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Pharmaceutical Automation

A LIMS Primer

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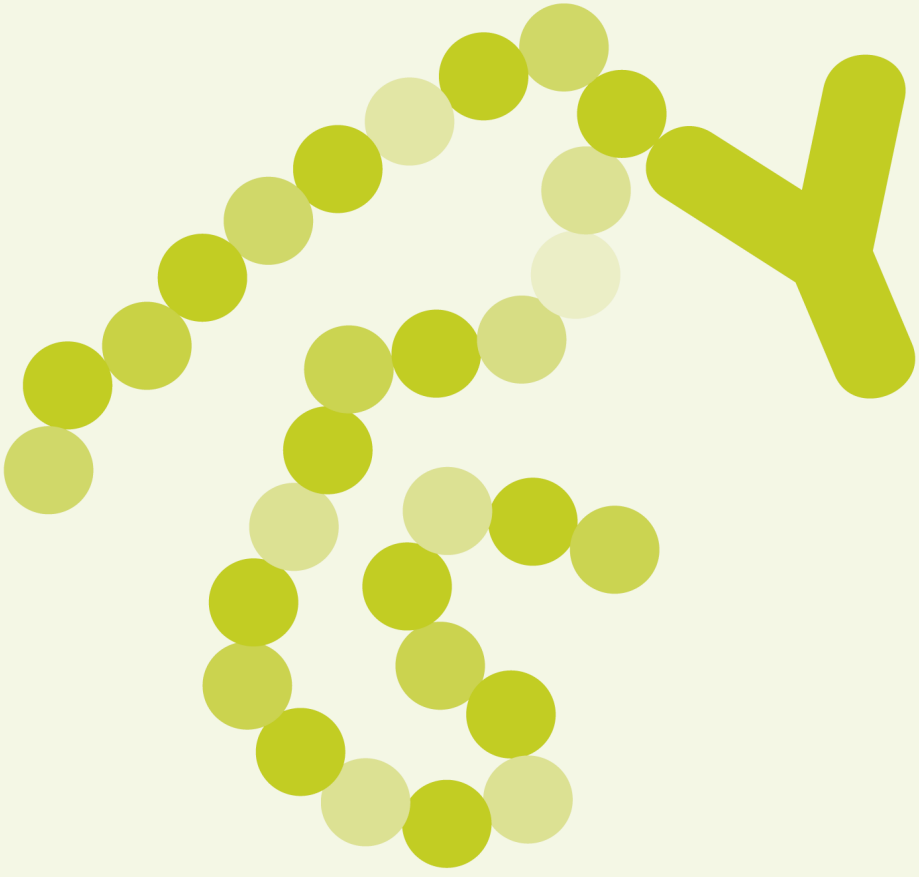

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Lab Manager Magazine® is a printed publication of resources, products, and information for today's laboratory manager. Articles should address some aspect of laboratory management from the perspective of a professional who is both a scientist and a manager. Topics areas would include: managing budgets, personnel, technology, information, funding, training, safety, risk, expansion, building or renovation, among others related to the role of a lab manager.

The article review process should begin with a query by e-mail or phone followed by a brief abstract or outline. Please state your topic and objective, and indicate your perspective as well as your professional relationship to the topic. Content must be unbiased and cannot promote a particular product or company. Article length may range from 1500-2500 words. All manuscripts must be submitted electronically by email or disk.

To submit an article query contact:

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One day, One Mission

If you are within driving distance to the Boston area, you won't want to miss Lab Manager Boot Camp on October 25th in Waltham, MA. Just ten miles outside Boston, Boot Camp will be held at the award-winning headquarters of the Massachusetts Medical Society. A recent visit and tour of the facility by members of the Lab Manager staff impressed us with the conference center and its very professional atmosphere. In particular, we found the lecture hall to be one of the most comfortable and meeting–friendly places we had seen in a long time. The theater where the sessions will be held offered comfortable seating with a writing surface, internet hook-up (the facility is wireless as well), and electrical outlets at each seat. To those of us who have logged long hours on metal folding chairs at conferences, the theater was a welcome sight.

LIVE OR VIRTUAL – THE CHOICE IS YOURS

Though there are many benefits to attending the live event, sometimes time, budget, and work demands don't allow you to get away from the lab. For those who aren't able to participate in person, we have recently made arrangements to offer the presentations live on the web via streaming video. Though details were not available at the time this issue went to press, more information on how to sign up and attend Boot Camp from the comfort of your desk will be available on our Web site, www.labmanagerbootcamp.com.

Of course, it's not all about the place but the content. That is taken care of as well. The goal of Lab Manager Boot Camp is to provide scientists with professional development in management skills and tools — "things they didn't teach you in chemistry class." Here is a brief sampling of some of the things you will hear at Boot Camp:

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Pharmaceutical Automation:
Key factors in the decision-making process

LIKE OTHER NEW TOOLS IN THE DRUG DISCOVERY PROCESS, AUTOMATION, IMPLEMENTED PROPERLY, CAN GENERATE THE INSIGHT NECESSARY TO DRIVE THE PHARMACEUTICAL BUSINESS FORWARD.

The use of automation across the pharmaceutical industry has increased in recent years. Although the pressures on the industry to improve efficiency and reduce costs have driven this trend, technological advances together with an increased acceptance of "automation" have also contributed to it. Today, automation is not necessarily implemented to reduce labor costs, but rather to improve experimental accuracy and workflow efficiency. In drug development — the mid-stage between discovery and clinical trials — scientists are testing many more samples to measure a drug's characteristics so the quality of results is crucial. Automation allows highly qualified scientists to focus on analyzing results or developing new areas for research rather than the laborious and repetitive manual steps of an experimental set-up.

CHOICES

Small automation projects can often be implemented in their entirety by an in-house team. Large, multi-equipment projects, however, almost inevitably involve the use of an outside vendor or development agency. Deciding whether to outsource an automation project is not easy. A major consideration is whether the company has the time and resources to undertake a project in-house that will effectively be a major distraction for some while, even if the results will enhance the core business. One of the first steps in the project life-cycle is careful process evaluation, enabling the team to determine the limitations of a specific research area or task and investigate the benefits that automation could bring. To get the most benefit, the process to be automated should be stable and consistent. If the work-flows are also complex, repetitive, and therefore prone to human error then automation is likely to generate better quality data.

To get the most benefit, the process to be automated should be stable and consistent.

Next begins the search for an equipment supplier or, ideally, an off-the-shelf solution that will do all, or nearly all, the required functions. Typically there will be gaps in the process where one instrument's functionality will fail to overlap with the functionality of the next piece of equipment in the work-flow and this commonly leads to the continuation of manual processes to cover the gap. This is often referred to as "manned automation."

Companies like AstraZeneca have in-house teams, part of whose role is to evaluate the company's technology portfolio. Mikael Arinder, Project Manager at AstraZeneca Strategy, Technology & Systems in Lund, Sweden explains, "We're currently evaluating where there are gaps, and where could we use technology to create benefits. Then we map these gaps or needs towards technology on the market — commercially available systems — and if we see that there are gaps which don't map against a commercial technique then we will proba-

Philip Blenkinsop

bly go to suppliers to see if we can get this equipment built for us."

Sometimes it will be the very specificity of the task to be automated that defeats the implementation of standard or off-the-shelf automation as each company will have its own special way of doing things. Compromises can be made to match the working practices imposed by automation, but the benefits of automation rapidly drop away once you start planning for the lowest common denominator.

It is at this point that the recruitment of outsourced automation expertise is most beneficial. Developing an automated solution to a pharmaceutical process that is optimized for specific company methodologies requires extensive scientific, engineering, and software expertise across a number of fields. It is unusual for this wide range of expertise to be available in-house. Furthermore, experienced systems integrators can avoid the pitfalls involved in bridging the mechanical and software interfaces between different suppliers' instrumentation. Writing application software that meets the specific needs of the company, is sufficiently flexible that it will cope with future extensions, and easily maintainable is a skilled job and not one that most companies who have tried to do it in-house have repeated. Simplistically, time is money and while chemists or biochemists are writing programming scripts or database queries they are not using their expertise to develop and direct experiments.

The main benefit of outsourcing automation is that, with the right company, you will get a much broader range of skill sets and experience, including mechanical, electrical engineering, software, and control engineering expertise, than if you tackle the task in-house — without the expense of supporting that expertise when you don't need it. You will also be presented with a dedicated team who will have a vested interest in meeting the user requirements in the simplest and most direct fashion, especially where there is a direct link between deliverables and the price of the job. In contrast, it is not uncommon for in-house projects to start out poorly defined and suffer from expanding objectives, mainly because, when users and providers are part of the same organization, it is difficult to inculcate the professional distance needed to run the project on a tight rein. Additionally, a less well-recognized benefit is technology transfer — a custom automation supplier can work across several areas of business and is in a better position to bring to your attention a technology that has been proven in another field but not yet applied to yours.

VENDOR SELECTION

AstraZeneca has a taxing selection process because the right automation company is so crucial. "If we select the wrong vendor then we often go wrong in the end," says Arinder. "We choose between 10 and 20, and then we funnel the list down to evaluating a few companies more thoroughly." The list of points to assess is exhaustive. "We would look at the vendor's ability in developing GMP compliant systems, look at Part 11 experience, look at quality assurance, at GAMP procedure — quality is important because the system that is being developed will be validated and when we have an FDA inspection in our labs they will also inspect the documentation on the development of the system." AstraZeneca also checks standards for project management, written standards, key control documents, development documentation, testing, and of course the skills required. In particular, they are interested in process knowledge. As Arinder explains, "If there's a tablet analysis system, then have you worked with tablet analysis systems before? We also look at track record — have you worked together with us before? How did that project go? Have you worked together with other pharma companies? Have you references? What came out of that? Then there are more things like, how stable is the company? How limited in size are you? Can you demonstrate value for money? How willing are you to agree on IP and such things? And finally, capacity to deliver and to support what's been delivered."

RISK MANAGEMENT

There's a considerable risk involved with developing new equipment, or enhancing or integrating existing instrumentation. AstraZeneca manages this risk in several ways — some developments involve going to the original supplier for enhancements; in some cases new technology is developed in collaboration with a supplier and then handed over to a supplier to deliver and support the system. Arinder explains, "There are significant advantages to this because if they sell it to many customers the supplier will take care of the support and upgrades. And the support will be much better if there are many customers than if there is only one customer. There are other advantages, for instance, if you are developing something that is GMP compliant, legal authorities like the FDA are often very suspicious about automated solutions. If we automate it, we need to prove the automated solution gives exactly the same result as the manual. If it is launched on the market and many companies use it, the FDA is more inclined to accept it, so it becomes easier for AstraZeneca to use."

