, and has ignited innovative solutions both by customers and service providers. Matters such as how asset tracking and utilization can be optimally deployed for efficiency and cost-effectiveness are being examined, according to Moore.

He dubs GE's Smart Asset Management Services program a hybrid model, in that the group also uses the services of other OEM vendors. "We don't profess to be able to do all the services, and do use niche vendors as the need arises, and for cost-effectiveness. GE engineers currently handle about 60 to 65 percent of our maintenance contracts, and that's probably as high as it would go," says Moore. GE healthcare and hospital services and maintenance operation was started about 15 years ago, according to Moore. He says that GE's 2004 acquisition of Amersham Biosciences provided a gateway into the pharmaceutical and biotech area, to which it applied operational efficiencies and best practices acquired in the hospitals market. "We had our first opportunity back in 2005–2006 with Eli Lilly, and the program has since grown to about 20 facilities in the U.S., Europe and Japan. The life science service business is approaching the $200 million mark now, and has about 300 employees globally."

Grecsek says that PE's OneSource is a global asset management solution built in partnership with customers to provide business continuity, increased scientific output and cost certainty, which are very important to lab managers. "This enables managers to streamline their operations and take their scientists out of the service workflow, enabling greater focus on their primary activities," says Grecsek. PE estimates that labs realize some 10 to 20 percent in cost savings in the first year of using a single-source system. The company operates about 200 OneSource programs, has about 400,000 multivendor accounts in multiple industries worldwide, and serves a wide range of labs including those in QA/QC and R&D.

OneSource was implemented at PE about ten to 15 years ago, and activities accelerated greatly during the past six years. "We offer a variety of services; our solution is truly vendor independent, which means that we perform services not only on PerkinElmer but on other brands as well." Demand has broadened internationally, and the industrial base has broadened also. "Initially, demand came from the pharmaceutical sector because of cost pressures there, but over the last 24 months, especially, it has expanded to broader market verticals, including food testing labs in the U.S. and overseas, where new regulations require more compliance testing." He added that PE has made "a significant investment in compliance testing via acquisitions, trying to provide holistic qualifications in metrology protocols for its customers. We do a lot of work with our customers on methods optimization, transfer and validation."

Dan Young is responsible for the Asset Management Services Group at Thermo Fisher Scientific, which has a customer base of about 130 facilities. This group offers a multivendor service engineering program, which stations service engineers at multiple customer facilities. He says that engineers are

trained and certified on all the equipment (from the multiple vendors) they are likely work on. Young says that reliance by labs on the original equipment supplier for services is not a sustainable model, and instead, "we are seeing a natural evolution away from exclusivity into a more open model, which focuses on process, efficiency and cost- effectiveness."

He says that while many other OEMs focus on specific niches, "Thermo's value proposition is that no other company can provide a single-stop solution—we do have the ability as a manufacturer, as a service provider and as a distributor to pull all the pieces together to provide a single-stop solution to lab managers to address all their needs." He adds, "This model is associated with tremendous efficiencies and allows the company to deliver simple and elegant solutions to the marketplace, and it is being received well."

Viewed as a growth area (revenue increases at 15 to 25 percent annually) in Thermo Fisher, the Asset Management Group has attracted considerable investment. Young says this is a reflection of the marketplace demanding more services and greater innovation. He adds that customers are also demanding that these services offer both hard dollar and soft savings consistently. "It is incumbent on us as a service provider to put together and present a scorecard on a regular basis demonstrating our adherence to those performance levels," says Young. He notes that at some point the degree of differentiation between consumables, plastics, glassware and chemicals, among other items, becomes subtle, and competitors begin to compete on price. "Our differentiator in the marketplace is the ability to add value for the customer that exceeds the price they are paying for the service."

From Agilent, customers see one support service operation that the company maintains to deliver a portfolio of services covering products for "self-maintainers" through a single-source program, according to Michael Pope, Laboratory Productivity Solutions Unit Business Manager at Agilent. "Internally, we are divided into two groups under this service umbrella—the core standard Agilent service agreements and some other ancillary services that fit along the continuum, and then the group I am responsible for: Laboratory Productivity Solutions," says Pope. "The lab productivity solutions group is responsible for the custom programs that compete in the multivendor or single-source space against GE, PE and Thermo," he says.

As capital budgets became constrained due to the economic downturn, companies look to save costs in as many areas as possible, notes Pope. "So as they try to eke out more mechanical life from their existing base of installed laboratory equipment, they will turn more frequently to service agreements. For the large companies in the service industry, the trend is to go to a single source provider to be able to extract economies of scale and cost savings across the installed base of equipment," he says. Pope says that depending on the customer, the level of customer sophistication, the number of assets installed and the service model, savings of 5 to 20 percent per year may be realistic. He says that 20 percent is what companies would like to reach, but sees 5 to 15 percent as more achievable based on his experience.

The Laboratory Productivity Solutions group has three territories in the U.S. that are managed at the senior level—both the financial aspects and the support delivery. Based on the distribution of equipment and customers in each of the three territories, there are districts that are headed by managers who oversee the field service engineers. There are also five world regions that essentially follow the same pattern.

Pope says that Agilent has a very thorough training program, and the company prides itself on the training of its engineers. "We have training centers throughout the world, which use a well-defined instructional curriculum for all Agilent instrumentation. We have a team responsible for curriculum development, and a team of engineers who serve as trainers—Agilent certificates are issued upon the successful completion of training on different equipment," he says. Engineers are required to maintain the skills for which they received certification. Agilent collects that information in a large database that is available to workload administrators who handle service calls, so that engineers can be assigned to particular jobs appropriately.

"For training, in addition to taking equipment off our production line, we buy other vendors' equipment for our service training labs around the world," says PE's Grecsek. "We have made substantial investments to build our servicing skills—PE has more than 1,500 scientific service engineers around the world—and in the last five to six years, invested close to $300 million in facilities, training and tools, so that our engineers will have the ability to 'turn the wrench' on other vendors, equipment."

According to Grecsek, "PE has invested substantially in building its lab relocation capabilities to give customers a single point of contact for an end-to-end solution to relocate assets from one site to another." PE's OneSource partners with customers on the logistics, transportation, compliance, breakdown of the equipment, packaging, shipping, receipt and reinstallation at the other end where it will be used," he said. "This is a turnkey solution for our customers, and we see a lot of demand in the marketplace for it."

"Once you are able to do that, it allows you to take advantage of the scale at a customer's facility. A customer might have three different brands of HPLC instruments in its lab; with the appropriate training, one of our engineers can go onsite and service all three HPLC machines. That allows lab managers to realize improvements in the operation of the lab and improve response time and downtime metrics substantially—and obviously, this improves productivity."

Moore says that GE approaches training in multiple ways. "Our core GE offering today is really a multivendor service within itself. We service a broad range of equipment that includes HPLC, DNA sequencing and bioreactors, among others, and our core engineers are becoming multivendor technicians in their own right, and that becomes the base of the program." Moore points out that GE also focuses on ensuring that its personnel assigned to customers' facilities are as self-sufficient as possible, and have the training and skill sets to deliver solutions based on the customer's specific inventory and needs. "To get there, we train internally and hire externally to get the skills needed to serve our customer base," he says.

All four OEM executives believe that the service model will continue to evolve. While customers will ask for services around key areas such as sample preparation and methodologies, one of the major growth areas in the future will be the utilization of tools to capture data for decision making within laboratory enterprises. There will also be a greater need to generate savings and improvements year over year, necessitating greater data utilization and the broader implementation of practical process improvement tools.

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THE ANALYTICAL LIFECYCLE APPROACH

ADDING STEPS TO TRADITIONAL METHOD VALIDATION DELIVERS HIGHER ROI

by Gregory Martin

Analytical methods are at the core of demonstrating the quality of pharmaceutical products. When these methods fail to perform as expected, the quality of these products is called into question. Certainly, we expect to identify quality issues if they exist, but we want to avoid raising the alarm if the issue is only because the method is not performing as expected. Virtually every laboratory has experienced issues resulting from methods that were not sufficiently rugged or well designed, and we propose that these issues may be avoided by implementing a systematic process for method lifecycle that addresses many issues that can be anticipated. This approach is illustrated in Figure 1.[1]

Building on the traditional processes of method development, method validation and method transfer, the lifecycle approach incorporates some additional elements including identification of an analytical target profile, use of quality-by-design elements to enhance method understanding, use of an expanded qualification process and introduction of a change control approach to continued method usage. This lifecycle approach can be broken down into three stages: method design, method qualification and continued method verification.

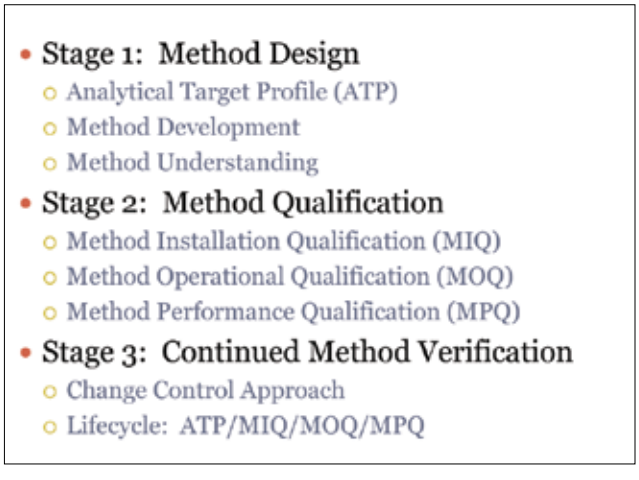


Figure 1. Overview of Analytical Lifecycle Approach

Stage 1

The first stage, method design, includes three components: the analytical target profile, method development and method understanding. The purpose of the analytical target profile (ATP) is to address the actual requirements of the method. These requirements and criteria are not necessarily the same as instrument capability; they should correlate to critical analytical performance characteristics and include meaningful acceptance criteria. They may include some or all of the characteristics described in ICH Q2[2] or USP General Chapter <1225>[3], as well as others that are important for the method or for the laboratory. The ATP attempts

> "Every laboratory has experienced issues resulting from methods that were not sufficiently rugged or well designed."

to address such questions as: What is the purpose of the method (e.g., to measure a major component, or stability-indicating)? What are the specificity requirements? What are the accuracy and precision requirements? What are the resource constraints (instrumentation, run time, reagents)? Are there other constraints such as extraction challenges or solution stability? An example of an ATP for a chromatographic stability-indicating method is shown in Figure 2. The second component is method development, for which most labs already have some excellent processes in place. We encourage their continued use, augmented with the guidance from the ATP. Once reasonable conditions for the method have been ascertained, and conformance to the ATP requirements has been established, it is time to enhance method understanding by incorporating some quality-by-design concepts. This includes exploring the method operating conditions and performing a risk assessment for the vari-

ous method parameters. For chromatographic methods, this should address sample preparation as well as chromatographic conditions.

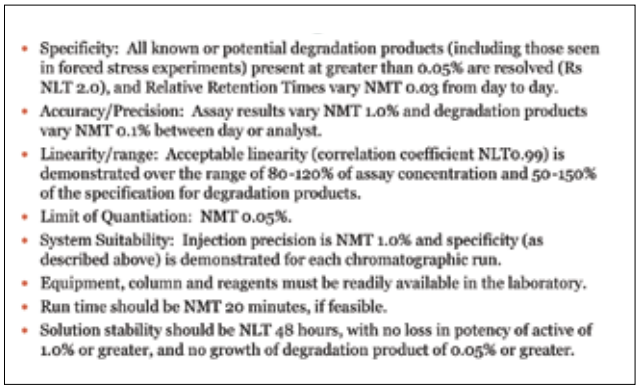
Practical Approach to Stage

Let's discuss how this might be implemented. We'll use a content uniformity chromatographic method for a solid oral dosage form (tablet) with two potencies as an example. In establishing the requirements, we consider the characteristics listed in USP General Chapter <1225>: accuracy and precision, linearity and range, specificity and limit of detection, and limit of quantitation. There may be other criteria that are important to the laboratory, for instance, the analysis must be able to be performed on equipment that is already in the laboratory, with a minimum time period for solution stability and a maximum run time. Previous experience with similar methods and familiarity with the laboratory data acceptance criteria are very helpful in establishing the acceptance criteria. Accuracy and precision are important characteristics for this method, and we want to set an acceptance criterion that limits the probability that we will generate an out-of-specification result if the tablet is within specification, or generate an acceptable result if the tablet is actually out of specification.

