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February / March 2009

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➔ "We'd like to say thank you to our subscribers and advertisers for making *Lab Manager Magazine* one of the fastest growing magazines serving the scientific research market. We look forward to continue serving the industry with unique, timely and relevant editorial. Thank You"

➔ Correction: Please note that the Vacubrand, Inc. phone number at the end of January's "Productivity in a Vacuum" article on page 25 should have been 860-767-2562.



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Lab Manager Magazine® (ISSN: 1931-3810) is published 10 times per year; monthly with combined issues in February/March and July/August, by LabX, P.O. Box 216, 478 Bay Street, Midland, ON Canada L4R 1K9. USPS 024-188 Periodical Postage Paid at Fulton, MO 65251 and at an additional mailing office. A requester publication, *Lab Manager*, is distributed to qualified subscribers. Non-qualified subscription rates in the U.S. and Canada: \$120 per year. All other countries: \$180 per year, payable in U.S. funds. Back issues may be purchased at a cost of \$15 each in the U.S. and \$20 elsewhere. While every attempt is made to ensure the accuracy of the information contained herein, the publisher and its employees cannot accept responsibility for the correctness of information supplied, advertisements or opinions expressed. POSTMASTER: Send address changes to *Lab Manager Magazine*®, P.O. Box 120, Georgetown, CT 06829.

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Laboratory Dreaming

“The whole idea of the dance-floor lab...is to support the institution with flexibility, adaptability and reduced costs over the long run.” So says Victor Cardona in this month’s feature story. Developed in the mid-90s to accommodate fluctuating medical school funding, recent enhancements to the open-plan design include “partial wet labs that can meet the space and HVAC needs of a dry lab;” clustered PI offices to promote interdisciplinary collaboration; 2-sided “ghost corridors” that expand their capacity and area as a transition zone; and demand-control ventilation that cuts energy use while enhancing safety and indoor air quality. “Call it a hybrid lab or a next-gen research platform: By any other name it’s still a boon for scientific breakthroughs,” says Cardona.

For a glimpse of three state-of-the-art research facilities outside the U.S., turn to page 36. All reflect the trend toward more flexible design, an emphasis on interdisciplinary research, greater energy efficiency and environmental sensitivity. Completely wireless facilities, closed-loop cooling systems, pneumatically-driven vacuum lines for chemistry labs and sensors that automatically turn off lights when unoccupied are but a few of their cutting-edge features.

In this month’s Leadership & Staffing feature, John Borchardt recommends a variety of programs and in-house practices to improve the writing skills of foreign-born staff members. Strategies range from workshops, to off-site writing courses, to editorial consultants, to mentoring, to online tools.

On page 24 we introduce a new feature to the magazine called Science Matters. Each month Rich Pennock will offer up his insights into trends, challenges, opportunities in laboratory staffing. This month he shares some interesting statistics on the increasing number of free agents in the workforce—“individuals freelancing with or without the support of a staffing agency, including independent consultants, temporary and contract employees, and entrepreneurs and business owners with or without staff.”

Other highlights of the issue include a case study on page 32 in which Boehringer Ingelheim Chemicals shares the benefits of changing to an integrated service delivery (ISD) program that pulls together on-site resources with administrative and operational back-office efficiencies to manage services across all of a lab’s systems. The article on page 44 stresses the importance of being able to demonstrate compliance to an auditor and available software that makes scheduling, tracking and documenting instrument and facilities maintenance simple. On page 80, Jim Coogan describes how to design a two-state or two-position constant volume ventilation system to fit and support your lab safety programs. And for a snapshot of the products, services and technologies you’ll be seeing at next month’s Pittcon, turn to page 62.

Please make a note to stop by *Lab Manager Magazine’s* booth 1673 to say hello. I look forward to meeting you in Chicago.

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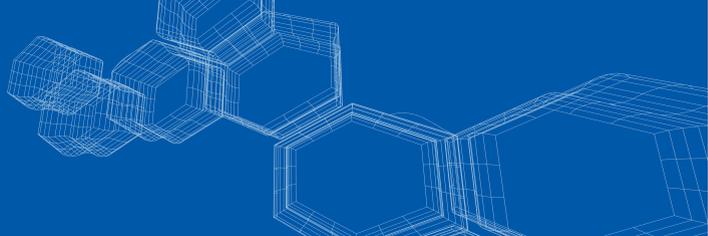
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NEXT-GENERATION LABORATORIES

ADAPTING WORKSPACE TO SCIENCE

by Victor J. Cardona, AIA, VP and director of lab planning, SmithGroup

Necessity is the mother of invention, and the open-plan laboratory is no exception.

The open-lab concept emerged in the mid-1990s at schools of medicine where funding levels fluctuated rapidly and hundreds of principal investigators had to share facilities and equipment. The challenges were so enormous that the walls literally came down: Research institutions embraced the flexibility of labs with few walls and movable, modular furnishings. Big benefits followed: Done right, the open labs reduced costs, helped accommodate the churn and even boosted collaboration among PIs and their teams.

Today, open-plan labs are so common that institutions rarely bat an eye when faced with a new project. They know that closed research environments might not serve their needs long-term. The question they're asking, however, is how to make open-plan labs better.

The secret of success, unsurprisingly, is to look at where science is going today. First, research is far more interdisciplinary than it was a decade ago. For example, as more computer simulations drive success in such key areas as biomedical science, there's an impetus to bring wet labs and dry labs closer together. For their part, researchers expect more customized lab settings, with the ability to modify their bench setup and support areas as needs change, sometimes on the fly. The increased interaction among researchers and the physical adaptability of their workplace are now seen as preconditions for scientific breakthroughs.

Lab managers and administrators of research facilities must weigh the end users' preferences,

such as more acoustical privacy and physical security, against the constant need to reassign space and staff. The answer, more often, is to build or renovate to create highly adaptable spaces that promote collaboration—at a reasonable cost and in a way that is as energy efficient and environmentally responsible as possible.

Evolution of open-plan labs

It may sound like a tall order, but the open-plan research floor has met these challenges adeptly and—in the views of many experienced lab managers and designers—their potential has not yet been fully tapped. Many of us envision a laboratory “dance floor” of the future that allows constant change and adapts intelligently to the needs of science.

Some features of this best-practice lab include:

- *Convertible wet and dry labs*
- *Clustered offices for PIs*
- *More lab support space per research team*
- *“Plug-and-play” equipment zones*
- *Adaptable, prefabricated casework systems*
- *Fewer under-floor utilities (such as plumbing) and more access overhead (for electrical, data, vacuum and air)*
- *Improved energy efficiency*
- *Sunnier, more transparent spaces with more places to meet and collaborate*

Is this nothing but a PI's fantasy lab? In fact, it's the emerging reality, and not just at the biggest and wealthiest Ivy League schools. To see how the dance-floor lab better supports science and research, it helps to look at each component in detail.



The first challenge is creating open labs that can convert from dry to wet with little investment of money or time. For example, today's typical PI might have a team in which one of four researchers is doing computer simulations and the rest are using wet bench areas. Locating the computational/bioin-

▲ *Open labs at the Arizona Biomedical Collaborative Building 1 provide flexible casework and benefit from controlled natural light and direct-indirect artificial lighting. Credit: Bill Timmerman, courtesy of SmithGroup*

formatics work off the lab floor might improve space utilization and reduce costly wet lab area, but the team will talk less—even if they're very close and separated only by a glass wall—limiting productivity and creativity. In the future, look for novel "flex zones": partial wet labs that can be modified to meet the space and HVAC needs of the dry lab.

There are already several other ways to organize lab space better. Among the most critical is to build on the inherent openness and transparency of the open lab to improve interdisciplinary researcher interaction, a goal outlined in NIH's *Roadmap for Medical Research*. For example, while some architects have



▲ *Pfizer Corporation's Building 20 West was designed with a flexible bench configuration. Credit: William Schumann Photography, courtesy of SmithGroup*

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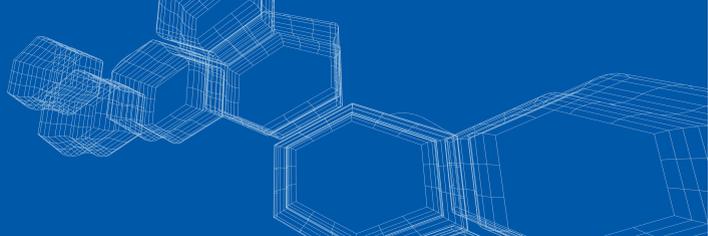
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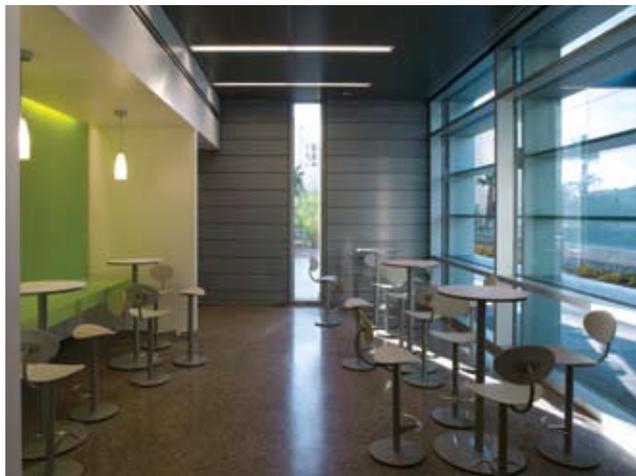


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proposed decentralizing offices for PIs, today everyone agrees that clustered PI offices better promote interdisciplinary collaboration.

Studies such as our *SmithGroup Lab 2030* report show that the most vital interaction occurs within the open lab and at the bench, so it helps to co-locate research teams and provide for collaboration space as close to the action as possible. Most institutions prefer an open-plan lab



▲ *Arizona Biomedical Collaborative offers spaces for interaction. Credit: Bill Timmerman, courtesy of SmithGroup*

“neighborhood” for as many as six PI teams, or between 24 and 36 bench positions. Add to the mix tables or other informal meeting zones in the ghost corridor, and locate lunchrooms, lounges, and seating areas nearby as well as in corridors and stairs, where they will get the most use.

By the numbers

In addition to the wall-free lab, the research dance-floor concept succeeds by providing the right amount of infrastructure and equipment where needs are most antici-



▲ *A “ghost corridor” at the University of Michigan Life Sciences Institute loads sinks and equipment on a single side. Credit: Justin Maconochie Photography, courtesy of SmithGroup*

pated (see “Benchmarks for the Open-Lab Bench,” page 16). One useful measure is the ratio of labs to lab support space, which in today’s lab is historically held at about 1:1. Yet equipment needs are expanding for today’s sciences, and the open labs are becoming more generic while the support areas become increasingly specialized. Today, lab support space is typically divided up with about two-thirds of the area devoted to dedicated support—fume hoods, lineal equipment, microscopy—while the other third is set off for shared support, split among a neighborhood of open labs. The key to making this work is flexibility.

An example of this shifting balance is the ghost corridor, which has traditionally been loaded on one side with sinks and equipment. Today, a number of leading institutions have built two-sided ghost corridors, expanding their



▲ *The University of Michigan’s Life Sciences Institute provides researchers with dedicated lab support space—an “intensive lab services” zone. Credit: Justin Maconochie Photography, courtesy of SmithGroup*

capacity and area as a transition zone. Another way to enhance flexibility is to provide modular lab support areas with a plug-and-play “kit of parts” for evolving use needs. A half-module, measuring approximately 10 feet by 12 feet, might serve a dedicated function, such as tissue culture work, while others remain flexible for sharing among PIs, such as a 240-square-foot space for analytical instrumentation. Ideally, every other partition is a wet wall, so needed services are available throughout the lab support zone. The key is to strike a balance between customizing those spaces and minimizing initial and ongoing costs to

the owner as rooms change from one use to another.

Similarly, the bench is becoming simpler and more adaptable to change. Cup sinks have disappeared, and most of the needed services—electrical and data cabling, vacuum and compressed air piping—drop down from the



▲ *At Arizona Biomedical Collaborative Building 1, segregated “ghost corridors” provide space for floor-mounted equipment. Credit: Bill Timmerman, courtesy of SmithGroup*

ceiling. In this way, the benches can be reconfigured without calling in every construction trade to rip up the floor.

New kinds of casework have emerged that take advantage of this planning approach. SmithGroup distinguishes between “adaptable systems,” which are generally floor-mounted and fixed in place, from movable casework,

“Done right, the open labs reduced costs, helped accommodate the churn and even boosted collaboration among PIs and their teams.”

such as floor-mounted workbench components on casters or wheels. The ultimate system, which we describe as “flexible casework,” includes both incrementally adjusted and movable components, usually with segregated utility distribution from the bench and base. For flexible systems, utilities are distributed utilizing overhead service carriers (vertical drops or horizontal carriers) or by means of ceiling connection points.

Flexible systems may cost more initially, but they can offer the ergonomic advantages of adaptable casework and the ability to relocate the bench and storage case as with movable furnishings. The best thing about flexible systems,

however, is that they make the “dance floor” even livelier: The furniture system can accommodate fast changes of location, configuration and services throughout the life cycle of the laboratory. As NIH funding ebbs and flows, for example, the labs can adjust accordingly.

Energy, environment and human factors

One well-studied drawback of the open lab is that, if not carefully designed, lab ventilation systems can make a science building an energy hog. NIH guidelines call for six air changes per hour (ACH), but by using demand-control ventilation, savvy engineers can cut energy use while enhancing safety and indoor air quality. This integrated sensing-and-actuation technology safely varies ventilation rates in lab zones from 4 ACH to 16 ACH, based on continuous monitoring of particulates, humidity, CO₂ levels and the like. (A more novel approach is called “multiplexed sensing,” which routes air samples simultaneously to central sensors integrated with the building automation system. Web-based data collection and analysis make the information easy for lab managers to find and use.) Being able to cut the air changes based on need means one can co-locate more people in the lab, making it even more energy efficient.

Of course, energy efficiency is only one component of sustainability, a top-level goal for many research institutions and universities. Fortunately, the dance-floor lab helps position these lab owners for more points toward the U.S. Green Building Council’s LEED ratings and other third-party certifications.

Whether or not recognition of one’s environmental efforts is a top priority, the sustainability advantages of open-plan labs also tend to make people happier. More natural daylighting permeates these spaces, and if 90



▲ *The Lawrence Berkeley National Laboratory Molecular Foundry provides natural daylighting conditions for laboratories in addition to transparency into labs from corridors. Credit: Timothy Hursley, courtesy of SmithGroup*



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percent or more of the occupied zones have daylight, a LEED credit may be earned. SmithGroup studies show that openness and transparency in the open work environment improve lab worker satisfaction, too, adding a sense of camaraderie and giving many a view to the outdoors. We are also using emerging building systems such as under-floor HVAC and chilled beams in some leading-edge projects. Imported from Europe, chilled beams combine radiant cooling with conventional overhead ventilation, ideal for spot ap-



- ▲ *At the IGC/TGEN headquarters in Phoenix, SmithGroup designed open lab modules to allow natural daylighting, which floods in from floor-to-ceiling windows. Credit: Bill Timmerman, courtesy of SmithGroup*

“Many of us envision a laboratory ‘dance floor’ of the future that allows constant change and adapts intelligently to the needs of science.”

plications in equipment alcoves and lineal equipment rooms.