To manage the risk associated with larger, bespoke projects, AstraZeneca adopts a phased approach where the risk is reduced by having several decision points. Arinder explains, "For one current project, the first thing we did was a design study, then we had a go/no go decision — should we proceed? Does it look promising? As it did, we then did prototyping for almost a year, then there was a new decision — should we proceed or not? Now we are building the first module. We will then implement it and test it. If it works, we will build an additional two modules and connect them. If we can't connect them for some reason, then we can at least use them as

stand alones."

A successful automation supplier will follow a well-defined process when consulting on the variety of projects they undertake. Good communication before, during, and after the project is essential with review meetings to discuss ideas explored, problems found, and any expansion of the project's objectives. As expected, progress reports on technical issues should be provided regularly and consistency is key. Both customer and supplier should be encouraged to use the same manager throughout the project's duration as this can significantly contribute to the success of the project. A professional supplier will also provide full training at project hand-over and ideally will be in a position to provide service and support teams to keep things running once the system has been commissioned. Bespoke automation is a big commitment for any company or laboratory, large or small, thus support and on-going development is an important part of the client relationship, whether it is for a new version of software or a mechanical tweak to the system.

FROM DESIGN TO IMPLEMENTATION

A first essential step in automating a specific process is the establishment of clear objectives. For example, not all drug discovery is deterministic and often the chance to explore a wider chemistry space or obtain finer granularity of information can lead to insights from your staff that the day-to-day duties of the lab won't permit. The next step involves conveying these accurately to the automation supplier to determine the viability of the project — at this point, detail and thoroughness are essential and simulation is an important tool to aid the process.

If a manual process is stable and consistent then the company stands a good chance that an automated equivalent will perform equally well. The automation supplier really needs to understand the science that the process involves if they are to supply efficient automation with in-built systems and software for monitoring and tracking process parameters. If they do not fully understand the science, they will simply mechanize the manual process but without the benefits of flexibility or the inherent quality control that is built into human actions. A successful company that boasts a team of engineers together with scientists (chemists, biochemists, cell biologists, and physicists, for example) can take a more informed approach and very specific skills sets can be utilized to deal with those tricky process issues as they arise.

So, how do customers define successful automation?

Arinder is clear, "When what's been delivered meets the expectations in the business case. It is often important to have something that is really robust and really works, really meets the requirements — that's really successful. All projects have to balance the demands of timescales, budgets, and quality. If we kept to the time plan and the budget but the result was unreliable, it would be useless — so quality is essential. However, we will not ignore the time plan and the budget to achieve it."

From a supplier's perspective, the most satisfying projects occur when the initial brief defines what appears to be a straightforward automated replication of a manual process but, by pooling the collective talents of the supplier's and customer's teams and a process of iteration, the end product is considerably slicker, or simpler, or more flexible than first conceived. There are often challenges along the way, but without challenges the benefits of the automation may be weak and the competitive advantage that automation can bring may be lost. For the customer, the delivery of a robust and reliable piece of hardware that meets or surpasses those initial objectives justifies the investment. The benefits of improving experimental accuracy and streamlining workflows can lead to a more efficient research program. Additionally, the development of a trusted long-term partnership between company and supplier can allow for an easy upgrade path as the company or laboratory grows and requirements change. When a new project arises, past experience provides assurance that a quality result will be delivered that can be developed and integrated with existing fully functional systems.

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Are you ignoring your lab's IT needs?

HOW A LAB MANAGER DEALS WITH THE IT REQUIREMENTS OF INSTRUMENTS DIRECTLY IMPACTS INSTRUMENT UPTIME, SERVICE COSTS, USABILITY, VALIDATION, AND ENTERPRISE NETWORK SECURITY.

Lab instrumentation today is becoming increasingly computerized. It seems that every piece of instrumentation is coming into the lab with a computer attached or one built right into the instrument itself. The data that these instruments generate flows at rates that require high speed network connections. As soon as you plug one of these computers into a wall jack, you need to worry about instrument stability, corporate network security, and IT/IS standards. At the same time, it is unusual to find a truly unified support system for lab computers in most research centers. This leads to many disagreements with stakeholders about the proper maintenance and support of these computers. Add to this situation a regulatory validation requirement and it is easy to see how any lab manager can become overwhelmed.

I wanted to share some of my observations on this subject and offer some very simple recommendations to help the average lab manager maintain computer systems in lab environments. Keep in mind that I said SIMPLE recommendations, not EASY ones. Your experiences may differ for any number of reasons and if they do, I would love to hear about it.

"WHAT MAKES AN INSTRUMENT COMPUTER DIFFERENT FROM ANY OTHER COMPUTER IN A CORPORATE ENVIRONMENT?"

Standard corporate desktop computers are usually tightly controlled and managed. They are part of a large population of computers that have the same software, operating system, patch levels, security systems, and other configuration parameters. The very nature of instrument computing runs counter to most standardization efforts. Instrument computers are different because of their value, use, distinctiveness, and environment.

Keep in mind that I said SIMPLE recommendations, not EASY ones.

Desktop computers have become a commodity. Instrument computers cost a small fortune. This is especially true if you purchase the computer bundled with the instrument from the vendor. It is not unusual to see a computer broken out of a system purchase costing $5,000 to $10,000 or more. That fact runs against what most people see in the consumer stores where computers cost under $1,000. This is just the upfront cost associated with these specialized computers. There are other backend costs such as repair/upgrades of software (usually not considered to be part of most service contracts) and validation/change control to consider as well.

Instrument computer usage varies, but for a large part, they are considered to be the primary data acquisition points of the lab. There used to be a time when instrumentation was used without a computer but those days are long gone. Modern lab instrumentation simply cannot run without them. Generally, people do not use them to prepare monthly financial reports, surf the web, or answer e-mails as these activities are supported in the office environment and only jeopardize the lab equipment's primary purpose. In the desktop environment, it is rather easy to swap out, borrow, or restore a computer when it breaks. Instrument computers are much more critical to the lab's primary product, much harder to temporarily replace, and nearly impossible for most desktop IT groups to service under standard service level agreements. The last point becomes even more exacerbated when desktop computer support is outsourced to a third party, which seems to be the general trend these days.

Anton Federkiewicz

Instrument computers tend to be both unique and diverse in a large lab environment. They run software that is usually not available from your computer superstore or standard desktop application library. These software packages can be complex, difficult to maintain, and/or expensive to repair or reconfigure. Researchers need to use a variety of instruments to do their jobs which leads to a variety of computers and configurations attached to those instruments. An additional source of diversity occurs when there is weak central asset management or planning over the instrumentation acquisition processes used by different lab groups. I have seen five different makes of the same type of instrument in the same location simply because each research group had their own favorite. Instrument computer diversity also occurs when instrumentation is purchased over time. Labs where instrumentation is running on the newest computers on one bench and ones that are seven years old on others are commonplace. The lack of lifecycle management may be due to multiple factors that may be purpose driven, technology-based, or financial in nature.

The operating environment of most instrument computers differs substantially from the carpeted areas of the corporate desktop computer world. Usually everyone in the carpeted areas gets their own PC. Instrument computers are generally shared by the entire lab staff. Lab systems are corrupted quite often because of constant power-user tinkering. Instrument vendor software packages sometimes require that users have administrative rights on the computer in order to even operate the software. That would never be allowed in a normal desktop computing environment for obvious reasons. Lab computers also generally run under higher workloads than desktops and consequently require higher maintenance. For instance, our service data indicates that instrument computer hard drives fail at a 20% higher rate than their desktop counterparts. These computers often work harder for longer lengths of time with less maintenance than desktop PCs.

Managing an instrument PC like just any other desktop computer has led to many lab managers reluctance to allow general PC service technicians to even walk into their labs. I have heard and witnessed multiple instances of well intentioned IS service technicians who have shut down labs by insisting that a patch needed to be deployed on an instrument machine in order for it to be "in compliance" with IS standards. Now don't get me wrong, IS standards are a good thing as they protect all of us from all kinds of nonsense. The problem with their heavy application in the lab environment is that it requires special knowledge and a gentle hand to implement those standards in the labs in a way that both satisfies the standard and keeps the lab running. One of the main reasons why "Parallel IT" organizations commonly spring up in lab environments is that they have those knowledgeable, gentle hands. That said, there are excellent IS organizations and people that have a genuine concern for lab computing and a good understanding of the differences from the desktop environment. Unfortunately, I find that both the "Parallel IT" people and the official IT people with lab systems experience are usually spread way too thinly to support instrument computing and are usually not coordinated across research organizations effectively.

"OK, SO OUR LAB COMPUTERS ARE DIFFERENT. WE SEEM TO BE GETTING BY JUST FINE."

I hear this argument from every person or group responsible for lab computer support. The problem is that this same logic is being repeated from many different groups with different interpretations of what "getting by just fine" actually means. Support groups include instrument services departments, vendor service engineers and organizations, subject matter experts, general lab users, IT/IS support groups, and anyone else who has even the slightest interest in maintaining instrument systems. Every group has their own interests and, usually, they assume that those interests are common to everybody. Interests are usually defined by the function that you serve in the organization.

An instrument service group functions to keep the lab's instruments operating efficiently at the lowest cost possible. The usual problem lies in the fact that they have little to no IT requirements other than what is imposed upon them from other organizations. It is unusual to find an instrument services department that includes an IT role. What little IT role that they do have consists of keeping the systems that they support operational. "Getting by just fine," for the instrument services organization that I describe, means that the instruments work and that the researchers are happy. Very little is done about security issues until it is too late. Malware, data security and integrity, patch management, and other IT functions tends to become an afterthought as these types of concerns are not about keeping instruments running or researchers happy. IT organizations are the ones looked to for prevention of those issues.

Vendor service engineers (VSEs) and vendor organizations are primarily service retailers who focus their efforts within the scope of their products advertised function. Services consist of "break-fix" repairs, software/hardware upgrades, installations, and preventative maintenance. Since these services usually focus exclusively on the instrument hardware and software, VSEs sometimes insist that the PC should be used "as is" and never altered to fit into the IT infrastructure of the company. Customers are advised that any changes to the OEM deployment may void the warrantee and generate additional service costs. My team has had to become very adept at proving that our modifications are not what are causing an instrument system to malfunction. "Getting by just fine" for a VSE means that the instrument runs as it did from the factory. Once again, general computer needs seem to be somebody else's problem and in all fairness, justifiably so.

