March 2015
Volume 10 • Number 2

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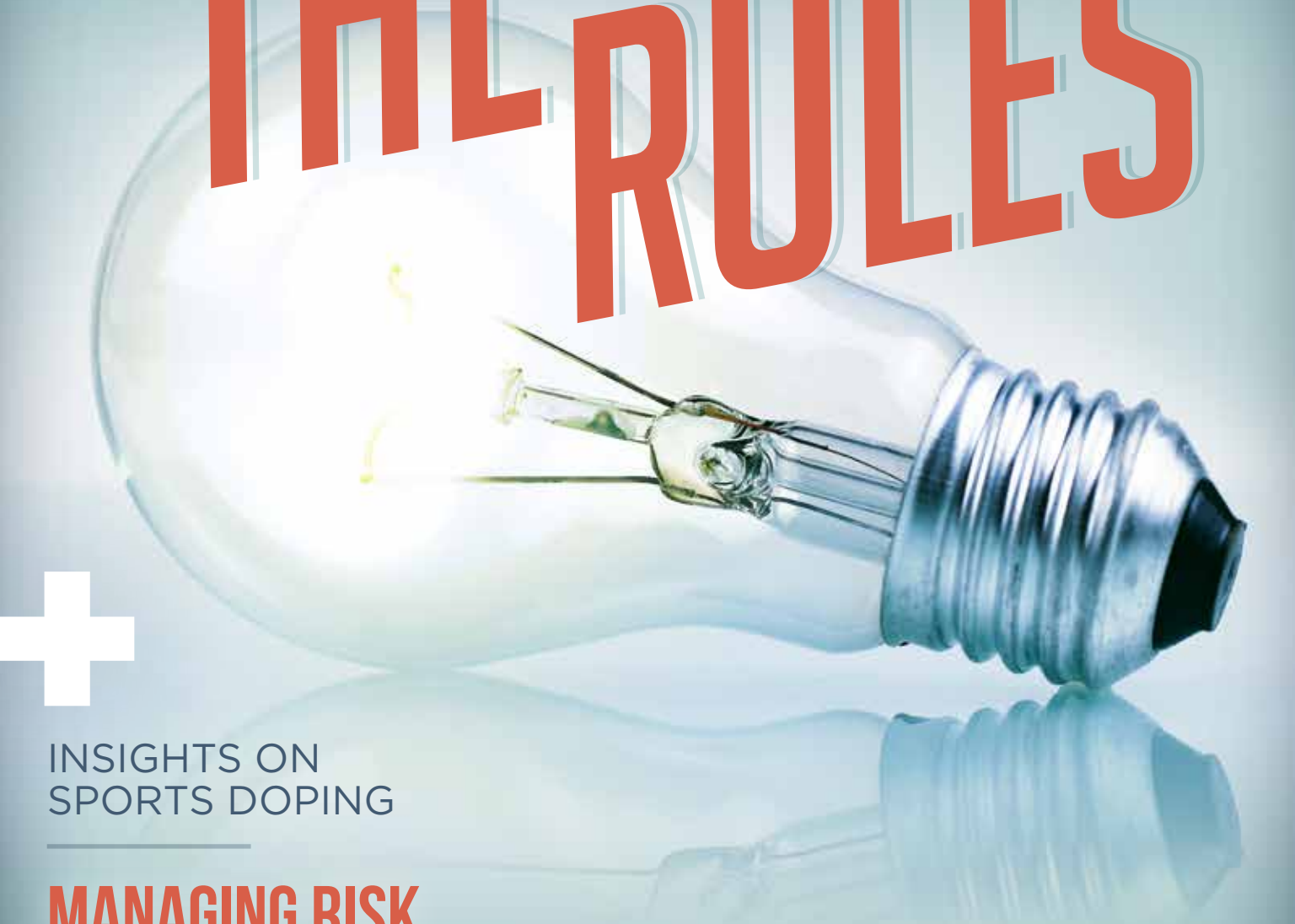
Changing THE RULES

WHAT THE FIRST-INVENTOR-TO-FILE PATENT PROVISION MEANS FOR R&D MANAGERS



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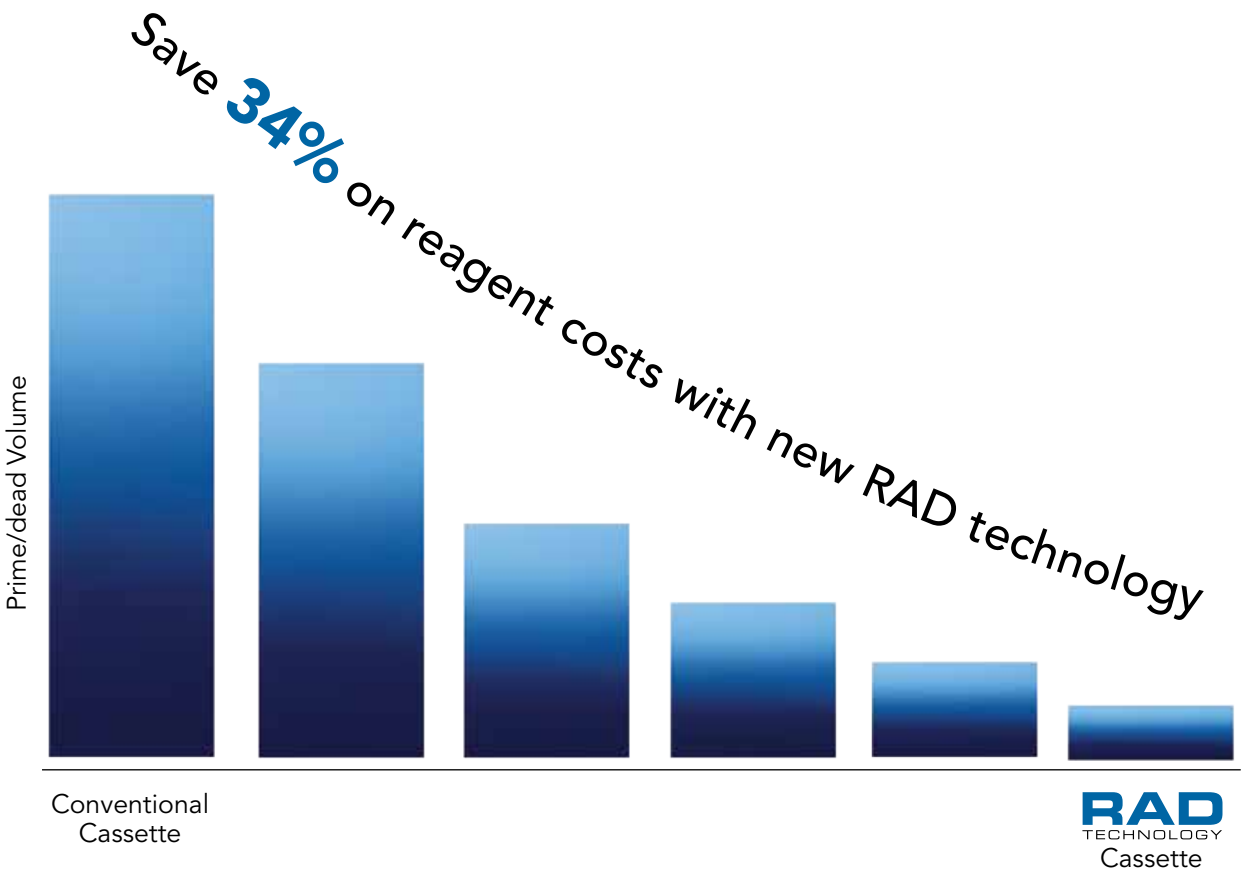

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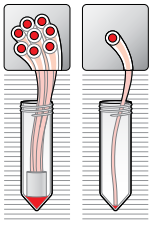

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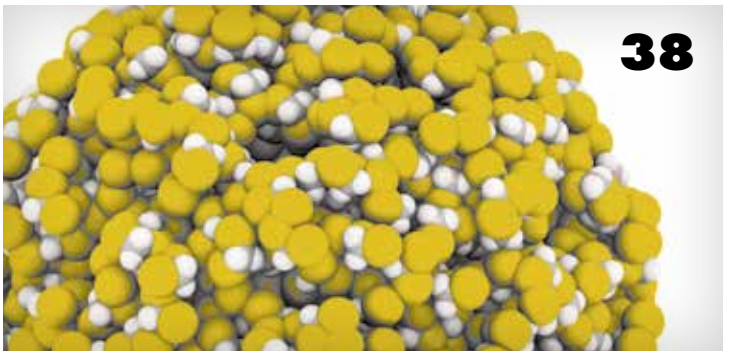
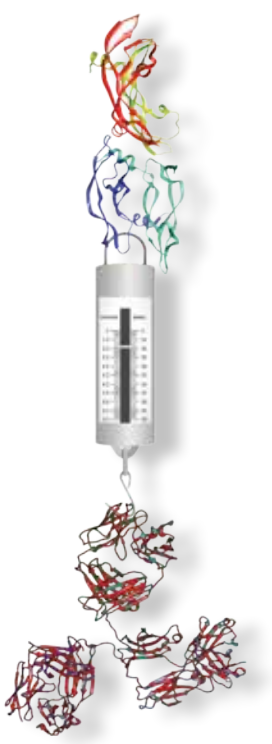
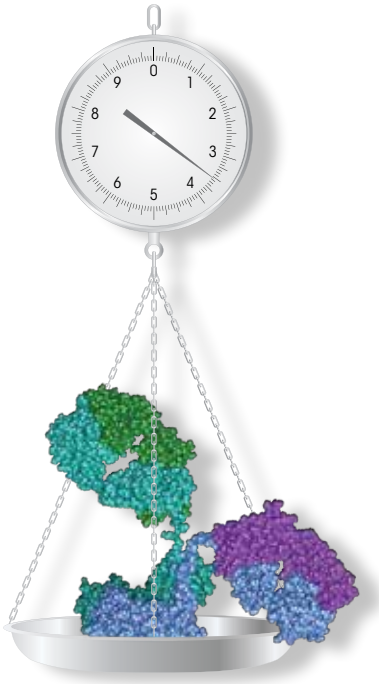


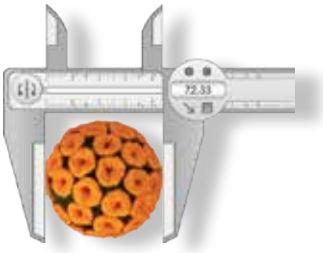


Interactions



Molar Mass

Charge



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Back in our November 2014 issue, we let you know that we would be adding exclusive online content to our website in the coming months. Starting with our Music in the Lab article, we have quietly posted three more web-only feature articles since then, and officially launched the section last month. You'll find this content area on our homepage, LabManager.com, directly below the "Current Issue" section, or you can head there directly via this link, www.labmanager.com/did-you-know. Be sure to check it out to catch up on any of the articles you may have missed. We will add a new exclusive at the beginning of each month, so pop back in to get the latest!

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Knowing the Risks

This month's cover story takes an in depth look at the impact of the first-inventor-to-file system that kicked in on March 16, 2013 under the America Invents Act. In addition to explaining the evolution of the new patent system, author Key Kidder lets R&D managers know what it might mean for them. "AIA puts R&D managers squarely on the spot. They must evaluate an innovation's commercial potential much earlier in the process with a larger group of stakeholders and maintain greater secrecy. Collaborations become dicey. Employee turnover can jeopardize IP. Managers, they say, must learn to think strategically to achieve market success." One more thing to add to your plate.

Forewarned is forearmed.

In addition to rethinking your strategy for dealing with patent laws, lab managers also need to understand the fundamentals of risk management. "There are many types or domains of risk in labs, including organizational and enterprise, health and safety, clinical and analytical, and environmental risks, to name a few," say authors Michael and Nanny Bosch in this month's Leadership & Staffing article. Turn to page 26 for some clear direction on how to create an effective and sustainable risk management program in your lab.

If you've been part of a big data implementation project, you already know the enormity of the task. If you haven't, but think you might be in the future, turn to page 32. "Laboratory managers helming such a project don't necessarily require the expertise to directly implement a big data project, but it is advisable that they have a general understanding of the process to be able to set realistic goals and timetables," which is exactly what author John Joyce provides in this month's article, "Launching a Big Data Project."

INSIGHTS articles in March include an examination of the latest analytical tools employed in today's sports doping laboratories (page 44), and technologies being used to develop promising new cancer treatments from antibody-drug conjugates (page 56). If your lab is involved in either of these areas of research, there is much to be gained from both articles.

As for other laboratory technologies, Product Focus articles this month look at GC systems, imaging systems for biology, microwave digesters, and lab stirrers. Survey Says reports cover HPLC systems, automated liquid handers, glassware washers, and glove boxes. And for the very latest in new product introductions across all categories, be sure to check out this month's Technology News section on page 70.

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Changing THE RULES

WHAT THE FIRST-INVENTOR-TO-FILE PATENT PROVISION MEANS FOR R&D MANAGERS

by F. Key Kidder

It has been over 40 months since President Obama signed the Leahy-Smith America Invents Act (AIA) into law in September 2011, climaxing years of feverish legislative wrangling. AIA was heralded as a game-changer, the dawning of an equitable intellectual property (IP) regimen that rewarded research scientists and innovators beset by ineffectual patent processes and procedures.

Is everybody happy? Far from it, but America's patent system "has always engendered bipolar reactions," said David Kappos, who helped preside over AIA's final formulation as then-director of the US Patent and Trademark Office (USPTO). If he was expecting a tepid reception for AIA, he got it.

As the final bill rounded into shape, stakeholders were restive and second-guessing the presumptive finished product. Post-passage, the roar of the crowd remains divided. The big multinationals and other well-capitalized interests figure they'll make out. The less well-endowed—independent inventors, government labs, nonprofit research groups, and some in academia—are more apt to perceive 2011's patent reform as patently offensive. Patent lawyers are laughing all the way to the bank. And some observers predict longer days in store for research managers burdened with new challenges under AIA.

AIA was heralded as the long-overdue legislative fix for what ails America's patent system. The last significant changes, enacted in 1952, produced an intellectual property architecture that left much to be desired as America entered the 21st century.

> "Patent lawyers are laughing all the way to the bank."

The dynamics of change and new technologies outstripped the ability of the USPTO to manage increased patent flows in timely fashion. Applications waited three years to be acted on. According to the Patently O blog, inventors who submitted valid patent applications endured a five-year wait. The pendency problem, or application backlog, was a bottleneck seen to stifle progress and impair America's competitive position in the global economy.

Reversing the systemic trend toward costly litigation as a common means of resolving disputes was another paramount concern of congressional leaders. Also high on their agenda was improving the synchronicity of America's intellectual property rights vis-à-vis other national patent systems to ensure that inventions retained their potency as they traveled through foreign jurisdictions.

Although the USPTO is one of the smallest of Washington, DC's federal agencies in terms of manpower, it hits way above its weight, to use a boxing analogy. Its roughly 9,000 examiners are on the front lines where the rubber hits the road in IP matters, deciding which patent applications make the cut, subject to review and reexamination and, increasingly, trial.

Congressional attempts to craft legislation began during the latter years of the administration of President George W. Bush. Proposed patent reforms failed to take flight in 2005, 2007, and 2009, but the players and approximate body of legislative work were assembled for the final push in 2011.

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AIA was among the most heavily lobbied issues of the past several decades. Among those agitating loudest for reform were well-funded software and information technology firms and pharmaceutical and life science interests. The latter group often have all their eggs in one patent basket. Many suffered financially toward the end of 2012 when a raft of patented medicines exhausted their 20-year term of protection and fell off the patent cliff. The former group is beset by the multiplicity of patents required to commercialize technologies and the plague of "trolls" who prowl for patents subsequently used for purposes many believe resemble extortion.

A complete understanding of AIA requires careful study and a good lawyer. The devil is in the details, and details are plentiful. As presented, AIA was a voluminous 59 PDF pages, broken down into 37 sections. With so many moving parts, it was no surprise that the bill contained bugs. One year after AIA's passage, a bill of "technical corrections" was fast-tracked through Congress and signed into law. Even this was ponderous, containing 14 separate sections of legislative fixes.

And still they didn't get it right. Robert Armitage, then senior vice president and general counsel of Eli Lilly and one of AIA's main architects, acknowledged that the bill of corrections contained errors.

The statute's complexity and broad language are problematic. Former USPTO director Kappos, commenting on the bill's clarity or lack thereof, admitted as much. "You do get a sense that there are many ways to interpret the statute," he said after its passage into law. "Some more wishful than textual."

"The devil is in the details, and details are plentiful."

The courts will have the last word. As with all laws, this statute is subject to judicial interpretation. Assessing the full impact of AIA remains on hold until the courts develop a mature body of case law—a process that observers agree will take years. The big question is how the Federal Circuit and ultimately the Supreme Court interpret AIA. The USPTO has been given new authority, but as long as the agency's decisions are subject to an overriding review by the courts, it remains unclear whether the USPTO's new powers in fact streamline the process.

This much is *extremely* clear: AIA will profoundly affect how patents are filed, prosecuted (considered by USPTO examiners), and litigated.

Owing to the founding fathers' concern with individual property rights, first to invent (FTI) was the operating principle of America's patent system prior to AIA. The intent was to reward the original inventor. But as proving one was first grew more problematic, litigation increased and the USPTO became mired in interminable disputes that stretched its resources. In this uncertain climate, venture capital receded, hurting start-ups.

Other jurisdictions—the European Union and most other developed nations—employ a system that awards whoever is the first to file (FTF) or apply for a patent. Changing from FTI to FTF, the centerpiece of AIA, was an attractive proposition for the bill's framers. FTF was a proven method at hand, and the switch would harmonize America with its major trading partners. Under FTI, parties in the process of taking a patented design to market were haunted by the prospects that another alleged inventor would

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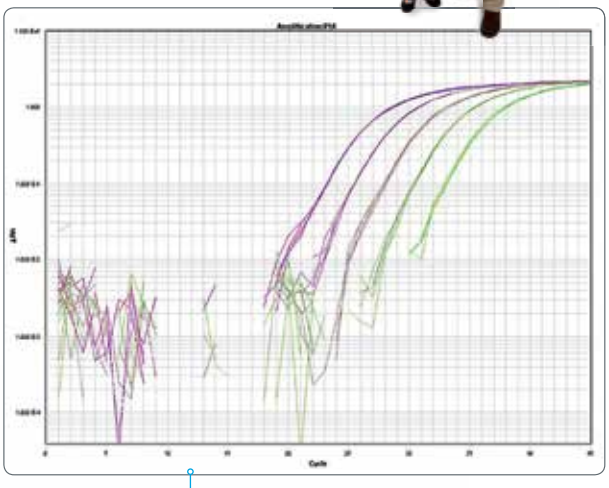

Standard Amplification Curves for COX gene. Standard cDNA samples were serially diluted 5-fold and amplified in 5 replicates (dilutions left to right: 5x, 25x, 125x, 625x and 3125x).

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emerge and throw the proceedings into gridlock. Under FTF, it's a simple matter of the filing date. What finally emerged under AIA was a first-inventor-to-file (FITF) system that kicked in on March 16, 2013.

An analysis on the Patently O blog suggests that AIA's purported harmonization is somewhat misleading. An FITF regime incorporates elements of both FTI (which it replaced) and FTF instead of integrating all combined aspects. So AIA may more accurately be described as a hybrid, and as such can produce outcomes different from those of FTF systems around the world—the sort of thing that should keep America's research community on its toes as it contemplates foreign and/or domestic IP rights.

AIA goes above and beyond the act of awarding a patent to the inventor whose application has the earliest priority date. The complexity of page after page of provisions creates loopholes that some will exploit and traps that will ensnare others, and puts lab managers on a steep learning curve.

To receive patent protection, an invention must be novel and not obvious. Under patent law, information previously in the public realm in any form is considered "prior art" that invalidates claims of originality. Under AIA, inventors have a one-year "grace period" after disclosure to file for domestic rights. But the European Patent Office and most other FTF regimes do not recognize a grace period, so any previous domestic disclosure is an absolute bar to subsequent patent protection abroad. The 2013 roll-out of the new Cooperative Patent Classification, which replaces European and American classification systems, is expected to ease the transition.

A careless or inadvertent disclosure at a trade show or conference or online is a misstep that can eliminate IP rights in foreign markets, but silence is costly domestically, and quick disclosure is paramount to preempt others from intervening. FITF is somewhat of a misnomer. The first inventor to file an application or conceive an invention is not necessarily the winner—it's the first to reduce an idea to practice and disclose the fact who stands to wins the patent, even if someone else came up with the same invention at an earlier date.

Researchers are now tasked with becoming more vigilant and proactive. An early analysis of prospective markets is essential, as is monitoring other relevant disclosures. Under AIA, the risk of IP theft increases, since internal documentation like notebooks becomes largely irrelevant in patent disputes—it's more a matter of the earliest date now. Preemptive defensive disclosures can thwart competitors but up the ante on international rights and one's own patent filing deadlines, since the 12-month clock starts ticking with any disclosure. Researchers seeking lucidity on this general issue may be displeased to learn that the USPTO still struggles with a precise definition of the word "disclosure."

Foreign considerations are routine for multinationals but another burden to bear elsewhere. AIA does include certain provisions designed to help independents and nonprofits—fee reductions for micro entities, fast-track patent examination, and expanded prior user rights. But less well-funded players will not take encouragement from the findings of a National Bureau of Economic Research study on the effects of Canada's switch to an FTF system in 1989. Noncorporate inventors suffered. Will America's colleges and universities—or their technology transfer offices—have trouble controlling academic researchers incentivized to publish to further their careers?

"We find that the switch failed to stimulate Canadian R&D efforts," said the study. "… reforms had a small

adverse effect on domestic-oriented industries and skewed the ownership structure of patented inventions towards large corporations, away from independent inventors and small businesses. These findings challenge the merits of adopting a first-to-file patent regime."

Venture capitalists invest on the future promise of technology with the expectation they can retain patented assets should the start-up fail. But the need for earlier disclosures and the 12-month clock make it harder for the little guys to shop their idea around for financial backing. It also suppresses innovation. Why keep inventing if you can't take ideas to market?

