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MAGAZINE

Run Your Lab Like a Business

June 2011

Volume 6 • Number 5

WORKPLACE SAFETY

IF YOU'VE UNDERESTIMATED
THE BUSINESS BENEFITS OF
OSHA'S VPP PROGRAM,
THINK AGAIN

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Protecting your organization's
confidential intellectual property

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Part 2**

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10

WORKPLACE SAFETY

The OSHA Voluntary Protection Program (VPP) brings together management, labor and OSHA in cooperative relationships that build comprehensive health and safety management systems and promote effective occupational programs to protect workers.

Vince McLeod



68

PERSPECTIVE ON: A FOOD & BEVERAGE LAB

The US food sector is experiencing its biggest changes in decades. This year, Congress passed the Food Safety Modernization Act, updating regulations first implemented in 1938. The act greatly expands the powers of the Food and Drug Administration (FDA), whose new clout now includes food recall authority.

Bernard Tulsi



LEADERSHIP & STAFFING

26 The Chocolate Fix

Laboratory managers agree that getting scientists to wear personal protective equipment in the laboratory is a daily struggle. After repeated violations for which the use of threats was ineffective, the author decided a more creative approach was in order—a compliance program based on positive reinforcement with a hint of fun.

Sandra Walker

TECHNOLOGY & OPERATIONS

32 Cell Culture Contamination - Part 2

Having discussed common sources of contamination in Part 1 of this 3-part series, we now look at the use of the CO₂ incubator and its role in providing a safe environment, free from any potentially contaminating microorganisms.

Mary Kay Bates and Douglas Wernerspach

LAB SAFETY

44 Chemical Management Planning for the Laboratory

There are literally thousands of chemicals available and new ones being developed every day. In order to plan chemical storage for the lab, it is ideal to begin with a chemical inventory or at least a list of substances anticipated to be used based on the focus of the laboratory's mission or research.

Vince McLeod

BUSINESS MANAGEMENT

61 Keeping Secrets

Laboratories need to protect their intellectual property if they are to use it to obtain competitive advantage. Intellectual property includes methods of making new compounds, product formulations, catalyst compositions, and design of production equipment and laboratory instruments.

John K. Borchardt

64 Proving Ownership

Fully secure, automated "sign and witness" solutions can be implemented today on any ordinary lab department desktop computer or integrated into an existing ELN. It's possible because of a unique, trusted time-stamping approach called hash-chain-link, "widely witnessed" time-stamping.

Robert P. Flinton

SAFETY FIRST

If you recently participated in our Second Annual Lab Safety and Health Survey, thank you. Survey results will be published in the September issue, where we will find out whether laboratory safety practices have improved or fallen short. Whether it's regulatory compliance, the use of personal protective equipment, or proper waste and chemical management, a commitment to laboratory safety should be job one. As a reminder of its importance, The Laboratory Safety Institute (LSI) has created a virtual Memorial Wall in memory of the more than 300 people who lost their lives in laboratory accidents during the past 100 years.

To visit the Memorial Wall, go to <http://www.labsafetyinstitute.org/MemorialWall.html>

"LSI would like to remember those who are no longer with us. Lab accidents are regrettably too frequent. It is sad when we read reports of fatal accidents that could have been avoided or prevented. Please help us to continue in our goal of making health, safety and the environment an integral and important part of education, work and life."

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CHOOSING THE RIGHT LC-MS SYSTEM 20

Panelists from our February 23rd webinar identify key features to consider when purchasing an LC-MS system. **Tanuja Koppal**

ASK THE EXPERT: 40

HOW TO BEST UTILIZE MASS SPECTROMETRY FOR DIVERSE APPLICATIONS

Stephen Barnes, Ph.D., talks about the changes taking place in the field of mass spectrometry as it migrates from the research lab to a clinical environment, for analysis of small molecules as well as large molecules like proteins and lipids. **Tanuja Koppal**

LAB MANAGER ACADEMY 28

The 'Re-Generation' Process **Ann Fry**

SCIENCE MATTERS 30

How the Younger Manager Gets it Right **Alan Edwards**

SURVEY SAYS

ARE YOU IN THE MARKET FOR A BIOLOGICAL SAFETY CABINET? 48

ARE YOU IN THE MARKET FOR AN HPLC SYSTEM? 56

ARE YOU IN THE MARKET FOR HPLC COLUMNS? 60

PRODUCT FOCUS

BIOLOGICAL SAFETY CABINETS 50

HPLC COLUMNS 51

HPLC SYSTEMS 52

INCUBATORS 58

EVOLUTION OF 42

BIOLOGICAL SAFETY CABINETS

TECHNOLOGY NEWS 76

The latest equipment, instrument and system introductions to the laboratory market.

HOW IT WORKS

SCREENING SAMPLES FOR PERSISTENT ORGANIC POLLUTANTS (POPS) 90

EFFICIENT DRUG DISCOVERY USING OPTICAL LABEL-FREE TECHNOLOGY 92

EXPANDING MS DETECTION LIMITS WITH CAPILLARY ELECTROPHORESIS 94

ADVERTISERS INDEX 96

MARKETPLACE 96

PRE-OWNED EQUIPMENT MARKETPLACE 97

PARTING POINTS 98

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Raising the Workplace Safety Bar... Voluntarily

"We must not think of OSHA as 'the enforcer' here to levy hefty fines when we are caught doing things wrong. OSHA is a resource, one that can help in big ways," says Vince McLeod in this month's cover story. For labs wishing to go above and beyond existing workplace safety standards, the OSHA Voluntary Protection Program's benefits include improved employee morale, reduced turnover and absenteeism, greater pride of place, and, most importantly, better health and safety protection for your laboratory staff.

However, even with the very best workplace and employee safety standards in place, staff compliance can remain a challenge. Someone in your lab forgets to don their safety glasses; someone else is wearing sandals or chewing gum; and another has failed to put on their latex gloves. What's a manager to do? For senior lab manager, Sandy Walker, the answer is chocolate. Turn to page 26 to learn about a sweet incentive plan which, along with a few other tricks, delivered more than 98 percent compliance on all PPE and 100 percent compliance on wearing safety glasses.

Wikileaks in the lab? Maybe.

When it comes to protecting intellectual property, laboratories are no different than other businesses or institutions. In fact, lab employees often have greater access to intellectual property than other employees. In this month's article, "Keeping Secrets," (page 60) John Borchardt reminds managers "to be sure their staff members understand what the confidentiality agreement legally binds them to do. Even experienced employees inadvertently and sometimes knowingly share or even sell the confidential intellectual property of their employer."

In the same vein of protecting intellectual property—in this case authenticity—author Robert Flinton, in his article, "Proving Ownership," (page 64) explains how an electronic "sign and witness" process can ensure indisputable authenticity and long-term legal defensibility throughout the chain of custody while saving hundreds of man-hours and costs each year.

In last month's Lab Safety article, "Use it or Lose It," John Borchardt shared a wealth of information on managing, disposing of and reusing laboratory chemicals. He said that the first step in recycling or disposing of chemicals is to know what you have by maintaining an inventory of all the chemicals in your lab. In this month's Lab Safety feature, Vince McLeod focuses squarely on chemical management planning. To get you started down the right path to safe laboratory operation, he identifies three important first steps: collecting MSDSs and references; developing an inventory system; and instituting a labelling program. Turn to page 44 to learn more.

Lastly, I hope you're in the market for a biological safety cabinet because this month's issue has everything you need to know before making that purchase. If you're curious about the evolution of BSCs—from 1900 to the present—turn to page 42. For a snapshot of trends in BSC design, turn to Angelo DePalma's Product Focus article on page 50. And if you want to know the BSC buying practices of your peers, turn to our Survey Says piece on page 48.

When it comes to all other lab equipment purchases, it's a good idea to start with labmanager.com's Lab Product Resource Pages (www.labmanager.com/?articles.labProductArticles), where you will find the latest product reviews, purchasing roadmaps, and new product introductions for over 40 of the most used laboratory products.

We're here to help.

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WORKPLACE SAFETY

IF YOU'VE UNDERESTIMATED THE BUSINESS BENEFITS OF OSHA'S VPP PROGRAM, THINK AGAIN by Vince McLeod



OSHA celebrated its 40th birthday this year. And to commemorate the milestone, Assistant Secretary of Labor Dr. David Michaels gave some excellent remarks at the Center for American Progress in April.¹ The Occupational Safety and Health Act, created by President Nixon and Congress 40 years ago, recognized that workers deserve workplaces free of hazards and that many workplace injuries, illnesses and fatalities are preventable and not just "acts of God." President Nixon described the Occupational Safety and Health Act as "...one of the most important pieces of legislation... ever passed..." Dr. Morton Corn, appointed as secretary of labor by President Ford, went even further, stating the OSH Act was "a new right in the Bill of Rights—a right to a safe and healthful workplace."

"OSHA has made significant strides in ensuring that all workers have the basic human right to a safe workplace."

The take-away message for us from Dr. Michaels' remarks: The evidence is in, and OSHA has made significant strides in ensuring that all workers have the basic human right to a safe workplace. Consider these statistics cited by Dr. Michaels:

- Work-related deaths are down from about 14,000 in 1970 to 4,400 in 2009.
- Reported injuries and illnesses are down from 10.9 incidents per 100 workers in 1972 to less than 4 in 2009.

- Worker exposures to asbestos, lead and benzene have been dramatically reduced following enactment of specific OSHA standards in recent years.

Clearly, progress has occurred. But 4,400 work-related deaths are still way too many, more than 12 deaths per day. And in addition to these deaths, more than 3 million workers suffer serious job-related injuries each year and many thousands more develop serious job-related illnesses. We can and must continue to do better, because injuries and illnesses can destroy families financially and in many other ways.

Now the big question: How do we keep moving forward with improving working conditions and workplace safety? First, we have to admit that on-the-job injuries, illnesses and deaths can be prevented by using basic precautions specified by existing OSHA safety standards, such as preventing falls, eliminating hazards and exposures, and guarding equipment and machinery. As Dr. Michaels stated, "OSHA doesn't kill jobs; it stops jobs from killing people."

Much more than enforcement—OSHA's safety management program

We must not think of OSHA as "the enforcer" here to levy hefty fines when we are caught doing things wrong. OSHA is a resource, one that can help in big ways. In fact, one OSHA service provides free information and assistance to small businesses before they are cited for violations, making more than 30,000 on-site visits each year. If you feel you have hit a wall, give them a call.

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Safety and Health Program Management Guidelines.² Recognizing that a strong correlation exists among sound and effective safety and health management and a low incidence of occupational illnesses and injuries, OSHA released general guidelines to help businesses and employers to develop systematic policies, procedures and practices to protect employees from job-related safety and health hazards. These voluntary safety management guidelines incorporate four general principles:

- Encourage employers to implement and maintain policies and practices that recognize and protect employees from occupational safety and health hazards.
- Effective programs are able to identify, evaluate and prevent or control general workplace hazards, specific job hazards and foreseeable potential hazards.
- Effective programs look beyond specific regulatory requirements and address all hazards whether or not compliance is at issue.
- Effective practice is more important than the extent of written programs, but as the size and complexity of the work site increase so do the hazards, and written guidance is needed to make sure communication of policies is clear and implementation is fair and consistent.

“One OSHA service provides free information and assistance to small businesses before they are cited for violations.”

At the heart of the voluntary safety management program are four major elements that define an effective program. Based on the cumulative evidence, systematic policies and practices are fundamental in reducing work-related illnesses and injuries and their associated high economic costs including workers compensation, insurance and medical services. Ensuring that your program incorporates these four elements will strengthen safety and health efforts and aid its success:

- *Management commitment and employee involvement.* Management commitment is the motivating force for the business or organization and provides the resources necessary to implement the programs. Commitment by management tells workers that their safety and health are valuable and important to the organization. Employee involvement is paramount and provides a way for workers to take responsibility for protection of safety and health for themselves and their fellow workers.
- *Workplace and job hazard analysis.* An effective management program actively examines the work site and specific jobs to anticipate and prevent

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WORKPLACE SAFETY

unsafe conditions. Regular analysis identifies existing hazards as well as operations that might create new ones.

- *Prompt implementation of hazard prevention and controls.* Once a hazard or potential hazard is found or recognized, elimination or controls are undertaken in a timely manner. Engineering controls, design or redesign are implemented first where feasible. Where engineering solutions to eliminate the hazard are not feasible, controls are put in place to reduce the exposure hazards and prevent unsafe conditions.
- *Health and safety training.* Comprehensive training is tailored to the size and complexity of the facility and the nature of the hazards. Safety training addresses responsibilities of all personnel and is best when tied to job practices and performance requirements.

Recognizing and promoting excellence—OSHA's Voluntary Protection Program

The OSHA Voluntary Protection Program provides official recognition to businesses and work sites that have demonstrated outstanding efforts of both employers and employees in achieving exemplary health and safety. The VPP brings together management, labor and OSHA in cooperative relationships that build comprehensive health and safety management systems and promote effective occupational programs to protect workers.

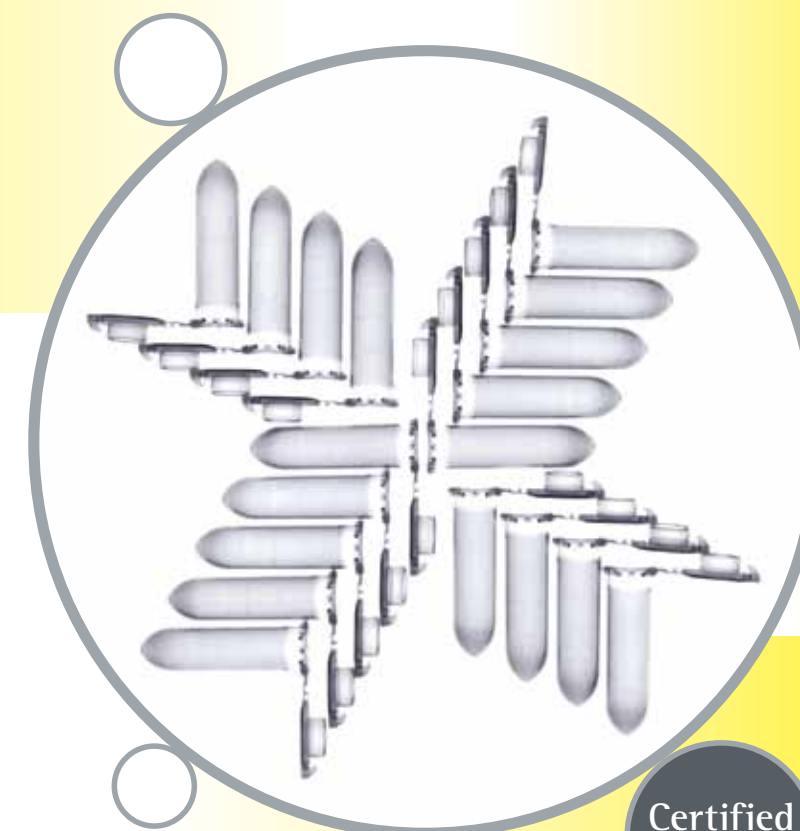
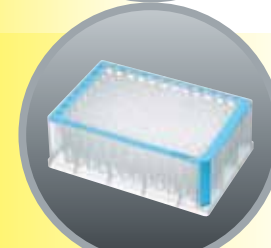
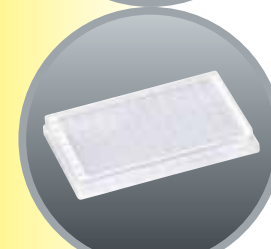
“Effective practice is more important than the extent of written programs.”

The impetus for the VPP was actually stated by Congress in the original Occupational Safety and Health Act of 1970. From section (2)(b) of the OSH Act: “The Congress declares it to be its purpose and policy...to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources –

(1) by encouraging employers and employees in their efforts to reduce the number of occupational safety and health hazards at their places of employment, and to stimulate employers and employees to institute new and to perfect existing programs for providing safe and healthful working conditions;”³

However, it was not until 1982 that OSHA began to approve work sites with exemplary safety and health management programs, thus creating the Voluntary Protection Program. The first word, “voluntary,” is the key. Participants willingly enter the VPP by seeking OSHA approval and gaining acceptance into the program. The VPP sets rigorous performance-based criteria for health and safety management systems and then assesses

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each applicant against these criteria. If the submittals pass OSHA's review and meet all criteria, an on-site verification evaluation is conducted by a team of OSHA health and safety experts. Facilities that pass the site assessment are approved as having achieved one of the three Voluntary Protection Program status levels. Once

qualified for VPP status, work sites must also complete annual self-evaluations and submit to periodic on-site assessments to retain that status.

There are three levels or categories within the VPP. VPP Star is the highest level of recognition, designed for model work sites that have realized comprehensive and successful health and safety management systems while achieving injury and illness rates far below the national averages for their industry. VPP Star participants meet all VPP performance criteria. VPP Merit, the next level, is intended for workplaces that show the potential and commitment to rise to Star status within three years. Merit-level VPP participants express the willingness to reach the highest level, but some aspects of their programs need expansion or enhancement. The last category is Star Demonstration. Participants in this category are testing alternative or new safety and health programs to achieve excellence that might lead to changes in VPP criteria. Once a workplace is approved, the company can begin using the appropriate VPP banners, flags and logos for recognition of superior safety and health performance.



Is it worth the extra effort? Does VPP work?

Is the VPP successful? We all know that programs that are not successful are left to fade away or given the axe. This is definitely not the case for the VPP. Since the program's inception, the number of VPP participants has

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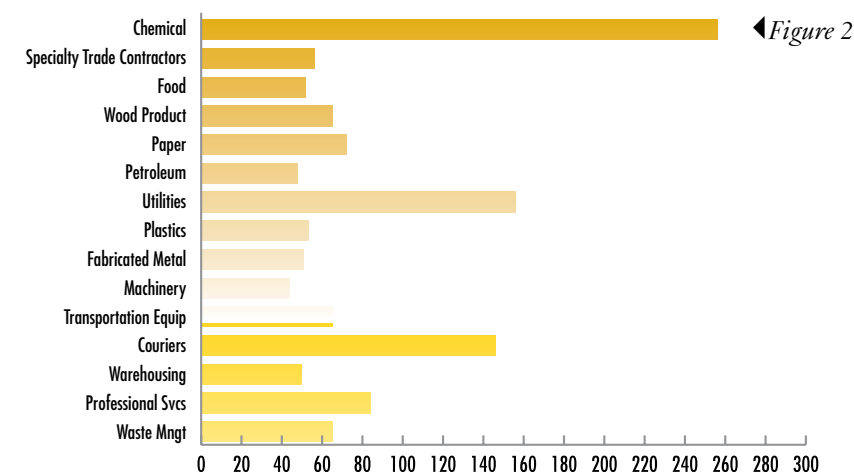
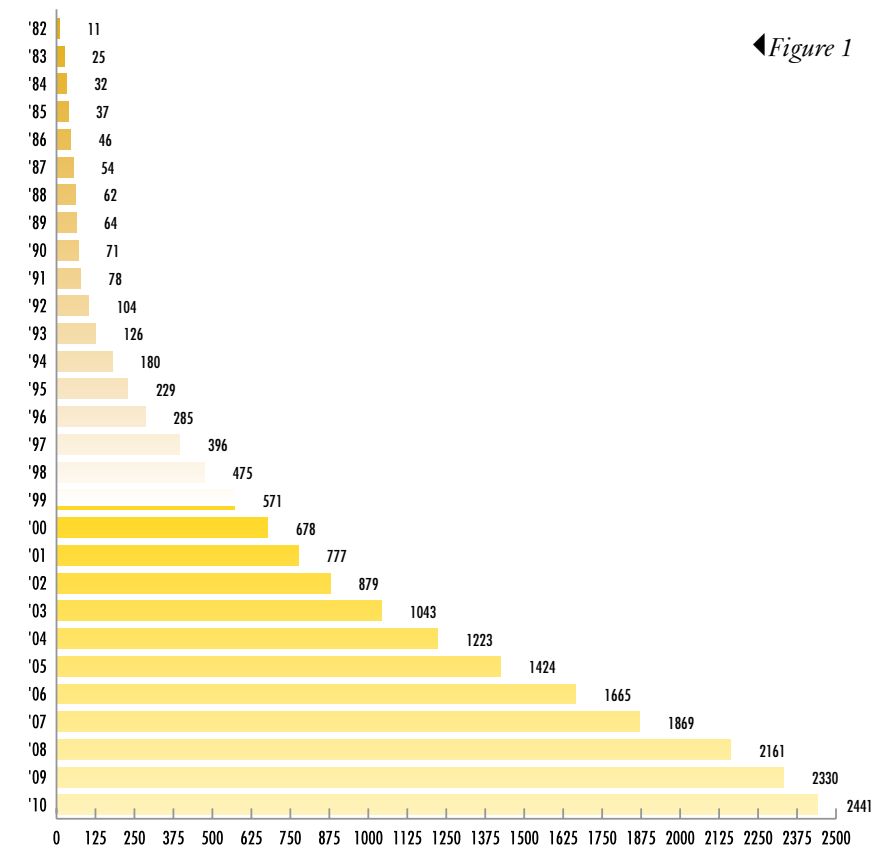
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increased steadily to more than 2,400 sites at the end of 2010. Figure 1 shows overall growth during the nearly 30-year life of the program. VPP participants are from a diverse array of industries representing more than 180 distinct industry classifications, from petrochemical plants to federal laboratories (Figure 2). And most of the participants are small work sites with fewer than 100 employees (Figure 3).