Subject matter experts (SMEs) are those lab personnel who

are savvy enough to be able to manage their particular lab PCs in a way that either attempts to accommodate IS security concerns or avoids IS security mandates altogether through isolating their network and forcing their users to have what limited functionality they can provide. They are primarily motivated to keep their particular lab instruments running and keep their own users needs as the most important thing. IS security tends to be something to be worked around instead of implemented. "Getting by just fine" for an SME means that their users don't become aggravated by restrictions caused by what they would argue are excessive security concerns. It also means that they are not swamped with support requests and can get their research work done and that nobody from corporate IT notices that they have set up their own independent lab environment.

General lab users are, of course, primarily motivated by their need for data. Their mantra is "Keep the data flowing at all costs!" I would consider this voice to be the most important voice of all the stakeholders. This voice should set the mission of all the support stakeholders. If you run a research lab, your product is data. It is uncommon for general lab users to worry about IT security or supportability. They tend to do whatever it takes to keep the data flowing. This includes all kinds of risky behaviors, workarounds, and general tinkering. I won't name names, but I have had to fix some very impressively damaged computer systems where the root cause was somebody thinking that they could fix that "little error box that kept coming up" because they did the same thing on their home PC.

Last but not least are the IT/IS support organizations. The overwhelming goal of this service group is to standardize, sterilize, and write procedures and policies because that is what works for their largest environment, the office desktop. Lab computing environments just don't fit into that mold for the reasons we have already discussed. These "non-standard" systems tend to either get exempted or put outside of standard IT/IS support scope. Resulting gaps in coverage seem to fall back on the researcher to fill or someone from IS/IT takes a "best effort" approach at supporting the instrument computer. An illustrative and all too frequent scenario occurs when the computer software that runs the instrument suddenly stops working. A lab manager knows that the instrument hardware is running fine and places a service call to their IT helpdesk. The IT analyst looks up instrument software on the call script and sees that the usual response is to ask the lab manager to "call the vendor." The researcher calls and after a few days, the VSE comes in and takes a look at the problem. Since the troubleshooting tree that we discussed for VSEs centers upon the sanctity of the OEM build, the VSE tells the lab manager that it was a "hot fix" that a well meaning IT person put on the PC that caused the instrument to stop working. Of course, the lab manager is furious and blames IT for pushing this critical patch to the computer. IT's honorable intention was to help protect the lab system and the larger corporate network in the only way that their policies, procedures, and resources would allow. The offending patch is removed by the vendor and the lab manager is warned that their system cannot be supported under the current service contract if they continue to alter the system. It tends to go around and around like this until either a compromise is made between functionality and security or the event is considered an escalated issue, straining the relations between organizations.

Now, don't get me wrong, there are MANY fine people out there supporting these systems. That includes people from all of these groups with their competing interests. Overwhelmingly, what I have found is that everybody on this list has the same general opinions of this situation. Everyone believes that we need to

come up with a solution to these instrument computing support gaps. The dilemma is in the combination of competing interests, resources (or the lack thereof), and general organizational momentum. It is difficult if not impossible to get anyone to stand up and agree to do anything about it. It is also hard to convince management that a problem exists when each stakeholder group tells the story singly and from their own perspective. Each group is performing their jobs correctly but the gaps between each support group's scope inhibit the optimization of the instrument computing environment. Ultimately, the disease seems to be that there is no unified voice that speaks for instrument computing.

SO WHAT SHOULD WE DO ABOUT IT?

1. *Stop ignoring the fact that there is a computer on the instrument and acknowledge that they are completely interdependent systems.* Many support philosophies simply forget that there is a computer attached to the instrument that has support needs of its own. Regular operating system monitoring, patching, anti-virus, defragmentation, networking, data management, upgrades, and other normal computer system maintenance needs to be addressed. The other thing to be avoided is the tendency for certain organizations to think of the instrument computer as just another computer. Instrument computer support has to be done in a holistic manner that is centered on maintaining the uptime of the entire instrumentation system.

2. *Unify your support philosophies.* No, I don't mean that there is one group that has to take on this whole issue. What we have done at Wyeth is to come up with a consortium of volunteers that bridges these problematic organizational boundaries and sets a unified direction for lab computing in our global environment. We meet regularly with IS/IT organizations in an open forum and share ideas, come up with solutions, align ourselves, and generally try to address the fact that there is indeed a computer on our instruments. It's not perfect but it is much better than the way things were done before. It also helps to remove the stigma of being part of a "Parallel IT" organization. I suggest that you start your own unofficial lab computing user group. Establish a grassroots effort to unify how these machines are supported. When you speak with one voice, management tends to lis-

ten better, understand more, and has the opportunity to get behind something other than a discordant series of opinions.

3. *Leverage enterprise class support tools*. This one can produce immediate return on investment and doesn't need a massive effort to implement. For years, we did lab computer support by hand. We visited each workstation personally, installed software, hot-fixes, and did repairs one at a time. This was both time consuming and ineffective. We were never able to say with any certainty if our lab systems were secure or even running properly. We began to collaborate and learn from each other about how certain support software could assist us in maintaining a more uniform and secure lab computing environment. Most people in our lab users group began to leverage the following enterprise class software packages:

a. ***Symantec Ghost Solutions Suite*** — Fact: Your lab computer's hard drive will fail! A hard drive that costs less than $100 can cause a lab software re-installation costing $1–10K and keep a lab system out of production for quite a few days. We found that by imaging (making a compressed snapshot) of the hard drive of each and every lab computer in our environment and maintaining them systematically we can get rid of that re-installation cost and have the users up and running again in under two hours. This software suite allows us to remotely image and restore all of our workstations hard drives. We can also do it with a few mouse clicks directly from the lab computers desktops so that downtime is momentary and images are refreshed before and after service by the end users themselves.

b. ***McAfee ePolicy Orchestrator*** — These days, a computer simply MUST have some anti-virus software. Most of our workstations had some form of anti-virus software. The problem was that they were inconsistent when it came to virus definitions, patches, and versions. This product allowed us to unify our anti-virus efforts. One thing that we should note is that we do not allow our standard corporate anti-virus policies to be run in our labs. We administer our own and deploy in a much gentler and more flexibly controlled fashion than the normal desktop computing environment does. We always remember that lab systems are different while recognizing the need for standardized methods and technologies.

c. ***VNC/Remote Desktop Connections*** — IT security usually frowns at this technology for the potential vulnerability but if managed correctly these applications can leverage your limited resource support organization greatly. These applications allow you to remotely access the lab computers desktops so that you can see exactly what the user is seeing and fix problems from your desktop. Our service call script has our technicians log into the instrument machine as soon as the call is received. About 80% of our call volume is resolved within 15 minutes or less using these remote tools.

d. ***A patch management solution*** — We use BES BigFix but we started with Shavlik HFNetChk Pro™. Some people simply let their instrument computers update themselves from Microsoft but we have found that this can be very disruptive to research efforts and generate concerns over change management. These OS patch management suites allow us to deploy patches to our instrument machines the way we like to do them. Some machines have patch issues. These machines are noted and excluded from certain patch deployments. All reboots are controlled by the user via dialogs that allow a flexible deployment window and reboot to happen when researchers are not using the machine. If a patch is found to have a software conflict it can be simply rolled off the machine and functionality is restored. For more problematic conflicts, the machine may be restored to its original configuration via our Ghost process.

e. ***Domain Authentication*** — One of the big problems that we ran into early on was the lack of a comprehensive user and policy management system that would be flexible enough to be used in the lab environment. One of the biggest time sinks in our early days was simply managing user accounts and policies. Password resets, user account creation, policies, and permissions were all done on a computer by computer basis. We then implemented an active directory/domain authentication scheme that solved all our problems. Now, user accounts are managed by our main IT organization and are synchronized with the rest of the desktop computing environment but their permissions on each workstation are controlled by us. This allows us the flexibility that we need in supporting such a diverse set of user requirements. We are very mindful of corporate policies and their purposes. We are able to accommodate the necessary policy differences for lab computing utilizing the Windows active directory container features to manage our own policies at a much more granular level.

f. ***Lab Network Segmentation*** — Lab computers are security risks but in a research organization, they are a necessary risk. This can also be the case in other special function environments like manufacturing, security, and building management. We run into trouble when that risk is taken on an enterprise-wide network. One of the major risk mitigation solutions was to segregate our lab machines from the general computing environment. This not only allowed us to satisfy IS security requirements, it made our labs run with less interruption and gave us lab support people more control over what happened in our environment.

There are plenty of options out there for enterprise class solutions to these problems and the ones that are listed here are just the ones that we have found to be effective. Not only that but many of these solutions are probably already available in your IT infrastructure. You would need to "tweek" it for the lab environment but I think with the help of your IT folks you would be able to manage well. Additionally, all of these solutions can be used in a GxP environment with the right amount of validation effort.

The important things to take away from this are the need for collaboration and focus on the business objectives of productivity AND risk management. There is help out there for these problematic instrument computers. You don't have to leave them unmanaged but it does take some work.

Remember, I said that I was going to make simple recommendations, not easy ones. Constructive partnerships, teams, and overlapping expertise remove the support gaps from the lab computing environment. At my particular research site, a team of two and a half (including myself) instrument service engineers implemented each of these solutions for approximately 350 instrument computers over three years. That is in addition to our normal duties of maintaining those instruments, scheduling vendors, doing upgrades, and other general instrument services functions. When it was all done, we had a system in place that allows us to maintain those 350 instrument computers in a manner that maximizes their uptime, minimizes their costs, and does so in a manner that is safe for our network. Additionally, we are well on our way to spreading this lab computer support model to all areas of our corporation. We had a whole lot of help from our IT organizations, lab managers, management, and others that were concerned about this issue. I found that people will come to your aid if you are willing to stand up for the business objectives, ask for help, and take on the challenge. We work in one of the most productive pharmaceutical research centers in the world and there is never a shortage of work to do. If we can do it, so can you.

Anton Federkiewicz *has a B.S. in Chemical Engineering from New Jersey Institute of Technology. He has 12+ years of diversified engineering experience focusing on computer development/support and process automation within the research and manufacturing environments. He is currently the Instrument Services Supervisor at Wyeth Research in Princeton, NJ. He wants you to know that he would welcome your comments, questions, criticisms, or topical conversations at 732-274-4070 or by e-mail at federka@wyeth.com.*

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A LIMS Primer

KNOWING ENOUGH ABOUT WHAT YOU NEED SETS THE STAGE FOR A SUCCESSFUL IMPLEMENTATION.