In the surge of technology, a patent's strategic value is more readily separated from its innovative value. Columbia University professor Rita McGrath makes the case that the traditional linkages between technology, innovation, and intellectual property are breaking apart, endangering sustained monopoly protections. As the pace of change accelerates, the window of opportunity to enjoy competitive advantage closes that much sooner. Monopoly investments fall short of producing long-term results. Successful inventors must become more agile and flexible—a quality more commonly attributable to smaller operators with less bureaucracy.

"Researchers are now tasked with becoming more vigilant and proactive."

An Industrial Research Institute study by W. Austin Spivey, J. Michael Munson, and Bernd Wurth takes an in-depth look at AIA's implications for lab managers. The authors contend that AIA puts R&D managers squarely on the spot. They must evaluate an innovation's commercial potential much earlier in the process with a larger group of stakeholders and maintain greater secrecy. Collaborations become dicey. Employee turnover can jeopardize IP. Managers, they say, must learn to think strategically to achieve market success.

A primary objective of AIA was to interject more certainty into the patent process. The last significant change was the Patent Act of 1952. If history is a guide, it may be a decade before the Supreme Court receives its first major case on FITF provisions. If that's not enough to generate misgivings, consider this: Congress called for no fewer than nine studies and reviews of AIA. Who knows what subsequent changes they will generate?

As the pace of innovation continues to outstrip the ability of intellectual property systems to manage change, the need for a new, updated system becomes more painfully obvious. So if you don't like this latest version, just stick around. The drumbeat for patent reform will go on and on.

F. Key Kidder *left journalism to pursue a career in government relations, politics, and PR, but he still likes to keep his hand in writing. He can be reached at k2@keykidder.com or by phone at 410-963-4426.*

YOUR LAB AS A MILITARY OPERATION?

By Tom Crea

High performing teams consistently fare better than their competitors, especially when the pressure is on.

Take the case of the military, where soldiers must work together as lives are at stake. Every soldier will want to take advantage of opportunities to work together and grow as a team because an occasion might arise where survival requires being able to depend on each other.

For instance, consider the complexity of teamwork and coordination required during the Allies D-Day invasion and establishing the beachhead at Normandy, France during World War II. Teamwork is critical to success.

A life or death scenario

Imagine a much smaller operation where an infantry unit of 100 men must attack an objective in a remote mountainous area. To get there, they must travel by helicopter and to increase safety, the operation must be done at night. Since it is a mountainous area, there isn't much open space and two helicopters are the most that can safely fit into the landing zone (LZ).

Now, let's say each helicopter can carry ten passengers, requiring ten aircraft to insert these troops. The infantry unit will have to be divided into five sorties arriving at the LZ in waves of 20 soldiers each. Coordination between the infantry and aviation units demands synchronization and confidence that everyone will perform their part.

Making a difference

To increase chances of survival, the groups of infantry soldiers must arrive as quickly as possible, one after the other. Upon arrival, they will need to clear the LZ and form a perimeter to provide security and allow the next sortie to land safely.

The helicopter unit will have to time their flights so that they land within seconds of the prior sortie's takeoff, offload the troops, and then clear the area for the next flight of aircraft. Finally, yet another aviation unit will provide close air support and the necessary firepower to protect the helicopters during the ingress, landing, and egress phases, as well as the soldiers who are on the ground.

Synchronization

Each infantryman must know how to safely enter and exit the helicopter, and once it lands, know exactly where to go and what to do when they get there—all of this occurring in the dark.

Each helicopter crew will have primary and secondary responsibilities such as flight navigation, coordination with the infantry unit, or coordinating air cover with the close air support aircraft. The close air support unit needs to know the helicopter flight routes and the location of the infantry soldiers so that there are no friendly fire casualties.

The complexity of the operation requires coordination and teamwork. Three separate organizations must be able to do their part and synchronize their efforts to work as one team.

Reality

So far, our scenario assumes everything is going as planned. *However, what if something goes wrong? How does each element react to a change? What are the individual responses and the collective reaction of the entire team?*

Inevitably, something may go wrong, but the best teams are so well prepared that they have a contingency plan for a variety of scenarios.

Whether lives are at stake or not, teamwork requires trust in one another and confidence in leadership; principles that apply to any team.

How do you motivate your team to stay committed?

"The most difficult thing for individuals to do when they are part of a team is to sacrifice. Without sacrifice, you'll never know your team's potential, or your own." – Pat Riley

Leaders who appreciate teamwork create an environment that allows their team to feel that they can learn, grow, and be a part of something greater.

How well does your team work together to answer these challenges?

Tom Crea *is the President of Blackhawk Consulting Group. A retired U.S. Army Lieutenant Colonel (LTC), his practice focuses on leadership, teamwork, and communication (LTC) within organizations. Contact Tom at www.BlackhawkLeader.com or call (412) 347-6151.*

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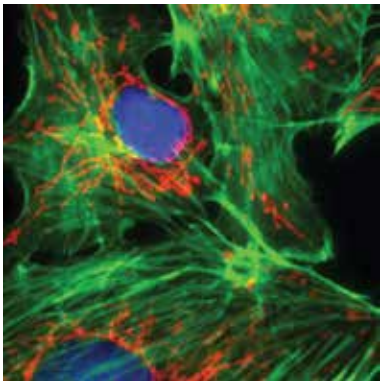

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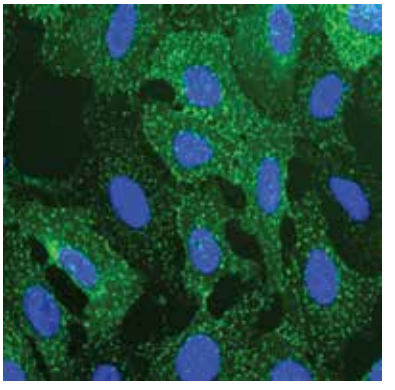

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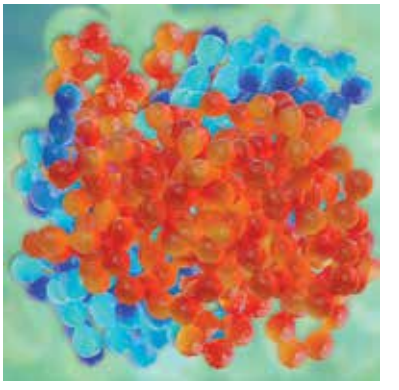

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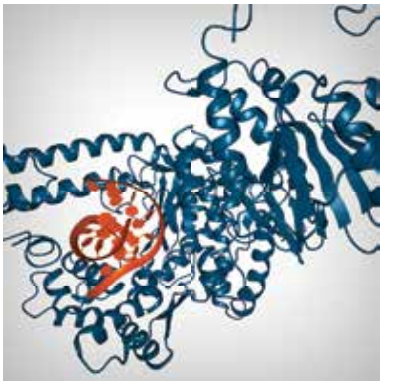

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LATEST TRENDS SHAPING THE SCIENTIFIC WORKFORCE

MANAGING RISK TAKES TALENT

By Mark A. Lanfear

Taking all the risk out of inherently risky situations has never been an easy task and probably never will be. (And no, I'm not talking about the Seahawks throwing a pass at the goal line instead of just running it in Super Bowl XLIX.) But for some industries and businesses, managing risk more successfully than others has become almost second nature.

Think about the construction industry in the U.S. for example: Over the past 100 years, due to increased oversight, regulations, and competition, it has had to steadily improve standard jobsite practices to ensure the safety of its workers. Successful insurance companies help enterprises manage risk, and that industry relies on experience, data, and statistics to the nth degree to keep going and remain profitable even in the worst of times. By recognizing areas of concern and dealing with them up front as part of their best practices, risk becomes a smaller part of their clients' business equation.

Managing risk successfully in the life sciences, consumer health, and biopharmaceutical industries involves how companies regulate liabilities in this vastly governed vertical and the litigation that might follow. A scenario might be how they deal with the untimely disruptions in the drug development process that can result in costly delays. But today, it's more often a company's workforce that can ensure successful business outcomes and decrease liability in the short and long term. Looking at the life science industry overall, you'll see that companies are increasingly utilizing contingent or contract-based workforce solutions globally. This means understanding the value of contingent workforce management (CWM) is more important than ever, and misunderstanding it is a great RISK.

Unlike days past when contingent workforce solutions might have been applied predominantly in relatively lower-skilled or short-term categories, CWM incorporates well-planned statements of work (SOW) put into action by highly talented, skilled consultants and independent contractors who undertake complex tasks for corporations. By sourcing highly skilled contingent labor, organizations can more effectively manage their spend for quality talent that is compliant with the SOW and help their customers not only reach tactical milestones, but also implement strategic goals.

It's probably safe to say that no matter how big or small, many companies aren't as well-equipped as they'd like to be to deal with the multifunctional demands and compliance that go along with hiring, managing, retaining, and releasing a capable contingent workforce.

However, there are ways to manage the talent risks you may be faced with in your research labs and manufacturing centers, while you continue to create opportunities for success. In fact, with the right contingent workforce strategies in place, organizations can meet or exceed their budget and production goals. An expert team of right-fit professionals yields greater flexibility, while at the same time holding down costs and surely decreasing the risk of overruns.

There's no question that accessing and managing the human capital required to keep workflow steady and productivity uninterrupted across time zones and across cultures can seem daunting, especially in the demanding, expertise-driven world of the sciences. There is the need to manage increased security around inert products and I.D. management with a global workforce flowing on and off campuses daily while also maintaining a controlled laboratory environment, compliant clean-rooms … the list goes on and on.

As if that isn't enough to put the importance of CWM into sharp focus, consider that without it, skilled talent will be harder to find, especially for peak or specialty projects that don't require long-term commitments, which are so common in the life sciences arena. And it's harder to manage costs without the predictability and discipline that dedicated, smart management provides.

So what's the best approach to take in order to minimize and manage your risk when it comes to outsourcing the contingent workforce talent you need? It starts with applying best practice principles to the human side of business and finding suppliers you can trust with this most critical aspect of your business.

From my point of view, having a disciplined program around the management of your external workforce is something every science-oriented company should consider. Within the framework of proven talent supply chain management, it offers organizations a single-source provider of temporary labor, free agents, and service projects that drive quality of talent, cost savings, and process efficiency—three areas that most companies are typically most interested in optimizing. Handled correctly, you'll get the high-caliber, culture-matched talent you need wherever you're doing business.

When labor market insight, data analytics, and supply chain management principles are put in place, organizations can optimize their contingent labor spend, giving them access to service providers and quality talent at competitive rates and with minimized risk. And ultimately, that gives you the best possible way to keep your business moving forward, no matter how complex it is or how flexible you have to be.

To operationalize any goal, you first need the talent. Truly forward-thinking organizations are moving toward taking advantage of this outsourcing approach, which incorporates management of their entire workforce needs under a single talent strategy. Taking all the risk out of every business situation isn't possible in the boardroom, in a lab, or on a football field for that matter. But taking the right steps to ensure success in achieving your business goals with a contingent workforce strategy will put the odds in your favor—not to mention, give you an opportunity to achieve the best possible, most consistent results wherever you are in the world.

Mark Lanfear *is a global practice leader for the life science vertical at Kelly Services, a leader in providing workforce solutions. He has operated clinical trials around the world for almost two decades. In addition, Mark is a featured speaker at many life science industry conferences and a writer for life science periodicals. He can be reached at MARL773@kellyservices.com or 248-244-4361.*

AUTOMATING SAMPLE PREPARATION

COST VERSUS PAYBACK

by Joe Liscouski

Sample preparation can be a labor-intensive and expensive process. What are the factors that should be considered when evaluating the possible transition from manual to semi-automated or fully automated systems? How do they impact your return on investment? The goals for improvements in sample prep include:

- Overall cost reduction, including labor and materials
- More consistent preparation
- Higher productivity—more samples processed, which may be coupled with automated instruments
- The ability to work with hazardous materials
- More extensive analysis—work that might be too expensive for manual efforts such as statistical experimental design and high-throughput screening
- The potential for 24/7 operations

For any ROI equation, there are two sides to consider. The first is what you want out of it, which includes some or all of the points above plus metrics—what level of performance are you looking for, what are you willing to spend, and what is the schedule requirement for implementation? You also have to evaluate the alternatives to automated systems, which include increasing head count or outsourcing work for comparison. Those last points would have to include an understanding of whether the need is a temporary spike in testing throughput or a long-term requirement; it is going to take time to implement a solution, and you don't want it coming online as the need evaporates.

The other side of the equation covers the costs. They include the development of the user and system requirements, a feasibility study, and prototype work, followed by the actual design, implementation, documentation, testing, validation, and user education. Given a set of requirements, the next major step is the feasibility study—this is going to provide the basis for the go/no-go decision on the project and guide the design effort. The first step in that study is an evaluation of the sample preparation procedure, the underlying process of the system.

Unless the process is specifically designed for automated implementation, the process is going to have to be analyzed to see what it will take to make it suitable for semi-automated or fully automated work. If there is a make-or-break step in the project, this is it. Lab procedures—and given the readership of this magazine, we're covering a broad spectrum of procedures—describe the science behind the work and what steps people should take to carry it out, relying on the individuals' intelligence to fill in gaps or make things work. The first item that has to be determined is whether you are using the current, up-to-date description of the process, including any undocumented workarounds, temporary fixes, etc.

Next, the feasibility analysis has to evaluate whether there is anything about the process that precludes automation. This would include working with objects or materials that depend on human dexterity and might not be usable with robotic systems. If that is the case, is it possible to modify the equipment or process to make the automation work without altering the science itself? Another consideration is whether the process can be optimized—this may be necessary in order to meet performance goals.

Early robotic sample preparation system implementations mimicked human activities, carrying out the same steps, one at a time, that people did. This removed people from the system (one goal) but often didn't process more samples per hour, although it did provide

a means for three-shift operation. Process optimization may require a change in how the process takes place, as long as it doesn't compromise the integrity of the results. Examples of this can be found in life science's implementations of assays and screening using microplates. Microplates can carry from as few as six to as many as 3,456 wells, although 96- and 384-well plates are more typical.

"It may be possible to apply microplates to analytical work outside life science applications."

Each well—essentially a miniature test tube—carries one sample, blank or standard for analysis, and allows for parallel processing of the plate's well contents. That allows for very high throughputs for colorimetric work or other analyses. One question is whether this technology can be applied to a wider range of lab applications. The plates can be made from polystyrene, polypropylene, cyclic olefin copolymers, and glass. Given the availability of microplate-handling equipment that includes washers, liquid additions, sealers, and readers, it may be possible to apply microplates to analytical work outside life science applications. There is one caution: the small sample size of the plates' wells (each well in a 96-well plate is 360 µl—the volume may vary for special configurations) requires highly homogeneous samples; that may not be a problem with liquid samples but could be with solid material that has to be dissolved. Solvent leaching of additives (antioxidants, etc.) is a potential problem when working with small volumes with large contact areas; you may not dissolve the material, but small molecules may migrate from the holder into your sample.

The high throughput of life science assays via microplates is a result of standardization of microplate geometry. Sample preparation methods that are based on standardized sample containers will reduce the effort in automating systems. This is particularly true of autosamplers that use standardized vials. The Agilent 7693A

ALS, for example, is an autosampler that can be programmed to process samples prior to injection into a gas chromatograph. It has the ability to carry out liquid/liquid extractions, small-volume sampling, reagent and standard additions, heating, mixing, reconstitution, dilution, aliquoting, and bar code reading programmed through a chromatographic data system. The use of standardized components reduces development costs, increases the likelihood of success, and permits reconfiguration of systems as needs change.

If your application requires a custom-designed solution based on individual components (robotic arm, sample holders, etc.), the cost of development can increase significantly. The service life of the sample preparation system has an impact on your choice of standards-based or custom solutions. This is one area where the formation of an active user community can benefit lab work. Unless you believe that having a particular automated sample preparation system provides a competitive advantage, consider having a partnership with companies with similar needs to jointly develop automated solutions. This should reduce the cost of development and provide a more robust system with better support. It may also provide enough market justification for an equipment vendor to step in and develop hardware to fit the application. Standards, in some cases, do not have to be universal but can be industry/community/application-specific.

A sample preparation system's service life can be measured two ways: by the calendar and by the number of samples. Sample volume (samples per day for the expected service life of the system) is the key factor. The ROI comparison between manual (including outsourced) sample preparation methods and automated systems is going to depend on the volume of samples needed to justify the cost of development. The calendar component comes into play when the system is going to be in use long enough to require software or hardware changes or upgrades—software update schedules will usually occur on an annual basis (but vary from one vendor to another), and hardware component changes may occur on an 18-to-24-month schedule (using computer hardware as a guide), about the time people start looking for more performance from a system. The potential for system changes is going to have to be factored into the system design; the upgrade process can cause systems to fail, particularly if developers have modified underlying system software that is compromised by the upgrade. Good development practices should take this into account, but they often require more effort. Systems based on standardized components are more likely to avoid this problem, requiring shorter development schedules and reduced development costs.

One point noted earlier was the use of a prototype system in the feasibility phase of the work. This stage is often ignored; once something that "works" is put together, it is left as is. There are important questions that have to be asked, and two of them are "If we had to do this again, how would we change/improve it?" and "What did we learn from this?" The answers to those questions separate a well-designed system from something that will have to be fixed later on. There is an unfortunate phrase that comes up in a project when schedules and budget are getting tight: *There is never time to do it right, but there is always time to do it over.* Doing it right is the only way that makes sense. The alternative is a compromised process that

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may not yield the quality of results that is expected, and you may not find out about it until a significant problem develops.

Automated sample preparation systems can address special needs that can skew the ROI evaluation. If you are working with hazardous materials or samples/reagents that require special handling or controlled environments, automated systems may be better from a safety standpoint. Centralized sample processing using pneumatic or rail-based sample delivery to instruments can make this feasible. The change to the ROI analysis is the cost of the system versus the safety and centralized material-handling benefits.

What has been described so far is a *scientific manufacturing* approach to laboratory sample preparation. We are looking at scientific processes that take incoming materials and transform them into samples ready for analysis or, ideally, continue the process to include automated introduction of the samples into instruments. The steps that have been outlined (cost considerations, feasibility analysis, process optimization, consideration for implementation methods) are common to any production process. They aren't within the experience of most lab or IT personnel. Where do you get help with doing this work? Find people with chemical process engineering, bioprocess engineering, and/or mechanical engineering backgrounds; it is a matter of applying their skills to lab work. In many cases it is just a matter of scale between typical process engineering and laboratory applications. In addition, they will be in a position to advise you about statistical process control and managing automated systems.

This is a different way of looking at laboratory work, a shift from hands-on experiments and procedure execution to working with systems that do that work for you. That will require a change in people's responsibilities and education. They will need to understand the process being carried out but also understand the equipment, how it functions, troubleshooting, evolutionary operations (making small, controlled, incremental changes to improve a process), and statistical process control to detect and correct process changes. This will add to the cost side of the equation, but the payback will be significant. Automated sample preparation has the potential to process samples at a lower cost and higher throughput than manual methods, with more control over the quality of the result—less variation in sample preparation. However, the system has to be carefully evaluated, tested, validated, and maintained to ensure that quality.

Automated sample preparation is not always the best approach. It takes time to design and implement, and some processes that are too entrenched in equipment designed for human use may not be cost-effectively converted. It may require new equipment designs. Processes need to evaluated and designed for automated use. If the justification is there, automated sample preparation can be a cost-effective tool in lab work.

Joe Liscouski *is the executive director of the Institute for Laboratory Automation, a nonprofit organization. He specializes in helping labs understand and apply technology to lab work. He is also the author of the soon to be released book, "Computerized Systems in the Modern Laboratory: A Practical Guide." Joe can be reached at j.liscouski@InstituteLabAuto.org.*

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MANAGING RISK

A PRIMER FOR LAB MANAGERS

By Michael Bosch, MS, PMP, and Nanny Bosch, MS, PMP

Risk and related concepts such as risk management and risk communication can be difficult for lab managers to fully understand. However, those same managers may be engaged in actions associated with potentially disastrous risks.

This article explains the fundamentals of risk management and the ways that lab managers can serve as their organization's primary risk manager.

Common risk terms

Risk	An event that has the potential to take place.
Risk Management	The monitoring, identification, analysis, assessment, control of, and response to unacceptable risks.
Negative Risk	Negative risks are what people are thinking of when they most commonly define "risk" as "a situation involving exposure to danger, harm, or loss." Unacceptable risks may be considered a subset of negative risks.
Positive Risk	Positive risk is a beneficial potential occurrence. That is, something you want to happen that might happen.
Risk Response	Actions taken to either reduce the likelihood of a negative risk, or to increase the likelihood of a positive risk. A number of common risk response strategies are provided below: **Acceptance**—Assuming the risk and its resultant impacts. **Mitigation**—Minimizing the potential impacts of a risk through various means. **Avoidance**—Taking steps to actively prevent the event's occurrence. **Transference**—Shifting risk to another party through various means. For positive risks, there is another response option: **Enhancement**, or promotion—in which the probability of the positive risk is enhanced to ensure its likelihood.

Measuring risk

Risk measurement commonly includes qualitative visualizations on a Cartesian field, with one axis measuring the risk's severity of impact and the other gauging its probability. Higher severity/probability risks should be addressed first and most expeditiously.

There are also ways to assign numeric values for risk using the criteria referenced above as well as others (response effort, alternative paths, etc.) so that they can be prioritized and categorized that way. A combination of scoring along with grouping of risks based on those scores into four or five categories is a common method (e.g., scores of 0 to 50, say, would be low risk, while 51 to 80 might be medium risk).

It also helps in measuring risk to have appropriate levels of metadata for each risk managed. Recommendations for what metadata to collect are provided below.

Areas of risk

Risk management fundamentals usually categorize risks as either negative or positive as mentioned, but it's important to remember that there are many "types" or "domains" of risk in labs, including organizational and enterprise, health and safety, clinical and analytical, and environmental risks, to name a few. In addition, there are areas of focus such as fraud risk management, contract risk management, terrorism threat assessments, and financial risk management associated with lab operations.

The difference between risks and issues

What is the difference between a risk and an issue? Answer: a risk has not yet occurred, and an issue has.

Thus, we commonly advise labs to develop a risk and issue management program. That way, risks and issues are being tracked together in an integrated way. When risks

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trigger, they are now tracked as issues. If issues are resolved but could possibly still occur, they should continue to be tracked—but now as risks.