Based on previous experience, if we keep accuracy to a mean of +/- 2.0% and method precision to not more than 2.0 percent, we will accomplish this requirement. This also implies that injection must be tighter than method precision, for which a relative standard deviation (RSD) of not more than 1.0 percent should be acceptable. The range required for this method will be selected such that it will cover both potencies, without need for unnecessary second dilutions. Linearity requirements will be fairly standard, so the acceptance criterion for the correlation coefficient of the least squares regression analysis will be set to not less than 0.99, with an added requirement that the y-intercept of the regression line be not more than 4 percent (to avoid unacceptable bias).

Specificity requirements may be minimal, especially if drug substance impurities and drug product degradation products are controlled in separate methods. In this case, let's assume there is a significant peak at the void volume, so a requirement will be established that the peak at the void volume and the peak of interest must be well resolved, that is, resolution factor (Rs) is not less than 2.0.

Since this method is not intended to address minor peaks, limit of detection and limit of quantitation are not critical quality attributes, and no requirements are set for this method. For the other requirements identified by this laboratory, the acceptance criteria might include HPLC with UV detector for the equipment; solution stability of at least 48 hours to allow the ability to rerun chromatography if necessary; and run time of not more than six minutes, which would allow same-day analysis and interpretation of results, when needed.



- Specificity: All known or potential degradation products (including those seen in forced stress experiments) present at greater than 0.05% are resolved (Rs NLT 2.0), and Relative Retention Times vary NMT 0.03 from day to day.
- Accuracy/Precision: Assay results vary NMT 1.0% and degradation products vary NMT 0.1% between day or analyst.
- Linearity/range: Acceptable linearity (correlation coefficient NLT0.99) is demonstrated over the range of 80-120% of assay concentration and 50-150% of the specification for degradation products.
- Limit of Quantiation: NMT 0.05%.
- System Suitability: Injection precision is NMT 1.0% and specificity (as described above) is demonstrated for each chromatographic run.
- Equipment, column and reagents must be readily available in the laboratory.
- Run time should be NMT 20 minutes, if feasible.
- Solution stability should be NLT 48 hours, with no loss in potency of active of 1.0% or greater, and no growth of degradation product of 0.05% or greater.

▲ *Figure 2. Example Analytical Target Profile (ATP) for a Stability-indicating Chromatographic Method*

Stage 2

The second stage involves demonstration of the method qualification. First, we need to ensure that the facility, the instruments and the analysts are appropriately qualified. This is analogous to installation qualification for instruments. Next, we need to demonstrate that the method meets the requirements identified in the analytical target profile. This is similar to traditional method validation. Finally, at this point we apply the method to actual manufacturing samples in the facility where they will be produced using the analytical equipment and personnel that will be used to generate data. Once again, the qualification experiments may be dependent on the stage of development. Also, it is anticipated that existing knowledge and data will be utilized whenever feasible. These qualification experiments provide the framework for future method changes or transfers.

By including a step that ensures that the facility, instruments and analysts are qualified, we ensure that the laboratory is prepared to move forward with the method validation (and, yes, there have been instances where this basic step was skipped and methods have subsequently failed the validation experiments), and we establish the expectations for future laboratories that may need to run this method.

Before proceeding to the traditional experiments that evaluate the characteristics listed in USP <1225>, it is valuable to verify that the other requirements (instrumentation, solution stability, run time) established by the laboratory have been met. Since the performance of the method is already well understood (based on the activities in Stage 1), demonstration that the method meets the validation requirements should be straightforward, and for most methods a well-designed experiment can accomplish this in two or three days, based on the solution stability requirements.

Looking next at the real-life situation (actual manufacturing samples, facility, equipment and analysts) is a very valuable addition, challenging the method under realistic conditions of use before releasing it for routine purposes.

"[The] lifecycle approach can be broken down into three stages: method design, method qualification and continued method verification."

Stage 3

The third stage addresses continued method verification. This would include continued use in the original laboratory for an extended period of time, but may also involve method revisions, transfer to a different laboratory or method verification, in the case of a compendia procedure. As we approach any of these changes, is it appropriate to consider the method lifecycle approach and revisit the earlier stages? Are the requirements identified in the analytical target profile still applicable? Have laboratory investigations, out-of-specification results or changes in expectations indicated the need to revisit the requirements? Most quality control or stability laboratories use some form of control charting to watch for trends. Do the control charts identify a cause for concern? For any changes to the method, or changes to the laboratory in which the method will be executed, a change control approach is recommended. This includes identifying the nature of the change, the

rationale for the change and then assessment of the potential impact of the change. Part of this process will examine the need for revalidation or partial revalidation. The data generated during the initial stages of the method lifecycle can be useful in evaluating whether the quality of the data that will be generated by the method following the changes will meet or exceed the quality prior to the changes.

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Conclusion

Using the lifecycle approach described here has the potential to improve the quality of data generated in pharmaceutical laboratories, and to reduce the frequency of laboratory investigations or out-of-specification results. This approach builds on the method validation experiences of the last half-century but adds several steps with very high return on investment, based on some real-life experiences. Experienced laboratory managers will recognize that the additional steps make sense and do not add significantly to the resources required to bring a method to the point where it can be implemented. The benefits of this approach will be realized throughout the life of the method. USP has recently convened an Expert Panel to review and update its general chapters on validation, verification and transfer of procedures, and perhaps some of these concepts will be incorporated into the revised chapters.

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Sukhanya Jayachandra, Ph.D.

ASK THE EXPERT

THE ECONOMIC BENEFITS OF LAB AUTOMATION

by Tanuja Koppal, Ph.D.

Sukhanya Jayachandra, Ph.D., Senior Research Investigator and head of the Cellular Resource Group, Lead Discovery Profiling Compound Management at Bristol-Myers Squibb (BMS), talks to contributing editor Tanuja Koppal, Ph.D., about her cell culture core facility and how it has been impacted by the adoption of automated technologies. She offers advice on why, where, how and which labs should go about automating their cell culture processes and what they stand to gain and lose, in turn.

Q: How did automation get implemented & adopted at BMS?

A: In the late 1990s, the trend in the pharmaceutical industry was to do a lot of high-throughput screening. BMS felt that the net had not been cast wide enough to capture compounds and look at all the small molecule entities for any given drug target. Enormous resources were put in place to automate compound screening and the infrastructure around screening, enabling automated high-throughput screening. If screening was going to be a continuous five- or seven-day operation, and continue for many weeks, it had to be consistent day in and day out. So, in the beginning, automation was required for consistent delivery of the cell lines, reagents and compounds for screening.

Q: Did you think about what aspects needed to be automated and to what extent?

A: Initially we looked to see what could be automated and where the greatest gains could be had. Clearly, automation could be applied to compound delivery; but from a cell culture point of view, could we take some of the scale-up processes and automate them? There were companies in Europe doing so at that time, so we got the first machines to automate one cell line and scaled that up. That was the first version of cell culture automation. In 2000, there was a consortium established with five big pharma companies working with a vendor, The Automation Partnership (TAP), to develop the next generation of mammalian cell culture automation. The designs were well thought out with specifications on what they wanted machines to do. That prompted the second generation of automation and the creation of the SelecT system and the Compact SelecT, which are now the industry standard.

Q: Were there some tasks that could not be automated and some that were more amenable to automation?

A: Almost all aspects of manual cell culture can be and have been automated, except decision-making capability and the thawing of cell lines. Visualization could not be automated, as that requires human intervention to examine cells to determine if they are healthy and of good quality. All the rest of the processes, including the routine care, culture and maintenance of the cell lines and the plating of cells into assay plates, have been automated. Another task that the instrument could not do was retrieve a vial from cold storage (-140°C) and thaw it, because there were neither thaw stations nor an online centrifuge within the system.

Q: How do you go about calculating the return on investment for something like automation?

A: One of these machines, like the SelectT, can do the work of at least four full-time employees (FTEs). Of course, in the first two years there was a learning curve for some of the engineering challenges, but over the years we have really optimized the system. Also it's a 24/7 operation, which we would clearly not be able to sustain with people. The biggest advantage of a 24/7 operation is the minimal downtime. In the past, Monday was a down day for cell based screening, as cells had to be plated overnight into assay plates. But now the machine is plating

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and getting assay plates ready on a Sunday and by Monday the cells are ready to go. The same holds true if there is bad weather or if there is a shutdown for some reason. Since these systems are all on backup power, even if people cannot get to the site, the machine runs and there is an uninterrupted workflow.

Q: Are you seeing any other kinds of economic benefits in terms of cost savings from reagents or the cells?

A: Since the same media conditions can be applied to multiple cell lines, you can definitely increase the throughput. As cell lines are processed sequentially, there is no cross-contamination between cell lines. So, over time, you use less material because the waste from manual errors is reduced. However, the machine is not faster than a human. The machine probably takes a little bit longer to process a flask, but it does it more consistently and accurately. Scientists are needed to understand the biology, but once the machine is set up and working, they are resourced to perform other scientific experiments that do not require repetitive tasks, which also cause a lot of ergonomic problems. That is the real benefit.

Q: Have you run into any major snags with equipment that is fully automated?

A: There have been occasional engineering issues, but most of the issues that we run into are biology-related. For instance, certain cell types cannot be automated and some cell types cannot go through the rigors of mechanical handling. We have been able to automate some primary cells but not all. So it all depends on the cell type.

Q: Did you plan the automation around the lab space that you had or did you have to redesign the labs?

A: Luckily for us, when high-throughput screening was initiated at BMS, they built an entirely new wing to the building with certain engineering caveats. With the engineering controls put in place and the right kind of air handling, we have not had major contamination issues over the last ten years.

Q: What kind of personnel training is needed for using automated equipment?

A: There are the super-users who go through extensive weeklong training, and they then train other users. So we do have a super-user who kind of maintains the system and collaborates with the engineering team, in case certain mechanical things go wrong. He or she coordinates all the basic operations and is trained in first-level error recovery.

Q: What would your advice be to those lab managers looking to automate their laboratory protocols?

A: With automation, the key benefit is consistency. However, the biggest challenge is the cost for the capital investment. So the questions are, do you run an operation that needs a high-throughput supply of one particular cell line or multiple cell lines, and what does your budget allow you to do? The investment is not just limited to buying the machine and having a biologist run it. You also need the engineering support to help you back it up. A lot of these systems use special flask types and pipettes that are custom-made for that particular equipment. So there is a certain operating cost associated with these machines, including the service contracts. We're talking about $200,000 a year going forward on an ongoing basis. If the budget permits, automation is a fantastic thing to have in place, because it helps remove the day-to-day drudgery associated with doing a lot of cell culture. With automation, you can reposition your scientists to do actual experiments, rather than have them sit in a hood, culturing and passaging cells. Culturing cells requires its own skill set but it also involves very routine tasks. If you can afford not to do those tasks, you shouldn't have to do them.

IPOD, THEREFORE I HEAR

BUT FOR HOW LONG?

by Vince McLeod

Remember the cellular telephone commercial cliché, "Can you hear me now?" Well we have adopted it as our slogan, and test, for use of audio devices in laboratories. What do we mean by "test?" Let us explain.

We know you have noticed the creep of white growths protruding from the ears of more and more people everywhere. Walking down the street, sitting in the movie theater or attending a sporting event, in line or in waiting rooms, ear buds and personal headphones have become ubiquitous. The thing is, now they are showing up in places where they may not be such a good idea, like at work and, in particular, settings where we wander, such as research laboratories.

Should iPods be prohibited in labs?

Many lab managers would ask, "Shouldn't they just be banned from use in labs?" Our response is that it depends on a number of factors. If there are no extenuating circumstances (more on this below), it really comes down to the test, which goes like this: If you are standing next to someone using ear buds in a laboratory setting and you administer the test in a normal voice, you should get an affirmative response. If you don't, that person has failed and you need to take action. Because it boils down to whether someone can hear what he or she needs to hear while using personal audio devices.

We believe that most lab managers and employees as well, are aware that excess noise is a problem. Noise-induced hearing loss (NIHL) is painless, progressive and permanent. And according to all the experts, like the National Institutes of Health (NIH) and the American Conference of Governmental Industrial Hygienists (ACGIH), NIHL is 100 percent preventable. However, we get a lot of push back: What's the problem with ear buds? My iPod, MP3 player, etc., cannot damage my hearing, right? Unfortunately, the answer is yes they can. Apple iPods with the stock ear buds are capable of producing sounds well above 100 decibels (dB).[1] The ACGIH has set a threshold limit value of 85 dB as protective of normal hearing. Therefore, portable audio devices can definitely produce NIHL if used inappropriately.