If you are considering buying or building a LIMS (Laboratory Information Management System) or just wondering what a "LIMS" is, this article is meant to get you started, as well as provide information about budgeting expectations and project activities that you might encounter.[1]

LIMS: WHAT IT IS AND WHAT IT DOES

The main purpose of a LIMS is to track samples through the laboratory. A LIMS commonly allows you to track both the location of samples and how much work has been completed on the sample. It will also enable logging and managing samples, as well as provide a central repository for the tests performed and results gathered.

Minimally, most LIMS typically allow you to track the following:

- Information related to the sample, such as its location or source
- The tests being performed on the sample
- Information related to the tests, such as which lab is doing a particular test or the date the test was finished
- Results, whether results are within acceptable ranges, and the appropriate units for the results

A LIMS usually allows for various types and levels of approval in order to hold back information from its next step. For example, some labs require peer review of all data before the data is sent to supervisors for their review. These types of review rules are common in many LIMS. Auditing data to track "who does what" and allowing electronic signatures are common functions as well.

Increasingly, LIMS allows users to set up role-based security.

These systems can usually perform a variety of calculations. However, even though many LIMS can perform basic statistical calculations, it is more common to purchase dedicated statistical and trending packages so more complex data analyses can be performed. On the other hand, some LIMS dedicated to a particular industry or purpose commonly include functionality that enables certain calculations specific to that industry or purpose. For example, a LIMS designed to be used in drug metabolism studies usually includes better tools for analyzing pharmacokinetic results than a LIMS that is not specifically targeted toward that use.

Many LIMS are integrated with instrumentation or with instrument software in order to electronically gather data. Some LIMS products include this functionality, although add-on products are available to perform these functions when they are not part of the actual LIMS software.

LIMS: WHAT ELSE IT DOES

When a LIMS is created for a specific customer or industry, it is common to include functions needed by that industry or customer. For example, a LIMS that services the pharmaceutical or biotech industries might include drug stability capability, clinical study modules, and/or a dissolution testing function. A LIMS for tracking manufacturing quality might include an interface to manufacturing systems, such as SAP.

Increasingly, LIMS allows users to set up role-based security. This is a significant issue to LIMS system administrators. If this sounds like something that is just "nice to

Gloria Metrick

have," that is not the case when you have many users. Role-based security means is that you can give access to users based on pre-defined roles that they are assigned. So, if you add functionality or make a mistake that must be fixed in the security setup, you can change it once and it affects everyone using that role, rather than having to fix each user's ID separately — a time-consuming process.

Many LIMS can interface directly with a reporting tool or other analysis tools. Many systems allow you to create a 21CFR Part 11[2]-compliant implementation. It is important to note that you cannot purchase a 21CFR Part 11-compliant system, because the way you treat your system determines whether it is compliant. So, it is only possible to purchase a LIMS that is capable of being 21CFR Part 11-compliant. Please note that not every system is capable of this.

LIMS: WHAT IT DOES NOT DO

Most LIMS do a poor job of document management, a function best left to dedicated document management systems. Most LIMS also tend to lack functionality to fully track inventory. Once again, in industries where there are specific and well-defined inventory applications that the system can provide, LIMS for those industries commonly include inventory tracking for those specific purposes, as opposed to providing inventory functionality to track all materials in a laboratory.

TERMINOLOGY

Although the terminology[3] used in the LIMS industry sounds common enough, it is not always straightforward. For example, we often use the word "configuration" to mean not merely pressing a button to set a particular function, but rather, that program code must be written.

A LIMS "sample" is not necessarily the same as what a particular lab might call a "sample." Many systems do not map well to the term "method" either. In LIMS, when we run tests, we usually set up the data that must be captured or calculated, which does not necessarily include the instructions from the method.

As a rule of thumb, define all such words when you begin your project, or at least try to be aware of the terminology used in order to easily implement your purchased software or to define what you are trying to build in your custom software.

WHAT IMPLEMENTATION OPTIONS DO YOU HAVE?

- Buy a system that is so limited or specific that it needs only to be installed. Then, supporting data must be entered into it, and possibly validated, before it is ready to be used.
- Build a system specific for your needs, which also needs to have supporting data entered, and then be validated, if applicable.
- Purchase a flexible system. Then, you would create a scope of the additions or changes you will make, plan your resources, and do the work. This choice has steps similar to those you would take when building your own system, except that your choices are narrower and based on the restrictions of the system. However, if you select a system appropriate for your situation, you should have less programming work to do and the LIMS will make it a positive addition to your laboratory much sooner.

These three options require somewhat different skills on your part. A person or group skilled in one of these methods of implementation does not necessarily have the skills required to support one of the other options.

FINDING A LIMS

Before purchasing a LIMS, list the major properties of your installation. For example, your industry is important, as is the type of lab within the industry, and the number of users you have in your system. Additionally, gather your requirements, not just of the types of lab functions you want the system to support, but also system requirements, such as the type of database you want to use, and whether the system needs to be Web-enabled. These are only a few examples.

Meanwhile, begin your search among the LIMS products at a high level. To do that, you might attend conferences that have LIMS exhibitors. You might begin an online search, as there are a number of Web sites that track available LIMS products. However, keep in mind that no site lists every LIMS vendor.

Once you have narrowed your search down, you can sometimes get good information from the Web sites of LIMS software vendors or at least, request more information from vendors using the contact form on their Web sites. Additionally, if you are looking for a LIMS specific to your industry and think that products are available, talk to other companies in your industry about what LIMS products they use, finding out as much as possible about both their positive and negative experiences.

Some of you are already thinking that your problem is that you do not know enough about what you need in order to start the process. Looking at what different systems have to offer as well as talking to people in your industry about what they are doing with their LIMS will give you a start.

FINDING EXTERNAL ASSISTANCE TO WORK ON YOUR PROJECT

If you need to find external expertise to work on your LIMS, the steps are similar. For example, there are Web sites that list companies that provide various services for your LIMS projects. When you talk to others in your industry about the external assistance they contracted for in their projects, ask for recommendations of both people to consider and those not to consider.

Similar to your LIMS product selection, you will need a list of what you need in outside services. You need to decide what tasks you want done. You also need to determine what skills are required to accomplish those tasks. That way, when potential resources insist that they are right for your task, you can ask some questions about the skills you have concluded are needed for your project. Based on the answers, you can weed-out a few of those people who insist they are experts at everything, but who obviously are not.

This is one of the many reasons why you should not accept resources for your project that you have not interviewed. Although you usually cannot interview specific resources far ahead of schedule, even some last-minute interviews help ensure that you are getting people with the skills you need. This is still not a guarantee, but a last-minute interview is your final opportunity to eliminate bad resources before they start charging you money.

For example, if you need people to write code, you might want to ask if each resource has software development life cycle skills, such as documentation and testing. Never assume resources have any particular background unless you ask them, specifically. There are many people out there who write code, but far fewer know how to test and document code properly. Even if you accept a person who does not have all the required skills, you will be doing so informed of that fact. That will enable you to make accurate decision about the type of supervision they will need, for example

THE PROJECT TIME-FRAME IS USUALLY LONGER THAN YOU THINK

Most of you will need to start looking for a LIMS long before you make an actual purchase of such a system. One common problem is that the budget for the LIMS must be set up in the budget year before you need it. However, by that time, if you do not know what LIMS you want to buy, you might not actually know how much you will need in your budget in order to buy it, nor will you know of the other equipment, software, and services you will need, along with training and support.

Plus, a number of LIMS implementation items take considerably longer than expected, including:

- Loading historical data
- Creating system templates
- Creating report templates
- Setting up trending
- Testing/Validating/Documenting

For example, most projects focus on merely gathering the data into the LIMS as it relates to the work process. If future reporting and trending needs are not considered before the very end, it is not uncommon to end up with a LIMS that is merely an expensive data graveyard — a place where the data go to die and cannot be retrieved in an efficient way.[4] Once such a system is put into place, the reporting function becomes more complicated; thus, takes much longer than planned.

BUDGETING FOR A LIMS SOFTWARE PRODUCT PURCHASE

It is difficult to budget for a future system based only on the number of users and type of system you wish to purchase. Typically, even if you purchase a number of licenses to use the LIMS software product, there are other items and activities that need to be included in your project budget:

- Ongoing product support costs
- Training costs
- Business services, such as help in selecting a LIMS software product, requirements analysis assistance, work-flow analysis, and project management
- Implementation and services, such as design services for new or modified features and programming services
- Validation services, if applicable
- Other documentation services, such as creating user guides and writing system documentation
- Outside software licenses, such as those required to support report development, if the report software is external to the LIMS product

Some of these related items that must be purchased separately tend to depend heavily on the following factors:

- Whether you have internal staff to do the tasks
- Size and complexity of your laboratory
- Any unusual functions your laboratory performs

Keep in mind that a number of these items are required whether you are buying a commercial system or writing your own system.

These are just a few examples of what you should have in mind before you begin your own LIMS project. This will give you enough information to get you started on the process and give you some issues you should begin to think about as well.