Why the different but related approaches? Because response to a risk is approached differently than resolving an issue is. However, a risk and an issue share a lot of the same metadata—assigned owner, status, escalation processes, etc. That being said, there are metadata that are associated only with issues, such as target resolution dates, and those only with risks, such as trigger criteria.

Standard risk management process steps

Risk management processes can be customized, expanded, and extended to suit individual organizational needs, but the most common components are shown below. Activity is usually ongoing in all of these steps at the same time.

Risk Monitoring	The risk management process begins with a vibrant elicitation and discovery of risks: sources, instances, metadata. This provides the data and information for the tracking, identification, and response phases of risk management. This is an ongoing process step.
Risk Identification	This step inputs those future potential occurrences found as part of monitoring into a risk register (see below), gives them an ID, and assigns them to a risk analyst to review. This step sets the stage for the process-driven control of risks through the register.
Risk Assessment | Analysis	This step may be an informal assessment of each identified risk by the risk team, or may include more formalized, rigorous analysis and assessment. Examples of artifacts include cause and effect diagrams, control charts, and time series graphs. Severity and probability ratings, risk owner assignments, and risk prioritization, among other tasks, are performed. Initial response may also be conducted as a result of this process step. Results of the analyses are input into the register. This is also the step where, if the potential event is found to be not a viable risk for any reason, it can be voided, or retired.
Risk Response Development	As described above, there are several basic response strategies to choose from, with customized blending of responses such as mitigation and transference being a standard scenario. Tasks associated with risk response include further analyses and investigations, corrective and preventive action implementations, process redesigns, audits, and stop works. Response strategies can often be quite complex, requiring extensive task management efforts and broad documentation and reporting.
Risk Response Implementation	The implementation of the risk response strategy planned in the previous step is carried out, usually by the business unit(s) for which the risk applies (i.e., not the risk team). However, risk team members commonly serve as oversight and consultation resources in risk response implementation.
Post-Response Review	This is the "lessons learned" step, discussed in more detail below.

People, process, and technology

We discussed the overall risk management process at a high level above, but here we want to delve deeper. At the very least, there should be someone assigned as the single point of contact for risk management in your laboratory, and a risk management team (governance teams

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often make excellent risk teams) should be empaneled. In addition, we recommend that you track your risks in a digital manner, preferably in a relational database (but at least in something like a spreadsheet). This is your risk register (see below).

Risk Manager(s)	Optimally, one person should serve as the risk manager for your lab, even if that person has other responsibilities—as is commonly the case. The risk manager leads the overall management approach, leads the risk management team, reports to management, conducts risk-related sessions and workshops, and chairs risk team meetings.
Risk Analyst(s)	Risk analysts are those specialists who engage in the actual assessment activities described earlier. They perform discovery, investigation, and reporting activities that support the risk team's management efforts. One or more of the analysts usually administers the risk register (see below).
Risk Register	The primary tracking and communication tool for your risk management program is the risk register. It can be something as simple as a spreadsheet or a multi-table relational database, or as complex as a component of an ERP system. It should track at least the following metadata for each risk: **Risk Title**—A short "name" for the risk **Risk Description**—A more narrative description **Identification Code**—A unique identifier for every risk **Identification Date**—An aid for tracking and prioritizing **Identified By**—An aid for tracking, assessment, and control **Potential Impacts**—A narrative description of what could result from the risk triggering **Severity**—Commonly "high/medium/low," a number ranking, or other logical coding system **Status**—Such as identified, in analysis, monitored, in response, triggered, and retired **Owner**—The person in charge of responding to this risk.
Intranet Collaboration System	Stepping up the communication game a little bit, we often recommend that our clients use an intranet or other type of web-based collaboration system to assist in the communication of efforts such as risk management; this could have its own website in the intranet, or be part of an operations or project management office (PMO) site. The important point is that risks can be further broadcast to (and received from) the staff.

The follow-up: Lessons learned

One of the most commonly overlooked, yet critical, components of risk management is post-response review sessions, commonly known as lessons learned sessions (LLS). LLS provide the assessment and improvement link that will prevent your lab from repeating the same scenarios. Furthermore, LLS can highlight what went "very right" with a risk management scenario so that it might be scaled out into the rest of your program. LLS also allow the discovery of risk patterns that you can proactively identify and manage in future operations and projects.

> "It helps in measuring risk to have appropriate levels of metadata for each risk managed."

At a minimum, capture the following information from the sessions:

- Description of the managed risk(s)
- Proposed and selected risk response actions
- Successes: what went well
- What did not go well
- Mistakes encountered
- Unexpected occurrences encountered
- Actions taken to prevent these mistakes and unexpected events
- Suggestions for improvement

Risk management takeaways

The following are some key points we want to underscore with regard to a sustainable risk management program:

- **Minimize negative risks, potentiate positive risks**—The key to any good risk management program is that risk retirement is quick, efficient, and sufficiently documented.
- **Create a risk register**—Don't try to do it all "in your head" or make the register process so arcane that no one follows it.

- **Hold lessons learned sessions**—Perform them after major risk response efforts at least, but we recommend starting with all but trivial responses being analyzed post-response at first.
- **Engage your staff in risk management**—Flagging potential risks for identification and analysis is the responsibility of each lab member.
- **Appoint and convene a risk management team**—Or extend the charter of a governance or change control team, but get a group of your sharp people from a cross-section of the lab involved in this effort.
- **Speak up, keep up the chatter, and keep your staff informed**—An enormous part of a risk management program's success is based on communication.
- **Constantly assess and improve**—Carefully assess your risk management program and continuously improve it.

"Risk management processes can be customized, expanded, and extended to suit individual organizational needs."

Michael and Nanny Bosch *are senior managing consultants of The Bosch Group, Inc. They have spent the last 20 years helping companies evolve their way of doing business, and they have both worked in multiple labs at the bench and management levels. They also teach a course in laboratory leadership management hosted through UC Davis Extension (UCDE). They can be reached at request@boschgroupinc.com.*

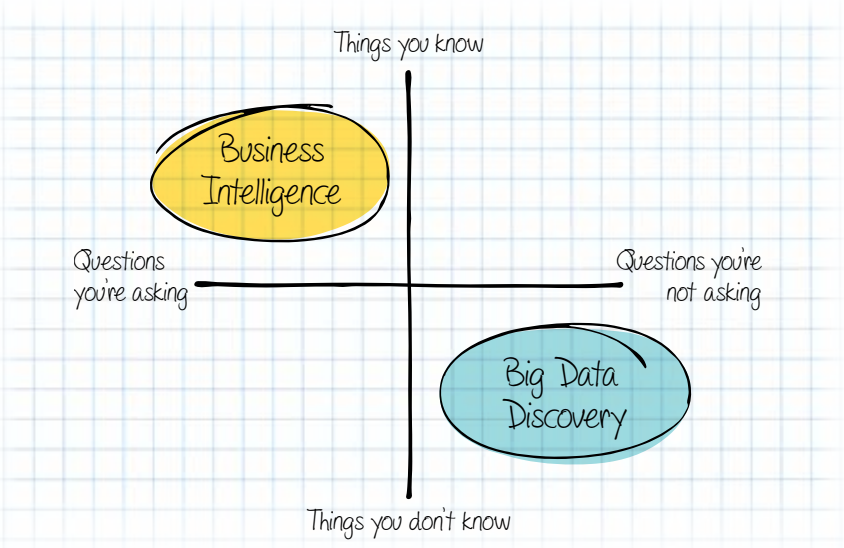
LAUNCHING A BIG DATA PROJECT

START SMALL AND TAKE YOUR TIME

By John Joyce, PhD

Big data is the current hot buzzword in data analysis. Laboratory managers helming such a project don't necessarily require the expertise to directly implement a big data project, but it is advisable that they have a general understanding of the process to be able to set realistic goals and timetables. Keep in mind that a big data project is not the same as a business intelligence project. While the differences are actually more complex, Eric Brown's[1] thumbnail description does illustrate the main difference in focus.

A good place to start is with an examination of what the term "big data" means. Unfortunately, this is somewhat like stepping off solid ground into quicksand. If you ask people in different organizations what they mean by big data, you are likely to get radically different answers from each of them. It turns out that there is no real consensus of what the term big data means. In reading through a variety of papers, it seems very much like Lewis Carroll's book *Through the Looking Glass,* where Humpty Dumpty states, "When I use a word, it means just what I choose it to mean—neither more nor less."



▲ *Business intelligence helps find answers to questions you know. Big data helps you find the questions you don't know you want to ask.*

Part of the reason for this is that big data is such a large umbrella term that it encompasses projects with very different goals. For the purpose of this article, the following criteria apply:

- Data is generally complex and unstructured.
- Data is frequently dirty and must be cleaned.
- Data is difficult to process with existing tools.

While exploring the possible benefits of big data, keep in mind that a big data solution is a technology while a data warehousing is an architecture. When talking with vendors, you may come across some who claim that a data warehouse is unnecessary if you have a big data solution. As the terms are referring to different types of things, the fact that you have one does not eliminate the need for the other, though there are a number of different ways that they can be used together.[2] The purpose of a data warehouse is generally to ensure that everyone in the company is using the same data.

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There are many ways to launch a big data project. However, the majority of the papers that I've examined all start with the same piece of initial advice: start small. By starting with a smaller subset of your data, or even with the external test data sets available, you'll allow your big data team to become familiar with the various tools available, reducing stress and minimizing the risk of errors.

When selecting people to staff and head the actual project, a good place to start looking is among your existing personnel. While the person heading this team should ideally be someone who is very computer literate and has an understanding of statistics, in most cases you are better off with someone who is a generalist, as opposed to a specialist in a single field. While some might find it surprising, the personality characteristic that is frequently cited as a requirement for driving a big data analysis project to a successful resolution is that of a philosopher. As Darin Bartik[3] argues, it is the application of the Socratic Method, the answering of a question with a question to push for hidden answers, that is imperative to the success of a big data program.

Depending on the size of your organization, you might have an internal Information Technology (IT) group. If you do, their expertise can be invaluable. On the other hand, I've observed a tendency with some IT groups to attempt to hijack various internal informatics projects because they were, well, computer related. While these groups may well have superior expertise in networking, database creation, or server support, they generally have no expertise in critical fields such as chemistry or pharmaceuticals or any clinical experience. This domain expertise is critical to being able to tease useful information out of your potential mountains of raw data. In the best of cases, all of the groups come together with the goal of making the project successful, with no attempts to extend an existing fiefdom. When the latter occurs, it may well fall to the lab manager to quell any departmental infighting, which can be a major challenge. Good communication lubricates a lot of things, but for this reason alone it is important that the designated team leader keep good communication going with the laboratory manager, not with the expectation of them resolving all the problems that inevitably occur, but so that the lab manager can recognize and act on any higher-level issues that the team leader might not have been made aware of.

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There are a variety of ways that a big data project might be implemented. The three most common approaches are:

- Contract to outsource the project completely.
- Hire a consultant to work with internal staff.
- Handle the entire project internally.

While turning the project over to an external company can be less disruptive to normal laboratory operations, it is fraught with hidden risk. The biggest risk is the same as allowing the company's IT team to take over the project: the odds that the external company's staff has sufficient domain expertise to successfully run the project to completion are small.

Hiring a consultant to assist in designing and installing the system definitely has its benefits, particularly if your staff resources are relatively small. This process does include the potential risk of your becoming dependent on the consultant and having their expertise leave with them. For this reason, you should maximize the value of the consultant by having the project staff work closely with them to learn as much about the process as they can.

Handling the whole project internally is definitely possible, but includes a number of caveats. Most important, the people selected for this team, particularly their leader, must understand that this implementation is their primary task, and this must be enforced. In other words, they should not be expected to also perform their normal assignments. It is critical that they be allowed to focus on this project and are protected from other people trying to divert them to other projects, even part time. Expecting them to handle both is unrealistic and generally leads to burnt-out personnel and failed projects.

Once the team has been selected, there is a natural tendency to want to figure out what tools they will be using and get familiar with them, but this would be a mistake. Picking your informatics solution first is somewhat like The Law of the Instrument, where if the only tool you have is a hammer, everything looks like a nail. Instead of starting by identifying the tools, the better approach is to identify the business problem you are attempting to solve or the business opportunity you are attempting to address. This is obviously a challenge, as one of the goals of a big data project is to identify previously unknown relationships.

If it doesn't already exist, now would be a good time to set up an information/data governance policy to manage your big data. Data governance can be defined as "…the business-driven policy-making and oversight of data. As defined, data governance applies to each of the six preceding stages of big data delivery. [Collect; Process; Manage; Measure; Consume; and Store.] By establishing processes and guiding principles, it sanctions behaviors around data. And big data needs to be governed according to its intended consumption, otherwise the risk is disaffection of constituents, not to mention overinvestment."[4]

This plan describes how the data is collected, processed, managed, consumed, and stored. Among other things, this document defines who has access to the data. While the company might have intellectual property concerns over the data, there are a variety of ethical[5] and regulatory concerns about it as well, with one of the major ones being privacy. More than 80 countries currently have data privacy laws in place. In the U.S., one must be concerned not only with federal regulations, such as Sarbanes-Oxley and the Health Insurance Portability and Accountability Act (HIPAA), but individual state laws as well. Forrester Consulting advocates creating multiple governance zones, instead of "a single set of standards, policies, and practices," which their research indicates "stifles the value that can be achieved from big data investment and insights."

In conjunction with this data governance policy, you should also have your team review the state of the current data to maximize its usefulness. I wish it went without saying, but if you have been deleting/purging data, stop! Almost as important, your data only has value if you know what it is. As big data is normally unstructured, or at best semi-structured, the only way to do this reliably is to make sure that you include meta data regarding your data (in other words, data about the data). This is even more important if you are pulling data in from a variety of sources, such as satellite labs.

Eventually, tools will need to be selected and the team trained in their use. Fortunately, this is somewhat easier than it sounds, as there are multiple online courses on data analytics and the various big data tools available. Many of these courses are free or inexpensive, though some can cost thousands of dollars. While it focuses on using Apache's Hadoop in a Linux/Unix environment, Russell Jurney's book *Agile Data Science*[6] provides a good tutorial regarding the approaches to handling big data and setting up the required software environment.

Nor does the decision regarding which tools to use need be made in the dark. Many vendors have trial versions of their wares available for evaluation, so that your team can see which ones best meet their needs. In some cases this may be a pre-integrated and configured

virtual machine that you can just install and run. In other cases, they may provide online instructions regarding how to download, configure, and run the applications. Most of the cloud providers also render free online access to their systems for evaluation. In almost all cases, there are associated webcasts available to assist in evaluating and using the packages. Many of these software "stacks" are based on Hadoop, but other options are increasingly available.

Despite what some vendors might indicate, your team will not be up and analyzing data within a half hour. Unfortunately, the learning curve for big data tools, while flattening, is still fairly steep. It will take significant time to just evaluate both the tools and your data to determine the best match. As *Lab Manager* has previously indicated, you should allow approximately 18 months before declaring a big data project to be a success or a failure.

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STRIPPER, ANYONE?

COMPLYING WITH OSHA STANDARDS REGARDING METHYLENE CHLORIDE

by Vince McLeod

Now that we have your attention, we have to dash your hopes. This is not a column about Vegas and "what happens in Vegas, stays in Vegas" kind of fun. It is going to provide vital safety information on one of the most widely used laboratory solvents. The title is derived from what is probably the best-known common use of the term outside laboratories—i.e., a chemical stripper or stripping agent. If you have ever refinished an old, treasured piece of furniture or tried to remove paint from an item being restored, you have most likely reached for Strypeeze®, the orange stuff, or a similar paint/varnish stripper at your local hardware store. That is methylene chloride, also known as dichloromethane, a potentially dangerous solvent responsible for at least 13 fatalities since 2000.

In the February 24, 2012, Morbidity and Mortality Weekly Report (MMWR), the Centers for Disease Control and Prevention published a brief report on methylene chloride fatalities among bathtub refinishers.[1] The CDC report states that OSHA identified 10 deaths related to methylene chloride stripping agents, and another three were investigated by the Michigan FACE (Fatality Assessment and Control Evaluation) program from 2000 to 2011. Granted, these fatalities are extreme cases involving bathtub refinishers and aircraft-grade stripping agents, scenarios not likely to occur in our laboratories. But when you consider that the average amount used in each case was only six fluid ounces (177ml) and that exposures as short as one hour were all it took, they do demonstrate vividly the potential dangers of working with methylene chloride.

In fact, methylene chloride and its associated hazards are serious enough for OSHA to produce a specific standard covering its use in the workplace—29CFR1910.1052.[2] The standard sets action levels, permissible exposure limits, and requirements for compliance—all the usual things that we will distill for you shortly. First let's get to know a little more about the chemical we are using.

The lowdown—Uses, chemical/physical properties, symptoms, and effects

In laboratories, the most common use for methylene chloride is as a solvent, especially as an extraction liquid for gas chromatography. Other uses include metal cleaning and degreasing, serving as a process catalyst, pharmaceutical and adhesive manufacturing, polyurethane foam and polycarbonate resin production, and chemical stripping, among many others. It is a colorless liquid with a moderately sweet aroma, similar to chloroform. Methylene chloride is highly volatile, with a low boiling point (104°F) and vapor pressure (350mm Hg). When those are combined with its heavier-than-air molecular weight (85), methylene chloride is a serious inhalation hazard.

The primary exposure route for methylene chloride is inhalation, although absorption through the skin is also a concern. Acute inhalation produces central nervous system depression, and at very high concentrations can lead to narcosis, eventually causing respiratory failure and death. Since methylene chloride is metabolized to formaldehyde and carbon monoxide, chronic exposure can produce CO-type symptoms of headache, nausea, vomiting, confusion, and

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dizziness. Skin contact can result in irritation and chemical burns. In addition, OSHA considers methylene chloride a potential occupational carcinogen.

Assessment first

The OSHA standard covers all occupational exposure to methylene chloride in general industry in all workplaces (separate standards cover shipyards and construction sites). If this solvent or chemical is used in your workplace, an exposure assessment and a hazard evaluation are required for those employees handling the material. The OSHA action level (AL) is 12.5ppm (parts per million methylene chloride in air), and if this is reached or exceeded, it triggers compliance activities such as monitoring and medical surveillance. The permissible exposure limit (PEL) is 25ppm, at which point employers must use engineering and work practice controls to limit employee exposures. Both the AL and the PEL are based on eight-hour time-weighted averages (TWA) or, in other words, an average exposure for a full work shift. Respiratory protection is an alternative as an interim measure while controls are being put in place or if engineering controls are insufficient or unavailable.

There is also a short-term exposure limit (STEL) of 125ppm based on a 15-minute TWA. This level should never be exceeded. To complete the standard, the limit for exposure immediately dangerous to life and health (IDLH) is 2,300ppm.

"In laboratories, the most common use for methylene chloride is as a solvent, especially as an extraction liquid for gas chromatography."

Assessments are conducted by measuring the air concentrations near the worker's breathing zone for a representative number of employees for each process or task where the chemical is used. An initial assessment and monitoring are required unless the employer has objective data that demonstrate the highest potential exposure (worst case scenario) does not exceed the AL and STEL or exposures are for fewer than 30 days per year.

Then compliance

Once the initial assessments are completed, the data are evaluated. If the AL and/or STEL are exceeded, then periodic monitoring is required, following Table 1 below.

TABLE 1: MONITORING REQUIREMENTS

EXPOSURE SCENARIO	REQUIRED MONITORING ACTIVITY
Below the action level (12.5 ppm) and at or below the STEL (125 ppm)	No eight-hour TWA or STEL monitoring required
Below the action level (12.5 ppm) and above the STEL (125 ppm)	No eight-hour TWA monitoring required; monitor STEL exposures every three months
At or above the action level (12.5 ppm), at or below the PEL (25 ppm TWA), and at or below the STEL (125 ppm)	Monitor eight-hour TWA exposures every six months
At or above the action level (12.5 ppm), at or below the PEL (25 ppm TWA), and above the STEL (125 ppm)	Monitor eight-hour TWA exposures every six months and monitor STEL exposures every three months
Above the PEL (25 ppm TWA), and at or below the STEL (125 ppm)	Monitor eight-hour exposures every three months
Above the PEL (25 ppm TWA) and above the STEL (125 ppm)	Monitor eight-hour TWA exposures and STEL exposures every three months

Regulated areas are established and clearly marked for all spaces where the PEL and STEL levels are exceeded. This includes any area where the limits are expected to go above the PEL or STEL. Minimize the number of employees authorized to enter these areas.

Hazard communication must inform all affected employees of the dangers of working with methylene chloride, including the health effects, symptoms of exposure, and safety requirements.

Finally, employers must implement a medical surveillance program and include every employee covered by the OSHA standard. The medical surveillance is provided at no cost to the employee and includes an initial physical exam and medical history, periodic exams based on the employee's age, emergency exams following any incident, and exams at reassignment or the end of employment.

SAFETY TIP

PROVIDE SECURE, ADEQUATELY SPACED, WELL VENTILATED STORAGE OF CHEMICALS

By James. A. Kaufman

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

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

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

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

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

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

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Karyn M. Usher

ASK THE EXPERT

GOING GREEN IN THE SAMPLE PREP WORLD by Rachel Muenz

Karyn M. Usher is an analytical chemist in the Department of Natural Sciences at Metropolitan State University in Saint Paul, MN. At Metro State, her research has focused on sample preparation for the determination of analytes in complex matrices by high performance liquid chromatography.

Q: What are some of the latest "green" sample prep techniques out there today?

A: When I was choosing the latest green techniques, I focused on those that had reduced solvent consumption, reduced energy demands, and that use more benign solvents. So some of the things that made it onto my list were supercritical fluid extraction, solid-supported liquid-liquid extraction [SLE], QuEChERS (Quick, Easy, Cheap, Effective, Rugged, and Safe), microwave-assisted extraction, gas-phase sampling, and solid-phase extraction [SPE]. Regarding solid-phase extraction, this is an older technique, but nowadays people are looking at developing the methods following the 12 principles of green chemistry, so in that case, it would be a newer, more green sample prep technique.

Q: Which of those methods have you used in your lab?

A: I have used QuEChERS, SLE, and SPE. QuEChERS was originally developed for multi-residue pesticide analysis and when compared to methods that have been used in Europe over the last 20 years, it's been shown to reduce solvent consumption up to 95 percent and reduce consumables costs up to 90 percent. So out of these three techniques, it's one of the greener sample prep techniques. The other two methods can be developed to use less solvent and we can also use solvents that are safer for the environment and also for the analysts, so they are also two green sample prep techniques.

