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Run Your Lab Like a Business

June 2009 Volume 4 • Number 5

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Safety First

State-of-the-art technology will never deliver the scientific results you're looking for without a well-trained staff to operate that technology and interpret the data it produces. And it's your job as lab manager to see to it that your well-trained staff is, above all else, safe from any and all hazards that exist in a lab.

This month's cover story opens with a nod to *Alice in Wonderland*, inviting you to revisit your lab the way Alice experiences her adventures in the rabbit hole—with eyes wide open. The exercise is intended to help you see safety problems brewing in your lab that might have previously gone unnoticed. It also reminds you to set an example to others when it comes to good lab safety practices.

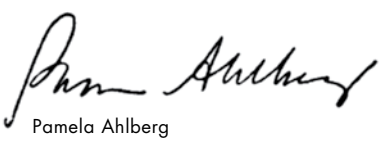
Job hazard analysis (JHA), one cornerstone of a successful safety and health program, is the topic of this month's Lab Safety article on page 56. JHA is method for figuring out the potential risks associated with a particular job and devising ways to control or eliminate them before an injury or accident occurs. It also provides one more tool for your lab safety toolbox.

If lab safety is management issue number one, then staff training is number two. To that, our Leadership & Staffing article (p. 14) describes the methods and benefits of a well-implemented cross-training program. "One of the primary reasons for cross-training is coverage," says lab manager, Benjamin Chew. "We want people to have the ability to take sick leave or go on vacation without worrying about their work piling up." In addition, a good cross-training program can keep a lab running smoothly, enhance career development and assist in knowledge transfer.

So, now that your staff is safe and well trained, how do you keep them from moving on? In this month's Science Matters column, Rich Pennock offers three keys to a good employee retention program. "Retention programs are as diverse as the businesses that implement them, but an ideal retention strategy is comprised of three key elements: managers who value their employees, customized employee recognition and opportunity for new challenges."

Not that you don't have enough on your plate—what with safety issues, training and retaining talent—in John Borchardt's article on page 18, we learn that you also play an important role in understanding and managing the legal requirements of inventorship. "Laboratory managers and team leaders heading a project, because of their knowledge of how research on a project unfolds, often play critical roles in deciding inventorship issues... Correct determination of the inventors on a patent is necessary if the lab manager's organization is to protect its intellectual property and financial interests," says Borchardt.

As always, we hope the articles you find here and in every issue of *Lab Manager Magazine* speak to your concerns and help you do your job better. If there is a topic of interest that we haven't covered, please don't hesitate to let me know.



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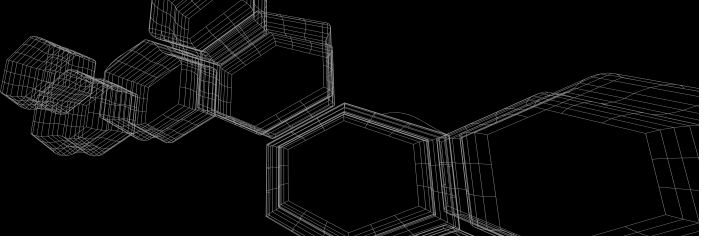


LAB SAFETY REVISITED

NOW IS THE RIGHT TIME TO TAKE A FRESH LOOK AT YOUR LAB'S SAFETY PROTOCOLS AND PRACTICES

by Glenn Ketcham and Vince McLeod

It's human nature to become complacent and relaxed in a familiar and comfortable setting. Things become routine, and you are able to navigate most of the day on autopilot. This is just as true in your lab, which can become like home or a comfortable old friend. But take a minute now and think back to when you first started working in a lab, and everything was new and challenging.

"Such easy things to do [that] can potentially preserve weeks, months or years of stored science as well as countless dollars in replacement costs."

You were probably a bit nervous at the beginning, not wanting to seem completely clueless. You also may have been somewhat awed by the equipment, the chemicals, the procedures and the ease with which others in the lab moved from task to task. You studied those with more experience and took your cues from them on how to conduct yourself and approach specific operations. Some things might have looked wrong or even dangerous, but you were reassured when you saw others walk past without a hint of concern. These people were your role models and the keepers of laboratory knowledge; anything that passed muster with them must be okay. Out in front of these lab guardians was the principal investigator (PI), who ran the lab. You met with the PI when you were hired. He or she probably gave you a lab tour and set up a schedule to meet with you about your research progress. After that, you were handed off to the lab staff for your practical training. As everything was new and unfamiliar, you accepted things as the way they should be.

Now that a good number of years separate you from those first impressions, you have probably experienced firsthand success, as well as some close calls and some mishaps. YOU are now probably one of the role models that others look up to. Is the message you want to pass on to those folks reflected in the lab you manage? Some yoga instructors tell us we should close our eyes and then open them as if we were a child to see the world anew. We would ask you to do the same with your laboratory. Take a walk through your lab and look at everything with the eyes of a child, as though seeing it unprejudiced and honestly for the very first time.

▲ *A host of problems, from inappropriately stored waste to blocked hood baffles, unlabeled and mislabeled containers to residual spills.* Photo courtesy of Mark Yanchisin

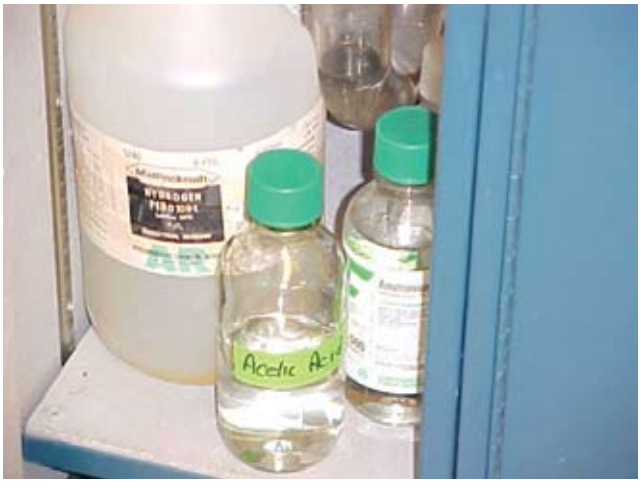
Let's start in the hallway outside the lab. Is the entrance to your lab labeled with up-to-date emergency contact and safety information? If a security guard heard a freezer alarm going off at 5 a.m. or a custodian discovered water pouring through the ceiling from a plumbing problem on the floor above, would they easily be able to contact the right lab staff who could take appropriate action? Is there an up-to-date call list in the lab should you need to call in "all hands"? These are such easy things to do, and they can potentially preserve weeks, months or years of stored science as well as countless dollars in replacement costs.

"We have seen inappropriate labeling of secondary chemical containers on many occasions, usually done by individuals wanting to prevent others in the lab from using their stock solutions."

We now move inside. What is your first impression when looking with "fresh eyes"? Is the lab neat, orderly and organized, or does it trend more toward chaos and entropy? Would your mother be proud of what she saw if she came to visit? The first impression that greets an outside inspector often sets the tone for what follows. The floors and aisles should be free from trip and spill hazards, such as randomly stored boxes, chemicals and waste. The absorbent, disposable paper bench coat should not be so contaminated that it documents the chemical usage of the bench student's entire graduate career. Bench coats should be replaced periodically and whenever gross contamination occurs. Are the waste receptacles overfull? Are they properly contained and labeled? Peek in the garbage cans. Is there any inappropriate waste? Look at the sinks. Is the lab keeping up with the dirty glassware, or does this area resemble a mountain of precariously stacked dishes in a fraternity house kitchen? Does the glassware prevent quick and safe access to the emergency eyewash at the end of the bench?

As we stroll up and down each aisle, let's focus in more detail. Look at what is on the benches and on the shelving between common benches. The bench top is where much of the science occurs. Are chemical containers labeled appropriately so that in case of an emergency, or even just a minor spill, all could decipher their content? We have seen inappropriate labeling of secondary chemical containers on many occasions, usually done by individuals wanting to prevent others in the lab from using their stock solutions. Inappropriate labeling of containers can present a hazard. It also is one of the most cited regulatory violations and can carry very stiff fines. Are chemicals stored properly and only kept out for the need at hand? Are sharps properly managed? Pull open some drawers; you may be surprised by what you find. Do bench-top equipment and apparatuses look properly assembled? Look at the glassware; are there chips or cracks, or starring on round-bottom flasks? Is there food on the bench? Are there any exposed electrical hazards or moving parts on equipment (e.g., belt guards on vacuum pumps)?

Take this opportunity to find and follow the electrical and extension cords. Are the cords in good repair? Things to look for include frayed or damaged insulation, missing ground pins on the plugs, electrical cords plugged into other cords and extension cords supplying power to equipment that is, for all practical purposes, stationary (e.g., freezers). If you find you have many extension cords and power strips throughout the lab, you may need to have additional outlets installed. Make sure that your important samples and operations are protected by emergency power (often identifiable as a red power receptacle).



▲ *Incompatible storage of chemicals.* Photo courtesy of Mark Yanchisin

We now come to the fume hood, one of our most critical yet most misused pieces of safety equipment. A number of conditions must be maintained in order for a fume hood to effectively capture and exhaust contaminants. Unfortunately, most of these can be short-circuited by the user, resulting in potential exposures to the user and others in the lab. For the hood to work properly, air must be able to enter the face of the hood and sweep from

the front to the rear with sufficient velocity but without excessive turbulence that can cause eddies. The hood sash must be positioned to produce effective capture velocity (capture velocity = volume flow/face area). The more open the sash, the greater the face area and the lower the capture velocity. The sash is also designed to provide user protection from explosions and other experiments gone awry in the hood. If the sash is up, this protection is removed. Make sure work is conducted at least six inches back from the face of the fume hood. Be sure that the air exhaust slots are not blocked at the rear of the hood. (This is where the air must go to leave along with the contaminants.) The front airfoil should not be obstructed; this provides direction to the air that sweeps the bottom surface of the hood. The same is true for biosafety cabinets. Make sure the front grill is not obstructed. This is critical for effective containment. As the interior needs to be decontaminated regularly, it is even more important that the front grill be free of clutter.

▲ *Where do we begin?* Photo courtesy of Mark Yanchisin

You get the idea. Continue on and look at your safety equipment: showers, eyewashes, fire extinguishers, etc. Are these easily accessible, tested and ready to use? Look at your storage cabinets and check for chemical compatibility, proper labeling, and secure shelving. Peek inside your refrigerators. What do you see?

Now that you've looked around carefully at the physical lab, take a look at the people in it. In many cases, these are people entrusted to you for their education as graduate students and post-docs or perhaps for their continued livelihood as technical staff. If you are the lab manager or PI, you are the role model and they will follow your lead. Your behavior will establish proper conduct in the lab. Are they making good choices? Are they sufficiently skilled to do the tasks necessary for their assignments? Do you intervene when necessary?

Most of the science world has heard of the recent tragedy at UCLA where Sheri Sangji, a 23-year-old research assistant, died as a result of severe burns received during an experiment. Though we are not privy to information beyond that provided by public press and professional news groups[1,2,3], it appears this was a case of an inexperienced chemist performing a dangerous procedure without proper training, equipment and supervision – a case of nonchalant, ad hoc procedures when in fact great care was actually needed. Now imagine speaking with the parents or spouse of someone in your lab who suffered a serious injury (or, even worse, died) and trying to explain why this happened. Could anything have been done to prevent it? From our years practicing safety in lab environments and investigating accidents, the answer is almost always "yes."

So, now you have looked with "fresh eyes." We hope you are satisfied with what you have seen. If you are not satisfied and you're considering approaches for improvement, we have three suggestions:

Lead by example. Those working in the lab will generally follow the lead of those in charge. Make it a point to put on a lab coat and eye protection whenever you go into the lab. Consistently and impartially enforce rules. Discipline doesn't have to be heavy-handed, but it does need to be consistent. If you see someone doing something that seems odd, don't hesitate to ask about it. You might be very glad you did.

"If you find you have many extension cords and power strips throughout the lab, you may need to have additional outlets installed."

Set a time for cleanup. One of the largest and most productive synthetic organic chemistry labs we've had the pleasure to work with had mandatory cleanup time. All work had to cease one hour before the lab meeting each week. All lab staff had to spend that hour cleaning and maintaining their areas. The lab manager announced the cleanup time and walked through the lab during that hour to oversee and address issues, with the motto "That which gets measured, gets done." The research manager also embraced the "lead by example" approach. Things never got out of hand; the lab was one of the best in terms of safety and compliance, and it produced quality science.

Have a productive method for bringing issues forward. This should be framed as a cooperative "we are in it for the common good" approach rather than a "gotcha"-type attitude. Require lab members, from the glass washer to the most senior staff member, to identify two or three safety issues at each lab meeting. Everyone should be able to come up with two issues regardless of how good a lab might be. These topics can then be opened to discussion and flagged for follow-up. This will set the stage for reinforcing safety as an important value in the culture of your laboratory.

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"As she withdrew the liquid, the syringe came apart in her hands, spewing flaming chemicals, according to a UCLA accident report. A flash fire set her clothing ablaze and spread second- and third-degree burns over 43% of her body.

Eighteen excruciating days later, Sangji died in a hospital burn unit."

From "Deadly UCLA Lab Fire Leaves Haunting Questions," by Kim Christensen, *Los Angeles Times*, March 30, 2009

CROSS TRAINING

IMPROVES LAB PRODUCTIVITY, FURTHERS CAREER DEVELOPMENT AND PROVIDES MULTI-TECHNIQUE EXPERTISE **Allison Champion**

When managers think about laboratory performance optimization, many typically think of obtaining a new machine or instrument. There are new technologies that can be purchased or new programs that can be implemented, but many managers often overlook the possibility of utilizing something they already have—human performance optimization in the form of cross training.

> **"Having knowledge in a wide variety of techniques allows technicians to share the often heavy workload."**

This isn't aerobics mixed with weight lifting, but a method used in the industry to expand knowledge among employees, and it's becoming more and more common as managers find the need for employees to be capable in a multitude of settings.

At Ashland Analytical Services & Technology (AS&T), the laboratory arm of Ashland Inc., cross training programs are part of the process used to keep the lab a top performer. AS&T is a comprehensive laboratory that provides analytical testing and problem-solving services for Ashland and also operates as a contract laboratory providing services for other companies.

▲ *Holly Sennhenn, senior research chemist, watches as Emily Stawicki, technician, prepares a sample for distillation to determine nitrogen content using the Kjeldahl method of nitrogen analysis.*

"I was hired to work in one area of spectroscopy, but after a few months on the job additional support was needed in another spectroscopy area, so I was chosen to cross-train," said Holly Sennhenn, a senior research chemist at Ashland. "Having capabilities in both areas turned out to be beneficial, because the techniques complemented each other. I could adjust my focus in either area depending on the demand, which helped alleviate bottlenecks in our workflow," she said.

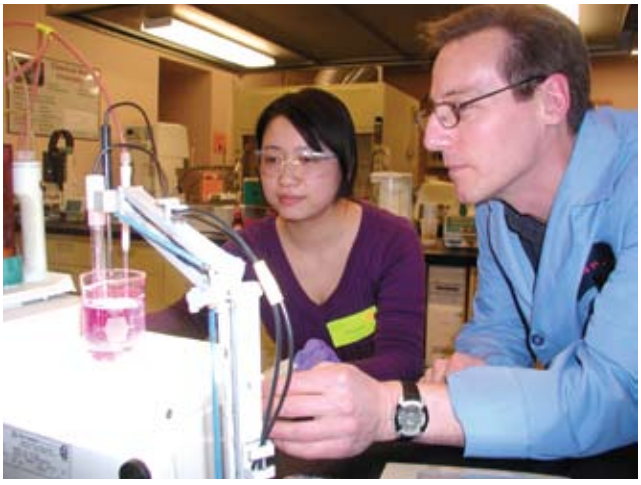
Ashland's cross training program

Ashland's analytical laboratory is divided into three specialty groups: Materials Characterization (MAT), Spectroscopy/Microscopy (SAM) and Separations/Environmental Analysis (SEA).

Initially, cross training was implemented at Ashland after ISO 9001 certification was obtained in 1996. Around that time, AS&T began tracking the workload in a more process-centered fashion. A newly implemented laboratory information management system was used to gather the information needed to make decisions about where more expertise should be distributed. The cross training came about naturally as the workload rose in some areas and decreased in others.

Much of the cross training ended up happening in the MAT group. Work done in that area of the lab tends to generate massive amounts of numerical data and results that come from routine analyses performed by technicians. Ashland managers realized they could improve productivity by cross training these technicians to perform different analytical tests. Having knowledge in a wide variety of techniques allows technicians to share the often heavy workload.

"One of the primary reasons for cross training is coverage," said Benjamin Chew, laboratory manager at AS&T. "We want people to have the ability to take sick leave or go on vacation without worrying about their work piling up." He also notes the importance of cross training in keeping the lab running. "If an emergency



▲ *Joe Curran, research chemist, at Ashland's Dublin facility, trains Wanxing Nancy Ni, chemist, Ashland Shanghai Technical Center, in performing acid value titrations.*

comes up requiring immediate answers, we need to be able to address that," he said. "For a service group that supports multiple internal business groups and multiple contract projects, as ours does, this is very important. If we have a single person assigned to run an analysis and that person is out of the office for a length of time, multiple projects will stop. That simply cannot happen."

The SAM and SEA departments employ the highest concentration of scientists with Ph.D. and Master of Science degrees in the entire lab. Their work does not generate as much numerical data as tests performed in the MAT lab does, but rather provides interpretation of data produced by the wide array of spectroscopic and chromatographic techniques performed. Because of this, it is more difficult to cross-train employees in these areas of the lab; however, Ashland has been successful in using its cross training techniques among those with high-level skill sets.

"We want people to have the ability to take sick leave or go on vacation without worrying about their work piling up."

The AS&T team uses a proficiency matrix to determine who to cross-train and in what areas. Everyone in the lab rates themselves on a skill-level scale of 0, 1, 3, 4, 6 or 8 for each technique. If a person indicates a zero, it means that the person has no knowledge or skill in the technique and no skill in running the instruments required for it. A skill level of 8 indicates that the person is considered an expert on that technique and can develop and implement new methods that address nonstandard requests.

The matrix is used to determine what areas could use more expertise, who would benefit from the training and who is knowledgeable enough to train someone new in a certain technique. Each trainee is assigned a mentor to help orient him or her to the technology and, when applicable, the new area of the lab. Thorough documentation of the trainee's work is kept and reviewed by managers throughout the training period.