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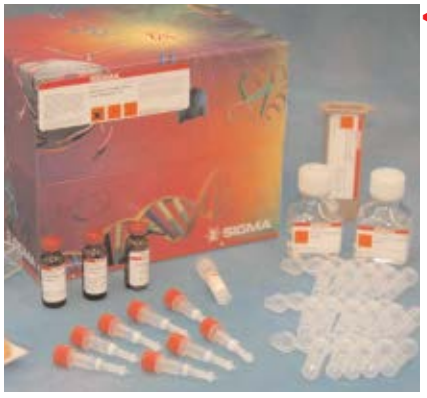

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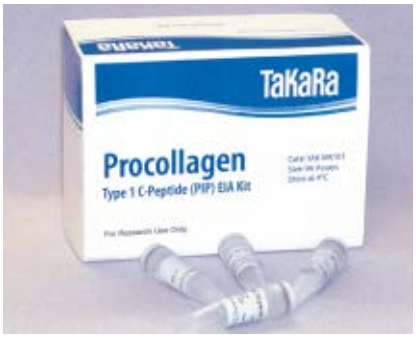

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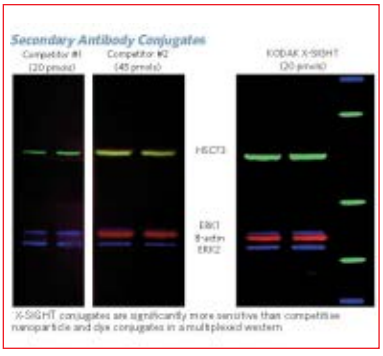

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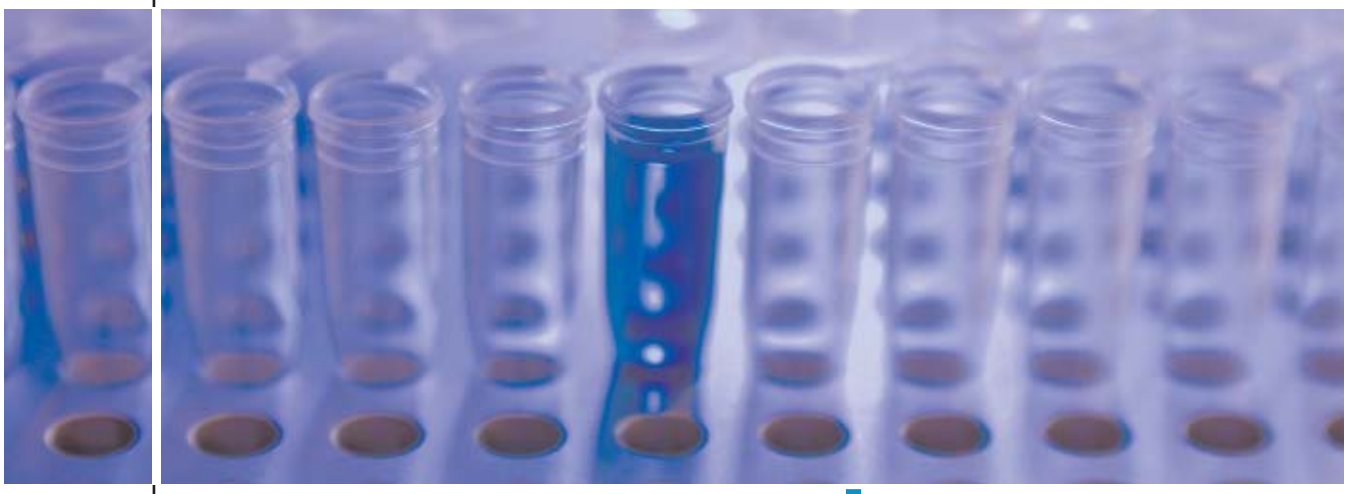

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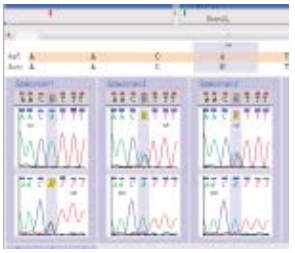

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These powders contribute to experimental accuracy for two-hybrid screening and production reproducibility for large-scale expression. A variety of pre-mixed powders containing vitamins, trace elements, salts, nitrogen, sugars, and a variety of amino acids are available. Custom recipes can also be formulated with no setup fee.

Sunrise Science
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MICROSCOPE

The DM1000 LED is designed for cytology, histopathology, and other clinical and biomedical laboratory applications. The microscope incorporates long-lasting LED illumination, which provides color-neutral illumination and rarely needs lamp replacement. An optional, portable solar power supply is available for field-based applications. Height-adjustable focus knobs can be adjusted to any hand size.

Leica Microsystems
www.leica-microsystems.com

SER/THR KINASE ASSAYS

The HTRF KinEASE™ Platform assesses serine/threonine kinase activity. These assays use a proprietary antibody and a choice of three biotinylated substrates. They provide low enzyme consumption and compatibility with a large range of ATP concentrations. The platform provides results in under two hours and miniaturization down to 4 µL. The assays can be used for serine/threonine kinase monitoring, high-throughput kinase screening, and kinase selectivity and profiling.

Cisbio International
www.htrf.com

Feedback Forum

In response to our March 2007 article, "Biomedical Light Microscopy Imaging Facility Management," by George McNamara and Carl A. Boswell, Tom Keller, Ph.D., Oregon Health & Science University, writes, "The article by McNamara and Boswell on setting up a microscopy core facility (www.labmanager.com/articles.asp?pid=70) had some good tips. However, it also made an erroneous statement regarding the thorny problem of funding new equipment. They stated that you can add a component to your charge back fee for the purchase of new equipment:

INCOME AND COSTS SCHEDULE ...

"Publicly funded resources are not allowed to generate a budget surplus, but arrangements (e.g., accumulated depreciation) can be made to set aside income to fund future needs, such as upgrades or new instruments."

The first half of this sentence is true, however, the second part, in bold, is incorrect and can get the institution into trouble if they are audited by NIH."

The authors reply, in accordance with their University Budget Office:

It seems that in the language of the A21 Federal Guidelines from the Office of Management and Budget regulating the use and spending of public funds, there is an allowance for depreciation of capital equipment. A depreciation rate is established by the budget office, and that rate can be incorporated into user fees and assigned to an "equipment reserve account." The monies may only be used for replacement or upgrade of current equipment. The accumulation of funds within these accounts have been audited and approved at our institution. My wording in the article may have been imprecise, but the above is what I meant to say. (Contributed by Carl Boswell on behalf of the authors.)

lab agenda

SEPTEMBER 13, 2007
DEVELOP and SUPPORT: Building on the Innate Skills of Your Staff to Prepare them for the Demands of Management
Web Conference – 1:00 PM EST
www.viconpublishing.com/audio.asp

SEPTEMBER 19, 2007
Laboratory Environmental, Health, and Safety Compliance Strategies
Web Conference – 1:00 PM EST
www.viconpublishing.com/audio.asp

SEPTEMBER 26–27, 2007
NIH Research Festival
Boston, MA
researchfestival.nih.gov

OCTOBER 2–3, 2007
Joint ELRIG and SBS Meeting: Drug Discovery
European Laboratory Robotics Interest Group and Society for Biomolecular Sciences
Nottingham, UK
www.sbsonline.org

OCTOBER 2–4, 2007
L.A.B. 2007
London, England
www.lab-uk.co.uk

OCTOBER 13–16, 2007
ACIL Annual Meeting
American Council of Independent Laboratories
Atlanta, GA
www.acil.org

OCTOBER 14–18, 2007
FACSS 2007
Federation of Analytical Chemistry and Spectroscopy Societies
Memphis, TN
www.facss.org/facss/index.php

OCTOBER 23–27, 2007
ASHG Annual Meeting
American Society of Human Genetics
San Diego, CA
www.ashg.org/genetics/ashg/menu-annmeet.shtml

OCTOBER 25, 2007
Lab Manager Boot Camp
Lab Manager Magazine®
Waltham, MA
www.labmanagerbootcamp.com

NOVEMBER 1, 2007
Congratulations, You're a Supervisor. Now What? (Proven Rules New Managers Should Know)
Web Conference – 1:00 PM EST
www.viconpublishing.com/audio.asp

NOVEMBER 3–7, 2007
Neuroscience 2007
Society for Neuroscience
San Diego, CA
www.sfn.org

NOVEMBER 7–8, 2007
SBS Symposium: Back to Pharmacology
Society for Biomolecular Sciences
Anaheim, CA
www.sbsonline.org

NOVEMBER 7–9, 2007
28th Annual ALMA Conference
Analytical Lab Managers Association
San Antonio, TX
www.labmanagers.org

NOVEMBER 11–15, 2007
2007 AAPS Annual Meeting & Expo
American Association of Pharmaceutical Scientists
San Diego, CA
www.aapspharmaceutica.com

How it Works

High Containment at Low Cost

Problem: Today, many laboratories need a small enclosure to establish a clean room environment for high hazard containment.

Contamination from environmental exposure can change reaction results and physical properties.

Applications involving costly ultra-pure chemicals or nanoparticulates are examples. In addition, many of these chemicals and new compounds have unknown toxicology. Researchers must take appropriate measures to protect their results, as well as themselves and the laboratory environment. However, few labs have the resources to dedicate an entire room for these ultra-clean applications.

Solution: The Precise™ HEPA-Filtered Glove Box addresses this need by providing ISO Class 3 clean room conditions in an affordable, versatile, and efficient containment device. Its shell of rotationally molded medium density polyethylene is chemical resistant, strong, and lightweight.

Particulate performance tests confirm the HEPA-Filtered Glove Box's ability to quickly create and maintain clean room conditions during positive and negative pressure operations.

Initial airborne particulate levels within the main chamber exceed ISO Class 5 conditions (= Class 100), and achieve ISO Class 3 conditions (= Class 1) at all operational airflow speeds, in both positive and negative pressure operational conditions. This performance equates to 1 particle at 0.5 micron per minute per cubic foot of air volume.

The Precise™ HEPA-Filtered Glove Box provides ISO Class 3 clean room conditions in an affordable, versatile, and efficient containment device.

The operator controls the main chamber dilution rates using a quiet, adjustable speed built-in blower. The main chamber is 13 cubic feet, resulting in total air volume changes between 1–7.69 per minute.

The blower pulls room air into the main chamber through an inlet HEPA filter, producing a negative pressure ultra clean environment. Particulates generated within the main chamber are then trapped on the exhaust HEPA filter. For high hazard applications, the glove box exhaust vents to a negative pressure exhaust system.

The Glove Box can adapt to changing applications. Re-routing the blower discharge to the inlet HEPA filter positively pressurizes the main chamber, resulting in ultra-clean conditions for handling lower hazard materials.

The HEPA-Filtered Glove Box is leak-tested with helium validating glove box seals to a leak level of 1x 10–3 mL/sec or less. An extensive validation test report including data on gas dilution rate, ASHRAE 110 containment, smoke removal, blower curves, noise levels, vibration, lighting, helium leak rate, and oxygen leak rate is available at www.labconco.com.

The Precise HEPA-Filtered Glove Box provides a cost-effective, versatile, chemical-resistant containment system for researchers requiring particulate protection for themselves and their sensitive materials.

For more information, go to www.labconco.com

Upcoming Web Conferences

DEVELOP and SUPPORT:

Building on the Innate Skills of Your Staff to Prepare them for the Demands of Management

Date: September 13, 2007
Time: 1:00PM ET

By participating in this web conference, you will be able to:

- Develop a person-specific plan for the success of your supervisory candidates.
- Build specific skills.
- Nurture them through their first few months on the job.