Another European trend that may inform U.S. projects over the next several years is the move toward more prefabricated open-lab systems, including integrated service ceilings and factory-assembled furniture. The ceiling and bench frames are prebuilt and fitted with as much of the equipment, electrical and piping runs, finishes and fixtures as can be accomplished prior to shipping. In this way, labs are built mostly in the factory rather than

on the job site, reducing waste and project duration while improving quality control. In the open lab, this works especially well and might push contractors and suppliers to adopt this new method. Lab support areas, on the

"Studies show that openness and transparency in the open work environment improve lab worker satisfaction...adding a sense of camaraderie and giving many a view to the outdoors."

other hand, will likely remain more customized on-site.

Cost, quality and scientific discovery

Regardless of the methods and means, the big question lab owners ask is, "Are open labs cheaper than closed labs?" SmithGroup's experience over the last decade shows that the answer is a definitive yes. Open labs might look a bit different: They are airy, they buzz with activity, and some of the bench systems and other furniture may look simpler because they're made to accommodate more kinds of end users.

The whole idea of the dance-floor lab, paired with dedicated lab support spaces and often designed to include flex zones, is to support the institution with flexibility, adaptability and reduced costs over the long run. Call it a hybrid lab or a next-gen research platform: By any other name it's still a boon for scientific breakthroughs.



▲ *UCSF Genentech Hall collaboration spaces allow opportunity for informal interaction. Credit: Timothy Hursley, courtesy of SmithGroup*

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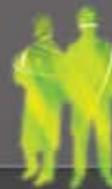


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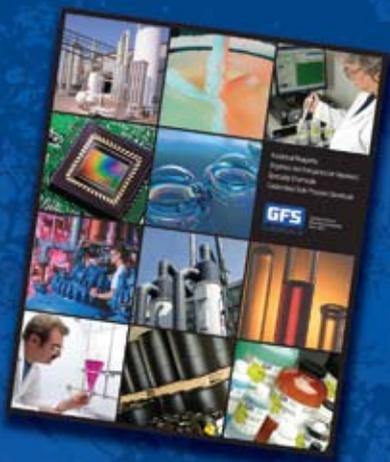
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The biggest advantage of the dance-floor lab is how it supports the cultural and professional trends driving the best research teams. Getting PIs and staffers to be more communicative and responsive is a priority, a goal that's not improved by walls, whether metaphorical or real. Perhaps that's why the open lab has opened new doors for science across the country.

Benchmarks for the open-lab bench

Open-plan labs demand attention to space standards to ensure functionality and relevance for real-world needs, such as NIH funding criteria. A few examples:

Bench positions. SmithGroup typically assigns about 12 equivalent linear feet (ELF) of lab bench or floor space per individual bench position in the lab, of which 6 linear feet is usually a dedicated bench, and the rest is allocated as write-up desks, sinks, shared bench and floor equipment space in the open lab.

Desk location. The location of lab desks has been revisited as well. Today's preference is for locating the post-doctorate desks outside the lab, near PI offices. For the most part, SmithGroup still locates undergraduate and graduate student desks within the open-plan lab area, allocating approximately 4 additional ELF of work surface per bench position.

Lab services. The open-plan lab has become more generic: Cup sinks and natural gas distribution have almost disappeared from these spaces. In our projects we usually provide electrical power, data, compressed air and vacuum—all utilities that can be routed from the ceiling cavity. To reduce cost, we limit pipe runs by placing sinks in the ghost corridors, adjacent to the lab support rooms that require wet plumbing services.

Lab support spaces. With the decreased utilization of high-level radioisotopes and the impending use of digitized images, shared lab support spaces have started to shrink. But increasing equipment utilization has led SmithGroup to plan most state-of-the-art biomedical research labs with as much open-plan lab as the dedicated and shared lab support areas, with a space ratio of 1.0:1.0 of open lab-to-lab support space.

While no two projects are exactly the same, reviewing these standards for application to a new or renovated research facility helps put needs into perspective. It also helps ensure that costs will be in line with needs and that the facility will be flexible enough to last for decades of service.

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ACTIVE LISTENING

TECHNIQUES FOR CHANGING SELF-CENTERED LISTENING INTO COMPASSIONATE COMMUNICATION by Mark Gorkin

“Learning to pause and segment or chunk your message helps the receiver catch the gist without fumbling the ideas.”

There are several ways to enhance listening effectiveness, especially when engaged in a complex or emotional exchange. A fundamental technique is active listening. CPRS provides an acronym to help transform less-than-attentive or self-centered listening into clear, concise and compassionate communication. If you are ready to revive a give-and-take relationship with members of your laboratory staff and are interested in becoming an assertive and empathetic communicator, below are the fundamental principles and guidelines of active listening.

C – Concern and Clarification Concern

The best way to start an engaging conversation is to give the other person undivided verbal and nonverbal attention. A relaxed yet alert posture, eye contact, modulated voice tone, etc., are essential for effective listening. (Naturally, as the communication begins to flow, there is more room for a wider array of facial expressions, bodily gestures and shared laughter.) As much as possible, the active communicational receiver wants not just to get the sender’s message, but to better understand the person and his or her situational context. Asking questions that give the other party a chance to speak his or her mind (and if desired, to also speak from the heart) defines “concern.” Yet showing empathy doesn’t mean there is not room for difference. As I like to say, “Acknowledgment does not necessarily mean agreement.” That is, a communicator can listen both attentively and respectfully and, after taking in the message, share his or her differing and even troubled perspective.

Clarification

Clarification involves asking the other party to provide more information, elaborate upon a statement or answer specific questions. A clarification attempt is

not an inquisitorial “Why did you do that?” It is more a recognition that something is not clear. Perhaps the listener has some confusion and desires more information, again, for better understanding. And clarification should not be the springboard to a harsh or blaming “you” message and/or a dismissive judgment, e.g., “You are wrong” or “You don’t really believe that, do you?” A much better response is “I disagree,” “I see it differently” or “My data says otherwise.”

P – Paraphrase and Pause Paraphrase

Paraphrasing involves repeating the other person’s message in his or her words or in your own distillation to affirm that the message sent is the message received. Sometimes, especially if you have conveyed a significant amount of information or complex instructions, it is wise to say, “I know I just said a lot. Would you paraphrase back what you heard?” Again, the motive is not to catch the other person, but to have both parties on the same page.

Pause

In a “T ’n T” (time- and task-driven) world, communicators often feel they have to cram in the information, as time is limited. Providing people with a lengthy, seemingly endless laundry list almost assures that key issues and ideas will be lost in the verbiage. Learning to pause and segment or chunk your message helps the receiver catch the gist without fumbling the ideas, intentions or implications. (The communicational analogy might be writing concisely, using short and to-the-point paragraphs.) Momentary breaks from the back-and-forth also allow the parties to ponder and posit new possibilities. Now active listening can morph into creative listening.

R – React vs. Respond and Reflect Feelings

React vs. Respond

Reactive listening usually occurs when you feel threatened or angry and then immediately engage in a counterargument (covert or verbalized). Unbiased or flexible listening has ended. Upon sensing an opening—for example, a perceived inconsistency or irrationality in the message—you reject or talk over the message and basically dismiss the messenger. Or sometimes you end a contentious listening process with a quick and reactive retreat: “You’ve hurt me” or “You made me upset,” and then the receiver vacates the communicational field and avoids an honest exchange. (Clearly, if one party is being abusive and does not feel safe to voice his or her position, then retreating is a wise strategy.) In contrast, a response often blends both head and heart and involves the use of an “I” message: “I’m concerned about what I’m hearing” or “I sense there is a problem. Is my assessment on target?” An “I”-message response is the opposite of a wildly emotional or knee-jerk reaction; it takes personal responsibility for both receiving and giving feedback. Shifting from blaming “you” messages to assertive and empathic “I” messages transforms a defensive reaction into a reasoned response. So, “count to ten and check within.”

“Listening and looking for verbal and nonverbal cues will facilitate more accurate reflection or discretion.”

Reflect Feelings

To reflect someone’s feelings means to lightly or kindly ask about or acknowledge overt or underlying feelings that are attached to the other party’s communication. A tentative or tactful approach is often best: “I know you are on board, still it sounds like you may have some frustration with the decision. Care to discuss it?” Sometimes you may not know what the other person is feeling. Instead of trying to guess or saying “Gee, you must be angry,” if you want to comment, better to say, “When I’ve been in a similar situation, I found myself becoming...” And then pause; give the other person time to respond or not. Also, especially regarding the emotional component of messages, both listening and looking for verbal and nonverbal cues—voice tone and volume as well as facial and other bodily gestures, for example, lowered head and eyes or arms crossed over the chest—will facilitate more accurate reflection or discretion.

S – Strategize and Summarize

Strategize

Strategic listening takes active listening to a next level. The goal is more than awareness and empathy. Now you want to invite the other person to engage in a mutual problem-solving dance. In addition to common and disparate as well as structured and spontaneous ideas, emotions and objectives are shared freely, akin to brainstorming. Though in this strategic interplay, questioning for understanding and triggering imaginative possibilities is encouraged. The purpose of such strategic back-and-forth is synergy—a sharing-listening-sharing dialogic loop yielding an expanded understanding: The consciousness whole is greater than the sum of the communicational parts.

Summarize

Finally, you are ready to review and pull together such problem-solving elements as mutual agreements, outstanding differences—factual as well as emotional—broad strategies and action plans to be executed (including the parties responsible for implementation), time frames, ongoing monitoring or interim reports, and follow-up procedures. And depending on the communicational context, a written summary is often advisable.

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Here is a succinct summary of the “Keys to Active or CPRS Listening”:

Concern – verbal and nonverbal attention, empathy and acknowledgment with room for difference

Clarification – clear up confusion and foster greater understanding without passing premature judgment

Paraphrase – two-way repeating or distilling of the message so that the message sent is the message received

Pause – take time to chunk your message, allowing the other person to get the gist and ponder possibilities

React vs. Respond – “count to ten, check within” to respond with assertive “I”s, not blaming “You”s

Reflect Feelings – tactful questioning or sharing acknowledges self/other and invites emotional reflection

Strategize – generate mutual listening-sharing loop for both idea generation and insightful imagination

Summarize – review and record agreements, unresolved differences and future problem-solving steps

WRITING IN A SECOND LANGUAGE

IMPROVING THE WRITING SKILLS OF FOREIGN-BORN LAB PERSONNEL by John K. Borchardt

Today's laboratory workforce includes an increasing number of scientists, engineers and technicians for whom English is a second language. Writing in a second language poses challenges for them. Poor written communication skills can slow career advancement, whether foreign-born professionals remain in a laboratory track or move into management or operations. How can laboratory managers help these professionals improve their written communication skills? Several approaches can be applied effectively. Using some of them in combination is even more effective. The suggested techniques discussed below apply to all staff members.

Effective solutions begin with recognizing the problem. Ideally, this is done before young scientists leave the academic environment. University research advisors should determine the writing skills of their graduate students and post-docs by asking them to write monthly research reports. If serious deficiencies exist, advisors should recommend that their students take technical writing and journalism courses. Journalism courses are useful because industrial researchers don't communicate only with other researchers in their field. They also have to communicate with business managers and personnel working in sales, marketing and manufacturing functions. They may have to communicate with customers as well. Journalism courses can help them do this.

Not only will taking these courses help graduate students and post-docs write clearly when they begin their industrial careers, it will enable them to write more effective résumés, cover letters and other documents when job hunting.

However, many foreign-born scientists and engineers begin their industrial research careers without participating in systematic efforts to improve their writing skills. Lab managers can use several strategies to help staff members in this regard.

Technical writing workshops

The first step is often to hire consultants to present technical writing workshops. These workshops are most effective when customized for researchers for whom English is a second language. If consultants are familiar with the particular challenges that foreign-born laboratory personnel face in writing reports, they will be more effective in helping them. Some of these challenges are summarized in the sidebar. Ideally, presenters will customize the workshops to the communications needs of the particular laboratory that hires them.

Workshops must be conducted in a diplomatic way to be considerate of the feelings of these highly intelligent researchers. Most of them are used to being the best; it's often difficult for them to accept that they have a major job-related problem.

Including before-and-after examples of effective editing to improve clarity is very useful. So is presenting workshop participants with editing exercises. Ideally, these before-and-after examples would be sentences or paragraphs that appear in their laboratory reports.

However, using examples from existing reports could embarrass the workshop participants who wrote them. To generate original examples, the workshop presenter needs some familiarity with the participants' technical fields. To do this and deal with other technical writing issues, workshop presenters should be experienced researchers as well as excellent writers, or they should team teach with someone who is. For example, chemist and book author Lisa Balbes team teaches with an English teacher in presenting writing workshops for industrial scientists and engineers.

Given the value of staff members' time, writing workshops must be kept brief. Because of the relatively short duration of these workshops (mine are half-day or one-day workshops) the most they can do realistically is sensitize laboratory personnel to their communications problems and introduce them to methods for improving their writing skills. Effective

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follow-up is needed to help foreign-born lab professionals improve their English language writing skills.

Workshop presenters also need to remind researchers, whatever their original languages, to follow certain basic principles in preparing reports and other documents:

- *Know your readers. Your readership determines the technical depth and amount of technical detail that needs to be provided. Researchers, customers, and sales, marketing and manufacturing personnel who often read laboratory reports all have different information requirements.*
- *Outlining the document before beginning to write can improve focus, reduce repetition and better enable writers to focus on the needs of their readers.*
- *Understand the editing process. Writers need to edit for focus to avoid submitting excessively long reports. Then they need to edit for clarity, often a challenge for writers for whom English is not their native tongue. Finally, they need to edit for technical correctness.*

Laboratory managers could fund researchers' tuitions to take technical writing or journalism courses. However, these courses may be less effective than desired because they aren't customized to the needs of the industrial laboratory workplace. They should be used in conjunction with workshops designed to focus on the communications skills required in the foreign-born professionals' laboratory environments and job assignments.

"Laboratory managers can hire the workshop presenter or another consultant to edit their staff members' reports for clarity."

Workshop follow-up

Laboratory managers can hire the workshop presenter or another consultant to edit their staff members' reports for clarity. The individual need not be a specialist in the technology field of the reports being edited, but should have enough of a technical background to understand the basics of the subject area. The consultant should also have an understanding of the different types of people who will read the finished documents and their basic information needs.

If the editor explains what has been changed and why, then the laboratory staff members will gradually learn how to edit their own reports. Speaking from experience, as time passes the editor needs to do less and less as staff members

gradually learn how to eliminate or correct their own writing problems and eventually decide to "fly solo."

This clarity editing can be quite cost-effective. Some laboratory managers have found that having to edit both for clarity and technical correctness can be very time-consuming and tiresome as they try to decipher what staff members are trying to communicate. Having someone else edit for clarity can make their own reviews of reports for technical correctness much easier and faster. Laboratory managers have reported to this author that they have reduced the time they spend editing laboratory reports by as much as 80 percent.