> "When you're doing extractions, you really need to pay attention to the efficiency and selectivity."

Q: Which technique did you prefer in terms of results?

A: I prefer solid phase extraction because I feel it gives you a lot of options for cleaning up your sample in different ways. However, the SPE method development can be quite intense and it can take a long time if you have a very difficult sample. [In terms of the one I liked to do the best], I think QuEChERS is kind of fun to do; it's a two-step technique and it's just a little more interesting since you get to do a few different steps. Also, with the QuEChERS technique, there's a little less variation. You determine the method that you're going to use based on the type of sample and sometimes you don't need to do a lot of method development with that one.

Q: How do the green methods impact workflow in the lab?

A: SLE and SPE can be done in parallel so the lab workflow was improved in comparison to an older technique like liquid-liquid extraction. With the QuEChERS method, however, it's a two-step method, like I mentioned, and it has an extraction as the first step. That step requires vigorous shaking. I don't have a lab shaker, so workflow is definitely slower on that step since I can only shake two at a time. In general, some of the other green sample prep techniques can be quite laborious compared to older techniques but as they're used more, you'd expect this to improve.

Q: You've mentioned a lot of the benefits of the different green methods already. What are some of the other main advantages?

A: There are a lot of benefits when you're substituting more benign solvents. Obviously, the techniques are going to be safer for the chemists and safer for the environment. Waste disposal processes are minimized and the costs for waste disposal may be decreased. If you're using a solvent that isn't hazardous waste or if you're using a solvent where disposal is cheaper, you're going to see those costs

decrease. When you reduce the amount of solvents, you get the same benefits but they are more noticeable. So if you decrease by 50 percent, you're going to see all the costs go down by 50 percent in addition to the cost of the solvent that you're using.

Q: Apart from being more laborious in some cases, as you already mentioned, what are some of the challenges of "going green"?

A: When you're doing extractions, you really need to pay attention to the efficiency and selectivity of the extractions, and some of the greener solvents don't have high extraction efficiencies. Some of them also show a lower selectivity when extracting analytes from complex matrices, so this is a big challenge.

"You do have to expect some time and money to be spent in developing the techniques."

Q: What are the main things lab managers need to consider when switching to such green techniques in their labs?

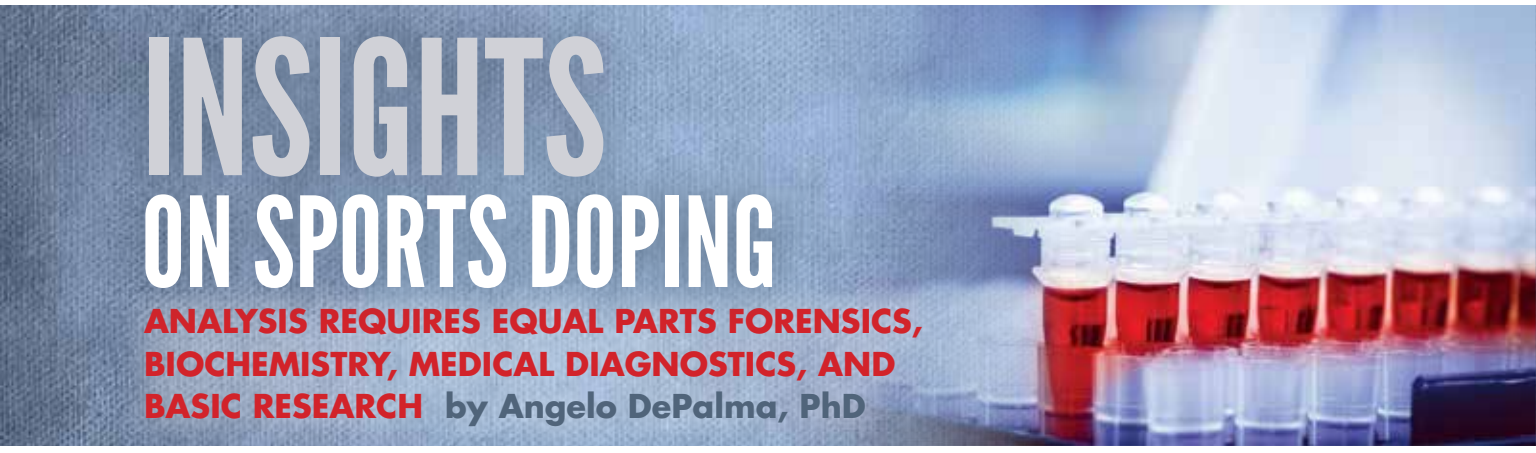
A: There are many different ways of going green, so figuring out the best choice for what you're trying to accomplish can be quite difficult. For example, if you're using a solvent that is not a green solvent, you might be able to simply substitute a more green solvent and get the required results. On the other hand, it's sometimes a better choice to keep the same solvent because the extraction efficiency is really high and the selectivity is good, but you could just reduce the amount of solvent that you have. There are also other options; for example, it might be better to just develop a new, greener method from start to finish. That's one of the main things you need to consider—which way are you going to try to go green? That needs to be done for each and every experiment. You can't just decide as a lab, 'I'm always going to reduce solvent,' or, 'I'm always going to change to a green solvent.' Another thing that lab managers should consider as well is, as you're changing things, you're going to have some costs associated with the development of the new, greener techniques. So you do have to expect some time and money to be spent in developing the techniques, but then that'll start diminishing over time as you continue using the techniques over and over.

Q: Where do you see green sample prep going in the future? What changes do you expect?

A: Instruments are becoming more selective and I think that the current trajectory towards greener sample prep methods that provide "just enough" cleanup will continue. I believe there will be continued decreases in sample size and solvent volumes but that there are limitations to this because we still need to ensure good sampling. We can go smaller and smaller, but there is a point at which we need to stop going smaller, and focus on the solvents that we're using. There are also other parts of the techniques that we might be able to make more green instead of just focusing on the volumes.

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

INSIGHTS ON SPORTS DOPING



ANALYSIS REQUIRES EQUAL PARTS FORENSICS, BIOCHEMISTRY, MEDICAL DIAGNOSTICS, AND BASIC RESEARCH

by Angelo DePalma, PhD

Sports is big business, which is why leagues and federations are desperate to keep their franchises honest. In the US, Major League Baseball (MLB) received a record $9 billion in revenues in 2014, while the National Football League took in close to $10 billion. Throw in athletes' salaries and endorsement fees and the huge economic activity generated by sports (e.g., hot dogs, beverages, advertising) and these figures perhaps double. But they are positively dwarfed by sports betting—which has been estimated at close to $1 trillion annually worldwide.

Yet with so much money afloat, athletes do whatever they can to gain a performance edge. Two responses from a 1997 *Sports Illustrated* poll of elite Olympic athletes are illustrative. When asked whether they would take performance-enhancing substances if they were certain not to be caught, 98 percent of responders answered in the affirmative. When asked if they could take performance-enhancing substances and thereby win all competitions for five years and then die, an astounding 50 percent answered yes.

The drug scandal that rocked Major League Baseball in the US several years ago personalized the issue of sports doping for millions of Americans. Yet we sometimes fail to recognize that this is in fact a global problem. Because of its contract with the players' union, MLB releases only vague information on players and "performance-enhancing substances." By contrast, the World Anti-Doping Agency issues a press release with specifics whenever an athlete is found to be in violation.

The sheer number of banned substances boggles the mind, in both human and animal sports. Essentially anything that is not explicitly permitted, whether it actually exists or not, is forbidden. "The list grows, it never shortens. Every time a new compound comes across the radar screen, it is added to the list and becomes another piece of data to manage," says Scott Stanley, PhD, professor of equine analytical chemistry at the University of California Davis School of Veterinary Medicine. "Processing that data quickly and efficiently, eliminating negative results, ferreting out positive or suspicious findings, and presenting that information to someone who can make a decision on it are the most significant bottlenecks."

Software that helps with data storage, retrieval, and interpretation is therefore just as "critical" as software to guide analytical method development, he adds.

Selectivity and sensitivity have obvious benefits for discriminating laundry lists of analytes from complex samples. Evolving analysis standards and the realities of dealing with complex sample matrices are not unique to sports doping. Instrument makers have responded with higher-performing analysis platforms that serve doping and related markets in pharmaceuticals, toxicology, and forensics.

Yet each week, each month, each year come new, more complex challenges.

"The sheer number of banned substances boggles the mind, in both human and animal sports."

"Years ago I thought we'd attained enough sensitivity with the instruments of the time. That was a very naïve position," Stanley admits. "Our customers keep asking for faster turnaround and greater sensitivity, so run times have to be short." Laboratories must also learn to live with smaller sample sizes and emerging matrices. For example, equine doping analysis traditionally focused on urine, but the desire for a fuller picture created an incentive to consider blood. The drawback with bodily fluids is that fast-acting performance-enhancing compounds may still work after the parent compounds and metabolites are gone. Hence the interest in hair analysis, which is even more challenging than blood but retains traces of banned substances much longer.

"We need instruments with the capacity for a large number of samples that can cycle samples quickly, with very little downtime or re-equilibration time, and the

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ability to evaluate the data in a high-throughput manner," Stanley tells *Lab Manager*.

THE CONUNDRUM OF WHAT TO TEST

Synthetic substances that are chemically identical to their natural counterparts are well characterized analytically, easy to grasp, and amenable to numerous analytical methods. But testing for them only makes sense for the duration of their persistence at above-normal concentrations. The same is true for exogenous substances—common drugs like stimulants and non-natural anabolic steroids.

Exogenous substances that persist in the body are similarly detectable provided they are known and not new molecules ("designer drugs"). For example, among the testosterone analogs the so-called suspension preparation is detectable for less than three days, but the oxandrolone analog persists for three weeks and nandrolone decanoate remains detectable for a year and a half.

> "Instrument manufacturers assure users that their data systems can read previous versions of data files."

Biotech drugs present a new set of problems. The red blood cell-boosting medicine erythropoietin has a half-life of up to 13 hours, but the erythrocytes whose creation it stimulates last for up to six months. Governing authorities therefore ban athletes based on their red cell count alone. Increasingly, however, proteins and peptides whose stimulatory effects are more subtle are expected to enter sports. These compounds, particularly those of low molecular weight, may well be impossible to detect within the logistics of sports activity.

"Authorities try to counteract the use of short-lived substances through indirect measures, by focusing on biomarkers that may be up- or down-regulated upon administration, and that persist longer than the actual drug," explains Daniel Eichner, PhD, executive director of the Sports Medicine Research and Testing Laboratory (Salt Lake City, UT).

Unlike in civil law, which requires actual legislation before prohibiting a substance, major world anti-doping agencies automatically ban designer drugs with activity similar to specifically banned substances. This puts pressure on testing labs to stay one step ahead. "We scour the medical and scientific literature to figure out the next drug or method used in cheating," Eichner says. "We need to have something already in place when these substances show up."

BIG BROTHER IS (STILL) WATCHING

A relatively recent change to anti-doping codes was the directive to test athletes for up to eight years after a competition. This challenges laboratories to store not just data for that time period, but samples as well. Labs must also develop and maintain methods for retesting samples that have been held in long-term storage, says Bernhard Wüst, global marketing manager of sports-doping/sports medicine at Agilent Technologies (Santa Clara, CA).

Wüst cites the 2003 tetrahydrogestrinone (THG) incident in 2003, in which an anonymous informant sent a syringe containing the substance to an accredited testing lab in Los Angeles. THG is a designer steroid with pharmacology related to those of banned anabolic steroids, but with a unique chemical structure that was unknown to anti-doping methods. "Many samples were reanalyzed in the wake of the THG scandal," Wüst says.

Maintaining data that labs can reexamine upon the emergence of designer drugs means that in addition to analyzing samples for specific banned compounds, labs must employ an untargeted analysis step using a scanning-type instrument (e.g., time-of-flight or Orbitrap mass spectrometry) that determines everything within a sample. "The advantage, though, is you can examine that data later on, and screen for compounds you had not originally thought of," says Wüst.

The drawback is data files become large and their formats perhaps obsolete. Yet they must be readable by current data management systems. "Think of finding an old eight-track tape in your basement and trying to find something to play it with," Wüst observes. Agilent and other leading instrument manufacturers assure users that their data systems can read previous versions of data files.

The validity of samples held in storage for up to seven years has been the subject of debate. Nevertheless, cold storage technology is generally trusted for even longer periods. In the April 2014 issue of *British Journal of Sports Medicine*, a consensus recommendation by world anti-doping agencies called for storing samples for up to ten years.

"Looking into the data file retrospectively and finding a peak or substance from a sample stored for many years is just the first step in the process," Wüst cautions. The entire

analysis chain, from sample preparation to the actual method, must be validated by an accredited lab. Methods should encompass metabolites as well as parent compounds.

EVEN DOGS AND HORSES CHEAT

"There are several major differences between the use of drugs in animal and human sports, but undoubtedly the biggest is that equine and canine competitors are unwilling drug takers," observes Paul Wynne, PhD, mass spectrometry business manager at Shimadzu Australasia (Rowville, Victoria, Australia).

While certain medications are permitted for limited use or in particular jurisdictions, much of the animal racing sport practices zero tolerance of drug use. As with human testing, equine and canine sports anti-doping laboratories face an increasing list of target compounds as new medications and illicit substances enter the market.

Beyond today's paradigm of small molecule drug screening looms an era that will increasingly emphasize protein-derived indicators—metabolomics markers—that confirm that substance abuse has occurred in the past, with testing done perhaps weeks or months after the drug of interest and its metabolites have disappeared.

The legal and regulatory basis for drug testing in sports demands methods that are highly specific or characteristic of the target substance. For this reason it is unusual for testing not to involve mass spectrometry for all but inorganic species.

Hence the emphasis on liquid chromatography (LC) as well. "The laboratory that 15 years ago was dominated by gas chromatography mass spectrometry (GC-MS) is now more likely to be equipped with a mix of LC high-resolution accurate-mass (HRAM) MS, triple-quadrupole LC tandem MS, and GC-MS/MS," Wynne explains. Tandem instruments add specificity and, with LC front ends, provide sample cleanup that reduces hands-on sample preparation. The switch to LC-based methods increases specificity but sacrifices the search for unknown compounds.

The move from GC has also been driven by workflow considerations, for example, eliminating the need for making chemical derivatives of polar compounds. "While LC inlet is easier for many compounds, we have lost the exquisite peak capacity of capillary GC and the utility of decades' worth of searchable library spectra," Wynne says.

As with environmental chemistry, GC-MS and GC-MS/MS remain highly reliable for structurally related nonpolar compounds such as the anabolic steroids. But the need to detect oily anabolic steroid esters that are too large for GC has driven ultra-high-sensitivity LC-MS/MS for steroids in blood plasma.

Wynne notes the recent trend toward dual-polarity, multi-analyte screens that cover structurally diverse analytes. "Such methods target many analytes with great structural diversity, and for which LC introduction provides a facile solution to the derivatization problem," he adds. "These methods are ideal for very fast triple quadrupole methods that cater to wide concentration ranges for individual analytes, but with the sensitivity required by volume-limited samples."

> "For sports drug testing, the new horizon is the point at which the mass spectrometer keeps pace with UHPLC."

Most sports doping laboratories have not yet exploited productivity and detectability benefits of UHPLC, Wynne says, as only a few instruments offer the benefits of high scanning speed, sensitivity, and polarity switching in a single platform. "For sports drug testing, the new horizon is the point at which the mass spectrometer keeps pace with UHPLC. Here, the analyst can begin to think about detection of sub-femtogram analytes, well-defined peaks less than three seconds in width, and triggered full-scan data without compromising sensitivity and diverse chemistries in run times of less than five minutes."

Sports doping analysis is equal parts forensics, biochemistry, medical diagnostics, and basic research. While LC-based methods have become the cornerstone of doping analysis, comprehensive labs also employ gas chromatography, clinical analyzers, blood analyzers, immunoassays, and gel electrophoresis, depending on the substances they are looking for. "If you saw what is involved in some of these testing programs, how much money people are shelling out to guarantee their programs are clean, you'd be blown away," says Eichner. "Given the large panel of analytes, you have to use more than one method. You can't just put the sample in and push a button, something turns blue, and you get a result."

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GAS CHROMATOGRAPHY SYSTEMS

THE SAMPLE AND APPLICATION DETERMINE THE BEST DETECTOR

by Mike May, PhD

Once gas chromatography (GC) separates a sample into its component parts, a detector identifies them. All detectors provide certain benefits and struggle with some limitations. Whether some feature is beneficial or detrimental, however, depends on the sample and the application.

Before getting to the detectors, let's consider GC. Stephanie L. Smith, scientific and technical advisor for the Security & Crime Prevention Group of the US Postal Inspection Service, says, "Gas chromatography is the quintessential chemical separation technique in the forensic science laboratory, offering incredibly simple analysis of extremely small samples." These features make GC useful in many other applications as well.

The first question is: Does the application require a universal or specific detector? The thermal-conductivity detector (TCD) was the first GC detector, and a universal one—meaning that it detects about anything that gets through the chromatography, but not very specifically. Other universal detectors include helium ionization detectors and barrier ionization detectors. Even mass spectrometry (MS) sits in this class.

A universal GC detector, such as a flame-ionization detector (FID), provides a collection of benefits. Overall, these detectors are easy to use and inexpensive and look for many compounds. For example, Eric Phillips, GC, GC-MS marketing manager at Agilent in Santa Clara, California, says that FIDs "are known for their linearity and dynamic range capabilities."

Although MS is also universal, it comes in a variety of forms. For instance, a single-quadrupole MS uses one filter to separate ions based on the mass-to-change ratio. Phillips says, "These types of MS systems provide the ability to quantitate known lists of compounds and information on unknown compounds."

Scientists turn to specific GC detectors when looking for a needle in a haystack. In these cases, the application doesn't need to identify every compound in a sample, just certain ones. "These detectors are blind to almost everything else," says Mark Taylor, chromatography marketing manager at Shimadzu Scientific Instruments in Columbia, Maryland. This category of GC detectors includes electron-capture detectors and sulfur-specific detectors.

Protecting posts

Until recently, Smith served as the assistant laboratory director of the US Postal Service's National Forensic Laboratory's Physical Sciences Unit (PSU). There, she says, "Scientists routinely use gas chromatography in the analysis of evidentiary materials." She adds, "The GC-detector complement in the PSU includes FIDs and mass spectrometers, both traditional quadrupole and ion trap."

The tools used at the PSU depend on the objective. For example, Smith says that GC/FID provides excellent separation of a sample and information about a molecule's retention time, but it does not reveal what molecules are in a sample. "Due to its linearity and sensitivity," Smith says, "GC/FID is the combination of choice for the quantification of controlled substances." She adds, "It is also a great initial screening tool, especially using a temperature program, when the sample size permits a series of destructive tests." GC/FID is also relatively inexpensive to purchase and maintain, and it is simple and rugged. As Smith concludes, "It provides low detection rates and a linear response."

> "The required detection level often determines the best detector for a specific application."

For much of the PSU's work, though, most of the detection falls on MS, which Smith calls the workhorse in the analysis of controlled substances and poisons and for the analysis of various types of "trace evidence," including fire debris, paint, explosives, and general chemical unknowns. With GC-MS, a sample gets separated very well and the MS provides a quantitative analysis of the components, even distinguishing compounds with very similar structures. Nonetheless, Smith adds, "While it is useful for quantitative analysis, the linearity is typically inferior to FID." In addition, MS costs more—sometimes much more—than FID, and requires more maintenance. Still, Smith says, MS, "when carefully maintained, can provide a reliable working life of up to a decade."

Picking your parts

The required detection level often determines the best detector for a specific application. For example, maybe someone needs to measure a gas, but not at a very low concentration. That probably calls for GC/TCD, which provides a sensitivity down to high parts per million.

For applications that need higher sensitivity, scientists need more sophisticated technology. For example, a pulsed discharge helium ionization detector (PDHID) can pick out components at concentrations in the high parts per billion.

For trace analysis of target analytes, scientists turn to GC-MS, which Taylor says can see down in the low parts per billion range. Along with sensitivity, GC-MS has the added benefit of positive compound identification via library spectral matching. "This is very important in, say, forensics or drugs of abuse analysis, where you need to unequivocally identify the drug," says Taylor.

It's not all about the concentration, though, because selectivity might also matter. A universal detector such as a TCD or a barrier discharge ionization detector (BID) has pros and cons. As Taylor says, "The good news is that you'll see everything coming through the GC, and the bad news is that you'll see everything." Consequently, this approach typically requires some higher resolution chromatography, such as a multidimensional technique, or cleanup steps at some point to partition some of the components. Otherwise, co-elution would render the data useless.

Some of this can be resolved with triple-quadrupole MS, which consists of two mass filters with a collision cell between them. Only the ions of interest get through the first mass filter, then the collision cell dissociates the components, and then the second mass filter measures the partitioned pieces. "This technology provides the best low-level detection of a known list of compounds in matrix," Phillips says. "However, it is not ideal to determine if there are compounds in your sample that are not in the list of compounds you are looking for."

Not every application fits an available option. In those cases, researchers need extra help to build the right GC/detector system, and that often means turning to a vendor for advice. Getting the system performing properly probably requires some back and forth with a vendor. In the end, most scientists must make some compromises, but the range of options improves the odds of finding an affordable and effective system.

Mike May *is a freelance writer and editor living in Ohio. You may reach him at mike@techtyper.com.*

FOR ADDITIONAL RESOURCES ON GAS CHROMATOGRAPHY SYSTEMS , INCLUDING USEFUL ARTICLES AND A LIST OF MANUFACTURERS, VISIT WWW.LABMANAGER.COM/GC

ARE YOU IN THE MARKET FOR AN... HPLC SYSTEM?

High-performance liquid chromatography (HPLC) is, for many scientists, an essential chromatographic technique. HPLC systems used for the separation, identification, purification, and quantification of various chemical and biochemical solutions are composed of a pump, a sample injector, a separation column, a detection unit, and a data-processor.