Although many of the newer devices have a volume limit control built into the software, and this is a good first step in setting the maximum volume, this does not equate to a sound or noise level in decibels. Actual noise levels are a function of the power output of the ear buds or headphones and the type of music or content you are listening to. Without getting too technical, we'll just say noise is additive to some degree; thus the noise created by auto-samplers, analytical equipment, vacuum pumps, centrifuges, etc., add to the sound level produced by the ear buds or headphones. A good rule of thumb to stay below the protective 85 dB is to ensure that noise, both that produced by the audio device and that produced by laboratory equipment, does not interfere with speech and communication. If it does, this situation can be problematic and even dangerous in busy research laboratories.

For most situations we have adopted the common-sense approach. If you can hear yourself clearly at normal conversation volume, chances are your ear bud or headphone sound level is OK. When we see personal audio devices in use in the lab we give the employee the test, and if the employee responds appropriately we will allow him or her to continue.

Having mentioned the negative effects of environmental noise and recognizing the accompanying tendency to turn up the volume, there are a couple of things you can offer before outlawing ear bud use. New in-ear-canal or

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SAFETY TIP

LABEL ALL CHEMICALS TO SHOW THE NAME OF THE MATERIAL, THE NATURE AND DEGREE OF HAZARD, THE APPROPRIATE PRECAUTIONS, AND THE NAME OF THE PERSON RESPONSIBLE FOR THE CONTAINER

By James. A. Kaufman

Don't leave a booby trap for another person. Make sure that all containers are appropriately labeled. OSHA's hazard communication standard and lab standards require labeling of containers.

As the containers get smaller, this requires some practice and creativity to provide sufficient information. Color coding, signal words, and flag label can be helpful.

Develop the habit of preparing the label and then filling the container.

Remove chemical label from empty containers before relabeling or discarding to avoid confusion about the contents.

When a new chemical is received, mark the date received, the full level, the initials of the individual who will be the "steward" for that container, and the date opened. The steward needs to be the one who wanted to order the chemical and is now most knowledgeable about the safe use, storage and disposal of the chemical.

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

noise-cancelling headphones can block an impressive amount of ambient noise.[1] By blocking external sound you can listen to your personal audio content at much lower volumes. Another idea is to allow use in "mono mode"—using just one ear bud/headphone and leaving the other ear unobstructed for communication and situational awareness.

When to regulate iPod use

Early on in this article we mentioned that extenuating circumstances might exist that would curtail or prohibit use of personal audio devices in lab settings. We recommend developing a written policy or guideline regardless of your decision to allow or prohibit use so the rules are in black and white for everyone to see. An excellent example is the Audio Device Safety Guideline authored by the Occupational Health and Safety Unit at the University of Queensland.[2]

Having recognized the explosive growth in use of personal audio devices, your guideline should safeguard iPod use so first and foremost the health and safety of users and coworkers are not adversely impacted. We also agree with the UQ recommendation that everyone receive training on the risks of permanent hearing loss from overexposure to noise, including excessive volume settings on personal audio devices. But the best advice is the requirement to conduct a specific risk assessment and obtain manager or supervisor approval prior to use of any ear bud/headphones in laboratory or workshop settings where:

- Moving machinery is operated, e.g., centrifuges, lathes, drills, etc., to ensure the risk of entanglement is not increased.
- Infectious organisms are present, e.g., BSL2 or BSL3 laboratories.
- Toxic/carcinogenic substances are present.
- Reduced situational awareness is considered too dangerous.[2,3]

In summary, control of noise exposure is an important task for laboratory managers. Excessive noise including that from iPods and similar devices makes conversation difficult, affects concentration, distracts workers and increases fatigue. Management of noise exposures includes management of today's personal audio device technology. If you are overwhelmed or unsure how to handle iPod use, call in a professional and have the risk assessed by someone knowledgeable about sound and its measurement techniques and overall lab safety, such as an industrial hygienist.

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AGITATING SAMPLES THE RIGHT WAY

by Angelo DePalma, Ph.D.

Laboratory stirring and mixing are carried out by either magnetic stirrers (including hot-plate models), table-type agitators and shakers, shaker-incubators, or overhead stirrers. All have their niches.

"Stirrers are laboratory staples that work with numerous other instruments, including homogenizers or pH meters, or by themselves to dissolve solutes or mix reactions," notes Marta LaForest, sales and marketing manager for laboratory products at Caframo (Wiarton, ON). A recent survey by *Lab Manager Magazine* shows the greatest uptake for stirrers in life sciences, medicine, pharmaceutical, chemical, and food and beverage industries.

Choice of stirrer type depends on the sample's size, composition, and physical properties. Magnetic stirrers are generally used for nonviscous liquids of up to a few liters in volume. Caframo specializes in overhead stirrers operating from bench scale (two-liter capacity) to high-torque models for mixing up to 80 liters of viscous product.

Viscosity's the thing

Thick, viscous materials or very large volumes do not lend themselves to shaking or magnetic stirring. Magnetic coupling may not be strong enough to overcome viscosity, and stir-bar vortices may not reach high enough into the fluid to provide uniform mixing. These samples almost always require overhead stirrers, which supply more energy to the sample.

> "Stirrers are laboratory staples that work with numerous other instruments."

Samples for which viscosity changes—either to more or less viscous—also benefit from overhead stirring. Joe Novotny, chief engineer at Eberbach (Ann Arbor, MI) cites starch electrophoresis, where starch is added to a buffer. "Once it gets hot and the starch starts dissolving, then polymerizing, the solution becomes quite viscous." Similarly, materials that change phase, say, from gel to liquid or vice versa, are good candidates for overhead stirring.

During the last 15 years, overhead stirrer manufacturers have shifted from using AC motors controlled by a rheostat to DC brush motors that provide better control. Today, many models employ small brushless DC motors. As electronics became smaller, more compact, and available for many types of instrumentation, overhead stirrers have benefited from the ability to program stirring "methods" directly into the instrument. These involve mostly stirring patterns, for example, slow to fast.

The new brushless DC motors incorporate Hall effect sensors that enable the stirrer to "see" how fast they're spinning. "Stirrers can change speed, unattended, in response to what is occurring in the sample," Mr. Novotny says. "On older models the operator needed to be present to increase motor power in such situations."

According to Ms. LaForest, the principal benefit of brushless DC motors is their efficiency. "All the power from this type of motor goes into mixing the product instead of toward generating heat or extraneous motion."

Computerization has been a significant trend in most lab instruments, including stirrers and shakers. However, beyond regulated industries where processes must be validated, little call exists for connecting overhead stirrers to computers. "I've seen shakers hooked up to computers for recording stirring time and speed," Mr. Novotny says, "but by and large this is unnecessary because the control features are already built into the instrument."

Not everyone agrees with that statement. Caframo's overhead stirrers lack the ability for computer control, "but that feature is on its way," says Ms. LaForest. Networking to a computer helps in logging results and

quantifying viscosity and speed values. "The main benefits here are repeatability and consistency," she says. "Operators want to set up a run and do it exactly the same way next time."

tures undergoing agitation. One common design is a shaking water bath, which shakes samples at up to 400 strokes per minute. Joseph Costello, North American sales and marketing manager for Grant Instruments (Hillsborough, NJ), says, "Water baths work well, within very tight temperature tolerances and good heat transfer to the sample." But he also admits that they can be messy, given the fact that the bottles are sitting in water.

"A significant number of mixing applications do not require the robustness of an overhead stirrer."

All shook up

A significant number of mixing applications do not require the robustness of an overhead stirrer. Many chemists go through their entire careers, for example, using only magnetic stir-bars or hotplate stirrers. Another industry that tends to avoid overhead stirrers is biotechnology, particularly for cell culture. While large-scale biomanufacturing does indeed employ impeller-type stirring at a small scale, one is more likely to see a shaker or tabletop rocking-type mixer.

Even at a large scale, biotech is moving away from stainless steel impellers, due to the shear stress they place on cells. Some single-use bioreactor bags still employ older stirring technologies, but these are giving way to magnetic stirrers, superconductively levitated stir-wheels, external actuators that compress and expand the bag, and gas-actuated paddle wheels.

At a small scale, however, biological mixers are the way to go. These come in several designs ranging from vortex mixers for single samples that require short-term mixing to sophisticated temperature-controlled "table" models for multiple samples and microtiter plates.

Temperature control is a critical feature for cell and microbiological cul-

On the other hand, microtiter plate shakers often run at faster frequencies, since the volumes are minuscule and samples tend to sit in place inside the wells.

Some somatic cells and most stem cells are so sensitive to shear that the only type of agitation they survive is gentle rocking on tabletop mixers. Until fairly recently, cultures grown in shake flasks were agitated in this manner. Wave Biotech, now a unit of GE Healthcare, built its entire business around tabletop rocking of plastic bioreactor bags ranging in size from a few milliliters up to 1000 liters.

One consideration when selecting a mixer or stirrer is what will occur downstream of your particular operation. If scale-up is not on the horizon, almost any suitable stirring or mixing solution will do. On the other hand, agitation does not always scale smoothly from plates to vials to large reactors. "But that is why companies have process development groups," Mr. Costello says.

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SOFTWARE, INTERFACE IMPROVE USER EXPERIENCE

by Angelo DePalma, Ph.D.

The news in analytical balances comes not from hardware but from user interface and software algorithms that translate electrical signals to weight. "When you put a weight on a balance, the measurement is so much faster than it used to be," says Ian Csiesniewski, technical director at Mettler Toledo (Columbus, OH). Software upgrades now provide "settling time" on a five-place analytical balance equivalent to times on top-loaders. "And measurement uncertainty—the accuracy level—is getting tighter and tighter. The end-user numbers are a lot more secure."

Lower measurement uncertainty arises from higher data acquisition speed and the efficiency of the algorithmic evaluation that turns data points into weight data. Key to this conversion is a fast onboard microprocessor.

Mr. Csiesniewski attributes these improvements to development groups that continue to develop products post-launch. "We're learning more about the hardware capabilities and constantly analyzing performance based on calibration certificates generated during customer service visits." Provided the balance has computer connectivity, customers can upgrade software via the Internet regardless of instrument age. "They get the benefits of buying a new balance today even though their unit is five or six years old," Mr. Csiesniewski says.

Improved algorithms provide benefits beyond better, faster weighing results. Since the weigh cells are much more reliable and robust, they maintain performance longer and therefore require less frequent calibration and maintenance.

Calibration and maintenance

Calibration is easy to take for granted or outright ignore, especially in academic labs that lack a business driver for regular, routine calibration. While today's balances do not require as much calibration and service as older models, users should be aware that operating environment and usage can easily affect both results and calibration frequency. "Modern balances tend to hold calibration longer than previous-generation instruments, but if you're in a production area, you should not back off on maintenance frequency," Mr. Csiesniewski tells *Lab Manager Magazine.* Vibration, noise, heat, cold, and movement, and in some cases frequency of measurement, are signals pointing to more frequent calibration and service.

Frequency and type of calibration vary among industries, and even among companies within markets. Pharmaceutical companies may perform a quick calibration daily; other firms, quarterly or twice yearly. "Remember, though, that simply zeroing a balance is not a calibration," cautions Markus Jansons, weighing product manager at A&D Weighing (San Jose, CA). "That's only one point on the line. A true calibration requires several measurement points."

Calibration can be as simple as procuring NIST (National Institute of Standards and Technology)-traceable weights and performing several measurements. Larger companies often employ outside service organizations that visit periodically to calibrate all of a company's weighing instruments.

Companies following ISO or industry standards must demonstrate that their balances have been calibrated, but for most firms no official regulatory or industry "guidance" exists stipulating the frequency or type of balance calibration. "It's up to the company–it depends on how valuable your data is to you," says Mr. Jansons.

> "Now, [balances are] racehorses in terms of abilities and workhorses in temperament."

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Yet, all in all, today's balances are quite forgiving. "Five-place balances used to be like racehorses—temperamental and requiring special handling," says Ian Csiesniewski. "Now they're racehorses in terms of abilities and workhorses in temperament. Users can be a good deal less respectful to these instruments."

Communication and data acquisition

With older mechanical balances fading from the picture, balances are becoming sophisticated in terms of user interface, ergonomics, data acquisition, and built-in diagnostics. Most balances interface with the user through a front panel, although some features are available through a computer connection. Newer models are designed to make sample introduction and removal a comfortable experience and to reduce the likelihood of repetitive-stress injuries.