Editors need to be considerate of report writers' feelings and diplomatic in making suggestions for improvement. This means evaluating the reports, not the writers. Editors should focus on what the writers should do rather than what they shouldn't, and be honest but not overly critical. On the other hand, they should not be overly permissive about problems such as poor organization, unclear explanations, poor sentence structure and poor grammar. Editors should help writers stay motivated and nourish self-esteem.

"Laboratory managers should understand the communications challenges faced by their foreign-born laboratory staff members."

Editing alternatives

An alternative to hiring a consultant to present a workshop and then work with laboratory staff members to improve their writing skills is to hire laboratory retirees or technical writers to edit reports. Retirees' familiarity with the workplace environment and its communications requirements can be a great advantage. However, without coaching, simply editing reports can be a "Band-Aid" approach that, while producing clearer reports, does relatively little to improve staff members' writing skills.

To improve these skills, coaching is needed. In addition to being excellent writers, coaches have to be diplomatic in their dealings with laboratory staff members. Editors often need a technical background to understand the report objectives and the information needs of report readers. Lab managers are often too busy to serve as writing coaches themselves.

Assigning a "writing mentor" to foreign-born staff members when they are hired can give them a fast start in improving their writing skills. Laboratory managers can often iden-

tify new employees who will benefit most from this type of coaching by reviewing their résumés, cover letters and other job-hunting communications. Writing mentors can be “all-purpose” advisors to new employees during the on-boarding process. Generally, senior laboratory personnel who are both accomplished researchers and excellent writers are the most effective writing mentors. However, some may be too busy to spend much time coaching or may be reluctant to take the time away from their own research.

Using computer aids to improve writing

Workshop presenters or writing mentors can also coach laboratory personnel on the use and limitations of word processor grammar and spelling checkers. Writers can modify the spelling/grammar checker in Microsoft Word to report the percentage of passive sentences, the Flesch Reading Ease score and the Flesch-Kincaid Grade Level score. By doing this paragraph by paragraph, writers can identify sentences that are excessively long, may need to be converted to the active voice, or contain phrases that either need to be eliminated or expressed in a separate sentence.

The Gunning Fog Index is one of the best-known methods for analyzing writing clarity. It measures the level of reading difficulty of any document. The Fog Index equals $0.4 \times (\text{average number of words per sentence} + \text{percentage of words of three syllables or more})$.

There is a Web site, www.online-utility.org/english/readability_test_and_improve.jsp, containing a free Fog Index calculator. One can enter text from a word processing document. Unlike the grammar checker in Microsoft Word, this program provides advice on improving the clarity of excessively long sentences and solving other grammatical problems in the document. Micro Power & Light Co. sells two programs: Readability Calculations (<http://www.readabilityformulas.com/readability-calculations.php>) and Readability PLUS (<http://www.readabilityformulas.com/readability-plus.php>) that calculate the Fog Index. Readability PLUS also offers tips on style, such as noting when a word is used very frequently.

Laboratory managers should understand the communications challenges faced by their foreign-born laboratory staff members. Improving their written communication skills will make researchers more effective in communicating with those outside the laboratory and thus more productive.

John K. 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.

COMMON WRITTEN COMMUNICATION CHALLENGES & THEIR CURES By John K. Borchardt

Excessively long sentences often are confusing and their meaning difficult to decipher. Many foreign-born professionals frequently use these sentences, perhaps because, when writing in English, they tend to write word by word rather than phrase by phrase or sentence by sentence. Editors need to break overly long sentences into shorter ones. Another alternative is [to use] bullet statements.

Overuse of the passive voice is common in research papers. Graduate students and post-docs become accustomed to this mode of writing as a result of their extensive reading and often transfer this habit to their industrial report writing. Researchers knowledgeable in the technology discussed can understand the meaning. However, other readers may be confused because passive-voice sentences are longer and often more convoluted than active-voice sentences presenting the same information.

Incorrect use of words due to limited vocabulary is also common. This can be remedied by experience and by checking the meanings of unfamiliar words. The availability of online dictionaries makes it easy to check the meanings of words while writing or reviewing a report.

Excessive word repetition is another common problem. Should the report writer notice this while writing or editing a report, consulting an online thesaurus to find a synonym is easy and convenient.



FREE AGENTS ON THE MOVE

BY RICH PENNOCK

Human capital is one of the keys to success in any industry. It is especially important to scientific industries such as pharmaceutical, where knowledge is the name of the game. It continues to be an important focus for pharmaceutical and biotechnology companies seeking to develop strategies to attract, develop and retain top talent.

In today's tough economic environment, more and more professionals are discovering the benefits of self-employment. According to a recent survey conducted by Kelly Services, Inc., slightly more than one-quarter of the U.S. working population is self-employed, a trend fueled by the current economy.

The web survey, representing all four generations in the workforce—Silent Group, Baby Boomers, Generation X and Generation Y—showed that 26 percent classify themselves as freelance professionals or “free agents”, up from 19 percent in 2006. The term “free agent” comprises individuals freelancing with or without the support of a staffing agency, including independent consultants, temporary and contract employees, and entrepreneurs and business owners with or without staff.

Free agents are often essential to a functioning business during tough

economic times because of the flexibility they provide employers as more work becomes project based.

Just who are these free agents? They are the fastest growing and likely the largest group of workers in America, with rapid international growth, as well. According to the survey, more than one-quarter of traditional employees are likely to consider working as free agents in the future.

“MORE THAN ONE-QUARTER OF TRADITIONAL EMPLOYEES ARE LIKELY TO CONSIDER WORKING AS FREE AGENTS IN THE FUTURE.”

So why do individuals work as free agents?

First, free agents define success in a different way than traditional workers. To them, it's not about making it to the top of the company's hierarchy. It's more about doing well in their

profession, acquiring more experience, improving their skills and being the best at what they do.

Second, free agents need to fit their work into their lifestyle, not their lifestyle into their work.

And third, free agents have a high degree of self-confidence in their employability and skills.

Free agents have three main attitudes in common: The way they define success; their commitment to fitting their work into their lifestyle; and their autonomous belief in themselves and their ability. To be a free agent, generally speaking, one must have all three of these characteristics.

The increase of free agents is driven by several workplace trends. These trends include shortened job-life cycles, the increase of project work, the acceptance of the new work style, and the emergence of new technology.

A job cycle is how long a job will have a purpose, so that it merits a salary and justifies hiring a person. In today's workforce, many people are in jobs that did not exist, in locations that did not exist, supporting products or programs that didn't exist as little as five years ago. Job-life cycles have shortened dramatically in the last decade. Many people are routinely changing jobs more frequently

than they used to—perhaps 14 or 15 times in the course of a career. Much of this movement is triggered by the shortened job-life cycles.

The second trend driving the increase of free agency is the rise of project work—work that has a fixed beginning and a fixed end, without an expectation that the position will become permanent.

The third trend is society's acceptance of the new work style. Research on various demographic groups, including those college-aged, indicates that, free agent or not, a long-term commitment to a particular company is no longer trendy or cool, and may not even be desirable.

It's not just college kids who've adopted these attitudes. It's the Silent Group, employees between the ages of 68 to 75, who have been there, done that, and aren't going back. They've seen firsthand the myth of "lifetime employment" and so many of them have chosen to join the free-agent workforce. In fact, the oldest respondents to Kelly's survey, the Silent Generation, included significantly more freelancers than younger generations (38 percent compared with 26 percent overall).

In summary, three of the most important factors in the increased free agent workforce are the shortening

of job-life cycles, the rise of project work, and the acceptance of the new work style—all of which are enabled by new technology.

As managers, when you think about managing a blended workforce, think in terms of people constantly moving in and out of your company. And whether they're employed by you or working on your behalf, they should be considered a truly important asset of the organization.

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

INCLUDING ALL FOUR GENERATIONS INDICATED BELOW, 26 PERCENT CLASSIFY THEMSELVES AS FREELANCE PROFESSIONALS OR "FREE AGENTS", UP FROM 19 PERCENT IN 2006.

GENERATION Y
(age 18 - 25)

GENERATION X
(age 26 - 46)

BABY BOOMERS
(age 47 - 67)

SILENT GROUP
(age 68 - 75)

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LIFE ONLINE

COMMUNITIES OF SHARED INTERESTS CONNECT TO ACHIEVE RESEARCH, SOCIAL, AND BUSINESS GOALS *By Gloria Metrick*

"We continue to see more sites and tools for online collaboration and networking and, increasingly, those specifically directed at scientific areas."

Do you find yourself increasingly answering yes to the question "Do you know this person?" even though you have never met him or her face-to-face?

In the Laboratory Information Management System/Laboratory Informatics (LIMS/LI) community, since we are geographically spread out, it is not uncommon for us to know each other only through discussion groups, e-mail, and other means of communication that require no face-to-face contact. Other consultants I know from unrelated industries are often shocked at the way I do business with people I've never met in person. But it seems the rest of the world is starting to catch up with us, and this is made possible by sites that make online networking and information sharing easier.

First, I want to point out that nothing takes the place of personal contact. Consider, though, that the right online site becomes just one more place to accomplish what we need to accomplish. Thus, we continue to see more sites and tools for online collaboration and networking and, increasingly, those specifically directed at areas such as LIMS/LI and various scientific areas. This article should give you enough of an overview that you will have an idea how to find a site or tool that specifically meets your needs. The examples I use are meant to give you a general overview, although actual sites and tools range from the varied to the highly specific.

Discussion boards

Discussion boards might be the oldest tools around for getting people together online. With these sites, one member posts a topic to which other members can respond. Some discussion boards are fairly unstructured, where anyone can post anything at any time, while other discussion boards funnel all submissions through a moderator who must approve them before they go out to the members.

Even though their main purpose is to discuss various issues, discussion boards are a way to meet and network with people within an area of interest as well as a way to look for jobs and employees, collaborate on various topics, or find people to collaborate with off-line.

Despite their age, discussion boards have not become obsolete and new ones appear to be created fairly regularly. Additionally, some of the other sites mentioned in this article are adding discussion boards to their tool kit of features.

Countless discussion boards exist in the world on a variety of topics. A few examples include:

- *LIMS/Lab Informatics:* <http://groups.google.com/group/lims-lab-inf>
- *Drug dissolution:* <http://www.dissolution.com/>
- *Laboratory robotics:* <http://tech.groups.yahoo.com/group/lrig-discussion/>

Somewhere, there is probably a discussion board on whatever topic you would like to discuss as well.

Blogs

Blogs, or "web logs," can be another way to collaborate on various topics, where people initially post their thoughts and others respond with their ideas. When we talk about "blogging," we mean either creating and posting to our own blog or responding to someone else's. Like discussion boards, blogs exist on a wide variety of topics. For example:

- *LIMS and LI issues specific to Italy:* <http://www.arealims.it/>
- *All things relating to science:* <http://www.scientificblogging.com/>

Unlike a discussion board, a blog usually consists of postings by a single person or company and responses from everyone else. Each has a different purpose, which is why both are popular tools in their own right. Many news sites are now

allowing readers to blog about the articles. For example, Science Centric (<http://www.sciencecentric.com/>) posts its articles in a blog so that readers can comment on what they have read. This can be considered an act of collaboration, depending on the article and its purpose.

Wikis

Wikis are a way to collaboratively create content. Everyone reading this article has probably heard of Wikipedia (<http://www.wikipedia.org/>) which, by the way, does include an entry on LIMS. Also, there is a wiki just for LIMS in Google (<http://sites.google.com/a/perceptivity.us/lims-wiki/>). Wikis can be set up to be “self-healing,” which means that when participants see an error they can correct it. Thus, the amount and overall correctness of the information in a wiki can be incredible. A wiki such as Wikipedia tends to be highly self-correcting because of the sheer volume of people using it, although some of the topics of lesser interest retain errors for a significant amount of time.

“Despite their age, discussion boards are not obsolete and new ones appear to be created fairly regularly.”

However, there are some wikis where this ability is purposely limited. Some wikis are set up to allow only certain people to update—and in some cases to read—content, and there are many options available for reading, writing, and approving the content. Examples of the more controlled type of wiki would be the ones that many companies are now setting up for their own internal use. One use for a corporate wiki is to keep SOPs (standard operating procedures) and other documents up-to-date and easily accessible. Even though the volume of people using these wikis is relatively small compared to those using Wikipedia, the content is still likely to be correct, as a corporate wiki of SOPs will still require formalized review of its content.

Growth of the online world

With all the discussion boards, blogs, and wikis that might be available to you, you might be wondering whether there is sufficient interest in these online communities to make the sites worth investing time in. After

all, if few people participate, it limits the networking and collaboration opportunities, which is certainly a factor to consider before joining any of these communities. But consider this: There has been incredible growth in the online social networking world. One article from August 2006 claims that there had been a growth in online communities of 109 percent since January 2004.¹ A recent article claims that “76 percent of all broadband users actively contribute to social media sites.”² Before you think that these numbers might not relate to the professional sites, yet another recent article points to the rising success of the professional sites as opposed to the original purely social sites.³

While these numbers might or might not be entirely meaningful, there are more online sites today than were available ten years ago. As we see more sites developing for professional use, we also see more sites with extremely specific purposes—more sites that relate to LIMS/LI and to the sciences, for example.

Online social networking

Even so, maybe you are wondering why online social networks are growing and why anyone would bother using an online site as opposed to networking in person. As I often say to people in my LinkedIn® online network, we do it “to find jobs, employees, projects, and consultants, and to share information.” We all need to do some of these things, and we do not always have the luxury of meeting enough people in person to satisfy these needs. Although we refer to this as “social networking,” we are doing much more than that now, as we are increasingly doing professional networking. Although these sites initially appear to merely provide networking, many of them also provide ways to collaborate by including tools such as discussion groups.

With the plethora of sites to choose from, consider each site’s variety of features. Some include discussion groups, ways to share articles and images, and many other options. Others don’t claim much in the way of features and tools but just happen to appeal to the right collection of people, which makes them worthwhile for whatever interest group they focus on. Even the sites we think of as purely social sites are being used to some extent for business purposes. As such, these sites are a major source for online networking and often include tools that encourage online collaboration as well.

Many of these sites allow members to create or request the creation of subgroups. Thus, if you cannot

find something that is specific to your own needs, it does not need to stay that way for long. In my personal effort to create more networking opportunities for myself and others, I created a group for LIMS/LI within LinkedIn. It allows those of us specifically interested in LIMS/LI to have discussions and networking activities that are specific to our needs. I requested the creation of this group upon finding that there was no LinkedIn group for LIMS. As the group's administrator, I am offering its link to other people so they can come and participate: <http://www.linkedin.com/e/gis/36640/>. Once again, this feature is not specific to LinkedIn but is merely one example of the opportunities we now have to create more ways to collaborate and network, as well as an example of how easy it is for any of us to fill a gap.

Online data sharing

More sites and tools are being developed for sharing scientific results online as well. Some sites are designed merely to allow you to internally share data on your own corporate intranet, while others are meant to broaden this concept of collaboration. China, for example, has worked to share its water data online nationally, to promote research.⁴ Meanwhile, Google is now offering online storage for the sharing of open-source scientific results.⁵ At this very moment, universities are discussing how to share data among themselves, and software developers are working on tools to allow better collaboration among companies and the universities that do some of their research.