Types of HPLC systems used by survey respondents:

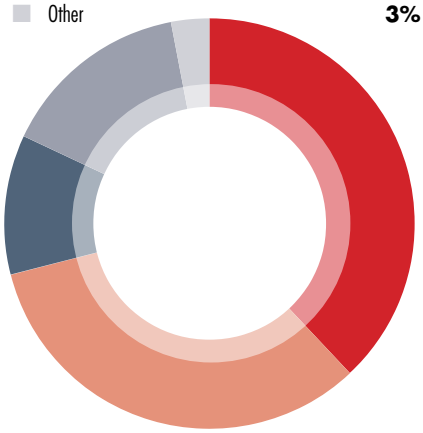
Analytical HPLC	96%
UHPLC	26%
Ion Chromatograph	23%
Preparative HPLC	14%
GPC	10%
FPLC/Bio	6%
Other	2%

HPLC separation modes utilized by survey respondents:

Reverse Phase	76%
Normal Phase	40%
Ion exchange	31%
Ion chromatography	27%
Ultra-high performance (UHPLC)	20%
Hydrophilic Interaction (HILIC)	19%
Size Exclusion (SEC)	18%
Gel permeation (GPC)	15%
Chiral	14%
Gel filtration (GFC)	6%
Ion exclusion	5%
Affinity	5%

Nearly 45% of respondents are engaged in purchasing a new HPLC system. The reasons for these purchases are as follows:

Replacement of an aging system	38%
Addition to existing systems, increase capacity	33%
Setting up a new lab	11%
First time purchase	15%
Other	3%



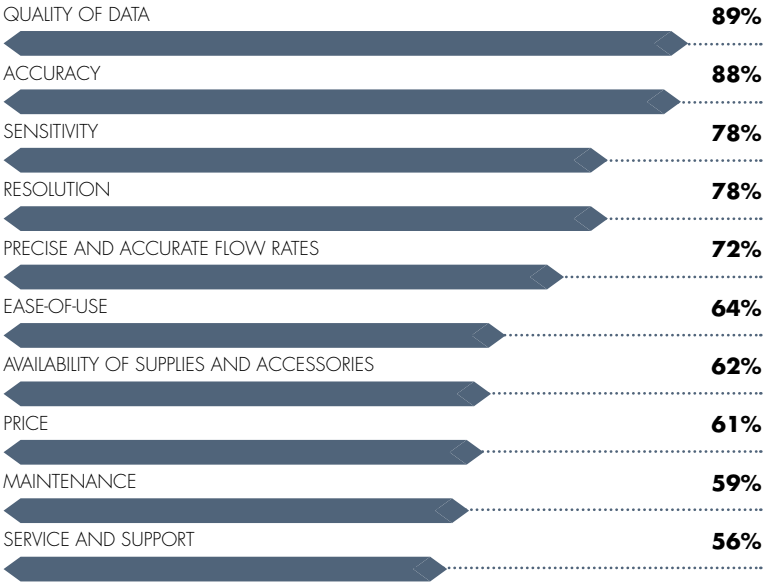
TOP 6 QUESTIONS

You Should Ask When Buying an HPLC System

1. How flexible is the system? Can the system be optimized to meet your laboratory requirements?
2. What tubes, vessels, and vials can it accommodate? Can components (such as additional detectors, valves, etc.) be upgraded in the future?
3. Is the software easy to use and operate? Can a demo version be put in place to get a feel for how the software functions for your laboratory's workflow?
4. How is the system (not just components) qualified during installation to meet manufacturer performance expectations?
5. Who provides the support and service for the product? Is it the manufacturer or a third party service group? If it is a third party service group, are they factory-trained?
6. Finally, ask about the total cost of the purchase—not just the price of the product being installed— but the total cost of ownership, which includes price, service expectations, warranty, etc.

TOP 10 FEATURES/FACTORS

Respondents Look for When Purchasing an HPLC System



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Dr. Guido Verbeck

ASK THE EXPERT

INNOVATIONS IN MASS SPECTROMETRY

by Tanuja Koppal, PhD

Dr. Guido Verbeck, associate professor of chemistry at the University of North Texas and director for the Laboratory of Imaging Mass Spectrometry, designs novel ion optical devices for miniaturization, preparative, and analytical mass spectrometry. He has developed a miniature ion trap mass spectrometer at Oak Ridge National Laboratory, three preparative mass spectrometers for combing new materials and catalysts, and a number of novel analytical applications for single cell and forensic analysis. Dr. Verbeck received his PhD as a Proctor & Gamble fellow in chemistry at Texas A&M University.

Q: What changes have you seen in the MS field in recent times?

A: The biggest change is the fact that previously, most MS experts came from the organic chemistry groups. Now MS crosses every discipline, and there are many more MS experts in each of these fields. On the instrumentation side the biggest change has been in sensitivity. It seems to be following Moore's Law [a computing term that states that the processing power for computers will double every two years], where sensitivity is now down to sub-pico and femto molar ranges. This is amazing, as it now allows us to do imaging and work with low sample volumes and still get good data. Miniaturization is another change, where mass spectrometers are getting smaller, with higher throughput.

In terms of coupling techniques, the one that the community has embraced is ion mobility as a separation technique for high-throughput MS (IMS-MS). With multiple reaction monitoring (MRM) and ion mobility, you can get a huge amount of structural data very quickly, in the same timeframe where previously you could collect only one spectrum. With ion mobility you can get separations in milliseconds, so it's incredibly fast. Back in the day when you had separation techniques in the front end of mass spectrometers, you had a certain time window to get all this information on an eluting analyte. Now, with ion mobility and MRM, you can get gigabytes of data from peaks that are eluting in 10 or 15 seconds.

Q: What about changes in the MS data itself?

A: With MS imaging, it's almost like a separation technique, where you are looking at an ion chromatogram per shot as opposed to when the analyte elutes. If you are going to collect MS-MS data on every shot, then a single MS imaging file, like the one you see published in our recent papers, can be up to 12 gigabytes. We have terabyte backup drives to store all this data. If there is a problem during the run or there are interruptions, we have to delete the file, since it takes up a lot of space to store it. As a part of our defense contracts, our lab is a closed system, so we cannot store anything in an external cloud.

Q: Which of the projects that you are currently working on most excites you?

A: In situ MALDI, where you don't have to prep the sample anymore, is very exciting. But more interesting is a recently published paper where we did true single-cell analysis using nano [manipulation] in MS. We extracted and looked at the lipodome of one organelle in a cell, and we could do that reproducibly, which is truly amazing. We could do that because of the MS technology moving to femto molar sensitivity, which gave us a lot of information using a very small amount of sample.

Q: Can you shed some light on nano manipulation and how you see it impacting applications in the future?

A: With the amount of sample you are dealing with on a single-cell level, separation is almost impossible. You have to rely on creating very specific chemistry within the tip (pulled capillary tip) of your extraction so that you are looking at a specific compound class that can then be charged. In our case, that was lipids, and so we used chloroform with ammonium acetate (a lipid solvent that you would typically use with electrospray MS applications). If you don't fine-tune the chemistry, then you will extract all the proteins, sugars, and everything else that is present in that cell. So we are using the same principles that we used for extractions with separation funnels, except now we do it on a single tip. We go to a particular location in a cell that we are interested in to extract the right compound using the right chemistry. So it's not a shotgun approach where you extract and analyze everything. We have to be very exact about what we want to see and how we are going to get it.

Q: What innovations in MS instrumentation have made this possible?

A: The innovations in nanospray have made it possible for us take a 1um capillary extraction tip and turn it into a nanospray tip. That was a huge leap forward from electrospray to nanospray MS. The MS ionization efficiency has also become very high in the new designs of instruments, which allows us to do what we do.

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We have used this nanospray technique for drug and residue extractions from fingerprints in forensic applications. Again, you have to tune the solvent chemistry to look for specific explosives or drugs, but if that chemistry exists, then you can use this technique for any type of extraction.

Mass spectrometers are also getting cheaper and smaller in footprint, making them portable for field use. You can now get a commercially available 12-pound mass spectrometer. It's not as comprehensive as most benchtop mass spectrometers, but it's truly field-portable. Hence, a lot of environmental and forensics groups are finding MS instruments that are perfect for their use and are also affordable.

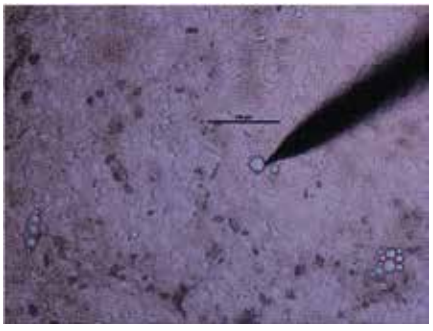
Q: Where do you see the next breakthroughs in MS?

A: Being able to do high-throughput large mass ranges and having high resolution over the entire mass range will be the next major leap. The other breakthrough will be in informatics—taking that 12 gigabytes of imaging data and being able to process it properly. The 12 gigabytes of data take only four hours to collect, but it takes my students a week to process [them]. Database and informatics innovations that will help people use algorithms to assess data based on what they are looking for will become very important. It can be done today, but it takes a very long time.

Q: Do you think people using MS should receive specialized training?

A: In all honesty, sometimes people get overconfident about the instruments because all vendors are making them "plug-and-play," with recipe-driven analysis. We just did an experiment for the U.S. Drug Enforcement Administration (DEA) that showed some of the underlying problems. We took three different mass spectrometers and looked at various nuances that can be controlled, such as trapping time, ionization current, buffer gas, [and] size of collision cells, and we found that even

▲ *Pictured is the nanospray emitter before nanoextraction of lipid droplets. These lipid droplets are contained within a single adipocyte (fat cell) that was differentiated from human skin fibroblasts. 100 µm scale bar.*



▲ *Lipid droplets eventually conglomerate into a single larger unilocular lipid droplet. This is common in human white adipose tissue. 100 µm scale bar.*

if the instruments were run under the same set of conditions, they didn't give the same results. For a person using MS as a research tool it may be fine, but for the DEA this is a huge problem when it comes to compound identification and quality assurance (QA). Hence, I think it's important for every lab manager to get some fundamental training on MS and not just rely on the instrument settings.

Q: Are there problems that have surfaced because of the recent innovations in MS?

A: MS has now become so sensitive and accurate that it can pick up any small amount of impurity or changes in reagents due to lot-to-lot variations. Lab managers and QA professionals need to be very aware of this. We have to routinely standardize our assays and protocols because we sometimes get a new peak from a solvent or from polymers leaching in from the centrifuge tubes. In lipid analysis we have to be extremely careful because the solvents we use can extract oils and polymers from everywhere, which is why we only use glass. With direct inject for MALDI imaging, everything comes up from the sample itself. We have to be exact in what we are looking for and then do a lot of MS-MS or even MS-MS-MS analysis to determine it is what we say it is.

Q: Any pitfalls lab managers should look to avoid?

A: One thing we have noticed on the separations front is that everyone is coming out with new gas chromatography (GC) and liquid chromatography (LC) columns, and because of the improved sensitivity of MS we are now picking up different bleeds. Not all columns are the same, and hence, we cannot blindly pick up any two columns and expect them to perform the same. The column consistency does not match the sensitivity of the mass spectrometer. So lab managers should look to buy the same columns and run them under the same conditions. This makes our standard operating procedures (SOPs) longer, but we have to include all the nuances to be able to stand behind our data.

Q: What resources do you turn to for advice and help?

A: The first place we turn to is another successful lab, [to] get their SOPs and build our protocols based on their consistent results. That's better than going to the literature, where you sometimes cannot reproduce what has been done. You could also turn to your instrument vendor and seek help from their application scientists. They are paid to help customers solve their problems, and it's very likely that they have seen this problem before and can help you troubleshoot.

***Tanuja Koppal, PhD**, is a freelance science writer and consultant based in Randolph, New Jersey. She can be reached at tkoppal@gmail.com.*

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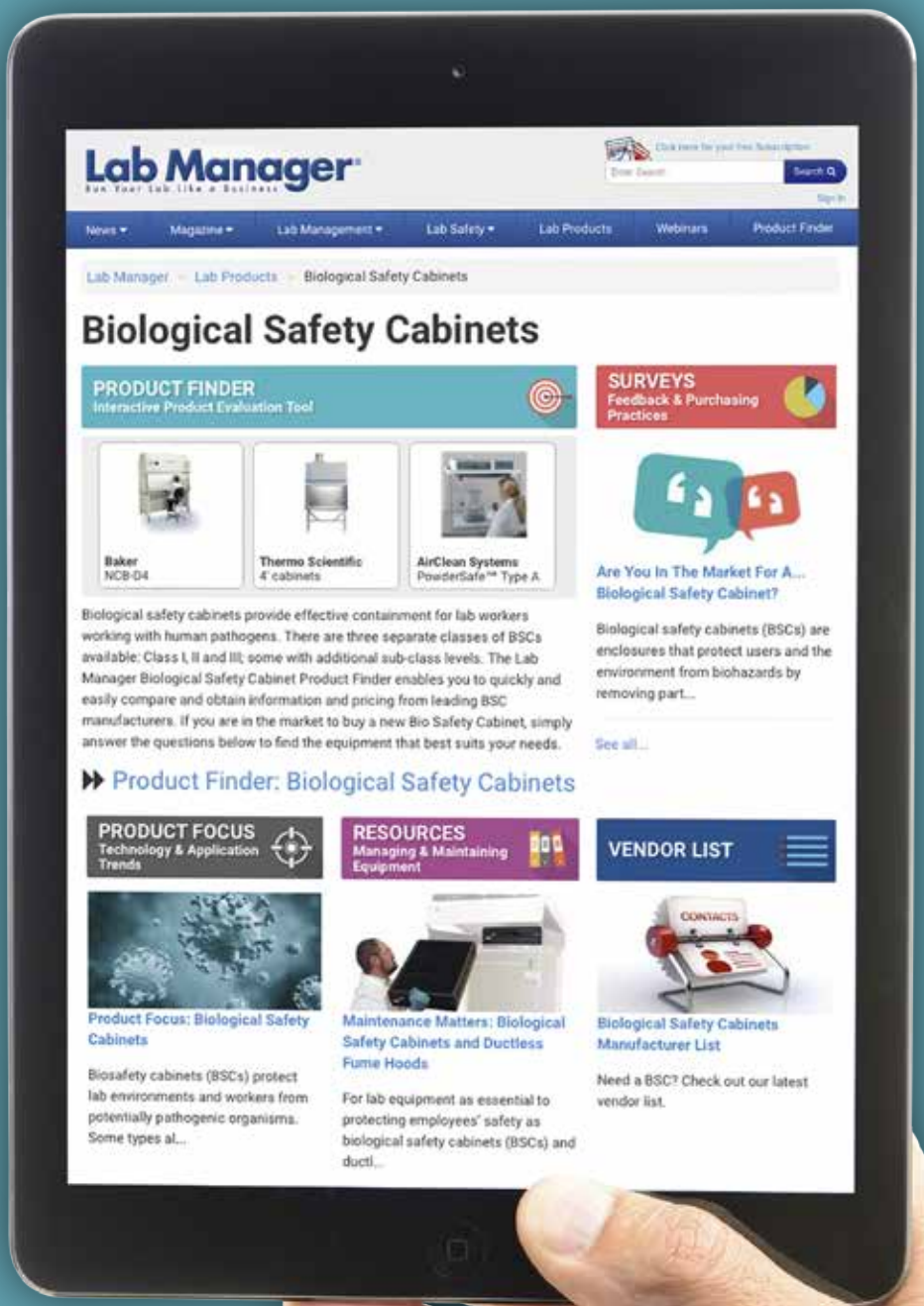

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INSIGHTS ON DEVELOPING ANTIBODY-DRUG CONJUGATES

THE PROMISE OF SAFER AND MORE EFFECTIVE CANCER TREATMENTS STILL FACES OBSTACLES

by Mike May, PhD

Clinicians and patients alike know that traditional cancer treatments beat up the person as much as the cancer. Success arises only if the treatment kills the cancer before the patient. For decades, researchers sought solutions that attacked only the cancer, not healthy tissue. In the past few years, some of the most promising and targeted new treatments come from antibody-drug conjugates (ADCs), in which an antibody delivers the drug to specific cancerous cells. Like all medications, though, ADCs have their pros and cons, but this arsenal of cancer treatments keeps expanding.

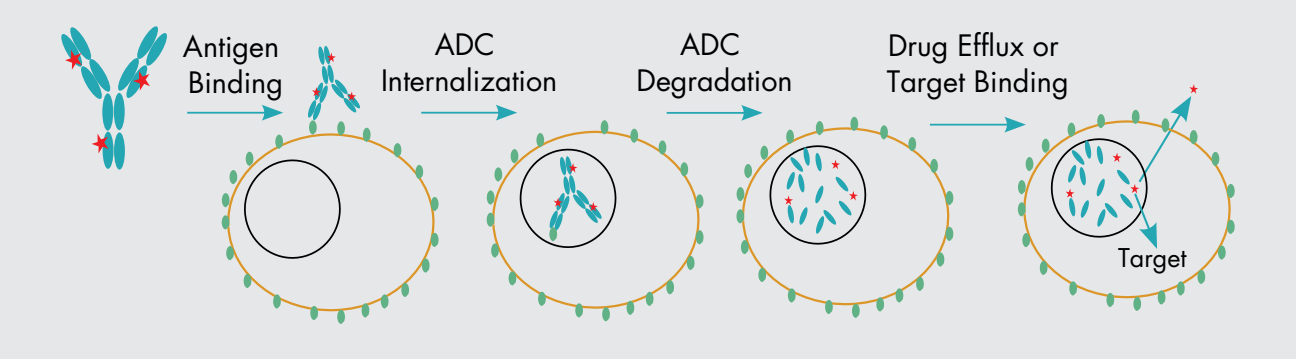
Nonetheless, ADCs got off to a rocky start as a cancer treatment. In 2001, the US Food and Drug Administration (FDA) approved the first ADC—gemtuzumab ozogamicin, which treated acute myelogenous leukemia—but it was withdrawn from the market in 2010, after a clinical trial showed no improved results in comparison with other treatments. In fact, the trial indicated that more patients on this treatment died. One year later, in 2011, the FDA approved brentuximab vedotin, which treats some forms of lymphoma. Then, in 2013, the FDA approved ado-trastuzumab emtansine for treatment of HER2-positive metastatic breast cancer.

Many more ADCs will probably be approved in the future. As of January 6, 2015, a search of antibody-drug conjugates on ClinicalTrials.gov revealed 222 current trials. To get more of these cancer treatments on the market, though, researchers need to overcome some challenges. Fortunately, new instruments surmount some of the obstacles, and technologies under development promise even more help ahead.

ADC OBSTACLES

Maybe making an ADC sounds simple enough, but in fact, it's not simple at all. As Bijal D. Shah, director of translational research initiatives in lymphoma and acute lymphoblastic leukemia at the Moffitt Cancer Center in Tampa, Florida, explains: "ADCs require internalization of antibody-antigen for the drug to kill tumor cells." He adds, "The internalization can vary dramatically depending on the antigen, as well as other treatments that may be given concurrently."

To know how an ADC might work, researchers must characterize many of its properties, including the drug-antibody ratio (DAR). Nonetheless, Daniel Some, principal scientist at the Wyatt Technology Corporation in Santa Barbara, California, says that it's difficult to measure



A drug (red) is linked to an antibody (blue) in a so-called antibody-drug conjugate (ADC) that binds to antigens (green) on a tumor cell. When a treatment works, the ADC goes into the tumor, where the drug gets released and attacks a target that kills the cancer cell. (Image courtesy of Katie Maass.)

the DAR, "which is a critical property that impacts efficacy and dosage."

To measure DAR, scientists can take several approaches, including mass spectrometry and differential UV spectrometry. But, says Some, "Specific ADCs may not be amenable to these analyses because of heterogeneity or lack of a suitable spectral response." When that's the case, a scientist can add a refractive index (RI) detector with a high-performance liquid chromatography (HPLC) system's UV detector, and combine that with size-exclusion chromatography (SEC) and multi-angle light scattering (MALS). Some says, "SEC-MALS-UV-RI analysis can determine the DAR of ADCs that are otherwise difficult to analyze."

> "ADCs got off to a rocky start as a cancer treatment."

Also, just because an ADC starts as one thing, it doesn't necessarily stay that way. "The binding of drug to antibody is not perfect," says Shah, "and its release into general circulation can come with unwanted side effects." If the cancer drug gets separated from the antibody, the treatment turns into traditional chemotherapy—killing any fast-dividing cells that it encounters, healthy or not.

ANALYZING THE AGGREGATES

In addition to coming apart, ADCs suffer from too much getting together, or aggregating. In fact, many ADCs aggregate more than the unconjugated antibody. Some says, "Since aggregation is an important obstacle to product development, technologies for screening and characterizing aggregates are central to working with ADCs."

To measure the aggregation of ADCs, scientists can use high-throughput dynamic light scattering (HT-DLS). "This is a critical technology used to screen ADC formulations rapidly for aggregation and propensity for aggregation," says Some.

This technology requires only microliters per sample, and measures the aggregation in a few seconds. For example, Wyatt Technology makes the DynaPro® Plate Reader II, which accommodates a 96- or 384-well plate reader format. "With this platform," says Some, "dozens or even hundreds of ADC candidates, excipients, and buffers may be

tested simultaneously to determine the aggregation onset temperature (T_{onset}), the colloidal interaction parameter (k_D), and the aggregate size distribution from nanometers up to a micrometer in radius." The results help researchers select the best ADCs to move forward with and conditions to use during development.

To characterize the aggregates, scientists often use SEC, but this produces inaccurate results with hydrophobic ADCs, which many are. Instead, Some recommends MALS. He says, "A MALS detector, such as a DAWN® HELEOS® II from Wyatt Technology, may be added downstream of any SEC separation in order to obtain correct ADC characterization via SEC-MALS."

While some scientists continue to analyze ADCs with HPLC, as mentioned above for measuring the DAR, many are turning to ultra-HPLC (UHPLC) for higher throughput, smaller required sample sizes, and reduced buffer usage. UHPLC also provides higher spectral resolution than HPLC. Adding light-scattering detection to UHPLC improves a scientist's ability to analyze aggregation in ADCs, and tools exist to do this. As Some says, "Last year, Wyatt Technology launched the μDAWN, the first MALS detector for UHPLC, which will bring the benefits of SEC-MALS to adopters of UHPLC."

To decipher the features that improve and detract from ADCs' therapeutic potential, researchers need this growing collection of analytical tools. These devices will accelerate research and also improve analysis of safety and efficacy in clinical trials.