"So much of analytical knowledge is gained through experience," said Sennhenn. "You could work in this profession for 20 years and still encounter new problems. Working closely with a mentor is the one of the best ways to learn, because throughout the course of the mentoring process you are able to draw on your mentor's experience and also see how he or she approaches problem solving. You also gain confidence as your mentor validates your results."

Benefits and challenges of cross training

Ashland has found that one of the most direct benefits of cross training is the amount of individual career development that takes place among staff members. Each person is considered an "expert" in at least one technique, but having a working knowledge of several other techniques enhances the problem-solving skills each person can bring to the team. Managers have found that those who have been cross-trained have a greater appreciation for the strengths and weaknesses of each

▲ *James Listebarger, senior staff scientist, shows Kristen Harvey, technician, a spectrum of elements within a material, collected using Ashland's Energy Dispersive X-Ray Spectrometer system.*

technique and can better focus on solving problems. Cross training also makes staff members more valuable to Ashland when opportunities arise to contribute AS&T expertise to outside clients.

Though valuable, cross training is complex as well. "Oftentimes during the course of analytical testing, the results you get lead to more questions," said Sennhenn. "Being cross-trained allows you to continue to investigate the problem beyond one technique. This is beneficial because performing an analysis from beginning to end helps you see the full picture and makes it easier to piece together the information from the multiple techniques. It also helps you approach problem solving differently because you have in-depth knowledge of the other testing that is available."

"The basic skills to run a sample can be taught in as little as a week; the skills to interpret those results can take years."

As beneficial as cross training is, problems arise in finding the time to perform the training. Ideally, employees would be cross-trained before a critical need for their skills arises, but that requires the ability to anticipate what future demand will surface. Workloads in various areas of the lab are very dependent on how well the businesses within Ashland are performing, so lab managers continuously track trends with consistent data gathering and work to understand the effects that different business maneuvers are likely to have on their workloads. The future plans and eventual actions of employees are other factors that affect the lab's workload.

"Potential retirements and a method for transferring knowledge are a major reason for cross training," said Chew. "We once had four analysts retire at the same time—a cumulative loss of 148 years of experience. We had been planning for this in the years prior by hiring new employees and placing them in roles where they could learn as much as possible, utilizing cross training as a teaching tool."

Lab managers also understand that training is only the first step to an employee's success. "Training may involve something as simple as showing a technician the commands used to run a specific instrument," said Chew. "However, it is the knowledge of chemistry specific to the company that needs to be taught. Certain job skills are transferable—good general lab techniques, attention to detail and clear technical writing—but knowledge of a material and how it will behave under a specific analysis can only be picked up when you actually run the sample yourself. The basic skills to run a sample can be taught in as little as a week; the skills to interpret those results can take years."

Allison Champion, *public relations intern at Ashland Inc., can be reached at ATChampion@ashland.com or 614-790-1832.*

Ashland Inc. has found cross training to be beneficial to employees as well as to the company as a whole. Managers have developed an efficient system to recognize opportunities for improvement and have developed methods to implement programs to capitalize on those opportunities. Using some simple techniques, cross training practices used at Ashland can be transferred to other labs.

- **Develop a matrix or grid indexing employees' skill levels at different techniques.**
- **Use the results from the matrix to ensure that each technique has sufficient expertise and coverage.**
- **Determine which areas of your lab could use additional help or expertise—plan ahead so that every area is covered for short-term events (such as employee absences for vacations or off-site training) and for long-term planning (such as employee retirements or career changes).**
- **Assign a mentor to each cross-trained employee and conduct frequent reviews of his or her progress.**
- **Track company businesses and trends, and anticipate employee actions in order to anticipate future laboratory demands.**

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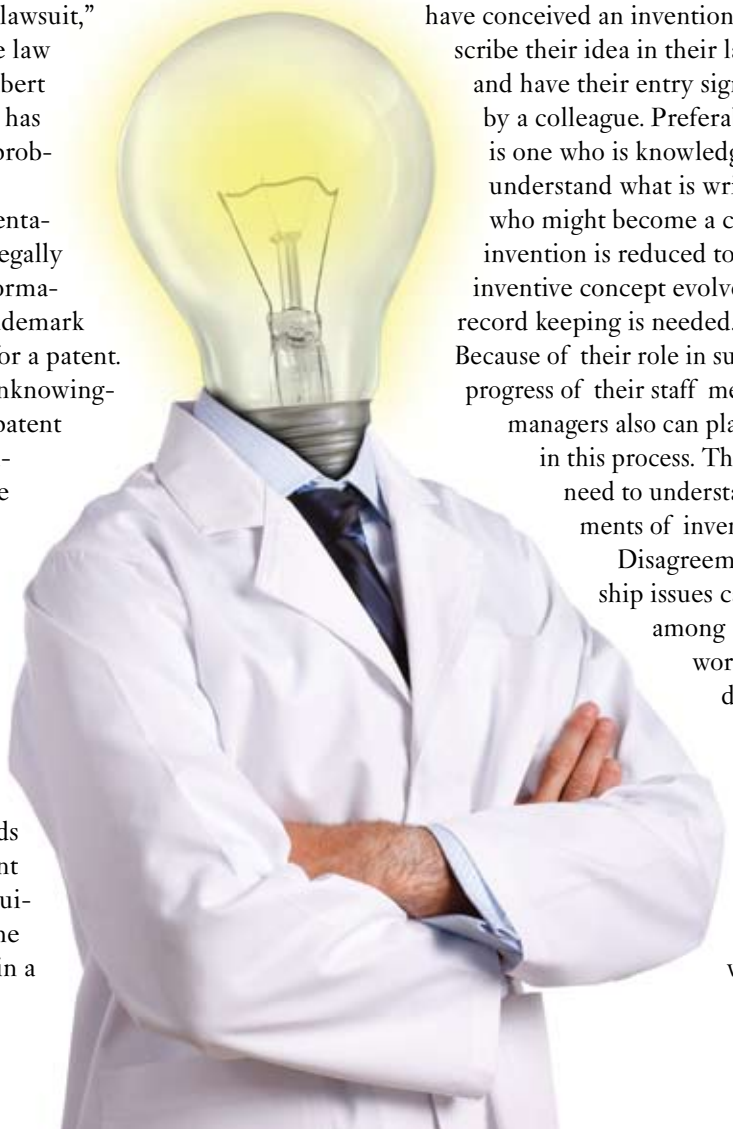
NAVIGATING PATENT INVENTORSHIP ISSUES

CORRECT DETERMINATION OF INVENTORS PROTECTS A LAB'S INTELLECTUAL PROPERTY AND FINANCIAL INTERESTS **John K. Borchardt**

Whose invention is it? Correctly answering this question is critical to the validity of your organization's patents.[1] "Inventorship issues dominate the landscape in patent prosecution and litigation, especially worldwide," [2] says Sandra P. Thompson of the Buchalter Nemer law firm. When it comes to correctly listing inventors, "dot your i's and cross your t's or you could be heading to (patent) invalidity," she advises.

"Failure to recognize a purported inventor (or giving inventorship credit where it doesn't belong) can lead to acrimony, hostility, loss of financial rewards, patent invalidity or a lawsuit," notes Bradley Crawford of the law firm McDonnell Boehnen Hulbert & Berghoff LLP.[3] This author has personally observed all these problems except the last one.

Inventors, their legal representatives and their employers are legally required to supply correct information to the U.S. Patent and Trademark Office (PTO) when applying for a patent. Failure, either knowingly or unknowingly, to do this constitutes what patent attorneys call "inequitable conduct." One form of inequitable conduct is incorrect listing of inventors in the patent application and issued patent. This incorrect listing can be due to omission of an inventor or inclusion of individuals who are not inventors as defined by the PTO (see below). The issue of inequitable conduct often arises when a firm defends itself against a charge of patent infringement by claiming inequitable conduct on the part of the patent holder. This can result in a court declaring an issued patent unenforceable.



Laboratory managers and team leaders heading a project, because of their knowledge of how research on a project unfolds, often play critical roles in deciding inventorship issues. Correct inventorship has to be considered whenever one or more of your staff members submit an invention disclosure to be considered for filing as a patent application.

Determining inventorship requires collecting details of each project member's contribution to the conception of the invention.[4] This in turn requires the careful keeping of lab records. When lab members think they have conceived an invention, they should describe their idea in their laboratory notebook and have their entry signed and witnessed by a colleague. Preferably, this colleague is one who is knowledgeable enough to understand what is written but not one who might become a co-inventor. As the invention is reduced to practice and the inventive concept evolves, the same careful record keeping is needed.

Because of their role in supervising the progress of their staff members' research, lab managers also can play an important role in this process. Therefore, lab managers need to understand the legal requirements of inventorship (see below).

Disagreement over inventorship issues can affect morale among all members of a workgroup, not just the disputants. Disagreements often arise when people collaborate on a project resulting in an invention. Since researchers increasingly work together on

teams, the potential for disagreements over inventorship is increasing. Another concern is that technicians in many laboratories are working with increasing independence and more and more of them may qualify as co-inventors.

Determining inventorship is often fraught with peril because everyone working on a project desires to be recognized as an inventor if patent applications are filed. If your staff members lack a clear understanding of the qualifications for inventorship required by the PTO, some can feel unfairly treated if they aren't included among the inventors. Crawford notes that being listed as a coauthor of a research paper, trade journal paper or internal laboratory report does not automatically qualify someone to be recognized as an inventor.[3] This author has personally observed resentments between researchers that persisted for more than a decade because one or more thought they deserved to have been listed as inventors of issued patents. These disagreements persisted because the non-inventors based their arguments on rules of authorship rather than on PTO inventorship requirements.

So what are the PTO requirements for one to be listed as an inventor on a patent application and issued patent?

Definition of inventorship

"Determining inventorship involves collecting the facts of researchers' contributions to conception and applying defined legal standards," explains Jay M. Brown of The Eclipse Group LLP law firm.[4] As noted above, this requires careful keeping of laboratory records as a matter of standard procedure.

Resolving inventorship issues begins with consideration of the Patent Act of 1952. Relevant sections read as follows:

- *"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of [the Patent Laws]." 35 U.S.C. § 101. To be an inventor or co-inventor, a person has to have made an original conceptual contribution to at least one of the claims of the patent.*

- *"When an invention is made by two or more persons jointly, they shall apply for patent jointly and each make the required oath, except as otherwise provided in this title. Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent." 35 U.S.C. § 116.*

Joint inventorship is "one of the murkiest concepts in the muddy metaphysics of patent law."[5] A good summary of joint inventorship law is provided in Reference 7. Each joint inventor must generally contribute to the conception of the invention. Each inventor is not required to make an equal contribution to the invention. For example, if a patent application has 20 claims, a person need only be involved in the original conception of one claim to be considered an inventor.[7]

"Laboratory managers often play a critical role in deciding inventorship issues."

When staff members work together to write an invention disclosure, they need to be aware that any inventorship decisions are tentative at this point. The patent attorney, after collecting information from various documents and in consultation with the authors of the invention disclosure and possibly with the lab manager, makes the final decision regarding who is an inventor. "Because inventorship is claim dependent, it can change during prosecution of an application when a claim is amended, added or cancelled, requiring the list of named inventors to be adjusted," notes Kassim Ferris of law firm Stoel Rives LLP.[8]

An inventor has to contribute to the conception of at least one claim. If all an individual does is use his or her ordinary skills to assist an inventor after that person has conceived the invention, this person does not qualify as an inventor. This is the prime reason that even a technician who plays a key role in a project may not qualify as an inventor.

Errors in listing inventors

"When an error in inventorship occurs, the good faith intent of those involved is critical," says Brown.[4] What can you do if your firm has supplied incorrect inventorship information to the PTO? According to Thomas Irving of the law firm Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, promptly filing the appropriate documents with the PTO to correct the improper listing of inventorship can enable a firm to avoid inequitable conduct.[9] Delaying filing of these documents after learning of incorrect inventorship can result in the loss of a U.S. patent.

This author has personally witnessed two cases of inequitable conduct. The first case occurred more than eight years after a young chemist left his first employer. He was ignorant of the requirements and procedures for filing invention disclosures. After he left the firm, his former mentor filed an invention disclosure that listed only the mentor as an inventor. After the U.S. patent had been issued, the patent owner filed a patent infringement suit against another firm. In examining documents associated with the case, the court decided that the young chemist should have been the sole inventor. The court invalidated the patent, leaving the alleged patent infringer free to continue the actions that had originally resulted in the lawsuit.

"Disagreement over inventorship issues can affect morale among all members of a workgroup, not just the disputants."

This author observed a second case, with a happier ending, while serving as technical advisor to the patent department of another former employer. The former employer had been first to file a patent application, but issuance of the patent was delayed by lengthy office actions. During these delays, a competitor obtained a patent on the invention. Once the patent was issued, this author's former employer filed an infringement case claiming the patent was invalid because the former employer had been first to file a patent application. While assembling documents and reviewing lab books relevant to the case, this author became aware that a chemist not listed as an inventor had actually invented the technology used in some of the claims and reduced it to practice. At the same time, there was no documentation to support listing another chemist as one of the inventors.

"Since researchers increasingly work together on teams, the potential for disagreements over inventorship is increasing."

After being informed of the situation, the patent attorney speedily filed the appropriate documents with the PTO and the inventorship on the patent application was corrected. Because the former employer had first acted in good faith and then quickly corrected the situation, the opposing party could not raise the inequitable conduct issue. The outcome? The issued patent was declared invalid and the former employer was later awarded a U.S. patent worth millions of dollars in business.

The academic lab perspective

Issues associated with correctly identifying and naming inventors also can occur in university and government laboratories. According to Sean Seymore of Washington & Lee University, "The rise in mentee claims for sole or joint inventorship, as well as the ever-present threat of an inequitable conduct defense in a patent infringement suit, jeopardizes the ability of the university to generate royalties from licensing agreements."[10] (Mentees are defined as undergraduates, graduate students, post-doctoral researchers and others working in a laboratory under a professor's supervision.) Seymore suggests that clear policies are required in determining inventorship to protect a university's licensing revenues. He believes it should not be up to professors alone to determine inventorship, as it is when determining who deserves coauthorship on a research paper. Instead, he suggests, "Universities must revisit their hands-off approach to the inner workings of the academic research group, at least with respect to determining the correct inventorship for a patent application." Patent attorneys in the university's technology transfer office or otherwise hired by the university on a case-by-case basis must work with the professor and other researchers to do this.[11]

Wrap-up

What all this means is that inventorship is more than a reward for hard work or a means to keep staff members happy. Correct determination of the inventors on a patent is necessary if the lab manager's organization is to protect its intellectual property and financial interests.

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LAB MANAGERS AS INVENTORS

By John K. Borchardt

Sometimes, a lab manager may decide that he or she should be included as an inventor. Bradley Crawford, of the law firm McDonnell Boehnen Hulbert & Berghoff LLP, poses the question, "Since I am the group leader, I am always an inventor, right?" Answering this question "yes" and proceeding accordingly was once quite common in industry. However, this is no longer the case. Lab managers and team leaders must meet the same PTO criteria for inventorship as their staff members. Any laboratory that does not subject both lab managers and their staff members to the same detailed requirements to be listed as inventors on documents at every stage of the patenting process—from writing the invention disclosure to issued patents—risks patent invalidation or other unfavorable court rulings. Staff members need to bear this risk in mind if the lab manager does not review invention disclosures prior to their submission to the organization's patent attorney.

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Dr. John K. Borchardt *is a consultant and technical writer. The author of the book "Career Management for Scientists and Engineers," he often writes on career-related subjects. He can be*

RETAINING TOP TALENT

Anyone who has ever participated in hiring a new employee knows how challenging it is to find top talent. Writing and posting job descriptions, reviewing resumes, interviewing candidates, processing background checks, negotiating offers—it's enough to boggle anyone's mind. Then, at last, a top-notch employee is identified, hired, and trained. Now a new, ongoing challenge presents itself—how does the candidate remain happily engaged within the organization?

"IT IS A WELL-KNOWN FACT THAT EMPLOYEES RARELY LEAVE COMPANIES; RATHER, THEY LEAVE THEIR MANAGERS."

Retention programs are as diverse as the businesses that implement them, but an ideal retention strategy is comprised of three key elements: managers who value their employees, customized employee recognition, and opportunities for new challenges.

Valued employees

It is a well-known fact that employees rarely leave companies; rather, they leave their managers. Companies with strong retention programs understand the importance of training their management in becoming leaders who value and respect their teams. Managers need to have a genuine interest in both the professional and personal well-being of their employees. Employees who feel their manager has their best interests at heart will be exponentially more likely to express loyalty to the company, dedicate themselves to excellence in their work product, and treat others with the same respect and concern.

Recognition programs

Each employee within an organization has his or her own unique motivations to come to work each day. Recognition programs should be designed with special consideration of these individual motivations and then customized accordingly. An employee with a family may appreciate being recognized with additional time off, while an employee who prefers casual attire over a business suit may appreciate an opportunity to wear jeans on Fridays. Some employees are motivated by peer recognition and would be delighted to receive awards in front of their co-workers, while others would cringe at the thought of public praise and would prefer more private forms of recognition, such as handwritten thank-you cards. The key is to know what motivates an individual employee and then recognize him or her in a way that is personally meaningful.

New challenges and growth

Talented people typically enjoy challenges and view them as opportunities to reach higher levels of achievement—giving them increased confidence and job satisfaction. Offering employees new challenges should not be mistaken for offering advancement or promotion. A simple opportunity to learn something new, participate in a new project, or help someone else grow in his or her position can be enough to provide a renewed sense of purpose and a break from the norm. Similar to recognition, offering opportunities for increased challenges should be customized to the individual. What one employee may consider an exciting new challenge may be old hat to another.

Retaining top talent is more of an art than a science. At the end of the day, it is about meeting the needs of your employees on both professional and personal levels. Employees whose needs are not being met will inevitably seek out organizations that better fulfill them. And how do we know what these needs are? We build relationships with our employees based on open lines of communication and mutual respect and then —we ask!