Other types of online communities

As you have probably noticed, it can be difficult to put labels on things these days. There are many combinations of any tools we want to make use of. So we also have online "communities" that are usually a collection of tools for a specific purpose, such as sites geared toward the sciences, some of which promote networking, some of which allow collaboration, and some of which provide both.

Let us consider, for example, a site such as LabRoots (<http://www.labroots.com/>). It bills itself as "a free, social networking site that enables scientists, engineers, and other technical professionals to connect, collaborate with, and learn from each other." But is it a way to do online

social networking, a place to get scientific news, or really a place to look for jobs? These are all tools that, in fact, LabRoots includes. As with any of these sites, the label is not important. What is important is the content and usefulness that you find in it.

Another example is LabSpaces (<http://www.labspace.net/>), which is labeled as "social networking for the sciences" but also has news of interest, blogs, forums, and other tools. MyExperiment (<http://www.myexperiment.org/>) is a tool that allows scientists to share workflows and other digital information.

A networking site currently under development is LabWrench (<http://www.labwrench.com/>), whose goal is to provide a community forum around scientific equipment and instrumentation. The discussions will be prompted by application notes, white papers, user manuals, and videos, as well as insights from other scientists—providing product-specific reviews and troubleshooting tips from end users and marketers.

For the sheer purpose of connecting people with one another, a site called BlitzTime (<http://www.blitztime.com/>), which I tried this past year, is a way to have meetings, including networking meetings, by combining the web with the telephone. It allows you to individually meet a number of people by phone, briefly, and then share contact information to speak more in depth outside the meeting or networking session. As you are about to be switched to speak to someone, his or her profile comes up on the web site so you can read it before talking to the person. I met some people in the sciences who had a shared interest in LIMS in this manner. Having discovered our mutual interest, we then went on to share information in order to have further conversations post-meeting.

Finally

Once again, nothing replaces the personal touch. Online networking does take more effort than networking in person, since there are neither facial cues to follow nor body language to watch. Still, as all these sites and tools for online networking and collaboration evolve, they are gaining a permanent place in most of our laboratories and businesses.

We have already seen that new technologies come and go, but good content and good connections seem to be what keep people interested in coming to a site and remain part

"Wikis can be set up to be 'self-healing,' which means that when participants see an error, they can correct it."

of it. A site that cannot provide useful content on a consistent basis is just not that interesting, no matter how cutting-edge it is. Thus, good networking and productive collaboration still require commitment and shared goals. As yet, no one has come up with an electronic replacement for that.

Gloria Metrick is the owner of GeoMetrick Enterprises (www.geometrick.com), which provides LIMS consulting services. She spends time networking, marketing, and creating business leads with tools such as LinkedIn® to supplement but not replace face-to-face networking. She can be reached at Gloria@Geo.Metrick.com or 781-365-0180.

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INTEGRATED SERVICE

A NOVEL APPROACH TO CONTINUOUS IMPROVEMENT OF QC LABORATORY PRODUCTIVITY
By Thompson Strode Ph.D., and Rembert Gunter

“An on-site inventory of high-use parts was established to increase the likelihood of same-day repairs.”

Continuous improvement in laboratory management is a constant and universal goal for pharmaceutical companies and their suppliers. However, the daily demand of meeting production schedules and keeping instruments maintained and calibrated while assuring regulatory compliance leaves little time for improving processes. A strong, company-wide plan for continuous improvement has been the key to streamlining the quality control operation at Boehringer Ingelheim Chemicals, Inc. (BICI), located in Petersburg, Virginia. It resulted in reducing instrument downtime by 50 percent, ensuring compliance with regulatory guidelines, and shortening time-to-market to near “just-in-time” levels. There also was an unexpected benefit: the ability to apply integrated life cycle management principles for ongoing improvement.

BICI manufactures active pharmaceutical ingredients (APIs) and drug intermediates. In 2007, the QC laboratory management team set out to significantly increase productivity and reduce costs as part of a Six Sigma commitment to continuous improvement.

The following objectives were defined:

- “Let chemists be chemists” by freeing them up from performing routine instrument maintenance tasks
- Reduce instrument downtime
- Streamline the process for complying with regulations

The challenge

The Petersburg QC lab contains more than 500 instruments from multiple manufacturers, which were being serviced and maintained by an in-house service team and multiple manufacturers’ service representatives. The latter required several service contracts, creating an administrative burden as well as operational complexity. In addition, Operational Qualification (OQ) using each manufacturer’s protocol was performed for each instrument, necessitating

the filing and tracking of many regulatory compliance documents. The paper-based, manual system added to delay, administrative overhead, and tedium.

After examining a number of alternatives, BICI decided to replace its traditional in-house service model with an integrated service delivery (ISD) program that addressed the organization’s needs more completely.

Choosing the right service model

In recent years, four main instrument service models have been in use depending on each lab’s requirements: in-house, service consolidator, independent service provider, and OEM. Each choice offers advantages and drawbacks, which BICI weighed carefully.

- *The in-house model generally offers the fastest response time and flexibility to work around laboratory schedules, since service personnel are on site. The tradeoffs are the high cost, the administrative load, and the necessity to stay current on the newest technologies.*
- *Service consolidators use actuarial tables to reduce service contract spending 15 to 25 percent compared to other models. There can be tradeoffs in terms of risk, quality, and convenience, since these firms are incented to perform only the bare minimum service at the lowest cost in order to maintain their thin margins.*
- *Outsourcing to independent service providers is generally the lowest-cost option. The tradeoff is that these vendors tend to have competencies only in specific areas and often lack the quality control processes, parts supplies, and operational infrastructures to support larger labs in mission-critical environments like ours.*
- *In the OEM service model, having each instrument serviced by its manufacturer falls at the high-quality/low-risk end of the service model spectrum. However, using the OEMs typically costs more, may be administratively challenging to work with, and often results in response times of days, not hours.*

Most recently, the concept of an ISD model, which is a blend of the others, has been emerging. This model typically pulls together the benefit of on-site, high-caliber resources with the administrative and operational back-office efficiencies to manage services across all of the lab's systems. After investigating our options, we decided to implement an ISD tailored to our unique QC environment.

The Laboratory Resource Management solution

Our management team worked with Agilent Technologies to design a Laboratory Resource Management (LRM) solution to address our current business requirements while providing us with the commitment to adapt to future needs. Agilent recommended an expert-level, on-site service engineer to provide same-day response to service events and flexibility in coordinating and delivering scheduled servicing around the lab's planned and ad hoc activities. An on-site inventory of high-use parts was established to increase the likelihood of same-day repairs.

BICI used Six Sigma principles to set the parameters of the new LRM program, but found that a black belt needn't be assigned to the project to obtain the efficiency gains. A new set of metrics was implemented and a continuous monitoring system was put in place to verify performance at a high level of detail for BICI management. If a specific incident deviates from the service target, the system facilitates root-cause analyses. Thus, BICI acquired the ability to set very tight standards and measure against them.

Increased productivity for bench chemists

BICI conducted a follow-up survey after the new system had been in place for 12 months. It revealed that the amount of time that bench chemists spent troubleshooting equipment was reduced by 22 percent for chromatography systems, 25 percent for other analytical systems such as UV/IR/AA and dissolution systems, and about 6 percent for ancillary apparatuses such as balances and pipettes. Chemists also cited increased productivity due to assistance and training from the on-site service engineer, resulting in more proficient use of the instrumentation systems and equipment. The end benefit to the bench chemists was more time to spend on the quality control of products as well as on methods development to increase the efficiency and capabilities of the lab.

Reduced instrument downtime

Reducing the amount of instrument downtime due to repair and maintenance was another key goal of this initiative.

Through improved operator training and a robust maintenance program, BICI experienced a 26 percent reduction in the incidence of unscheduled downtime of chromatography equipment and a 33 percent reduction for other analytical systems attributable to the new LRM program. And the efficiency gains carried through into the scheduled maintenance events themselves, with reductions in scheduled maintenance downtime of 54 percent for chromatographic systems and 50 percent for other analytical systems. Nearly all scheduled maintenance and operational qualification activities were completed as scheduled.

Real-time troubleshooting, the expertise of the service engineer, and the immediate availability of service parts all contributed to increased instrument availability and service efficiency. When unplanned service events occurred, the Agilent solution paid big dividends: Greater than 75 percent of all repair events were resolved in the first service visit and 95 percent of all repairs were completed within two days. This translated into a 51 percent reduction in the amount of time required to repair chromatography systems and a 33 percent reduction for other analytical

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equipment. These results far exceeded our expectations and have impacted our lab chemists positively, enabling them to spend substantially more time focused on their analyses and allowing us to move closer to our goal of just-in-time inventory management.

Improved compliance process

At BICI, our previous compliance process comprised a myriad of OQ procedures from each manufacturer of QC lab instrumentation. Qualification was carried out manually, adding considerable delay, tedium, and overhead to the process. We were able to automate this function by adopting the Agilent Enterprise Edition Compliance system. In addition to increasing efficiency, stakeholders had higher confidence in the reporting accuracy, including regulatory audit readiness.

One of the biggest realized benefits from the new compliance solution was the substantial reduction in time spent on compliance qualification report reviews. Report review tasks that used to take up to three hours per report in the past now can be completed in less than 30 minutes each—an 80 percent reduction. Over the course of a year, approximately 200 hours of Ph.D. chemist time was saved, making this high-value talent available for what it was hired to do. Instrument downtime due to compliance testing also was reduced. Downtime due to compliance qualification was decreased by 55 percent for HPLC and GC instrumentation, 46 percent for other analytical techniques, and 17 percent for equipment such as balances and pipettes. The automated reporting system also allowed BICI management to track trends, compare performance through a library of searchable PDF reports, and provide a strong scientific basis for operational decisions. The result is compliance reporting in which we have a high level of confidence, regardless of changes in the regulatory environment.

Cultural factors

One key concern was how readily this major change would be accepted by our QC lab staff. People are by nature resistant to change, and this is amplified in the QC lab environment. Internal and external customers rely on the lab to provide highly reproducible QC data, using methods and procedures that rarely change. BICI was

careful to involve lab personnel early in the process and engage in an open dialogue with them. There was initial resistance and skepticism when the new ISD model was introduced; however, resistance ceased to be a concern once benefits began to be realized. About half the staff reported increased familiarity with chromatographic instrumentation after implementation of the new service model and more than 40 percent noted that they spend less time on service activities.

Laboratory administration

The BICI QC operation was able to reduce the number of service contracts it carried by 70 percent, freeing up 280 hours per year of purchasing team time. In addition, our in-house service team now spends 67 percent less time in support of the QC function. The in-house service team also now helps identify other process improvement opportunities at the site.

“Chemists also cited increased productivity due to assistance and training from the on-site service engineer.”

Continuous process improvement

BICI created a business process excellence team to identify methods to improve customer-facing business performance. The team knew that productivity could be improved and, as a result of the relationship with Agilent, they have identified a number of time wasters and designed a highly effective solution. BICI chemists now have significantly more time to spend at the bench, instrument downtime has been cut as much as 50 percent, and other productivity benefits have been identified. Most importantly, the mechanism is in place to facilitate continuous process improvement to accommodate future needs.

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TOMORROW'S LABS TODAY

EXTRAORDINARY DESIGN, ENVIRONMENTAL SENSITIVITY, AND CUTTING-EDGE TECHNOLOGY ARE BUT A FEW OF THE LATEST FEATURES **by Karen Appold**

"The centralized campus layout and underground entry were designed to minimize environmental impact."

Pressure to improve laboratory efficiencies, reduce environmental impact and accommodate a myriad of advanced technologies is driving current research facility design. The latest and most noteworthy examples from Japan, Canada, and Switzerland are presented here.

A self-sufficient laboratory village

A government-funded scientific research campus and graduate university, The Okinawa Institute of Science and Technology (OIST), in Onna, Japan, will include several state-of-the-art laboratories. Phase 1, begun in September 2004 and scheduled to be completed in March 2012, will accommodate 500 researchers and contain 700,000 square feet of research buildings, a central energy plant, and the first portion of a new village that will house half the campus staff. The 2.5-million-square-foot campus will include Japan's first and only English language graduate university campus, generic biomedical research laboratories, and a central research core facility.

"The campus was organized with a centralized master plan to grow to 3,000 researchers, including biologists, chemists, computer scientists, mathematicians, physicists, and engineers, working in an integrative approach to understanding the mysteries of biological and ecological systems," says Ken Kornberg, AIA, president, founder, and architect, Kornberg Associates Architects, San Diego and Menlo Park, CA, and Tokyo, who collaborated with Nikken Sekkei, Japan's largest architectural/engineering company, and Kuniken, Okinawa's largest architecture firm, on the campus design.

The campus begins at a beachfront area facing the East China Sea coast and rises 300 feet into the tropical rain forest. The three laboratory buildings are perched on forested ridges in a cluster formation and are connected by glass bridges that span ecologically sensitive 100-foot-deep canyons that will remain undisturbed.

Facilities will be accessed from the village by a covered bridge suspended above a man-made lake. The bridge connects to a 100-yard underground tunnel-



▲ *The three laboratory buildings of The Okinawa Institute of Science and Technology look out toward the East China Sea.*

shaped gallery that terminates at an in ground elevator core that emerges 100 feet above in a glass atrium overlooking the ocean. Lower level laboratories look directly into the forest and upper level laboratories have 180-degree views of the beachfront and sea.



▲ *The Okinawa Institute of Science and Technology facilities will be accessed from the village by a covered bridge suspended above a man-made lake.*

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The library, auditorium, and cafeteria will be centrally located in the research campus grounds. The centralized campus layout and underground entry were designed to minimize environmental impact.

The campus' entrance is through the central core, which has radiating bridges to access each research building. "The centralizing concept brings researchers together in the hopes of producing a dialogue among varied disciplines focused on nature and biologic systems," Kornberg says.



▲ The campus entrance of The Okinawa Institute of Science and Technology is through the central core, with radiating bridges to access each research building.

OIST is unique because of the large number of state-of-the-art research support facilities at one site. "This was necessary because the research institute is in a remote location and must be self-sufficient," Kornberg explains. "Additionally, each facility is designed to be versatile and flexible to accommodate the development of technologies over many years."

Ample space for further development exists. "As the university grows, it plans to acquire additional property for affiliated industrial spin-offs and start-ups," Kornberg says.

Cutting-edge technology

OIST's core facilities were designed to accommodate functional imaging disciplines and equipment that will be ordered in the future. "The facilities were specifically sized not for each piece of equipment but for an array of different products that are likely to be needed," Kornberg says. "The research core must provide for experimental work for scientists who will be coming to the new institute over the next 10 years."

Core research facilities at the campus center will include a synchrotron, electron microscopes, nuclear magnetic resonance

devices, mass spectrometers, sequencing center, zebrafish, eight patch clamp laboratories, and 10 flexible generic laboratories.