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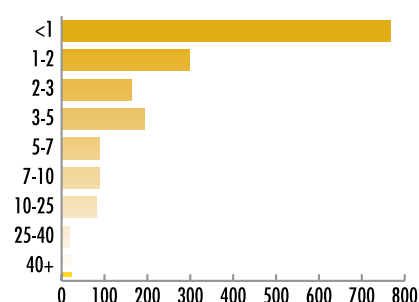


Figure 3

Everyone wants to know how attaining VPP status benefits your work site. The bottom line is that there are many positives, both tangible and intangible. It is worth the effort because, realistically, if you are in compliance now, attaining VPP status is not going to be that much extra work. VPP participants' statistics are impressive. VPP work sites generally have lost-workday case rates significantly lower than the rates experienced by average work sites. In fact, the average VPP work site has a Days Away, Restricted or Transferred (DART) case rate 52 percent below its respective industry average. Other tangible benefits in addition to reduced accident, injury

and illness rates are decreased workers' compensation costs and potential rebates from workers' comp and liability premiums, as many carriers are offering incentives for performance. OSHA reports that VPP work sites have saved more than a billion dollars since the program began in 1982.⁴

On the intangible side, OSHA's experience from the VPP indicates that effective management of safety and health greatly enhances the work environment. Obviously, the reduced DART rates lead to increased employee productivity and less disruption, especially important in small, tightly knit work teams. But improved employee morale, lower turnover and less absenteeism are

"Participants willingly enter the VPP by seeking OSHA approval and gaining acceptance into the program."

also frequently reported by VPP participants. Perhaps the greatest rewards stem from the sense of pride felt by all involved, including management, health and safety directors, supervisors and frontline workers. There is also a sort of community pride both among industry peers and with the general public, knowing that your company has taken steps above and beyond strict regulatory compliance to protect the health and safety of your workers.

Snapshot of a local case study

United Space Alliance, a NASA contractor at the Kennedy Space Center in Florida, achieved VPP Star status nearly nine years ago and has maintained it ever since. It was tough at first; as the company grew and acquired smaller contractors, it discovered that some safety programs needed much work and improvement and others were missing altogether. But by reaching for VPP, the company was able to develop and implement one program and a singular way to assess safety across multiple work sites and different divisions. Gaining VPP status brought a 15 to 25 percent drop in accident and injury rates

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for the various divisions in the company. One segment of the company with fewer than 100 employees had its recordable injuries go from 25 per year to zero, earning the segment a \$47,000 rebate on its workers' compensation premiums and another \$48,000 from its liability carrier. But the biggest reward was perhaps the fact that the programs instituted as a result of the VPP were directly responsible for saving three lives. That is a statistic that everyone can point to and feel very good about. Isn't it time you considered participation in OSHA's VPP?

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CHOOSING THE RIGHT LC-MS SYSTEM

PANELISTS FROM OUR FEBRUARY 23 WEBINAR IDENTIFY KEY FEATURES TO CONSIDER WHEN PURCHASING AN LC-MS SYSTEM by Tanuja Koppal



HAYLEY CROWE



DIAB ELMASHNI



ROBERT CLASSON



FRANK STEINER, PH.D.

In March 2011, *Lab Manager Magazine* organized a “Product Showcase” webinar focused on the new features and applications of LC-MS systems, which are analytical systems involving liquid chromatography (LC) separation coupled with mass spectrometry (MS)-based detection. The webinar featured a panel of four experts representing some of the leading vendors in the field, who provided their perspectives on the trends in the LC-MS market and what users should consider when deciding which LC-MS is right for their lab based on their samples and applications. Once again, this on-line event attracted a large international audience from diverse industries who were looking for an opportunity to interact with the panelists in real time and get their advice on the key factors they should consider when making their buying decisions. Each panelist gave a brief presentation to outline the latest in LC-MS systems and to help users decide which one is right for them. Webinar participants included:

- Hayley Crowe, *Mass Spectrometry Detection Specialist, PerkinElmer*
- Diab Elmashni, *Senior Marketing Manager for LC and LC/MS, Thermo Fisher Scientific*
- Robert Classon, *LC-MS Business Development Manager, Shimadzu Scientific Instruments*
- Frank Steiner, Ph.D., *Manager for Small Molecule Solutions, Dionex Corporation*
- **Moderator:** Tanuja Koppal, Ph.D.

Below are answers provided by the panelists to attendees’ follow-up questions.

Q: If you already own an LC-MS system, when do you know it’s time to upgrade? What are some of the advantages of transitioning to a UHPLC-MS?



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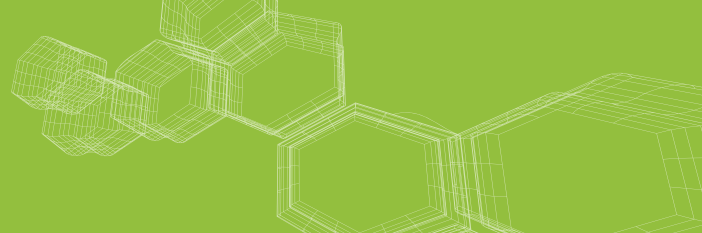
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Crowe: The UHPLC technology has proved to be a powerful approach for improving chromatographic analysis in terms of throughput and resolving power. When it is coupled with MS, users are getting more information, better response time for process monitoring and product release, and ultimately more samples analyzed per day.

Elmashni: It is time to upgrade your LC-MS when its level of performance is no longer suitable for your needs or when it is too slow to keep up with newer technology such as the speed of UHPLC. Also, as MS instruments age, if they are not refurbished, they tend to lose sensitivity as the internal components age. The advantages of transitioning to UHPLC-MS are that it provides the user with a much higher throughput, lower solvent costs, and shorter method development times. UHPLC also provides better separation than traditional HPLC.

Classon: The choice should be application-driven. If your old instrument isn't sensitive enough to detect or quantify at the levels you want, then you should consider an upgrade. However, do not assume that a more sensitive instrument will be suitable for all applications. Quite often the problem is sample prep or chemistry-related. But if you need faster speed to improve productivity or throughput, then consider the LC-MS instruments that have been introduced in the past year. There has been a considerable increase in speed in many of the more recent instruments.

Steiner: Mass spectrometers for LC have made significant progress in sensitivity and speed, and also have improved in mass resolution and accuracy. At the same time, electrospray sources have been optimized for higher sensitivity even at increased flow rates. High scan speed to achieve data rates of more than 20 Hz are crucial in order to benefit from the throughput potential of UHPLC on short- and medium-length columns. If the typical 2.1 mm internal diameter (id) columns are to be used at highest speed, the MS should support flow rates of 1 to 2 mL/min without significant loss in sensitivity. A transition to LC-MS with an appropriate instrument and software

combination can significantly boost lab productivity and data quality, thus increasing value in all markets.

Q: What are some of the key challenges around sample prep, carryover, and cleanup for LC-MS and how can you minimize those problems?

Crowe: A significant breakthrough in LC-MS functionality is the snap-in probe design. The probes can be specific to a user, application, or sample type, helping to minimize the risk of carryover, cross-contamination, and instrument downtime.

Elmashni: Samples injected into an MS detector must be cleaner and smaller in quantity than those injected in a UV detector. Carryover becomes extremely important when you add an MS detector, because the level of sensitivity is so high that it can easily see carryover that would not be seen in a UV detector. Carryover can make your sample appear larger than it really is, thereby giving you false results. An MS detector requires cleanup in the source and the source housing because the sample is sprayed at the analyzer. If they are not cleaned regularly, it will cause carryover.

Classon: With UHPLC chromatography columns, the frits and packing can clog easily. So sample cleanup, especially how you remove proteins from biological matrices, becomes quite important. Faster chromatography also means a greater probability of having co-eluting components that could affect ionization and make quantitation more variable. Solvents too may require filtration to get longer life out of the pump seals.

Steiner: LC-MS does not normally require different sample prep or cleanup than other LC techniques for accurate short-term results. Long-term signal stability of ion sources generally improves with matrix removal, although good progress on auto-clean options has been made on the MS side. The UHPLC part can be more demanding as small particle columns with finer-mesh retainers clog more easily. Small-volume, high-resolution



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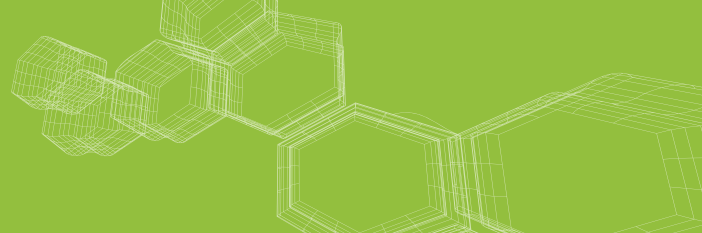
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columns are less forgiving of solvent mismatch (if sample solvent elutes stronger than mobile phase). This can be addressed by smaller injection volumes, but at higher detection limits. Smallest sample carryover is a key metric but must be assessed based on identical compounds and injection/ needle wash procedures.

Q: What are some of the key factors that need to be considered when choosing the right software for data analysis and data integration?

Crowe: Modern LC-MS instrumentation generates a lot of data very quickly. Being sure the reported results are correct is critical to any analytical laboratory. Things like homogenized data treatment, high accuracy of data processing and result analysis, and high-throughput review of results are paramount for productivity and ease of use.

Elmashni: With MS detection, every vendor controls only their own instrumentation. This is not the case with HPLC/UHPLC, mainly because the software control for MS detectors is very labor intensive and has proprietary information that assists in the performance of the MS detector. Ideally, you would look at the different features with respect to ease of use, standard data reporting templates, and customized software options for your specific application and choose the one that works best for you.

Classon: Pick the software that is easy to use and protects the instruments from doing things that might lead to contamination or clogging. Most instrument software will check to make sure you have liquid flow and gas flow before making injections, or will start up or shut down properly in the event of a power outage. Although such events might not occur often, it is very worthwhile to have the software protect everything from even a temporary power interruption.

Steiner: This depends on what the focus is. MS software packages provide good tools for de-convolution on the mass axis and support all the tandem MS features, but are usually not as good to assess peak shape and separation quality parameters on the time axis, which is crucial for the chromatographer. Accurate peak integration for quantitation is usually better supported in LC software, and this recently underwent significant improvement in some chromatography data systems. Ideally, the user should be free to choose his hardware-software combination and be able to use the best of both worlds to his advantage.

Q: How important should factors like technical service and warranties, user training, and availability of supplies and accessories be in your decision making, and what's the best way to get information about them up front?

Crowe: In today's challenging environment, having a complete solution is critical for the laboratory's performance. Ease of use, cost of operation, and cost of maintenance of the equipment can sometimes be even more important than the pure instrument performance, especially in a QA/QC environment.

Elmashni: These items are extremely important when choosing an MS vendor. MS detectors cannot be serviced by the user, so it is very important to have a vendor with a fast-responding and competent service organization. The same goes for user training. These are very difficult instruments to learn how to use, and the user training is vital to becoming efficient on the instrument. Supplies and accessories are important because a vendor who has all the items provides the customer with time savings, better negotiating power for discounts, and the certainty of getting the specific parts for that instrument.

Classon: I recommend getting to know your local service person/manager. Warranties are nice, and training can be helpful, but when something needs repair or adjustment, it is the people that matter. A lot of companies have tried single-vendor repairs for all products and some have been disappointed with the reliability of repairs or the non-factory parts that have been utilized. Stick with people you can trust.

Steiner: The more technically advanced the analytical instrument, the more crucial these criteria are. While modern instrument development increasingly focuses on robustness, usability, and serviceability, this still provides an intrinsic challenge both on the LC and the MS side. Hence, a critical comparison of the complete package is mandatory. The best way to get information is to speak to the vendor's customer base, e.g., at conferences and user meetings, but ideally speak to people who you can trust. Opinions in forums can sometimes be misleading as one never knows exactly how the information was introduced there. Social media are another emerging source of information.

Q: In what areas of LC-MS can users expect to see most changes and improvements in the near future?

Crowe: Chromatography might become less critical in some quality control assays. The advent of direct sampling analysis for MS ion sources is providing the opportunity to minimize sample prep or to deal directly with samples with no preparation at all. This allows one to run many samples/hour and eliminate artifacts.

Classon: Improvements in sensitivity will continue, but we are getting close to the practical limit now. We may see some greater convenience features in new models and improvements in speed and mass accuracy. I expect to see more development of ambient ionization sources, increased use of ion mobility technologies in the high pressure/ambient regions of the instrument, and perhaps some overall size and cost reductions.

Elmashni: Software is going to be the next major development area. As more laboratories employ technicians to run standard testing, the software of the instrumentation has to be conducive to that environment by making the detectors easier to use and maintain.

Steiner: The current technical progress will not slow down, and we will see further improvement in specifications on both the LC and MS fronts. Hopefully there will be more new LC columns with low bleed that allow benefits from improved LC instrument specifications. A strong focus of the development will certainly be on ease of use and instrument uptime. Both will be enhanced through development on the hardware side, but even more important on the software side, where the worlds of LC and MS are yet far from being fully integrated. Further improved integration of method development and sample prep into the automated instrument workflow is another driver for development in the near future.

To view the archived webinar, please visit www.labmanager.com/lcmsshowcase. The website also hosts a number of LC-MS systems-related articles, application notes, and information on upcoming events and webinars.

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THE CHOCOLATE FIX

HOW ONE LAB'S SWEET EXPERIMENT DELIVERED 98 PERCENT PPE COMPLIANCE
by Sandra Walker

Laboratory managers agree that getting scientists to wear personal protective equipment (PPE) in the laboratory is a daily struggle. After repeated violations for which the use of threats was ineffective, I decided a more creative approach was in order. Following the principles of operant conditioning explained by Karen Pryor in "Lads Before the Wind, Adventures in Porpoise Training," my company began a compliance program based on positive reinforcement with a hint of fun.

Dubbed the CIP (Chocolate Incentive Program), the program was introduced in January 2010 with the viewing of a YouTube video on lab safety (<http://www.youtube.com/watch?v=WZ-1lfammjk&feature=related>). The incentive program was outlined with the following rules:

- 1) Anyone entering the laboratory must wear safety glasses. No open-toe shoes or food (including gum or mints) allowed at any time.
- 2) Scientists working on the bench must also wear gloves and a lab coat.

Based on random inspection, every laboratory worker who is NOT found out of compliance is given a Lindt (Lindor) chocolate truffle at his desk. (Scientists spending the day working at their desks are assumed to be in compliance.) If a scientist is found to be in violation: no chocolate. Candy is handed out two to three times per week and inspections are random.

The Lindt chocolates were chosen for a number of reasons. This is an upscale brand that comes in a variety of flavors. All Lindt chocolate truffles come individually wrapped and are color coded as to flavor. Part of the

"game" was the scientists becoming familiar with the colors and flavors and developing specific preferences. (An aside, when I attempted to substitute an "inferior" brand of chocolate, the attempt was met with open hostility and the Lindt were immediately reinstated.)

In addition, there are monthly draws for \$25 and quarterly draws for \$100 cash. (This constitutes the Random Jackpot element of positive reinforcement.) At the beginning of each month, each scientist is given three tokens toward the monthly raffle. Anytime he is not in compliance he loses a token. An additional token can be earned by having a properly labeled and maintained laboratory bench (checked during random inspections). At the end of the month all outstanding tokens go into the draw. Quarterly winners are drawn only from those lab workers who are 100 percent compliant for the three-month period. Winners are announced in a public lab meeting.

Besides the obvious rewards involved, full compliance requires buy-in from the corporation for creative funding as well as from all the managers for their daily support. We started by researching why employees were loathe to wear safety glasses. The reasons were universal: Glasses are uncomfortable and they look "dorky." So we went online and discovered Bolle Lightweight Safety Glasses. These are French designer glasses that come "silvered" and are both comfortable and "cool" looking. They were an instant hit with the younger scientists. A little negotiation with the company (Optics Planet.net) brought the price down from \$12 per pair to a little over \$8 when we purchased in lots of 50. We added a range of other (less chic) styles as well as corporate-purchased prescription



Photo and permission by Lindt chocolates.

"Full compliance requires buy-in from the corporation for creative funding as well as from all the managers for their daily support."

◀ Dr. Joe Salas and Tamera Asbworth, Biogen employees.
Photo credit: Stacie Seidel

safety glasses in a variety of frames to further add to the employee choices.

We did similar studies on gloves and settled on Kimberly Clark Safeskin and Evolution One for powderless latex and Safeskin Nitriles for nonlatex. Glove comfort improved compliance.

Lab coats are provided in cotton and disposable tyvek with knitted cuffs. One improvement was to lower temperatures in the laboratories so that lab coats are not only more comfortable to wear but help scientists keep warm.

Throughout the process, the laboratory manager and fellow supervisors are vigilant in encouraging the use of PPE. Small improvements are noted and rewarded, and complete behavioral turnaround from noncompliance to total PPE compliance is quietly rewarded with a jackpot bonus.

Results

Sixteen months after the project's inception, the scientific laboratory staff is more than 98 percent compliant on all PPE and 100 percent compliant on donning safety glasses, based on our routine inspections. (The idea that wearing PPE would become second nature, like buckling an automobile seat belt, has proven valid.) The program is very popular with the employees who are instrumental in teaching new hires the many benefits of compliance. Peer pressure has been a major contributing factor in the success of the program. An added incentive is the biological boost that chocolate, with its mood-enhancing qualities, can provide during the mid-afternoon biorhythm low. With the timing of rewards at between 2 and 3 p.m., the lab workers are greeted by the treat when returning to their desks after a long day in the lab.

The cost to the company has risen from \$50 per month in chocolate to \$150 to \$200 per month, as now approximately 150 chocolates are earned each week in a 50-employee, three-day rotation. (The chocolate can be purchased on sale or with bulk discount.) The overall cost of compliance is \$700 in cash awards and \$2,400 in chocolate per year. The savings in injuries?—Priceless.

Sandra Walker, Senior Laboratory Manager, Biogen Idec Hemophilia, can be reached at Sandy.Walker@biogenidec.com or by phone at 781-522-4162.

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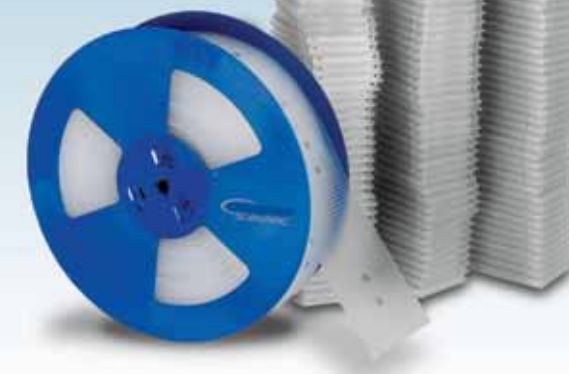
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THE 'RE-GENERATION' PROCESS

NO MORE STATUS QUO by Ann Fry



We probably all have things that we say to ourselves when we are trying to push toward something new or different. Some of mine are: "Enough is enough," "Wake up," and "Aw, what the heck, do it anyhow." The last one is to give me courage to try something new and different, especially when I have some fear or I feel stuck. We are living in challenging times. No one will deny that. People have lost jobs and huge percentages of their wealth. People who still have jobs are holding onto them with their fingers crossed that it stays that way. In some ways, with fewer options available, people are "staying put" and not rocking the boat. They are settling for "the status quo."

Interestingly, labs are doing much the same thing. They are trying to maintain a sense of equilibrium and calm in the face of turmoil. They're pushing people to their limits, trying to do more with less. They continue to stick a square peg in a square hole, rather than creatively figuring out how to put a round peg in a square

hole. They go back to the drawing board, analyze why things might not be working, spin their wheels, and then often end up not doing anything differently. However, if what used to work is no longer working, then you have two choices. You can continue doing what you're doing in the same old way, or you can learn how to regenerate/reinvent yourself and your workplace.

To regenerate means to re-create, or make over; to revive or produce anew. It's this revitalization that will keep you original, fresh and on top of your game. Here are a few tips:

1. Be willing to look at how things are, tell the truth about them and then take on creating change.
2. Stop doing the things that no longer work effectively. While you might not yet know what to put in their place, the truth is that you must first stop. Staying in the status quo is what causes the "stuck" places that we get into.

3. Work in teams to brainstorm and harness new ideas. Allow all ideas to be on the table. Meet regularly and allow lots of input.
4. Then, start trying out new things ... one at a time. See how they work, get feedback and forge ahead.