Rich Pennock *is vice president of Kelly Scientific Resources, a leader in scientific staffing solutions. For more information, visit www.kellyscientific.com.*

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AVOIDING POWER DISTURBANCES

CHOOSING THE RIGHT UPS IMPROVES TEST ACCURACY AND COMPLETION RATES By Michael A. Stout

In the lab environment, every key piece of equipment must produce accurate and repeatable results. Great care is taken by lab personnel in following detailed written procedures that specify sample preparation, equipment setup, preconditioning and conducting required testing. Most of the time all goes well, ending with accurate results. When inaccurate test data results—due to the complexity of the procedures, processes and equipment—determining exactly what went wrong can be difficult.

Take, for instance, a typical gas chromatograph (GC). One or more high purity gases are supplied to the GC. One of the gases flows into the injector, through the column and into the detector. The sample to be tested is fed into the injector, which has been allowed to stabilize at a temperature of 150°C–250°C for 24 hours. The heat in the injector causes the volatile solutes to vaporize. The vapor is then carried into the column by the gas. The critical temperature of the column is maintained by its location inside a temperature-controlled oven. The solute vapors travel through the column at differing rates depending on their physical properties, temperature and design of the column. The fast-moving vapor exits the column into the heated detector. An electronic signal is generated upon interaction of the solute with the detector. The size of the signal is recorded by a data system and is plotted against elapsed time to produce a chromatogram. The ideal chromatogram has closely spaced peaks, with no overlap of the peaks. The time and size of a peak are important in that they are used to identify and measure the amount of a specific compound in the sample. The size of the resulting peak corresponds to the amount of the compound in the sample. The time it takes for the sample to travel through the column is called the retention time. This value can be compared against the results of known samples to determine what compound is present.

> **"[GC] manufacturers . . . attempt to design the power supplies with enough internal stored energy to ride through momentary utility voltage disturbances."**

Any number of variables during testing can cause inaccurate results, but most of the variables in the process can be rechecked and verified. As with most lab equipment problems, the most often overlooked is the lab's utility power source and specifically its voltage regulation.

GC equipment manufacturers go to great lengths to design the power supplies used in the systems to have the widest input range possible. The manufacturers also attempt to design the power supplies with enough internal stored energy to ride through momentary utility voltage disturbances when operating from a nominal 120VAC utility voltage. Should the disruption be longer than the power supplies can withstand without their outputs going out of regulation, the equipment will malfunction. Another area of concern is a low line voltage condition in the lab, usually created by the large amount of equipment being powered in the lab. A low line voltage of less than 105 volts to below 100 volts can result in the equipment power supplies being hypersensitive to the smallest power disturbances.

Even if the power supplies operate from a normal nominal utility voltage, problems may occur due to other equipment. Motors, refrigerators, copy machines, etc., operating from the building's main electrical panel outside the lab can cause the utility voltage regulation to vary widely. For example, a low or unstable voltage source supplied to the GC could result in the following problems: Critical temperature controllers for the injector, the column and the detec-

tor stages could go out of calibration, skewing test results. Computer-controlled solenoid valves regulating gas flow could be adversely affected. Sustained low utility voltage levels may result in the GC's associated computer or internal microprocessors experiencing memory problems or even crashing. This could result in a wasted sample and lost test results. Finally, without an uninterruptible power system (UPS) battery backup connected to the entire GC system, the integrity of the 24-hour preconditioning and testing cycles could be compromised.

These problems can be avoided if the correct type of UPS is purchased at the time of GC installation. Often the UPS purchased to back up a $50,000 GC is a low-cost office computer–grade UPS, obtained at a local office supply store. One cannot blame the purchaser for looking at the bottom line or having little knowledge of the differing UPS designs available. Unfortunately, the worst possible decision has been made, considering the application—one that may even magnify the problems.

The IEEE defines UPS products in three distinct categories: off-line, line-interactive and online. They provide the following three increasing levels of protection:

1. *The off-line UPS gives users battery backup, basic surge protection and no voltage regulation when operating from utility power. This low-cost solution provides "square-wave" AC output power when operating on battery. This output is compatible only with a computer, since the power supply inside is robust enough to accept this distorted power.*

2. *The line-interactive UPS is similar to the off-line design, except it provides grossly regulated AC power. Voltage regulation is accomplished by electronically changing transformer taps whenever the utility power changes drastically. Paradoxically, this UPS can actually make a greater change in output voltage than the power provided by the utility company (Figure 1). In addition, the attempt to regulate the output voltage in this manner takes a toll on the batteries, which are used frequently as part of the boost-buck automatic voltage regulation (AVR) feature. Typically, this AVR feature is used several times a day to mitigate sag and brownout conditions. The line-interactive UPS design usually provides a sine-wave or semi-sine-wave output when operating on battery.*

3. *The online UPS maintains a regulated sine-wave AC output voltage (±2%) to the critical equipment 100% of the time, whether being powered by the utility or from internal battery power. First, the incoming AC is passed through the MOV surge-protected rectifier stage, where it is converted to DC, which is heavily filtered by large electrolytic capacitors. This removes line noise, high-voltage transients, harmonic distortion and all frequency-related problems. The input capacitors also act as an energy storage reservoir, giving the online UPS the ability to "ride through" momentary power interruptions without battery drain. As the battery source is also connected to this DC circuitry, it simply takes over as the energy source in the event of a complete utility loss. This makes the transition between utility and battery power seamless, without the 4–25 millisecond interruption in the UPS output associated with the other two UPS designs. The filtered DC is sent to a DC/DC converter or chopper circuit that acts as a DC voltage regulator. The DC voltage is tightly regulated and fed to a second set of filter capacitors. This stage gives the UPS its ability to provide a constant output even during sustained deep brownouts or low line conditions, which require the off-line or line-interactive UPS to go to battery mode. The regulated DC voltage is fed to a 100% continuous duty cycle inverter, where a totally new AC sine-wave output is generated. Some online models on the market will accept a drop-in utility line voltage below 60V, while maintaining a perfect sine-wave output voltage of 120VAC (±2%).*

"Another area of concern is a low line voltage condition in the lab, usually created by the large amount of equipment being powered in the lab."

The real-world graph and pictures on the following page show the difference in output voltage regulation and quality between a high-quality line-interactive and an online UPS. As can be seen, when the utility voltage changes (black dotted line), the output voltage of the line-interactive UPS (red solid line) at some points drops under 100VAC and increases to over 130VAC. Over the same utility voltage range, the output of the online UPS (green solid line) steadfastly remains at the 120VAC level without deviation. Even when the online UPS goes to battery mode, the output stays at the 120VAC level without interruption or voltage dropout.

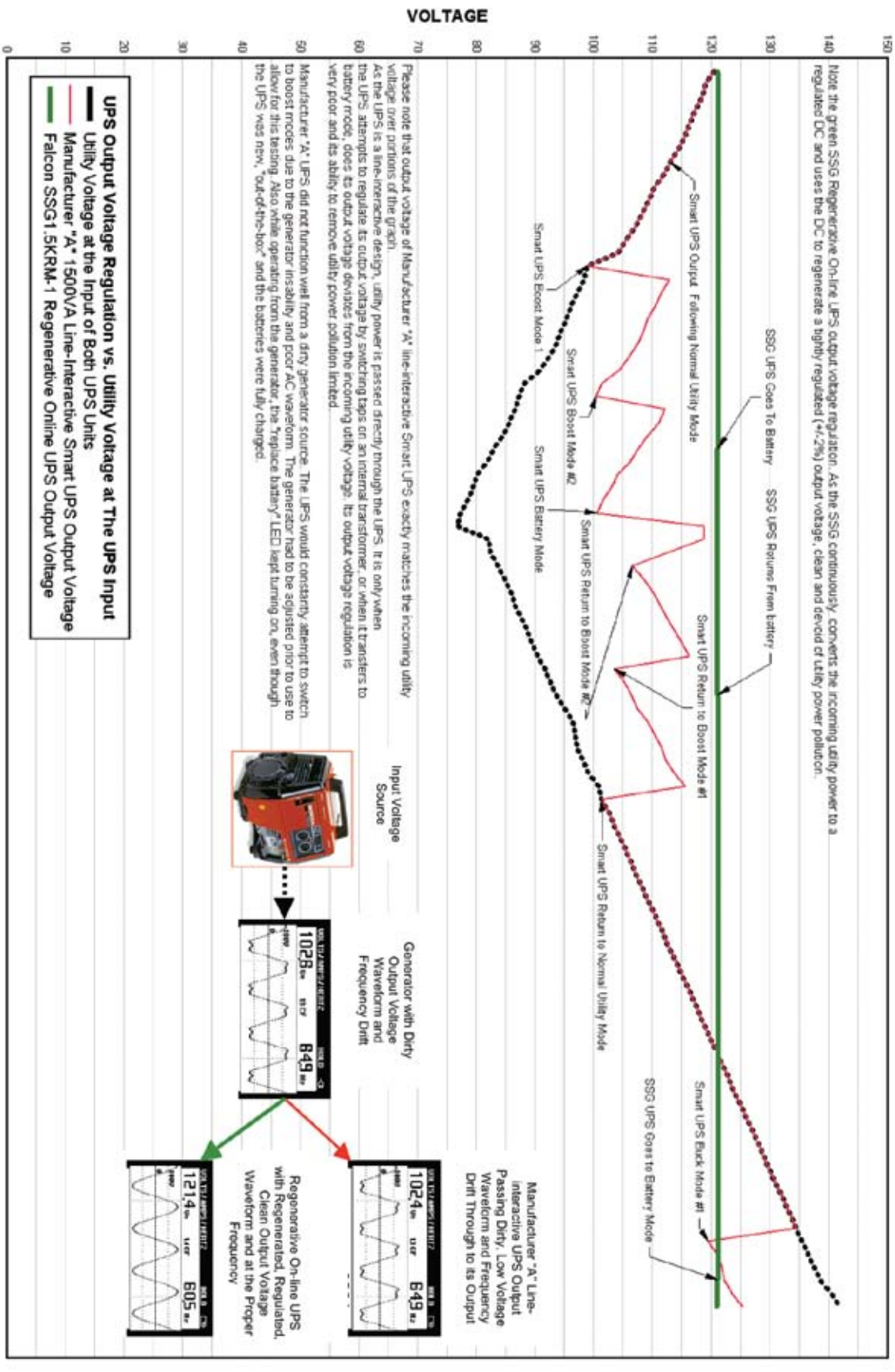

VOLTAGE
Note the green SSG Regenerative On-line UPS output voltage regulation. As the SSG continuously converts the incoming utility power to a regulated DC and uses the DC to regenerate a tightly regulated (+/-2%) output voltage, clean and devoid of utility power pollution.
SSG UPS Goes To Battery
SSG UPS Returns From Battery
Smart UPS Output Following Normal Utility Mode
Smart UPS Return to Boost Mode #1
Smart UPS Buck Mode #1
SSG UPS Goes to Battery Mode
Smart UPS Boost Mode 1
Smart UPS Boost Mode #2
Smart UPS Battery Mode
Smart UPS Return to Boost Mode #2
Smart UPS Return to Normal Utility Mode
Please note that output voltage of Manufacturer "A" line-interactive Smart UPS exactly matches the incoming utility voltage over portions of the graph.
As the UPS is a line-interactive design, utility power is passed directly through the UPS. It is only when the UPS attempts to regulate its output voltage by switching taps on an internal transformer, or when it transfers to battery mode, does its output voltage deviate from the incoming utility voltage. Its output voltage regulation is very poor and its ability to remove utility power pollution limited.
Manufacturer "A" UPS did not function well from a dirty generator source. The UPS would constantly attempt to switch to boost modes due to the generator instability and poor AC waveform. The generator had to be adjusted prior to use to allow for this testing. Also while operating from the generator, the "replace battery" LED kept turning on, even though the UPS was new, "out-of-the-box" and the batteries were fully charged.
Input Voltage Source
Generator with Dirty Output Voltage Waveform and Frequency Drift
Manufacturer "A" Line-interactive UPS Output Passing Dirty, Low Voltage Waveform and Frequency Drift Through to its Output
Regenerative On-line UPS with Regenerated, Regulated, Clean Output Voltage Waveform and at the Proper Frequency
UPS Output Voltage Regulation vs. Utility Voltage at The UPS Input
Utility Voltage at the Input of Both UPS Units
Manufacturer "A" 1500VA Line-Interactive Smart UPS Output Voltage
Falcon SSG1.5KRM-1 Regenerative Online UPS Output Voltage

Figure 1

"Motors, refrigerators, copy machines, etc., operating from the building's main electrical panel outside the lab can cause the utility voltage regulation to vary widely."

Next, note the picture to the right showing a generator. The three output waveforms shown are actual waveforms taken while the line-interactive and online UPS units were being powered from a very dirty and polluted generator source. Note the line-interactive UPS fed the dirty, polluted power through to the sensitive connected equipment. It did not clean the dirty power. Also note that its output voltage dropped to 102.4VAC, with an output frequency of 64.9Hz. Both the output voltage and frequency are great areas of concern. In addition to affecting the lab equipment's performance, when subjected to sustained low utility voltage conditions, the lab equipment's internal power supply has to work harder to power the equipment, putting added stress on the supply, elevating operating temperatures and in some cases overheating. Note the output of the online UPS. It completely removed the power pollution and regenerated new pristine AC power. The output voltage was a tightly regulated 121.4VAC at a frequency of 60.5Hz.

This amazing cleanup of dirty power can be accomplished only through true online UPS technology. You truly get what you pay for with an online UPS. The connected lab equipment continuously receives the optimum power and voltage levels and the added benefit of added overall reliability. An improved test accuracy and completion rate will also be realized.

Michael A. Stout, *VP of Engineering, Falcon Electric, Inc., can be reached at Mstout@falconups.com or 800-842-6940 x 107.*

CERTIFIED PRE-OWNED

A PERFORMANCE VERIFICATION SYSTEM ENSURES ACCURATE AND PRECISE DATA FROM REFURBISHED AUTOMATED LIQUID HANDLERS.

Low-volume liquid handling is a core component of almost every modern laboratory. With continued advances in the automation of liquid handling, laboratories are realizing new gains in throughput and overall efficiency. With these industry advances comes a growing focus on quality and the need to ensure that all equipment is performing to specifications all of the time.

However, as budgets for laboratory equipment get tighter, many laboratory managers are purchasing used equipment in an effort to stretch their limited funds. Yet when purchasing used or refurbished equipment from auction sites, equipment brokers and third-party vendors, laboratories aren't always provided with product certification to guarantee that their equipment will operate according to the manufacturer's specifications upon arrival.

Biodirect Inc. is a company aiming to raise the bar of assurance for lab managers purchasing pre-owned equipment. Located in Taunton, Mass., the company sells an array of pre-owned laboratory equipment, including dispensers, thermal cyclers, incubators, centrifuges and microplate detection systems. All equipment, including automated liquid handlers, is guaranteed to meet the original manufacturer's specifications.

> **"As budgets for laboratory equipment get tighter, many laboratory managers are purchasing used equipment in an effort to stretch their limited funds."**

Because of customer need for automated liquid handlers with proven accuracy and precision, Biodirect has recently upgraded its liquid handling quality control program. Now, as part of the quality system, the performance of each automated liquid handler is validated for precision and accuracy using the Multichannel Verification System (MVS®) from ARTEL (Westbrook, Maine), and subsequently sold as "ARTEL Certified."

Importance of quality

For Biodirect's customers, precise and accurate automated liquid handling is essential. Many laboratories today work with extremely rare and expensive reagents that can cost thousands of dollars per liter. Any dispensing inaccuracy can lead to unnecessary waste, increased costs and loss of precious reagent. Because automated liquid handlers process very minute volumes, performance verification is critical. Inaccuracies as slight as a fraction of one microliter have the potential to drastically alter results.

Biodirect's equipment validation processes contribute to the avoidance of errors by refurbishing, reconditioning and customizing automated liquid handlers using the original manufacturer's specifications as a baseline for quality. This procedure ensures that customers receive the same or better results from their refurbished equipment as they would from a brand-new automated liquid handler purchased directly from a manufacturer.

"We put automated liquid handlers through rigorous testing to ensure that every aspect of the machine is working to manufacturer's specifications, alleviating our customers of this burden," said Rich Tula, CEO, Biodirect Inc.

Certifiably accurate

When an automated liquid handler is obtained by Biodirect, it undergoes an extensive maintenance inspection for the identification of deficiencies and any worn or missing parts. At the end of the inspection, the ARTEL MVS is used to thoroughly assess the instrument's accuracy and precision on a channel-by-channel basis in one rapid experiment.

The ARTEL MVS is based on proprietary ratiometric photometry, which is a dual-dye, dual-wavelength photometric method for accurate and precise measurement of small target volumes. Described in the ISO 8655 part 7 guideline of the International Organization for Standardization, this technology uses two dyes with distinct absorbance maxima at 520 nm (red dye) and 730 nm (blue dye). The MVS is used to quantify volume dispensed from each channel or tip of an automated liquid handler into a microplate by measuring the absorbance of these dyes, calculating volumes and flagging any deliveries outside of preset tolerances.

When purchasing a liquid handler from Biodirect, customers receive a checklist detailing all service checks and refurbishing tests that have been conducted, thereby verifying the performance of the liquid handler in each test. The

company also provides automatically generated, detailed reports from the MVS showing the volume transfer performance of the instrument during the calibration event. These reports provide summary statistics by channel, by row and by column. The MVS also provides results that are traceable to international standards, allowing for comparability of all liquid handling devices regardless of model, location or number of dispensing channels.

For example, a laboratory recently purchased a refurbished automated liquid handler from Biodirect to complement its existing automated liquid handler. Biodirect completed a comprehensive preventive maintenance inspection and installed a low-volume option on the refurbished automated liquid handler so that it could perform as well as the existing automated liquid handler. However, laboratory staff experienced different results with the two systems and questioned the validity of the refurbished system from Biodirect. The NIST-traceable results and documentation provided by the ARTEL MVS provided indisputable proof that the refurbished system performed well within laboratory specifications with an accuracy tolerance of 5 percent for a target volume of 50 microliters. As a result, the laboratory requested that Biodirect use the MVS to test the accuracy and precision of the original automated liquid hander.

"We strive to go above and beyond customer expectations. We do this by not only repairing equipment to manufacturer specifications, but by also verifying dispensing accuracy and precision with the MVS," said Tula.