Bio-safety level 3 (BSL3) laboratories, the third level in a system of standards/protocols to maintain safety and contain biohazards, will also be included. These technologies are either the latest generation of support equipment or are still under development.

Other technologies that OIST plans to purchase include:

- *Illumina Genome Analyzer II, Roche 454 GS FLX, and ABI Solid 2.0, providing a full-service sequencing core to cover a versatile range of polynucleotides.*
- *The JEOL 300 kV electron microscope under development offers extremely high resolution imaging.*
- *Thermo Scientific's LTQ Orbitrap will provide both high resolution and accurate mass spectrometry, enabling definitive protein characterization.*
- *MIRRORCLE tabletop synchrotron provides high-intensity X-ray technology for large molecule structure research.*

New materials take shape

4D LABS, a \$40 million facility that opened in January 2007, is an applications-and science-driven research center at Simon Fraser University (SFU), in British Columbia, Canada. The facility "focuses on accelerating the design, development, demonstration, and delivery of advanced materials and nanoscale devices that can lead to major advances in information and health technologies," says Byron Gates, PhD, director of the Nanofabrication Facility in 4D LABS and professor of nanostructured systems.

"It's one-stop shopping. If you want to make a material and then analyze it, you can do it here from start to finish."

"Rather than creating departments or networks of researchers with similar interests, like other university research centers, 4D LABS identifies technologies that require significant advances in fundamental science to become commercially viable," Dr. Gates explains. "Then, it defines multidisciplinary projects and recruits chemists, physicists, and engineers with expertise in nanomaterials engineering and devices. It's one-stop shopping. If you want to make a material and then analyze it, you can do it here from start to finish."

The 2,000-square-meter concrete building complements the

modern style of Canadian architect Arthur Erickson, who designed the SFU campus. The high-tech, energy-efficient center is completely wireless, has a closed-loop cooling system that minimizes water usage, has pneumatically driven vacuum lines for chemistry laboratories, and contains sensors that automatically turn off lights when unoccupied. The facility can accommodate more than 100 students, professors, and researchers.



▲ 4D LABS at Simon Fraser University in British Columbia, Canada, is situated atop scenic Burnaby Mountain.

A closer look

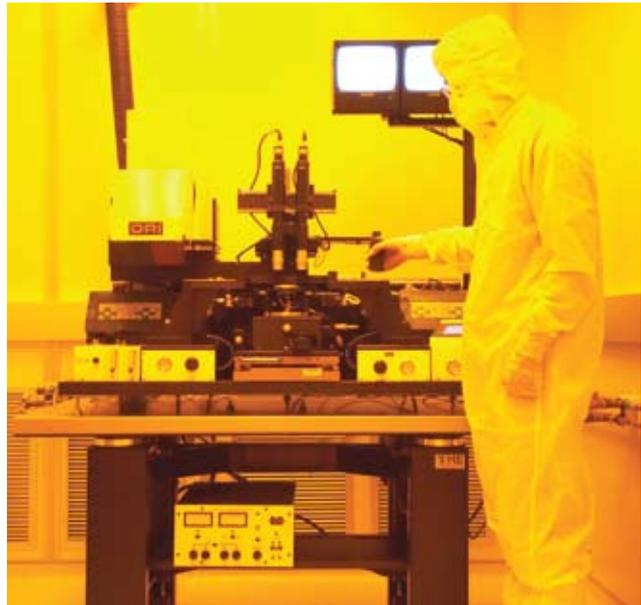
The first floor was custom built to house state-of-the-art instrumentation for fabrication and materials analysis. An integrated clean room will be completed in the early spring of 2009. The second floor houses offices and research laboratories where researchers interact across disciplines, combining their skills to address specific materials-related challenges.

The clean room will be the primary site for constructing new molecular electronic, photonic, and magnonic devices. The Class 100 facility with local Class 1 environments will permit handling of sensitive samples. It will house essential fabrication equipment, including an electron beam writing facility, mask aligners, dry etch facilities, process furnaces, and physical vapor deposition systems, as well as wet processing equipment, including a unique Class 1 robotic cluster tool for multilayer construction. “Unlike the majority of clean rooms, we are open



▲ The clean room facility within 4D LABS is divided into 14 suites that house fabrication and characterization capabilities.

to almost any type of material. Our clean room will permit development of novel processing chemistry and incorporation of new materials into functioning devices,” says Dr. Gates.



▲ This Class 100 facility at 4D LABS contains controlled settings (Class 1 environments and filtered lighting) for the fabrication of devices incorporating materials that are sensitive to volatile impurities and/or exposure to ultraviolet light.

The nano-imaging laboratory provides high magnification tools to look at structures and materials. Some of its imaging technology can also be used to create and modify nanoscale features within devices. Equipment includes scanning electron microscopes, scanning transmission electron microscopes, a dual beam scanning electron microscope/focused ion beam system, and a full array of scanning probe microscopy.

The growth and characterization laboratory houses facilities aimed at atomic-scale control of the growth and characterization of materials. It also contains high-vacuum characterization spectroscopies for analysis of a broad range of materials, including an integrated PEEM/LEEM system for characterizing the influence of surfaces on the growth of materials. Additional characterization equipment includes the photoelectron and Auger electron spectroscopies useful in the characterization of a wide range of materials.

The visiting scientists’ laboratory facilitates international research collaboration by providing space for external teams and 4D LABS researchers to work together.

The Laboratory for Advanced Spectroscopy and Imaging Research (LASIR) is a joint initiative between SFU and the Uni-

versity of British Columbia that brings advanced spectroscopy tools to the Pacific West Coast. The SFU hub provides materials characterization facilities that offer researchers the tools to investigate the properties of electrons in superconductors and a variety of properties related to magneto-optic and nonlinear optical behavior.

Equipment consists of ultraviolet and X-ray lithography sources including a femtosecond laser system. It also houses a tunable nanosecond laser system, which forms the heart of the nonlinear optical characterization beam line, which is used in conjunction with the SQUID for magneto-optic experiments. The LASIR clean room will be integrated with a central clean room, allowing use of the lithography facilities in a continuous, clean environment.



▲ Researchers in 4D LABS are given hands-on training and access to state-of-the-art equipment, including the Class 1 robotic cluster tool.

A nanoscience partnership

In Switzerland, IBM and Swiss Federal Institute of Technology (ETH) Zurich, a premier European science and engineering university, have partnered to construct a new nanotechnology laboratory—Nanoscale Exploratory Technology Laboratory. Constructed on the campus of the IBM Zurich Research Laboratory in Rüschlikon, the center will focus on exploratory and basic nanotechnology research to applied and long-term projects.



▲ Model of Nanoscale Exploratory Technology Laboratory in Rüschlikon.

The center will be built over the next two years, with completion expected in spring 2011. The 6,000-square-meter building will have four floors. The first floor will house a 1,000-square-meter clean room for micro technology and nanotechnology. Special laboratories for the characterization of small and sensitive nanostructures, i.e., noise-free laboratories, will be located in the basement. The remaining two floors will contain offices and other characterization laboratories.

The center's modern design will complement the existing campus' architecture. Focusing on both practical and modern design, the glass façade of the clean room will feature a light-shielding metal cover with a unique pattern of inclusions (little holes), mirroring molecular and atomic scale structures. The cover will reduce the amount of light entering the clean room, creating optimal conditions for conducting experiments.

Making the building energy efficient is a high priority. Highly efficient thermal insulation, geothermal energy, and photovoltaic elements will minimize energy consumption.

“Highly efficient thermal insulation, geothermal energy, and photovoltaic elements will minimize energy consumption.”

Key components: Clean room and noise-free laboratories

“The clean room is a prerequisite for the fabrication of any micro- and nanostructures on semiconductors and other materials,” says Roland Germann, PhD, manager, Nanocenter Operations, IBM Zurich Research Laboratory. The clean room will accommodate approximately 50 processing tools used for such procedures as lithography, deposition, and etching.

Space will be dedicated to research projects, such as carbon-

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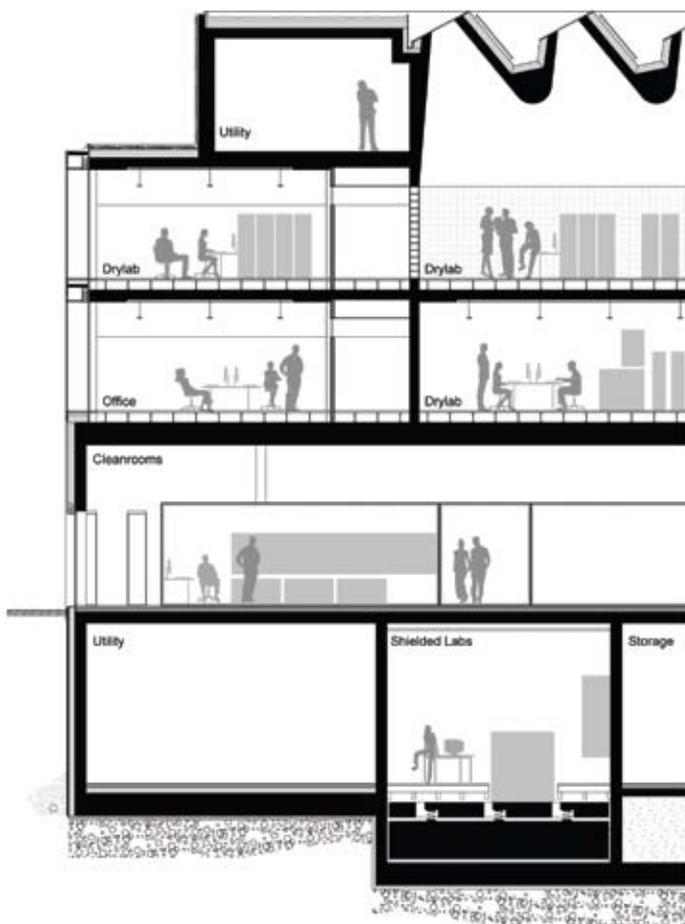
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based materials, nano-photonics, spintronics, nanowires, and tribology. It will allow for research on new device concepts based on carbon materials using quantum mechanical effects for computing and sensing, and it will contribute to resolving upcoming challenges in nano-manufacturing via research aimed at directed self-assembly of nanostructures and molecular functional materials, as well as 3-D integration.

“The clean room is custom designed for our specific research application and is combined with noise-free laboratories.”

“The center is unique because the clean room is custom designed for our specific research application and is combined with noise-free laboratories,” Dr. Germann says.

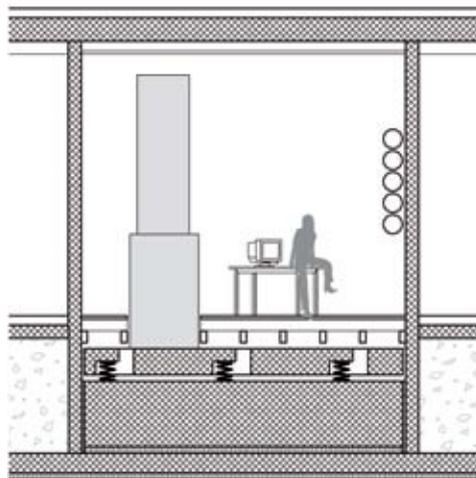
“The noise-free laboratories will be indispensable for the

electrical and structural characterization of tiny and sensitive nanostructures,” says Germann. Special and complex measures will be taken to shield these laboratories against mechanical vibrations, acoustic disturbances, and magnetic fields.

Looking forward

Under the \$90 million multiyear program, researchers and engineers from IBM and ETH Zurich will join forces to conduct research into new atomic and molecular-scale structures and devices that can be used for information technologies, for example, as well as research into discovering and understanding their scientific foundations—all in dimensions below 100 nanometers (approximately 400 times thinner than a human hair).

“By creating this common research center, IBM is expanding a collaborative and cooperative research program aimed at ac-



▲ A cutting-edge insulation concept will be implemented to shield the noise-free labs of the center, including minimization of vibration-acoustic disturbances; limitation of low-frequency magnetic fields by passive and active screening; HVAC climate control system.

celerating our understanding and implementation of nanotechnology and its broad range of applications,” says Dr. John Kelly III, senior vice president and director, IBM Research. “This is an emerging model for future industry/academic partnerships.”

Preparations for more of these laboratories of the future are under way worldwide.

Karen Appold is an editorial consultant based in Royersford, PA. She can be reached at Karen.Appold@comcast.net or 610-948-1961.

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REQUIRED MAINTENANCE

A PROACTIVE MAINTENANCE PROGRAM DEMONSTRATES COMPLIANCE, KEEPS AUDITS MOVING FORWARD AND CAN INCREASE PRODUCTIVITY AND PROFITABILITY

by Gerry Hall

Many consider the '60s through today as an era of analytical and technological revolution. In the '50s, labs were running manual chemistries, using handwritten QC charts and keeping data in log books and file cabinets. Lab technicians were creating calibration curves by hand. No auto-sampling, no computer control, no electronic interpolation of data. Technicon offered a few automated chemistries in the '60s. In the '70s, handheld calculators, ranging from the simple Texas Instruments four-function adding machines to the elaborate Hewlett-Packard scientific calculators, marked the end of slide rules, and Apple introduced its first computer. In 1981, IBM launched its first PC.

Companies such as DuPont, Hewlett-Packard, PerkinElmer and Varian began to introduce computers into their analytical instrumentation systems. Computers helped provide lab data management and automated instrument control.

From the '60s onward we have seen growth at logarithmic rates—growth in computer programs, analytical instrumentation, test protocols and the number of analytes to quantitate. Along with this growth has come the need for instrument control and data analysis. Controls, which have ranged from very good to overly cautious, have been self-imposed, auditing-agency imposed and sometimes court-mandated.

Always the need for better control

Though agencies now control standard practice analytical protocols and maintenance requirements, this still hasn't guaranteed that data produced by two different instruments or in two different labs is in agreement. Sometimes, all the maintenance and proven chemistry in the world will not generate miscible data streams. One example goes back to enzyme analysis in and prior to

the '80s. There were no National Bureau of Standards-certified 99.99% pure enzyme standards. Enzyme results were reported in International (activity) Units rather than concentration units. Different manufacturers built instruments with different reaction-chamber temperatures. The bottom-line result was that enzymes were reported in International Units at 37 °C, at 30 °C or at room temperature. Hospitals would have different normal ranges depending on their method of analysis.

Another example of well-maintained and "in-control" instruments giving differing results occurred in the earlier days of automation. An iron test run on a flow system utilizing membrane filters was the industry standard. Most labs had this instrument. The next generation of instruments used a different technology—an automated spectrometer. This analysis

processed whole blood. The result? Some samples run in correlation tests did not agree. Both systems were in control but not always in agreement. The reason was that the new technique was more accurate, which required much of the industry to reprogram its thinking.

Why do we track and apply maintenance?

If you don't maintain your car, out-of-control actions will become noticeable over time. An untimely breakdown or unexpected repair cost can ruin the family budget. Manufacturers know their equipment best. They determine when various maintenance actions are required in order that the operation consistently generates the highest quality product or data. Well-maintained equipment will help minimize downtime and unbudgeted costs. We document maintenance to help ensure consistent quality.