***Ron Pickett** is a consultant with more than 30 years of experience. He has written a column for CLMA publications for more than 10 years and is a frequent speaker at national and state meetings. He has been closely involved in establishing formal and informal leader identification and development programs in large and small organizations. This challenging process will help you take a clear and honest look at your staff and develop quick and simple individualized development plans.*

Laboratory Environmental, Health, and Safety Compliance Strategies

Date: September 19, 2007
Time: 1PM ET

This web conference will review common US federal laws pertaining to the research and process laboratories and provide attendees with practical compliance solutions. The speaker will discuss laws and compliance solutions from OSHA, the EPA, the US Center of Disease Control and Prevention, US Nuclear Regulatory Commission, and the US Department of Homeland Security.

Topics discussed include:

- Whether lab safety or hazcom applies for occupational exposure to hazardous chemicals in laboratories
- Recording and reporting occupational injuries and illnesses
- Assessing need, selection, and training for personal protective equipment
- Storing, using, and the limitations on flammable and combustible liquids
- Regulated areas for carcinogens
- The Resource Conservation and Recovery Act and the Clean Water Act
- The approvals needed to work with select biological and toxic compounds
- The Standard for Protection against Radiation and the Chemical Facility Anti-terrorism Standard

***George Bleazard** is currently the Corporate Director of Environmental Compliance, Health, Safety, and Security for Sigma-Aldrich where he is responsible for worldwide environmental compliance, occupational health and industrial hygiene, safety, and security functions. In 2003, he led the environmental waste minimization efforts resulting in the company's St. Louis facility receiving the EPA's Region Seven "2003 Pollution Prevention Award". He obtained his Bachelor of Science and Masters of Science from Central Missouri State University and has also worked for Pfizer, Hoechst-Celanese Corp., Monsanto, and the St. Louis County Health Department.*

Register at www.viconpublishing.com/audio.asp

Vicon Publishing, Inc
WEB CONFERENCES

Drafting Phase

Welcome back you SOP warrior. This month we continue our journey through the PDCA framework by working on the DO phase. Remember Figure 1, our model for continuous improvement? Well, during the DO phase you'll breathe life into your PLAN by drafting your SOP.

Armed with management's purpose and scope, the drafting phase begins. Yogi Berra once said, "If you don't know where you're going, when you get there you'll be lost." Without a clear title, purpose, and scope for your SOPs it is very likely that they will be of limited value. This doesn't mean that you can't make adjustments along the way, but a good idea the beginning will serve you well. You might even consider this a mini PDCA!

Every SOP is built to accomplish something. In laboratory management, there are millions of things to control (slight exaggeration intended). So, best to keep it simple for success in providing direction and control. Find the best route from Point A to Point B and write it down. That becomes your draft SOP. The drafting phase consists of determining information needs and collecting information, drafting the SOP, and conducting a peer review.

INFORMATION NEEDS AND COLLECTING INFORMATION

To write effective SOPs, information needs to be collected in two broad categories — technical (or content) information and user information categories. Both categories are important. An SOP that is technically accurate, but cannot be understood by the user is an ineffective SOP. On the other hand, a well-written user friendly SOP that is technically inaccurate or incomplete can have serious consequences. So from a planning standpoint the who, what, where, and how of collecting information for the SOP has to be planned out.

Figure 1. Plan-Do-Check-Act (PDCA): Time-honored Model for Continuous Improvement

The technical information to be collected depends on the subject of the SOP. Technical information has to be accurate and current. Sources of such information include vendor manuals, regulatory documents, Material Safety Data Sheets (MSDS), drawings, subject matter experts, facility, or contractual requirements (statements of work, facility policies, and directives} and related SOPs.

For user information consider readability factors and task-related factors. Readability is the quality of written language that makes it easy to read. Readability factors include:

- Grammar, punctuation, and format
- Reader's experience with the subject
- Age and education level
- Cultural background and language of origin
- Complexity of task

Readability measures are primarily based on factors such as the number of words in the sentences and the number of letters or syllables per word (i.e., as a reflection of word frequency). Two of the most commonly used measures are the Flesch Reading Ease formula and the Flesch-Kincaid Grade Level. Microsoft Word offers a handy way check the readability of your SOP. Go to Tools – Options – Spelling & Grammar and turn on Show Readability Statistics. Then run Spell Check – F7. Out comes the ease at which your SOP can be read and at what grade level it is oriented. It also tells you whether you were writing in the passive or active voice (an article for another time).

So how did this article do? If this were an SOP, not so well. The Flesch Reading Ease was about 52 and the Flesch-Kincaid Grade Level just over 9th grade. The ease level should be over 60 and for SOPs the grade level should be about 7 and 8. Remember you're not writing a book or

Norm Moreau, PE

a thesis. You are writing a document that will help someone to successfully complete a serious of steps or tasks. The longer the sentences and the more complex terms used, the more likely confusing and misinterpretation will occur.

These and other readability factors are simply meant as a guide — use them this way. In the management of laboratories there are many technical terms that are long and contain many syllables. If they are the right term, use them.

FOR TASK-RELATED FACTORS CONSIDER:

- The education and experience of the person doing the task
- The workflow or sequence of the tasks to be performed
- Health and safety always have to be foremost on everyone's mind

In today's information connected world there is no reason to start writing an SOP from scratch. Search the web for a title that is similar to what you would like to write and you'll have your starting point. One caveat, watch for copyright considerations.

DRAFTING THE SOP

At this point the information that has been collected and is ready to be translated into your SOP. When drafting the SOP consider the following:

- Procedure format
- Level of detail
- Document design
- Writing style and language

So is that it for the DO (drafting phase)? On no, not at all. I'd to talk in more detail about drafting methods such as flow charting and mind mapping. We also haven't talk about peer reviews and you probably want to know more about why format matters and writing styles — yes all things to come.

Norm Moreau *is a consultant and trainer known for developing SOPs and implementing SOP programs that demonstrate GLP/GMP and nuclear QA compliance. His products and services are used to achieve ISO 9001 registration and ISO 17025 accreditation or by organizations that simply want to improve their operational efficiency and effectiveness. Since 2000, Norm has been offering the Writing SOPs that Work workshop at the National Meetings of the American Association for Laboratory Animal Science (AALAS). He welcomes comments, questions, even criticisms and can be reached at nmoreau@theseuspro.com.*

Glenn Ketcham, CIH and Vince McLeod, CIH

Lucy in the Lab with Diamonds

We all know how diamonds are formed. You take a lump of carbon and subject it to intense pressure and high temperatures and magically those carbon atoms are pressed into a diamond. The diamonds we are going to form will be a tad easier.

This month's safety column is the third in our series on safe laboratory chemical management. The first article explained that proper management of laboratory chemicals begins with a complete, up-to-date, and accurate chemical inventory. Our second article was a tutorial on understanding material safety data sheets. This issue we are going to discuss the National Fire Protection Association (NFPA) hazard diamond, sometimes referred to as the fire diamond, and how to decipher the information it contains.

CLASSES AND THE NFPA HAZARD DIAMOND

Most chemists and experienced laboratory managers know that there are four basic categories of chemicals: toxic, corrosive, flammable, and reactive. However, in our chemical world there are many additional categories and subsets of these main four. We should also keep in mind that many chemicals exhibit a combination of properties and would fall into more than a single class or category. These four properties are the foundation of the NFPA hazard diamond. In addition, these four categories are the main criteria used to define wastes as hazardous under the federal Resource Conservation and Recovery Act (RCRA). The hazard diamond has gained wide acceptance and most manufacturers include it on their labels when appropriate. Figure 1 shows the layout of the different sections and our discussion will start at the top and work clockwise around the diamond.

Figure 1: The NFPA Hazard Diamond

FLAMMABILITY

The top of the diamond indicates the flammability hazard. The chemical is rated from zero to four. A zero means the material will not burn under most common circumstances. Examples include hydrogen peroxide and sodium hydroxide. A one indicates the material will ignite and burn at temperatures greater than 200 °F. Materials that fall into this category are glycerine and propylene glycol. A two indicates substances that will burn at temperatures less than 200 °F, like naphthalene, octyl alcohol, and nitrobenzene. A rating of three denotes materials with flashpoints below 100 °F, such as xylene, amyl acetate, and butyl alcohol. Finally, a four indicates extremely flammable substances. These are materials like acetone, ethyl ether, acetylene, and cyclohexane.

Flammability may be the single most hazardous characteristic causing more injuries and damage than any of the others in the diamond. If there is anything other than a zero in this part of the diamond make sure to use this material with adequate ventilation, clean up spills immediately and, above all, keep heat and flame well away from the area of use.

REACTIVITY

Moving clockwise, the next part of the hazard diamond designates the potential reactivity of the material, which is also rated from zero to four. Zero indicates a stable chemical under most all conditions even fire. Substances that are normally stable but can become unstable when heated or may react with water, but not violently, are rated a one. Chemicals that are rated a two are normally unstable and readily undergo violent decomposition. They may also react violently with water. Materials with a rating of three are capable of an explosive reaction or detonation if subjected to a strong initiating source such as heat or shock. A four indicates substances that are readily capable of explosive decomposition or detonation at normal temperatures.

For illustration of the reactivity consider the following examples. Liquid nitrogen would receive a zero rating. It is stable, non-flammable, and non-reactive with water. Phosphorus (red or white) is rated a one since it

can become unstable at elevated temperatures. Calcium metal rates a two. Less reactive than sodium, it reacts violently with water, alcohols, and other materials and burns in air. Fluorine gas is an example of reactive material rating a three. It is the most reactive non-metal, decomposes water to produce hydrofluoric acid and other hazardous compounds, and reacts vigorously with most oxidizable substances at room temperature, usually with ignition. An example of a class four reactive substance is trinitrotoluene or TNT. We are all familiar with its explosive properties.

SPECIAL HAZARDS

At the bottom of the diamond is the white section. This section is used to denote special hazards. NFPA 704, Standard System for the Identification of the Hazards of Materials for Emergency Response, mentions only two approved symbols:

OX This denotes an oxidizer, a chemical which can greatly increase the rate of combustion or fire. And,
W This means the substance is incompatible with water. It indicates a potential hazard using water to fight a fire involving this material.

Some organizations and manufacturers use additional symbols to indicate hazards associated with the substance.

HEALTH

The final section of the diamond is the blue section on the left hand side. This area denotes the health hazard of the compound and is also rated from zero to four. A zero indicates no toxicity and no additional hazard beyond normal combustible materials under condition of fire. A one means the material is slightly toxic and usually considered innocuous when used responsibly. It may cause some irritation, but only minor even without treatment. Moderately toxic materials are rated a two and may cause temporary incapacitation or injury with continued exposure unless medical treatment is given. A rating of three indicates a serious toxic material that can cause injury upon short exposures even if medical attention is given. Deadly or extremely toxic materials rate a four. Very short exposures could result in death or serious injury even with medical treatment.