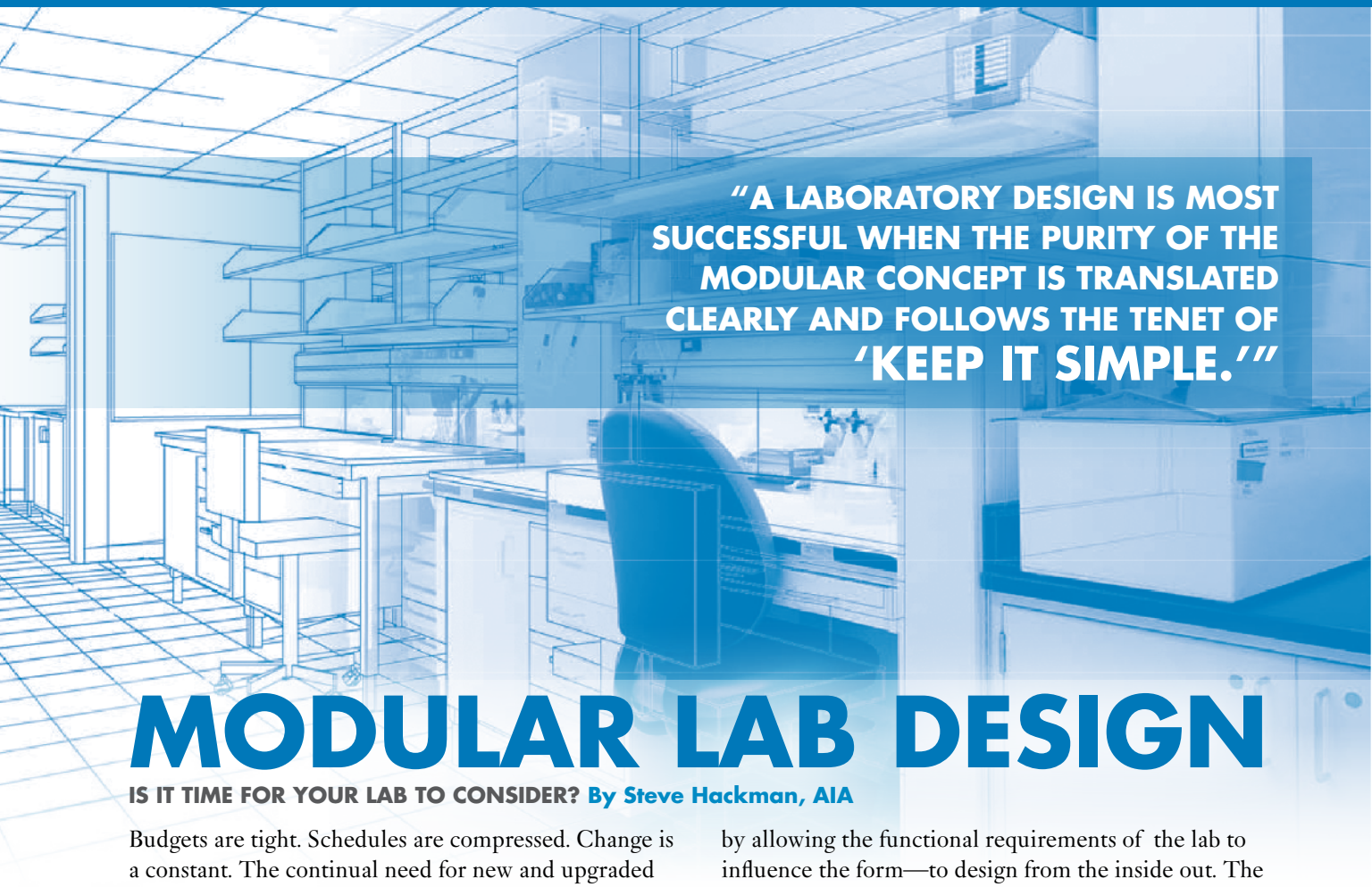
Improved methodology

Before incorporating the MVS into its quality assurance processes, Biodirect relied on gravimetric technology to measure the performance of its refurbished liquid handling devices, and this method was time-consuming and tedious. Verification of one automated liquid handler using gravimetry required approximately four hours of labor, as compared to the 30 minutes required with the MVS. Additionally, the results provided by the gravimetric method were affected by environmental conditions (especially humidity). Another drawback was that gravimetry only provided an average assessment of volume dispensed from the liquid handler, while the MVS provides information on the exact volume dispensed from each individual channel.

In addition to gravimetry, Biodirect previously used a microplate reader and commercial dyes to test the precision performance of its refurbished automated liquid handlers. These dyes required a dilution step, causing the method to be lengthy and untraceable.

"My staff is always excited to get tools that help them do their jobs better and faster. With the MVS, they're now able to get their jobs done quicker with a higher quality end product," said Tula.

For more information about Biodirect and its certified pre-owned laboratory product offerings, visit www.biodirectUSA.com. For more information about the ARTEL MVS and other liquid handling quality assurance products and services, visit www.artel-usa.com.



"A LABORATORY DESIGN IS MOST SUCCESSFUL WHEN THE PURITY OF THE MODULAR CONCEPT IS TRANSLATED CLEARLY AND FOLLOWS THE TENET OF 'KEEP IT SIMPLE.'"

MODULAR LAB DESIGN

IS IT TIME FOR YOUR LAB TO CONSIDER? By Steve Hackman, AIA

Budgets are tight. Schedules are compressed. Change is a constant. The continual need for new and upgraded laboratory space begs a question: Can one design approach fit all?

Fundamental to the process of laboratory facility planning is an understanding of some basic design principles that ensure future adaptability. Laboratories of all types—from corporate to clinical, research to instructional, and forensic to biocontainment—must have the flexibility to adapt to future, as-yet-unknown changes in technology and scientific processes.

While each lab type remains unique, the purposeful application of modular design, zoning of tasks and implementation of flexible planning concepts will produce the most efficient and cost-effective solutions. Modular design is by no means a cookie-cutter approach but rather a simplified approach to achieving a wide range of goals in laboratory design.

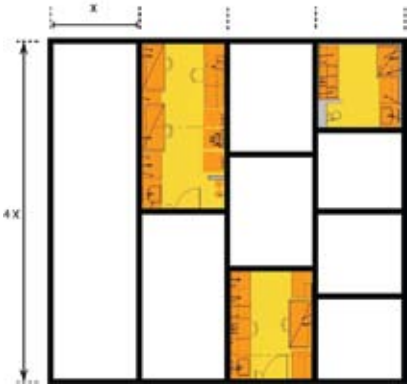
By following 10 core planning and design principles, it is possible to achieve a highly functional and highly adaptable facility.

Modular design

The first and most fundamental concept of laboratory planning is the application of modular design. This approach maintains the highest level of flexibility by allowing the functional requirements of the lab to influence the form—to design from the inside out. The modular approach provides interchangeability of spaces as well as opportunities for increased efficiency.

1. Integrated module

The module is the basic building block for organizing the laboratory. It is the unit of space required for lab occupants and equipment to function safely and effectively and is created by considering the depth of useful zones on both sides of an aisle. Ideally, the length of the module is calculated as a multiple of the width, for



▲ *The module can be combined to form large, open labs or divided in half, thirds, or quarter-size increments for various lab support requirements.*

added flexibility in two directions, thus making it easier to adapt to a new scientific process with optional space orientation. A module that is integrated allows for multiple room sizes that share a common denominator or fit within a holistic, implicit approach. When the integrated module is implemented, even a multistory facility can be effectively designed to accommodate such varied functions as parking, imaging, vivarium, patients, labs and specialty processes.

2. Right-sizing

Right-sizing of infrastructure such as mechanical and structural systems is key to long-term adaptability. Systems design should be fully integrated into the planning process at the earliest stages and utilize modular concepts to allow future changes to occur with minimal disruption. Air systems, power, data and piped services such as lab gases and water must be planned to anticipate future requirements and minimize a "fatal flaw" that could impede flexibility. The structural grid should pose minimal obstruction to work tasks. Floor-to-floor heights should permit space for routing future utilities for a range of scientific tasks, from wet chemistry and bioprocess experiments to physical/electrical and computational science.

3. Limited inventory

Using fewer basic design elements will result in a greater number of workable solutions. This is the principle of less is more, in which minimizing the inventory of customized spaces or modular differences can actually help achieve more flexibility of options. Customization is still possible through the ability to create endless configurations from a limited library of parts and pieces—not unlike the limitless variations of Tinkertoys™ or Legos™. Casework elements should be standardized based on current or anticipated scientific needs, to maximize options for reconfiguration. The design phase of a new or renovated laboratory project is the best opportunity to develop or improve upon current building standards; for example, replacing odd-sized spaces with like-sized universal rooms that can serve varied functions.

Zoning of tasks

The second concept of laboratory planning, zoning of tasks, refers to the way a building is organized—the interrelationship of spaces and the distribution of those spaces. Zoning embodies the thoughtful arrangement of laboratory activities to achieve the highest degree of flexibility. The application of this concept benefits the occupants by enhancing lab safety and fostering interaction.

▲ *For the St. Jude Children's Research Building in Memphis, SmithGroup introduced multiple planning options with the implementation of a two-directional integrated module and a lean approach to systems distribution and room sizing.*

4. Lab/office zoning

The lab/office relationship is critical to maintaining connectivity between the research bench and desk functions. There are several advantages to zoning offices and labs separately. First, costs and operational energy savings are realized; for example, unlike in the laboratory, office air can be recirculated, making office systems easier to maintain for human comfort. Through proper zoning, lab flexibility is increased by limiting the potential obstacle of offices "inside" the laboratory. The desired connectivity can be maintained between the lab and office zones by designing for proper proximities in conjunction with a networked lab management system.

"Using fewer basic design elements will result in a greater number of workable solutions."

5. Space distribution

Providing appropriate space distribution of lab and non-lab functions is the outcome of a collaborative programming and planning process. An understanding of what is unique about each lab, combined with satisfying critical relationships and adjacencies, will produce

a synergistic plan. Benchmarking of similar facilities is important to gain insight from peer institutions. Building elements such as stairs and elevators, mechanical risers, and utility rooms should be positioned outside of the zones that require the most flexibility. The grouping of multiple labs to create neighborhoods with amenities can enhance team dynamics and foster interaction. The careful placement of like spaces such as offices, lab support and open labs can turn an average facility into an efficient working whole.

6. Separated support

Sequestering support zones can free general wet labs to function as generic labs, for use by multiple occupants and multiple purposes. The quantity of lab support varies based on the science; for example, there is a need for a higher ratio of lab support in a biomedical research facility. It is more common to find biosafety labs, clean rooms, imaging and specialized functions in today's laboratories. These unique space types often require a higher level of infrastructure and greater construction costs. When collocated and distinctly zoned, they are more readily shared, improving operational costs and minimizing utility distribution.

With this accomplished, the generic labs can support a wider array of functions and remain adaptable. Zoning within the generic lab includes the separation of wet-bench functions—such as sinks and services, fume hoods, and other exhaust devices—from dry-bench areas to improve performance and flexibility.

▲ *At the Arizona Biomedical Collaborative in Phoenix, a central lab corridor provides ready access and increased interaction among the open labs, lab support and the office zone, increasing efficiency and flexibility.*

Flexible planning

Flexible planning is the final concept of laboratory design, integrating the principles of modular design and zoning of tasks within the entire facility. The benefit of clear organization, open labs and selection of highly functional casework provides long-term sustainability for the entire facility.

7. Clear organization

A laboratory's design is most successful when the purity of the modular concept is translated clearly and follows the tenet of "keep it simple." Lab safety is increased with organized pathways for egress and materials handling, alcoves for fume hoods, and functional zones for efficient wet-bench work. A single corridor scheme with offices opposite labs reinforces collaboration. Ghost corridors provide a simple and efficient interconnection between labs and lab support while also serving the purpose of internal lab circulation. By organizing the lab with clear and distinctive concepts that are meaningful to the particular facility, the life expectancy of the lab and its ability to adapt to change are greatly extended.

"Truly adaptable laboratory space is inherently sustainable."

8. Open environment

There are many advantages to an open laboratory environment, where contiguous modules form a generic lab zone. Open labs are less costly to construct due to fewer walls and material interfaces. They are inherently safer, providing occupants with a higher level of visual and audible knowledge of a potential threat or incident. Open labs are more easily assigned and reconfigured for people and processes, leading to shared opportunities for a variety of functions. More important is the potential for collaboration and interdisciplinary activities that occurs in the open lab environment.

▲ *Transparency by the use of architectural techniques and ample glass keeps lab interiors bright and open. At the Lawrence Berkeley National Laboratory's Molecular Foundry, researchers gain a sense of what's going on beyond their immediate tasks.*
Photo Credit: David Wakely, courtesy SmithGroup

9. Functional furniture

Today, casework solutions have emerged that are quite flexible—just add wheels. Simple, table-based systems achieve improved performance over fixed casework, with the added benefit of mobility. By maintaining a limited kit-of-parts inventory for the lab casework and furniture, the lab can be more easily reconfigured, resulting in savings of time and money when physical changes are necessary. This is accomplished with interchangeable parts, adjustable shelving and countertops, mounting devices that make more efficient use of vertical space above the bench, mobile base cabinets, and flexible connections to ceiling-mounted service outlets. Good laboratory design must also include attention to ergonomic issues such as proper casework selection, materials, task lighting and seating.

▲ *Simple, open labs allow for maximum transparency between and through modules. A kit-of-parts approach to casework selection permits endless configurations utilizing mobile pedestals and ceiling-mounted services.*

10. Sustainable

Truly adaptable laboratory space is inherently sustainable. Sustainable design strategies—including the use of daylighting, energy-efficient building systems and sustainable materials—will assist in reducing the environmental impact while producing a building that functions longer than its normal life expectancy.

But consideration for a building's long-term use and carbon footprint suggests that a simplified, low-tech but robust approach, like a historic factory or warehouse loft building, is an appropriate design model that adapts easily to change. This concept of sustainability through simplicity and flexibility challenges the understandable impulse to overdesign in order to meet every potential contingency. A low-tech approach can successfully allocate space for future needs without overinvesting in current and soon-obsolete technologies. For example, it may be sufficient to provide limited bench utility services in strategic locations instead of in an entire lab.

▲ *The loft-like versatility of the lab designed for the Arizona Biomedical Collaborative in Phoenix allows for the adaption of wet and dry benches while maximizing the use of daylight.*

Photo Credit: Bill Timmerman, courtesy SmithGroup

Conclusion

Laboratories are expensive buildings and must be designed to evolve with the continual shifts in scientific discovery and advances in technology. The concepts of design, when grounded in the 10 core principles above, will result in a facility that is highly functional yet has the flexibility to adapt to future change.

Good design looks easy. However, given the complexity of a laboratory, simple and fundamental principles are in fact often difficult to apply and achieve. The rigorous application of modular design, zoning of tasks and implementation of flexible planning concepts will improve the process of design and ultimately the use of the facility to achieve the greatest adaptability possible.

Steve Hackman, AIA, *is a principal and senior laboratory planner at SmithGroup, one of the nation's largest architecture, engineering, interiors and planning firms, with 10 offices across the United States. With 23 years of experience, Hackman is a leader within the firm's national Science & Technology practice and supports SmithGroup clients in the strategic design of laboratories. He can be reached via email at steve.hackman@smithgroup.com.*

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THE ANALYTICAL LAB AS STRATEGIC ASSET

MANAGERS NEED TO UNDERSTAND EXISTING OPERATIONAL CAPABILITIES AND REQUIREMENTS, JUSTIFY AND DEMONSTRATE RETURN ON INVESTMENT, AND PROVIDE DETAILED IMPLEMENTATION PLANS by Cozette Cuppett

These days, laboratory operations are more visible than ever to management, whether they're the organization's shining star for profits or a capital expense black hole. If you are managing a lab and a budget, chances are you've gotten to know your organization's purchasing and finance team—and they've gotten to know you—much better within the last year.

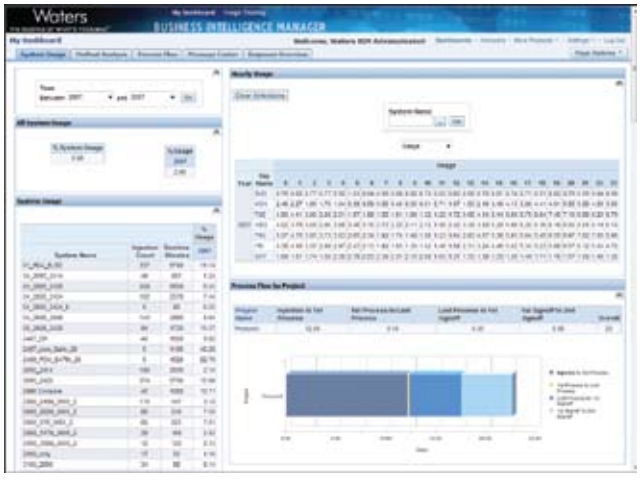
This increased visibility can be unnerving, especially for lab managers who have previously been more focused on the science than the business of the laboratory. Prepare for increased exposure and expectations of today's management teams. Draw upon your experience and use the information at hand to confidently address budgetary, resource allocation, and other project management inquiries. Develop a strategy and a realistic implementation plan to enable your operations to meet or exceed your organization's demands. Most important, deliver meaningful results. Position yourself so that your interactions across functions in the organization build your credentials rather than destroy your self-esteem.

Easier said than done. Begin by taking stock of your laboratory. Review your management's expectations, factor in external influences that are out of your control, and determine how you're going to deliver on your goals. Put yourself in a state of readiness so that you can recognize the short-term opportunities that will allow you to justify and drive a longer-term transformation of your laboratory into a strategic business asset—whether this means putting business systems in place to understand where to focus your efforts and assets or introducing forward-looking technology platforms to meet the needs of an ever-evolving business climate.

Get a clear picture of your current operations: Assets and liabilities

Ongoing review of asset utilization and internal analytical process workflow is increasingly a way of life in the analytical laboratory. It's necessary to plan strategic projects, justify capital requests, decommission assets, shift resources as necessary, and, in general, understand the facility's operations.

Tools such as the Waters Empower™ 2 Business Intelligence Manager™ (BIM) provide a web-based dashboard software solution for rapid analysis of chromatography instrumentation performance data for faster, more qualified decisions on laboratory and business operations. Designed with proven business intelligence concepts that have been successful across many industries, the BIM allows lab managers and system administrators using Empower 2 Enterprise chromatography software to critically understand and exploit the strengths of their laboratories and identify areas that need added support.