FIGHTING TO THE FRONT LINES

Like most new forms of therapy, ADCs approved so far can be prescribed only after a patient's cancer fails to respond to traditional treatments or if the patient relapses. Nonetheless, Shah notes that his work on brentuximab reveals that this treatment could be used as a frontline approach to fighting Hodgkin lymphoma and anaplastic large cell lymphoma. He says, "We have very encouraging early data."

In addition, Shah and his colleagues are working on SGN19A—an ADC that targets B-lymphocyte antigen CD19—as a treatment for aggressive B-cell non-Hodgkin lymphomas and acute lymphomblastic leukemia. Shah says, "This agent is similarly demonstrating encouraging early results, with a safety profile that may allow for combinatorial strategies, as well as extended use in maintenance."

To push ahead the potential of ADCs in general, scientists need a better understanding of how the treatments get inside the targeted cells. As Shah says, "In general, understanding how to accelerate antibody-antigen internalization is likely to facilitate an improvement in efficacy at lower doses, with concomitant reduction in any toxicity that might emerge from the liberation of the free drug."

THE ACADEMIC ANGLE

While many equipment and pharmaceutical companies, plus private research institutes, explore applications of ADCs, many academic labs also work on these structures. For example, Katie Maass—a doctoral student in K. Dane Wittrup's lab at the Koch Institute for Integrative Cancer Research at MIT—studies intracellular processing and trafficking of ADCs. She says, "ADCs are an exciting new field for cancer treatment, with much promise but also many unanswered questions."

Shah mentioned above the trouble of predicting the cellular internalization of a particular ADC, and Maass hopes to develop, as she says, "a general kinetic model for how ADCs get processed by cells and how various properties of an ADC affect its intracellular processing." She believes that past research might have focused on the wrong steps, such as binding and internalization. Instead, she thinks the key might lie in degradation of the ADC and its being kicked out of the cells.

Mapping this process will require examining the complex collection of parts within an ADC. Maass says, "Figuring out what is the optimum design is not straightforward." The problem goes beyond that; it's not just how an ADC starts but what it becomes in the body. To find out, says Maass, you need to keep track of all of the possible degradation products and then understand what effects each degradation product causes. She says, "This is definitely tricky, especially when using patient samples."

Despite all of those obstacles, some aspects of ADC work are getting easier, but only to a certain extent. Seattle Genetics in Bothell, Washington, and ImmunoGen in Waltham, Massachusetts, license ADC technology to companies that have antibodies they would like to use as ADCs. Although Maass notes that this has increased the number of ADCs in development currently, she says, "conjugation is still often not as straightforward as it seems like it would be."

Maass's work, though, could make it easier and more efficient to predict what sort of ADC would work in a particular treatment. Her model could also help researchers tweak existing ADCs to improve safety or efficacy.

COMMERCIAL CONNECTIONS

A variety of pharmaceutical companies license ImmunoGen's ADC technology. According to an ImmunoGen spokesperson, the partners include Amgen, Bayer, Biotest, Eli Lilly, Novartis, Roche/Genentech, and Sanofi.

Other companies also team up to improve the odds of moving ahead with ADCs. In 2012, Celgene in Summit, New Jersey, and Sutro Biopharma in South San Francisco, California, arranged a collaboration to develop ADC-based treatments. Both companies possess useful capabilities in this area. Sutro, for instance, developed a technique that can attach more than one cytotoxin to one antibody. In addition, Celgene specializes in—among other things—cancer treatments. The relationship continues as the companies work toward powerful cancer-fighting tools.

Beyond licensing its technology, ImmunoGen also develops its own cancer treatments. For example, its IMGN853 is an ADC that is a potential treatment for cancers that express folate receptor alpha (FRα), and many ovarian and endometrial cancers do. The linker in IMGN853 keeps the cytotoxic element stably attached to the antibody while the compound is in the bloodstream, but also—once at the tumor site—helps counteract the multidrug resistance that can make previously treated tumors more difficult to kill. For now, ImmunoGen has this ADC in early-stage clinical testing. It is being assessed specifically for the treatment of FRα-positive platinum-resistant ovarian cancer and relapsed/refractory endometrial cancer.

Despite the availability of new ways to develop and analyze ADCs, the ongoing clinical trials, and the promise of safer and more effective treatments for cancer, the fact that only two are FDA-approved reveals some of the difficulty of working with these structures. As some experts revealed here, it's not as simple as popping a chemotherapeutic onto an antibody and saving someone's life. The connection takes bioengineering skill and experience. Building an ADC structure that gets through the body intact, reaches the intended cellular site, and gets inside the cells takes a wide range of knowledge and biomanufacturing skills. Subsequently, the ADC, like any other new treatment, must go through clinical trials; there is no magic that moves a new ADC to patients. It's still hard work that is both time-consuming and expensive, but with cancer continuing to afflict more people around the world, every tactic must be tried to fight off this deadly family of diseases.

Mike May *is a freelance writer and editor living in Ohio. You may reach him at mike@techtyper.com.*

IMAGING SYSTEMS FOR BIOLOGY

RESPONDING TO MULTIDISCIPLINARY NEEDS

by Angelo DePalma, PhD

Advances in computer hardware and software, data storage and processing, optics, systems and instrumentation, labeling agents, and reagents have all contributed to the current surge in imaging in the life sciences. "The widespread use of fluorescent proteins has in particular had a tremendous impact," says Magnus Persmark, PhD, product manager at Life Technologies (Carlsbad, CA). "We have had leapfrogging in these various areas, for example bioinformatics, reagents, and instrumentation."

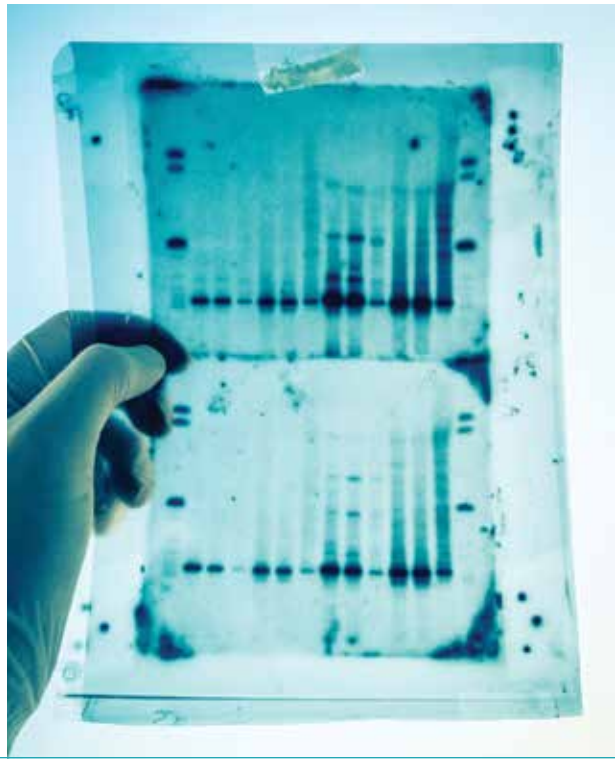
Continuous improvement has been driven by translational and interdisciplinary research that defines modern biology. Rare is the biologist who can make a career from one type of project. Even rarer is remaining within one well-defined area, say, transcription in lower organisms. As biological complexity has revealed itself, imaging tools have kept up. "We now have the technologic foundation to explore connectivities on a cellular and multicellular level in ways that we have never had before," Persmark adds. "We're able to visualize complex cell models, spheroids, mixed cell populations, and stem cells, with the ability to label cells and components, their structure and function, and follow that in time and space."

For imaging, then, necessity has been the mother of invention. New luminescent tags emerge almost weekly that push the limits of detectors and image processing systems, which in turn spawn novel methods and experiments. "At the same time imaging is becoming democratized," Persmark comments. "With instruments designed for nonexperts entering the market, researchers can more immediately access and assess these new experiments."

Out with the old

Labs store data from most electrophoresis gels and thin layer chromatography data as standard photo images, providing the media hold their stain or immobilized bands absorb or reflect ultraviolet strongly. A bit more finesse is required for gel bands detected through enzymatic chemiluminescence. "In those situations, you need a camera that will stare at the sample and collect electrons until the enzyme runs its course, which can be 15 minutes or more," explains James Joubert, application scientist at Photometrics (Tucson, AZ). "The camera should have very low dark current, high quantum efficiency, and extremely low noise so as not to build up a lot of spurious electronic signal."

Modern biology imaging is nearly synonymous with advanced microscopy, whose macro components are remarkably constant across biology, materials science, and forensics: a light source, a collector/magnifier (usually a microscope), and a collector (camera). Size domains are similar as well, as defects in semiconductors are approximately as large as biology's top subject matter, cells. Materials and structural imaging differs in its upper size domain, which is sometimes many feet. Within and across those disciplines, however, considerable difference



exists in excitation mode and energy. For example, probing into semiconductor material or tissue requires greater power than does skimming surfaces for dopants, or cells for receptors.

Imaging biological systems is arguably the most challenging due to the complexity and dynamism of cells and tissues, and the size and sensitivity dynamic ranges involved. Following single molecules through cells, for example, often requires imaging of surrounding cellular structures that may respond well to white light, while simultaneously measuring rapid fluorescence from deep inside the cell.

> "Imaging biological systems is arguably the most challenging."

"Within biology alone there is such a swath of things, from whole organisms to large tissues, cells, organelles, and molecules," notes Joubert. His company specializes in charge-coupled device (CCD), electron multiplier CCD (EMCCD), and multichannel imaging systems that all rely on microscopy.

The application list for biology reflects the breadth of applications: digital image restoration, FISH, fluorescence imaging, fluorescent speckle microscopy, FRET, green fluorescent protein imaging, ion imaging, surface trafficking, FRAP, sequential color imaging, single-molecule fluorescence, TIRF—and those are just the microscope-based techniques.

Democratization

For more than a decade, advanced confocal imaging systems provided high-end, high-content visualization of assays and screens. Models from GE Healthcare Life Sciences, PerkinElmer, Molecular Devices, Thermo Scientific, and Olympus cost anywhere from $100,000 to $750,000 —well beyond the budgets of many labs.

Subsequently, GE and Life Technologies pushed cell imaging technology down to a lower price point with, respectively, the Cytell and EVOS instruments that cost around $50,000. Notes Eric Matthews, Midwest sales manager at BMG LABTECH (Cary, NC), "You can think of these as benchtop automated microscopy for cell imaging."

The next evolutionary phase involved product debuts from BioTek Instruments, Molecular Devices, and PerkinElmer—microplate readers that incorporated automated microscopy functions. "So for a little more than those other entry-level imagers, you could get plate reading and imaging in the same box," Matthews says. The Cytation from BioTek, SpectraMax from Molecular Devices, and PerkinElmer's EnSight are actually multimode plate readers with well-imaging capability.

BMG LABTECH does not manufacture such an instrument, but has been "thinking of its pros and cons," according to Matthews. "They allow you to do pretty advanced imaging, for example, protein co-localization, cell motility, morphology, cell counting—as you can do with any microscope, but in automated format."

At issue is whether labs should own two standalone instruments or one combination system that is somewhat less expensive. Assuming the combo is the only plate reader in the lab, it's easy to envision workflow and utilization bottlenecks. "Maybe you have to read two plates and it takes 90 minutes. Meanwhile, your technician can't read basic protein assays and ELISAs." In those situations, Matthews says, lab managers may wish they had purchased standalone imagers.

But he's quick to point out the "obvious advantages" of a dual-mode imager/reader. Economics is one plus: Labs may have $80,000 for the combined system but not $110,000 for two instruments. "Plus, you have the ability to do more. Just a few years ago your only option was a very large, half-million-dollar box."

These systems are also a gateway for companies that previously could not afford imaging except through a core facility. But for these labs, plate readers are already essential workflow components. "Everyone needs a plate reader, so if your lab needs one, and by adding another $20,000 to $30,000 on top of the cost you can get imaging as well, it all seems more doable," Matthews explains.

As noted, BMG does not have a dual-mode product, but plans to investigate pitching stand-alone readers and imagers with a corporate partner on the imaging side.

Matthews views imaging as another wrinkle in the evolution of microplate readers. "Every five to eight years it seems a new mode comes to plate reading, for example fluorescence. Today's interesting new mode is imaging."

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

ARE YOU IN THE MARKET FOR AN... AUTOMATED LIQUID HANDLER?

Automated liquid handling (ALH) systems span the range from semi-automated multichannel pipettors to room-sized systems. The industry is trending toward versatile, modular ALH systems—seemingly for every budget. Likewise, instrumentation, software, and methods have followed the trend toward greater user accessibility.

Types of automated liquid handling systems used by survey respondents:

Stand-alone	54%
Individual benchtop workstations	54%
Self-contained multi instrument systems	28%

Applications for automated liquid handling systems as reported by survey respondents:

Serial dilution	61%
Plate replication	39%
Plate reformatting	34%
PCR setup	30%
High-throughput screening	27%
Cell culture	22%
Whole genome amplification	14%
Array printing	7%
High-density array printing	3%
Other	20%

Nearly 30% of respondents are engaged in purchasing a new automated liquid handling system. The reasons for these purchases are as follows:

Replacement of an aging system	24%
Addition to existing systems, increase capacity	43%
Setting up a new lab	22%
First time purchase	11%

TOP 7 QUESTIONS

You Should Ask When Buying an Automated Liquid Handler

1. What kind(s) of dispensing technology is used? Peristaltic pump dispensing offers low prime volumes and backflushing; microprocessor- controlled syringes have fast output and high precision. Hybrid detection systems combine both technologies in one and can even add washing functions.
2. Is plate handling automatable? Manual plate handling can slow productivity. Automating the process with a compatible microplate stacker increases throughput with walk-away operation.
3. Can it accommodate magnetic or plastic bead-based assays? If using bead-based assays, it should be equipped with appropriate magnets or vacuum filtration for critical wash steps.
4. What is the volume range, and how many different sample vessel types may be used?
5. Ask about the software—is it integrated and user-friendly? Does it allow for pre-programmed and custom protocols?
6. What is the flow rate spectrum? A wide flow rate spectrum allows use with sensitive cell-based assays to viscous liquids.
7. What assay validation data is available for this specific liquid handler? This provides proof that the instrument performs as indicated.

TOP 10 FEATURES/FACTORS

Respondents Look for When Purchasing an Automated Liquid Handling System

ACCURACY AND PRECISION FOR A WIDE RANGE OF COMPATIBLE FLUIDS	81%
SAFE SAMPLE HANDLING – NO CROSS-CONTAMINATION	80%
MAINTENANCE / SERVICE / AVAILABILITY OF ACCESSORIES AND REPLACEMENT PARTS	62%
RAPID THROUGHPUT	49%
PRICE	47%
PIPETTING FLEXIBILITY – PIPETTE WITH 384, 96, 24, 16, 12 OR 8 TIPS	41%
MAXIMUM OPERATOR SAFETY	37%
SAMPLE TRACKING	34%
SIZE – SMALL FOOTPRINT	30%
ABILITY TO EXPAND ON INSTRUMENT AS REQUIREMENTS CHANGE	29%

For more information on liquid handlers, including useful articles and a list of manufacturers, visit www.labmanager.com/liquid-handling

STIRRERS

SAMPLE CONDITIONS TODAY AND TOMORROW DETERMINE THE SPECS TO SELECT

by Mike May, PhD

Some scientific and even industrial stirring applications seem no more complex than mixing milk in your coffee, but others demand much more control. In fact, some of the most demanding stirring applications might not even sound so complicated, including dissolving powdered milk in water, combining oil and water, incorporating pigments in a base coat of paint, and so on. But in general, nearly every stirring application includes a complex aspect or two, says Jim Jacso, director of sales and marketing at Glas-Col in Terre Haute, Indiana. "There is always something tricky in trying to get information about what the customer is really doing or really wanting to do," Jacso says.

Given the vast variety of stirring applications, Oliver Vogelsang, product manager for stirrers at IKA Werke in Staufen, Germany, says, "It is important to choose the most suitable test conditions—stirrer performance, geometry of the stirring element, vessel type and geometry, rpm, temperature, etc.—in order to achieve the optimal mixing result."

To select the best stirring technology for a specific application, Vogelsang recommends defining the conditions. This includes knowing the sample volume and viscosity, the required rpm, and whether it needs vacuum. Some stirring applications must also measure characteristics of the sample, such as temperature, pH, or change in viscosity. The systems might also need to adjust to changes that develop during stirring. "When the viscosity changes as you run a reaction," says Jim Dawson, president of Heidolph North America in Elk Grove Village, Illinois, "you need to keep the stirring speed the same. So you need a system that will adapt to that."

In addition to understanding how the stirring must be performed, users should also consider what technological features would come in handy. Maybe it's as simple as needing a stirring device with a display of all the functions. Many scientists want a computer connection, such as a USB or RS-232 port, programmable functions, and a remote control. As Jacso points out, "Computer interfacing is becoming more prevalent."

Accuracy or else

One researcher, who preferred not to be mentioned by name, used specific forms of stirring in a process that makes large amounts of oligonucleotides. Asked how crucial stirring rpm and temperature control are to his work, the researcher replied, "Absolutely critical."

In addition, this scientist would like some specific features in stirring technology. For one thing, he expressed an interest in "speed control with motor feedback." Moreover, he says, "It would be great also to have cooling capacity rather than the standard heating." Then, he added, "Saying that, such a model may exist, but I have never really searched for it."

Scaling up

Some of the most complex stirring applications arise in a pilot project that must eventually be scaled up. "So we need to know someone's long-term plan even from the start," says Jacso, "especially when a process will need scaling up later."

In those cases, the vendor must be mindful of the necessary speed and torque, particularly as the sample size increases. "There's lots to think about," Jacso says, "like the horsepower you'll need." The specific application also impacts how complex scale-up can get. The more viscous the sample, the more complex the potential scale-up problems. As Dawson says, "As you scale up, data capture helps you quantify and understand all of the characteristics."

So when it comes to what you need in a stirrer for a demanding application, do make a search for all available options. The technology might have advanced in ways that you haven't realized.

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

MICROWAVE DIGESTERS

ASSURING SAFE OPERATION

by Angelo DePalma, PhD

Microwave digestion in concentrated acid reliably eliminates sample matrix while rendering metals to species appropriate for analysis by inductively coupled plasma-mass spectrometry or atomic absorption.

Common-sense safety precautions include safe handling of solvents and acids. "But users need to pay a certain degree of respect to the corrosive, high-temperature, high-pressure operation of digesters," says Johan Nortje, product manager at Milestone (Shelton, CT). "Safety, above all other factors, influences microwave digester [MD] design and construction."

MDs are closed systems, which enables reaching temperatures much higher than the boiling point of the digestion medium (usually concentrated acid). Consequently, construction from high-quality stainless steel is essential to resist mechanical stresses and the corrosive effects of heat and acid. Milestone, for example, uses no polymers either in critical contact surfaces or in components.

Probes that monitor temperature and software that controls heating are essential for safe operation and method development/consistency. Rotors come in many configurations, and are normally selected on the ability to speed digestion. However, rotors play a role in safety as well because their design affects heat generation.

"Temperature is the number-one safety factor," Nortje explains, "because the pressure generated inside the vessel is directly proportional to temperature."

Digestion methods consist of two steps: ramp to temperature, and hold at temperature. Heating should be gradual, particularly on samples containing significant carbon matrix, due to the possibility of the sample going exothermic. Rapid digestion of carbon contributes to both temperature and pressure.

Nortje advises users to consider MDs equipped with exhaust hoses for venting corrosive gases after a run to an acid trap or fume hood. Another suggestion is to begin method development on very small samples—no larger than about 100 mg, preferably much lower. This provides a good estimate of what to expect from much larger samples in the event that the sample goes exothermic. If temperature is difficult to control at 100 mg, it will likely lead to unsafe conditions at half a gram or one gram.

Microwave digesters from reputable suppliers will operate well within safe conditions, provided users take these precautions. Moreover, vendor sites and online searches can provide excellent guidance on specific methods in the way of case studies and application notes. While "nothing new under the sun" may not strictly apply, finding a method that is both safe and effective for your samples will not be difficult.

> "Safety, above all other factors, influences microwave digester design and construction."

Safety by design

All commercial MDs undergo safety-based design and manufacturing. Systems employ mechanical interlocks to prevent vessel breakage. Many units employ access rights that prevent untrained or otherwise unapproved individuals from operating the equipment. Software controls method parameters such as digestion temperature and duration, temperature ramp-up, and cooling. Firmware or software controllers perform diagnostic checks before a run to ensure that temperature and pressure sensors are working, and that interlocks are performing as specified. After a run, the control panel alerts operators when opening the unit is safe. Opening before reaching safe temperatures and pressures is impossible with Anton Paar digesters due to a hard-lock safety mechanism.

"Thanks to these safety features, despite the high temperatures and pressures they generate, microwave

digesters may be located safely anywhere in a lab," says Reynhardt Klopper, product specialist for microwave synthesis and digestion at Anton Paar USA (Ashland, VA). While fume hoods are not required for operation, the vent hose for releasing gases should be vented to a hood. "The main caution, since microwave digesters contain magnetrons, is that workers with implantable electronic devices should keep their distance."

Klopper advises laboratory managers to pay special attention to safety-related certifications. European manufacturers apply the CE logo

"If temperature is difficult to control at 100 mg, it will likely lead to unsafe conditions at half a gram or one gram."

to goods they sell globally, indicating that these products meet strict European Union safety standards. Anton Paar digesters are produced under a somewhat stricter German government standard, GS (*Geprüfte Sicherheit* or "Tested Safety"). "GS indicates that an independent third-party organization, in this instance Intertek, has confirmed safe design and operation," Klopper says. "GS certification provides added peace of mind."