"What we're seeing is a greater need for communication, especially from the balance, as users move away from paper laboratory notebooks into laboratory information management systems (LIMSs) and electronic laboratory notebooks (ELNs)," Markus Jansons observes. "Communications may be wired or wireless, but in every case the goal is to reduce human error."

For example, quality control or environmental laboratories may run several hundred samples per week; the busiest establishments may encounter such workflows in one day. Copying numbers to three or four decimal places is not only tedious—it may result in skewed results through miscopying weight values or entering them into the wrong location on a spreadsheet. Analysts may not notice anything is wrong until after completing several days' worth of measurements. The last thing a busy lab wants is rework: having to reweigh samples or, in a worst-case scenario, having to prepare a tray of samples and rerun an experiment.

> "Remember, though, that simply zeroing a balance is not a calibration."

Most top-line balances include some sort of connectivity option. For example, Rice Lake Weighing Systems (Rice Lake, WI) includes a connection that outputs data directly into Microsoft Excel or Word on a desktop computer. "USB connections are becoming more popular, as many users want data in spreadsheet format," says Ann Crowley, product manager. Analytical balances are not quite up to HPLC and MS in terms of internal diagnostics: There is no equivalent to messages indicating a leak between the injector and column, for example. But modern balances will indicate if gross excursions occur in terms of instrument readiness.

Analytical balances are no longer considered to be simply weighing instruments that take point measurements. "They have become workflow tools that allow analysts to take care of a process rather than just giving a data point," Mr. Ciesniewski says. "At one time users had to work very carefully to get great results. Now poor technique is neutralized by instrument capabilities."

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AUTOMATION ENABLER FOR MICROPLATE OPERATIONS

by Angelo DePalma, Ph.D.

Microplate handlers are specialized robotic devices that transfer microtiter plates in three-dimensional space from one location within a workflow to another. The "locations" are actually operations such as solvent addition (through liquid handling), aspiration, heating, shaking, incubation, washing, reading, and storage.

Plate handlers are common in laboratories that process hundreds or thousands of microplates per week, for example, high-throughput screening labs in the life science and pharmaceutical industries. Most plate handlers are used in life science industries, particularly pharmaceuticals and biotech.

One can make the case for incorporating some type of robotic handler even for low-volume labs. Unfortunately, cost and complexity frighten off many potential users.

Microplate handlers are indeed the "glue" that binds mission-critical microplate applications. Their value accrues from accurate, timely, unattended plate transfer that frees lab workers to perform more complex analytical tasks such as secondary screens. Many users acquire microplate handlers for speed, but their greatest benefits are the abilities to standardize microplate operations and workflows, provide greater consistency, decrease the chance of error, and track every operation that plates undergo.

It's all in the workflow

Early microplate handlers were clumsy devices borrowed from the world of industrial robotics. "They could hold microplates, but were not designed for that purpose. They were overkill," notes Todd Christian, head of global marketing for automation solutions at Agilent (Santa Clara, CA). Today's handlers are better-suited to their delicate task.

> "Microplate handlers are indeed the 'glue' that binds mission-critical microplate applications."

Plate handlers are part of what Alisa Jackson, marketing manager for genomic chemistries and Biomek consumables at Beckman Coulter (Brea, CA) calls "workflow solutions" intimately tied into application needs. Robotics allow users to modify and create custom workflows; for example, the user may insert a new step such as centrifugation, adding buffer, and transferring the plate to the next operation. How smoothly the process runs depends mostly on how well end users understand their workflow.

"That's the first place to start," Ms. Jackson says. Users need to understand how movement affects each operation, how often plates need to be moved (and to what degree the operators care to move them manually). Sometimes plates need to be transferred to a location that is off the "deck," to an operation that has not yet been, or cannot be, integrated physically into the workflow.

These are factors that must be considered when selecting an automation tool like a plate handler. "Do you need a large industrial robot to move plates among ten devices, or will a simple pick-and-place robot and some human intervention do just as well?" she asks. Software is also a consideration in terms of user-friendliness, ease of programming, and tracking samples. "Is your process serial? Do you need incubation or scheduling? That's where software comes into play," Ms. Jackson adds.

Traditional plate handlers move plates in 3-D space, but they are expensive and can be difficult to program. Jackson mentioned two other automation tools that can augment robotic handlers, perhaps reduce some of the complexity of workflow automation, and help utilize all available space. The first are labware shuttles (also known as conveyors), which move plates horizontally. Conveyors may be belt-driven or incorporate a sealed magnetic transport mechanism. Shuttles move plates horizontally by fully supporting the plate from below. Some operations, like pipetting, may occur on the shuttle itself. The second tool is an elevator, which can help optimize the work area in the vertical dimension.

"With lab space at a premium, users need to make the most of vertical space," Mr. Christian says, "using less benchtop space for the same workflow."

Integration

Laboratory robotics are not as intuitive as other labware and provide value only within a context of other instruments. That is why most vendors emphasize support for microplate handler sales both before and after the purchase, particularly in workflow analysis and setup. They also emphasize software and user interfaces in an effort to flatten the learning curve and allow more end users to fully exploit the robot's functions.

As with any instrument, power users who write code or macros will always exist—but automation companies need to placate users at both ends of the expertise spectrum. "You don't want the usability of your instrument to be limited to the super-user," says Kasia Proctor, product manager at Molecular Devices (Sunnyvale, CA). "We want anyone to be able to walk up and do what they need to do."

"Traditional plate handlers move plates in 3-D space, but they are expensive and can be difficult to program."

Molecular Devices sells microplate readers, washers, and stackers and integrates its instruments with plate handlers and other microplate "operations" from the likes of Agilent, Beckman Coulter, and Thermo Fisher. "It depends on what the customer wants, and what they already have," Ms. Proctor observes. Users may already own a washer and reader connected by a simple pick-and-place robot and require a different reader, or liquid handling, or both. Generally speaking, users should be able to swap out a reader or washer without calling in a service team. It gets much more complex when multiple functions are added to an existing workflow and, depending on the level of automation desired, the robotics may require upgrading as well.

The level of support required to set up a microplate workflow that includes plate handling depends on how attached customers are to the components they already own and on the level of in-house expertise. Some customers still create their own homebrewed systems, picking and choosing among components from different vendors—often legacy instruments from times when these instruments were operated in full manual mode.

"But as automation moves into newer areas, integration becomes more important," observes Agilent's Mr. Christian. Components need not specifically require seamless interoperability; however, a versatile plate handler run through a user-friendly interface can smooth over many of the workflow disconnects between company A's microplate storage "hotel" and company B's shaker.

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INNOVATING AROUND THE EDGES

by Angelo DePalma, Ph.D.

Refractometers are analytical instruments that measure the refractive index (RI) of liquids. Physicists define RI as the ratio of the speed of light in a vacuum divided by its speed through a test medium. Any substance that is denser than a vacuum—pretty much anything—will have an RI greater than 1. The RI of pure water is 1.33, which means that light passes through a vacuum 1.33 times as fast as through water.

A recently completed survey by *Lab Manager Magazine* indicated that the most common industrial applications of refractometry were medical (34 percent), food/beverage (28 percent), chemicals (19 percent), and academia or research (15 percent). Of all the features and factors entering into the purchase decision, price was "very important" to 97 percent of 273 respondents.

Depending on the solute, adding materials to water causes the RI to rise or fall above 1.33. Salt and sugar raise RI in a linear, concentration-dependent way, while alcohols like methanol and ethanol lower RI, since they are less dense than water.

Pluses and minuses

Refractometry brings several benefits as an analytic modality: Instruments are simple and relatively inexpensive, measurement is rapid, and quantitation is highly accurate.

On the negative side, refractometry brings value only when the constituents of a solution are well-known. It is possible to formulate two solutions, one sugar and the other salt, with exactly the same RI. In fact, one could mix and match a dozen constituents to reach the same RI value. If a solution contains only sucrose, an analyst can measure a very wide range of concentrations from an appropriate calibration curve. But if a second constituent is also changing, all bets are off.

> "[Refractometers] are simple and relatively inexpensive, measurement is rapid, and quantitation is highly accurate."

Refractometers are limited in other ways as well. Unlike some other analysis types, refractometry is not sensitive enough to pick up part-per-million concentration differences. And if special care is not taken to hold all but target analyte concentrations constant, concentration changes of a high-RI ingredient or impurity may swamp out the response from the target. On the other hand, if two or more constituents remain constant but the sugar changes, a suitable curve may be constructed for that solution.

Since all solute materials have unique mass and optical spectra, and quite often different chromatographic retention times, refractometers are often employed with other instruments. Polarimeters or densitometers are instruments that also provide concentration-type readouts without specifically identifying what is in the sample.

Format and function

While refractometers lack the granularity of analysis of other instruments, they are quite versatile in terms of format. Refractometers are available as handheld, benchtop, and in-line (or bench) units. Stationary lab refractometers are the most accurate and versatile but are best kept out of harsh environments, while handheld or field instruments bring the instrument to the analyte. Analysts and production engineers use in-line refractometers, which are also stationary, to monitor process liquids in real time.

"All three types have their benefits and drawbacks," says Noah Radford, technical specialist at Atago (Bellevue, WA), "but handheld units are the only way to go for someone taking measurements at multiple locations."

In-line refractometers are normally associated with process industries (chemicals, foods, pharmaceutical,

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biotech), but the same company may use all three refractometer types, depending on the situation. For example, metalworking companies may have 150 machines on a large shop floor, each requiring cooling fluid. Workplaces with a centralized coolant sump will benefit most from an in-line refractometer that monitors the common cooling fluid in real time. Where every machine has its own coolant reservoir, the most appropriate solution is a handheld refractometer. "It's impractical to take samples from all those machines and bring them back to a benchtop unit," Mr. Radford says.

Similarly, a pharmaceutical company may employ handheld refractometers to provide a quick identity scan for incoming raw materials, an in-line unit to monitor composition during the formulation of a fermentation nutrient medium, and a benchtop model to quantify salt concentrations in a cell culture buffer ingredient.

Toward "smart" refractometry

Richard Spanier, sales and marketing director at Rudolph Research Analytical (Hackettstown, NJ), notes that instrument-related errors in flat-prism refractometers arise from improper cleaning or inappropriate application of analyte to the prism surface. Instrument makers compensate for such variability through "smart" features that detect trapped air bubbles or smudges.

"While refractometers lack the granularity of analysis of other instruments, they are quite versatile in terms of format."

Another source of error is poor temperature control, which can cause not-so-subtle changes in sample composition. Some analytes, like volatile organics, evaporate quickly above ambient temperatures, while others (e.g., salt solutions) are hydroscopic. Analysts did not appreciate the impact of temperature until quite recently, according to Mr. Spanier. Many top instruments today feature Peltier cooling; Rudolph's instruments also employ a technique whereby samples are heated or cooled from above and below.

"Just as automobile companies are developing smart cars, instrument makers are constantly adding 'intelligence' to refractometers," Mr. Spanier says. "The goal is to reduce erroneous results and rework."

According to Wallace Harvey, national sales manager for laboratory products at Anton Paar (Ashland, VA), his company's principal interest in refractometers is making analysis easier, more accessible to the average user, and more versatile. These upgrades include interconnectivity with other common instruments, for example, density meters, pH meters, polarimeters, or colorimetric analyzers. "It's often useful to take measure density and refractive index more or less together," Mr. Harvey says.

Another innovation is a flow-through sample measurement cell for automated in-line or semi-inline measurements that are repeated at regular intervals. "It is now possible to hook up a pump and meter in sample directly, measure it, then rinse and clean the sample cell without having to remove, open, and close it."

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PRECISION, SMALL VOLUMES PREDOMINATING

by Angelo DePalma, Ph.D.

"In an era of limited research dollars, customers are looking for value and a more secure investment," says Merja Mehto, product manager for automated liquid handling at Thermo Fisher Scientific. For automated liquid handlers (ALHs), that means modularity, flexibility, scalability, and upgradability. At the same time, space limitations are causing a shift from large core-facility, high-throughput screening systems to smaller, dedicated, more distributed screening within individual laboratories.

Lab or bench-scale ALHs often lack the capabilities of core lab instruments, and workflows change as well. Users therefore demand scalable, relatively low-cost instruments to which they may add functionality later on. Many of these customers operate at what Ms. Mehto refers to as an automation decision threshold. "We're trying to provide users with an on-ramp to automation that they can enter at reasonable cost, and have the flexibility to adapt the instrument over time."

Most of these use handheld electronic pipettes daily, and sample volume is beginning to take its toll. No "magic formula" exists for when automation begins to make economic sense—that depends on budgets, workflows, and skill levels.