▲ *Large volumes of complex information, such as chromatographic system usage, method analysis, and process flow, can be presented and visualized using dashboard tools like Waters Empower™ 2 Business Intelligence Manager.*

As time passes, many laboratory technologies no longer provide a significant benefit to the laboratory—whether they are warehoused, sit unused on the lab bench, or consume more supplies and service time than is paid back in analytical impact. To determine the value of your facility's technologies, take advantage of instrument vendors' service

and support organizations and asset management solutions. These services assist in evaluating where your technology is in its life cycle, so that you can intelligently decide when to decommission instruments or shift them to other departments where they'll best achieve capacity utilization. If the technology no longer fits your organization's needs, many times trade-in opportunities exist whereby you can get credit toward the purchase of a newer, more efficient or higher-capability model.

"Position yourself so that your interactions across functions in the organization build your credentials rather than destroy your self-esteem."

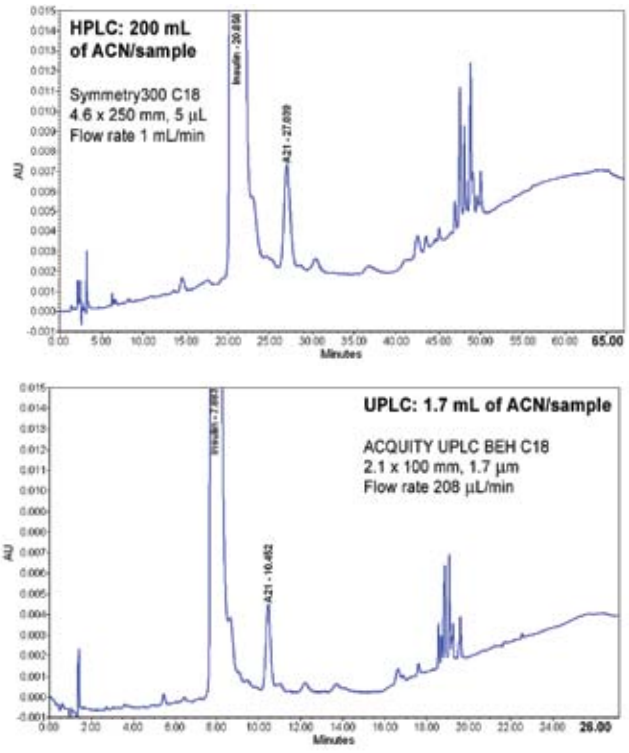
Embrace opportunities for change

The supply-side shortage of acetonitrile (ACN) has created an impetus for change in many laboratories. Even in facilities that are not directly impacted by this solvent shortage, the potential risk it poses to product supply and revenue generation is enough to catch the attention of senior management. With attention comes opportunity.

Savvy laboratory managers are leveraging the solvent shortage[1] in conjunction with internal sustainability initiatives as a way to promote investment in technologies that not only minimize solvent consumption and disposal and their associated costs, but also improve laboratory productivity. Two technologies that have been cited by industry as tools that support greener laboratory operations are UltraPerformance LC® (UPLC®) and supercritical fluid chromatography (SFC).[2]

"Ongoing review of asset utilization and internal analytical process workflow is increasingly a way of life in the analytical laboratory."

By employing sub–2 µm particles, UPLC delivers more efficient chromatographic separations, enabling the instrument to use less solvent in shorter run times while maintaining or improving the performance achieved with traditional HPLC[3] For example, the USP human insulin related-compounds assay consumes 20 mL of ACN per sample with a 68-minute run time by HPLC, whereas a UPLC separation of similar performance consumes 1.7 mL per sample with a 27-minute run time.[4] This translates into a 92 percent decrease in acetonitrile consumption and a greater than 250 percent improvement in throughput. In a business environment where acetonitrile is being rationed and laboratory productivity is intensely monitored, this type of process improvement has been the basis of internal recognition awards for several of Waters' customers by their own senior management teams.



▲ *Technologies such as UPLC can greatly decrease analytical run time and solvent consumption when compared to traditional HPLC—shown here, a 92 percent decrease in acetonitrile consumption and a greater than 250 percent improvement in throughput.*

Alternatively, using carbon dioxide as its primary solvent, SFC enables scientists to generate excellent chromatographic results, particularly for chiral and preparative separations. In a solvent-intensive application like preparative chromatography, SFC simultaneously reduces solvent costs and shortens dry-down time for collected sample fractions.

Adopting alternative technologies is one approach a lab manager can take to address problematic external influences such as the solvent shortage. Adapting processes is another. With high-purity acetonitrile being prioritized for quality control, scientists in development laboratories find themselves in a position where methanol and other solvents are increasingly part of their method scouting and optimization protocols.

Where methods are being created or changed to use less acetonitrile, an opportunity is created for laboratory managers to modify existing method development and validation practices; for example, to make quality-by-design (QbD) part of the process. By introducing a design of experiment (DoE) approach into method development studies[5,6,7], scientists can define a knowledge space where the impact of the chosen chromatographic parameters on separation performance is fully characterized. Once such a method is validated, operating within that design space provides chemists with a statistically defendable range of chromatographic parameters that can be used without having to invoke regulatory change control processes.

This regulatory flexibility can pay significant dividends downstream as methods are transferred to different laboratories and where unforeseen changes in materials and processes occur. In the past, DoE approaches were limited to individuals who had access to statisticians for appropriate study design and whose laboratories had the analytical capacity to run the relatively large sample sets required. Commercially available DoE software, such as FusionAE™ from S-Matrix® and the highly efficient, fast chromatographic separations provided by UPLC, now make the DoE approach tenable for more laboratories.

Build a strong platform for the future

Technology standardization has much to offer laboratory management: efficiencies in operator training, standard operating procedure (SOP) maintenance, service and support, purchasing decisions, and technology transfer. On the flip side, many scientists shudder at the thought of being confined to a predefined, standardized solution to their application challenge. Platform technologies introduce flexibility to standardization. Built from the core facets of the standardized technology, these platforms allow scientists to customize components to achieve specialized tasks.

"The supply-side shortage of acetonitrile has created an impetus for change in many laboratories."

Take, for example, UPLC. This liquid chromatography platform technology first manifested itself in the ACQUITY UPLC® system and its bridged ethylene hybrid (BEH) columns, launched in 2004 by Waters with the core functionality needed to support mainstream LC separations. Since its launch, the UPLC platform has expanded to include the nanoACQUITY UPLC® system, which adapts the hardware and columns to support sample-limited and two-dimensional applications such as those encountered in life science laboratories. For scientists exploring the use of chip-based technologies with mass spectrometry, the TRIZAIC™ UPLC® system with nanoTile™ technology brings simplified user interaction and increased consistency to nanoscale separations.

Further evolution of the UPLC platform is evident in its open architecture UPLC configuration and user interface

that supports walk-up sample analysis and quantification. The platform even extends to the manufacturing floor, in the PATROL™ UPLC® process analyzer for online and atline analysis of production processes. UPLC also transcends typical vendor boundaries, with the ACQUITY UPLC and nanoACQUITY UPLC systems being controlled by many key suppliers' chromatography and mass spectrometry (MS) software packages. This provides access to UPLC for scientists who have already standardized on a specific data management platform. In addition, expansion of UPLC column offerings and specialized application kits broadens the platform's use to include separation of amino acids, peptides, oligonucleotides, aflatoxins, and perfluorinated compounds, to name a few.

The platform concept is not limited to chromatography. Due to the individual design of their ionization sources, switching among mass spectrometers can require different optimization settings, in particular the ionization and fragmentation parameters. With the Xevo™ MS platform from Waters, scientists can efficiently move between a tandem quadrupole and time-of-flight MS with the Xevo TQ and Xevo QTof, respectively, and expect the same ionization settings to transfer between the instruments. Moreover, tools such as IntelliStart™ automate system setup and optimization steps, removing the subjective influence of individual chemists and increasing the accessibility of these instruments to more analysts.

As organizations move toward lean operation, where any unnecessary step is stripped from a process, platform technologies are a natural fit. They provide a base level of consistency that facilitates servicing, training, and procurement while offering the versatility necessary to accomplish business-critical tasks.

Source smart and make your investments deliver

Today's business environment is making everyone work and invest smarter. In the laboratory, this may mean stretching available capital by purchasing used instrumentation. Some original equipment manufacturers offer certified pre-owned instruments for sale at a significant discount. These systems are refurbished by certified technicians using ISO-documented processes. Whether you purchase new or used technology, once your capital is spent, the expectation is that you will demonstrate results. Whom you source the necessary equipment from is as strategic a decision as what equipment you buy.

The value of every technology investment is dependent on the implementation. How often is an instrument purchased and then not used to its full potential? Or worse, it sits idle on the lab bench—misused, misunderstood, or abandoned completely. Often this is the result of insufficient training, education, and application support services either at the time of purchase or throughout the technology's lifetime in the laboratory. By not availing your laboratory of these services from the technology vendor, instruments can languish in an obscure corner of the laboratory, never fully achieving the promise of the technology or delivering the expected return on investment.

This is a period of simultaneous challenge and opportunity for lab managers. Laboratory transformation and investment are taking place, but not without a comprehensive understanding of existing operational capabilities and requirements, justification and demonstration of return on investment, and detailed implementation plans. Leverage today's short-term business challenges as an opportunity to transform your laboratory into one of your organization's greatest assets.

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ENGAGING YOUR SERVICE PARTNER

LET SUPPLIERS CONTRIBUTE TO YOUR SUCCESS THROUGH MUTUAL PROCESS IMPROVEMENT AND ORGANIZATIONAL LEARNING by Joachim Joerger

Automation is becoming more common in research labs due to its benefits: less manual intervention results in standardization and reliability. Although these benefits have their merits, the root cause of today's automation hype is increased competition in all markets. Very tight project budgets, low reimbursement rates, and increased commoditization of formerly sophisticated molecular biological process (i.e., many more companies offering molecular testing services) drive project groups and companies to strengthen their competitive position. Automation is one of the tools that enable companies to outperform their competition.

One of the initial activities required to manage a lab is identifying the critical path of the lab's applications. In a laboratory, the critical path is the sequence of sample preparation and handling activities that ultimately leads to the desired result: a set of experimental data or a diagnostic output. The ability to actively manage this critical path is the foundation for gaining competitive advantage. When lab managers want to take their automation to the next level to optimize the application, they want to know that they have a partner to call on to help ensure that the critical path runs smoothly.

Lab managers must have two key objectives in order to successfully manage the critical path:

1. Maintain & constantly ensure the quality of results.

Regulatory bodies request that laboratories ensure that their applications are robust, reliable, and reproducible for the sake of the quality of the results. Managers strive to meet these obligations as part of actively supervising the critical path.

2. Maximize profitability/project efficiency.

This objective includes productivity management of the validated application. Productivity management covers the active assessment and improvement of processes as well as the identification of alternative methodologies, technological advancements, and supply chain gaps.

Whatever the manager's particular focus is in the arena of molecular testing, he or she will most likely have these two objectives in mind. These are also the areas where your service partner should be able to provide assistance. Team up with suppliers that play a strategic role within your critical path, and allow them to contribute to your success through mutual process improvement and organizational learning. In essence, let them provide you with the customer service you deserve.

Trends in service

Great customer service is about developing a true business partnership between a company and a supplier with strategic value. The arrangement is usually long term in nature and addresses not only the buying of parts, products, or services, but also the advance of process design, regulatory support, and mutual learning.

Developing a partnership depends on trust and mutual understanding. Partners share their ideas and requirements on an operational level. Discussions are conducted on the basis of techniques and methodologies, with both partners freely deciding how much information they disclose.

It is suggested that the partnership be focused on three key topics: maximizing productivity of routine operations, supporting quality management topics, and engaging in a learning community.

Maximum productivity

An imperfect process or work routine is a time killer and cost generator for any organization. This is true for both suppliers and users. A continuous exchange of process data, material demand forecasts, and other information benefits both the lab and the service partner. A basis of trust and a clear commitment to development helps both partners identify deficits. Gaining knowledge of obstacles as they occur enables the supplier to more quickly provide recommendations for process improvements. Annual reviews that include a fair exchange of knowledge regarding business requirements help build and strengthen the framework for partnership.

Immediate support

Potential for error exists in any type of operation. Lab managers must be prepared to manage those interruptions to the routine, while suppliers must be ready to provide convenient, timely assistance. In order to manage the critical path of applications, lab managers demand adequate problem resolution in order to manage downtime. Quick response on the part of the supplier allows the lab to keep operating, ensuring maximum productivity and profitability.

True partnership takes immediate support to the next level. Managers and suppliers must be aware of the actual costs and impacts of potential downtime. Since downtime is the most crucial aspect of the critical path, resolution strategies should be jointly agreed upon by both parties. In this context, a lab manager should consider how to position his or her own resources and structures to help mitigate errors. Training superior users and engaging the company's technical units are proven ways to find quick solutions.

It is important that lab managers check with their service partners to make sure service is provided in alignment with their business hours for phone and on-site support. Optimal support comes from trained specialists rather than a switchboard or "quick fix" functions. This allows questions to be addressed during the first call. Well-structured self-service web resources further support immediate resolution.

With so many labs being part of worldwide networks, it is important to know that service partners can be called upon to provide support globally in order to maintain the flow of the critical path. Great service also should come with a team of field specialists who understand a lab's systems and the applications it performs. These specialists need to know how to maintain current applications and how to take them to the next level to enhance productivity and profitability.

Supply chain management

Lab productivity is driven, in large part, by the availability of materials. It is imperative to ensure a continuous supply of materials. Lab managers count on their suppliers to deliver ordered materials of the highest quality, in the right amount, at the right time, and to the right place. In particular, if a lab depends on the availability of one critical material, it is advisable to actively influence that material's availability. Sharing forecasts with suppliers allows a company to generate more precise production forecasts, resulting in a high probability that the requested product will be available when needed.

In a time of limited budgets, procurement is becoming a strategic function for companies focused on managing available capital and reducing overall spending. E-commerce solutions have become the first choice for reducing costs and workload. Modern integrated e-commerce solutions are helping to cut transactional costs by up to 80 percent through intervention-free ordering and paperless invoicing. Service partners can provide central procurement portals. They also have competent personnel who can discuss integrating into an existing procurement system or help an organization engage in e-procurement activities.

The learning community

In an age when information doubles every five years, it is extremely difficult to stay current on all the latest trends. Service providers have a natural tendency to survey the market for the latest trends in order to prepare for the next

product and remain innovative. These partners are willing to share this information with their customers in exchange for feedback about the relevance of the technology or methodology in the context of a customer's business or application. The ideal supplier is engaged in constant exchange, offering knowledge through well-structured and meaningful web pages, seminars, customer focus groups, and customer education classes. Through this process, end users can take in information quickly, gain experience, and generate knowledge that enables them to innovate and remain ahead of the competition. For example, lab managers should look for partners whose application services and training programs provide the freedom and flexibility to adapt critical path applications to specific or changing research needs. Continuous development of the lab team enables process knowledge sharing, with the added benefit of providing proof documents for labs with compliance requirements.

Quality management support

At the end of the day, managers want to know that they are working with a partner that understands the lab's business needs/challenges/environment right from the beginning of the relationship. Service partners should be able to assist with equipment selection, operating principles, and performance characteristics. They also should be able to support their partners with validation and qualification procedures. The records from this process will define success by documenting operating parameters compared to supplier specifications, ensuring accurate performance.

In particular, labs with limited experience in quality management and regulatory compliance can greatly benefit from partnerships with their suppliers. Good suppliers work along the guidelines of standards organizations such as ISO. Their expertise can be used to assist in compliance with a variety of regulatory systems in the diagnostic market and the forensics market. Suppliers that understand these market segments as part of their core competency should undoubtedly be able to provide expert knowledge on elements of compliance systems; even this topic is part of their standard product portfolio.

And so the partnership begins…

In order to maximize the benefits of a partnership with a supplier, it is necessary to engage the functions behind the sales organization. The sales team is generally the main point of contact for customers. In many cases, however, salespeople are account managers who act on behalf of the organization. Account managers hold the contacts to other departments within the company, such as service, which can bring added value to their lab partners. A strong partnership between a supplier and a lab is necessary in order for the lab to remain competitive. It is important to build that strong foundation early in the relationship, as this creates a critical path free of obstacles. Maximizing productivity, creating a learning community, and demanding quality management support will keep a lab operational and innovative.

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REGULATORY COMPLIANCE

GETTING THERE AND STAYING THERE by Mark Stevens and Tony Gasson

Today's challenging business climate presents a number of issues that pharmaceutical companies must address if they are to remain competitive. The industry is not in the same condition it once was, as drug manufacturers are coming under increasing pressure to release new drugs in the quickest time and with the least expenditure possible. This includes identifying unsuitable compounds and products as early in the development process as possible. As a consequence, it is vital that companies ensure that they have the right staff in place with the necessary knowledge and resources to implement best practices in the research, development and manufacture of new drugs; at the same time, they must comply with the strict regulations put in place to protect public safety. However, as competition between companies to maximize profitability of new drugs increases, the ability to retain knowledge within a company becomes more of a challenge.

This article discusses the issue of achieving and maintaining Good Manufacturing Practices (GMPs) and regulatory compliance efficiently and cost-effectively. It also discusses the issues of knowledge transfer and the key challenges of retaining skilled staff.

"All QC testing associated with the development, clinical studies, regulatory approval and manufacture of the licensed product is, in effect, part of the 'product' and must be treated accordingly."

Achieving regulatory compliance in drug manufacturing

It is imperative that pharmaceutical companies comply with the strict rules imposed by regulatory bodies such as the U.S. Food and Drug Administration (FDA). In addition, companies must ensure that best practices, such as GMPs and Good Laboratory Practices (GLPs), are followed.

Because customers cannot deal directly with the manufacturer of a drug, regulatory authorities do this on their behalf. In addition to imposing strict quality control and testing processes, the FDA enforces controls to ensure precise batch traceability. To ensure that manufacturing procedures are compliant with regulations, they must be validated and follow written procedures each time. Batch records are key; these documents are the only records that can be relied upon when the procedures have been completed and should enable the retracing of the entire batch history. The full account of accumulated records detailing the full history of a product must be stored in the event of regulatory inspection. To ensure that this is possible, the records must be accurate at the time the procedures are carried out, which means that they must be comprehensive enough to truly represent the production and be well-organized for easy referral and cross-referencing.