Remember the exhilaration you felt when you started your career and were excited about what you could bring to the table? You were filled with passion and purpose. I invite you to re-ignite that feeling, trust that change is possible, and work with others to create new and different directions. Tough times call for creative ideas. "ReInvention" is a way to tackle the old and bring in the new. Aw, what the heck ... give it a try.

Ann Fry, MSW, The ReInvention Hot-shot!, is a Professional Speaker/Executive Coach and founder of "We Are Booming: Helping Individuals and Companies Reinvent at Any Age, Stage or Circumstance." Ann can be reached at ann@annfry.com or by phone at 646-895-9295.

LABCAST

If you missed Ann Fry's Lab Manager Academy webinar "The Re-Generation Process: How to Re-Energize, Re-Purpose, and Re-Invent Your Lab," originally broadcast on Wednesday, June 1, visit www.labmanager.com/regeneration to watch the archived video.

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HOW THE YOUNGER MANAGER GETS IT RIGHT

No matter how old or young workers may be, certain management principles are usually effective: make them accountable for their work, treat them with respect, and say thank you. These principles have value whether you work at a large corporation or in a small scientific laboratory.

But even when you have a general plan for effectively managing your lab's workforce, it is crucial to recognize that the workplace is not

the same as it once was. It has evolved from a traditional place in which people spend their entire

careers to one of "versatility", a change that demands the ability of both employees and managers to adapt on a regular basis.

This is particularly crucial for those in their twenties and early thirties—dubbed by the media as "millennials" or "Generation Y"—who are increasingly taking on management roles that would not have been available to them years ago in a more traditional setting. As a result, these young professionals are often put in the position

of navigating a multigenerational workforce. At the extreme end of this scenario, younger managers can end up managing people who, at least age-wise, could be their parents. While there's definitely the potential for conflict and awkwardness, younger managers will succeed if they are able to adapt to the generational differences and similarities that are certain to have an impact on the relationships with their employees.

"Younger managers can end up managing people who, at least age-wise, could be their parents."

The first step is to focus on the fact that younger and older workers are not as different as they seem. It might come as a surprise that millennials and those of the older generation—the "baby boomers"—actually are similar in many key areas despite common concerns about how to bridge the generational divide in the workplace. In this age of e-mail and social networking, for instance, Gen Y managers actually prefer face-to-face communication just like their baby boomer colleagues.

Recent results of the Kelly Global Workforce Index™ also indicate that people still in the infancy of their careers and those who already have climbed the ladder want the ability to be mobile in their work and to pick and choose what jobs are right for them. Both groups are aware that money is not necessarily the most important thing when it comes to being happy on the job. And both groups recognize that there must be value in their work

in terms of the societal relevance of the products or services produced in order to derive any

amount of satisfaction from their careers. Joint clarity on intent and purpose helps align employee teams striving to achieve shared goals and realize a company's vision.

So instead of approaching baby boomers as people who have a completely different work philosophy, younger managers can harness these strong similarities between the generations in order to discover common ground. Taking this approach ultimately will help every employee contribute to a lab's business goals and be as productive as possible.

Also know, however, that generational differences do not exist in a vacuum. All employees in the workplace are influenced by their individual experiences and worldview as well as the time in which they grew up, which is why it can be a mistake for younger managers to manage with a "one-size-fits-all" approach. In fact, the better one can recognize both generational commonalities and uniquenesses, the better one can establish a sense of unity in a company culture. And the so-called softer skills regarding the integration of individuals into the workforce are playing an ever-increasing role in the productivity of a company.

"Young professionals are often put in the position of navigating a multigenerational workforce."

Take the time to consider how an employee's experiences affect his or her work, as well as how workplace concepts such as success and performance can sometimes mean different things to people who have been in the workforce much longer.

By always being aware of an individual's work values and sources of personal satisfaction, the younger manager will succeed in creating an optimal work environment in which that worker will be the most productive.

Alan Edwards is senior director and product leader of the Kelly Services® Americas Products Group—Science. Kelly Services, Inc., a leader in providing workforce solutions, is headquartered in Troy, Michigan. For more information, visit kellyservices.com. Alan can also be followed on LinkedIn (linkedin.com).

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CELL CULTURE CONTAMINATION

— PART 2

THE ROLE OF THE CO₂ INCUBATOR
IN REDUCING CONTAMINATION

by Mary Kay Bates and Douglas Wernerspach

This is the second in a three-part series on cell culture contamination.

As mentioned in the first installment of this three-part article series, biological contamination is a serious issue for every cell culture laboratory. With implications for the reliability of resulting data, it is vital that the occurrence of contamination is kept at an absolute minimum. Having discussed common sources of contamination, here we look at the use of the CO₂ incubator and its role in providing a safe environment, free from any potentially contaminating microorganisms.

“Good laboratory practice is the most effective way of preventing contamination.”

Cell culture relies on the use of incubators to maintain the right conditions for keeping cells alive. The CO₂ incubator specifically aims to simulate mammalian physiological conditions. Therefore, the incubator combines the elements needed for cells to thrive: a stable temperature at 37 °C (98.6 °F), a controlled pH of 7.4 to 7.6 balanced with a controlled CO₂ level and a high relative humidity of 95 percent. Unfortunately, the ideal environment for mammalian cells also provides an ideal environment for a range of biological contaminants that are normal flora in and on our bodies. This is why it is so important to understand good laboratory practice and how choosing the right equipment can help reduce contamination. Certain CO₂ incubators, for example, have been designed to reduce contamination and can make a real difference in the laboratory setting.

Getting it right: Good laboratory practice

Good laboratory practice is the most effective way of preventing contamination. By wearing a laboratory coat with elastic cuffs to cover street clothes, washing hands

thoroughly before beginning any work with cells and wearing disposable gloves, workers can greatly reduce the potential for contamination. As much as possible, culturists should also avoid touching items such as door handles, telephones, calculators, etc.; avoid wearing jewelry; and tie back long hair. Anyone suffering from a cold or other respiratory infection should wear a face mask to minimize the potential spread of infection.

Working areas and the tops of refrigerators, freezers, storage cabinets and benches should be kept clean, uncluttered and free of dust. Floors should be cleaned regularly, especially corners, to minimize dust and dirt that will circulate as a result of traffic in the room. In addition, laboratory equipment (e.g., mechanical pipettor, vortex, water bath, centrifuge) should be cleaned and regularly checked for signs of contamination.

There is no substitute for proper aseptic technique. Cultures and media should be opened only in the biosafety cabinet and should not be shared between personnel. A common route of contamination is entry by a liquid “bridge” that forms when a droplet of culture medium remains between the culture vessel and its lid or on the neck of a culture medium bottle. It is not uncommon for lab workers to relax their technique after a contamination-free period, as demonstrated graphically by Ian Freshney,¹ who also provides a complete discussion of aseptic best practices that should be standard in every lab.

The CO₂ incubator, as the home for your cultured cells, is a key point where good laboratory practice must be maintained. Remember that the perfect environment for mammalian cells is also an inviting environment for microbial companions. Since the route of entry for any incubator contaminant is through the open door, a working system needs to be established that keeps door openings to a minimum. Try to limit the number of people sharing an incubator to reduce sources of contamination. Set a stan-



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dard and regular cleaning procedure (weekly or monthly) and immediately clean any spills using 70 percent alcohol.

Incubator design: Keeping contamination in check

The design of the CO₂ incubator can be an important factor in the reduction of contamination by biological agents. There are a number of helpful features that simplify cleaning and provide ongoing protection from contamination during routine use. These capabilities differentiate incubator choice, and it is important to recognize that similar options from different manufacturers will not necessarily provide the same results.

“Cultures and media should be opened only in the biosafety cabinet and should not be shared between personnel.”

Easy to clean

When the incubator is easy to clean and features minimal internal surfaces, the presence of microbes can be significantly controlled. An incubator with rounded corners eliminates cracks and edges where microbes can hide and prosper. Surfaces that are electro-polished remove tiny depressions that would otherwise serve as hiding holes for germs.

There are a few good rules to follow when cleaning an incubator:

- Remove all cultures from the incubator and turn it off.
- Remove all separate internal components of the incubator and clean them using a soapy disinfectant.
- Sterilize all removable parts in an autoclave.
- Thoroughly clean all interior surfaces and then apply a disinfectant to all surfaces and allow it to dry. Any remaining residue can be removed using distilled water.
- Wipe all surfaces with 70 percent alcohol and allow them to air dry.
- Disinfect the outside doors and handles of the incubator using 70 percent alcohol.

If a water pan is present, adding a safe antimicrobial agent to the water is a good idea. Use distilled water in the pan and change it every week. Be sure to wear gloves and

a lab coat throughout the cleaning procedure to minimize the introduction of new contaminating organisms.

► *External water reservoirs eliminate a potential breeding ground for contaminants inside the incubator.*



High-temperature disinfection

A convenient option available on some incubators is an automated high dry-heat or moist-heat disinfection cycle. Most of these are designed to be run overnight with an empty incubator. High-heat disinfection offers an effective way to ensure that the interior of the incubator is free of germs when your cells first enter the incubator after a cleaning cycle. There are different options available from different manufacturers, but not all of these are similarly effective,^{2,3} and users should decide which option will best suit their needs.



◄ *On demand decontamination cycles eliminate the need for autoclaving or use of toxic chemicals inside the incubator.*

While the disinfection cycle does not eliminate the need to routinely clean the incubator, it can remove the

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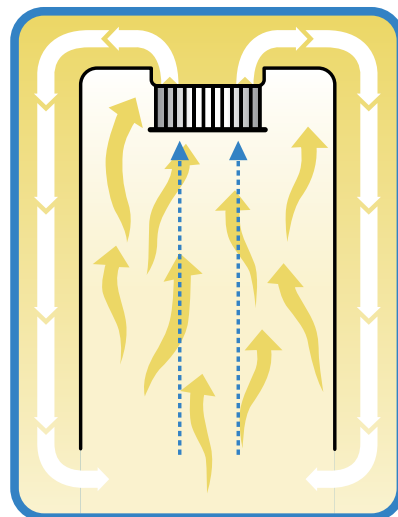


need to separately autoclave internal components and eliminates the risk of “resident” contamination.

Air filtration

A popular feature available on some CO₂ incubators is a HEPA filter, which will filter the internal air, removing microbes, particulates, aerosols and even, in some cases, volatile organic chemicals. A Class 100 HEPA filter should quickly provide clean-room air quality so that any contamination entering through the door is removed.

Consider the time that it takes to achieve maximum air quality after a door opening, especially if frequent door openings are inevitable. This recovery time can vary depending on the manufacturer.⁴ HEPA filters require little maintenance but should be replaced on a regular basis (i.e., every six months) for best results.



▲ In-chamber HEPA system surrounds cultures with Class 100 (ISO Class 5) cleanroom-like air quality.

Antimicrobial surfaces

Historically, copper has been used as a way to control microbial contamination, including that of bacteria, viruses and fungi. Ancient civilizations including the Aztecs, Greeks and Romans used copper as a topical treatment for skin diseases and wounds,⁵ and copper vessels have long been safely used to store water and other foods. Copper can inactivate enzymes and damage proteins in the cell, since Cu²⁺ ions penetrate the pores of cell membranes and react with the -SH groups of enzymes, thus altering protein structure. Stainless steel and aluminum do not inhibit microbial life, and alloys with minimal copper content show much less benefit. The antimicrobial effect is directly related to the amount and quality of the copper used. Pure copper has been proven to be the most effective antimicrobial surface material, with an ability to inactivate methicillin-resistant *Staphylococcus aureus* in only 1.5 hours. Alloys containing less copper, such as brass, show a much slower response and considerably less antimicrobial effect overall.⁵

“... the perfect environment for mammalian cells is also an inviting environment for microbial companions.”

Some CO₂ incubators offer an option of copper interiors to inhibit growth of any germs that may enter the incubator when the door is opened. As noted above, only 100 percent pure copper will eliminate microbial contaminants effectively within minutes. The Cu²⁺ ions in solid copper will not become airborne, so

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cultures in dishes and flasks are not at risk. This is a great way to have continuous antimicrobial protection in the cell culture incubator that will last the life of the incubator while requiring minimum maintenance. Imam El-Danasouri of California Reproductive Laboratories, a long-time user of copper-lined incubators, explains, "...copper incubators reduce the possibility for infection in the humidification water or on the incubator walls."⁶

Protection from external environment

Most incubators come with a solid-glass inner door to protect samples from inadvertent exposure to the outside environment.

sphere inside the CO₂ incubator, the water pan is especially inviting. Antimicrobial compounds, copper wire and even pennies are often added to the water pan. Laboratories with advanced applications or particularly valuable samples may also consider an incubator design that moves the humidifier water source outside the incubator, thus entirely removing this source of contamination from the incubator interior.

Conclusion: Fighting a winning battle

The biological contamination of cell cultures is an occasional problem for every cell culture user. Contamination costs millions of dollars in lost time and materials

"... the disinfection cycle does not eliminate the need to routinely clean the incubator..."

A divided gas-tight inner door will further help to minimize exposure and speed recovery to set conditions after a door opening. This divided inner door may offer three or six separate smaller doors that allow access to specific sections of the incubator without disturbing other areas. The divided inner door reduces any opportunity for microorganisms to enter the incubator, and minimizes the loss of heat, atmosphere and humidity from the incubator.

External water source

Water is required for life, including, of course, microbes. While they enjoy the warm, humid atmo-

every year, which could otherwise be spent on research and development. While cell culture contamination cannot be totally eliminated, because microbes are our constant companions, carefully controlled processes can be implemented that reduce the impact of an episode. Good aseptic technique, a clean laboratory and an understanding of the routes of contamination, including entry to the CO₂ incubator itself, are crucial. Manufacturers of CO₂ incubators are partners in the process and now offer many options that help to minimize contamination of the incubator.

In the third and final article of this series, we will expand on the

preventive measures and technologies mentioned here, enabling you to confidently maintain a contamination-free culture environment.

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« EXPERT: Stephen Barnes, Ph.D.

ASK THE EXPERT

HOW TO BEST UTILIZE MASS SPECTROMETRY FOR DIVERSE APPLICATIONS

by Tanuja Koppal, Ph.D.

Stephen Barnes, Ph.D., Professor of Pharmacology & Toxicology and Director of the Targeted Metabolomics and Proteomics Laboratory at the University of Alabama at Birmingham (UAB), talks about the changes taking place in the field of mass spectrometry (MS) as it migrates from the research lab to a clinical environment, for analysis of small molecules as well as large molecules like proteins and lipids. He also discusses some of the challenges facing MS users, particularly with data analysis and storage, when working with large amounts of MS data.

Q: Can you tell us about the types of MS instruments you have and what you use them for?

A: We cover a very wide range of applications: quantitative pathway analysis; quantification of phospholipids; oxidation and other post-translational modifications of proteins; lipidomics and individual lipids (e.g., prostanooids and isoprostanones); and other small molecules (polyphenols, particularly isoflavonoids). We don't do much in the way of discovery proteomics. We tend to focus on measuring particular compounds that people already know about before they come to us or studying a particular pathway that has been found to be undergoing a lot of changes. What we then do is set up quantitative assays for all the proteins in that pathway. We are also

working in an interesting frontier that I have named "metabolo-peptidomics" or "peptido-metabolomics." Proteins are not just proteins but are sources of peptides, which have different properties than the parent protein, and we have been studying lots of small peptides involved in interesting biology. In our lab we have three hybrid triple quadrupole/linear ion trap MS systems from AB Sciex, including the Triple-TOF (time-of-flight) 5600 and an older matrix-assisted laser desorption/ionization (MALDI)-TOF instrument. We have a specific set of uses for each instrument, and we find that very useful.

Q: Have you seen a shift in the use of MS in recent years?

A: It's coming back to a more precise form of MS. I have done MS since the 1960s, and the interfaces that we take for granted today were not there then. But what we could do was measure the mass of ions very accurately. In the late 1980s with the advent of the modern MS like MALDI, and the electrospray process, the instruments had very high resolution and people were able to apply MS to a ton of things they had never been able to do before. We certainly rode that wave and acquired our first triple quadrupole instrument in 1992. But by many accounts it was a lousy mass spectrometer since it didn't have good mass accuracy, which is what a mass spec should be. So now the field has moved back to high-accuracy MS, and

this is absolutely necessary in proteomics if we have to turn the corner to get to actual clinical usage. Triple quads have been the mainstay of quantitative analysis for the past 18-plus years, and they may still have their place in low-complexity scenarios. But for complex biological matrices, they are no longer enough. The proteome is denser than people seem to understand, and if a mass spectrometer is to be used for clinically meaningful analysis, the mass analyzer for the compound's fragment ions has to have high mass accuracy and high mass resolution—a quadrupole analyzer or an ion trap can't provide that. With newer instruments, like the AB Sciex 5600, instead of collecting one fragment at a time, the instrument collects all the ions with a mass accuracy of about 2 to 4 ppm, and then the odds that you are measuring the right peptide are considerably enhanced. Personally, I think this is a game changer and I suspect that for quantitative proteomics, the day of the triple quadrupole is over.

Q: How should people go about choosing the right MS instrument for their needs?

A: I did an experiment several years ago with a colleague, Dr. Jim Mobley, looking at some protein samples on an ion trap LTQ and on a Q-trap. Both experiments were done on the same day, so there was no day effect. We then put the data into the same informatics format and analyzed it with a single search program.

Stephen Barnes, Ph.D., is the Professor of Pharmacology & Toxicology at the University of Alabama at Birmingham and holds additional professorships in Biochemistry & Molecular Genetics, Environmental Health Sciences, Forensics Science, Genetics and Vision Sciences. He was the Associate Director of the Purdue University-UAB Botanicals Center for Age-related Disease from 2000 to 2011. Dr. Barnes' degrees are in chemistry and biochemistry. His expertise lies in the use of various forms of mass spectrometric techniques to study metabolism of small molecules, as well as in protein chemistry. He has authored 235 peer-reviewed articles and 28 invited chapters. He was the founding director of the UAB Comprehensive Cancer Center Mass Spectrometry Shared Facility from 1993 to 2009. He was recently appointed as Director of the Targeted Metabolomics and Proteomics Laboratory, which supports other NIH-sponsored UAB centers.

My colleague found the same number of proteins that we found, but only 25 percent of the proteins were in common. We have done other experiments since and found that this represents the bias of the instrument. The Q-trap is biased toward measuring peptides with an m/z below 1000, and the ion trap does best for peptides with an m/z above 1000. We got a center grant to perform platform analysis, and I worked with a group of statisticians to improve experimental design to make sure we got rid of such systematic bias. What we found is that each instrument sees a different picture, which is really hard for clinical purposes because you can get different outcomes in different places. The fact that MS is so variable is not quite appreciated.

Q: So where should people turn to for advice when making their buying decisions?

A: I always do a demonstration with the companies that I am interested in. I give a company one half of the sample to run and analyze and then have them analyze the other half for us in real time. We don't just get the data from them, but we want to see how easy it is to get the data. I then ask the companies for the names of their users and I go and talk to these users, which is very important. I have had quite a few people call me, and I have given them forthright advice.

Q: Quality control is probably very crucial in mass spectrometry experiments, right?

A: Quality control (QC) is really important in every lab. There was a period of MS development that I refer to as the "cowboy period," when, God forbid, you repeated anything. Today when we run samples, every fourth sample is a QC sample. Anyone who is a real analyst, particularly in the small-molecule field, is already doing this. People run QC samples and standards; they keep records; they have procedures for determining whether or not to accept an assay. All this has to be translated to the proteomics field if MS has to be used as a more definitive instrument. We spent a lot of money on our laboratory information management system (LIMS) and now everything is monitored by LIMS. When an assay goes wrong, we can track back and find what could have gone wrong. People who use LIMS regularly have found it to make the reproducibility much more effective and sustainable.

Q: Is there anything you do on a more routine basis to run and maintain your instruments?

A: We have service contracts on instruments and we have people who are very well trained. We have made it more efficient and less expensive by doing some of the maintenance ourselves. The companies sometimes advise us remotely and they come in only when we have a persistent problem. We have just about halved our total service cost doing things ourselves.

Q: What are some of the biggest challenges you face today?

A: With MS, we are able to see only part of the proteome, so everyone is trying to get to high resolution, mass accuracy and speed. The outcome is not an instrument problem but an informatics issue. We are generating about 2 terabytes of data a month, on one instrument. At that level we are unable to move the data around on the computer network, and we are now in consultation with the IT group at UAB to try and transfer the data out into the cloud. I am also trying to get some funding to rewrite some of the classic programs that are used in MS into a cloud format so that the data analysis in the future will be done in the cloud. This requires some serious rewriting, and then the data in the cloud can be made more secure than in your building. The other problem is, we don't want to move the data around more than once. We have been doing cost analysis on what it would take to store the data on computers, and that model simply won't work. We are in the same position as those people doing deep sequencing, who are probably dealing with data an order of magnitude bigger than ours. We are now talking about "deep" proteomics and "deep" lipidomics, and they all come with these huge data sets and there is going to be a huge problem with data management.