"Well-maintained equipment will help minimize downtime and unbudgeted costs."

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People perform maintenance. Part of being compliant is maintaining employee training levels and capability records. One “people factor” rarely discussed is “current mentality.” Whether you have two or 200 employees, you can never be absolutely certain what percentage of any one person is on the job right now. Severe storms, a bridge collapse, personal or family illness, service activation and love are some factors that can distract an individual from remembering those proactive maintenance steps required by manufacturers. One of our customers told of an employee who forgot a couple of remote location autosamplers. The auditors found them. Ding. (I highly recommend proactive maintenance software programs whenever possible.)

Maintenance of your chemical inventory is another very important part of laboratory compliance. A lab manager told us that last month her staff had a project with time-sensitive samples come into their lab. They found that two project chemicals had passed their expiration dates. They lost a day securing new chemicals.

Compliance

Licensing and accrediting agencies were created to perform a needed function. This was (and is) to make sure that labs take the right steps to unite, correlate and validate data streams. When systems are in control, predictive models can be developed, utilized and built upon. Various labs can run the same project samples and generate correlative data. This year’s studies can be compared to another year’s findings. This normalization of data is the result of the need to ensure that all analyses can be correlated to existing data.

Certification programs can be your business partner

Certification programs can serve you well. Licensure programs can increase the productivity and profitability of your business. Proof of this is often difficult to document. Before working with a quality program, proof might be back-calculated by asking the following questions:

Did audits go smoothly? Were records current, legible, easily found, complete and defensible? Good things happen when an auditor sees that you are prepared. Frequency of audits may be reduced. Audits will move faster. Employees get back to their jobs faster, rather than obsessing about the audit.

Was there scrap product? How much? How much money did losses cost you?

Were losses reduced when working with a quality program?

Reworks? Costs? Frequency of reworks reduced? Reworks cost time, labor and materials. Reworks might delay shipment or data release.

Certification inspections are part of the business of science. Auditors can (and should) routinely ask to see instrument maintenance records and technicians’ documents of capability. The first step in generating reportable data or saleable product is practicing a proactive program to ensure that instruments, equipment and facilities are always maintained to manufacturers’ recommendations.



▲ Some software systems document out of service and unscheduled maintenance.

In the early '70s, Philip Crosby wrote books titled “Quality Is Free” and “Zero Defects.” His target audience was manufacturing operations. But production is production—whether it’s a car, a soft drink, an aspirin or data. His premise was that the cost of a quality program more than paid for itself based on fewer reworks or reruns; fewer discarded, lost or expired samples; fewer exception reports; and a higher yield of billable results.

Maintenance

All your assets require maintenance. And your assets include the physical plant, all equipment and instruments, chemicals and reagents, and your employees. The relationship between maintenance and compliance is obvious. Maintaining your lab, equipment, people and chemicals are all audit requirements. Documenting maintenance actions demonstrates compliance.

It is not hard to see a direct link between maintenance, productivity and profitability. Here are two examples of these critical relationships that I have experienced personally:



▲ Some programs allow one to list instruments and link to maintenance manuals.

1. I was managing a customer training function for an instrumentation company. Twice each month we hosted “new customers.” Once each month we gave a class for advanced users. At advanced dinners I would always ask the question: “Is anyone having instrument problems?” The group then took it upon themselves to diagnose the situation as if indeed someone was having problems. Almost every time it turned out that those accounts that had nagging instrument problems were the same accounts that did not accept the serious responsibility of routine maintenance. If you are troubleshooting an instrument problem, you are consuming precious production time and materials. Many times, the down instrument was caused by forgotten maintenance. Lack of maintenance will impact your productivity. Productivity relates directly to profitability.

2. Eighteen months ago, Systea Scientific LLC commissioned my company to make a special maintenance monitoring software program for its EasyChem Discrete Chemistry Analyzer. Two months ago, I was notified that its technical service group was seeing a 50 percent reduction in service calls. Our software tracks maintenance, links to manuals and securely documents actions to help keep users—especially newer users—always on time with all maintenance actions. Users are more productive when following the guidelines. And with the help of the software, users become more proficient. The company also is more productive because

it spends less time dealing with customer calls caused by neglected maintenance issues. This has allowed the company to offer extended warranties at no extra cost because of improved efficiency.

Meeting the requirements

Here is an example of documentation required for a typical certifying agency. These selections were taken in 2007 from Chapter 5 of the DOD-updated National Environmental Laboratory Accreditation Program (NELAP) version:

8.0 b) Equipment and Reference Materials – All equipment shall be properly maintained, inspected and cleaned. Maintenance procedures shall be documented;

9.4.1 Support Equipment – a) ... maintained in proper working order... records kept;

9.4.1 Support Equipment – e) ... documentation on all routine and non-routine maintenance;

– e) 8) ... details of maintenance carried out to date and planned for the future; and

– e) 9) ... histories of any damage, malfunction, modification or repair.

Documentation requires a fair amount of written records and/or paper-trail notes. Due to the rigid requirements of producing data and reports within time constraints, records may not be updated immediately, fully



▲ This software schedules, tracks and then documents maintenance.

or legibly, if handwritten. In environmental labs, several analyses are limited by time. Analyses have to be completed within 24 to 48 hours after sample collection. To meet time requirements, these actions might supersede documentation of recently performed maintenance and repair. This can become troublesome later if paperwork has been set aside for the moment and is then forgotten.

Two truths

First, consistently good product or accurate data produced in a timely fashion is your goal. It is critical that every organization and every employee understand and participate in a proactive maintenance program. (The old DuPont rule was safety first, housekeeping and maintenance second, and production third.) This helps ensure that data reported or product released is of the highest possible quality. Well-maintained instruments consistently generate good data and perform within acceptable limits. The good data can be compared to your own lab and other laboratories.

Second, workloads are increasing. Computers are doing more and more for us in the lab. Lab managers need to stay open and receptive to the new products that are entering this marketplace. You may consider building your own supplemental lab computer programs. These programs will require extensive programming time. Debugging new programs is a monumental task. Program modifications and debugging are never-ending tasks as certifying agencies continue to grow and add

to or change existing audit criteria. I believe it is cost-effective to find the pre-developed programs that meet your needs.

New software companies are addressing these needs for task tracking and documentation. LIMS do an excellent job tracking samples from when they are drawn through to final report generation. In the past few years, some LIMS programs have added modules to address lab asset management components. Unfortunately, LIMS are fairly complex. And asset management always seems to be the last function programmed with a new LIMS. (And I often find that this job is never completed.)

“Well-maintained instruments consistently generate good data and perform within acceptable limits.”

New software products coming into the marketplace now complete the laboratory compliance circle. Commercial products are being created to perform or guide you through scheduled and unscheduled maintenance actions—and at affordable prices. You must control the validity of your data or product by ensuring that all maintenance is addressed properly. Being compliant helps keep audits moving forward. This in turn helps increase lab (or industry) productivity and profitability.

When agency auditors see handwritten entries that are illegible, incomplete or nonexistent or appear to be written all at the same time, alarms will go off and inspections will go much deeper. They take much longer. This will impact your productivity.

Explore all the emerging opportunities. Take all the steps possible to stay proactive in protecting your lab’s product. The basic fact is that with or without software programs, your lab needs to be compliant and then demonstrate that compliance to an auditor. This demonstration includes scheduling, tracking and documenting instrument and facilities maintenance. This also includes being able to show an ongoing maintenance program that also plans for future actions.

Gerry Hall, president, TimeKeeper® America, can be contacted at gerry@timekeeperamerica.com or 727-457-3105.

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NO DEARTH OF OPTIONS FOR DESIGN AND MATERIALS USED FOR LABORATORY CABINETS AND STORAGE

by Tanuja Koppal

Laboratories are complex workplaces and all require easy-to-maintain storage cabinets and countertops with appropriate safety mechanisms in place as well as room to satisfy multiple users. Cabinets and countertops must also fulfill the specific needs of the laboratory in terms of accommodating various types of equipment, and they should be able to withstand long-term exposure to various radioactive, biological, and other hazardous materials to which they may be constantly exposed. Cabinetry, or casework, includes base and wall cabinets, storage and supply cabinets. Other components may include fume hoods, sinks and plumbing options, and power outlets.

"Choosing the right laboratory cabinetry depends on . . . the type of work being done, safety, durability, budget, and long-term plans."

Choosing the right laboratory cabinetry depends on a number of criteria, including the type of work being done, safety, durability, budget, and long-term plans. Options range from fixed installations to modular cabinets and mobile units and from custom-designed and installed systems to generic units. Modular cabinets can be adjustable and designed to meet changes in procedures, instrumentation, and personnel. Mobile units can be reconfigured by technicians, without the need to wait for maintenance personnel.

"Mobile benches, made of high-grade steel, can be useful when flexibility and mobility are required."

Casework can be made of several different materials, including wood, metal, or plastic laminate. Stainless-steel metal cabinets are extremely durable and used in labs with aggressive atmospheres or ones that require decontamination. Wood casework, usually made of oak, birch, or high-grade plywood, is useful in all types of commercial, indus-

trial, and research laboratories. It offers a traditional decor, provides a stable base for equipment, and can withstand decades of use. Plastic laminate is economical and offered in colors and patterns that blend with or accent any decor. Phenolic resin cabinets are very durable and can be used in custom configurations. They are useful in wet or corrosive environments. Polypropylene cabinets, while high in cost, are useful in metal-free and corrosive environments. Mobile benches, made of high-grade steel, can be useful when flexibility and mobility are required.

"Countertops experience the most day-to-day use, and abuse, in laboratories and should be chosen to withstand the work being conducted."

Countertops experience the most day-to-day use, and abuse, in laboratories and should be chosen to withstand the work being conducted. There are more than ten categories of countertop materials used, including epoxy resin, solid phenolics, plastic laminate, stainless steel, and natural stone, as well as wood or wood composites, calcium silicate, ceramics, and modified plastic composites. Although no material is impervious to everything and suitable for every application, there are a number of options now available that help researchers meet their specifications for unique applications. Casework manufacturers and other vendors often work with researchers to help customize the designs and choose materials best suited for their budgets and applications.

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

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FROM CELL CULTURE MEDIA TO EXTRACELLULAR MATRICES, THERE IS A LOT CHANGING IN THE IN-VITRO WORLD

by Tanuja Koppal

While the technology for culturing cells has undergone significant changes—from using manual skilled labor to installing automated systems—the reagents for culturing cells have not changed all that much in the past 50 years. What has changed in the past few years, however, is that cells themselves have become reagents. As with other biochemical reagents, laboratories can now buy cells in bulk and freeze them until needed. This has proved very useful, especially for such applications as high-throughput screening, where having millions of cells available from the same batch from the same vendor has reduced both inter- and intra-variability in assays. Use of frozen cells also eliminates problems associated with human variability, scalability, and homogeneity of cells.

“As with other biochemical reagents, laboratories can now buy cells in bulk and freeze them until needed.”

Having a reliable source of cells that perform consistently is very important for most applications, and performance of the cells often depends on the health of the cells. The health of the cells in turn depends on the quality of the cell culture media. Typically, a synthetic basal medium is chosen to meet the nutritional needs of a given cell line. Basal media comprise amino acids, vitamins, inorganic salts, organic compounds, and trace elements needed for cell growth and are usually supplemented with at least 5 percent animal serum.

The synthetic basal media formulations are continually tweaked and combined with various supplements to closely mimic metabolic conditions in vivo. Manufacturers now offer options that are chemically defined, serum free, and optimized specifically for certain cell needs. Sometimes, researchers find that reducing or eliminating serum concentrations leads to increased cell definition, more consistent performance, easier purification and downstream processing, precise evaluations of cellular function, increased growth or productivity, better control over response, and enhanced detection of cellular mediators.

Cell culture reagents are available in both liquid and powder forms to promote attachment and spreading of various cell types and sub culturing adherent cells. A broad range of proteins is available to coat cell culture surfaces to promote cell

“Manufacturers now offer options that are chemically defined, serum free, and optimized specifically for certain cell needs.”

attachment and monolayer formation. A solution of proteolytic and collagenolytic enzymes can be used to detach cells from tissue culture surface, allowing high plating efficiency. Cell detachment enzymes are also used to create single-cell suspensions from clumped cell cultures for counting cells accurately and detaching cells from primary tissue.

Disassociation reagents can be tailored to passaging and culturing requirements for experimental needs with non-enzymatic formulations for cell dissociation. Non-mammalian-derived solutions for cell detachment also are available. Formulations and media also are customized by vendors for specific applications or cell lines.

In addition, there is a lot of innovation taking place in the creation of cell culture matrices that recapitulate a more physiologically relevant environment. The creation of 3-D cell cultures using complex media and structures like beads rather than a flat plastic surface is an attempt to get closer to replicating the complex organization and function of interacting cells. The ultimate goal is to be able to re-create in vitro an environment that resembles what goes on in vivo.

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

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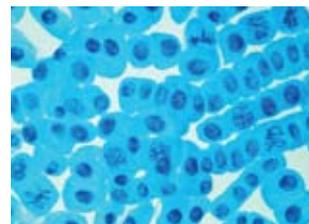
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BOOSTING TECHNICAL AS WELL AS MANAGEMENT SKILLS TO IMPROVE PERFORMANCE

by Tanuja Koppal

According to the American Association for the Advancement of Science (AAAS) careers Web site, sciencecareers.com, many scientists in industry and academia are pursuing careers with an eye toward laboratory management. But while they may have a good handle on the science and the technical aspects of their job functions, they have little or no training in personnel management, budgeting, interpersonal skills, time management, making hiring decisions, developing policies, improving communication and teamwork, and building group dynamics—all essential skills for functioning as a good manager.

Many companies, organizations, and university partnerships have discovered this lack of management training among scientists and are seeking to plug the gap by providing training in general management, as well as in scientific management training, through on-site courses, publications, online courses, and self-help software. Conferences, seminars, workshops, and teleconferences are also utilized

"Many companies prefer on-site management training, often customized to meet their specific needs and goals."

for providing such training. Many companies prefer on-site management training, often customized to meet their specific needs and goals. These training opportunities, offered one-on-one or in small groups, help develop leadership and communication skills among their scientists and improve performance by increasing awareness and acceptance for implementing necessary changes. Many training programs also provide extensive technical training and help teach scientists how to use various types of software programs to maintain good laboratory practices and laboratory information systems.

A variety of off-site training options also are available. Many universities and business schools offer short-term, intensive leadership and management courses to train scientists working at companies, research hospitals, and government laboratories. Scientists participate in evening

or weekend classes to boost their management skills and business acumen. A number of online business courses and self-help programs are a good alternative for people seeking to expand their knowledge on their own schedule and at their own pace.

"Online business courses and self-help programs are a good alternative for people seeking to expand their knowledge on their own schedule and at their own pace."