The analytical laboratory should be considered a manufacturer of a GxP-compliant product, the assay result. This product needs to be produced reliably, consistently and cost-effectively and be reproducible from site to site. All QC testing associated with the development, clinical studies, regulatory approval and manufacture of the licensed product is, in effect, part of the "product" and must be treated accordingly. All persons associated with testing and storing of assay results must therefore consider this to be a GxP-compliant product for which they are responsible. It must be "fit for purpose" of the customer. This means it has to be based on sound reproducible science (i.e., validated). To achieve this requires that all procedures be well-organized in an appropriate routine that reaches the level of compliance. The manager and staff are responsible for keeping abreast of any scientific changes that can improve this "product" in accuracy and speed so that by "continuous improvement" they can maintain compliance.

It should be remembered that even unexpected results are useful if they are discussed with the Development or Production group in order to try to help everyone understand the probable causes of the result and the corrective action needed to produce what is required.

All records of validated processes are as important as the product itself. Without these records, there is no evidence to verify that the product has been manufactured and tested

correctly and is therefore fit for purpose. Both the product and documents must be stored under conditions that ensure that they are of the same standard at both the beginning and end of their life. The documents should be in controlled fireproof facilities, while the product itself should be stored at a suitably controlled temperature to guarantee that it will perform its function after the permitted period of storage.

The FDA is becoming more thorough in its enforcement of regulations. Previous FDA actions against pharmaceutical companies include those against Abbott, which was fined $100 million, and Tennessee-based Wyeth-Ayerst, which paid out $30 million. FDA re-inspections can also lead to losses for companies. In 2003, Eli Lilly predicted reduced earning forecasts as a result of delayed FDA approvals.[1]

Maintaining regulatory compliance

Once the necessary validated processes and control systems have been implemented, today's competitive market presents a fresh set of challenges to pharmaceutical companies. The ability to achieve regulatory compliance is a significant issue, but maintaining regulatory compliance also remains a major concern.

Because of the clear challenges of complying with the often-complex FDA guidelines, many companies are still failing to implement an effective and systematic process to cope with the regulations. It is estimated that 30 to 50 percent of the 483 citations by the FDA are related to corrective and preventative actions.[2]

What can be done to make QC testing better? There are many existing and new tools available that enable scientific, risk-managed pharmaceutical development, manufacturing and quality assurance to comply with FDA regulations. These tools offer a means of acquiring information to facilitate process understanding, develop risk-mitigation strategies and achieve continuous improvement, as well as share information and knowledge.

Process Analytical Technology (PAT) is one set of tools used to achieve compliance. PAT has been defined by the FDA as a mechanism to design, analyze and control pharmaceutical manufacturing processes through the measurement of Critical Process Parameters (CPPs) that affect Critical Quality Attributes (CQAs).[3] The concept aims at understanding the processes by defining their CPPs and monitoring them in a timely manner. This ensures more efficiency in testing while at the same time reducing overprocessing, enhancing consistency and minimizing batch rejection.

Statistical Process Controls (SPCs) are another effective method of monitoring a process via control charts. Control charts in SPCs are used to determine whether a manufacturing process is under control. If the chart indicates that the process is currently under control, it can then be used with confidence to predict the future performance of the process. If the chart indicates that the process being monitored is not in control, the pattern it reveals can help determine the source of variation that needs to be eliminated in order to bring the process back into control. By continually tightening limits, it is possible to improve the overall process.

Good Practice consultants, such as GxP Consulting, can assist pharmaceutical companies in achieving compliance by providing training on aspects of GMP for production and QC. They also can act as a facilitator to develop the culture that integrates other essential activities, especially engineering and maintenance.

"All records of validated processes are as important as the product itself."

Retaining and growing knowledge

In order to establish and maintain a GMP and GLP culture at a company, it is vital that the correct staff be in place, armed with the right knowledge to implement the necessary processes to ensure regulatory compliance. However, retaining that knowledge is becoming more of a challenge in today's market, as personnel often move between companies more frequently. This poses two problems that need to be dealt with: How do we retain knowledge and consistency within the company? And how do we get new members of the team working effectively as quickly as possible? The answer to both questions, though often poorly executed, is this: communication and documentation. Policies, guidelines and procedures, in whatever format, need to be current, contain an appropriate level of detail, and be owned by the right people and readily available to those who actually need the information. The purpose of the documentation is to help people understand how the organization wants them to complete a task, not just to satisfy auditors and inspectors. The manufacture and testing of a drug are the result of a combined effort by many people, teams and business functions. The value of knowledge sharing and cross-functional understanding is paramount to an organization's ability to work efficiently and effectively. It also provides the ideal forum in which to help new members of the team understand

the organization as quickly as possible and start the process of sharing knowledge and experience. These are all obvious answers, but how well does your organization manage these elements of knowledge management and sharing?

Good Practice consulting firms can rapidly deploy a team to provide interim management and/or training and coaching of new staff in order for an organization to meet its regulatory responsibilities. This provides an effective way to manage staff replacement and the transfer of necessary skills and knowledge. It also provides a smart way to support activities such as expansion and relocation of operations. For new organizations or those not familiar with regulatory requirements, these firms provide a straightforward way of introducing and implementing the controls and measures necessary to demonstrate compliance.

A consulting company is also able to provide an assessment of an organization's current practices against the regulatory requirements. A GxP consultant will have firsthand experience identifying and implementing the standards and changes necessary to help achieve GxP compliance as quickly and efficiently as possible. This experience will have been gathered from companies of varying size and types of product. Once the assessment is complete, the consultant will work with the organization to deliver the necessary actions, such as a strategy to enable continuous improvement and to develop procedures and individual staff members.

Conclusion

Achieving and maintaining regulatory compliance as quickly and efficiently as possible is vital if a pharmaceutical company is to remain competitive. Failure to adhere to the strict regulations imposed by the FDA carries serious risks and can result in costly delays or even fines. The function of the QC laboratory within a GMP or GLP operation is critical to regulatory compliance. By considering the "product" of this business function as the assay result, clear definition, management and control of all testing that is associated with a drug product is possible.

A number of tools can be deployed to assist companies in their goal of achieving, maintaining and improving regulatory compliance, but a consideration of equal importance is the development of a long-term GMP culture. Effective documentation, communication, training and leadership can and do help an organization retain and share its knowledge within the organization. By doing so, there is less risk of knowledge loss, inconsistency or inefficiencies brought about by the higher turnover of staff that exists in the industry today.

Use of the correct GxP consulting services can help an organization identify what needs to be done in order to best meet its regulatory requirements; provide training, coaching and interim management; and develop pragmatic continuous improvement strategies.

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GAS CHROMATOGRAPHY IN THE FAST LANE

INNOVATIONS IN GAS CHROMATOGRAPHY FOCUS ON THROUGHPUT AND FLEXIBILITY *by Tanuja Koppal*

Gas chromatography (GC) systems are similar to HPLC systems in that they are used to identify, separate and quantify compounds of interest. However, GC systems use an inert, gaseous mobile phase, as opposed to a liquid phase, to bring about the separation of molecules. The basic components of a GC system include an injection system, an oven, a column, a detector, and a computer system to analyze results.

There have been significant changes in GC in the past decade, and most of them have focused on maximizing throughput and decreasing run time. One of the factors limiting throughput has been the rate at which proper oven temperatures can be reached. Recent efforts have led to the development of ultrafast GC systems that incorporate advanced column heating devices and controls that can rapidly heat and cool columns. Improving speed of analysis also has been the driving force leading to changes in column technology. The use of small, nanobore capillary columns has improved throughput without sacrificing efficiency or precision. "There is a market out there for ultrafast GC columns, although they need specialized instrumentation to run it," says Rob Bunn, product manager for GC columns & consumables at Thermo Fisher Scientific. The GC columns also have undergone improvements in sensitivity that offer lower detection limits and ultralow column bleeds. "The deactivation process has improved significantly in the past few years and has led to low activity on the column," says Bunn.

Another development in the GC field has focused on the use of multidimensional systems that incorporate different columns and detection systems to improve sample resolution and throughput. The strategy involves using multiple columns to facilitate the separation of co-eluting peaks, such as enantiomers, or of samples that contain complex mixtures or a large number of components. A switching valve is used to route portions of effluent from one column to another column, and under certain conditions, the columns can be operated independently to increase throughput. The ability to incorporate a variety of different detectors within the system also is a huge benefit. "Mass spectrometry is fabulous as a universal detector, but we are seeing resurgence in the use of selective detectors for very specific types of applications," says Laura Chambers, senior product specialist for chromatography products at OI Analytical Corp., who works with customers to help them reconfigure their GC systems. "In some systems you can now have an MS and three other detectors that can work in tandem."

However, to take advantage of these improved technologies, customers must first understand what it is that they need. "Customers really need to know what they want to do with the system or they are going to waste a lot of money buying things they don't need," says Chambers. Since most methods for GC analysis are well standardized and documented, the application and protocol often determine the types of columns, detectors and other accessories to be used. Chambers therefore advises lab managers to think carefully about what the GC system is going to be used for, the skill level of the personnel using it and where it is going to be used. "That will help them make cost-effective decisions as they go through their configuration processes," she says. Taking the type of sample, the sample load and the sample preparation into consideration also is important. Thinking through these issues will determine if any special equipment is needed and will ensure that the samples don't overwhelm certain components of the GC system. There also are other accessories like syringes, filters and septa that play important roles in sample analysis. "When people are involved in new method development, they try a series of different columns and sometimes find that they are not getting the results they are looking for," says Bunn. "Often, when things don't work people blame it on the GC column, but the choice of liner and the septa are equally as important."

Planning ahead and consulting with the vendor are important, as technologies and applications continue to evolve. "Talk to your vendor, because they have experts who know those instruments and applications inside and out, and they can be an extraordinarily valuable resource," says Chambers. Bunn also advises GC users to regularly scan resources on vendor Web sites. "There is not just product information, but there is detailed information on specific applications [as well as] work flow solutions—from sample collection to analysis. A lot of companies have resources on their Web pages that help users make informed decisions," he says.

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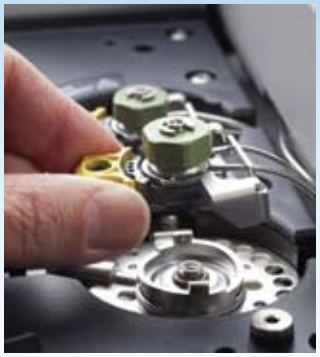
For a complete list of Gas Chromatography manufacturers and suppliers, go to www.LabX.com.



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The Multimode gas chromatograph inlet with split, splitless and programmable temperature vaporization (PTV) capability is available at a lower cost than the previous version and features lower maintenance requirements. In addition to split/splitless operation, the inlet's temperature programming capability facilitates a wide range of injection volumes, analysis of thermally unstable samples, and better productivity through fewer sample-preparation steps. The inlet design incorporates the proprietary Turn-Top feature, which allows liners to be changed in seconds without special tools or training. Sensitivity can be enhanced through large volume injections and inlet discrimination can be reduced for high molecular weight components. The Multimode inlet is compatible with the Agilent 7890A GC, 5975C GC/MS, 7683 and 7693 autosamplers, and the CTC Combi PAL autosampler.

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Designed and developed with chemical, biochemical and pharmaceutical research laboratories, SepacoreControl software controls all Buchi chromatography systems, from simple Flash Systems to advanced Preparative workstations. Intuitive and easy to use, the software allows quick and efficient setup of general chromatography parameters. This method management enables simple programming and operation of purification parameters such column conditioning, separation, column cleaning and system purging. A database of column specifications, suggested flow rates and maximum pressure ratings for the extensive range of proprietary cartridges and columns helps set up the run quickly and efficiently. Peak tracking, the ability to highlight fractions of interest and the generation of user-specific flow charts are definable advantages. Operation panels can be adjusted and an export function allows detailed reports to be created.

PHENOMENEX

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The Zebron ZB-XLB-HT Inferno high-temperature GC column reduces total run time to less than four minutes. Stable up to 400°C, it delivers more consistent performance and longer lifetime than other GC phases. The high temperature capability allows bake-off of matrix contamination, present in milk and other food products, which would otherwise decrease column lifetime. Standard fused-silica columns are not engineered to withstand temperatures above 380°C and their coating begins to degrade, eventually becoming brittle and inflexible. The Zebron Inferno non-metal columns incorporate proprietary coating and bonding technologies that provide stability at high temperatures, low bleed and low activity. The company's Zebron ZB-5ms column is ideal for routine analysis of milk products using the FDA-recommended GC/MS method.

SHIMADZU

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The Multi-Dimensional Gas Chromatography system (MDGC) expands the capabilities of chemists who perform target compound analyses in complex sample matrices. The multidimensional heart-cutting system, incorporating a "multi-Deans switch," greatly increases separation power by combining two capillary columns of different selectivity for a more efficient separation of the target analytes from a complex sample matrix. The improved separation allows more positive identification and improved quantitative analysis of the target analytes. The "multi-Deans switch" directs flow from the first column directly to a monitor detector or to the second column and detector. This device is based on the use of an advanced electronic flow controller to balance the pressure on both sides of the transfer line between columns. Multiple heart-cuts can be made from the first column without shifting the retention times of compounds eluting after the cuts, greatly simplifying method development.

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WATER DEMANDS YOUR RESPECT

THERE IS MORE TO PROCURING PURE WATER THAN INVESTING IN THE RIGHT WATER PURIFICATION SYSTEM

by Tanuja Koppal

Water is perhaps the most utilized reagent in a laboratory and is often critical for an experiment. As instruments have become more sensitive and applications increasingly complex, the demand for high-purity water has also increased. "A few years ago, parts per million (ppm) was a very small level of contamination, but now people are looking for parts-per-billion (ppb) or parts-per-trillion (ppt) levels of contamination," says Renaud Bardon, director for North American Sales Lab Water at Millipore Inc.

There are several types of contaminants in water, such as particulates, organics, inorganics, microorganisms and pyrogens. In the past, people were mainly concerned with ionic contaminants and measured ionic conductivity or resistivity as a way to determine water purity. "Today people are more concerned with organic contaminants, particulates and microorganisms, such as bacteria and gases that are dissolved in water," says Bardon.

"When considering a water purification system, both the quality and the quantity of water have to be taken into account."

There are eight commonly used methods to purify water: distillation, deionization, reverse osmosis, activated carbon filtration, microporous filtration, ultrafiltration, ultraviolet oxidation and electrodialysis. The National Committee for Clinical Laboratory Standards (NCCLS) has specified three types of water: I, II and III, as well as special-purpose water, depending on their use. While Type I refers to water with minimal interference and maximum precision to be used for most analytical applications, type III water refers to that used for general washing. The special-purpose water refers to water that has been treated to remove specific contaminants.

When selecting the right system for purifying laboratory water, several factors need to be considered. However, according to Bob Applequist, product manager at Labconco, the most important one is to "fit the product to the application." You have to differentiate between the need for pure and ultrapure water. In most cases, the pure water generated from tap water can be used for most applications, while ultrapure water generated from a point-of-use system can be used for applications that have more specific and stringent purification needs. "The first-step purification or the system that is used to convert tap water into pure water has to be very good and efficient," says Bardon. "If you have that first step right, then converting that pure water into ultrapure water is going to be very easy and consistent."

When considering a water purification system, both the quality and the quantity of water have to be taken into account. "You have to take into account instantaneous as well as daily water volume requirements," says Bardon. For labs that have variable demands on quality and quantity, flexibility and modularity become very important. "The key then is to invest in a flexible system that will meet your needs today and can grow with the lab and change with the applications," says Matthew Hammond, global sales and marketing director for ELGA LabWater.

After choosing the right system, performing regular, preventative maintenance is equally important. The newer versions have built-in alarms and calibrators that warn customers if certain components are coming to the end of their life cycles. "Sample the water routinely to make sure that it doesn't contain the impurities that will interfere with your analysis," says Hammond. The level of monitoring can be done daily, weekly or monthly, depending on the stringency of the application and the laboratory environment. "Whatever system you buy, make sure it's dynamic, so that the water can recirculate regularly," says Hammond. "Water needs to be kept moving, as still water ends up building biofilms quicker. So look for a system that is easy to sanitize." If properly maintained and used, most water purification systems can last up to two decades.

Finally, ensure that the pure water obtained is being used in the right way. "I know of customers who will invest a large amount of money buying an ultrapure water purification system and then dispense that water into a plastic container before they use it," says Hammond. "It's an unfortunate truth, but for most people, water is just a utility. It's the most pure reagent that is available at a relatively low cost, and so it often doesn't get the respect it deserves."

Tanuja Koppal, PhD, *is a freelance science writer and consultant based in Randolph, N.J.*

For a complete list of Water Purification Systems manufacturers and suppliers, go to www.LabX.com.

AQUA SOLUTIONS

www.aqua-sol.com

Proprietary type I systems produce 2-3 liters/minute of 18+ Megohm-cm reagent grade water directly from tap water. Analytical, biological, and ultra-low TOC models are available with or without built-in reverse osmosis pretreatment. They accept 100-240 VAC at 50/60 Hz input power and operate internally on 12 VDC. Systems with built-in RO can operate on tap water containing up to 1,000 PPM of TDS. Systems are CSA-certified, have the CE mark and include a 2-year warranty.

ELGA

www.purelabflex.com

The PURELAB® flex water purification system integrates in-hand monitoring and pure water dispensing in one product. The dispenser's easy-to-read digital display shows both volume and water purity (either resistivity or conductivity and Total Organic Carbon). The dispense handset has precise fingertip control (like a pipetter) and can be easily programmed with pre-set volumes that can be repeated with the press of a button. The system is easily upgradeable to facilitate changes to laboratory layout and applications.

LABCONCO

www.labconco.com

The WaterPro RO station's large capacity filters and membrane produce reverse osmosis purified water that may be dispensed at a typical rate of 1 liter per minute (at inlet water at 25° C) or manually from a valve or optional gun. The timed dispense feature allows unattended operation. The system may also be used to produce laboratory grade feedwater for final purification by a polishing station and allow dispensing of both RO-purified and Type I water.

MILLIPORE

www.millipore.com

The Milli-Q® Integral water purification system features unique Points-of-Delivery (POD) dispenser systems that give users direct control over water quality throughout the entire purification process. Separate POD dispensers deliver either ultrapure water (from the Q-POD® unit) or pure water (from the E-POD™ unit) at adjustable flow rates ranging from drop-by-drop to 2 L/min. POD dispensers can be adapted with contaminant-specific final polishers to remove pyrogens, nucleases, bacteria, particulates and organics.