EVOLUTION OF BIOLOGICAL SAFETY CABINETS

BY JOHN BUIE

Biological safety cabinets (BSCs) are one of the few pieces of laboratory equipment designed specifically to provide protection for personnel, the product, and the environment. They were born from a need to protect researchers from laboratory-acquired infections, from early studies of tuberculosis to more recent studies into hepatitis B and AIDS.

Biological safety cabinets work by capturing and retaining infected airborne particles that are released during certain procedures in the laboratory, thus preventing their inhalation by laboratory workers.

1900-1940 – EARLY BIOLOGICAL SAFETY CABINETS

At the beginning of the 20th century, the German scientist Robert Koch constructed the first 'bio-containment' cabinet after discovering that germs could float in air. Despite various leaks and design flaws, this system allowed Koch to work safely with anthrax, tuberculosis and cholera.

In 1909, the W.K. Mulford Pharmaceutical Company designed a ventilated hood for working with *M. Tuberculosis* in the production of tuberculin. The cabinet used cotton to filter air flowing into the cabinet, and the exhaust air was drawn by a vacuum pump through a flask containing disinfectant.

Despite these early rudimentary biological safety cabinets, scientists continued to die of infections acquired in the laboratory. The incidence of laboratory-acquired infections grew at an alarming rate, with as many as 2,456 infections and 164 deaths by 1940. Particularly common lab-acquired diseases included tuberculosis, Q-fever and the bubonic plague.

In **1948**, the design of biological safety cabinets took a further leap forward when the first biological safety cabinet incorporating many of the design features of the modern cabinet was made available. These features included stainless steel casing, glass viewing panels, interior rear baffle, service piping, exhaust blower, and spun-glass fiber filters, which offered both improved user safety and greater ease of use.

In **1985**, a biological cabinet developed by Thermo Scientific became the world's first safety cabinet to receive TUV-certification, indicating that the unit was independently examined and found to meet specified standards of quality and safety.

In **1978**, Germfree received a patent for a 100% exhaust cabinet - the Class II type B2.

In **1973**, The Baker Company introduced the first mass-produced Type B biosafety cabinet.



▲ The Baker Company's SterilGARD® III Class II Type A2 biological safety cabinet from 1998.

In **1998**, The Baker Company introduced the SterilGard III, the first mass produced bio-safety cabinet with an angled sliding sash for improved ergonomics.

In **1998**, Labconco introduced the Purifier® Delta® biosafety cabinets.

By **1996**, the development of cytotoxic drugs was becoming an increasingly popular area of research. Unfortunately, many conventional biological safety cabinets were ill-equipped to protect users from the dangers of cytotoxic drugs. Thermo Scientific attempted to address this need in 1996 with the first DIN-12980-certified safety cabinet designed specifically for preparing and handling cytotoxic drugs.



▲ ESCO's Labculture® Class II biological safety cabinet.

In **2009**, the Labculture Class II, low-noise biological safety cabinets were first made available by ESCO. These cabinets were developed in response to increasing demands in cell culture, life science and biological safety procedures that required laboratory users to spend longer periods of time working in biological safety cabinets. Labculture® biological safety cabinets were able to operate at sound levels as low as 50dBA, at least 50 percent quieter than any other biological safety cabinet on the market at the time. This helped improve lab workers' concentration, productivity, and safety.



In **2008**, Thermo Scientific launched the advanced Thermo Scientific HERAsafe KS and KSP biological safety cabinets to replace the 1400.

▲ Thermo Scientific's HERAsafe KS-2008 microbiological safety cabinet.

In **2007**, Labconco introduced the Purifier® Logic® BSC with ECM motor technology. Upgrades included digital display and CAP (Constant Airflow Profile Technology), a sensorless system that accurately controls airflow even as HEPA filters load. This design demonstrated that airflow is maintained with only a 1 to 2% difference in airflow as the HEPA filter loads. The ECM motor is 60% more efficient than other types of motors, running cooler and more power so filters last longer.

In **2002**, NSF 49 became the American National Standard NSF/ANSI 49.

In **2009**, The Baker Company, Labconco and NuAire all offered Brushless DC, or variable frequency drive motors on their cabinets to improve energy efficiency.

Also in **2009**, Labconco introduced the Purifier® Cell Logic® with ECM motor technology that allowed a user-supplied microscope to be integrated into the cabinet. Both Logics use sensorless airflow control and feature digital display — an upgrade to the old gauge tool.

▲ Labconco's Purifier® Cell Logic® Class II biosafety cabinets allow a user-supplied telescope to be integrated into the cabinet.

By **2009**, concerns were growing about the amount of energy and electricity required to operate a biological safety cabinet, many of which were in near-constant use.

▲ The Bio II Advance Class II biological safety cabinet from Telstar.



FUTURE OF BIOLOGICAL SAFETY CABINETS

Advances in biological safety cabinet technology have been driven over the years by advances in laboratory procedures. As research has involved increasingly hazardous and intricate work, so the biological safety cabinet has evolved to meet these needs. The design of these units has also become more ergonomic over time, as scientists spend more and more time working within a biological safety cabinet. Recent innovations have included energy-efficient models that address concerns over greenhouse gas emissions and dwindling fuel resources, as well as compact models that optimize increasingly precious laboratory space.

1940

In **1943**, Van den Ende published the first formal description of a dedicated biological safety cabinet. This system created an inward airflow through the use of a furnace, which was also used to incinerate the exhaust air.

During the same year, the first prototype Class III biological safety cabinet was created by Hubert Kaempf Jr., then a U.S. Army soldier at the United States Army Biological Warfare Laboratories in Fort Detrick, Maryland.

Also during the war years, the high-efficiency particulate air (HEPA) filter was developed by the body which later became the Atomic Energy Commission. The development of the HEPA filter had a dramatic effect on the effectiveness of biological safety cabinets, providing substantial increased protection for users.

In **1951**, The Baker Company developed the first clean air work station, representing a significant advance in standards in biological safety cabinets.

1950

In **1965**, The Baker Company introduced the first mass produced, commercially available biological safety cabinet.

Early in the **1970s**, NuAire was awarded the first contract to design and manufacture biological safety cabinets in compliance with the new U.S. specification (NIH-03-112C) for laminar flow biological safety cabinets.

1960

In **1976**, The National Sanitation Foundation (NSF) published NSF Standard Number 49, a voluntary standard establishing minimal construction and performance requirements for listed Class II models, as well as annual unannounced audits of the participating cabinet manufacturers. NIH and NCI abandon their standards and defer to NSF.

1970

In **1983**, The Baker Company published their research relating biosafety cabinet performance to inflow and downflow velocities, developing the concept of a "performance envelope."

Also in **1983**, Labconco offered the first mass produced Class II cabinet with an angled sash for improved ergonomics.

1980

In **1989**, NuAire introduced the NU-427 series of cabinets, the first Class II, type B1 bench top cabinet.

1990

In **1995**, NuAire introduced its LabGard 440-series of cabinets, the first Class II cabinet to use airflow sensors to regulate cabinet operation.

In **1993**, Thermo Scientific introduced the first safety cabinet that offered a motorized front window and aerosol tight window sealing. These innovations improved both user safety and convenience.

2000

In **2000**, Thermo Scientific offered the first Class II cabinet equipped with a brushless DC motor for improved energy efficiency.

Also in **2000**, Labconco introduced the Purifier® Digital Delta® biosafety cabinets, maximizing ergonomics by continuing the slanted sash, making all operable components of the cabinet ADA compliant and the introduction of the curved air inlet grille.

2010

GET A GOOD START

**CHEMICAL MANAGEMENT
PLANNING FOR THE LABORATORY**
by Vince McLeod

One of the most common and important things we Safety Guys deal with is the start-up of new laboratories. As construction is completed, new research buildings open and the labs come online, issues inevitably arise. Related changes we have wrestled with are lab close-outs and new investigators moving to our facility. Common critical issues in these situations are ensuring that proper organization, storage and segregation are provided for the chemicals that will be used and kept in the labs. So this issue's column will provide fundamental information on managing chemicals in laboratory facilities and offer initial suggestions and guidance for proper chemical handling.

There are literally thousands of chemicals available and new ones being developed every day. In order to plan chemical storage for your lab, it is ideal to begin with a chemical inventory or at least a list of substances anticipated to be used based on the focus of the laboratory's mission or research. Your job is much easier with the chemical inventory in hand listing the items and quantities that will be used and stored. Without an inventory, or when setting up a general purpose lab, you will have to plan storage areas for each major chemical class (more on these chemical classes further on). Given the sheer number of chemicals available, even with a good inventory, you will probably need a few reference sources on chemicals and their properties. So, let's get started.

Chemical information sources and references

Since 1991, federal law has required every laboratory where hazardous chemicals are used to have a written Chemical Hygiene Plan (CHP). The CHP includes the

chemical inventory and standard operating procedures for protecting personnel from the health hazards associated with the chemicals present in the lab. If you are lucky enough to have a CHP when an existing lab is moving into a new space, you have a jump-start on planning the chemical handling requirements. Without one, when setting up a new research lab, for example, you will need to do more homework. After checking for a CHP

or chemical inventory, the next task is to collect the material safety data sheets (MSDSs) from the vendors or chemical manufacturers. In order to fill the inevitable gaps in the MSDS, we suggest you combine these MSDSs with a good chemical dictionary or two, such as the *Merck Index*¹ or *Sax's Dangerous Properties of Industrial Materials*.² You will also

want to secure a few quality chemical references such as the *NIOSH Pocket Guide to Chemical Hazards*³ or the *DOT Emergency Response Guidebook*,⁴ or similar compilations.

Material safety data sheets, chemical dictionaries and references like the pocket guide provide essential information on specific chemical substances. Included are data on the physical, chemical and toxicological properties of the substance, along with concise information on handling, storage and disposal. Most of the references mentioned will outline emergency and first aid procedures as well. One other reference that we highly recommend is the National Research Council's *Prudent Practices in the Laboratory: Handling and Management of Chemical Hazards*.⁵ This book contains invaluable information on many topics, including planning experiments, evaluating hazards and assessing the risks associated with waste disposal. It also introduces the concept of Laboratory Chemical Safety Summaries (LCSS) and contains them for 88 commonly encountered chemical substances.

"There are literally thousands of chemicals available and new ones being developed every day."



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General chemical management, inventory and labeling

Prudent management of any laboratory using dangerous substances begins with a chemical inventory. If you are opening a new laboratory facility, we recommend that you consider how chemicals for that location are going to be managed and tracked prior to setting up any new lab where hazardous chemicals will be used. Establish written procedures for acquiring chemicals

and developing the inventory, and ensure that laboratory occupants understand and adhere to them. Keep in mind that in many jurisdictions fire codes and local ordinances may establish maximum limits for both the total quantities and container sizes allowed for the various classes of chemicals.

Chemical inventories can range from simple, such as a listing of each container on an index card, to sophisticated, robust dedicated computer systems. Some advanced systems make use of product bar codes (or allow users to affix their own), thus speeding up data entry and eliminating entry errors. Most laboratories have a computer, and a computer-based system provides many advantages. One is being able to incorporate a tracking system by regular updating of quantities and locations of chemicals. This promotes economical and efficient use by allowing the sharing of chemicals held by different labs or research groups. Accurate inventories are also essential to emergency responders.

Regardless of the type of inventory implemented, here are a few recommended guidelines to follow. We feel in general that each record in the database should correspond to a single container and not merely the chemical itself. Information fields for each record should contain at least the following:

- Chemical name
- Chemical Abstract Service (CAS) registry number
- Size of container
- Date of receipt
- Storage location

Optional fields recommended:

- Molecular formula
- Hazard classification
- Owner's name
- Expiration date

The CAS number is important for ensuring accurate identification in light of different naming conventions and numerous pseudonyms. Received dates and expiration dates ensure that unstable chemicals are not kept beyond their useful life.

In order to maximize the benefits of an inventory system, you must institute a diligent labeling program. Most commercially packaged chemical containers will have adequate labels that include hazard information. However, we recommend that you supplement commercial labels with date received, principal investigator's or researcher's name, and storage location, at a minimum.

Also, ensure that any older containers that might be re-located are updated to meet current requirements. And keep an eye out for chemicals that are transferred or re-packaged into secondary containers; make sure they are marked with all essential information, just as the original.

Organizing and handling chemicals for a busy research laboratory is a daunting task. Here we have given you three important first steps—collect your MSDS and references; develop your inventory system; institute a labeling program—to get you started down the right path to safe laboratory operation.

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

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SAFETY TIP

DEVELOP SPECIFIC WORK PRACTICES FOR INDIVIDUAL EXPERIMENTS

By James A. Kaufman

This simple idea preceded by 15 years the requirements of the OSHA Lab Standard for "Standard Operating Procedures," "Control Measures" and "Special Provisions for Working with Particularly Hazardous Substances." Today "it's not just a good idea, it's the law!"

While the Lab Standard does not require specific work practices for individual experiments, it does stipulate that employers generate a list of recognized good practices which lab workers are expected to follow, i.e., wash hands before leaving the lab, never work alone, leave lab clothing in the lab, don't eat, drink or smoke in the lab, etc..

Control measures include elimination, substitution, engineering, administrative, and personal protective equipment (PPE) as methods for managing risks. Employers are responsible for insuring that their lab employees understand these controls and can easily determine when to implement them. For example: when should chemical splash goggles be worn? Chemical splash goggles should be worn (1) whenever a chemical/biological known to be hazardous to the eye is being handled, (2) whenever a chemical/biological with unknown eye hazard is being handled and (3) any liquid hotter than 60 degrees Celsius.

Particularly hazardous substances include "select carcinogens, reproductive toxins, and highly toxic substances." The Lab Standard says that the employer must decide (1) whether these must be used in a "designated area," (2) when to work in a fume hood or other enclosure, (3) if procedures need to be developed for "decontamination," and (4) how to achieve the "safe removal of contaminated waste."

LSI believes that the scope of particularly hazardous substances should be expanded. There are others in the lab that may need some additional precautions. We would like to see highly flammable (class IA solvents), highly corrosive (concentrated and fuming acids), and highly reactive substances (picric acid, explosives).

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

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SURVEY SAYS: ARE YOU IN THE MARKET FOR A BIOLOGICAL SAFETY CABINET?

A very specialized research laboratory that deals with infectious agents, organisms or perhaps even laboratory animals, requires the proper degree of protection. Protection for laboratory personnel, the environment and the local community are of the utmost importance and must be considered and ensured.

Biological safety cabinets (BSCs) are enclosures that protect users and the environment from biohazards by removing particulates and aerosolized pathogens from the work area through HEPA filtration, then recirculate or exhaust the purified air, hence, cleansing the workspace air.

BSCs provide protection to users/operators and/or samples. Whether performing research or production activities, the proper degree of protection should be maintained. The protection required by these types of activities is defined as biosafety levels.

The levels of containment within respondents' labs.

Containment level 1	41%
Containment level 2	49%
Containment level 3	8%
Containment level 4	2%

BSCs are categorized as Class I, Class II or Class III, depending on their construction, airflow characteristics and exhaust systems. Each of the levels is selected based on the agents or organisms upon which the research or work is being conducted. Each level builds on the previous level, adding constraints and barriers. The Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) are the main sources for biological safety information for infectious agents. These classifications are based on each BSC's suitability for samples at various biosafety levels. Class I and Class II cabinets handle Biosafety Levels 1, 2 and 3 (low to moderate risk), while Class III BSCs are intended for use with Biosafety Level 4 agents (high risk).

Types of Biological Safety Cabinet respondents are using.

Class I	29%
Class II	60%
Class III	10%
Other	1%

Respondents' fields of research.

Biochemistry and biology	39%
Hospital/medical center	17%
Pharmaceutical industry	16%
Quality control	7%
Environment	5%
Chemical	5%
Food and beverages	3%
Other	8%

Within Class 2, there are four major categories, A1, A2, B1, and B2, which differ in terms of air flow but not degree of protection. A2-type biological safety cabinets comprise about 90 percent of all units sold in the United States. Users are not likely to keep track of the sometimes fine distinctions between models, but vendors are more than happy to help match workflows with cabinets.

Class II Biological Safety Cabinet Sub-types.

Type A Class II	43%
Type B Class II	18%
Don't know	39%

A biological safety cabinet's primary mission cannot be compromised—users count on these cabinets to shield them from the dangerous biohazards they work with and to protect their experiments from contamination.

Respondents' thoughts on the following safety statements regarding BSCs.

	Agree & Strongly Agree	Disagree & Strongly Disagree
All biological safety cabinets have been tested within the past year	79%	21%
Test labels are properly affixed to the biological safety cabinets tested	79%	21%
Storage in biological safety cabinets is kept to a minimum and is placed so as not to impede proper airflow	85%	15%
Workers using biohazards, toxins and regulated carcinogens have received special training	74%	26%
Rooms and cabinets containing regulated carcinogens, biohazards and radioactive materials are properly labeled	87%	13%

Ongoing trends in BSCs include improvements in the user interface, cabinet usability, ergonomics, and lower operating cost. Today, most labs select either an electronically commutated motor running on direct current or a three-phase AC motor. Both designs cost more than a PSC (permanently split capacitor) motor but run more efficiently and have an operating life of about 50,000 hours, compared with anywhere from 10,000 to 15,000 hours for a PSC. HEPA filtration affects operating costs directly. The more life you can get out of the filters, the lower your operating costs. Safety-conscious purchasers tend to go with powerful blowers, but some vendors urge users to consider energy efficiency as well and balance the two needs, otherwise you're compromising one in favor of the other. Ergonomics play into purchase decisions for BSCs: due to the nature of their work, chemists often set up experiments, close the hood sash and walk away for hours, while biologists spend many hours glued to the BSC. The cabinet should be large enough to accommodate all anticipated reagents and equipment, which users should be able to reach comfortably. A lot of customization goes into cabinets from features and functions to materials of construction that are tailored to specific applications and workflows.

Top ten factors/features that influence the decision-making process when buying a Biological Safety Cabinet.

Ease of use	93%
Safety	93%
Low maintenance/operating costs	89%
Controlled airflow	86%
Price	84%
Service and support	79%
Warranty	77%
Ergonomic design	74%
Energy efficiency	73%
Ease of installation	69%

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BALANCING SAFETY WITH ENVIRONMENTAL CONCERNS

by Angelo DePalma, Ph.D.

With most manufacturers providing solid biological safety cabinets (BSCs) with more or less standard features, total cost of ownership has become a hot-button issue with purchasers. “It all began a few years ago with energy efficiency,” says David Phillips, a technical applications specialist at Thermo Fisher Scientific (Asheville, NC). Until around 2000, exhaust fans were driven by AC permanent split capacitor motors. Manufacturers gradually switched to more advanced variable frequency drive AC motors that provided greater motor speed control. These have been standard for the last three or four years.

The “green shift” resulted from a better-educated user base that appreciates equipment that saves money while sparing the environment.

Since older motors did not compensate for filters clogging over time, airflows decreased between annual certifications, compromising contamination control and user safety. In newer cabinets, motors speed up to maintain a constant air velocity into or out of the cabinet. “They sense the increased resistance,” Mr. Phillips notes.

“But the coolest thing about them is they are anywhere from 50 percent to 75 percent more energy efficient than the older models, which translates into phenomenal energy savings, and they’re much safer. Buyers really are getting more value for less money.”

Although the new motors are more expensive than the older models, this has not been reflected in the overall cost of a new BSC, according to Mr. Phillips. Energy savings can be as high as \$800 per year per cabinet.

AC or DC?

In addition to driving BSC sales and marketing, environmental consciousness has become a major driver behind the push for abandoning AC motors in favor of DC designs. But as Mike Martin, general manager at ESCO Technologies (Hatboro, PA) notes, the AC-DC issue is far from straightforward. “DC motors draw fewer amps when filters are new or clean. AC motors draw higher amps with clean filters, but fewer as the filters load.”

The upshot is confusion among buyers who wish to save money but end up

purchasing a particular design that is incompatible with their usage. While cabinet standards exist, most manufacturers do not adequately document performance in real-world situations.

“Anyone with the right story can sell a cabinet without any real documentation or long-term life studies. Purchasers assume they will save money long term because of low watt usage, but that is not always the case.”

Regardless of the motor type, BSCs should have a means of compensating for filter loading, and provide enough reserve motor capacity to maintain at least 90 percent of maximal air flow as filters clog. Otherwise safety is compromised and downtime increases due to the need for more frequent decontamination and filter changes.

Reducing big-ticket maintenance

Mr. Phillips says that Thermo Fisher devotes significant, ongoing effort to improving overall reliability and extending motor and filter life—two of the most noteworthy maintenance

analyte partitioning into the stationary phase is enhanced, resulting in shorter runs and sharper peaks.

Most stationary phases fall apart at a temperature approaching 250°C, and systems are generally not equipped for heating. “Conventional C18 bonded phases are simply not stable at high temperatures,” Dr. Milton tells *Lab Manager Magazine*.

interactions. Run times, he claims, are reduced by 90 percent.