Throughput is always a factor in deciding to "go automated." But many experts have noted that speed is secondary to analysis quality. ALH provides accuracy, repeatability, and essentially error-free record keeping while freeing lab workers to do more creative activities such as planning experiments and analyzing data.

> "Users ... demand scalable, relatively low-cost instruments to which they may add functionality later on."

For this reason, says Peter Mrozinski, product manager for workflow automation at Agilent Technologies (Wilmington, DE), vendors who stress throughput miss the value of automation. "Automation does not have to be faster than manual techniques to provide value. Its contribution to improving workflows is consistency and reproducibility—as accurate as your best technician on a good day, but with the reliability and reproducibility of an analytical instrument."

Mrozinski believes that ALH can do more for standards preparation than for sample prep. One Agilent customer reported that by making up standards on demand, in many cases overnight, they saved $16,000 per year in solvent costs and $20,000 on rework in one year.

The sound of accuracy

One of the most significant breakthroughs in ALH was the introduction of acoustic droplet injection, which uses ultrasonic energy to eject droplets from open wells. Conventional ALHs employ mechanical displacement to draw liquid into pipette tips and dispense into vials or microwells.

"The problem with traditional liquid handlers, regardless of whether they are based on a pipetting mechanism, pin tool, or piezloelectric effects, is that their fluid contact surfaces get wet," explains Joe Olechno, VP of R&D at Labcyte (Sunnyvale, CA), which specializes in acoustic droplet injection. The effect of wetting is close to undetectable when transferring milliliters, and negligible even with microliter transfers. "But for very small liquid delivery, the holdup becomes a significant percentage of the total. And the error increases the smaller you go."

Nucleic Acid Quantification

Protein Quantification

Micro-Volume Analysis

Endotoxin Analysis

Spectral Scanning

Enzyme Kinetics

PAMPA

ELISA

Biofuels Research

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"Throughput is always a factor in deciding to 'go automated.' But many experts have noted that speed is secondary to analysis quality."

Acoustic injection in essence utilizes a "nozzleless nozzle" in which no surface is wetted. Published studies have shown coefficients of variation as high as 20 percent for typical ALH, while for acoustic injection the variance was less than 3 percent.

Pipetting accuracy can have immense consequences on experiments. Perhaps as important are unfavorable interactions between pipette tips and labile proteins. In 2010, AstraZeneca reported that binding to pipette tips caused conventional liquid handlers to deliver a thousandfold less of an active pharmaceutical ingredient to a drug screen than did acoustic technology. Differences of that magnitude can easily cause assay results that should be positive to come back negative.

Pipette-less dispensing can also have direct cost benefits. Bristol-Myers Squibb and AstraZeneca have reported that acoustic delivery saved them $200,000 and $160,000 per year, respectively, in pipette tip savings. "You wouldn't think this would be a huge area of savings, but with millions of dispenses per year it adds up," says Mr. Olechno.

In September 2011, Labcyte and Thermo Fisher Scientific announced an agreement whereby Thermo Fisher will offer customers of its siRNA (small interfering RNA) libraries the option of receiving these products in Labcyte Echo® source plates, thus eliminating manual handling, improving efficiency, and reducing the risk of cross-contamination for siRNA transfections.

Among the first adopters were research groups at the Institute of Cancer Research (London, UK) and the Southern Research Institute (Birmingham, AL). Dr. Spiros Linardopoulos, a team leader at the London institute, mentioned "greater flexibility" and "total control of the remaining volume" as justification for the novel siRNA reagent format.

And now for something completely different

ALHs are normally used to deliver precise quantities of fluids to test wells. PhyNexus (San Jose, CA) has come up with a twist on this idea: separations on a pipette tip. The company's PhyTip® "columns" consist of ordinary-looking pipette tips charged with chromatography resins. Almost any resin can be used, including normal phase, ion exchange, affinity, reverse phase, and protein capture.

PhyTips work by drawing fluid from test samples into the pipette arrays. A typical 200-µL column holds anywhere from 5 to 20 µL of resin. As the fluid travels through the tip, analytes bind to the resin. Buffer is then drawn into and out of the tip to wash away impurities. Finally, the ALH draws in an elution buffer and dispenses the purified macromolecule into a new plate or set of vials.

"PhyTips are compatible with liquid handling systems from all major vendors," says PhyNexus CEO Douglas Gjerde. Since the entire process is automated, significant time savings are possible. PhyNexus claims throughput improvements of between 10 and 100 for protein sample preparation.

As expected, PhyNexus's main customers are pharmaceutical companies that multiplex assays and protein preps. Some customers use PhyTip columns to screen chromatography resins or separation conditions, which they then scale up. The technique is also applicable upstream, to purify proteins from cells or microorganisms raised under an array of conditions.

Angelo DePalma *is a freelance writer living in Newton, NJ. You may reach him at angelo@adepalma.com.*

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Lab Manager MAGAZINE

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LABCONCO CORPORATION: The 87 year old Kansas City based company is showing no signs of slowing down.

by Nancy Simonds, Marketing, Labconco

In 1925, Calvin Coolidge was President, annual income was $1,280, a new car could be purchased for $366 and gas was 22¢ a gallon. Record grain yields over the previous five years resulted in Kansas City becoming the third largest milling center in the world. This is the setting where **Laboratory Construction Company** began and still remains.

The company started out making Kjeldahl Nitrogen Determination Apparatus which gave the company a niche with the area milling companies and laboratories. Not long afterward, the Goldfisch Fat Extractor was developed and the agricultural companies saw the importance of the Laboratory Construction Company's importance to their industry.

In 1936, the Suction Fume Hood was introduced into the market. Soon after came Laboratory Carts which are still offered today. Catalogs of this period began to use the acronym "Labconco" as a trade name for the company's laboratory furniture products.

In 1959, Labconco designed the first Labconco Fiberglass Hood. Labconco mastered fiberglass reinforced polyester fabrication techniques and, in 1961, the Fiberglass-47 Fume Hood was released to the market.

Labconco presented its Fiberglass Tissue Culture Hood in 1965 and in 1966, the Fiberglass Glove Boxes made their debut. In fact, several versions of the glove box were created for controlled atmosphere, bacteriological and radioisotope applications.

While the name Labconco was becoming synonymous with fiberglass hoods and enclosures, the company wanted to explore new product opportunities. Laboratory washer offerings in the industry were limited to large, central supply type washers. So in 1969, Labconco developed its own line of Glassware Washers. The designs met washing requirements by adding more cycles and a purified water pump. By creating an assortment of glassware racks and baskets, the washers could serve a wide variety of laboratory washing needs. A sign of the times was reflected in the 1970 Labconco catalog—women in go-go boots and lab coats were shown next to the product pictures. Needless to say, it was a very popular catalog!

In 1974, an extensive line of lyophilization equipment, also known as freeze dryers, was introduced. Labconco's reputation as a leader in laboratory equipment manufacturing was increasing, but it would be its safety ventilation that still reigned supreme.

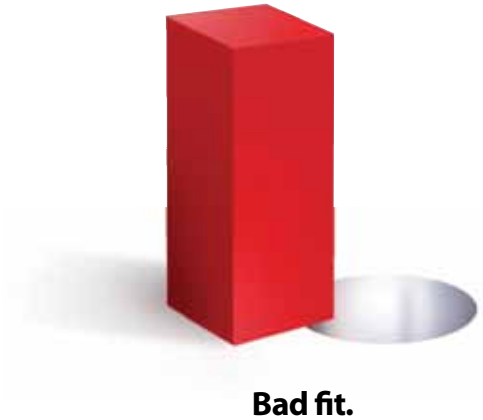
In 1976, Labconco embarked on the design of a new enclosure concept that provided protection from biological hazards. The new enclosure combined laminar airflow and high efficiency particulate air (HEPA) filters. It would become Labconco's first generation of the "Laminar Flow Biohazard Safety Cabinet." In the early 1980s, those models were redesigned and resulted in the successful "Purifier®" line of biological safety cabinets, clean benches and enclosures.

The 1980s were busy times for Labconco engineers. New products were being developed and by 1984, WaterPro® Water Purification Systems were introduced. Also making their debut was the CentriVap® line of Vacuum Concentrators.

In the 1990s, the Protector® Fume Hoods and Purifier® Biosafety Cabinets underwent vacuum redesign and continued to grow in the importance to the overall product mix. Customers without means to hook up a fume hood to an outside duct needed an alternative—a ductless fume hood. Labconco answered that demand with the new Paramount® Filtered Enclosures, which further expanded our safety ventilation product offering, and were introduced in 1996.

With the new millennium's arrival, the heart of Labconco's growth was the continued flow of internally-developed products such as the Protector® XStream High Performance Hood and many, many more. This U.S. company prides itself in saying their products are "Made in the U.S.A.". In 2012, look for new product introductions as Labconco continues its steadfast commitment to *"Protecting your laboratory environment."*

CELL Logic



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SURVEY SAYS: ARE YOU IN THE MARKET FOR A FUME HOOD?

Indispensable equipment for laboratories, fume hoods protect personnel from exposure to chemicals handled during experiments. Fume hoods ventilate the hazardous and noxious chemicals, vapors, gases, or dusts released during experiments. Sample protection is another important advantage of fume hoods. Fume hoods may either be ducted or recirculating. Both types operate by allowing air to be drawn in from the front (open) side of the cabinet, and either expelled outside the building or made safe through filtration and recirculated back into the room.

We recently surveyed a select group of our readers on fume hood use in their labs.

Maintenance

Fume hoods cannot protect lab personnel without scheduled maintenance to keep them operating properly. The most critical part to maintaining hood performance is a regular check or testing of fume hood flows. Routinely checking the hood for adequate flow and velocity must be incorporated into your lab safety program. Vendors recommend labs post flow test results or performance checks directly on the hood and request a recheck if they suspect a problem.

Fume hood inspection and periodic maintenance

- Inspect the fume hood for chemical storage and other blockages.
- Measure face velocity, complete an airflow visualization test (smoke testing), and conduct a tracer gas containment test (a measure of a fume hood's containment effectiveness).

Annual fume hood maintenance

Exhaust fan maintenance: Lubricate moving parts, check belt tension, inspect fan blade for deterioration, and record rpm — according to the manufacturer's recommendations.

Most of our surveyed readers inspect their fume hoods at least every year. Here's what they had to say about how frequently they inspect the fume hoods in their labs:

Monthly	**12%**
Quarterly	**12%**
Every six months	**16%**
Annually	**47%**
Every two years or more	**5%**
Not applicable	**2%**
Don't know	**7%**

Design location principles for fume hoods

Layout of the laboratory and location of the fume hood is very important for optimum performance and minimal interference. Fume hoods must not be located near doorways or exits. Ten feet from any door or exit is recommended by the National Fire Protection Association. Also, to the greatest extent possible, locate fume hoods away from high-traffic areas, air supply diffusers, doors and windows. Any area that produces air currents or potential turbulence could affect the ability of the hood to capture and exhaust contaminates as designed. Do not locate fume hoods opposite workstations, desks, microscope benches or other areas where personnel spend significant time. Ensure that there is an emergency eyewash and safety shower within ten seconds of every fume hood. This is a requirement wherever a worker could be exposed to corrosive, toxic or severely irritating substances.

Safety is clearly a priority with our readers, as shown by their responses to these fume hood safety statements:

	Agree	Disagree	Don't Know
All fume hoods have been tested within the past year.	**87%**	**10%**	**3%**
Test labels are properly affixed to the fume hoods tested.	**80%**	**16%**	**4%**
Storage in fume hoods is kept to a minimum and is placed so as to not impede proper airflow.	**91%**	**6%**	**2%**
To maximize hood effectiveness and minimize personnel exposure to toxic vapors or gases, our lab uses fume hoods in accordance with the operational guidelines.	**92%**	**2%**	**5%**

The top ten most important factors for our respondents in their decision to buy a fume hood:

Durability of product	**95%**
Ease of use; ergonomic operation	**95%**
Low maintenance / easy to clean	**92%**
Low operating costs	**89%**
Performance of product	**100%**
Safety and health features	**92%**
Service and support	**78%**
Total cost of ownership	**79%**
Value for price paid	**92%**
Vendor reputation	**73%**

Conventional ducted fume hoods are the most popular with our surveyed readers, with benchtop ductless fume hoods a distant second. Here is the breakdown of the types of fume hoods respondents are using:

Benchtop ductless fume hood	**16%**
Canopy ducted fume hood	**11%**
Conventional ducted fume hood	**58%**
Down flow workstation	**5%**
Portable ductless fume hood	**2%**
Variable air volume ducted fume hood	**8%**
Other:	**1%**

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SURVEY SAYS: ARE YOU IN THE MARKET FOR A ROTARY EVAPORATOR?