SIEMENS WATER TECHNOLOGIES

www.water.siemens.com

The Axius™ E-Plus RO/CEDI water purification systems with reverse osmosis and continuous electro-deionization deliver more consistent water quality. They combine the proven technologies of reverse osmosis (RO) and continuous electro-deionization (CEDI) to produce high quality ASTM type II water. With low initial upfront costs, simple maintenance and minimal consumable change-outs, the systems provide an economical and environmental choice for consistent high purity water up to 1300 liters per day, direct from tap.

For more information on lab products, please visit www.labmanager.com and click on Lab Product News. There you will find more lab products and a complete list of suppliers.

Product Focus: WATER PURIFICATION SYSTEMS

ARIES FILTERWORKS

www.ariesfilterworks.com

The Gemini-Mini Basin is a wall mounted, high flow, point-of-use polisher that can dispense ultra-pure water at a rate of 3.7-lpm; a flow rate over 3 times faster than traditional polishing systems. With PLC control, the Gemini-MB can be intuitively programmed to automatically fill and stop at precise volumes. Flexible dispensing features include: the ability to program four independent batch volumes; remote dispense gun with full recirculation; and submicron filter and direct feed of equipment downstream. Filtration technology includes: multi-pass UV sterilization of the flow path and dispensing port; TOC UV destruction unit to reduce the total organic carbon content of the product water; submicron filtration to remove bacteria and viruses; and ultra filtration for R-nase, D-nase-free water.

THERMO FISHER SCIENTIFIC

www.thermo.com/purewater

The Barnstead NANOpure® water system offers a combination of reliable, ultrapure water with easy operation and maintenance and low operating cost. Application-specific models utilize cartridge packs tailored for specific feed water types and uses. They provide the ideal water for the most sensitive requirements, including: IC, ICP/MS, HPLC, GC/MS, HPLC and TOC determinations. These advanced systems produce water that consistently achieves 18.2 megohm-cm resistivity and TOC values of < 1 ppb.

SMALLER IS BETTER

SMALLER COLUMNS AND PARTICLE SIZE OFFER HIGHER THROUGHPUT AND REQUIRE LESS SOLVENTS

by Tanuja Koppal

While the fundamental components of a high performance liquid chromatography (HPLC) system—pumps to deliver solvent, an injector, a column for separating the constituents of a sample, a detector and computing software—have remained the same, there continues to be innovations in their design and capabilities. The selection of an HPLC system is predominantly driven by the end users' needs; however, the availability of specialized, customizable platforms has given rise to many more options. Preparative HPLC, for instance, is ideal for large-scale purifications of small molecules or peptides, while high-throughput HPLC systems, optimized for short run times and integrated with autosampler units, allow for rapid analysis of large numbers of samples.

"The recent shortage in acetonitrile, the most common solvent for HPLC analysis, also is causing people to reevaluate their protocols and chromatography systems."

HPLC accessories such as columns and detectors also can be modified to suit the application. While a fluorescent, UV or visible light detector is often a standard component in an HPLC system, customizable platforms include other detection technologies ranging from radiometric to electrochemical to mass spectrometry (MS). Multiple detectors also can be integrated, such as tandem MS/MS systems that offer more focused, quantitative analyses. Two major variations in the pump design include high-pressure and low-pressure gradient systems. High-pressure gradient systems mix the solvents after reaching the pump and are more suitable for low flow–rate applications, such as high throughput sampling. In contrast, low-pressure gradient systems mix solvents before the pump inlet and may operate in a higher flow-rate range. Additional components, such as column ovens and autosamplers, also can be integrated, depending on the customers' needs.

There also has been significant innovation in column technology. Newer columns, such as the monolith, amide, polar embedded and fused particle, are more resistant to changes in temperature, pH and flow rates, and they allow users to explore new methodologies and applications. The recent shortage in acetonitrile, the most common solvent for HPLC analysis, also is causing people to reevaluate their protocols and chromatography systems. "We have gotten used to using acetonitrile as a solvent, but there are many other options," says George Limpert, advisory scientist for the Analytical Services Division at Celsis International plc. "You can solve some problems with what we have on hand without investing in very expensive equipment." Some of the new column technologies, for instance, are certainly amenable to the use of other solvents like water, methanol and THF.

Using columns with smaller particle size not only reduces costs but also improves the throughput. "Smaller particle size is where the industry is headed," says Elizabeth Hodgdon, senior product manager in the Waters Division of Acquity UPLC Systems. Ultra performance liquid chromatography (UPLC) systems use columns with polymeric particles less than two microns in size that allow rapid analysis of samples at sub-micromolar flow rates. "We have always focused on chemistry, and UPLC is really a chemistry change," says Hodgdon. Although the separation principle for UPLC is exactly the same as for HPLC, the differentiation is in the design of the system, which takes advantage of the smaller particle size. "We found that we could reduce the particle size and yet have a particle that was robust enough to withstand high pressures and could be suitably packed in a column. Then we realized that in order to truly reap the benefits of the increase in efficiency with using a smaller size particle, we needed to redesign the system."

"Vendors and service providers are becoming more proactive in sharing information and offering technical support."

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Besides the systems and the accessories, the software programs for HPLC also are getting more sophisticated in order to handle and organize the large and complex data files generated. Web-based operations now allow data sharing across multiple users and multiple sites, while enabling complete automation and access. While these new technologies do exist, users have to carefully evaluate what they need. "Lab managers need to evaluate their lab procedures and hone in on processes or products that are slowing down their work flow, and find ways to improve their efficiency and performance in critical areas," says Hodgdon. For their part, vendors and service providers are becoming more proactive in sharing information and offering technical support. Companies are becoming increasingly aware of the need for customer service and periodic monitoring and troubleshooting. "We can't always predict when maintenance will be needed, but we can certainly plan for it," says Hodgdon.

Tanuja Koppal, PhD, *is a freelance science writer and consultant based in Randolph, N.J.*

CECIL INSTRUMENTS

www.cecilinstruments.com

AutoQuest LC autosamplers are designed for use with the Adept HPLC, Q-Adept HPLC and IonQuest ion chromatography systems. They may also be used with third party LC systems. The autosamplers are available with 50 or 100 sample positions and provide for ultra low carryover, ultra high injection precision, priority sampling, replicate injections and sample volumes from 5 µL to 2 mL. The ultra low carry-over provides for the ultimate in effective sampling for trace residue analysis, impurity determinations and contaminant levels. The autosamplers fit neatly with the Adept HPLC, Q-Adept quaternary HPLC and IonQuest ion chromatography systems, each of which is designed to achieve long-term, fast and reliable measurements. Because the systems are modular and versatile, different detectors may be accommodated depending on analytical requirements. These detectors include variable wavelength UV/Visible, WaveQuest UV/Visible, electrochemical, refractive index, conductivity and fluorescence.

EKSIGENT

www.eksigent.com

The ExpressHT™-Ultra HPLC system provides short cycle times and high throughput for LC/MS studies of pharmacokinetics and drug metabolism. With cycle times as short as 60 seconds, the ExpressHT-Ultra can run six 96-well sample plates overnight. Running at a maximum pressure of 10,000 psi, it enables the use of small particle stationary phases to deliver narrow peaks to the mass spectrometer. Employing columns with diameters of 1 mm or smaller, the system uses up to 95 percent less solvent per analysis than traditional HPLC systems, helping customers meet green initiative goals and reduce purchase and disposal costs. Proprietary Microfluidic Flow Control (MFC) technology generates accurate and reproducible flow rates from nanoliters per minute to hundreds of microliters per minute. Control software includes integrated drivers for the most widely used mass spectrometry programs including Applied Biosystems/MDS SCIEX Analyst™, Thermo Scientific Xcalibur™ and Bruker Daltonics HyStar™.

SMI-LABHUT LTD

www.labhut.com

The HT800L HPLC autosampler handles up to 110 autosampler vials or two microplates in an ambient or cooled environment with no re-calibration. Complete flexibility of sample handling ensures that up to 10 reagents can be added for derivitization, addition or dilution. The contents of any vial may be added to any other vial. Samples can be combined, mixed, and injected in microliter or full/partial loop volumes through the integral injection valve, with precise accuracy and exceptional reproducibility. For simple applications, the user sees only the required options in the control software, thus making the HT800L very simple to use. Thoughtful features such as internal lighting and a special safety mode of operation when the door is open, ensure its usefulness for retrofit and Private Label applications.

For a complete list of HPLC manufacturers and suppliers, go to www.LabX.com.

WATERS

www.waters.com

The ACQUITY UPLC® system eliminates time and cost per sample from analytical processes while improving the quality of results. By outperforming traditional or optimized HPLC, the system allows chromatographers to work at higher efficiencies with a much wider range of linear velocities, flow rates, and backpressures. UPLC® technology is a highly robust, dependable, and reproducible system. What differentiates the system's holistic design is the patented sub-2 µm hybrid particle chemistry, offering significant benefits over today's HPLC systems equipped with standard 5 µm particle chemistries. The ACQUITY system, used on its own or paired with proprietary optical and MS detection technologies, provides end-to-end solutions for applications including ADME screening, food safety, bioanalysis, clinical, metabolite identification, and more. The system also routinely handles demanding applications such as the turn-key solutions built for amino acid and peptide analyses.

RESTEK

www.restek.com/hplc

Ultra II™ LC columns are specifically designed for universal application—optimal chromatography on any system. This column line is built on highly inert, high surface area silica that is completely Restek-manufactured, providing excellent column-to-column reproducibility. The columns are available in a comprehensive range of particle sizes (1.9µm, 2.2µm, 3µm, and 5µm), creating truly scalable chromatography on any type of LC instrument, from conventional to ultra-high pressure systems. Ultra II™ columns are available in traditional phases (C18, Aqueous C18, Silica) and unique chemistries that provide alternate selectivity (Biphenyl, Aromax, PFP-Propyl).

SHIMADZU

www.ssi.shimadzu.com

Prominence nano HPLC supports high-precision gradient analysis by providing advanced flow-rate precision in the nano flow-rate range. It delivers exact flow rates via two LC-20ADnano pumps that are independently controlled by feedback from integrated high-precision nano flow sensors. The instrument's Reflux Flow Control System (patent pending) stabilizes solvent delivery and ensures low solvent consumption with no disposal of split flow, minimizing environmental impact. Prominence nano is configured with a proprietary FCV nano switching valve to optimize bio sample analysis in the nL/min level for trap injection and 2-D LC applications. With the low dead volume FCV nano, the volume between ports is as low as 25 nL, so there is virtually no peak broadening in the nano flow-rate range.

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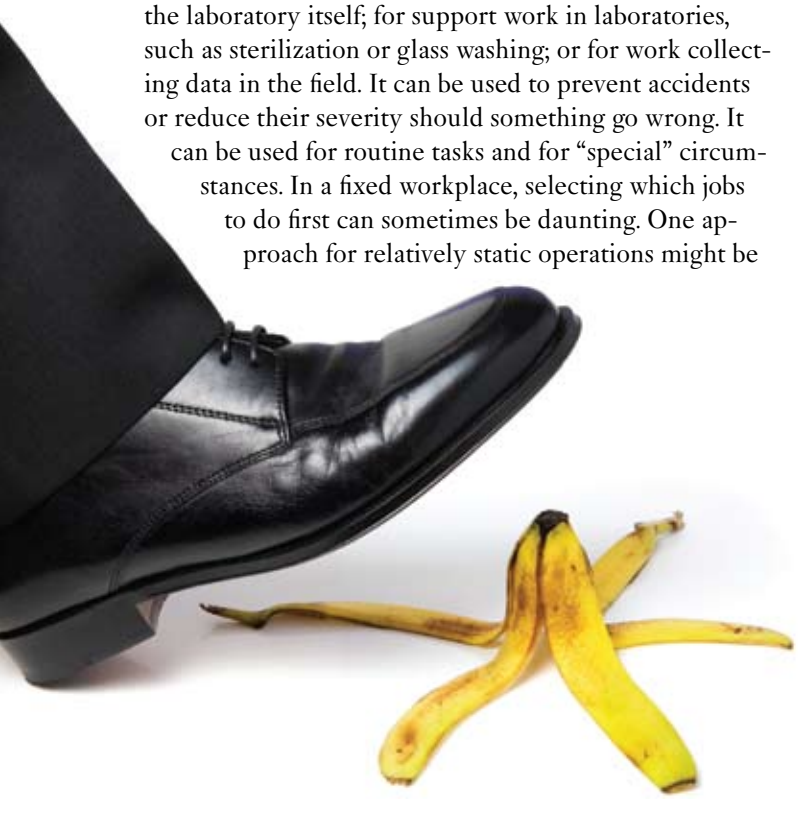
JOB HAZARD ANALYSIS

A FUNDAMENTAL ELEMENT OF ANY ACCIDENT PREVENTION PROGRAM By Glenn Ketcham and Vince McLeod

One of the cornerstones of any successful safety and health program is a process called job hazard analysis (JHA). This is a fancy term for figuring out the potential risks associated with a particular job and devising ways to control or eliminate them before an injury or accident occurs. The JHA technique focuses on the individual tasks/components associated with a job, whether it is collecting water samples from a boat or running a new chemical procedure in the lab. It entails identifying anticipated hazards and developing controls for each job component or step. JHA is like performing anticipatory detective work in which you solve the mystery or problem before it happens. This is done by proactively examining what could go wrong, how it could happen, what would be the result if it did, how likely it is to occur and how you can prevent it from happening.

When to do a JHA

A job hazard analysis can be performed for any job: in the laboratory itself; for support work in laboratories, such as sterilization or glass washing; or for work collecting data in the field. It can be used to prevent accidents or reduce their severity should something go wrong. It can be used for routine tasks and for "special" circumstances. In a fixed workplace, selecting which jobs to do first can sometimes be daunting. One approach for relatively static operations might be to identify tasks with "close calls," injuries or employee complaints. Obviously, the jobs with injuries and illnesses should be first to be analyzed. Tasks where "close calls" or "near misses" have occurred or where simple human error could lead to serious injury should also be given priority. A JHA should be performed on jobs that are new and should be considered whenever changes are made to existing tasks. Ideally, this should be done first, as the job is being developed, to address anticipated hazards, and then amended once the job is functional. In the field, there should always be a JHA performed, as the hazards could run the gamut from exposure to the elements to transportation issues to wildlife encounters to chemical exposure. In simple situations this might be just taking quick stock of any unusual concerns; in others it could become very complex and require expert assistance to keep staff safe. Hazards requiring consideration could include work performed near traffic or on the water, falls from elevation, exposure to chemicals or biological agents, electricity, poisonous plants or insects, entry into confined spaces, severe weather, or exposure to dangerous machinery, to name a few.



Employee involvement

Usually no one knows more about how jobs are actually done than the employees doing them. They have a unique understanding of the jobs, and that understanding may be the key to identifying hazards. Other workers who have performed the same jobs should be brought into the discussion if possible. Solicit information from your employees and students about hazards they suspect in their current work or surroundings. The workers should be involved in all phases—from the review of job steps to discussion of potential hazards to development of solutions. If through discussion hazards are identified that present an immediate threat, take prompt action to protect employees. Fix easy problems right away. Don't wait to complete the hazard analysis before taking action.

Conducting the job hazard analysis

Before actually beginning the job hazard analysis, size up the general conditions. For instance, in a field situation the following are some general observations you might make:

- *Is this in a traffic area?*
- *Is lighting adequate?*
- *Do you need to work near the edge of something that could present a fall hazard?*
- *Are you near uncontrolled power sources? Do you need power? Are extension cords in use? Are there other electrical concerns?*
- *Will you be in cell phone contact or will you need alternative communication?*
- *Are you familiar with and qualified to operate the required equipment?*
- *Are there chemicals involved? Do you know what they are? Do you know how to protect yourself from them?*
- *Are there any explosive hazards?*
- *If heading into the "wilderness" or on the water, how will people know where you are and when to expect you back?*
- *Are there any issues associated with transportation?*
- *Are contamination control procedures needed?*
- *Do you have proper personal protective equipment for the job? Are people knowledgeable in its use?*
- *Are there material movement issues?*
- *Have you communicated your intentions to those who need to know from a safety perspective?*

The list can go on, depending on the circumstances.

"Photos and videos both can help with later discussion and analysis."

Outline the steps or tasks

Once you move past the general conditions, you can start to examine specifics. Most work activities can be broken down into job tasks or steps. If this is an ongoing job, watch the process and list each step as the workers take them. Take enough time to get a feel for the work and that you are seeing representative actions (sometimes workers "posture" when first observed and work the way they think you think they should be working). Be sure to record enough information to describe each job action, but do not get too detailed. Photos and videos both can help with later discussion and analysis. Later, go over the job steps with the employees to make sure you have not missed something important. There are many examples of job hazard analysis forms available on the Web. Use of a form during these exercises helps keep the analysis organized and also serves as a good documentation tool.

Identifying hazards

After you have recorded the job steps, examine each one to determine the hazards that exist or that might occur. When describing hazards it helps to identify:

- *Where it is happening (location, environment)*
- *Who or what is it happening to (who or what is exposed)*
- *What is the "trigger" for the hazard*
- *What would occur if an accident does happen (consequence)*
- *Other contributing or interrelated factors*

Usually there are a string of factors that come into play that result in the hazard. In more complex situations, one may have to repeat the job observation a number of times before all hazards have been identified.

Recommending safe procedures and protection

After you have listed all hazards or potential hazards, review them with the employees performing the job. Determine whether the job could be performed in another way to eliminate or reduce the hazards. For example, make physical changes to the environment, alter the procedure, or use additional or different safety equipment to control the hazards.

Don't make general statements about the procedure, such as "Be careful." Be as specific as you can in your recommendations. The job hazard analysis can provide a good foundation for employee safety training.

Revise the job hazard analysis

A job hazard analysis can do much toward preventing injuries in the workplace, but it remains effective only if it is reviewed and updated periodically. This is true in the lab as well as in the field. In field situations, it is never a bad idea to do an after-action review to improve the process and take note of and incorporate any lessons learned.

"The job hazard analysis can provide a good foundation for employee safety training."

When to hire a professional

Hiring a professional, such as a certified industrial hygienist (CIH) or certified safety professional (CSP), may be appropriate in certain circumstances. Such circumstances could include when there are many different or complex processes surrounding a job, when working under the threat of regulatory or legal scrutiny, when there is a new regulatory limit, or if there are employee allegations of exposure. Regardless of who provides outside expert advisement, it is important that you and your employees remain part of the process.