In addition, there are numerous books written specifically for laboratory management, and thousands written on general management, that offer practical advice that can be implemented in a variety of laboratory settings. One resource that provides a collection of practical information is the partnership between the Burroughs Wellcome Fund and the Howard Hughes Medical Institute. They have published such books as *Making the Right Moves: A Practical Guide to Scientific Management for Postdocs and New Faculty* and *Training Scientists to Make the Right Moves: A Practical Guide to Developing Programs in Scientific Management*, both of which are available free for noncommercial use on their Web site

"Universities and business schools offer short-term, intensive leadership and management courses to train scientists working at companies, research hospitals, and government laboratories."

at www.hhmi.org/resources/labmanagement/moves.html. Additional materials available include case studies, interactive exercises, and other materials used for training events for beginning scientists.

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

AMERICAN ASSOCIATION FOR LABORATORY ACCREDITATION

The American Association for Laboratory Accreditation (A2LA) is a non-profit, non-governmental, public service, membership society. The mission of A2LA is to provide comprehensive services in laboratory accreditation and laboratory-related training. Services are available to any type of organization, be it private or government. Laboratory accreditation is based on internationally accepted criteria for competence (ISO/IEC 17025:2005). A2LA also offers programs for accreditation of inspection bodies, proficiency testing providers, reference material producers and product certification bodies.

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www.research.ucdavis.edu/home.cfm?id=OVC,14



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RECENT TRENDS IN SMALLER PARTICLE SIZE DRIVES DOWN COSTS AND IMPROVES COLUMN EFFICIENCY *by Tanuja Koppal*

There is no dearth of options—both in terms of variety of columns and vendors—for analyzing samples using column chromatography. The challenge is to be able to pick the right analytical column to analyze the right sample correctly. The decision is based on several factors: column specifications, dimensions, media particle and pore sizes, and chemistry of the bonded phase, all of which can affect separation efficiency, inertness, durability, pH range, batch-to-batch reproducibility, resolution, solvent usage, and more. There is also the complexity and quantity of the sample available and the desired cost and accuracy of analysis to be considered.

“Even before the solvent shortage occurred, the trend had been toward increasing the use of columns packed with smaller particles because of advantages associated with costs and efficiency.”

“What is really important to the consumer is lot-to-lot and column-to-column reproducibility,” says Dafydd Milton, product manager, LC and LC/MS columns, at Thermo Fisher Scientific Inc. “They have to have the confidence that the column will elute the analyte peaks at the same time, every time.” Along with elution times, the ability to get good peak shapes—sharp, narrow, symmetrical peaks—is also important, especially for applications such as method development.

“Many companies have now introduced hydrophilic interaction chromatography (HILIC) columns for analysis of such polar analytes.”

Conventional liquid chromatography uses plastic or glass columns that can range in size from a few centimeters to several meters in length. Commonly used lengths vary from 10 to 100 cm, with longer columns being used for prepara-

tive scale separations. High-performance liquid chromatography (HPLC) columns are made of stainless steel and are typically shorter, approximately 10 to 30 cm in length. Short, highly efficient HPLC columns allow shorter analysis times, better peak shapes, and better quality data while also reducing cost per analysis. Narrower columns also offer better mass sensitivity and significantly reduce solvent use.

“Along with preparative and process analysis, there are also analytical columns being introduced for the fast and accurate detection of biomolecules.”

Milton mentions that in recent months there has been a shortage of acetonitrile, a solvent routinely used for HPLC analysis. Acetonitrile is a by-product of the automobile industry and, since there are no dedicated plants to manufacture acetonitrile, the recent slowdown in the production of cars has caused scarcity of the solvent. “We find many customers moving to smaller columns, packed with smaller particles (sub2-micron) because they use less solvent,” says Milton. Even before the solvent shortage occurred, the trend had been toward increasing the use of columns packed with smaller particles because of advantages associated with costs and efficiency, although slower, longer columns that offer better resolution are sometimes preferred to separate sample components in extremely complex samples. “It’s been a couple of years since the sub2- or 2.5-micron columns were introduced into the marketplace, and the smaller particle-size columns are now proving to be very important,” says Maureen Joseph, product manager in the Columns and Supplies division at Agilent Technologies Inc. These columns have proved very efficient in terms of cost and performance, and they cover a wide range of applications in industries that span food, environmental, pharmaceuticals, biofuels, and others.

There is also an increased demand for the analysis of polar analytes for applications in both drug discovery and development, such as the identification of metabolites. Hence, many companies have now introduced hydrophilic interac-

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tion chromatography (HILIC) columns for analysis of such polar analytes. "More and more drugs that are being developed seem to have a polar component, which the traditional C18-type columns don't seem to retain very well," says Milton. The HILIC columns use hydrophilic interactions to facilitate the transfer of polar analytes to the stationary phase for increased retention and better sensitivity.

There are a lot of changes also taking place in the area of biomolecule analysis. "Along with preparative and process analysis, there are also analytical columns being introduced for the fast and accurate detection of biomolecules," says Taegen Clary, who is also a product manager in the Columns and Supplies division at Agilent but is involved more with biomolecule analysis. People involved in antibody sizing, analysis of protein isoforms, and clinical samples are becoming increasingly concerned about time and cost of analysis. Reducing the time needed to analyze samples, increasing efficiency, and improving data quality can result

in significant savings for laboratories that run hundreds of samples per day. Such laboratories are also continually evaluating alternative methodologies that can overcome some of the limitations associated with column chromatography. Microfluidics, for instance, is beginning to play a role in analyzing samples that are rare and available in small quantities, such as for proteomics. However, it has yet to play a role in mainstream analytical applications. While there is definitely a trend toward miniaturization, microfluidics is unlikely to completely replace column technology. "There will always be a place for traditional column technology," says Joseph.

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

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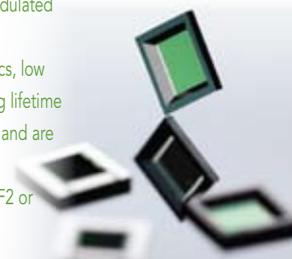
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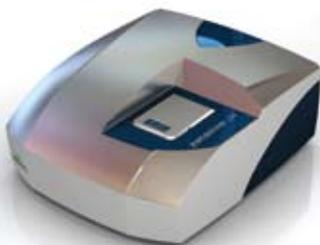


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THINGS YOU SHOULD KNOW...THINGS YOU SHOULD DO

Concern about musculoskeletal disorders (MSDs) has escalated during the last two decades as work cadences, techniques and time pressures have intensified in the life sciences arena^{1,2} Extensive pipetting practices, once on the periphery of ergonomics discussions, now form the core of a hot debate because they are considered a major risk factor that could lead to strain-related injuries, especially in biology research laboratories.²⁻⁵

Based on an independent evaluation of the activities performed in a typical cellular biology laboratory and conducted by ergonomics consultants, this article reaches beyond the present-day controversy about pipettes and their relationship to the appearance of MSDs and attempts to re-establish the importance of this indispensable tool. Additionally, we propose general recommendations to improve comfort while performing pipette-oriented tasks and reduce the risk of developing MSDs in the laboratory.

Musculoskeletal disorders — Repetitive strain injuries

MSDs are disorders of the osteoarticular and muscular systems involved in movement. Their severity and the physiological regions affected may vary. MSDs result from an imbalance between biomechanical demands and an individual's functional capacities. Their precise developmental mechanism is not fully known, although some studies have identified contributing factors. Inadequate circulation due to static contractions, highly repetitive work and selective muscular activation over long periods of time are believed to be major factors in the development of muscle, tendon, cartilage and bone lesions. Canadian ergonomists have suggested the name repetitive strain injuries (RSIs) as a subcategory of MSDs attributable to repetitive work.⁶ Carpal tunnel syndrome (CTS), the most widely recognized RSI, is identified by swelling of the membrane linings and surrounding tendons in the base of the palm. Its symptoms include pain or numbness in the wrist, thumb and first three fingers and loss of strength or dexterity in the hand. Musculoskeletal disorders have multiple origins. Most authorities agree that MSDs result from different factors acting

simultaneously, and their severity and individual impact are impossible to foresee. The three main categories of factors associated with the appearance of MSDs are biomechanical, psychosocial and individual (Figure 1).



▲ Figure 1. Contributing Factors to Musculoskeletal Disorders

Ergonomics study in a research laboratory

The ergonomics study sought to determine the relationship between the risk of MSDs and activities involving the use of pipettes and other common tools within a research laboratory specializing in cellular biology. The consultants noted distinct differences in the study participants' operating modes, primarily because of the high variability of tasks but also because of their individual differences in aptitude, skills and morphology. Lab sci-

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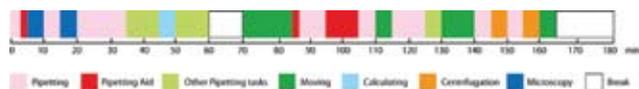
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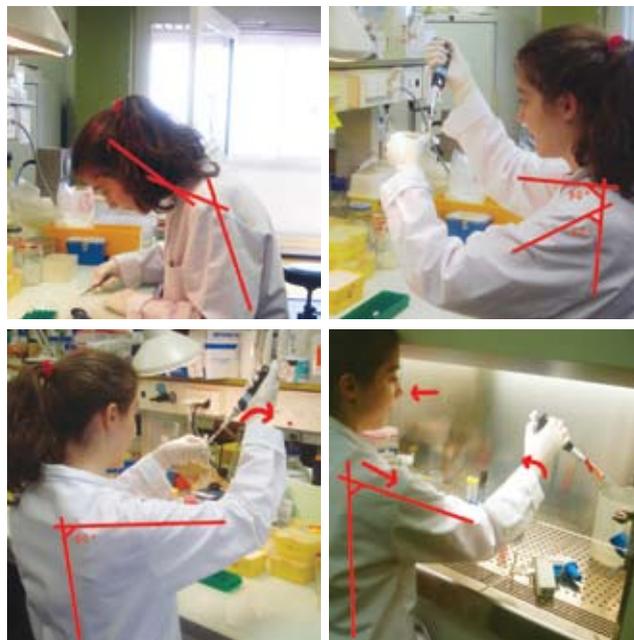
entists perform multiple tasks—pipetting, centrifugation, microscopy, calculations, etc.—all of which are governed by time, precision and safety constraints (Figure 2). The study results indicated that 57 to 88 percent of a scientist’s time spent working in the lab involves the use of pipettes. Except for work breaks, which range from 0 to 14 percent of the time worked, the remainder of the scientist’s day, between 9 and 22 percent of the time, is devoted to operations such as centrifugation, microscopy and calculations. The study also reported that intense repetitive movements, ranging from 59 to 89 per minute, were maintained over prolonged periods. Cramped rooms, poorly adapted laboratory furniture (sadly commonplace in laboratories), disorganized workstations and stress resulting from the acoustical assault of droning apparatus all contribute to a greater probability of the appearance of MSDs.



▲ Figure 2. Distribution of Tasks of One Operator (Cell Cloning)

The use of pipettes requires dexterity that is often complicated by tasks that force the operator to adopt awkward postures (Figure 3). For example, manual gel loading demands the technician’s full attention as each sample is transferred into a separate well. Maintaining a reasonable distance can only be theoretical. As with working under the fume hood, one must maintain a non-physiological alignment of the shoulder, wrist and finger joints.

Accelerations of the heart rate were observed during these tasks, owing to the emotional strain that probably originates with the responsibility for errors and their heavy consequences. Bench work causes difficulties linked with worktable dimensions, which are adapted to neither the sitting nor standing position. The table is either too high for pipetting gestures to be conducted without exaggerated flexion of the shoulder, or too low for techniques that require a short eye-task distance. Other commonly used laboratory apparatuses such as safety screens and microscopes force researchers to assume a boxer’s dodge stance, with arms outstretched in an elevated position for the entire duration of a manipulation. A prolonged static position can generate muscle fatigue in the neck region, leading to pain.



▲ Figure 3. Awkward and Static Postures Lead to Muscle Fatigue

Ergonomics Recommendations

Pipette users acknowledge the transformative effect the RSI debate has imposed on pipette manufacturers, which now develop product plans based on the principles of ergonomics. Pipettes now require less force to operate, and motorized electronic versions drastically reduce hand pain related to prolonged repetitive pipetting. Pipettes aside, there are universal recommendations for improving one’s comfort level in the laboratory^{7,8} (Table 1). The study revealed that the risk associated with extended use of pipettes depends not only on the ergonomics of the pipettes, other laboratory devices and furniture, but also on factors such as an individual’s physical characteristics, work rhythm, postural constraints and environmental conditions. Choosing the appropriate tools and organizing a work space in a more ergonomic manner can enable one to work smarter and greatly reduce strain-related injuries.

➔ **עבד סאף** For protective measures to help eliminate or reduce ergonomic stressors during routine laboratory procedures, visit:
www.chem.purdue.edu/chemsafety/SafetyClass/Injury/lecture/chap11.htm

Target	Recommendation	Reference
Physical Premises	<ul style="list-style-type: none"> • Minimal space requirement per person >10m² • Minimal width for passageways (1 person: 60 cm, 2 persons: 80 cm) 	NF X35-102 ISO 557
Furniture & Apparatus	<ul style="list-style-type: none"> • Use adjustable tables and seats • Opt for a fume hood with easy access and comfortable seating • Place frequently used devices in logical locations 	NF X35-104 and X35-105 ISO 9241-5 Ref. 9
Manual Devices	<ul style="list-style-type: none"> • Choose a pipette adapted to the task • Prefer tips recommended by the pipette manufacturer • Use multichannel pipettes for 96-well plate applications • Opt for motorized pipettes for repetitive and mixing tasks 	ISO 8655
Work Organization	<ul style="list-style-type: none"> • Do not exceed a gesture frequency of 30 gestures/minute • Take frequent, short breaks • Take a mandatory pause after each sequence of repetitive work • Vary tasks (work with different muscles) 	NF EN 1005-5
Work Conditions	<ul style="list-style-type: none"> • Noise < 55 dB(A) • Maintain a comfortable ambient temperature • Ensure the workstation is sufficiently lit (300 to 600 lux) • Eliminate dazzling sources of light • Eliminate glare and reflections from computer screens 	ISO 9241-6 ISO 7730 NF X35-103

▲ Table 1. General Ergonomics Recommendations

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VENTILATION STRATEGIES

CONSTANT FLOW, VARIABLE FLOW, AND ALL THE SPACE BETWEEN

by Jim Coogan, P.E.

Truly constant volume laboratory ventilation systems are almost obsolete, but there is a wide range of “nearly constant” systems that respond in steps to users’ activities and needs. These systems, sometimes called two-state or two-position constant volume systems, offer many options to ventilation designers.

The ventilation strategy should fit and support the safety programs for the laboratory. Ideally, the ventilation designer and safety officer work together to produce a coherent program of exposure control.

“Two-state or two-position constant volume systems offer many options to ventilation designers.”