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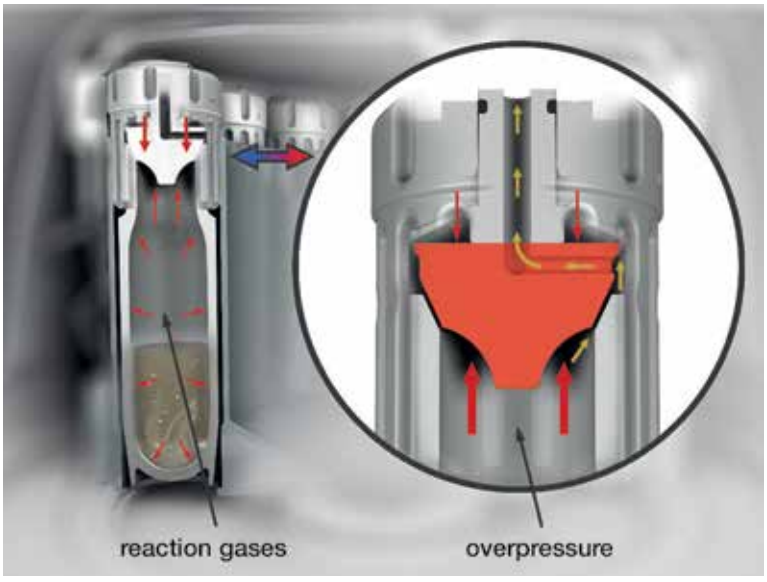
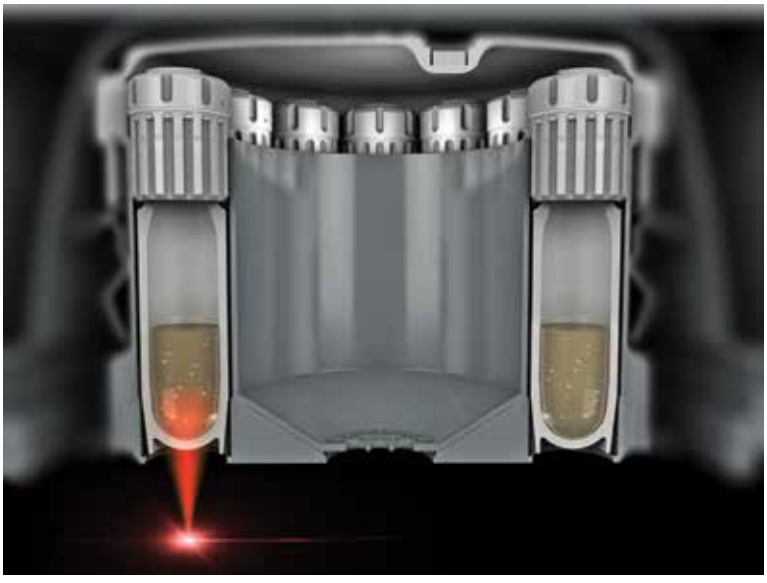


▲ *Microwave vessels have built-in pressure regulation mechanisms which ensure that pressure build-up inside the vessels does not exceed the design limits.*



▲ *Microwave systems have built-in temperature monitoring devices to prevent overheating of vessels.*

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

ARE YOU IN THE MARKET FOR A... LABORATORY GLASSWARE WASHER?

Whether to employ central washing stations or point-of-use washers located under a lab bench or in a corner is something that has to be addressed with regards to laboratory glassware washers. The former provide an economy of scale and are popular with lab workers who, almost universally, hate to "wash the dishes." The downside for central washing stations is that glassware tends to disappear over time, due to breakage and operator error.

Types of lab glassware washers used by survey respondents:

Small Capacity Washer	36%
Medium Capacity Washer	55%
High Throughput Washer	7%
Large Capacity Washer	8%
Other	1%

Frequency of lab glassware washer use as reported by survey respondents:

Several times daily	19%
Once a day	27%
Several times each week	28%
Once a week	15%
One to three times a month	7%
Less than once a month	4%

Nearly 25% of respondents are engaged in purchasing a new glassware washer. The reasons for these purchases are as follows:

Replacement of an aging system	52%
Addition to existing systems, increase capacity	10%
Setting up a new lab	17%
First time purchase	17%
Other	4%

TOP 6 QUESTIONS

You Should Ask When Buying a Lab Glassware Washer

1. How is the product manufactured? Ask about the quality of the materials used and the product life expectation based on manufacturing testing. Also find out about the product's warranty.
2. What differentiates the lab washer from others offered in terms of performance?
3. Does the company offer application support and technical phone support before and after product installation?
4. How sustainable is the product? Ask the company to provide details on energy and water consumption as well as the recycle ability of the product.
5. If the product is discontinued, for how many years does the company provide accessories and parts for the washer?
6. Finally, ask about the cost of the purchase—not just the price of the product being installed but the total cost of ownership, which includes price, service expectations, warranty, etc.

TOP 10 FEATURES/FACTORS

Respondents Look for When Purchasing a Glassware Washer

CONSISTENT WASHING AND DISINFECTION RESULTS	80%
DURABILITY OF PRODUCT	79%
LOW MAINTENANCE – EASY TO USE AND CLEAN	77%
SERVICE AND SUPPORT	70%
WARRANTY	63%
PRICE	57%
RELIABILITY OF VENDOR	51%
ABILITY TO CUSTOMIZE RACKS	49%
SAFETY FEATURES	48%
ENERGY EFFICIENT / LOW OPERATING COST	48%

For more information on laboratory glassware washers, including useful articles and a list of manufacturers, visit www.labmanager.com/washers

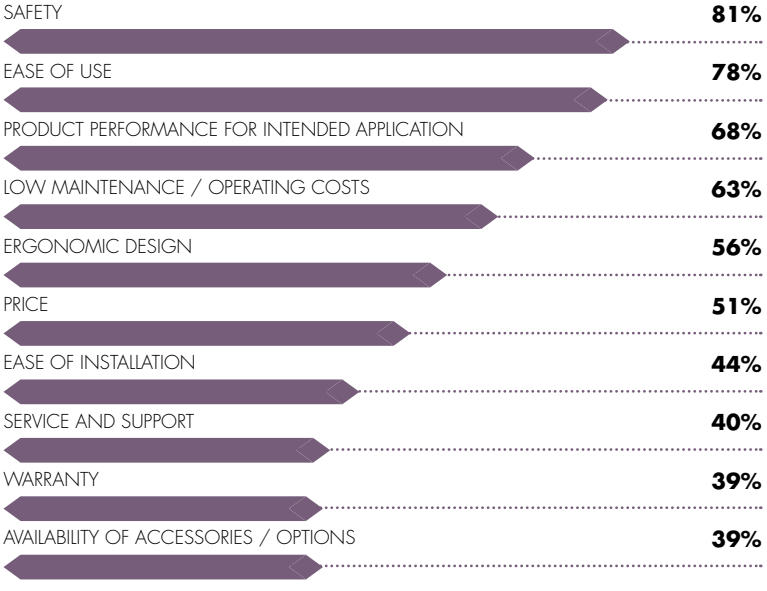
ARE YOU IN THE MARKET FOR A...
GLOVE BOX?

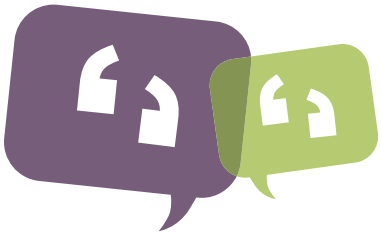
Glove boxes go by many different names and are used for many purposes. However, their essential attribute is the ability to maintain a completely separate environment from ambient. Glove boxes are completely closed compartments ranging in size from a few cubic feet to several hundred cubic feet and differ from other safety enclosures in two significant respects: users can introduce articles into glove boxes and manipulate them inside through ports fitted with gloves, and glove boxes typically use a specialized atmosphere.

TOP 5 QUESTIONS
You Should Ask When Buying a Glove Box

1. What applications are you using the glove box for? This will determine exactly what you will need in a glove box, such as an oxygen-free atmosphere, etc.
2. Are the incubation and processing separated in order to prevent contamination? This is important if you will be using the glove box for cell culture.
3. How much will the glove box cost to acquire and maintain? Are warranties offered? Custom glove boxes are the most expensive, so if a standard model can fit your needs that is probably the better way to go. Making small customizations to an off-the-shelf model is also another less costly option than a fully-custom unit.
4. What are your future needs? This will help determine if the smallest unit is really the best option or if a larger option which can accommodate future expansion would make more sense.
5. What sort of safety features does the glove box have? These are especially important if you are working with very hazardous materials.

TOP 10 FEATURES/FACTORS
Respondents Look for When Purchasing a Glove Box





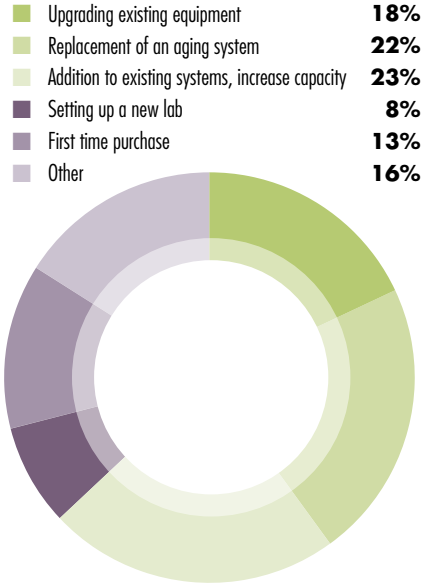
Primary use of glove boxes as reported by survey respondents:

Research	55%
Clinical	21%
Quality Control	14%
Production	11%
Other	6%

Glove box applications as reported by survey respondents:

Manipulating dangerous, toxic, or moisture-sensitive substances	33%
Anaerobic Bacterial growth	20%
Cell culture	19%
Other	19%
Air- or moisture-sensitive analyses	14%
Storage and processing of chemical, metals, calcium, etc…	12%
Maintaining cleanliness for microchips or fabricated parts, sensor calibration	10%
Virus production	6%
Controlled-atmosphere welding	2%
Compounding pharmacy, vaccines	1%

Nearly 32% of respondents are engaged in purchasing a new glove box. The reasons for these purchases are as follows:



For more information on glove boxes, including useful articles and a list of manufacturers, visit www.labmanager.com/glove-boxes

HIGH-PRESSURE MASS SPECTROMETRY

Problem: In the analytical sciences the common image of mass spectrometry involves researchers in a core facility, analyzing spectra generated by a machine the size of a refrigerator. Because conventional mass spectrometers operate under extreme vacuum, they must be coupled with pumps that are expensive, bulky, noisy, and fragile. These powerhouse systems are designed to accommodate a wide variety of often-disparate needs, and this flexibility adds complexity in both operation and maintenance. Overall, the size, cost, and complexity of conventional systems typically limit the deployment of mass spectrometry to specialized laboratories. However, many applications do not require this level of complexity, leaving many to wonder how mass spectrometry could be deployed on the workbench of the average researcher.

Solution: Within the past few decades, there has been remarkable growth in the demand for purpose-built and user-centric analytical tools. Personal PCR, flow cytometers, and handheld Raman or XRF tools are all examples of technologies that were complex, specialized, and expensive a decade ago but which are now usable by the average technician. These disruptive developments are deployed in such diverse implementations as life science research labs, first responder HazMat calls, and mining exploration and are operated by users who do not need to be instrument specialists.

Until recently, mass spectrometry had yet to join this analytical revolution. A promising new technique called high-pressure mass spectrometry™ (HPMS), commercialized by Boston-based 908 Devices, suggests how the personalized mass spectrometer can become a reality.

HPMS not only allows for several key components of the mass spectrometer to be miniaturized, it also removes the need for large, cumbersome vacuum pumps that limit conventional mass spectrometry approaches. A typical ion trap used in traditional mass spectrometers is roughly the size of a soda can and is a high tolerance, precision assembly. Ion traps used in HPMS, while physically functioning through the same mechanisms, are much smaller—around 1mm in diameter or smaller. This miniaturization directly allows for the mass spectrometer to operate within a much less extreme vacuum—at approximately 1 Torr. This is four to five orders of magnitude closer to atmospheric than a conventional system. In turn, these simpler vacuum requirements can be achieved with a small, robust, and cost effective pump and a much simplified vacuum chamber.

The first implementation of the HPMS platform is the M908, a self-contained handheld tool weighing only 2Kg and battery-operated for around six hours on a single charge. Robust to MIL-spec standards, M908 is used by civilian and military first responders for fast detection and identification of toxic industrial compounds and weapons.

Beyond M908, HPMS offers the path to simple, personal mass spectrometry implemented in the research or analytical laboratory. The small, robust HPMS engine will allow for tiny footprint, simple-to-operate, and cost effective analyzers, putting mass spec analysis within arms reach of the researcher directly on the workbench.

For more information, please visit http://908devices.com/

▲ *908 Devices' M908 instrument utilizes high-pressure mass spectrometry™ (HPMS) for chemical detection and identification of solids, liquids, and vapor targets at trace to bulk quantities.*

A SAMPLING DEVICE FOR MUCOCELLULAR MATERIAL

Problem: Research into gastrointestinal diseases often presents clinicians and researchers with difficulties in terms of collecting samples from patients for analysis. The very nature of the gastrointestinal tract makes it relatively inaccessible for simple, effective sampling. Current processes require the patient to collect samples of stool, have a rectal swab taken or a tissue biopsy during endoscopy. Each of these methods is not without its problems, whether for the patient, the clinician, or the researcher. Stool samples are often deemed unacceptable to patients and the inconvenience of providing a sample and having to return it to the clinician or laboratory often results in patients not returning the sample. Rectal swabs can be taken by a clinician but do not provide quantitative, reproducible samples. Finally, endoscopic biopsies require the patient to follow a specific diet, take laxatives at least 24 hours before, and undergo sedation for the procedure.

All told, these problems combine to create barriers to research into gastrointestinal disease, which can result in additional processing and sample collection costs and, perhaps more significantly, inconvenience, discomfort, and undue stress for patients.

Solution: Origin Sciences has developed OriCol™, a device for the convenient and effective sampling of mucocellular material that has migrated along the entire colon to the rectum. The mucocellular sample is rich in exfoliated cells, protein, nucleic acids, and bacteria.

The sampling device incorporates a hydrophilic nitrile membrane that, upon insertion into the rectum via a standard proctoscope, is inflated with air using a syringe. The inflated membrane remains in contact with the rectal mucosa for ten seconds and is then deflated and retracted into the device prior to removal from the patient. The sample is retained within the device and can be stored, with or without buffer, prior to transportation to a laboratory for testing or fixed onto slides for further processing. A trained professional can conduct the sampling procedure in less than five minutes. No prior preparation of the bowel or special diet is required prior to sampling and data from a study involving over 700 patients demonstrates that the procedure is acceptable and well-tolerated.

The samples collected using the OriCol™ device contain a range of biomarkers to enable clinical analysis and research into gastrointestinal conditions such as colorectal cancer, inflammatory bowel disease, irritable bowel syndrome, allergies, and gut dysbiosis. The samples can provide diagnostic information relating to the presence of tumors, inflammation, bleeding, infection, and the bacterial profile of the gut. Calprotectin, haemoglobin, carcinoembryonic antigen, various antibodies, and gut microflora, are all examples of biomarkers that can be measured in samples taken using the sampling device.

With the benefits of 100 percent patient compliance, high patient acceptability, no requirement to undergo bowel preparation, dietary restrictions, or sedation; no need to handle stool samples; a reduction in the number of processing steps; and a lower risk of sample loss/spoiling in transit, the OriCol™ sampling device provides a convenient method to collect, store, and transport the samples for further analyses.

For more information, visit http://www.originsciences.com/index.php/oricol/introduction

▲ *The OriCol™ sampling device for the convenient and effective sampling of mucocellular material.*

TECHNOLOGYNEWS

This month, we highlight companies that will be exhibiting at two upcoming tradeshows, **Experimental Biology 2015 (EB 2015)** and the **American Association for Cancer Research's 2015 annual meeting and exhibit (AACR 2015)**. EB 2015 will take over the Boston Convention and Exhibition Center in Boston, MA from March 28-April 1. AACR 2015 will be held at the Pennsylvania Convention Center in Philadelphia, PA, from April 18-22, 2015, with exhibit dates April 19-22. Remember that these specific technologies may not be at the show, but their manufacturers will be on hand to answer any questions you may have.

ANALYTICAL

Portable FTIR Package

4500 Polymer Package

Booth 323 (EB 2015)

Booth 711 (AACR)

- Designed to help manufacturers ensure the quality and safety of products made from PVC polymer
- Can non-destructively determine the chemical composition of a polymer in seconds
- If the polymer is identified as PVC, the 4500 will accurately measure the amount of phthalate present
- Brings the analytical precision of Fourier transform infrared spectrometry to any location and delivers lab-quality results

Agilent www.agilent.com

Discrete Analyzer

Smartchem 600

- This fully automated, direct read, discrete analyzer maximizes productivity for routine and special chemistries, up to 600 tests/hour
- Utilizes washable cuvettes with an integrated wash and control station, guaranteeing a lower running cost and reduced risk of contamination
- Offers automated system quality control in addition to automated analysis
- Provides a high capacity of 200 samples

AMS Alliance www.amsalliance.com

Medium-Pressure Chromatography Systems

NGC Discover™ & NGC™ Discover Pro

Booth 262 (EB 2015)

Booth 1527 (AACR)

- Automation capabilities of both systems make them suited for advanced purification applications such as method optimization and multi-step and tandem protein purification
- Available with a 10 ml/min pump module or with the recently-released NGC 100 ml/min pump module
- Increase throughput by being able to load multiple samples and run up to 15 columns sequentially

Bio-Rad www.bio-rad.com

UV-Vis-NIR Microspectrophotometer Concept

FLEX™

- Flexible in configuration, capabilities, and pricing
- Operates from the deep ultraviolet to the near infrared
- Depending upon the configuration of FLEX™, samples can be analyzed by absorbance, reflectance, luminescence, and fluorescence with high speed and accuracy
- Allows the user to image microscopic samples directly with DirecVu™ optics and with high resolution color digital imaging

CRAIC www.microspectra.com

Orthophosphate Analyzer

YSI P 700

- Measures the amount of orthophosphate throughout the wastewater treatment process
- Can be used as a standalone analyzer in a facility or in conjunction with other sensors in an YSI IQ SensorNet system
- Continuous data it provides can help verify phosphate elimination in the wastewater process and improve operational efficiency

Xylem www.xylemanalytics.com

PRODUCT SPOTLIGHT

SPEEDY SPECTROMETER

NEW INSTRUMENT ALLOWS EASY SWITCHING TO AND FROM AXIAL PLASMA OR RADIAL PLASMA OBSERVATION

Near the end of January, SPECTRO Analytical Instruments announced the first spectrometer that allows users to quickly and easily select axial plasma or radial plasma observation in a single instrument without any optical compromise—the ARCOS.

In a release, the company stated that the ARCOS "easily surpasses the performance limitations of conventional ICP-OES instruments—dramatically improving sensitivity, stability, and precision, while lowering operating costs with the introduction of innovative components, unique capabilities, and optimum flexibility."

The company added that the instrument establishes a new ICP-OES performance class for complex analytical tasks that resolves a wide array of the problems inherent in traditional spectrometer design.

Key features of the new spectrometer include a unique MultiView capability, which is what allows simple switching between axial plasma and radial plasma observation and also improves stability and accuracy, and the ORCA optical system. That system "delivers a matchless resolution of 8.5 picometer in the wavelength range from 130 to 340 nm," according to SPECTRO.

The ARCOS also includes a solid-state power generator design that provides the highest plasma power available for extreme or quickly-changing plasma loads and its UV-PLUS sealed optical chamber ends the need for the purging of argon or nitrogen gases—along with the related supplies, maintenance costs, and downtime. Lastly, air-cooled interface technology and the completely air-cooled generator eliminate the need for an external cooling system, along with the associated costs of such a system.