Conclusion

The JHA is a proven and worthwhile tool in the quest to prevent job-related injuries and illnesses in the workplace. We often do it on an informal basis when performing health and safety evaluations or audits. Performing formal JHAs provides a framework to address all the hazards associated with a job and help prevent partial corrections from being accepted as complete solutions. A quick search on the Web provides many examples of JHA forms that can be modified to meet your particular preferences. Until next time, stay safe.

Resources:

OSHA Guidance: www.osha.gov/Publications/osha3071.pdf

From the Canadian Centre for Occupational Health and Safety: www.ccohs.ca/oshanswers/hsprograms/job-haz.html

From the US Forest Service: www.fs.fed.us/r1/people/jha/jha_index_www.html

Glenn Ketcham *is a certified industrial hygienist with 25 years of experience in the health and safety field. He is currently the risk manager for the University of Florida, with responsibility for the general liability and insurance programs, loss prevention, ergonomics, emergency management, and the occupational medicine surveillance program. He has managed the laboratory safety programs for the University of California, San Diego and the University of Florida. In addition, he served as an industrial hygienist with federal OSHA compliance and has a Master of Science degree in environmental engineering sciences with a health physics concentration.*

Vince McLeod *is a certified industrial hygienist and the senior IH with the University of Florida's Environmental Health and Safety Division. He has more than 20 years of occupational health and safety experience in academic research, with a focus on the research laboratory. His specialties are hazard evaluation and exposure assessment.*

SIMPLIFYING PURE WATER SYSTEMS

Problem: Water purification systems are required for a variety of applications, all of which require different degrees of purity. With a wide range of pure water systems available, it can be difficult to know which one will provide the best results for your lab. The water system should be suited to the available feed water, as well as the application and capacity requirements of the laboratory. Not all feed water is the same and some applications require the removal of different specific contaminants. For example, tap water in North America commonly contains chlorine, which can damage reverse osmosis membranes and shorten the lifespan of the deionization cartridges within your pure water system. By having a system that effectively removes the chlorine, cartridge and membrane life are successfully extended and the laboratory is able to save on unnecessary expenses. Matching the correct system to the type of feed water and application can be a challenging task, but if performed correctly, the validity of resulting data can be maximized and the laboratory can be run as cost-effectively as possible.

Solution: A feed water analysis service will provide a detailed and accurate method to help simplify the process of selecting an appropriate pure water system. Through the generation of a customized summary and system recommendation based on the quality of the feed water, users are provided with clear recommendations as to what will best suit their needs. The Thermo Scientific H2O SELECT water testing program is a free, no-obligation service in which customers receive a system configuration recommendation based on what contaminants need to be removed from the water to create the desired purity along with an estimated lifespan for the consumables. This will aid the laboratory in effective budgeting of resources.

Established to test the feed water of customers considering the purchase of a water purification system, the H2O SELECT™ kit is the most comprehensive water testing program currently available, providing expert analysis of feed water. Based on the customized results, the best system for your application will be identified. A summary of the results and a system recommendation will be produced from the quality of the feed water, the laboratory applications it is used for, as well as the daily water demand and budget. As all water systems are slightly different, some cartridges have a lower capacity than others, resulting in an increased operational cost. This program will identify annual operating costs and inform you of these before you purchase the system.

The H2O SELECT water analysis program is extremely easy to use: Having requested a free kit from Thermo Scientific and filled the test bottle with feed water, the scientist just needs to fill out a brief questionnaire and return it with the sample for analysis. Upon evaluation, the resulting data is matched to the laboratory requirements stated on the questionnaire. Based on this, a water system recommendation along with estimated annual operating costs will be mailed directly to the laboratory.

For more information, go to www.thermo.com/select

YOU'VE BEEN ASKED TO PERFORM A LABORATORY QUALITY AUDIT...

NOW WHAT?

"It is strongly recommended that a laboratory conduct its own internal quality audit with sufficient frequency to assure that test analyses provide continuously reliable results. An internal audit will also provide the lab with knowledge of how well it follows its own quality program and prepare it for audients by clients." ***Guidelines for Laboratory Quality Auditing,*** **Donald C. Singer and Ronald P. Upton**

Data generated by laboratories are used to make strategic decisions for all types of projects (investigation, remediation, compliance, etc.). It is important that the data are of the highest quality to avoid costly resampling and budget overruns. A laboratory audit ensures that the laboratory has quality systems in place, follows good laboratory practices, and generates data of integrity and quality.

The success of the audit is based on adequate preparation, precise performance, well documented and insightful reporting, and productive follow-up.

HOW TO PREPARE:

1 Define the purpose of the audit

Quality audits are performed to analyze the effectiveness and implementation of programs designed to maximize the quality of goods or services delivered to the customer. The scope and technical processes involved lead to determining the needed audit team resources.

2 Define the scope of the audit

The scope of the laboratory quality audit is defined as to limits or boundaries. Will the scope be corporate/organization-wide; the central laboratory; or a satellite laboratory? Will all analytical methodologies or a specific subset be covered? What impact will the audit scope have on the laboratory personnel and operations?

3 Determine the audit team resources to be used

Determine what special skills/knowledge is needed among the team members to efficiently and effectively handle the scope of the audit.

4 Identify the authority for the audit

The authority for the audit comes from the company/organization quality assurance manual, the contract for the analytical services or the request for the third party audit.

5 Identify the performance standards to be used

The laboratory quality system has as many shapes, pieces and names for the pieces as there are authors. As a result, the audit team must evaluate the auditee's quality system against a standard. This does not mean that all laboratory quality systems are identical or should be. The challenge is to make sure that however the auditee's quality system is named and described; all the necessary functions are covered and implemented. The audit team will correlate the auditee's system against the auditor's system for equivalency of coverage.

6 Develop a technical understanding of the processes to be audited

The audit team will function more effectively and efficiently if it has a good understanding of the laboratory's quality system. Studying the Quality Manual and implementing procedures and historical information from prior audits (if available) prior to reaching the laboratory provides the mechanism to focus on the "mission critical" issues and develop better checklists.

7 Contact those to be audited

The auditee is informed of the audit by the mechanism appropriate for the situation. The Lead Auditor needs to make sure it is done or do it, as the situation dictates. This initial contact provides the opportunity to establish rapport with the auditee, to work out the logistics of the audit and to acquire documents necessary for preparation, if not already available. The formal audit plan is transmitted to the auditee upon its approval.

8 Perform an initial evaluation of lower-tier documents to higher-level requirements

This process is part of the education of the audit team. The process also provides much of the focus for the actual on-site data gathering efforts.

9 Develop written checklists of the data needs.

The focus developed in the preceding section is documented in the development of the checklists. Where the audit program is used to cover multiple comparable laboratories, some parts of the checklists are generic. Since the main function of the checklist is to gather data, the specific issues to be examined are listed. The audit question must also be directly linked to the standard that established the requirement. This technique provides protection from the checklist being an auditor's "wish list". Checklists are reviewed or approved (generally by the Lead Auditor).

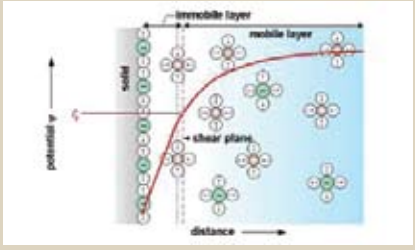
**The above information is based on a presentation given at the ACS Central Regional Meeting, June, 2001.*

ZETA POTENTIAL DETERMINATION FOR MACROSCOPIC SOLID SAMPLES

Problem: The majority of the zetameters are based on the electrophoresis measuring principle where the zeta potential for a colloidal system is analyzed by measurement of the electrophoretic mobility of the particles. However, the measurement of the charged macroscopic surfaces is not possible with electrophoresis. Electrokinetic measurements will enable users to analyze the charged macroscopic surfaces where the zeta potential will give information regarding the adsorption and adhesion processes as well as hydrophobic and hydrophilic nature of these surfaces.

Solution: With the SurPASS, the zeta potential becomes accessible by the streaming potential or (alternatively) the streaming current method. A dilute aqueous electrolyte solution (such as 1mM KCl) is circulated through the measuring cell that contains the sample, which may be a porous sample (permeation method) or a pair of planar surfaces separated by a small gap (tangential method). The sample arrangement represents a mechanical resistance and the liquid flow generates a differential pressure between the inlet and outlet of the measuring cell. Electrical charges, which are accumulated at the interface between the solid surface and the surrounding liquid, are sheared off and accumulated on one end of the measuring cell. The generated potential difference is detected by the Ag/AgCl electrodes.

SurPASS (Surface Potential Analyzer for solid samples)



Electrochemical double layer]

The zeta potential itself is defined as the electrical potential at the interface between the immobile layer of solid surface charges and the diffuse layer of counter ions and is proportional to the streaming potential coefficient dU/dp. The complete equation for the zeta potential ζ reads

$$\zeta = \frac{dU}{dp} \times \frac{\eta}{\varepsilon \times \varepsilon_0} \times \kappa$$

Besides the solid surface properties, the viscosity η, the dielectric coefficient $\varepsilon \times \varepsilon_0$ and the electrical conductivity κ of the liquid phase contribute to the magnitude and sign of the zeta potential. The conductivity and the pH of the electrolyte are measured externally in the electrolyte reservoir. SurPASS also features a built in automatic titrator that ensures that the zeta potential can be measured as a function of varying pH or conductivity of the electrolyte. It is also possible to add small quantities of additives to detect the changes to the sample surface due to adsorption processes.

This electrokinetic analyzer enables the measurement of the zeta potential for a variety of solid samples that can range from powder, fibers and planar samples such as membranes, filters, polymers, biomaterials, silicone nitride wafers etc. These samples can be mounted into the SurPASS by using three types of measuring cells.

For more information, go to www.anton-paar.com

JM Science is proud to announce the new **CLD-100 Salt Analyzer** which achieves speedy and accurate determination of chloride ions by coulometric titration method. Measurement occurs when silver ions react with chloride ions in the samples. The concentration of Cl or NaCl is calculated from the quantity of electricity required to produce silver ions.

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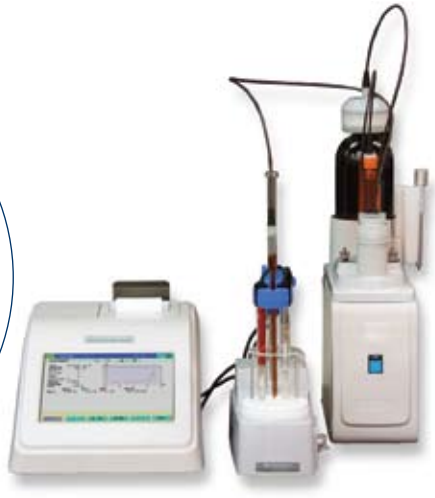
Shown with Sample Changer



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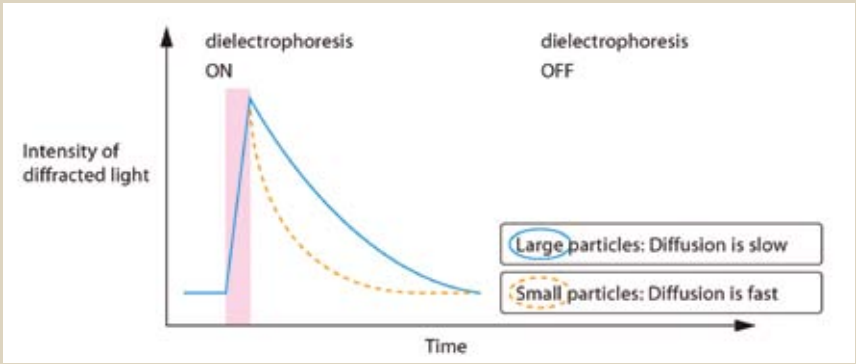
INDUCED GRATING TECHNOLOGY IN PARTICLE SIZE ANALYSIS

Problem: Currently nanoparticles are measured by most particle size analyzers using scattered light; however in some cases this presents many physical restrictions and also requires the input of the refractive index as a measurement condition. Future trends in science indicate the need for accurate sizing of nano and even sub-nano particles, particularly in the area of drug development and pharmaceuticals.



Solution: Although traditional particle sizing methods using scattered light alone have not been ruled out as a solution to this problem, a new technology that has received considerable attention and an Editors' Choice bronze award for best new product at Pittcon 2009 is the induced grating (IG) method from Shimadzu Scientific Instruments' IG-1000. IG is a new technique for measuring the size of nanoparticles using dielectrophoresis and diffracted light that delivers excellent reproducibility and acquires stable data, particularly for sub-10 nm particles.

How it Works Particle size is measured using the diffusion rate of a grating that is composed of particles in the liquid. The diffusion rate of large particles is slow and that of small particles, especially nanometer particles, is fast. The diffusion behavior of particles can be monitored by detecting the change of primary diffracted light.

In the Shimadzu IG-1000, a diffraction grating is formed by drawing particles toward the electrodes when dielectrophoresis is on, and the diffraction grating disappears when the dielectrophoresis is turned off and particles are released away from the electrodes. The decay process of this particle density diffraction grating is measured via the change in intensity of the diffracted light, and a relationship between particle size and diffusion rate is then established.

Stable measurement with good reproducibility is possible because IG utilizes optical signals emitted by the diffraction grating formed by the particles and not scattered light emitted by the particles. Even in the single nano region, a good S/N ratio can be obtained.

The new measurement principle is resistant to contamination and, even if the sample is mixed with small amounts of foreign particles, information about the particles to be analyzed is captured reliably. The filtering of samples in order to remove coarse particles is not required.

An alternating voltage is applied to cyclically arranged electrodes, and a cyclic concentration distribution of microscopic particles is formed in the liquid by dielectrophoresis. Although the cyclic concentration distribution of microscopic particles acts as a diffraction grating (a particle concentration diffraction grating), if the alternating voltage is stopped, the grating diffuses and disappears (patent pending).

The cyclically arranged electrodes also function as a diffraction grating, although the light created is weaker than the diffracted light created by the particle concentration diffraction grating. The electrode configuration has been modified as shown in the figure so that the pitch of the electrode diffraction grating is half that of the particle concentration diffraction grating (patent pending). In this way there is a more precise measurement.

The IG method also ensures high reproducibility and the acquisition of stable data. In particular, high reproducibility for particle sizes of less than 10 nm removes the uncertainty of particle analysis in the single nano region.

For more information on the IG method of particle size analysis and Shimadzu's new IG-1000, please contact Bob Clifford, PhD at 1-410-381-1227 or email rhclifford@shimadzu.com

ADVERTISER INDEX

Marketplace

PARTING POINTS

Takeaways from this month's issue:

Lab Safety Revisited, p.10

First, take a look at every inch of your lab with "fresh eyes"—as though seeing it for the very first time. Is the safety message you want to pass on to your lab staff reflected in the lab you manage? If not, the authors recommend the following three approaches for improvement:

- Lead by example
- Set a time for cleanup
- Have a productive method for bringing issues forward

Cross Training, p. 14

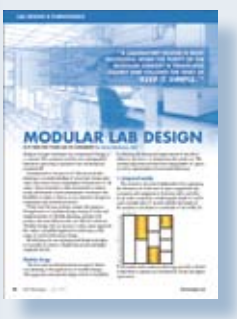
"So much of analytical knowledge is gained through experience. Working closely with a mentor is the one of the best ways to learn, because throughout the course of the mentoring process you are able to draw on your mentor's experience and also see how he or she approaches problem solving." Benefits of cross training include:

- Improved productivity
- Coverage for staff vacation or sick time
- Individual career development
- A method for transferring knowledge

Avoiding Power Disturbances, p. 24

As with many lab equipment problems, the most often overlooked is the lab's utility power source and specifically its voltage regulation. The benefits of an uninterruptible power system (UPS) battery backup include:

- 24-hour preconditioning and testing cycles will not be compromised.
- Connected lab equipment continuously receives optimum power and voltage
- Overall reliability
- Improved test accuracy and completion rate



Modular Lab Design, p 30

Laboratories must be designed to evolve with the continual shifts in scientific discovery and advances in technology. The concepts of design, when grounded in the 10 core principles below, will result in a facility that is highly functional yet has the flexibility to adapt to future change.

- Integrated modules
- Right-sizing
- Limited inventory
- Lab/office zoning
- Space distribution
- Separated support
- Clear organization
- Open environment
- Functional furniture
- Sustainability

The Analytical Lab as Strategic Asset, p. 38

This is a period of simultaneous challenge and opportunity for lab managers. Leverage today's short-term business challenges as an opportunity to transform your laboratory into one of your organization's greatest assets. To begin the process, first:

- Take stock of your laboratory
- Review your management's expectations
- Factor in external influences that are out of your control
- Determine how to deliver on your goals
- Recognize short-term opportunities
- Introduce forward-looking technology platforms to meet evolving business needs

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- Conference topics include: Accountability at Work in Challenging Times; Influencing Difficult People; Managing Your Boss and Your Career; Utilizing Diversity in Teams; Digging out of the Management Dumpster: The Keys to Sustaining High Performance.
- Keynote Speaker: Dr. Charles L. Liotta, Chair of the Department of Chemistry and Biochemistry, Georgia Tech University
- Roundtable Discussions on Effective Networking; Right-sizing and Reorganization Aftermath - Rebuilding an Adaptable Team; The Current State of the Technical Laboratory and Future Trends.
- Exclusive Tour of the State-of-the-Art Chemistry and Biochemistry Facilities at Georgia Tech University
- Presentation of the 2009 Distinguished Service Award for Laboratory Management
- Conference Banquet: Guest Speaker Mike McMullen, Senior Vice President, Chemical Analysis Division, Agilent Technologies

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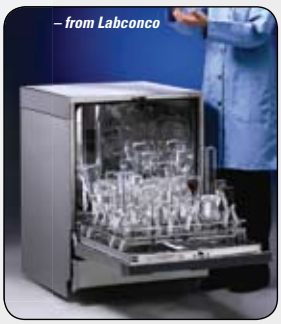

FlaskScrubber (shown), ideal for narrow-neck and general purpose lab glassware, comes in freestanding and undercounter models. SteamScruber models are perfect for accessory inserts and smal items

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- Laboratory hoods provide safe ventilation of fumes
- Benchtop models provide space-saving performance and economy
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