Rotary evaporators have for decades been staples in labs and industries performing chemistry, including labs in the chemical, environmental, materials, life science and forensics industries. Key applications include sample concentration, solvent recycling, extractions, and separation of solvent mixtures.

In their simplest embodiment, "rotovaps" consist of a temperature bath, rotating flask, condenser, collection flask, and vacuum source. Solvent distills from the sample under the combined effects of heat and vacuum, and collects after condensation in the collector. Recovered single-phase organic solvents may be dried and re-used; binary, tertiary, or quaternary solvent mixtures are also re-used but may need adjustment for composition.

Water is the fluid of choice for the bath, but some laboratories use oils to reach heating temperatures of up to 180°C. Several choices are available for the condenser coolant. Until about 10 years ago, almost everyone used house water. Concerns over water consumption caused many labs to switch to a chiller to recirculate coolant into and out of the condenser coils. Chillers provide more precise cooling, greater control over condensation, a greatly reduced environmental footprint, and are overall less expensive to use than water. High-efficiency trapping of low-boiling solvents is achieved with a "cold finger" charged with dry ice and acetone.

An important new concept in laboratory rotary evaporation is systems integration. This means the main components of the evaporation solution are fully integrated with respect to parameters and control.

The rotary evaporator components our readers use in their labs include:

Diaphragm pump	15%
Chiller	13%
Digital bath	13%
Recirculating cooler	13%
Dry ice condenser	5%
Condensate trap	8%
Vertical condenser	12%
Diagonal condenser	9%
Cold finger condenser	6%
Reflux condenser	6%
Other (please specify):	1%

Rotovaps can also be used for flavor extraction in the food industry and HPLC and natural product sample prep. The fields of work our respondents' labs most closely align with are:

Pharmaceutical industry	12%
Biochemistry and biology	13%
Chemical	16%
Food and beverages	8%
Environment	13%
Quality control	7%
Hospital/Medical center	7%
Other (please specify):	24%

Other applications rotary evaporators are used for include drying down powders using a test tube adapter and trapping hazardous waste liquid. Here are the most common applications our respondents are using their rotovaps for:

Distilling of low-boiling solvents	20%
Distilling of temperature-sensitive substances under vacuum	10%
Recycling of solvent waste	7%
Extractions	11%
Concentration of substances	29%
Drying of powders	6%
Separation of material mixtures	6%
Chemical synthesis under reflux	5%
Other (please specify):	5%

Newer rotovaps may incorporate thermocouple-controlled operation, in which a pump integrates with a controller and a thermocouple located in the vicinity of the condenser coils. As the coil temperature rises through heat transfer between the condenser and the evaporated solvent, the vacuum is bled out through valving to maintain steady distillation. Another technique, known as "RPM" control, speeds or slows the pump's inner workings to control the delivered vacuum.

Purchasers should consider several vacuum and condenser cooling options before buying a rotovap: Cooling method should be decided based on the expected solvent load and buyers should also consider whether automated, volume-dependent rotary evaporation is desired.

Here are the factors our respondents found most important in their buying decision:

	Important	Not Important	Don't Know
Built-in vacuum controller	47%	31%	21%
Clockwise and counterclockwise rotation of the distilling flask	22%	51%	28%
Coated glassware	44%	33%	23%
Ease of installation	74%	13%	13%
Ease of use	79%	8%	13%
Energy efficiency	49%	30%	21%
Fully integrated	33%	49%	19%
Low maintenance/easy to clean	84%	1%	14%
Low operating cost of ownership	78%	7%	14%
Motorized lift systems	26%	54%	20%
Price	82%	4%	14%
Quiet drive motor	47%	36%	17%
Reliability	82%	4%	14%
Safety	81%	4%	14%
Service and support	69%	13%	19%
Small footprint/size	52%	30%	17%
Temperature sensitivity	43%	39%	17%
Versatility	62%	15%	24%
Warranty	70%	14%	16%
Other	0%	33%	68%

For more information on rotary evaporators, visit www.labmanager.com/evaporators

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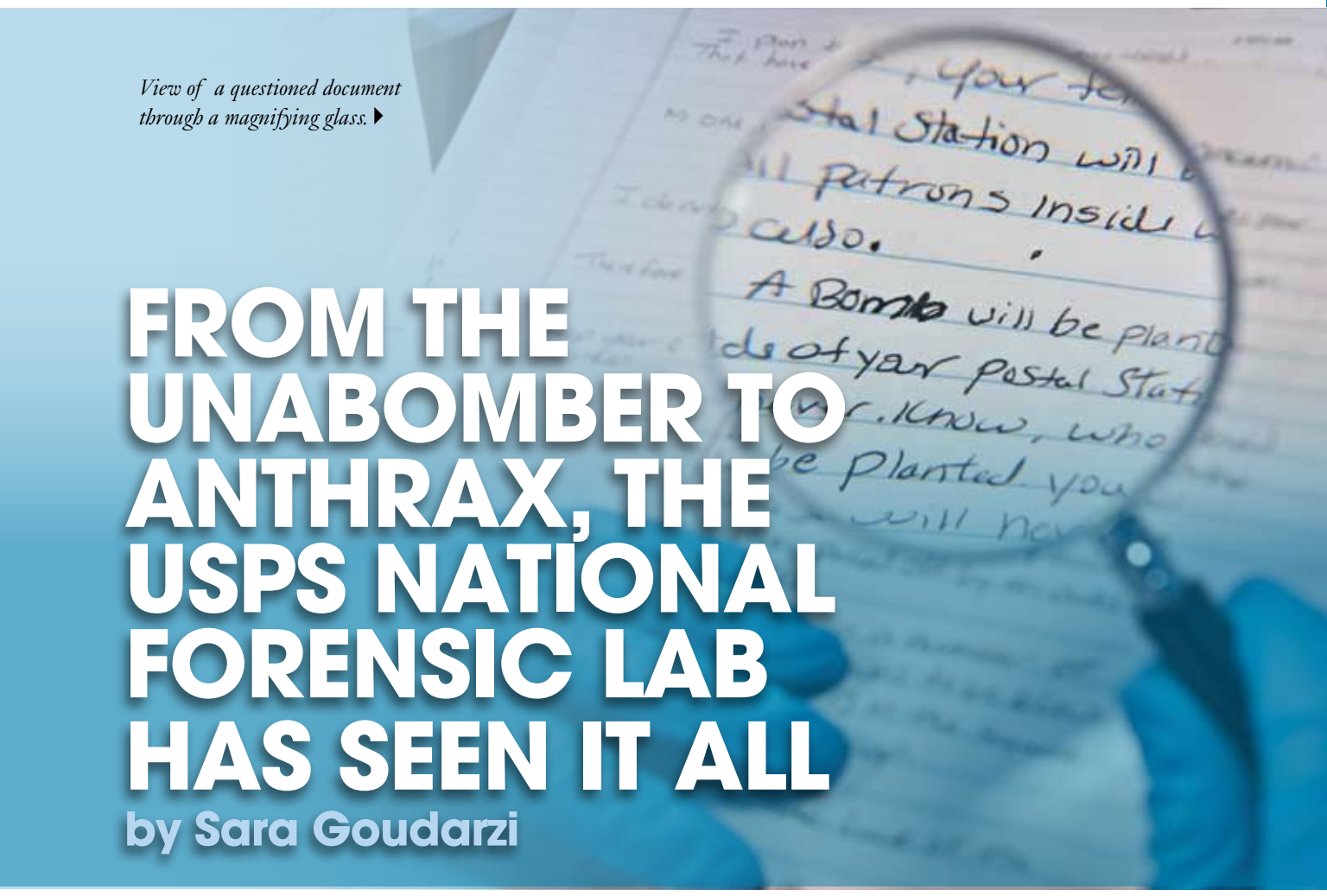


View of a questioned document through a magnifying glass.

FROM THE UNABOMBER TO ANTHRAX, THE USPS NATIONAL FORENSIC LAB HAS SEEN IT ALL

by Sara Goudarzi

Stephanie Smith has an exciting job. As assistant lab director of the Physical Sciences Unit at the National Forensics Laboratory of the United States Postal Inspection Service (USPIS)—the law enforcement arm of the United States Postal Service—she puts her daily efforts into making the U.S. mail safer by helping solve thousands of postal crimes.

"The USPS National Forensic Laboratory is a full-service forensic laboratory that primarily provides analyses of a wide range of materials that may find their way into the mail stream or into postal facilities or are deposited during the commission of a crime against the U.S. Postal Service, its employees or its customers," Smith says.

Additionally, her lab routinely supports the investigations of the U.S. Postal Service's Office of the Inspector General, and occasionally the investigations of state, local or other federal agencies that might benefit from the specialized skills and knowledge of forensic analysts or forensic lab services.

"While few people know we exist and fewer still understand what we do, the work we perform is profoundly important."

"We also provide response for major crime scenes and provide on average two tours of the facility per month to customers, international law enforcement personnel, [and] students from middle school to college-age and other groups," Smith explains.

Smith's most serious, but luckily infrequent, investigations involve dangerous mailings, which include explosive devices and assaults upon dedicated mail carriers. Her team also investigates robberies, vandalism and burglaries of postal facilities; child exploitation; controlled substances sent through the mail; mail theft; identity theft; and fraud.

"The Postal Inspection Service is often referred to as the 'silent service,'" Smith says. "While few people know we exist and fewer still understand what we do, the work we perform is profoundly important."

"The past and present scientific staff of Forensic Laboratory Services worked closely with the Postal Inspection Service on high-profile cases including the Unabomber case;

the Chugiak, Alaska, mail bomb case; the conviction of televangelist Jim Bakker on mail fraud; a fraud case involving Clifford Irving/Howard Hughes; and the Amerithrax case, to name but a few."

Lab structure

The National Forensic Laboratory is a specially designed 44,000-square-foot facility spread over two levels. Within that space, the Physical Sciences Unit takes up about 10,000 square feet.

"[Forty-four thousand square feet] is an amazingly tight operation in terms of space for a laboratory that serves the whole country," says Smith.

Just 65 employees—58 scientific staff members supported by an administrative staff of seven—run the entire operation. The laboratory is divided into four units, each managed by an assistant laboratory director, which report directly to the laboratory director.

"The administrative personnel and the scientific personnel of three of the units (Fingerprints, Physical Sciences and Questioned Documents & Imaging) are located at the National Forensic Laboratory, and the personnel of the Digital Evidence Unit (except for the assistant laboratory director), which includes 23 of the 65 positions, are located throughout the United States," says Smith, who as the assistant lab director of the Physical Sciences Unit leads the work of seven forensic chemists and a firearm and toolmark examiner.

Within the Physical Sciences Unit, there's a Chemistry Section and the Physical Evidence Section. The eight analysts in the unit cover 14 disciplines and sub-disciplines that represent more than 75 percent of the competencies offered by the Forensic Lab Services.

"The disciplines and sub-disciplines offered by the personnel of the unit include analysis of controlled substances, adhesives and tapes, explosives, fibers, firearms, footwear marks, general chemical unknowns, glass, hair, ignitable liquids, paints and polymers, physical fits, serial number restoration, serological screening, and toolmarks," Smith says. "Most of the members of the unit are also trained and experienced in crime scene processing."

In addition to extensive work training, the employees of the unit possess degrees ranging from a bachelor's degree to a PhD in chemistry, forensic science, forensic chemistry or natural sciences.

"While the mighty Physical Sciences Unit might represent less than a quarter of the staff and about a quarter of the physical space, we pack a wallop in the force of the services we offer," Smith says.

Smith herself earned a bachelor's degree in forensic science from the University of Central Florida and began a career in forensic science at the Louisiana State Police Crime Laboratory in Baton Rouge. She then worked at the Commonwealth of Virginia's Division of Forensic Sciences and later at the Dallas County Medical Examiner's Forensic Laboratory.

"I am beginning my 26th year in forensic science and my fifth year in forensic science management," she says.

Processing Samples

In the 2011 fiscal year, Forensic Laboratory Services received about 2,500 sample submissions. The Physical Sciences Unit processed about 300 of those submissions. Smith, along with her eight analysts within the unit, processes these samples, which turn out to be about 20 to 25 per month.