We know you would be disappointed if we did not provide examples for the different health hazards as we have done for the flammables and reactives, so here goes. Peanut oil is an example of a material that would rate a zero on the health scale. Turpentine would rate a one being irritating to skin and mucous membranes. Ammonia gas would rate a two since it is definitely irritating and corrosive, but generally regarded as nonflammable unless mixed just right in air. Also, ammonia has an exposure limit of 50 ppm and is immediately dangerous to life and health (IDLH) at 300 ppm. Extremely corrosive chlorine gas ranks a three for health hazard. It can form explosive mixtures and cause fatal pulmonary edema. The OSHA permissible exposure limit (PEL) is 1 ppm and the IDLH limit is only 10 ppm. An example of a health hazard four substance is arsine gas. A colorless gas with a mild garlic odor, it is extremely poisonous. For comparison, the OSHA PEL is a diminutive 0.05 ppm and arsine is IDLH at only 3 ppm.

ACID	This indicates that the material is an acid, a corrosive material that has a pH lower than 7.0
ALK	This denotes an alkaline material, also called a base.These caustic materials have a pH greater than 7.0
COR	This denotes a material that is corrosive (it could be either an acid or a base).
	This is a another symbol used for corrosive.
	The skull and crossbones is used to denote a poison or highly toxic material. See also: CHIP Danger symbols.
	The international symbol for radioactivity is used to denote radioactive hazards; radioactive materials are extremely hazardous when inhaled.
	Indicates an explosive material. This symbol is somewhat redundant because explosives are easily recognized by their Instability Rating.

Figure 2: Some additional symbols to indicate hazards associated with a substance.

Now you understand diamonds, those that provide colorful gems of knowledge. Be on the lookout for them and pay attention to what they are telling you. Hill Street Blues fans will remember Sergeant Esterhaus said it best, "Let's be careful out there."

References

1. Standard System for the Identification of the Hazards of Materials for Emergency Response, National Fire Protection Association, Publication 704. http://www.nfpa.org/aboutthecodes/ AboutTheCodes.asp?DocNum=704.
2. NIOSH Pocket Guide to Chemical Hazards. National Institute of Occupational Safety and Health. Publication 2005-149. http://www.cdc.gov/niosh/npg/.
3. The Merck Index, an encyclopedia of chemicals, drugs and biologicals, 14th edition. Merck & Company, Inc. Rahway, N.J., 2006.
4. OSHA Hazard Communication Standard - http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10099.

Glenn Ketcham *is a Certified Industrial Hygienist with 22 years experience in the health and safety field. He is currently the Risk Manager for the University of Florida with responsibility for the loss prevention, ergonomics, disaster preparedness, and the occupational medicine surveillance programs. He has managed the laboratory safety programs for both the University of California, San Diego (UCSD) and the University of Florida. In addition, he served as an industrial hygienist with federal OSHA compliance and has a masters 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 17 years of occupational health and safety experience in academic research with focus in the research laboratory. His specialties are in hazard evaluation and exposure assessments.*

Retaining Institutional Knowledge: What Every Lab Manager Can Learn from the NFL's Recruiting Secrets

The start of another NFL gridiron season is only a few precious weeks away, and if you're a loyal football fan, you may already have some opinions about how your favorite team will play this year.

But you don't have to be a diehard pro football devotee to have witnessed some of the disturbing headlines involving two exceptional athletes who have proven themselves utterly unfit for the responsibilities that come with being a modern-day role model for thousands of young fans.

The challenges now faced by their respective teams are not unlike the kind of issues facing employers who've invested too many resources on too few people, who've failed to develop talented lab managers from within, who live comfortably with mediocrity, and who fail to recognize when one misfit begins to degrade workplace culture.

The latter can't be overlooked because of how issues invariably surface whenever the organization fails to holds one or more stars accountable for their actions because they are key performers.

The keys to success in professional football, it turns out, are remarkably similar to the keys to success in business, because of the importance of having the best-skilled players in the most critical roles. And the way NFL teams draft and recruit talent can offer some compelling insights for lab managers concerned about keeping their workforce on the leading edge.

So says executive recruiter Isaac Cheifetz, author of *Hiring Secrets of the NFL: How Your Company Can Select Talent Like A Champion* (Davies-Black Publishing), which is due in print next month, just in time for the start of the looming NFL season.

Cheifetz has recruited managers for technology and consulting companies for most of the past 20 years from his office in Minneapolis. And given that he's originally from New York, it hasn't been easy for him to watch the New England Patriots develop a reputation for building the quintessential talent pipeline on their way to three Super Bowl titles over the past six seasons.

No, the Patriots haven't built a winning team based on their picks in the annual NFL draft, which is really a lottery for losers — that is, for teams who need special help building a winning program.

The Patriots have positioned their team for success by creating a culture that puts the team before the individual, by taking a chance on that demands each starter be backed up by a hardworking

"What the Patriots do really well is…they're really great at taking people and leveraging their strengths in their system," says Cheifetz, who cites management guru Peter Drucker by invoking this important team-building consideration: "'What does he or she do well and how can we leverage that?'"

The author says the Patriots have proven that you shouldn't have to pay a king's ransom to recruit top performers, he adds. That's because hustle, intelligence, and good (not exceptional) physical ability can go a long way when you're part of a system, a development pipeline, and a culture that demands personal excellence from everyone on the team.

What It Means For Your Career: It's no coincidence that market-leading companies are also the ones that invest the most time and resources in their recruiting, interviewing and candidate assessment. If you're part of an organization that relies too much on the annual campus draft or on lab superstars recruited exclusively from the outside, that should tell you something about the weakness in your employer's current system. Top performers gravitate to winning teams, and winning teams know how to recruit, retain and reward top performers. If you're not already on a team of winners and in a position to learn and boost your own skills, it may be time for you to consider a career move.

Joseph Daniel McCool *is a columnist and contributing editor with BusinessWeek and a writer, speaker and trainer on recruiting best practices, talent management and corporate leadership succession. He is the author of a forthcoming book, Deciding Who Leads: How Executive Recruiters Drive, Direct & Disrupt the Global Search for Leadership Talent, to be published next spring. He also works as senior contributing editor with ExecuNet, a leading business, recruiting and management referral network. Contact him at JoeMcCool@comcast.net.*

Joseph Daniel McCool

Conducting R&D Staff Reductions

R&D staff reductions have become a fact of life in many organizations. Mergers, divestments, and other forms of organizational restructuring plus outsourcing and technological changes have made staff reductions common events even in profitable firms. However, conducting staff reductions remains a very unpleasant duty for most lab managers. Perhaps this is one reason why so many staff reductions are planned and executed poorly. Carefully managing staff reductions can maximize their intended effects: reducing R&D expenses and increasing focus on high growth areas. Careful management also can reduce adverse effects on: employees losing their jobs; morale and productivity of the remaining R&D staff; workflow disruption; quality of customer service; your own morale as manager.

To accomplish these goals, communication with your staff members must be open and honest. Tell them as much as you can. Admit when you don't know something. However, don't let your sympathy towards employees worried about their job security lead you to disclose confidential information or make promises you can't keep.

DESIGNING THE STAFF REDUCTION

There are two basic options to designing staff reductions. The first is an across the board percentage reduction in each unit of the organization. This design is relatively easy to implement but provides poor control over the need to retain essential skills and minimize adverse effects on R&D programs with the most business growth potential.

The second option is to retain people with essential skills on projects with the most growth potential and focus staff reductions elsewhere. These are more difficult to execute because of the need to prioritize R&D programs and the often different skills of the laboratory personnel staffing these programs. However, when implemented well, this approach provides better control in retaining essential skills and minimizing adverse effects on programs with the most business growth potential.

Managers should base decisions on which employees should be retained on the above design principles: each employee's previous contributions, technical and interpersonal skills, and the need for information retention within the organization. To aid in making good decisions, managers should work with their lower level managers and team leaders. These discussions should be private and the need for confidentiality should be stressed.

There are advantages to executing a staff reduction all at once to end staff members' uncertainty and distraction. However, by staging the staff reductions rather than performing one massive one, managers can begin reducing R&D spending more quickly and think more deeply about which reductions need to be made in each stage of the process.

THE DEVIL IS IN THE DETAILS

In designing the staff reductions, the devil is in the details. Important questions to answer include:

- What R&D activities can be cut back with the smallest negative impact on current and future business?
- What essential skills must be retained within the organization?
- What skills and programs can be outsourced more cost effectively than retained within the organization?
- What programs and activities can be eliminated with the least harm to the organization?

Before making these determinations, managers must develop a new vision for the organization and redefine its goals. Work processes need to be redesigned to be commensurate with the resources remaining after the downsizing.

EXECUTING THE DOWNSIZING

Having established the design of the staff reduction, which employees will be retained and the shape of the future organization, decisions that have to be made include: designing the severance package ; financial aspects; advance notice ; outplacement services; designing the communications process with both the departing employees and the remaining R&D staff.

Severance pay calculations are usually based on two weeks pay per year of service although three weeks pay is not uncommon. Two to four weeks advance notice is most common. However, some firms still prefer to escort employees from the premises immediately after informing them of their job loss.

Outplacement services are good for the morale of both retained and departing employees. These services can enable departing employees to update their job-hunting techniques, and identify their most marketable skills.

AFTER THE DOWNSIZING

Instituting redesigned work processes to improve focus and productivity should be done as soon as possible after the downsizing. So should reassigning staff members to projects that will provide the greatest financial reward to the company in a timely way. Low productivity activities should be reduced, eliminated, or outsourced quickly. To aid in implementing these changes quickly after the downsizing, decisions regarding these issues should be made before the downsizing begins.

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

John K. Borchardt

Achieving Optimum Accuracy with Adjustable Volume Pipettes

Air-displacement pipettes are among the most commonly used lab tools. Given most scientists' familiarity with these instruments, the selection of the right pipette for any particular task may seem obvious. Yet our experience is that while many scientists want the most accurate pipettes, many also misunderstand a key specification, and that misunderstanding can compromise their results. Specifically, it is vital to understand how "accuracy" specifications are calculated to select the pipette for any particular task that will provide the most reliable results.

WHAT IS AN "AIR-DISPLACEMENT" PIPETTE?

Most common laboratory pipettes (single- and multi-channel, mechanical, and electronic) are air-displacement pipettes. They are so-named because they operate by having a piston of consistent diameter pushed through a seal to move a column of air. The movement of the air column, in turn, moves the liquid to be measured into and out of a disposable polypropylene tip.