Hypercarb manufacture involves infusing a silica template with polymer, removing the silica, and “graphitizing” the polymer through high temperature. The final chemical form resembles graphite sheets rather than amorphous carbon.

“SPPs have completely changed our ideas about pressure, particle size, and performance.”

Users considering high-temperature operation will need to invest in third-party column ovens and systems for preheating the mobile phase. They will also require rugged columns, like Thermo’s Hypercarb, which uses a porous graphitized carbon packing.

According to Dr. Milton, Hypercarb is a “specialist” media intended for “difficult separations.” It operates in both reverse- and normal-phase modes through both polar and steric

But what about my methods?

Novel column technologies such as SPPs, hydrophilic interaction chromatography (HILIC), and monoliths provide more options, but they also resurrect sticky questions about method transfer. Labs that submit instrument results to legal and regulatory authorities live by standardized, validated methods, as do QC and

other high-volume functions. And while some complaints are no doubt exaggerated, organizations can rarely justify revalidating all their analytic methods. “Transferring methods between platforms is a huge challenge,” admits McGinley. “It’s one of the biggest hurdles toward adopting novel column and system technologies.”

There is no simple answer, as labs must justify everything economically. Solvent savings and higher throughput alone might justify method transfer for a large pharmaceutical organization, but not perhaps for a forensics or environmental laboratory that makes twenty or thirty injections per week.

Angelo DePalma holds a Ph.D. in organic chemistry and has worked in the pharmaceutical industry. You can reach him at angelo@adepalma.com.

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POWERFUL NEW FEATURES, AND A RENAISSANCE FOR OLD SYSTEMS

by Angelo DePalma, Ph.D.

Manufacturers of high-performance liquid chromatography (HPLC) systems continue to innovate, while simultaneously providing upgrade paths for older instruments.

Modular HPLC systems provide maximum flexibility and upgradability compared with “one box” integrated chromatographs. By switching modules, users can access the latest technology while reducing downtime during repair or servicing.

“Method transfer has been... a major roadblock in the adoption of novel HPLC technology.”

On the other hand, integrated systems are more affordable. Agilent's 1220 Infinity, which is modular, costs about 25 percent less than a comparably equipped 1260 model, yet the two use identical subcomponents. According to Dr. Michael Frank, marketing manager for analytical HPLC at Agilent (Waldbronn, Germany), integrated systems are less expensive because they use only one power supply, one set of communication electronics, and one cover.

Since HPLCs are long-lived instruments, upwards and downwards compatibility is a major concern. Compatibility also provides a relatively straightforward upgrade path, provided components are replaceable and the manufacturer has embraced open architecture. Agilent's diode array detector, available on the company's latest HPLC models, also works in instruments sold in the 1990s. “All users need to do is replace the detector and they obtain almost twenty times

the sensitivity of their old detector,” Dr. Frank tells *Lab Manager Magazine*. Similarly, older instruments may access quick-change valve technology, which facilitates plumbing tasks.

Advanced valve technology plays into the need for speed, including rapid column switching and automation, which has become the name of the game in high-volume labs that run samples more or less continuously and often unattended.

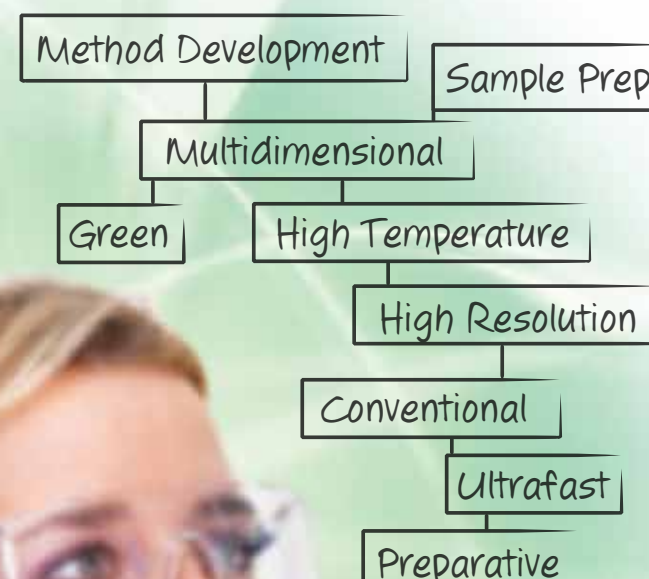
Software emulation of older methods

Method transfer has been the bane of chromatographers for years, and a major roadblock in the adoption of novel HPLC technology. Many established methods, for example from the U.S. Pharmacopoeia and the Environmental Protection Agency, specify not only solvents and gradients but columns. As a result, many labs feel tied to old technology. There are other aspects to this story: Users tend to exaggerate the cost and time involved in re-validating methods (read: inertia), and that chromatographs last so long is a tribute to the craftsmanship of HPLC manufacturers.

Regardless, a solution may be on the way. Agilent's Intelligent System Emulation Technology (ISET), available on its top-end HPLC systems, creates a software environment in which a chromatography run on, say, an Agilent 1290, can be made to emulate any older HPLC system and, according to the company, deliver “exactly the same results.” ISET is pure software and does not require hardware modifications.

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In a company announcement at Pittcon, Agilent senior marketing director Stefan Schuette described ISET as "...the beginning of a new era" in which users "...will be free to develop, validate, and execute all methods on one single instrument... and to emulate those HPLC and UH-PLC instruments to which a method should be transferred or on which it has been developed."

Dr. Frank believes legal and regulatory authorities will accept these "virtual" chromatography runs. "I've spoken with experts in regulated industries, and they don't think it will be an issue."

Columns drive instrument evolution

The advent of small-particle-size columns has caused HPLC vendors to rethink system design to exploit the new columns' resolving power, says Alessandro Baldi, Ph.D., senior business director at PerkinElmer (Waltham, MA). "We pay close attention to reducing volumes not only

inside modules but between modules, and to positioning components as closely as possible to the column."

That means positioning the injector and gradient mix almost on-column, and the detector immediately outside at the back end. Proximity reduces volumes between modules and therefore helps eliminate dispersion while improving signal to noise and resolution.

"Many labs feel tied to old technology."

Perhaps the most exciting development affecting HPLC systems over the past several years has been the introduction of superficially porous silica particles. These are discussed in greater detail in an accompanying article.

The novel particles promise performance approximating—some vendors say exceeding—that of UHPLC but at normal back pressures. This means that labs with a significant investment

in older HPLC instrumentation can continue to use their equipment and achieve results normally associated with very high back pressures.

Interestingly, system manufacturers have embraced superficially porous stationary phases despite an obvious desire to sell high-pressure systems. Dr. Baldi approaches the issue philosophically: "Remember that the HPLC market is variegated. Different users have different goals." He calls the new particles a "step in the right direction" for busy labs that want better results without changing methods and upgrading equipment. At the same time, researchers, Baldi says, will still desire the resolution, sensitivity, and solvent-sparing capabilities of UHPLC.

Angelo DePalma holds a Ph.D. in organic chemistry and has worked in the pharmaceutical industry. You can reach him at angelo@adepalma.com.

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SURVEY SAYS: ARE YOU IN THE MARKET FOR AN HPLC SYSTEM?

The origins of high-performance liquid chromatography (HPLC) date back to the invention of chromatography in the early 20th century, then to partition and paper chromatography in the 1940s, and finally to the introduction of liquid chromatography in the early 1960s. Shortly thereafter, the need for better resolution and high-speed analyses of non-volatile samples led to the development of HPLC.

In HPLC, a pump pushes the mobile phase with the sample through the column. This is similar to classical LC, in which the mobile phase and analyte are driven through the column by gravity alone. HPLC separation media are typically very dense, which creates a high back pressure, usually measured in the hundreds to thousands of psi. This allows for higher resolution and faster separation on columns of shorter length when compared to open column chromatography.

HPLC is, for many scientists, an essential piece of apparatus for the separation, identification, purification and quantification of various compounds. Users of HPLC work in a variety of fields including biomedical research, and the cosmetics, energy, and food industries. UHPLC is gaining rapid acceptance for its performance, speed of analysis and low consumption of eluent.

Types of HPLC systems respondents are using.

Analytical HPLC	53%
UHPLC	14%
Ion chromatograph	12%
Preparative HPLC	11%
GPC	5%
FPLC/Bio	3%
Don't know	1%
Other	1%

Many LC systems incorporate a detector that analyzes different fractions. As a researcher, your detector needs to be matched to identify your compounds of interest. UV/Vis, a common detector, comes in a few different types, including diode array. Other popular detectors include ultraviolet, fluorescence, mass spectroscopy (MS) and refractive index (RI).

UV/Vis	22%
Ultraviolet (UV)	18%
Fluorescent	14%
Mass spectroscopy (MS)	12%
Refractive index (RI)	11%
Conductivity	7%
Light scattering (LS)	6%
Electrochemical	4%
Other	6%

Separations based on polarity utilize reverse-phase chromatography (most popular) and normal phase. The reverse-phase columns separate analytes based on their hydrophobicity, with the more hydrophobic compounds being retained longer on the column. Separations based on charge utilize ion exchange chromatography. Recently, many companies have introduced hydrophilic interaction chromatography (HILIC) columns for analysis of polar analytes.

Reverse phase	26%
Normal phase	19%
Ion exchange	9%
Ion chromatography	8%
Ultra high-performance (UHPLC)	8%
Hydrophilic interaction (HILIC)	7%
Size exclusion (SEC)	7%
Chiral	6%
Gel permeation (GPC)	4%
Affinity	3%
Gel filtration (GFC)	2%
Ion exclusion	2%

Manufacturers typically offer HPLC components as a system; however, there can be a mixing of the system components from various vendors. Today 95 percent or more of HPLC systems from major manufacturers ship with autosamplers, a testament to the improved reliability and reproducibility of autosampler hardware and controls. No wonder it's the most commonly used HPLC component among survey respondents.

Autosampler	24%
Column heater	20%
Data system	19%
Degasser	19%
Automated valve	9%
Fraction collector	7%
Solvent recycler	2%

Average annual budget for supplies, accessories, maintenance, repairs, etc.

\$0 to \$5,000	20%
\$5,000 to \$10,000	22%
\$10,000 to \$15,000	17%
\$15,000+	32%
Don't know	9%

The need for speed and quality of data among researchers has led to faster, more efficient HPLC separations. Some purchasers prefer an integrated chromatography system in which all components are supplied in a single unit. Other purchasers prefer a modular system, in which individual components are purchased separately.

More researchers are identifying operating and acquisition cost, service, support and training as key factors in their decision-making process. Vendors recommend, when looking for a new HPLC instrument, to look a little into the future (about six to 12 months ahead) to figure out exactly what you need. For a smaller lab with lower throughput, cheaper machines working at low pressure may suffice, depending on the application. All vendors offer a range of different machines, and there are instruments that fall somewhere between HPLC and UHPLC that are sometimes 20 percent cheaper.

Top ten factors/features	
Accuracy	100%
Low maintenance	100%
Quality of data	100%
Sensitivity	100%
Service, support, training	100%
Availability of supplies/accessories	99%
Price	99%
Precision and accurate flow rates	99%
Resolution	99%
Ease of use	96%

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COMPLETED SURVEYS: 233



MAINSTAYS OF CELL, TISSUE CULTURE, AND MICROBIAL TESTING

by Angelo DePalma, Ph.D.

Carbon dioxide (CO₂) incubators are mainstays in traditional biology labs engaging in cell or tissue culture. Incubators provide a stable environment designed to mimic a cell's natural environment: pH of 7.2 to 7.5, temperature of 37°C, and a relative humidity of about 95 percent. The CO₂ concentration, about 5 percent, is controlled to match physiologic conditions and to maintain a constant pH.

Incubators are used wherever cells must be maintained, expanded, or cultured over periods ranging from a few hours to many weeks. Common applications include expansion of manufacturing cells for cell banking, virology, microbiological testing (both environmental and medical/diagnostic), small-scale production of cell products (proteins, genes, toxins, viruses), in vitro fertilization, and drug testing. Very high-volume applications such as clinical microbiology often use large reach-in incubators.

Deepak M. Mistry, manager for strategic development and marketing at Sanyo (Wood Dale, IL), notes that an upswing in biological therapeutics and stem cell research has created additional demand for high-performance CO₂ incubators. "Applications that fall under pharmaceutical Good Manufacturing Practices (GMPs), which employ highly regulated protocols, use incubators extensively."

The need to validate incubator operations and cleaning for regulated work is a driving force behind the tight control over conditions inside incubators. Conditions inside an incubator change rapidly when someone opens the door to introduce or remove samples. In some cases, the health or viability of cells may be compromised. "Uniformity of conditions is a problem in incubators just as with refrigerators," Mistry tells *Lab Manager Magazine*. Sanyo and other companies use infrared sensors that automatically measure the CO₂ concentration and initiate re-equilibration of gas concentration.

Keeping it clean

Maintaining cleanliness inside an incubator is of prime importance, particularly for units that house several cell lines at once or that change over samples rapidly. Incubators, after all, provide ideal growth conditions not just for cells of interest but for invasive fungi, yeast, and bacteria.

Traditionally, disinfection is achieved via heat or ultraviolet (UV) light.

Heat is effective, but is energy-intensive and stresses materials of construction. UV also works quite well, but only on line of sight: nooks and crannies that are not directly irradiated may remain contaminated.

"You need at least 170 degrees to eliminate not just microorganisms and cells but DNA."

Sanyo has pioneered the use of hydrogen peroxide gas for incubator disinfection. Gas permeates every surface area within the box and provides close to 100 percent kill of pathogens. The company claims that cycle time between removal of cells, cleaning, and introduction of new cells is about two hours after peroxide disinfection.

Several vendors make peroxide sterilization equipment that is catching on in cell culture, pharmaceutical, and food safety work. Mistry mentioned two: Steris (Mentor, OH) and Bioquell (Hampshire, UK).

Maintaining the health of cultured cells used in research or biomanufacturing is of utmost importance—not just while they're in the incubator, but during use and storage. "Since cell lines can take

weeks or months to make, they're very expensive," Mistry says. "Users expect them to be viable for many months after they leave the incubator."

David Craig, product manager at BINDER (Bohemia, NY), sees increasing demand for tri-gas incubators, which are traditional CO₂ devices that incorporate oxygen control. Oxygen normally ranges between 15 percent and 20 percent by volume; here O₂ is as low as 0.2 percent.

The term "tri-gas" refers to separate hookups for CO₂, nitrogen and oxygen. "Low levels are achieved by injecting nitrogen to drive out the oxygen," Craig says.

Tri-gas units are popular in biology and oncology labs handling tissues that thrive under specific atmospheric conditions. For example, they are used for cancer cells grown under low oxygen and stem cells under higher oxygen concentration. The explosion in tissue regeneration studies has been a boon for incubator manufacturers. "The idea is to replicate physiologic growth conditions."

A lot of hot air

BINDER specializes in hot air sterilization, which occurs at 180°C. According to Craig, sterilization provides the most robust and reliable cleaning. "The next closest, decontamination at 140 degrees, doesn't remove everything, while disinfection at 90 degrees just knocks down some

"CO₂ incubators don't just grow things you want; they also grow things you don't want."

organisms. You need at least 170 degrees to eliminate not just microorganisms and cells but DNA."

Hot air sterilization practically eliminates condensation—a breeding ground for microorganisms—and does not require the use of HEPA filtration. HEPA units are

expensive and are another potential source of contamination.

Perhaps the most attractive feature of sterilization is that it occurs without user intervention. "You complete one experiment, press a button, and the next morning you're ready to go," Craig observes. The sterilization cycle takes just under ten hours. Cleaning incubators normally involves disassembly, autoclaving parts, and hand-scrubbing.

"It's important to remember that CO₂ incubators don't just grow things you want; they also grow things you don't want," Craig says.

Angelo DePalma holds a Ph.D. in organic chemistry and has worked in the pharmaceutical industry. You can reach him at angelo@adepalma.com.

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SURVEY SAYS: ARE YOU IN THE MARKET FOR AN HPLC COLUMN?

High-performance liquid chromatography (HPLC) columns are considered the “heart” of the instrument used to transport the analyte and the mobile phase and provide the environment in which separation is achieved.

HPLC columns are stainless steel tubes generally 30 to 300 mm in length with internal diameters of 2 to 5 mm, internally coated with a stationary phase. Plastic or glass may also be used, but steel supplies the highest mechanical strength. Conventional columns are filled with porous particles coated with a polymeric material that interacts with the injected sample. In contrast to gas chromatography columns, HPLC has a true stationary phase: column “chemistries” are bonded tightly to the base material and do not bleed off.

Reverse-phase and normal-phase chromatography separation methods are based on polarity. Reverse-phase columns separate analytes based on their hydrophobicity, with the more hydrophobic compounds being retained longer on the column. Separations based on charge utilize ion-exchange chromatography.

More recently, many companies have introduced hydrophilic interaction chromatography (HILIC) columns for analysis of polar analytes. Reverse-phase is the most popular method among survey respondents.

Reverse phase	26%
Normal phase	17%
Ion exchange	13%
Ion chromatography	9%
Hydrophilic interaction (HILIC)	7%
Chiral	7%
Gel permeation (GPC)	7%
Gel filtration (GFC)	5%
Affinity	5%
Ion exclusion	3%

As particles decrease in size from conventional 10-, 7-, 5-, and 3-micron diameters, back pressure build-up increases exponentially. Thus, a 3-micron column is about twice as efficient as a 5-micron column, but attendant pressures are three times as high. While additional separation efficiencies are possible by further reducing particle size (to below 2 μ), more expensive hardware is required to handle extremely high pressures. Such systems are referred to as UHPLC, a significant trend in LC column technology.

Analytical scale	54%
Narrow-bore (1 to 2 mm diameter)	20%
Large ID (>10 mm diameter)	11%
Capillary (<0.3 mm diameter)	11%
Chip-level (microfluidic)	2%
Other	2%

Of the three common chain lengths, C4 is generally used for proteins and C18 is used to capture peptides or small molecules. Peptides are smaller and need longer chain lengths to be captured, so C8 and C18 are appropriate.

In reverse-phase HPLC, the stationary phase is often a silica-based packing covalently bonded with hydrophobic alkyl chains of C8 (octyl group) or C18 (octadecyl group), though there are many variations on this theme.

C18	20%
Silica	19%
C8	12%
C18 (polar end-capped)	10%
Anion exchange	9%
Phenyl	8%
Cation exchange	8%
Cyano	6%
Amino	6%
Biphenyl	3%
C4	3%
PFP	3%
Other	1%

In an effort to be economical, many users are moving to smaller columns, packed with smaller particles (sub-2 μ) because they use less solvent. However, slower, longer columns that offer better resolution are sometimes preferred to separate sample components in extremely complex samples.

Since high-pressure instruments work with both conventional and UHPLC columns, users might prefer an instrument with greater capability even if they don't yet need its higher-end performance. Some vendors have discontinued older HPLC systems in favor of those that can handle both conventional columns and ones that generate very high back pressures.

What can we do to reduce analysis time and increase resolution?	21%
How do I determine which column(s) makes the most sense for my lab?	19%
What should I consider when selecting a column(s) for faster throughput and higher resolution?	18%
What are the considerations for selecting a column(s) to achieve longer column life/retention?	18%
Are newer models of LC columns significantly better for developing faster LC methods?	15%
What type(s) of column(s) could be used to reduce solvent use and waste?	12%
Other	1%

It's a challenge to pick the right column to analyze the right sample correctly. Several factors, including particle and pore sizes, can affect separation efficiency, inertness, resolution, solvent usage and more.

Lab professionals need to know that the column will elute the analyte peaks at the same time, every time. Along with elution times, getting good peak shapes—sharp, narrow, symmetrical peaks—is important for various applications.

Important	
Technical performance of HPLC columns	98%
Shorter run times/increased throughput	94%
Lot-to-lot reproducibility of HPLC columns	93%
Ruggedness/durability of HPLC columns	92%
Lower operating costs (reduce solvent use and waste)	87%
Reputation of column manufacturer	75%
Purchase price of column	72%
Breadth of HPLC column offering (selectivity)	70%
Applications support	62%
Method validation/compliance support	57%
Covers/lids	73%
Safety and health features	70%

KEEPING SECRETS

THE LAB MANAGER'S ROLE IS PROTECTING THEIR ORGANIZATION'S CONFIDENTIAL INTELLECTUAL PROPERTY by John K. Borchardt, Ph.D.

“Intellectual property has the shelf life of a banana,” commented Microsoft's Bill Gates. So why should laboratory managers worry about keeping intellectual property confidential? Gates' statement may be true for computers and information technology. However, in many other business areas, intellectual property can have a much longer shelf life and needs to remain confidential for many years, often as trade secrets. Well-known examples of long-lived trade secrets include the formula for Coca-Cola or the Colonel's eleven herbs and spices used in original-recipe Kentucky Fried Chicken.

“Laboratory employees often have access to and use confidential intellectual property more than most employees.”