The team is able to run a smooth operation by keeping to an inventory and maintenance schedule set by the main lab.

"Forensic Laboratory Services utilizes a laboratory information management system (LIMS) designed by and created for FLS," Smith explains. "The system allows for most customers to enter evidence directly into a property and evidence program and then transfer custody electronically. The personnel working out of the National Laboratory are supported by a single laboratory technician who receives all evidence and opens assignments as requested by the customer."

Managers, such as Smith, assign each case to a particular employee. The employee holds custody of the evidence in a storage area until an analyst is ready to start work on the case.

> "With a plan I come closer to my goals than simply reacting to the loudest problem or the person who has a false priority created by a lack of planning."

"Custody is tracked electronically through LIMS. The LIMS system was modified in the past few years to include tracking of all chemicals received, used and disposed of by Forensic Laboratory Services."

The Physical Sciences Unit team utilizes a variety of common laboratory instruments, such as gas chromatography–mass spectrometers (GC-MS) and Fourier transform infrared spectroscopes (FT-IR). To ensure that the complex instrumentation functions properly, the forensic lab utilizes service contracts for annual preventive maintenance and repairs.

"We also utilize the concept of the primary operator as the responsible party for routine calibration and maintenance associated with ensuring quality performance and results on each instrument," Smith says.

▲ *Forensic document examiner Lisa Stadmeyer examines Postal Money Orders for evidence of counterfeiting.*

Hiring

Working at Forensic Laboratory Services requires a special skill set and training. Given the specialized and intricate nature of the work, lab managers take great care when looking for someone to add to their team. Each time a position opens up, upper management puts together a selection committee made up of members who are experts in the disciplines for which the lab is hiring.

The committee reviews each application carefully and picks candidates who seem promising based on experience and skill level. If an applicant proves to be a strong candidate on paper, the committee brings him or her in for an intensive interview process.

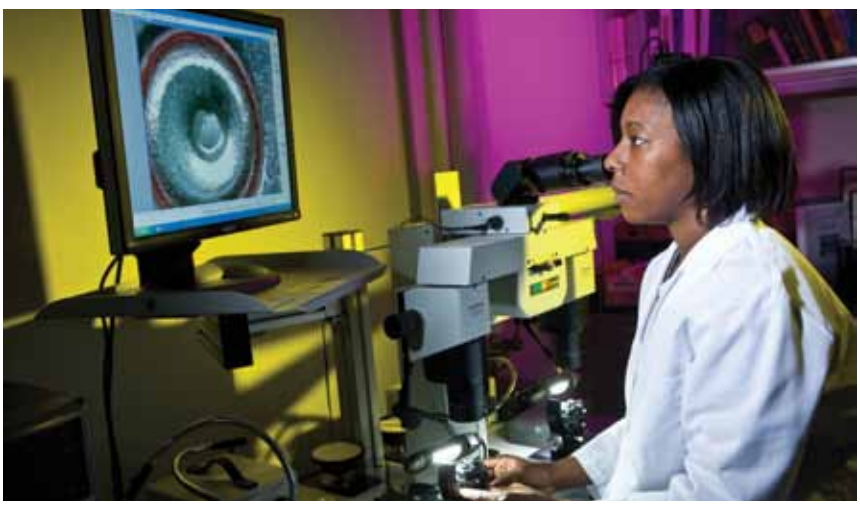
"I recently had the privilege of serving as chair of the selection panel responsible for selecting six new employees to Forensic Laboratory Services," Smith says. "The final decision is made by a selecting official who may apply even greater scrutiny to those recommended by the selection panel."

Challenges

Like many organizations, Forensic Laboratory Services is facing financial challenges. Contrary to what many believe, the Postal Service doesn't receive funding from the federal government.

"We are struggling to remain a vibrant service provider to the American public," Smith says. "All of the employees of the USPS play a

▲*Forensic latent print analyst Ken Thomas removes tape from envelopes to be processed for latent fingerprints*



▲*Firearm and Toolmark Examiner Shirley Marc examines a firing pin impression using a comparison microscope.*

role in this effort and it has not been without real pain and sacrifice."

One example of this is being able to keep the technical staff up to date by providing continuous training, cutting-edge equipment and exposure to developments in technology. Managers like Smith have to work hard to ensure that despite budget constraints, their staff benefit from learning about advances in their field.

"At the National Forensic Laboratory we host quarterly internal forensic seminars, where peers are encouraged to share knowledge of research or interesting and challenging casework," Smith says. "We also expect employees who attend outside training to provide updates to their peers."

Smith and other managers also take advantage of online resources such as webinars to update their staff, ensuring that they provide the best possible methods for advancements within their means.

In the end, Smith believes that sharing challenges with other colleagues is one way to overcome those challenges and loving what you do is another way to conquer hard times.

"Some agencies might have fewer challenges in one area or another, but finances are tight everywhere; keeping employees trained, engaged, productive and enthusiastic is challenging; and finding a convenient stopping point at the end of the day is not just challenging, it is often impossible," she says. "There is something to the adage that if you do something that you like, it doesn't seem so much like work. The work that we lead is so very important, and we have the ability to affect the work product directly through our leadership."

Day-to-day

To manage the lab and make sure that all her duties are met, Smith adheres to a routine that's proven successful for her.

"I typically start the day by addressing e-mails from the evening before and then creating the to-do list of the day," she says. "Every day I plot the plan for the day—I rarely complete exactly what I set out to do but with a plan I come closer to my goals than simply reacting to the loudest problem or the

person who has a false priority created by a lack of planning."

Smith is also responsible for assigning the diverse caseload to the members of her unit. She tries to do this within three days of receiving the cases, but only performs this task once a day or every other day, unless the case is urgent.

Smith also responds to inquiries from the unit's customers almost every day and serves as the national coordinator for DNA services.

"We do not offer in-house DNA analysis, but we contract for such services when the investigative needs warrant it," she says. "We encourage a lot of communication with our customers, as a courtesy and because it improves the overall work product."

Most of her workday, however, is taken up by performing administrative reviews of all the work that leaves the Physical Sciences Unit and technical reviews of about a quarter of the disciplines.

"This action, though challenging, results in a consistent quality work product," she says.

It's a lot of detailed work but Smith can't imagine doing anything else with her days.

"I love forensic science and I believe in the truth that comes through science. I am grateful every day that I chose this career," Smith says. "Rare is the career that permits one to apply an affinity and respect for science to diverse problem-solving challenges, the results of which can have such a profound effect on the criminal justice system."

"My colleagues and I are committed to helping to keep the U.S. Mail, its customers and its employees safe and to ensure the public trust in the mail," Smith adds.

Sara Goudarzi *is a freelance writer based in New York City. Her website is www.saragoudarzi.com*

TOP 5 INSTRUMENTS:

- Gas chromatography–mass spectrometers (GC-MS)
- Fourier Transform Infrared Spectroscopes (FT-IR) with microscope and attenuated total reflectance (ATR) attachments
- Assorted microscopes including stereomicroscopes, Polarized Light Microscopy (PLM), and comparison microscopes
- X-ray diffraction (XRD)
- Scanning Electron Microscopy—Energy-dispersive X-ray spectroscopy (SEM-EDAX)

TECHNOLOGYNEWS

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HPLC Method Development Calculator

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- Provides an LC column selection tool
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Thermo Fisher Scientific www.thermofisher.com

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PRODUCT SPOTLIGHT

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There's a new solid phase extraction (SPE) system on the market that aims to make life much easier for those in the environmental/oil and grease analysis industries.

The SPE-XPress system from Environmental Express is specifically designed for the extraction and evaporation required by EPA Method 1664 for Oil and Grease Analysis.

The company says the Xpress is also the only SPE system that: extracts the sample and evaporates the n-Hexane, eliminating the transfer step; verifies that the sample vessel is empty utilizing a fluid sensor rather than a timeframe, improving accuracy; and runs multiple samples simultaneously on up to six stations, improving analyst efficiency.

"We interviewed our customers and asked them where the bottlenecks in the extraction process occurred and how we could improve on existing systems," said Debbie O'Hara, marketing director at Environmental Express, of why they included these unique features.

The company adds that the system is easy to operate, with users loading the Xpress with standard one-liter sampling jars and walking away, leaving the system to flush itself clean and perform the SPE process.

"With the automated system, the test is less dependent on analyst technique," O'Hara said. "It also requires less intervention, so it frees the analyst's time to do other projects."

PC software also makes the system simple to control and records data for downloading to a LIMS and the system itself is self-contained so it doesn't need to be placed under a fume hood.

O'Hara added the system's unique abilities will help standardize analyst technique, improving reproducibility.

For more information, visit: www.envexp.com

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TandD www.tandd.com

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Burkert's Type 6624 twin power solenoid valve combines the consistent reliability and industry-proven rocker principle with an innovative new actuator.

That new actuator means improved performance but with a smaller profile, as the 10 mm valve with a 1.6 mm orifice provides a pressure resistance of 2 bar (30 psi) – the same as a 16 mm valve. There are several other benefits to users as well.

"The 6624 rocker valve, with our new Twin Power coil design, allows users to replace a traditional 16 mm valve with a 10 mm valve, saving up to 50 percent of the space that a 16 mm valve would require, and reducing power consumption by 75 percent," said Craig Occhiato, Micro-fluidics Field Segment Manager at Burkert.

He added the 6624's performance-to-size ratio is one of the major features customers are demanding now, along with reduced energy consumption.

"For next-generation instruments, manufacturers are focusing on smaller footprints and lower power consumption while increasing throughput," Mr. Occhiato said. "As more companies adopt green designs and methods in their equipment and labs, these features will become even more demanded."

Because of its rocker design style, the 6624 is a great fit for applications that require low dead volume / low carry-over, no pumping, and no back pressure effects, Mr. Occhiato said.

Such applications include clinical chemistry, hematology, flow cytometry, cell analysis, immunoassay, genomics, bio-defense, drug discovery, chromatography, and environmental analyzers.

The system can also reduce heat transfer into the fluid and is available in a 2-way and 3-way version.

For more information, visit www.burkert-usa.com

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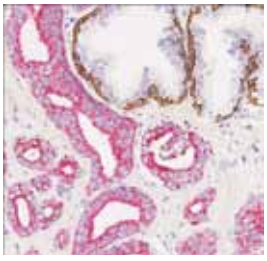

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Real-Time PCR Instruments

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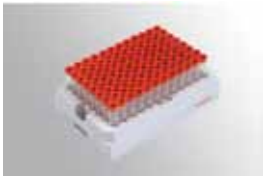

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File Management and Sharing

Problem: Many laboratories generate thousands or even tens of thousands of files of important data which are frequently disorganized and scattered among multiple computers throughout the lab, and even on laptops that end up outside of the lab. Maintaining a complete history means a constantly expanding collection of information, and locating data at a later time is often a challenging task that involves multiple issues including locating the correct computer. When there are multiple versions of the same file, it is often very difficult to distinguish which is the desired one; in many cases, a critical file may have been overwritten.

In addition, an increasing number of laboratories collaborate with others, leading to the challenge of sharing specific data both inside and outside the institution. While e-mail can be utilized for this purpose, keeping track of different versions of data can be very difficult, and many files are too large for e-mail servers to accept.

Solution: File management and sharing software can make dealing with all that data much easier in the lab. For example, LabArchives uses the latest computer technology to provide a web- (or local server)-based software application specifically designed for the storage and organization of laboratory data. In its "hosted" form, LabArchives can be implemented immediately without the need to purchase hardware or install any software. All that is needed is a computer (Windows, Mac, or Linux) and an Internet connection. Much of this software, including LabArchives, also works on iPads and Android devices.

Management software such as Lab Archives also allows each user to customize the organization of their data by dividing it into folders, subfolders, pages, and entries. Each level of information can be viewed by authorized users from anywhere in the world, and every entry is automatically date- and time-stamped by a trusted third-party application (National Institute of Standards and Technology). Furthermore, this software prevents data deletion. For example, no data can ever be deleted from LabArchives Notebooks, and every version of every file is stored securely and redundantly. Instant "Google-like" searching is provided with the software as well, including the ability to locate words in files such as PDFs and Office docs.

Data is stored on multiple-redundant secure servers to ensure complete reliability and nearly 100 percent uptime. If desired, notebooks may be downloaded to local devices for additional copies.

▲*LabArchives Electronic Laboratory Notebook (ELN)*

File management and sharing software includes administrative tools that enable simple sharing of selected information. Users of the notebook(s) may have access to both private and shared information. When collaborating outside of the lab, access may also be granted to specified parties.