To aspirate once the tip is attached, the piston is moved forward from its resting position through the seal to push air out of the pipette. The tip is placed into the liquid to be aspirated and the piston is allowed to move backwards, powered by a low force spring. This creates a vacuum in the pipette tip and atmospheric pressure pushes the liquid to be pipetted into the tip, much as a U-tube manometer responds to pressure differentials.

Adjustable volume pipettes work with the assumption that the piston is completely uniform so that the relationship between the distance traveled by the piston and the volume of air (and thus, liquid) moved is linear. To adjust the pipetted volume, a screw mechanism is used to adjust precisely the distance the piston travels; cut the distance traveled in half, and you cut the pipetted volume in half, and so on.

HOW ACCURATE ARE AIR-DISPLACEMENT PIPETTES?

For the most common volumes handled by adjustable-volume microliter pipettes (from about 50 µL and higher), most of the inaccuracy of the instrument can be thought of as a constant volume[1] that applies through the entire volume range of the instrument. This volume of inaccuracy is a constant regardless of the volume setting on the instrument.

Table 1. Volume of inaccuracy of a 1,000-µL adjustable volume pipette with "1.0% accuracy" at nominal volume

Volume Setting (µL)	Percent of Nominal Volume	Volume of Inaccuracy (µL)	± % Inaccuracy
1,000	100	10	1.0
900	90	10	1.1
500	50	10	2.0
200	20	10	5
100	10	10	10
50	5	10	20

Akbar Anwari and Peter G. Coffey

On the other hand, when the "accuracy" [2] of an instrument is shown in catalogs and other literature, it is often displayed as a percentage. The percentage is based on the nominal capacity, or maximum volume, of the instrument. This one specification is responsible for a lot of misunderstanding. As noted above, the instrument's volume of inaccuracy remains constant through the volume range, so that fixed volume of inaccuracy represents a larger percentage inaccuracy for lower volume settings on the same pipette (Figure 1). For example, a pipette with published "1% accuracy" at full scale translates to a 2% inaccuracy at 50% of full scale, and a 10% inaccuracy at 10% of full scale (Table 1).

Because of this phenomenon, the most accurate measurements will be made when operating a pipette as close to the nominal capacity (maximum volume) as possible. In fact, when different pipette manufacturers choose to specify a lower volume limit of 5% or 10% of maximum scale, the choice may have little to do with the quality of the pipette or the accuracy at those low volumes, and more to do with the manufacturer's perception of what constitutes "acceptable" inaccuracy in scientific work.

WHICH PIPETTE FOR WHICH TASK?

Most labs need to pipette a wide range of liquid volumes and are equipped with a set of pipettes that cover the volume range. Suppose you have three pipettes with nominal capacities of 1–10 µL, 10–100 µL, and 100–1,000 µL, respectively, and that each pipette has a specification of 1% accuracy. Based on the discussion above, we know that "1% accuracy" refers to the volume at nominal capacity, and that at the bottom of the range, the volume of inaccuracy will be the same, and the percent inaccuracy ten times as high.

Now imagine a case in which you need to pipette 200 µL. You have three choices. You can rely on the 1,000-µL pipette, and know that you will have an accuracy of ±10 µL, or 5% at this volume. You can select the 100-µL pipette, and have an accuracy of ±1 µL (1%), but have to pipette twice (for a total inaccuracy of ±2 µL) to achieve the desired volume. Your third choice is to buy a new pipette with a nominal volume (or fixed volume) of 200 µL, with ±1% accuracy (2 µL). Any one of these choices may be acceptable, depending on your budget and need for accuracy and productivity, but it is critical to understand the choice you are making so that you make the right choice for your lab.

The illustration is simplest, as above, when one option is to purchase a pipette with the exact volume you need. In most cases, the desired volume falls somewhere within the volume ranges of several pipettes. For example, 20 µL can be pipetted with 2–20 µL, 5–50 µL, or 10–100 µL pipettes. We know that the highest accuracy will be achieved with a 2–20-µL pipette, but if you don't have such an instrument, it will always be more accurate to choose instrument with the lowest volume relative to your aliquot volume. In this case, the 5–50 µL will be a better choice than the 10–100 µL.

EQUIPPING A NEW LAB

In view of the foregoing discussion, one can equip a lab with a range of pipettes that just cover the anticipated pipetting range. In such a case, it is critical to realize that the accuracy of the work in that lab will vary greatly depending on whether a particular sample can be pipetted at the top, middle, or bottom of the ranges of the available pipettes. If budget permits, the accuracy can be made much more consistent (and, typically, better) by having a set of pipettes that overlap in their volume ranges. For example, if your lab has pipettes of 1–10 µL , 10–100 µL, and 100–1,000 µL , equipping a lab with just two more pipettes of intermediate volumes (say, a 5–50 µL and a 20–200 µL) will ensure that many more procedures can be performed at accuracies close to the manufacturer's percent accuracy specification for your pipettes. Without these two additional pipettes, a lab may be forced to run some tests that risk inaccuracies of up to ten times the nominal volume specification, or to pipette repeatedly using a smaller volume pipette.

NOTES

1. *Inaccuracy is the difference between the actual pipetted volume and the intended volume. Since this value is calculated as an average, the actual volume of inaccuracy in individual pipetted volumes varies. For this discussion we are referring to the specification represented by the average inaccuracy. Smaller, but significant, contributors to manufacturers' inaccuracy specifications are the precision of manufacture and — in volumes below 50 µL — factors such as the compressibility of air and capillary action. Outside of the optimal conditions of the manufacturer's calibration lab, user technique and the quality of tips used are also significant contributors to inaccuracy.*

2. *The "accuracy" specification used to describe a pipette is technically the accuracy tolerance, that is, the absolute value of the anticipated deviations from the intended volume. In this article, since we are repeatedly referring to that volume error, we refer to the "inaccuracy" of the pipette except where we refer to published specifications.*

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George Bleazard
Corporate Director of Environmental Compliance, Health, Safety, and Security
Sigma-Aldrich

Farming is hazardous in nature, so as a farm boy in rural Missouri, George Bleazard received an early education in occupational safety and health the hard way.

A cousin suffocated to death in a grain bin, entangled in an augur. Then there was the time Bleazard was fertilizing the fields with hydrous ammonia before the spring planting, when the main line to the tank suddenly severed. He leapt from the tractor and "ran like the dickens" to shut off the fuel valve, racing to stay ahead of an advancing ammonia cloud.

"As with any accident, it was very easily preventable," says Bleazard, whose restive mind entertained notions of a career that melded his interests in science and worker well-being.

It all clicked after a college counselor floated the idea of a career in industrial hygiene.

"My first thought was it meant cleaning the teeth of industrial gears or something. I had no idea what industrial hygiene was."

Now he targets those with imperfect ideas about workplace hazards; as Corporate Director of Environmental Compliance, Health, Safety, and Security for Sigma-Aldrich Corporation, Bleazard is responsible for good health and safety at company operations in 35 nations.

Throughout the industry, laboratory safety and environmental programs are moving from the backwater toward the mainstream of management functions. The pursuit of safe science is evolving from its traditional reactive focus on injuries and accidents, and moving toward a more effective systemic approach and a proactive orientation. They work, says Bleazard, to the extent "these systems involve everybody" in the safety process.

And the industry continues to add resources, both as regulatory and public scrutiny increase, and as the issue of safety is increasingly perceived to add value to the corporate bottom line. But while the new wave of behavioral modification systems is promising, Bleazard says there is no silver bullet to assure lab safety, for one simple reason: to err is human.

"If you look at accident statistics in an industrial environment, eight out of ten relate to the human element. So even if you properly design and build and maintain equipment and facilities, you still must address that other 80%," using combinations of procedures, tools, training, competency tests, performance management, and observation monitoring.

To deal with downside of behavioral training — it takes workers away from the bench and decreases productivity — labs are increasingly turning to outside software vendors. Sigma-Aldrich developed its own e-learning program, enabling its workforce to "learn at their leisure," said Bleazard.

He also touts the ability of software to help bridge communication gaps in increasingly multilingual and diverse laboratory settings.

In the post 9/11 regulatory climate, compliance has become a moving target, says Bleazard. Sigma-Aldrich supplies more than 180,000 different products to the research science community and other industries. "If there's any regulation out there that applies to products, it's fair to say it covers us," says Bleazard.

It is bad enough that managers have to contend with regulations that sometimes appear to conflict, said Bleazard, citing OSHA's hazardous communication standard and its laboratory safety standard as an example.

But regulatory complexity is being ratcheted up by security concerns. "There is a new Department of Homeland Security standard coming out for the chemical industry, where minimum threshold quantities of some very common chemicals" could trigger FBI involvement, covering access, inventory, storage, and disposal.

"I'm not sure how many lab managers are actually even aware of this requirement, although I'm sure most procurement officers are.

"And it's not just meeting the requirements of this standard, but its timelines. Say you want to add someone to your program. If you need background checks and the like, what's the lead time before this individual is cleared to start working in your lab?"

At Sigma-Aldrich, "a large part of what we do is focus on the new employee," said Bleazard, who said it typically takes two months to vet newcomers for good EH&S lab practices.

Whereas private industry practices have been conditioned by OSHA's regulatory regime, "most colleges and

universities were exempt from that until recently, and some still are," said Bleazard. "Academia is improving regarding their prevention practices" involving rates of addition, excess energy control, equipment inspection, and set-up."

Francis Key Kidder *started out as a journalist before moving on to politics and government relations, where he still keeps his hand in writing. He may be reached at 410-828-6529; info@labmanager.com.*

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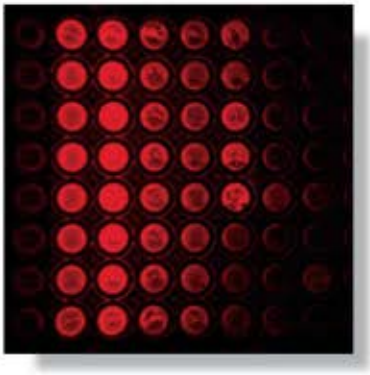

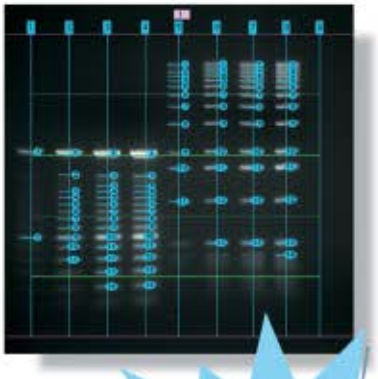

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