For more information, visit http://www.spectro.com

BASIC LAB

Mass Flow Meters and Controllers

GFM Meters and GFC Controllers

- Designed respectively to read or set gas flow rates
- Now include upgraded features that enhance the products' performance without impacting the cost, including faster response times and easy serviceability
- Offer instrumentation-grade ±1% accuracy for models up to 100 liters
- Constructed of aluminum and brass for non-corrosive gases and 316 stainless steel for corrosive applications

Aalborg Instruments www.aalborg.com

High Performance Centrifuge

AACR Avanti JXN-30

Booth 1934

- Improves workflow by delivering high throughput performance and an expanding and increasingly varied separations capability
- Capability ranges from high efficiency, high volume separations using fixed angle rotors to high force zonal separations with swinging bucket rotors
- MobileFuge remote application enables customers to access all types of data, carrying out remote monitoring, control, and error-handling via networks and mobile devices

Beckman Coulter www.beckmancoulter.com

Digital Refractometer

HI96801

- This portable and water-resistant meter can be used for sucrose measurements in the lab or field
- Employs the measurement of refractive index to determine parameters pertinent to sugar concentration analysis
- Measures the refractive index of a sample and converts it to %Brix within seconds
- Temperature can be displayed in Celsius or Fahrenheit and is automatically compensated for with each sample measurement

Hanna Instruments hannainst.com

Fume Hood

UniFlow CleanAire II

- Designed to meet DH I requirements as defined by SEFA 9
- Features a built-in carbon filtration system to adsorb non-toxic fumes and odors
- Equipped with an integral blower, vapor-proof light, fan, and light switches
- Superstructure is constructed of chemical and flame-resistant, non-metallic no-rust composite resin with a molded one-piece seamless interior fume chamber

HEMCO www.hemcocorp.com

50 µl Electronic Pipettes

AACR VIAFLO II

Booth 2235

- Now available for single-, 8-, 12- and 16-channel VIAFLO II pipettes, the new models deliver optimized precision pipetting in the volume range of 2 – 50 µl
- Fill the gap between the 0.5-12.5 µl and 5-125 µl ranges
- Combine ultra-lightweight design and operational comfort, enabling users to improve efficiency in their working environment

INTEGRA www.integra-biosciences.com

Mobile Bases for Workbenches

- Now available for almost all Lista workbenches and workstations, including the Arlink® and Align® brands
- Maximize convenience and allow users to easily reconfigure their workspace to keep up with changing demands
- Complimentary ListaWorks™ service allows for even further personalization

Lista www.listaintl.com

High-Speed Storage Tube Code Reader

Tracxer TS201 MINI

- Reads 1D rack barcodes, 1D barcoded tubes and 2D Data-Matrix coded tubes (in 96-, 48- and 24-well formats) all in less than a second
- This compact, plug-and-play reader requires no software installation and is very easy to use
- Read data can be sent to multiple applications due to its proprietary keyboard wedge functionality

Micronic www.micronic.com

3D Scanning System

Lab-robot Top-Eye™ LT

- Allows users to scan large samples without any sample preparation
- Provides ultrafast and precise 3D scanning up to 7000X magnification
- Easy add-on accessories allow the system to adapt to all sorts of applications
- Features versatile and powerful software
- Also features "Never lost navigation," high throughput, and allows particle counting (morphometric analysis), fiber analysis, and more

MicrOptik www.microptik.eu

Freeze Dryer

STELLAR Series

- Uses high-quality components and design techniques combined with an advanced PC/PLC control system
- Suited to both protocol development and small scale production needs
- Offers up to 6.25 sq ft of shelf area and 12L of condensing capacity with 63mm of shelf-to-shelf spacing
- Easy-to-use software provides automatic freeze-drying, defrost, and system testing

Millrock Technology www.millrocktech.com

Universal Fluorescence Illumination System

Lumen 1600-LED

- Offers individual control for 16 selectable wavelengths
- Compatible with all simple and multiband filter sets
- Provides ease of use through a "white light" mode with simple on/off and intensity buttons
- Fitting directly to most microscopes, the system enables for rapid switching between LED wavelengths to allow for capture of high speed events

Prior Scientific www.prior.com

Beads for Lab Ice/Water Baths

Thermal Lab Beads™

- Help reduce the risk of losing samples due to waterborne contaminants and are an ideal alternative to ice or water
- Aluminum construction of the beads means they will not melt, evaporate, or require significant maintenance
- Eliminate floating samples and the need for racks or weights
- Provide stable support for most glass and plastic sample vessels and reduce messy dripping water

tecaLAB www.tecalab.com

Peltier-Driven Benchtop Cooler

Electric Ice Bucket™

- Can save time, money and energy as compared to traditional water baths and ice buckets
- Filled with aluminum tecaLAB™ Thermal Beads™ in place of ice or water
- Samples are held securely by the Thermal Beads™ —in any orientation—without the need for racks or other accessories
- Thermal Beads™ reduce dripping water, floating accidents, and the risk of lost samples due to water contamination

tecaLAB www.tecalab.com

CELL CULTURE

Cryopreservation Solution

PRIME-XV® FreezIS DMSO-Free

- This chemically-defined cryopreservation solution for human mesenchymal stem/stromal cells (MSCs) is free of dimethyl sulfoxide (DMSO) and animal-derived components
- Allows researchers to characterize cells in DMSO-free environments during basic and translational research, which may add valuable insight downstream and facilitate scale-up
- Maintains the potency of MSCs throughout cryopreservation while sustaining comparable cell viability to solutions containing 10% DMSO

Irvine Scientific www.irvinesci.com

Compact Bioreactor/Fermenter

BIOSTAT A

- Designed specifically as an entry-level model for fermentation and cell culture as well as for educational purposes
- System's control tower features a complete array of measurement and control functions like easy-load peristaltic pumps, an aeration module, and conveniently accessible probe ports and supply connections
- Aeration system provides automatic flow control over the full range of each gas used

Sartorius www.sartorius.com

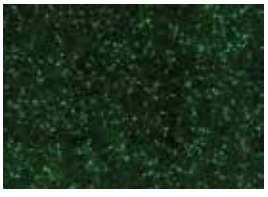
CHEMICALS, KITS & REAGENTS

Transfection Reagent

DNA-In™ Neuro

Booth 668 (EB 2015)

Booth 814 (AACR)



- Developed specifically for maximum nucleic acid delivery into neurons, typically achieving a two-fold or greater improvement in efficiency over currently-available competing reagents
- Offers researchers a cost-effective, robust, and easy-to-use DNA delivery solution for transfecting freshly-isolated and cryopreserved neurons
- Reproducibly transfects neurons and neural stem cells at optimal efficiency with very low toxicity

AMSBIO www.amsbio.com

INFORMATICS

Life Science Software Package

GeneSpring

Booth 323 (EB 2015)
Booth 711 (AACR)

- Newly-optimized for researchers focused on genomics, proteomics, metabolomics, transcriptomics, or any combination of life science disciplines
- Inlcudes GeneSpring GX and Mass Profiler Professional, which now allow users to examine the strength and direction of the relationship among samples or between genes, proteins and metabolites, using Correlation Analysis
- Also includes Pathway Architect, which now supports the Kyoto Encyclopedia of Genes and Genomes pathways

Agilent www.agilent.com

FT-NIR Networking Software

ONET

Booth 846 (EB 2015)
Booth 2227 (AACR)

- This server application is accessed via a browser-based web interface (WebUI)
- Allows users to set up, administrate, and control a network of FT-NIR instruments from a central remote location anywhere in the world
- All data measured on local spectrometers are stored first locally and replicated to a ONET database for central access

Bruker www.bruker.com

ELN Software

E-WorkBook 10

- A technology overhaul provides users with new ways to visualize, present, and consume data, including enhanced charting and canvasing capabilities
- Modern, clean web browser simplifies and speeds data capture and workflow, delivering flexible access away from the bench
- Primed to support scientists with today's research complexities and is also a foundation for future iterations

IDBS www.idbs.com

Mass Spectrometer Software Upgrade

ChromaTOF-HRT version 1.81

- New features and functionality improvements make data review and acquisition easier and more intuitive for users
- Tools include advanced filters and compound class-specific mass defect plots
- Automated formula matching for deconvoluted fragment ions and ChemSpider to help identify "unknown/unknowns" give users the best means to evaluate their results fully and efficiently
- Includes acquisition-centric upgrades with a focus on ease of use

LECO www.leco.com

LAB AUTOMATION

Robotic Plate Handler

CFX Automation System II

Booth 262 (EB 2015)
Booth 1527 (AACR)

- Enables high-throughput, walk-away real-time PCR automation for all Bio-Rad CFX real-time PCR detection systems
- Facilitates hands-off, around-the-clock data generation and analysis
- Allows users to operate two CFX systems with a single plate handler using a fraction of the space required by other systems
- Users can begin with one real-time system and scale up to two systems when required

Bio-Rad www.bio-rad.com

Automated Sample Management System

Tube Auditor™ 2.0

- Increases lab productivity and helps remove uncertainty from the high-throughput screening process
- Enables the rapid, non-contact sample volume measurement and precipitate detection of SBS-format microtubes in a single audit pass
- Minimizes downstream costs from the processing of empty plate wells
- Avoids damage to liquid-handling tips caused by failed de-cap operations
- Increases confidence in the concentration of delivered output samples

Brooks Life Science Systems www.brooks.com

Automated Storage Platform

Verso™

Booth 331 (EB 2015) (Hamilton Company)
Booth 751 (AACR) (Hamilton Robotics)

- Easily configured to meet the needs of demanding sample management applications
- Can be scaled to fit sample capacities ranging from 100,000 to over 5 million tubes at temperatures from ambient to -20°C
- Capable of storing and processing up to 1,500 tubes and plates per hour, and allows loading and unloading of up to 70 sample racks at a time

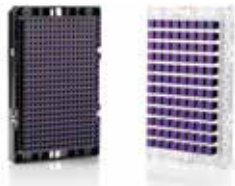
Hamilton Storage Technologies www.hamilton-storage.com

LIFE SCIENCE

Genotyping Arrays for Agrigenomics

Axiom® Porcine and Axiom Equine

Booth 1613



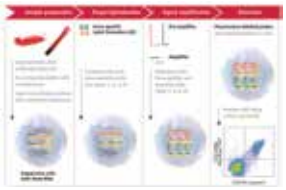
- Each feature more than 600,000 markers
- Available to the agriculture community under the Axiom Expert Design Program
- These two high-density arrays add to the product portfolio that includes bovine, chicken, maize, salmon, and wheat
- Offers the agriculture community the capabilities to rapidly design and develop custom arrays

Affymetrix www.affymetrix.com

RNA Assay

eBioscience PrimeFlow™

Booth 1613



- Capable of simultaneous detection of RNA and protein within millions of cells at single-cell resolution
- Allows researchers to incorporate the simultaneous analysis of RNA transcripts and proteins to elevate their understanding of single-cell dynamics
- Enables high throughput detection of RNA and protein expression
- Features a user-friendly protocol

Affymetrix www.affymetrix.com

High-throughput Oligonucleotide Microarray

GenetiSure Pre-Screen Kit

Booth 323 (EB 2015)

Booth 711 (AACR)

- Used for screening aneuploidy and other genomic aberrations in the 5- to 10-Mb range from single cells in three- and five-day embryos
- Allows for a turnaround time of less than eight hours from DNA extraction to data analysis
- Consists of a microarray that can run up to 14 samples and two reference samples simultaneously

Agilent www.agilent.com

Mini PCR Cardboard Cryo Boxes

PolarSafe™

- Designed to hold single PCR tubes or strips of 8
- One-inch height of the box prevents tubes from falling down inside the grids
- Hold (64) 0.2mL tubes
- To maximize storage utility, two of the boxes can be stacked inside each slot in vertical freezer racks used for 2" mini boxes

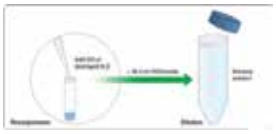
Argos www.argos-tech.com

Nuclear Staining Dyes

PureBlu

Booth 262 (EB 2015)

Booth 1527 (AACR)



- These high-purity formulations simplify nuclear staining for fluorescence imaging experiments
- Eliminate the need for weighing and require only a single dilution step upon resuspension
- Five-vial pre-aliquoted format ensures that only the amount required is reconstituted to avoid wasting reagents
- Can be easily combined with other stains and dyes for multicolor imaging experiments

Bio-Rad www.bio-rad.com

Automated Droplet Generator

AutoDG™

Booth 262 (EB 2015)

Booth 1527 (AACR)

- Combined with the QX200™ droplet reader and a laptop computer with QuantaSoft™ software, this system provides a worry-free, automated way to generate droplets for high-quality data
- At maximum capacity, the system can generate droplets for 96 wells in less than 45 minutes
- Sensitive enough to detect differences in users' pipetting habits

Bio-Rad www.bio-rad.com

Gel Documentation & Analysis Systems

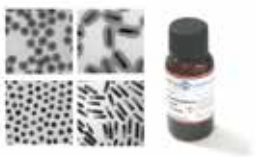
omniDOC

- Provide researchers with a quick, simple, and flexible solution for their gel documentation needs in a compact and affordable benchtop unit
- Easy-to-use, yet powerful
- omniDOCi shares all the same features as the standard omniDOC but adds wireless connectivity, enabling the system to be run in a darkroom from a remote PC or tablet

Cleaver Scientific www.cleaverscientific.com

Gold Nanoparticles with Specialized Coatings

Gold NanoRods and Gold NanoSpheres



- Available in a range of different sizes and peak absorption wavelengths
- Suited for use in imaging, tumor targeting, microscopy, lateral flow assays, SERS, catalysis, photonics, and several other high-technology applications within the fields of life science and materials science
- Silica-coated nanorods resist melting and shape distortion even when subjected to extreme heat

NanoHybrids www.nanohybrids.net

Real Time Thermal Cycler

Eco 48

- Capable of running 40 cycles in 15 minutes while still using standard chemistries and plastics
- In a typical run, can still complete 40 cycles in 40 minutes compared to 2 hours with competitive systems
- Features a very uniform block (±0.1°C recorded at 95°C with no settle time)
- Includes adaptive LED control

PCRmax www.pcrmax.com

Microsampling Device

Neoteryx Mitra (RUO)

- Designed for the collection, transport, storage, and analysis of biological fluids
- Consistently collects 10 µL of fluid in seconds while eliminating the volumetric blood hematocrit bias typically associated with the dried blood spotting technique
- Offered in two formats, including an automation-friendly option for high-throughput environments
- Suited for non-experts and requires no specialized lab equipment

Phenomenex www.phenomenex.com

RNA Target Enrichment System

AACR

SeqCap

Booth 1011 (Roche Diagnostics)

- Includes a comprehensive lncRNA (long non-coding RNA) design and a full range of custom enrichment offerings
- Designed to enable researchers to achieve significantly enhanced discovery power and targeting efficiency of RNA-Seq
- Dramatically increases RNA-Seq's sensitivity to low-abundance transcripts without introducing any systematic bias
- Also suitable for researchers who would like to focus on a subset of genes or transcripts

Roche NimbleGen www.nimblegen.com

Fermenter/Bioreactor

BIOSTAT® Cplus

- Designed for the cultivation of microorganisms and cell cultures
- Equipped with a DCU controller and a number of added functions like gravimetric feed control, advanced DO controller, and integrated off-gas measurement
- Culture vessels are supplied with operating volumes of 5, 10, 15, 20, and 30 liters
- Features a modular design that allows for individual system configuration

Sartorius www.sartorius.com

Compact Confocal Microscope

LSM 800

AACR

Booth 707 (EB 2015)

Booth 413 (AACR)

- Complements the recently-introduced ZEISS LSM 8 family
- Features highly sensitive GaAsP detector technology and fast linear scanning
- Provides high image quality and offers enhanced productivity and throughput, as well as greater flexibility in live cell imaging
- Optional Airyscan module delivers 1.7 times higher resolution and higher sensitivity than conventional confocal microscopes

ZEISS www.zeiss.com

SUPPLIES & CONSUMABLES

Cartridge System

SecurityGuard™

- Cartridge-based system protects any non-aqueous gel permeation chromatography (GPC) column
- Replaces traditional guard columns, offering a more convenient and cost-effective system for protecting expensive GPC columns from the damaging effects of contaminants and microparticulates
- Design enables the user to visually inspect the surface of the column's packing material at any time and monitor contaminant build-up

Phenomenex www.phenomenex.com

Low Profile 96-well Deep Well Plate

- Achieves a storage volume of 1.1ml / well in a height of just 27 mm, enabling more plates to be stacked or stored in a given space
- Manufactured from extractables-free polypropylene in an ISO 10,000 approved clean room environment
- Comply with ANSI/SLAS dimensional standards, ensuring complete compatibility with all automated sample handling systems, microplate readers, and washers

Porvair Sciences www.porvair-sciences.com

Volumetric Glassware

VOLAC and FORTUNA®

- Made according to ASTM, USP, and ISO standards
- Certification is available, either as a batch or individually, with appropriate ring marks
- Calibration of flasks and cylinders is "IN"; indicating that the liquid poured out equals the volume indicated
- Pipettes and burettes are calibrated "EX", which requires observance of the discharge waiting time

Poulten & Graf www.poulten-graf.com

GET CONTROL IN GMP ENVIRONMENTS

Centrifugation that supports compliance and eliminates hassle.

Floor-standing ultracentrifuges and high-performance centrifuges are vital to many bioproduction processes. Instruments are run in Good Manufacturing Practice (GMP) environments, and must support compliance with these regulations. Innovative features built into Optima XPN and Avanti JXN Series centrifuges support GMP compliance while eliminating much of the administrative work of other systems.

User Management

Controlling access to equipment within a GMP environment is critical. The Optima XPN and Avanti JXN Series centrifuges feature password protection for up to 50 unique user profiles. Users can be classified by one of three available security levels—Administrator, Super User, or Operator. Security levels provide the ability to control the level of access each user has to the centrifuge based on their permissions.

Data Logging

The Optima XPN and Avanti JXN Series allow for detailed run tracking that builds and stores an archive of each run. In addition to the standard centrifuge run parameters, it is possible to capture user comments entered before or after a run in the run log history. These comment fields can include batch numbers, the name of the product being produced, or anything else related to the run that would be useful to store in the log for future reference.

Electronic Signature

In addition to capturing and storing run data, the Optima XPN and Avanti JXN Series centrifuges also offer electronic signature capability. The electronic signature includes the user's name, date and time stamp, the instrument serial number, and any notes that were entered at the time of signature.

User-Defined Programs

The Optima XPN and Avanti JXN Series centrifuges allow up to 1,000 user-defined programs consisting of up to 30 steps each, ensuring that virtually any protocol can be set up and stored for future use. Once established, user-defined programs can be assigned to specific operators, limiting the number of users with access to the protocol.

Rotor Tracking by Serial Number

The Optima XPN and Avanti JXN Series centrifuges are also able to track the number of cycles accumulated on specific rotors. Once set up, users can choose rotors by serial number from an onscreen rotor library. The centrifuge tracks the number of cycles, so the life of the rotor can be precisely tracked and retired before it becomes unsafe.

Remote Monitoring and Control

The remote monitoring and control capabilities of the Optima XPN and Avanti JXN Series centrifuges make monitoring multiple instruments easy. Users can check the status of all instruments from virtually anywhere via personal computer using Virtual Network Computing (VNC) software, or mobile device using the custom MobileFuge application available for iOS and Android™ devices. The VNC software allows users to operate the centrifuge from a PC just as if they were standing in front of it.

Email Diagnostic Alerts

Using the email diagnostic alerts feature on the Optima XPN and Avanti JXN Series centrifuges, production managers can be notified whenever there is an issue with a centrifuge. Users enter the email address(es) where the notifications will be sent, then if a diagnostic issue occurs, the centrifuge will send a notification to everyone on the list alerting them to the problem.

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E-WORKBOOK 10: ALL THE POWER YOU'D EXPECT FROM E-WORKBOOK, NOW ON THE WEB

At IDBS, our sights are firmly set on enabling collaboration, helping research and development (R&D) organizations gain greater insight from their data and getting their products to market quicker. So we asked ourselves how we could make this simpler. With E-WorkBook 10, not only will you have the power and performance you've come to expect from E-WorkBook, you'll also discover the simplicity and ease of use that comes from an intuitively designed interface, and the flexibility and mobility that comes from our web-based spreadsheet technology.

One of the most groundbreaking features of E-WorkBook 10 is the ability to make use of our spreadsheet technology via the web client. This makes the technology more accessible to many more users and lets them work in a more mobile way, when and how they want, and using different platforms. Aside from accessibility and mobility, we've also put a lot of effort into looking at how people use our software day-to-day and making everything in the spreadsheet environment simpler and more intuitive to use.

With our spreadsheet technology now available on the web client, we believe that E-WorkBook 10 will revolutionize the way users relate to our technology. The opportunities created for collaborative working across departments, geographies and between third-parties are boundless. The intuitive and simple interface cuts down on complexity and training costs while deployment of the web client makes installation much easier. Its supporting infrastructure also allows for greater flexibility and scalability to meet your future resource needs. We believe it represents the future of research and development (R&D) data management.

"Today's labs are asking for so much more and we're aligning our software with where the science is taking our customers. We've invested significant R&D into E-WorkBook 10 to deliver game-changing enhancements to our proven technology," said Scott Weiss, Director of Product Strategy at IDBS. "Our customers are already impressed with our depth of functionality and now we've added an intuitive and simple interface to enable them to work faster and with increased flexibility through the browser. It means researchers can spend less time searching for things and more time doing science with advanced data insight."

Available now, E-WorkBook 10 is based on a heritage of rich user-centric enterprise software. This major step forward in the E-WorkBook journey offers a tried and tested solution, unlike some of the more niche software currently on the market. Existing users of E-WorkBook can add the browser-based functionality at any time. Total cost of ownership is reduced as the browser-based software enables central changes which can be deployed across the organization with minimum installation.

idbs.com/achieve

SCRUBAIR PIPET WASHER/DRYER

Water conservation has become a topic of interest in modern lab design. And in keeping up with current market needs, Labconco researched lab water usage and discovered one major sink hole — glass pipet washing.

Gallons upon gallons of tap water are poured down the drain as the common, siphon-style, pipet washers fill then drain repeatedly. When washing is complete, rinsing generally begins using deionized (DI) water – a very expensive solvent. After the time-consuming process of washing and rinsing, the pipets must be carefully removed, sorted into drying baskets and placed in an oven overnight. Total elapsed time to wash and dry a single load of pipets — more than 24 hours.

Tapping into our experience of designing and manufacturing laboratory glassware washers, we decided to address this issue. Combining direct injection cleaning, scrubbing action of percolation and consistency of automation, we streamlined the washing process with considerably less water and substantially less time.

The new ScrubAir™ Pipet Washer/Dryer is a one-of-a-kind automated unit to wash and dry in one place. The durable, steel-constructed unit can wash, rinse and dry up to 60 pipets with just the touch of a button. And it reduces water usage to as little as 10L for wash and rinse versus the 400L (at 2L/min) easily required for four hours of manual washing. At the completion of the wash and rinse cycles, forced-air drying is initiated through direct injection. Total elapsed time to wash and dry a load of pipets with the ScrubAir — just under five hours. This drops to 3.5 hours with the heated model.

The user-friendly interface has three flexible and lockable program cycles including options for both wash and dry duration and number of rinse cycles. The standard model is equipped with a single water inlet and pressurized air inlet. The heated model has an additional water inlet built in, giving the user the added ability to rinse with purified water.

A previously labor-intensive, time-consuming and overall environmentally unfriendly process has been transformed into a fast, simple, environmentally friendly one. Users no longer need to babysit their pipettes. Press a button, walk away, and let the ScrubAir do the work.

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ADVERTISER INDEX

LAB MANAGER ONLINE

We look back at our web content since January/February's issue and look forward to what's in store for April's upcoming issue.

1 Culinary Market Proves a Wise Choice for Lab Equipment Manufacturers

Scientific equipment being used in the kitchen is not a new trend, but such equipment designed from the ground up for culinary use is a fairly recent development. We talk to four laboratory equipment manufacturers about how they got into the culinary side of things, the differences between equipment designed for the laboratory and that designed for the kitchen, their favorite dishes, and more.

Read more at **LabManager.com/culinary**

2 Trending on Social Media: Dealing with Abrasive Leaders

As of Feb. 17, *Lab Manager*'s top article posted to Facebook was Bonnie Artman Fox's Lab Manager Academy article, "Four Strategies to Deal with Abrasive Leaders." This article received the most likes and shares of all our magazine articles posted last month, focusing on what you should do when interacting with your boss is negatively affecting your overall job satisfaction.

Read more at **LabManager.com/abrasive**

3 Most Popular Webinar

Last month's top webinar on LabManager.com was Karla Brandau's, "No More Procrastination!" which had 481 registrants. This online presentation showed attendees how to stop procrastinating and how 'creative' procrastination can be a positive in their work days. If you missed this webinar, you can learn more about it and watch it on demand at the link below.

Read more at **LabManager.com/procrastination**

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NEXT ISSUE ➡

Green Laboratory Initiatives

Researchers from academia charged with sustainability and the conservation of resources in their labs share insights into how big data/shared/distributed databases are being used to promote environmental sustainability and other green initiatives.

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