This management software can also make using automated equipment in the lab much simpler. LabArchives' optional Folder Monitor utility, for instance, provides an easy-to-configure mechanism to ensure that all generated files are transferred directly to the appropriate notebook. Folder Monitor for Windows is included with a LabArchives subscription.

Compatibility with other software is an important part of many file management and sharing systems. For example, LabArchives includes a built-in "Office Suite" of products, enabling users to create and edit documents that are fully compatible with Word, Excel, and PowerPoint even without having these products on their computers. As with all data, software like LabArchives maintains versions of all edits to these documents.

For more information, visit www.labarchives.com

Analysis of Macromolecular Interactions Using CG-MALS

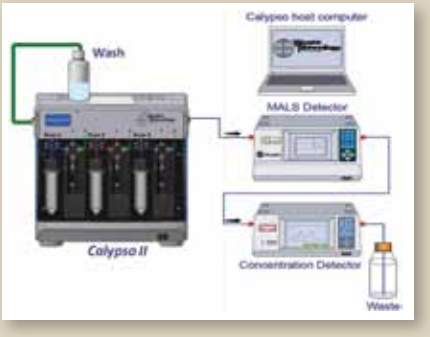
Problem: Macromolecular interactions enact vital functions necessary for life, including DNA replication, transcription, mRNA translation, protein degradation, and signal transduction. It is essential to characterize the intermolecular affinity and stoichiometry of these interactions for a variety of biochemical applications, such as understanding in vivo processes and studying disease pathways. In addition, the development of therapeutic antibodies and other biopharmaceuticals brings the characterization of complex, multivalent interactions to the forefront of biotechnology.

An array of techniques exists for analyzing macromolecular interactions, but many cannot provide a complete picture of a macromolecular interaction. Methods that require tagging or immobilization, such as surface plasmon resonance (SPR) and enzyme-linked immunosorbent assays (ELISA), can potentially influence the interaction of interest since the molecules are no longer free in solution or in their native state. Isothermal titration calorimetry (ITC) and analytical ultracentrifugation (AUC) are both label-free methods that provide quantification of affinity and stoichiometry. However, ITC can only provide stoichiometric ratio—not absolute stoichiometry—and has a limited affinity range, and AUC experiments require many hours to days to perform, which may degrade sensitive molecules. Thus, several complementary techniques are often required to describe macromolecular interactions fully.

Multi-angle light scattering (MALS) has long been coupled with separation techniques, such as size exclusion chromatography (SEC-MALS) and field flow fractionation (FFF-MALS) to provide an absolute measure of the molar mass of macromolecules and define their molecular weight distribution in solution. These techniques allow the analyst to determine the stoichiometry of macromolecular complexes through the combination of information from multiple detectors (MALS with UV absorption, differential refractometry, and/or viscometry). However, these techniques are limited in their study of interactions, due in part to the process of dilution and fractionation.

Solution: Composition-gradient multi-angle light scattering (CG-MALS) enables characterization of macromolecular interactions in solution without immobilization or tagging. This batch technique involves delivery of different compositions of one or more macromolecular species to a light scattering and concentration detector. For each composition, the flow is stopped to allow for slow kinetics and ensure that the solution has reached equilibrium. The presence of interactions is observed as a change in the apparent molar mass of the solution, measured by MALS, as a function of composition.

CG-MALS offers the unique capability of determining both the binding affinity and stoichiometry of all interactions present in solution with no need for immobilization or tagging. This method is capable of quantifying equilibrium binding affinity of self- and hetero-associating proteins with KD from ~100 pM to ~1 mM, kinetics of reversible or irreversible aggregation, and complex stoichiometries including infinite self-assembly. Furthermore, CG-MALS can account for nonspecific intermolecular attraction and repulsion via virial coefficients. The data from CG-MALS experiments complement results obtained from other techniques and can provide additional information about the equilibrium association state that is not accessible to traditional methods.



▲*Calypso II connected in series to light scattering and concentration detector.*

A new technology was recently developed to automate CG-MALS measurements and provide the analyst with rapid, reproducible results. The Calypso system (Wyatt Technology) prepares a sample of the appropriate composition and delivers it to a MALS detector flow cell. All experimental parameters, including injection volume, flow rate, and amount of time the flow is stopped, are easily controlled by the user, and data analysis is facilitated via a graphical software interface. Compared with traditional batch measurements, the Calypso provides a robust platform for achieving fast, reliable results.

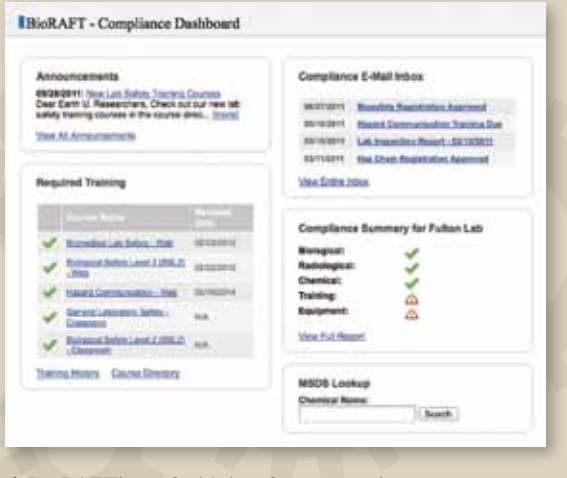
For more information, visit www.wyatt.com/calypso

A Lab Safety Research Management System

Problem: Laboratories are filled with hazardous chemicals, biological materials, animals, and equipment. It's often the responsibility of lab managers to make sure everyone in their lab completes the various safety training, inventory, and individual registration requirements. Managers must also make sure the lab as a whole complies with regulatory agency and internal rules relating to the equipment they use, lab-wide registrations of their research projects and activities, and the proper maintenance of their lab spaces. Yet, few labs come close to managing a comprehensive program. In fact, many researchers do not even receive all of the required safety training. Maintaining the status of safety and compliance is next to impossible using traditional methods such as spreadsheets and binders. Today's laboratories need a new approach and better tools to adequately and cost-effectively manage lab safety and compliance to prevent fines and avoid errors, accidents, and even death.

Solution: Lab safety research management systems offer a solution to manage the complexities of safety and compliance. These software solutions track all of the compliance information required on both lab members individually and the lab as a whole, and manage the cross-references. They enable lab safety managers, for example, to know which equipment has been certified, what equipment is due for testing/calibration and when, which people are certified on each piece of equipment, who needs training and when, and more – all with a click of a button. While there are numerous individual systems that track individual pieces of the equation, the answer lies in research management systems' ability to interconnect information into a cohesive, researchable, and reportable database.

Several commercial solutions are available for managing various aspects of this problem, including from BioRAFT, which provides a unified management and reporting system. Lab safety research management systems replace paper-based tracking systems and multiple individual applications with an integrated suite of modules that track and manage compliance for biosafety, hazardous chemicals, radiation use, and more. These modules eliminate the silos of data that lead to administrative nightmares, fines for non-compliance, and accidents, and cost-effectively increase performance by allowing scientists and other lab workers to concentrate on their work rather than on managing their compliance status.



▲*BioRAFT's unified lab safety research management and reporting system*

Systems such as these accommodate the interrelationships between the labs the scientists work in, the hazards they are exposed to, and each scientist's specific activities in order to set requirements. They enable lab managers to track by multiple criteria, including lab-wide requirements, individual requirements, equipment-specific requirements, chemical or pathogen risk-level requirements, etc. PI's and lab managers can see and modify, on a restricted level, their lab-wide and scientist-specific activities that drive requirements.

Lab safety research management systems also issue auto-reminders to scientists about required training and forms they must complete. This not only removes a time-consuming manual task from the to-do list of lab managers, it raises compliance levels. A web-based interface simplifies and streamlines the process of forms completion and submission. The systems also generate comprehensive reports.

Lab safety research management systems enable laboratories to become safer and to spend less time managing the processes surrounding compliance. Most importantly, they enable a laboratory's scientists to focus on their research, and to do so more safely.

For more information, visit www.bioraft.com or email nathan.watson@bioraft.com

PARTING POINTS

Takeaways from this month's issue:

BUDGETING 101

No one enjoys the budgeting process, but it's something that must be done. If done well, it's worth the effort. Find out some tips on how to get your budget together for the year, such as:

- Start with a SWOT analysis
- Meet with management to discuss constraints/funding
- Also include lab staff to find out budget needs
- Staff scientists/engineers can use software to propose their own budgets

10

20

TO OWN OR NOT TO OWN?

With the current tough economy, leasing laboratory equipment could be the way to go for many labs that must now work with very tight budgets. Though leasing does carry some risk, it also has many advantages, including:

- Flexibility with terms and equipment
- Conservation of working capital and credit lines
- Increased opportunities from not tying up working capital resources
- Tax benefits

26

INTEGRATING SYSTEMS

"Integration" within lab automation is a bit like the word "free" in a store window: It gets your attention and you want to find out more. An integrated lab system can yield highly desirable benefits such as:

- They require less effort to get things done
- Provide improved productivity, streamlined operations
- Produce fewer transcription errors
- Improve workflow and movement of lab data

30

THE EVOLVING SERVICE MODEL

Faced with shrinking budgets, laboratory managers are constantly seeking more effective ways to service and maintain their equipment, which they must now keep operational over lengthening life spans. Some recent service trends are:

- Customers demanding more service resources from manufacturers
- Growth/advancement in OEM service sector
- A move away from exclusivity to a more open service model
- Increased need for savings and improvements year over year

40

iPOD, THEREFORE I HEAR

If you can't hear other people speaking over the sound of your iPod, then it's too loud to be safe in the lab. Here are some tips on how to avoid noise-induced hearing loss through the use of such devices:

- Make sure noise from audio devices/lab equipment combined do not interfere with speech and communication
- Use only one earbud/earphone to leave one ear free for listening
- Develop a policy for audio device use in the lab

ADVERTISER INDEX

Company	URL	Page
A & D Weighing	www.andweighing.com	24
Adam Equipment Inc.	www.adamequipment.com	47
Agilent Technologies	www. agilent.com/chem/CrossLab	5
AirClean Systems, Inc.	www.aircleansystems.com	63
Beckman Coulter Inc.	www.beckmancoulter.com	51
BioTek Instruments, Inc.	www.biotek.com/eon	57
Buck Scientific	www.bucksci.com	32
Burkert Fluid Control Systems	www.burkert-usa.com	2
Caframo Limited	www.caframo.com	45
Conquer Scientific	www.conquerscientific.com	83
Douglas Scientific	www.DouglasScientific.com	21
Drummond Scientific Company	www.drummondsci.com	9
ELGA LabWater / Veolia Water	www.vwr.com/elga	3
Eppendorf North America	www.eppendorf.com	73
EquipNet, Inc.	www.EquipNet.com	83
Erlab, Inc.	www.captair.com	69
GenTech Scientific, Inc.	www.gentechscientific.com	83
Hamilton Robotics	www.hamiltoncompany.com	68
HEMCO Corporation	www.HEMCOcorp.com	71
Horizon Technology Inc.	www.horizontechinc.com	22, 23
IAC Industries, Inc.	www.furnitureforlabs.com	19
IKA Works	www.ika.com	25, 31
INTEGRA	www.integra-biosciences.com	13
KNF Neuberger Inc.	www.labpumps.com	33
Lab Manager Magazine	www.labmanager.com	59, 65
Labconco	www.labconco.com	60, 61,67
Metrohm USA, Inc.	www.metrohmusa.com	7
Mettler Toledo Inc.	www.mt.com	48, 53, 84
OI Analytical	www.oico.com	37
Proton Onsite	www.protononsite.com	41
RADWAG USA L.L.C.	www.radwagusa.com	14
Rudolph Research Analytical	www.rudolphresearch.com	55
Sonntek, Inc.	www.sonntek.com	70
Thermo Fisher Scientific Inc	www.thermoscientific.com	17, 43, 65
Universal Electric	uecorp.com/raceway	27
W.A. Hammond Drierite company	www.drierite.com	6
Waters Corporation	www.waters.com	11, 35

INSIGHTS

Proton Onsite	www.protononsite.com	2
Bioconference Live	www.lasconference.com	23
Buck Scientific	www.bucksci.com	4
Horizon Technology Inc.	www.horizontechinc.com	20, 21
Lab Wrench	www.labwrench.com	7
LabX	www.labx.com	9
Pittcon	www.pittcon.org	5
Shimadzu Scientific	www.ssi.shimadzu.com/FAMILY	24
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