Companies need to protect their intellectual property if they are to use it to obtain competitive advantage. Intellectual property includes methods of making new compounds, product formulations, catalyst compositions, and design of production equipment and laboratory instruments. It also can include sales data, business agreements with other firms, and business plans. Commercial information such as customer lists, products that customers purchase, names of individual contacts at customer firms, etc., may also be trade secrets.

Nearly all laboratory managers, scientists, engineers, and other employees sign a confidentiality agreement when first employed. This is a legal document—a contract between the organization and the employee. In signing, employees agree to keep company intellectual property confidential. Laboratory employees often have access to and use confidential intellectual property more than most employees. So laboratory managers need to be sure their staff members understand what the confidentiality agreement legally binds them to do.

Even experienced employees inadvertently and sometimes knowingly share or even sell the confidential intellectual property of their employer.

A January 2011 issue of *C&EN* (*Chemical & Engineering News*) carried two stories of high-profile 2010 incidents in which laboratory employees shared their employers' confidential intellectual property with outsiders. In the first, a senior DuPont Company researcher included confidential company information in a review article published in a journal. In

the second, a researcher shared confidential information from a previous employer with his current one. I have overheard people discussing obviously confidential research information in airport departure lounges and on airplanes.

So what should and shouldn't lab managers and their staff members do to safeguard confidential information?

Lab managers

Periodically remind employees of their legal obligations to keep proprietary information confidential. Do so again should they leave the company to retire or for other employment. This can be difficult to do when a large number of employees are involved in a mass layoff. Some companies require employees to sign an exit document reminding them of their legal obligation not to disclose confidential intellectual property to third parties after leaving the company. When firms want to specify R&D intellectual property that must be protected, it is usually laboratory managers who prepare this list for each departing staff member in their group.

Be sure staff members return all confidential company documents before leaving your department to work elsewhere in the firm or leaving the company.



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COMPLETED SURVEYS: 311

Staff members

As noted, lab managers need to periodically remind staff members of what information must be protected and how to protect it. This is particularly important for new and recently hired employees who are used to the open exchange of information in the academic research environment. Some useful guidelines are summarized below:

- Do not discuss confidential information in the presence of non-employees or fellow employees who have no need to know it.
- Log off your office computer when away from your desk. If your work area has a door, lock it when leaving the vicinity. Keep confidential papers and reports in a locked cabinet or drawer when not working on them. Store confidential reports you work with in locked drawers or file cabinets. If you don't need them in the near future, don't store confidential reports in your own files; return them to your company's technical information department. Don't bring confidential papers to meetings unless you will need to refer to them.

- Check recipients' e-mail addresses carefully before sending confidential information over the Internet. Of course, do this only if your company allows such information to be sent over the Internet. Many companies prefer to use a corporate intranet for information transfer between employees.
- Your employer may have signed a confidential disclosure agreement (CDA) with a customer or supplier with whom you work. Indeed, you may have been asked to sign a copy of this agreement yourself. Be aware what information is covered by these agreements and how much you can disclose to third parties.
- When traveling, do not work on or read confidential papers in the presence of non-employees while on an airplane or in a crowded airport departure lounge. If you travel with a notebook computer, keep it shut down so you need to use your password to turn it on and open files. Carefully pack flash memory drives so you don't lose them. While using your computer when traveling, a vision panel placed on your computer screen can make it impossible to read your screen from an angle, helping to protect confidential information. When traveling, take only the confidential papers you will need. Keep these with you or in a locked case or a hotel safe. Do not discuss confidential company business in areas where outsiders can overhear your discussions or cell phone calls.

Consultants and temporary employees

As a consultant, one of the first things I am asked by lab managers and other managers when I am hired is, "Do you have a confidentiality agreement with our company?" Lab managers need to be sure their consultants, contract employees, and temporary staff members sign confidentiality agreements obligating them to not disclose confidential information they learn. Lab employees need to be coached to disclose only the minimum amount of information these workers need to do the job for which they were hired.

Sometimes temporary staff members are required to sign secrecy agreements with the agencies that contract their services out to laboratories. Even if this is the case, it can't hurt to have them also sign your own firm's standard confidentiality agreement. Remember, these people could be working for one of your competitors next week.

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@botmail.com.



Sarah Klemuk, Ph.D.
Co-Director of The Laryngeal Molecular and Cell Biology Lab at The University of Iowa

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Of the many challenges a teacher faces, being heard is one of the most important. Teachers have to speak for long periods of time nearly every day, and often over the voices of their students. Public school teachers are up to 32 times more likely to report voice problems compared to other professionals.

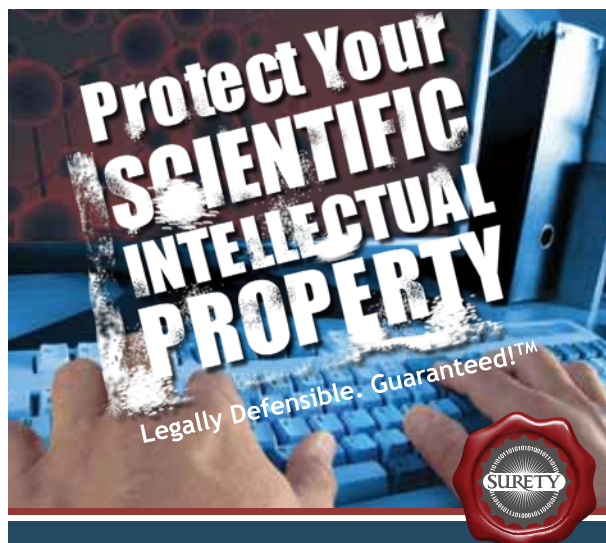
At The University of Iowa, Dr. Sarah Klemuk is replicating the stresses that affect the human voice by studying how vibration affects laryngeal cells. Working in a biosafety cabinet by The Baker Company, she uses a device called a rheometer, which allows her to both administer the vibrations and measure their effects on cells in real time—in a near-sterile atmosphere. The reliability and efficiency engineered into the cabinet is designed to let users focus on their work without distraction.

One day Dr. Klemuk's research could result in a treatment to heal damaged voices or prevent damage all together. Then teachers and other speakers could always count on being heard.



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PROVING OWNERSHIP

HOW ELECTRONIC “SIGN AND WITNESS” PROCESSES CAN ENSURE IP AUTHENTICITY AND LEGAL DEFENSIBILITY by Robert P. Flinton

To appreciate the significance—or the ubiquity—of commercial tamper protection, one needn't go any farther than the local grocery store.

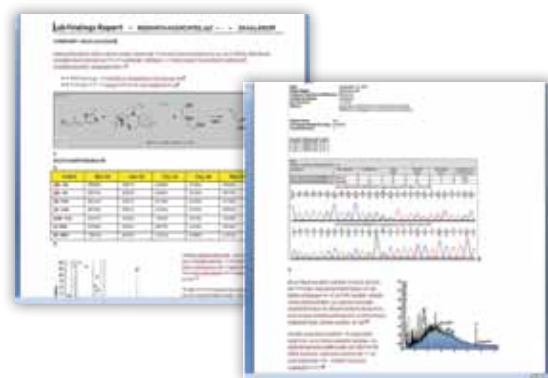
Toothpaste, aspirin, multivitamins, and milk are just a few of the items you're likely to find equipped with visible tamper-detection seals. In fact, if you're like most consumers, you wouldn't knowingly purchase any of these products without some form of asset integrity assurance. But if you got home and discovered that a “seal” had been broken, what are the odds that you would let your family consume that product? Let me take a guess—ZERO!

Of course, a damaged seal doesn't, in and of itself, prove tampering; it merely raises the possibility to some value greater than zero. But if grocery store patrons have a low tolerance for uncertainty, imagine the burden of proof facing scientific intellectual property owners in a court of law.

Surely, validating the integrity and ownership of complex lab information takes more than a plastic seal. The typical researchers, in truth, will spend several hours per month “signing” and “witnessing” each other's lab notes through inefficient manual administrative processes, based on company procedures.

For electronic content and records, the procedure is even less efficient, with added steps for printing and pasting into paper notebooks. But until recently, this was the only reliable method for establishing the legal defensibility of research-based intellectual assets inside the lab.

Today, with the advent of an electronic “sign and witness” process, that's all changing. Researchers are finally free to focus on what they do best—research. And in a world where you have to prove ownership, saving hundreds of man-hours and costs each year is no small achievement.



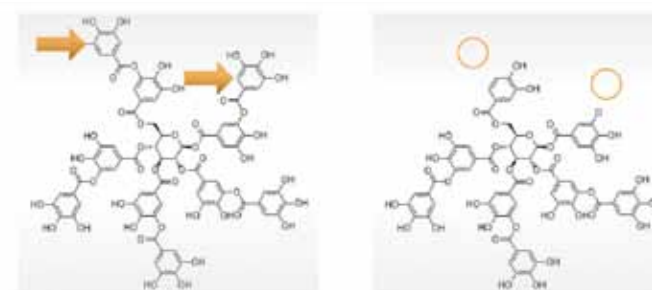
▲ As electronic lab notebooks (ELNs) and records replace paper-based lab records, organizations are looking for ways to answer the inefficient “sign and witness” requirement to ensure the legal defensibility of their electronic records.

But how does the electronic “sign and witness” process ensure indisputable authenticity and long-term legal defensibility throughout the chain of custody? The answer, believe it or not, is a modern-day wax seal. Or, you might say, its digital equivalent.

The price of uncertainty

For good or ill, electronic tampering of records, files, or any form of digital content is extremely difficult to detect. Whereas physical manipulations are usually crude and basic, digital tampering is more often elegant and sophisticated. We see images every day on TV that have been manipulated, such as “first down lines” during televised football games and ball-park ads in the background that aren't really there. And while the seamless manipulation of digital images and electronic files may work wonders for Hollywood and their high-priced

corporate sponsors, those same capabilities present an enormous obstacle to the verification of authentic scientific research.



Furthermore, recent court opinions¹ pertaining to e-discovery have forced most scientific-based businesses to significantly alter their digital asset protection schemes or else risk losing hundreds of millions of dollars in funding, revenues, legal fees, and damages.

Hence, there's been considerable migration toward more aggressively protecting digital, scientific intellectual property, namely the attestation of content ownership through the “sign and witness” process.

Meanwhile, a quick scan of the latest headlines reveals just how dearly R&D-centric companies have paid for recent protection inadequacies. As recently as 2010, several of the nation's largest scientific research organizations found themselves mired in unwinnable lawsuits that jeopardized their revenues, their community standing, and in some cases even their market position.

To make matters worse, the threats these companies face are often diverse in origin. Just as motivated insiders might alter data to protect reputations or to thwart regulators, unintended gaps in the chain of custody might easily arise from system upgrades, employee turnover, or cross-organizational collaboration.

Plainly said, lab managers are well advised to adopt comprehensive, transparent, and—above all—legally defensible methods for proving ownership of their intellectual property “crown jewels.” The question is only at what cost?

It's about time

Thus far we've talked about the price of “uncertainty.” But “certainty” has its price too.

For instance, mainly in paper-based lab notebook environments, there's a reason the words “sign and witness” send chills down the spines of even the most scrupulous

lab researchers. For all its practicality and utility, the “sign and witness” ceremony has always been—to put it mildly—tedious and inefficient.

◀ On the left: The molecular structure of a cutting-edge cure to a leading epidemic under review by the FDA. On the right: Can you tell if slight alterations were made to the research that could impact its approval?

Countless man-hours have been wasted for want of a simplified, automated solution. But the potential security and authenticity risks associated with digital signing and witnessing have persistently outweighed the potential efficiency gains.

Even as researchers migrated to electronic lab notebooks (ELNs) over the past several years, nearly all retained paper journals for printing, cutting, and pasting the signed, witnessed data sets.

It's been a model of inefficiency and a huge disrupt-

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tion to research teams, which can perform much more soundly when unburdened by repetitive administrative tasks. But will streamlined electronic “sign and witness” ever prove legally defensible over the long term? Actually, it already has.

Believe it or not, fully secure, automated “sign and witness” solutions can be implemented today, immediately, on any ordinary lab department desktop computer or integrated into an existing ELN.

“There’s been considerable migration toward more aggressively protecting digital, scientific intellectual property.”

It’s possible because of a unique, trusted time-stamping approach called hash-chain-link, “widely witnessed” time-stamping. This technique enables the signing, the witnessing, and the unassailable authentication of that research data provable over the long term, mainly for the life of the “sealed” content.

“Sealing” for long-term protection

Binding data and signatures to a legally defensible time stamp doesn’t have to be difficult. While most time stamps are usually supplied by local machine servers, or even PKI-based time stamps from certification vendors, they are solely dependent on the trustworthiness of internal system clocks, all of which can be easily discredited in a court of law or are dependent on a company’s level of proven protection against hacking. But to solidly prove trustworthiness in electronic records, an unbreakable “sealing” process of complete indelibility is required.

Realizing the need for this type of solution, Surety brought to market a technology service called AbsoluteProof®. AbsoluteProof provides laboratory R&D-centric industries with an independent, cryptographically verifiable solution that establishes the exact contents of every record or transaction and the time it was created, in such a way that it is beyond challenge and unimpeachable. This solution utilizes a patented “hash-chain-linking” and “widely witnessed” approach to securing electronic content and incorporates four key components for legally defensible, long-term record authentication:

- The ability to *digitally seal* any kind of electronic

record, including ELN and LIMS records, formula design diagrams, device readings, audit logs, spreadsheets, videos, and email correspondence

- A digital timeline of proof of the progress or development of scientific IP in support of a company’s ownership claims
- Validation of the authenticity of electronic records, and evidence that content was created when claimed and has not been altered since
- Compliance with 21 CFR Part 11 mandates for tamper-proof time-stamping and secure audit logs.

If a lab’s IP protection strategy involves associating identities with protected content (e.g., as part of a “sign and witness” process), the seals can be combined with digital or electronic signatures in a way that overcomes the legal shortcomings of the signature technology.

But the real secret to this method’s legal defensibility is the “widely witnessed” component. At the end of each week, hash values for each of Surety’s data sets—and their “sign and witness” attestations—are published in the *New*



◀ Surety’s AbsoluteProof Service for the “sign and witness” process is portable, independently verifiable, and long-lasting.

York Times, ensuring that any independent cryptographer can verify that the content in question existed at that point in time and hadn’t changed since the newspaper’s printing. In many cases, this could stretch decades, as newspaper editions are protected and stored for the long term, as well.

Much like state lotteries televise their drawings, this simple step is what gives lab managers the transparency and auditability necessary to satisfy a courtroom’s stringent burden of “widely witnessed” proof.

So long as data authentication solutions depend on the reliability of outside parties—no matter how trustworthy—there will inevitably be credibility and security risks.

But with “hash-chain-link” time-stamping, one need only trust the strength of the underlying hash algorithms themselves. And to date, there is no other legally

defensible, electronic “sign and witness” solution available.

The future of “sign and witness”

Just as tamper detection on packaging buoyed the food and drug industries, so, too, can tamper detection strengthen the electronic world and position it to revolutionize laboratory IP safety and validation.

“So long as data authentication solutions depend on the reliability of outside parties ... there will inevitably be credibility and security risks.”

We’ve come a long way since “sealing” content by using wax seals on important documents, but the principle remains. And each day, we as an industry move that principle forward, into the digital landscape, by molding the technology for better efficacy, availability, and ease of use.

Empowering lab scientists is the bottom line—with unobtrusive, streamlined processes that maximize productivity while protecting intellectual accomplishments for generations to come.

That’s the power and the promise of electronic “sign and witness.” It’s science fiction no longer.

References

1. The Federal Rules of Evidence (FRE) now allow for electronic records, including electronic lab notebook (ELN) content, to be equally admissible as paper records in patent or legal proceedings, provided that they are kept in the course of regularly conducted business activity and that the source of information or the method of preparation is trustworthy.

Robert P. Flinton, vice president of marketing & product management, Surety, LLC, can be reached at bfinton@surety.com or by phone at 571-748-5795.



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GLOBALIZATION, NEW REGULATIONS AND DIETARY GUIDELINES INCREASE TESTING REQUIREMENTS

by Bernard Tulsi

The food sector in the United States (US) is experiencing its biggest changes in decades. This year, Congress passed the Food Safety Modernization Act, updating regulations first implemented in 1938. The act greatly expands the powers of the Food and Drug Administration (FDA), whose new clout now includes food recall authority. Also in 2011, the Dietary Guidelines for Americans, which is revised every five years, were updated to push for healthier diets overall, and especially for children. The guidelines target obesity now, and have already earned kudos for declines in some cancer incidences; folic acid enhancements during pregnancy; heightened awareness of the value of dietary fiber; and the eschewal of dietary trans fats, saturated fats and cholesterol.

To be sure, both the new act and the guidelines have been on the drawing

board for some time, and food laboratories of all stripes have been gearing up for them. But having time is only a part of the advantage. Food labs have benefited from renewed vigilance following high-profile food contamination cases—melamine in pet foods and salmonella in peanut butter, among others, in the recent past, and the current radiation concerns about Japanese foods. Another major advantage stems from investments in advanced instrumentation, such as mass spectrometers, which significantly enhance analytical capabilities and productivity.

“Melamine had a large impact on the food industry, not just government agencies, because it was global in scale and generated a great deal of publicity,” says Antonietta Gledhill, Market Development Manager, Food and Environment with Waters Corporation. She notes

that this focused the attention of the food industry on fitness-for-purpose of analytical methods, because the melamine scandal occurred as a result of the tests employed to assess protein content being open to manipulation. Many in the food industry are now employing more advanced technologies to detect this type of fraud.

Dr. Paul Young, a former European food regulator, and now Director, Chemical Analysis Operations with Waters, spends considerable time assessing and speaking on food safety regulations globally, and especially in China, India and Japan. “Most countries have revised their food safety regulations in the past ten years. Until January 4 [of] this year, the US labored under a 1938 law, so this has really been a long time coming.” Young explains that US food safety requirements require less testing than in Europe, for example,

and were less stringent than for pharmaceuticals. The new law has the potential to usher in substantial changes, he says.

Paul Zavitsanos, Worldwide Food Segment Manager at Agilent Technologies, says that the new regulation empowers the FDA to deal with the likely effects of the globalization of the US food supply. He explains that the US has had substantially different food safety requirements compared with Europe and other parts of the world—largely because of safety controls at the point of production in the US.

According to Zavitsanos, the US controlled food safety through agricultural modernization procedures, and benefited from large-scale production and enhanced safety procedures at its mega farms. “The United States Department of Agriculture (USDA) also had the vision to invest heavily in agriculture

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modernization that stressed quality control standards throughout the production process. As a result, we did not have to test heavily at the end, because safety was controlled during production.”

where there was testing for safety at the end as opposed to producing in a safe manner. The result was two different environments—sophisticated testing systems in Europe and sophisticated agricultural processes and education in the US.”

“Food labs have benefited from renewed vigilance following high-profile food contamination cases.”

On the other hand, in Europe, there were many small farms and myriad regulations, especially before the European Union (EU) was formed. “That generated an environment

such as pesticides and water quality used in food production worldwide. “Post globalization, a lot of the controls went away, and we had to adopt the European testing paradigm.

Now there’s a lot more testing in the US, as opposed to reliance on agricultural controls,” he says.

One reason is that it is difficult to differentiate between foods originating in the US and overseas. “Both raw materials and finished products are sourced from sites outside of the US agricultural system. As a result, there is a need for verification, testing and certificates of analysis like in Europe—this has been happening in the US over the past five to seven years, maybe more,” he says.

Young acknowledges the stellar role of the USDA in the US, but points to budgetary concerns.

“The USDA, whilst not subject to the new law, does operate surveillance and testing programs under its Food Safety Inspection Service (FSIS),” he says. The department has been the subject of substantial budget cuts, however, especially for research that supports monitoring. “The new law has the potential for increased vigilance, but the budget isn’t matching that,” says Young.

Despite the inherent challenges, the new regulations have been greeted with considerable good will and optimism. Gerry Broski, Food Science Marketing Director for Thermo Fisher Scientific, says, “The new developments set standards that will help the reputation of the food industry as a whole. There’s broad agreement about the act. There are questions over how all the requirements will be funded in light of current budget cuts—everything I see suggests that they will be funded.”

Broski says that the increased testing and traceability, certification of testing labs, and the overall harmonization of global food testing practices are net positives that will help ensure the quality and safety of our foods.

Implications for food labs

“Within the new US food safety law, there is a complete section on controlling the safety of imported foods. The US really has its options open—retaining the ability to work collaboratively with competent authorities and the right to audit current systems and foreign supplier verification systems,” says Young.

“This law, as structured, has potential for both collaborative and inspectional approaches. The FDA must carry out in the first year alone 600 overseas inspections of facilities,



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and will double that number every year. Five years from now, we are looking at about 20,000 overseas facility inspections," says Young.

He cautions that an inspectional approach alone will not be sufficient given the volume of food imported in the United States. "There needs to be more collaboration, such as the International Food Safety Training Laboratory established jointly by the University of Maryland and the FDA—the Joint Institute of Safety and Applied Nutrition (JISAN). The facility will be dedicated to food safety and provide training to foreign scientists," he says. Waters Corporation has important collaborative functions with the facility.

Zavitsanos says that these developments will translate into great increases in contract research, research expenditure, method development and analytical procedure development. "We have already started seeing heavier demand for and more emphasis on mass spectrometry for the development of new and more sensitive and rapid confirmatory techniques. The confidence and speed of the methodologies were increasing." He expects that workload would be pushed not to the FDA but to contract labs servicing the secondary and primary food industries.

There will be greater use of ICP-MS and ICP-OES for trace metals analysis. In addition, more use will be made of novel techniques for emerging contaminants like persistent organic pollutants such as dioxins, PCBs, dioxin-like PCBs, and PBHs, which were prevalent in the Gulf of Mexico during the recent oil spill. In the near future, there will be stepped-up efforts in the analysis of emerging contaminants, according to Zavitsanos.

There will be stepped-up research efforts to catch the next melamine—that is, unknown and unexpected contaminants that could affect the food supply, he says. "There will be considerable expansion in the testing capacity of the private contract lab infrastructure in food safety testing, both in the chemical and biological areas," he says. He notes that even in Europe, which currently does much more testing than the US, no

to food testing. As a result, there is greater demand for instrumentation, especially premier tools like GC-MS and LC-MS and triple quad instruments. Like Waters' Young, he too points to a shift away from older techniques to mass spectrometric techniques in food safety specifically. He says that obtaining results rapidly is essential now—it is not enough to identify bacteria—it is important to rapidly trace them back to their



▲ The Agilent 1290 Series UHPLC used in conjunction with a 6490 triple quadrupole mass spec, a workhorse category instrument used throughout the food testing industry.

more than one percent of the testing is done by states—all the rest is conducted by contract labs. "This is becoming a worldwide trend now—China has made some important shifts toward contract testing as well."

Zavitsanos says the number of food labs worldwide is increasing, and the established facilities are boosting their capacity. He says that with the reduction of contract testing in the pharmaceutical sector, a number of contract labs are turning

source to mitigate further outbreaks and spreading.

"Another major issue now is the measurement of allergens, such as peanut, shellfish and gluten in foodstuffs. The idea is to measure precisely to determine whether they were in an ingredient incorporated into a product or they were processed in a facility that may have contaminated them indirectly," he says.

Young does not envisage whole new lines of instrumentation and



▲ The Agilent 5975C GC/MS, a popular platform for detecting and identifying food contaminants such as pesticides on fruits and vegetables.

technologies emerging in response to the new guidelines, because what is required is already in place. "I suspect that any changes or improvements would have happened anyway. Producers are constantly trying to improve the quality and efficiency of their products—I often see legislation following industry efforts."

"Quality control labs are typically associated with more core detector instrument types, whereas food safety labs are characterized by high-tech, time-of-flight types of analyses for accurate mass measurements and broad purpose readings. R&D labs use high-end instrumentation, such as tandem quadrupole GC-MS-MS or high-resolution time-of-flight."

Young says that there is a visible migration toward high-end instrumentation, not only for food safety, but also for routine nutrient analysis. "We see a number of quality control labs, especially those involved with infant formulas and vitamins, moving to mass spectrometry and

away from core detector systems. The mass spectrometry systems enable them to work more effectively—they can consolidate processes, and instead of having one method for one vitamin, they can have several vitamins in one method. This increases productivity, accuracy and precision."

The food lab in a major food company

Unlike many food companies and the global trend, Hormel Foods does most of its laboratory work in-house. Its primary research facility

descriptive analyses to describe attributes of different foods. That is a specific skill set based on the ability to determine better taste, color and other attributes. We also use the chemical and microbiology labs to formulate products from a nutritional and functional perspective, and also to validate processes and food safety interventions," he says.

Addressing the impact of the Food Safety Modernization Act on their processes, Minerich says, "A lot of our primary products are

"The FDA must carry out in the first year alone 600 overseas inspections of facilities, and will double that number every year."

has a little over 100 employees, with the staff equally divided between new product development and quality and safety. "Some of our subsidiaries may contract out their microbiology work because of time constraints. We handle about 250,000 different product samples over the course of a year. Included among those are about 300,000 microbiological assays and 550,000 chemical assays," says Phil Minerich, VP for R&D. Hormel's worldwide operations include two plants in China, one each in Beijing and Shanghai, and joint ventures in South Korea, the Philippines, Vietnam, Australia, Denmark, England and Central America.

The R&D side develops dozens of new products every year. "Product development scientists access the sensory methods for qualitative

FSIS controlled. So, we are kind of a step ahead of what came in the modernization act."

"Most of our products are USDA based, and our labs have updated equipment, methodologies, and the required proficiency and efficiency to properly analyze these samples. As the act was unfolding, we worked with the GMA, AMI and other organizations to understand how to make the transition," says Rick Christianson, Group Manager of Lab Services.

This is more likely to relate to us through our ingredients suppliers, says Christianson. "After the melamine and Salmonella incidents, we reviewed all our supplier arrangements and validations. We rely on our ingredient manufacturers—so



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▲ Hormel Lab Technician Lindsay Weisberg setting up environmental analyses in the microbiology laboratory.



▲ Hormel Senior Laboratory Technician Beth Fanton using a segmented flow analyzer to perform chemical analyses.

in the last five or six years we have drastically reduced suppliers we work with, particularly those that provide more than 90 percent of our ingredients. Our relationship with them has become much stronger through validations, interventions, environmental monitoring, auditing and the certificates of analysis they provide us. We better understand their methodologies, and QC conducts site visits and our own or third-party audits through the Global Food Safety Initiative (GFSI)," he says.

With respect to the dietary guidelines, Minerich says, "In our health and wellness initiatives, we are looking at a number of ways to develop healthy products—with low fat, low sodium, moderated calories, portion control, higher fiber and other key attributes."

He says, "I thought the 2010 guidelines were presented quite

well. They were extremely neutral in terms of not turning it into a good food/bad food scenario. It was about portion control, balanced diets—meats, fish and different protein sources. It focused on cutting calories and exercise, and was based on common sense. A number of interest groups target and demonize certain foods for one reason or another—so I really applaud the FDA for applying neutral ideas like

"Food safety is not a competitive issue—we work together as a whole scientific community to address these issues."

portion size and calorie counting."

He says that requirements such as those around trans fats have not been

a large problem for the protein-based industry. "At Hormel, we do have some fryers with tortilla shells and we have a few products where oils would be a concern, but we switch those oils out to eliminate trans fats. The fat industry has really been cooperative in that initiative; they have modified their chemistry so that trans fats have been virtually eliminated from the retail market."

Turning to the centrality of the food lab in their operations, Christianson says, "The labs

help all our processes—whether through formulation, nutritional analysis, sensory analysis, shelf-life determination, validation of food safety interventions, or the use of less or different kinds of energy, water recycling, verifying the potability of the water we use, or in efficacy of water treatment. These are the host of ways that the lab provides sound scientific support to our initiatives."

Future prospects

Hormel's Christiansen says that in the food industry, competitor companies often work together on safety issues. "Food safety is not a competitive issue—we work together as a whole scientific community to address these issues," he says.

That bodes well for the future, and Agilent's Zavitsanos concurs, "In the US and Europe, the quality of the food supply will continue to be safe, and will get safer. It will be protected against a wider range of contaminants, both chemical and biological. The possibility that you will encounter a contaminated product will go down.

"This is against the backdrop that the amounts of imported food are going up every year. In China and India, there will be dramatic increases in food safety both for export products and for domestic consumption—both countries have domestic food safety testing laws and they are building an infrastructure for domestic and export testing."

Bernard Tulsi is a freelance writer based in Newark, Del. He may be contacted at btulsi@comcast.net or 302-266-6420.

The Institute for Food Safety and Health (FSH), formerly the National Center for Food Safety and Technology, which is engaged in a broad range of food-related research, provides an excellent profile of the vital tools and instrumentation required for food testing. Jack Cappozzo, current director of chemistry, who had served in senior chemistry positions at ConAgra Foods for nineteen years before joining the institute, says that FSH has always been associated with the Illinois Institute of Technology (IIT) in Chicago.

"Our consortium consists of our academic group and a group from the FDA. We are the only group in the country that has embedded FDA staff, and our mission is to work on applications in food processing to increase food safety. The third member of our consortium is industry. We have over 50 industry members, such as Kraft, Unilever, Coke, Pepsi, Agilent, Nestlé, Mars, Charm Science and many others."

FSH projects represent a consensus of industry needs to solve problems with input from the FDA, says Cappozzo. The work flow encompasses process engineering, packaging, microbiology, molecular biology and chemistry. The chemistry group is involved in research in food processing, such as removal of pesticides for fresh produce, mitigation of acrylamide in the frying process, sanitation to validate the removal of allergens and development of methods to reduce the level of mycotoxins in raw commodities.

"In addition, we have a nutrition group that has a clinical laboratory. This group has been focused on natural phenolic antioxidants (flavonoids/anthocyanins) and their effect on health and the bioavailability of these compounds. The chemistry group has been very involved in the separation, identification and quantitation of these compounds in the food materials and patient blood (serum)," says Cappozzo.

He says that the FSH provides services to food companies based on its capabilities and expertise. "We are not a contract lab, but we have contracted out research and used our services to fulfill that work. We have a tremendous amount of capability, but the time needed to do the work is at a premium. We have numerous methods that we have optimized for better detection and throughput," he says.

FSH Instrumentation Profile

	Instrumentation In Hand and Wish List
What instruments do you have in your lab?	HPLC, HPLC-MS/MS, HPLC-MS-TOF, GC-MS, GC-MS/MS, GC-MS-Head Space, ICP-OES, ICP-MS, GC
Which is most important and why?	"We do a great deal of work on the HPLC-MS/MS system. We need to quantitate, and this has the greatest sensitivity with the least background (signal to noise). We still do a lot of GC-MS, but are expanding into GC-MS/MS," says Cappozzo.
What instrument do you wish you had but don't and why?	For throughput, we would like to get another HPLC-MS/MS, but we have been interested in getting an FTIR with a microscope.

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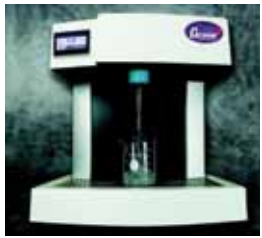
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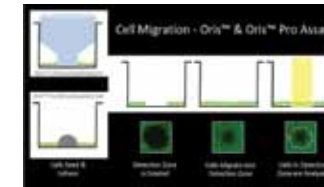
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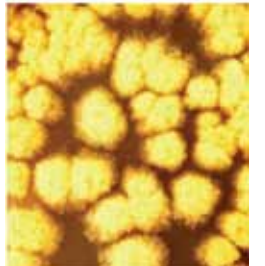


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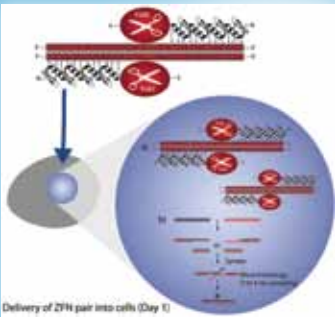


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Although DNA sequencing throughput has been progressively increasing and processes have become more precise, gene editing capabilities have been lagging behind. Sigma Life Science has addressed this issue with the release of CompoZr Knockout ZFNs, which are pre-designed and validated reagents to generate permanent gene knockouts in human cell lines in as little as a few weeks, as opposed to several months.



Current methods, which rely upon homologous recombination, can be very inefficient. They don't always work well, and there is a great deal of time and effort required to screen resulting cells.

Keith Hansen, Product Manager for ZFNs at Sigma Life Science, says existing methods are done in a haphazard kind of way, and can eat up a lot of time. "People might irradiate cells, treat them chemically, or try to make use of... homologous recombination," Hansen said. "All of those traditional methods are very random. People can't target where the modifications would occur, so you end up having a lot of side effects... and you're left needing to screen many more cells to find the specific knockout that you're looking for."

CompoZr Knockout ZFNs help to cut down the time required to knockout genes in the human genome. They do so by introducing a double-strand break at a defined site within the first two-thirds of a gene's open reading frame. This double-stranded break stimulates the cell's natural DNA repair mechanisms, which in some instances can create nucleotide insertions or deletions that disrupt protein function.

"We've pre-determined where each zinc finger will cut for any particular gene," Hansen added. "This really speeds up the process."

Supriya Shivakumar, Global Commercialization Market Manager at Sigma Life Science, says the CompoZr ZFNs help users in a variety of applications, including disease studies. "You can take a gene that's implicated in a disease and knock it out. You'll have both a cell line that has it and [one] that doesn't, so they're identical except for that one gene mutation," she said. "You can then directly investigate that particular gene's role in the disease. That hasn't really been possible before, except for a handful of genes."

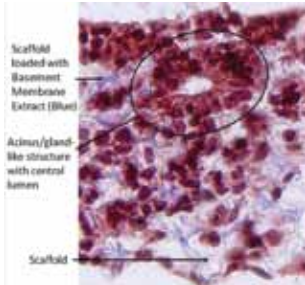
Sigma's CompoZr Knockout ZFNs are priced to fit within a typical lab's consumables budget, and arrive ready to be used.

For more information, visit www.wherobiobegins.com/knockout

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CLASS II BIOLOGICAL SAFETY CABINETS: MANAGING A FACILITY'S TOTAL COST OF OPERATION

David Phillips, Technical Applications Specialist - Laminar Flow, Thermo Fisher Scientific

Managing groups of biological safety cabinets (BSCs) in a biomedical research, healthcare or academic facility requires three strategies to optimize the total cost of ownership. These strategies address both performance and cost. An inexpensive BSC that does not provide the needed cleanliness and containment has no value to an institution; conversely, a BSC device that provides unneeded or unused protection is a waste of important resources that could be better utilized elsewhere.

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STRATEGY ONE: THE RIGHT TOOL FOR THE JOB

BSCs, clean benches, chemical fume hoods and all other airflow cabinetry are all commonly called "hoods". Although the laboratory hoods are often lumped together, they provide very different types of protection with different TCO structures.

BSCs, laminar flow clean benches and cleanrooms capture and control particles including biological agents with HEPA filters. With proper maintenance most of these filtration based devices can last five to ten years between filter changes.

Chemical fume hoods use airflow to capture, dilute and expel hazardous gases and fumes from the laboratory or work area. Chemical fume hoods tend to be simpler in construction and do not have internal fans or filters. The major cost is heating, cooling and conditioning the air required to replace the expelled air. Mills and Sartor estimated the annual cost of external exhaust at \$4.50 per cfm per year. A typical fume hood with an opening 3 ft wide and 18 inches tall would require approximately 450 cfm and cost over \$2000 per year in energy.

If biological containment or protection is required, then filtered equipment is necessary. If the containment or protection required is from volatile chemicals or gas, then externally exhausted equipment is necessary.

From a cost standpoint, the decision that a BSC must provide protection from gases and volatile chemicals in addition to biological hazards increases the overall cost of the BSC significantly. For safety and efficiency, it becomes vital to determine precisely what type of protection is needed. Table 1 provides a rough comparison of total costs in energy and upkeep for the three types of containment equipment discussed. Note how the decision to provide protection from both biological hazards and volatile toxic chemicals more than doubles the total cost of operating the BSC.



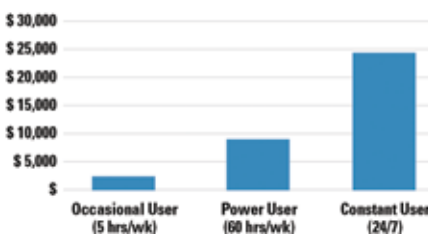
STRATEGY TWO: NOT ALL BSC USERS ARE THE SAME

With the exception of external exhaust, the major ongoing costs of a Class II BSC are associated with use. When the cabinet is operating; the fans are spinning, the fluorescent lights are on, the filters are loading up with captured particles and motors are wearing down. None of this happens when the cabinet is completely off.

Some BSCs are used only occasionally when only some of the work requires the cleanliness and containment of a BSC, and turned off when they are not in use. Other BSCs are always in use, particularly if they are connected to external exhaust systems where air is constantly flowing through the cabinet.

Table 2 shows a comparison for total costs in energy and upkeep for three different types of use of a traditional BSC. These costs will vary with the energy and operational efficiency of the particular model of BSC.

Table 2. Total Cost of Operation for Non-Exhausted BSC (15 years)



A part of an overall strategy to maximize the cleanliness and containment provided by a facility's BSCs while optimizing the costs requires recognition that the usage and costs can vary significantly.

Some energy efficient BSCs available today operate at 75% lower levels than popular and much more inefficient models common in the past. The heaviest users should have the most efficient cabinets for the maximum reduction in a facility's overall costs.

STRATEGY THREE: TIMING IS EVERYTHING.

The costs of operating a BSC are not evenly distributed over the 15 or 20 years of the BSC's life. In the first year, the only costs will be for electricity and cooling. At some point the filters and/or motors will need replacement. The cost for this will be between \$1,000 and \$2,000 or even more. For the traditional BSC, filters and motor replacement are approximately 35% of the total cost of operation over 15 years.

Table 3 shows the typical pattern of expenditure for a BSC power user. Note the annual expenses are the same from year to year unless the filters need to be replaced as in years seven and fourteen or the motor needs replaced as in year ten. Newer BSC technologies further improve the TCO model due to longer filter and motor life.



PUTTING IT TOGETHER

These strategies can be implemented as part of an overall approach using these steps:

1. Conduct a BSC inventory survey with guidance from Thermo Scientific.
2. Identify the top 20% in terms of operating cost
3. Review application requirements with environmental health and safety.
4. Identify cost/benefit for unit replacement
5. Identify cost/benefit for timed unit replacement.

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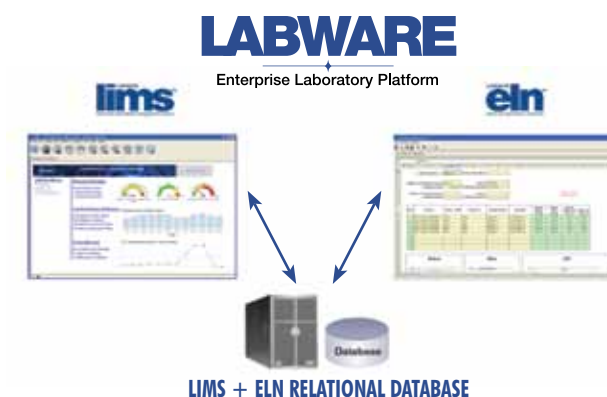
The **LabWare ELN™** system is a unique entry in the Electronic Laboratory Notebook solution space, and is a key component of the company's formidable Enterprise Laboratory Platform (ELP) solution strategy. The ELP refers to LabWare's ability to deliver an integrated and scalable solution that has the functional breadth to span broad portions of its customer's business operations. LabWare ELN is an innovative product that provides scientists and other laboratory personnel with the automation tools necessary to manage experiments, to properly execute tasks, and to capture, preserve and safeguard intellectual property.

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with LabWare's flagship product, **LabWare LIMS™**, allowing any data within LIMS to be accessible by ELN and vice versa. The ability to seamlessly interact with LabWare LIMS and to utilize any data or content stored in the LabWare LIMS relational database including customer-defined fields, tables, or record types is at the heart of the unique power of LabWare ELN. In addition to its ability to automate scientific experiments, the system also provides guided method execution capabilities. Laboratories that work on GMP samples are required to follow standardized testing methods (STMs) when testing samples in the laboratory. LabWare ELN helps ensure that laboratory technicians are performing standardized test methods according to the proper sequence of steps stipulated in the SOP, improving operational efficiency and enhancing regulatory compliance.

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▼ The architectural schematic below shows the relationship between LabWare LIMS and LabWare ELN.



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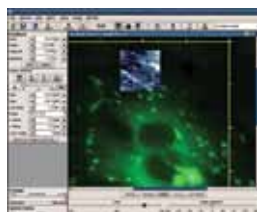
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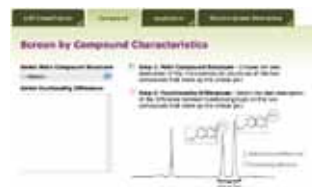
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With support for statistically designed experiments, the system ensures that the experiments can be correlated with similar ones. In addition, it tracks the workflow of R&D-wide experiments and gathers data produced from instrument files, spreadsheets and databases, eliminating the need for users to manually collect this information.

"The complexity of the laboratory information environment has led to an explosion of experimental data," Pawela added. "Existing systems don't allow scientists to extract knowledge from data. The end result is that up to 40% of all experiments run are repeats—a tremendous waste of time and money."

EKB enables users to be more productive, sustainable and efficient by providing algorithms for ad-hoc analysis of experimental data, as well as the automation of standard data operations. Configurable report templates offer integrated charting and scatter plots, and enable mining of existing data for trends and patterns.

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EXPERTS: Tamie Webber & Anne Sefried Seamlessly Integrate MSDSs with Chemical Inventory Management



Tamie Webber

Director of Product Management at 3E Company, is responsible for product management initiatives, product planning and strategies and product development, including MSDS Distribution and Management, Emergency Response, Regulatory Reporting, Training and Waste Services.



Anne Sefried

Technical Specialist/ Inventory Consultant for ChemSW, provides implementation, data migration, custom reporting, and general technical support to ChemSW customers. She graduated from Chapman University with a B.S. in Computer Information Systems.

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"Historically, MSDS management has not been integrated with chemical inventory management, so two separate processes and databases are maintained," says Tamie Webber, Director of Product Management at 3E Company. "However, the two workflows are integral to each other, so it makes logistical and financial sense to integrate the two tasks."

"The most efficient R&D labs typically automate as many manual processes as possible to optimize lab productivity," adds Anne Sefried, Technical Specialist/ Inventory Consultant for ChemSW. "Integrating MSDS and chemical management processes streamlines the lab's workflows, eliminates duplicate work across locations, provides an accurate picture of chemicals in lab inventory, and reduces operating costs."

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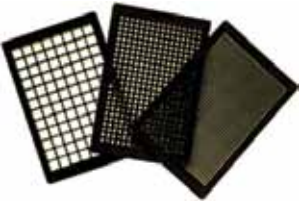
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OPTIMIZING EVAPORATION CONDITIONS OF REVERSED-PHASE PREP HPLC FRACTIONS

The V-10 Rapid Solvent Evaporator quickly evaporates reversed-phase prep HPLC fractions using a pre-set method. However, when evaporating Acetonitrile-containing fractions, the Acetonitrile (MeCN) will sometimes evaporate too quickly causing an issue with product yield. A study was conducted to find optimal conditions for evaporating MeCN/water solutions, looking for the conditions which evaporate the most liquid and allow the least to pull through the vacuum pump.

EXPERIMENTAL CONDITIONS:

Variables:

Vacuum settings: 14 to 22 mbar

Evaporation time at different pressure and pump settings:

Pump 1 Hi, Low

Pump 2 Med, Low

Test Conditions:

Solvent: MeCN/H₂O (3:1)

Vial: 20-mL scintillation

Volume/vial: 4 mL

Method: HPLC frac

Vial rotation: 6000 rpm

Temperature: 36° C

RESULTS AND DISCUSSION:

Table 1. Vacuum settings

# of vials tested	Vacuum (mbar)	Volume in pot (mL)	Volume in vial (mL)
7	14	1.50	0.21
7	16	0.67	0.10
7	18	0.40	0.06
7	20	0.20	0.03
7	22	0.10	0.01

Table 2. Evaporation time test

# of vials tested	Vacuum (mbar)	Pump speed 1	Pump speed 2	Evaporation time (min.)
1	22	Hi	Med	6.53
1	20	Hi	Med	6.25
1	14	Hi	Med	6.36
1	14	Low	Low	8.50

The data in Table 1. indicate that by reducing the vacuum (increased mbar) the MeCN/H₂O mix becomes more efficiently evaporated as evidenced by both lower vial and pot volumes. At higher vacuum, MeCN can “flash” off and bypass the condenser.

The data in Table 2. shows the impact of altering the pump 1 and pump 2 speeds (pump 1 is the speed of the vacuum pump in mbar/sec when the pressure is >150 mbar and pump 2 is vacuum pump speed when the pressure is <150 mbar). The results indicate that by reducing the vacuum (pressure) to 20 mbar and the setting pump 1 and 2 speeds to Hi and Med, respectively, that evaporation time is minimized. This information combined with the data in Table 1. show that optimal evaporation conditions are 20 or 22 mbar with pump speed 1 set to Hi and pump speed 2 set to Med.

CONCLUSION:

From this data, the recommended conditions for evaporating Acetonitrile/H₂O fractions are:

Temperature:	36° C
Pressure:	20 or 22 mbar
Maximum evaporation power:	100%
Final dry time:	3.0 min.
Rotation speed:	6000 rpm
Pump speed 1:	Hi (mbar/sec)
Pump speed 2:	Med (mbar/sec)
End evaporation:	Auto
Min. evaporation time:	0.8 min.
Max. evaporation time:	20 min.
External vacuum:	No



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Screening Samples for Persistent Organic Pollutants (POPs)

Problem: The environmental safety and food production industries are facing a rapidly changing climate, being increasingly affected by regulatory and financial pressures. Development and expansion of their portfolio of chromatography techniques, to develop and maintain a competitive edge, can be expensive in terms of the laboratory downtime and consumables required. A new chromatography method needs to be tested and validated for use on existing instruments, with new or repurposed columns and often with entirely new types of sample matrix. With many environmental and food safety analyses there is a requirement to meet regulatory standards in method sensitivity and contaminant concentration, i.e. EPA Method 1613 Rev.B1. In screening samples for persistent organic pollutants (POPs), for example, scientists must validate and confirm the parameters and results of the method development process, in order to meet the regulatory standards applying to these compounds. This additional process adds to the time taken and expense of introducing the method into the lab. Fundamental changes to the workflow for introducing a new separations technique are needed, therefore, to enable the scientist to reduce the lengthy and expensive method development process.

Solution: Currently, there are few products on the market aimed at improving and enhancing the chromatography workflow to save time and cost. A new range of Thermo Scientific Application Kits has recently been launched to address these issues, by helping to reduce the downtime and expense of developing new chromatography methods. These chromatography Applications Kits provide a complete package for resourcing new separations techniques in an established laboratory. All Application Kits are provided with a column and the chromatography consumables required for the method. Many kits also contain a full written protocol and CD of instrument settings, for download to the instrument computer. Kits are available for a number of LC, GC and MS-linked applications and are designed to ease the transition into the new separation technique.

Workflow for the analysis of POPs,



▲ Thermo Scientific POPs kits contain a GC column that enables identification of a broad range of organic compounds.

within both food and environmental samples, needs to be rapid and accurate. Separation of these compounds is very heavily regulated and so detection of these compounds needs

to be both sensitive and reproducible, to consistently provide high-quality data. Rapid, accurate and sensitive analysis for POP levels is provided for in two Applications Kits, the Thermo Scientific POPs Screening and the Thermo Scientific POPs Confirmation kits. Both kits fully comply with U.S. regulations (EPA Method 1613 Rev.B1) on the acceptable levels of contamination and sensitivity of detection of these compounds.

These kits are fully compatible with existing Thermo Scientific GC or GC-MS systems for the analysis of food and environmental samples. The POPs Screening kit contains a Thermo Scientific TRACE TR-Dioxin 5MS GC column (30mx0.25mmx0.1µm) and consumables, enabling sensitive identification of a broad range of organic compounds in the sample. The POPs Confirmation kit contains a Thermo Scientific TRACE TR-Dioxin 5MS GC column (60mx0.25mmx0.25µm) and chromatography consumables, and is designed to allow accurate quantification of low-level amounts of POPs contaminants.

Resourcing a new methodology in this way, by providing the scientist with all of the protocols and consumables required, enables the set up and validation of a method in a much reduced timeframe and at a lower cost. The chromatography Applications Kits range goes a significant way towards speeding and easing the diversification of methods in established chromatography laboratories. Using the Applications Kits as a resource to increase productivity can provide a very real competitive edge in any industry where chromatography is a core requirement.

For more information, visit www.thermo.com

Automation and Cost Savings Using Photometric Analysis for Food and Beverage testing

Thermo Scientific Gallery and Gallery Plus are discrete photometric analyzers with a broad menu of industrial and environmental system applications. Both instruments are easy to use, automated systems that allow laboratories to simplify their testing, and thus realize both time and financial savings. These new superior bench-top platforms offer a wide range of application areas in food & beverage, water and environmental testing and quality control. The Gallery and Gallery Plus bring excellent analytical performance to colorimetric, enzymatic and electrochemical measurements in a compact and affordable design. Simultaneous determination of several analytes from a single sample, and its many automated features ensure efficiency in analysis.

The Gallery's high level of automation means that it is easy to operate. The analyzers arrive ready for immediate analysis. Start-up and shutdown protocols are automated and, once loaded, the analyzer automates all necessary steps, providing a walk-away time of up to two hours.

All food products require analysis as part of a quality control management program; they are analyzed throughout the development process, during productions and sometimes even after the product has been delivered to the market. The Gallery instruments have several parameters that can be predefined for specific applications, and a wide variety of reagents help to optimize the analysis in tests e.g. controlling fermentation processes, and monitoring water quality and ingredients in food samples. System reagents are available for different sugars, acids and alcohols, as well as nitrite, phosphate, sulphate, calcium, magnesium, total iron, total protein, urea, ammonia, and chloride. A wide range of calibrators are also available to support the testing process. The ready to use kits eliminate time-consuming reagent preparation steps allowing for additional cost savings.

The unique low-volume cuvette design makes it economical to use. It guarantees low reagent costs and minimizes the amount of reagent waste. Cuvettes are disposable, so there is no need for extra washing steps to prevent carry-over. Reagent kit sizes

and on-board stability are optimized and bar-coded vials provide reliable and easy identification. In fact, the reagent usage and expiration date are automatically monitored in real-time.

The Gallery and Gallery Plus offer a compact design only requiring a small footprint, which is particularly attractive to laboratories with space limitations. The analyzers are fully self contained and they do not require external water or drainage. Also the uptime is maximized by minimal daily and weekly maintenance and the intuitive, self-guided graphical interface makes the Gallery and the Gallery Plus easy to learn, making operation and information management streamlined. The capacity of the Gallery Plus is up to 350 tests per hour. The on-board sample capacity is 54 and reagent capacity is 42 with the flexibility to load samples and reagents at any time without interrupting analysis.

The Thermo Scientific Gallery and Gallery Plus systems allow users to simplify their food, beverage and water testing to realize both time and financial savings. Once loaded, the system allows an analyst to walk away for several hours and return later to find accurate reliable results. The basis for Gallery's flexibility and analytical excellence is in over 35 years of experience in developing analyzers and fulfilling high demands for reliability and quality.

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▲ The Thermo Scientific Gallery Plus is an excellent platform to automate colorimetric, enzymatic and electrochemical testing.

Efficient Drug Discovery Using Optical Label-free Technology

Problem: Pharma and biotech companies are striving to reduce drug attrition rates within the drug discovery process. G-protein coupled receptors, a major target class within drug discovery, have traditionally been assayed in recent years using fluorescence calcium flux assays. However, inherent to these assays is the generation of false positives due to fluorescence compounds within compound libraries. Potential drug candidates can therefore be missed. There is a need for highly sensitive counter-screening across different targets within hit follow-up to ensure potential lead compounds are fully characterized prior to decisions regarding their progress.

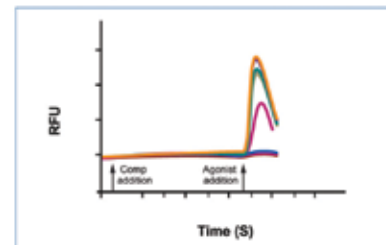
Solution: Orthogonal screening approaches are now being deployed earlier in the drug discovery process. The incorporation of label-free Epic® technology has improved the process both in assay development and post-HTS screening for structure-activity-relationship (SAR) and hit profiling studies.

Optical label-free technology measures changes in light refraction resulting from dynamic mass redistribution within the cell. This occurs in response to receptor activation or deactivation in a zone within the cell's monolayer. The response is indicated by a wavelength change in the emitted light. Labeled technologies such as fluorescence, however, measure a particular biomarker within an individual signaling pathway. The integrated cellular response obtained from a label-free assay enables characterization of the signaling pathways involved that can be affected by biased agonism, dimerization and allosterism.

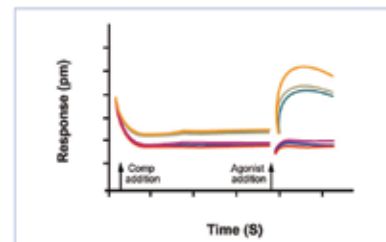
The PerkinElmer EnSpire® Multimode Plate Reader now incorporates Epic® optical label-free technology, offering an orthogonal approach to the drug discovery process.

An example of the benefit of incorporating label-free in the drug discovery process is that of a fluorescence Ca²⁺ flux assay using a FLIPR[®] High

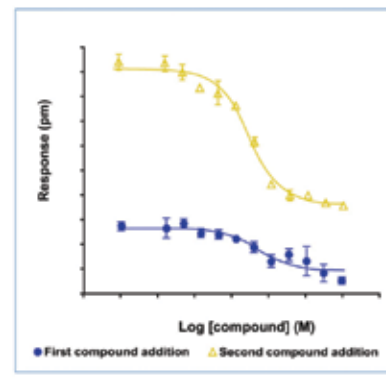
FLIPR® Response Identifying 1st and 2nd Compound Additions



Epic® Response Identifying 1st and 2nd Compound Additions



Epic® Dose Response Curves Identifying 1st and 2nd Compound Additions



Throughput Cellular Screening System and confirmation studies using the Corning® Epic® label-free system.

Novel compound activities that are missed by a traditional labeled method can be revealed using Epic® technology. In the top figure, a compound was tested in a FLIPR® Ca²⁺ flux assay and shown to behave as a neutral antagonist. The Epic® DMR response shown in the middle figure similarly demonstrates the antagonist activity of the compound and identifies inverse agonist activity after the first addition. No such response was observed in the FLIPR® Ca²⁺ flux assay. The dose response data for antagonist activity (yellow curve) and inverse agonist activity (blue curve) on Epic® is shown in the bottom figure. For assay development, the process benefited from being both more rapid and generic.

Label-free technology is ideal for use in drug discovery, enabling the study of GPCRs and cell signaling. It has already been adopted within the hit-to-lead process for target confirmation and lead optimization within secondary and orthogonal screening, SAR studies, biophysical testing and ADME/toxicity.

Pathway-unbiased, label-free technology offers more fully characterized information about cellular and biochemical systems, pathway-independent analysis, non-invasive, more physiologically relevant data and the ability to study difficult targets or weak biological interactions. Rich information can be obtained for difficult targets, endogenously expressed receptors and recombinant cell lines in 384- or 96-well plate formats.

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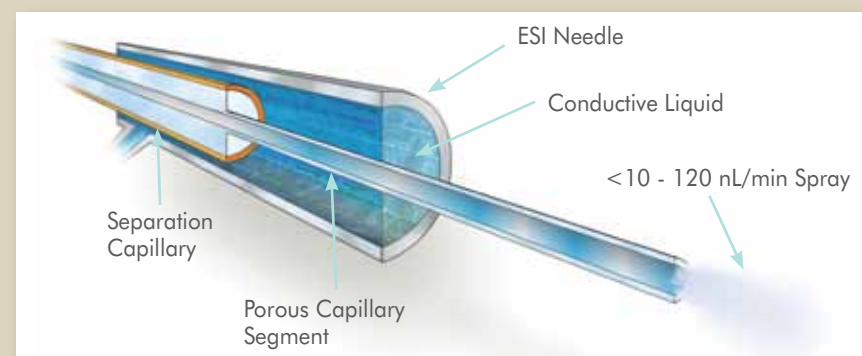
Problem: Mass spectrometry (MS) has become an indispensable technology for the analysis of compounds of biological interest, is widely available and offers rapid and accurate detection with broad applicability. Current upstream separation technologies may fall short of taking advantage of the full sensitivity range of the mass spectrometer. How can MS sensitivity be significantly increased while simultaneously expanding analyte coverage?

Solution: CESI is an upstream separation technology that combines the ultra-low flow of capillary electrophoresis with sheathless ESI (electrospray ionization) to minimize ion suppression, increase sensitivity and expand the capabilities of mass spectrometry. The CESI 8000* from Beckman Coulter is a capillary electrophoresis platform that, like MS, separates analytes on the basis of their M/Z ratio, but in liquid, rather than in gas phase. Capillary electrophoresis (CE) is known for efficient separations with high peak capacities and exemplary resolution, and has become the gold standard for applications such as the characterization of therapeutic proteins.

CE works at its best with polar and charged analytes such as metabolites, basic drugs and peptides. Its ability to separate intact proteins, highly charged peptides and protein complexes that are exceedingly difficult to resolve will provide new information not easily achievable by LC-MS. Traditionally, CE-MS has been performed using a coaxial sprayer, which adds sheath liquid and nebulizing gas to achieve stable ESI spray. This coaxial "triple-tube sprayer" design, although functional, leads to sample dilution and decreased

signal. Beckman Coulter's new CESI 8000 High Performance Separation-ESI Module with OptiMS technology provides the first ever commercial sheathless CE-MS sprayer, giving researchers a robust, high-sensitivity interface that takes advantage of highly efficient, low-flow CE separations.

The benefits of this technology have already been noted in proteomics, metabolomics, identification of drugs and their metabolites in biological fluids, and the analysis of intact proteins. Limits of detection of drug metabolites in the low pg/mL range and of peptides at the low pM level have been observed.



▲ OptiMS Porous Tip Cutaway. ESI spray delivers the intrinsic advantages of CE to the mass spec, providing limits of detection, for example, at the low pM level for peptides.

OptiMS technology combines an intrinsically low flow CE separation with ESI in a simple device that has no liquid junction or dead volume. Sample components are separated in an electric field that is applied between the inlet vial and the OptiMS sprayer. The electrical contact for CE is achieved through the porous tip within the ESI needle, which is filled with conductive liquid, and for the ESI spray by the porous capillary protruding from the needle, allowing electrospray formation at the capillary tip. When ESI voltage is applied, the low flow at the tip terminus instantly vaporizes into a spray. This ensures that the intrinsic advantages of CE are delivered by the sprayer to the mass spectrometer in a robust manner without dilution or disturbance, even at flow rates as low as 20 nL per minute.

OptiMS technology is exclusively available on the new CESI 8000 High Performance Separation-ESI Module and specifically designed for mass spectrometry applications. The CESI 8000 incorporates automated sample handling from microvials or 96-well microplates. Easy switching between LC-MS and CE-MS allows the addition of CESI to existing workflows and obtaining sought-after, complimentary information.

More information about CESI is available at www.celeader.com.

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Biotope, Inc.	www.biotope.com	89	Labconco	www.labconco.com/safe	PPG	Thermo Fisher Scientific	www.thermofisher.com	85
BioTek Instruments, Inc.	www.hyndreader.com	45	Labnet International, Inc.	www.labnetlink.com	6	Thermo Fisher Scientific Inc.	www.thermofisher.com	81
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Conquer Scientific	www.conquerscientific.com	97	LabX	www.labx.com	97	Tuttnauer USA	www.tuttnauerUSA.com	25
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PARTING POINTS

Takeaways from this month's issue:



WORKPLACE SAFETY

The OSHA Voluntary Protection Program (VPP) brings together management, labor and OSHA to build comprehensive health and safety management systems and promote effective programs to protect workers. Four major elements make the program effective:

- Management commitment and employee involvement
- Workplace and job hazard analysis
- Prompt implementation of hazard prevention and controls
- Health and safety training tailored to the size and complexity of the facility

10



26

THE CHOCOLATE FIX

Getting lab workers to wear personal protective equipment can be challenging. After repeated violations for which the use of threats was ineffective, the author decided a more creative approach was in order. Here are some of the highlights of this approach.

- Every worker who is NOT found out of compliance is given a Lindt chocolate truffle
- A token system results in monthly draws for cash prizes
- Regular safety glasses were replaced with "cool"-looking ones, so employees would be more inclined to wear them



61

KEEPING SECRETS

Companies need to protect their intellectual property if they are to use it to obtain competitive advantage. This can include product formulations, catalyst compositions and business agreements, to name a few. How can managers and staff safeguard this confidential information?

- Log off your office computer when away from your desk
- Store confidential reports in locked drawers or cabinets
- Be aware of any information covered in confidential disclosure agreements (CDAs)
- Ensure staff members return all confidential documents before leaving your department to work elsewhere



44

CHEMICAL MANAGEMENT PLANNING FOR THE LABORATORY

There are thousands of chemicals available and new ones being developed every day. Prudent management of any laboratory using dangerous substances begins with a chemical inventory. Consider how chemicals will be managed and tracked. Some suggestions:

- Information for each chemical should include at least: name, CAS number, container size, date of receipt and storage location
- Older containers that might be relocated should be updated to meet current requirements
- Make sure the above information is included when chemicals are transferred into secondary containers



68

PERSPECTIVE ON: A FOOD & BEVERAGE LAB

The food sector in the United States is experiencing its biggest changes in decades. This year, Congress passed the Food Safety Modernization Act, updating regulations first implemented in 1938. The act expands the powers of the Food and Drug Administration (FDA), whose new clout now includes food recall authority. What does it mean for food labs?

- With the new regulations comes increased testing, traceability and certification of testing labs
- The FDA will conduct 600 overseas facility inspections in its first year, and will double that number every year
- Higher demand for mass spectrometry techniques is likely, for more sensitive and rapid confirmatory techniques

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