Four steps to designing two-state ventilation

The following four design steps will lead to a system that ventilates a lab efficiently and works with the institution’s safety programs:

- First, identify the conditions in the room that call for differing flow rates. Often, the presence or absence of people in the room calls for differing flow rates. The need to use a particular exhaust device, or some other aspect of the lab users’ work, can also necessitate differing rates.
- Second, determine the flow rates for the device and the other flow devices that coordinate with it. The ventilation engineer should share this task with the health and safety professionals. Typically, each person has information and expertise to contribute. To set flow rates that effectively protect workers, designers should consider the principles of industrial hygiene, along with issues of room air distribution and ventilation efficiency. These concepts, however, do not lead directly to simply calculated answers. Designers should resist the temptation to fall back on rules of thumb. Instead, they should
- consider the intended laboratory tasks and document any assumptions about lab use. The process is actually simplified by the fact that they are selecting two different flow rates rather than trying to cover all circumstances with one.
- Third, select the control system inputs to trigger flow rate changes. Although this step is closely related to the first step, there is an important distinction. The question in step one was “What conditions change the requirements for airflow?” Now the question is “How does the control system detect the changes?” The answer might be manual inputs from the user or perhaps something more passive. The building automation system is likely to execute some control logic to select the high or low flow setting. For example, there are usually timers involved to limit unnecessary changes of state. If there is more than one input involved, then a process that combines their effects is necessary.
- Fourth, design an indicator that informs lab users of the ventilation system’s state. Users should understand that the system has multiple flow states and recognize how that supports their work. They can verify at any time that the system is operating in the appropriate mode. If the system is in the wrong state, lab users can take steps to restore safety.



▲ Typical flow indicator on a two-state fume hood



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For an exhaust device, the indicator is typically on or at the device. For a two-state room, indicators might be within the room or in the corridor outside.

It is important that the information sent to the user be based on measured airflow, not just on the state of the control device. Since mechanical systems can be complex, the airflow is not always what the controller commands. Consider an actual case of a two-state fume hood system that used a two-speed fan motor to set the flow. The exhaust was directed through a barometric damper. When the fan ran at low speed, the damper closed, causing the hood to leak. The system indicated that the hood was working at the low flow rate since the motor was running, when in fact there was effectively no flow and no containment.

“Flow rate, or face velocity, is just one factor affecting the performance of a fume hood as a containment device.”

Two-state rooms

Some systems reset flow rates room by room. Safety professionals reduce the ventilation rate for some rooms if they are confident that workers are not inside those rooms executing procedures that create hazards.

If the flow rate is based on occupancy, a familiar set of methods for the building automation system can determine the rate. Such methods include schedules, manual switches, people detectors, and combinations of these. It is important to select methods that make sense for a particular room and the way people use it. For example, in a teaching lab, a schedule might be appropriate. On the other hand, the instructor might need to take responsibility for manually selecting high or low ventilation.

Designers should carefully examine their assumptions about what users will do. For example, sometimes a light switch is used to indicate occupancy. In a facility with good daylight, that might not work. People detectors are not always effective, either; it depends on the kind of sensor and the activity of the people inside the room.

Some lab rooms change state for reasons other than occupancy. Emergency ventilation is one example. If the lab workers have an accident, they can exit the room and

initiate the emergency mode. They may press a switch or make a phone call to signal the emergency. The ventilation system then switches over to a set of flow rates selected for the emergency condition. In emergency operation, it is important to avoid the pitfall of pressurizing the room to the extent that it becomes difficult to open the doors.

Two-state fume hoods

When airflow reduction applies to a fume hood, a health and safety official and a ventilation engineer identify two operating states:

- *Sash open with a worker at the hood*
- *Sash closed*

Determining the flow rates required to contain the hazard in each state requires consideration of the hood’s containment characteristics as conditions change in the actual working environment. This means paying attention to the “As Installed” and “As Used” performance.

Flow rate, or face velocity, is just one factor affecting the performance of a fume hood as a containment device. Before setting the airflow, designers should consider other factors, such as room air currents and equipment within the hood. For support, the design team can turn to the large body of published industrial hygiene research that emphasizes the other influences on hood performance (Ahn, Woskie, DiBerardinis & Ellenbecker, 2008). To automatically apply a rule of thumb would neglect worker safety and energy efficiency.

Detecting the opening of a sash is usually easy, with one or more switches that respond to sash movement. When a sash is opened, the system selects the higher flow rate. When the sash is closed, the system selects the lower flow rate.

“Anecdotes abound of sophisticated ventilation systems that fail to save energy because the sashes are left open.”

Some designs switch the flow rate for all the ventilation equipment in the room (supply, general exhaust, and fume hoods) as a unit. In such a case, the controller checks each fume hood sash and the occupancy state of the room to select the flow setting.

Getting decision-makers to all agree on a fume hood technology is next to impossible.



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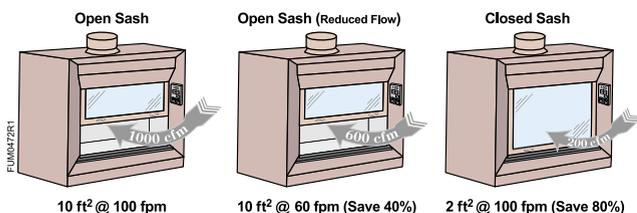


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Reduced flow with an open hood (not recommended)

In some cases, designers propose lowering the hood flow rate while the sash is still open, but when the worker is apparently not present. This approach has serious disadvantages. Whether the criterion is energy conservation or safety for workers, closing the sash is a better idea.

Consider the energy use first. (Energy use is not the most important issue, but typically it is the reason to reduce airflow.) Advocates of reduced flow for an unattended hood sometimes go as far as to achieve a 40 percent reduction (e.g., 100 fpm attended and 60 fpm unattended). Closing the sash, however, frequently enables an 80 percent flow reduction. That's twice the savings. The drawing below illustrates a numerical example.



▲ Sash position and airflow rate

Clearly, closing the sash saves more energy than leaving it open and reducing the flow, but it is apparently easier said than done. Anecdotes abound of sophisticated ventilation systems that fail to save energy because the sashes are left open. There appear to be difficulties getting lab workers to use equipment correctly. That does not mean designers should give up, as it sends exactly the wrong message when we improve the efficiency of unsafe practices.

Nearly any Chemical Hygiene Plan requires hood users to close the sashes whenever possible. This basic principle appears throughout lab safety literature, including standards from NFPA, ACGIH, SEFA, and AIHA. We need to take this idea seriously and address the real problem. There is a wide variety of approaches to sash management from which to choose. Solutions include the technical fix (automatic sash closers), human behavior changes, and a combination of the two (Coogan, 2008). There are many options, but giving up is not one of them. A sash management plan is a prerequisite in the Energy Performance Criteria from Labs21 (Labs21, 2008). Lab managers need to address it; lab designers ought to help.

Conclusion

With attention to the design process, two-state ventilation control systems can be very efficient and fit well into an organization's safety program. This paper presents a four-step design process that encourages the ventilation designer to work with the institution's safety programs rather than against them.

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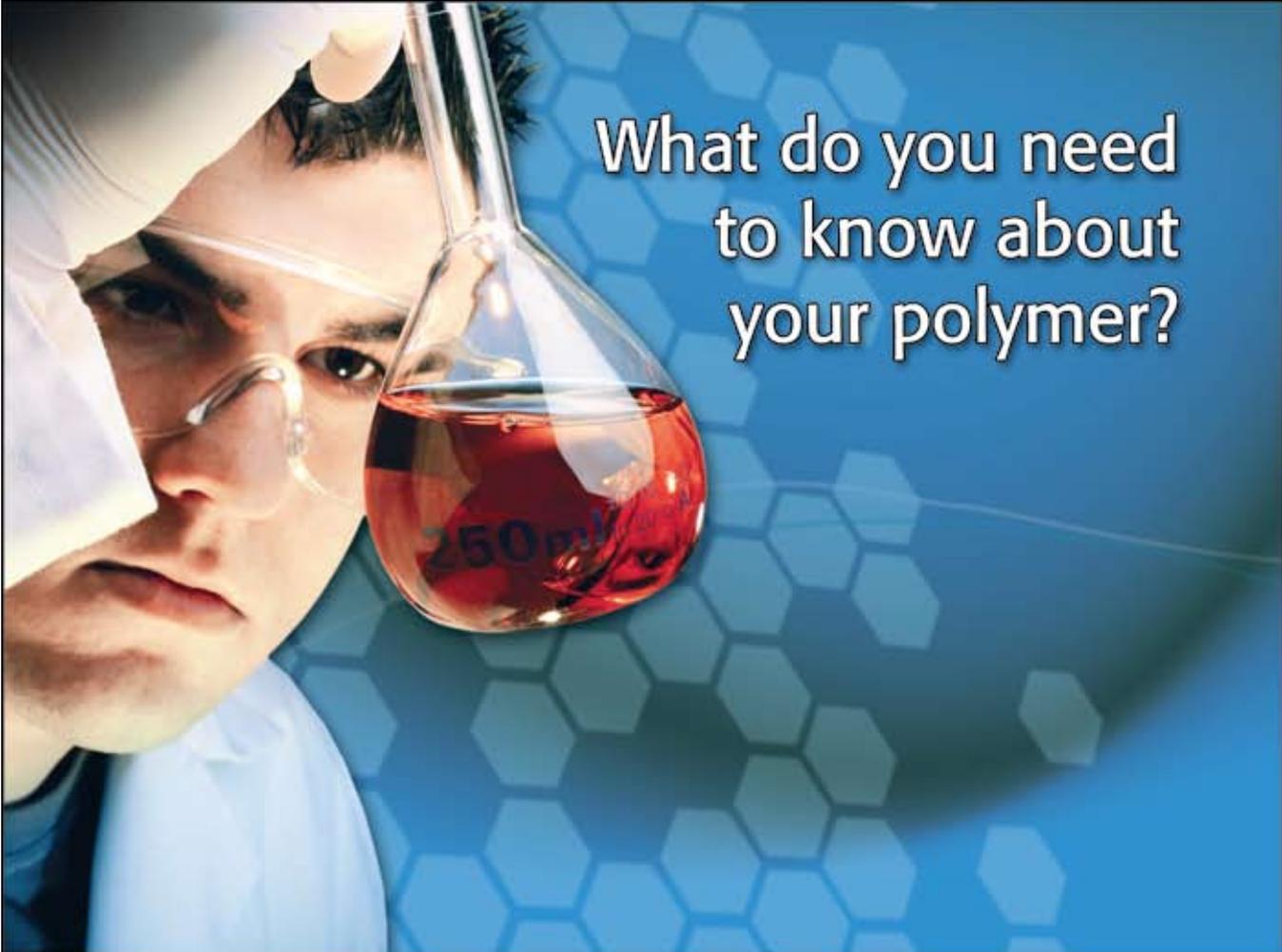
sterilization techniques including autoclaving with little to no risk of cross-contamination. Additionally, continuous volumes can be dispensed in multiple channels for increased versatility with low dead volume, and reagents can be recovered by reversing the direction of the peristaltic pump. In counterpoint, peristaltic pump technologies are limited by high cohesive forces such as high viscosity fluids or micro-volumes. These cohesive forces can also cause inconsistencies if the liquid is dispensed in fractions rather than full volumes. The peristaltic pump integrated in the EL406 uses three different autoclavable cassettes (1 μ L, 5 μ L, and 10 μ L) with flexible tubing to deliver full incremental volumes to eliminate the effects of cohesive forces

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Syringe drive dispensers offer a high degree of accuracy and precision regardless of microplate format, and through a wide volume range. Additionally, syringe pumps do not require the use of consumables, therefore reducing or eliminating any ancillary maintenance costs. The flow rate can be controlled for a variety of applications from gentle cell washing to vigorous reagent dispensing. Dispensing in multiple channels is available, but only in finite volumes. With the addition of two syringe drive dispensers on the EL406, one can rapidly dispense one to three reagents with a high degree of accuracy and precision without operator intervention.

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VALIDATING PROCESSES

VALIDATION PROJECT MANAGEMENT SOFTWARE OFFERS A UNIFORM METHOD FOR MANAGING PROJECTS, DOCUMENTATION AND DATA

by Keith Williams and Patrick Hughes

All laboratory equipment used for drug discovery, analytical methods use and routine manufacturing support must be validated in order to comply with Good Laboratory Practice (GLP), a set of industry guidance and regulations that are constantly changing. In busy laboratory environments, dealing with the large amount of documentation related to validation processes can be challenging. It is therefore important for organizations to implement tools for managing these validation activities. Although these tools can vary from site to site, many large organizations are now looking at standardizing validation project management. Such tools offer efficiency gains to smaller, resource-limited organizations as well.

The methods used to manage validation projects vary widely across the life sciences industry and even within the same company, depending on the style of individual project managers. There are several stages in validating equipment, and having several methods of managing validation projects can be time consuming and cause confusion within an organization. Some laboratories change equipment and therefore validation processes regularly, which over time can prove more costly and less efficient than having a standard validation project management system in place to ensure that existing equipment is re-validated at set intervals.

Traditional data and document management methods

Historically, multiple validation tools have been used to manage validation projects and documents. These include creating individual templates in a word processing package for each piece of equipment or system, creating a specific document for that particular project and circulating the document via email as well as using File Manager and printed paper documents for review and approval. E-mails can be difficult to track, with complex documents taking up a lot of electronic storage, and can easily be lost when sent to numerous recipients, which means that project managers are not always accessing the most up-to-date information. Paper documents can also be misplaced, old versions not destroyed or shredded, and document

versions unable to be easily tracked without cumbersome management systems. Furthermore, a significant amount of physical space and human activity is needed to store, manage and archive these documents. Such methods can lead to inconsistencies and errors, which means that projects rarely meet the validation and regulation requirements within the time frame or budget. Larger companies have had the luxury of being able to throw resources at the problem. But with the increased number of resource-limited SMEs (Small Medium sized Enterprises) operating in the same space and the need for larger corporate departments to address costs, laboratories are beginning to incorporate computer-based validation management tools that are capable of managing the whole project lifecycle.

“Computer-based validation management tools are capable of managing the whole project lifecycle.”

Regulatory requirements

There are a number of regulations relating to the validation of systems and equipment as well as the storage of electronic documents. The GLP guidelines deal with the organization, process and conditions under which laboratory studies are planned, performed, monitored, recorded and reported. These specify that all equipment must be periodically validated to ensure accuracy, reliability and consistency, which influence the validity

and quality of test data.¹ Laboratories required to follow the guidelines produce significantly more documentation than laboratories that do not and must be able to store, retrieve and trace all data, even long after the project has finished. This audit trail is critical to the regulators, and indeed life science customers of contract laboratories.

Organizations dealing with electronic documents and records must comply with FDA 21 CFR Part 11 guidelines, which define the criteria under which electronic records and electronic signatures are considered to be trustworthy, reliable and equivalent to paper records. The electronic records must be securely stored in a controlled-access environment and tracked throughout the document's entire lifecycle. This includes storing clear audit trails and version histories so each individual document can be followed from creation to archiving and recalled if needed many years from its creation by project manag-

ers— tasks that are difficult and costly when using File Manager and email-based document management methods or, worse, paper records.

Emerging technologies

To address the common problems and costs associated with traditional validation projects, Good Products has developed ValMan™, a simple and complete validation project management tool designed to streamline validation projects in one easy-to-use package. The software allows documents and activities for specific validation projects to be stored in separate secure areas. A set of predetermined workflow templates facilitate effective project management. They allow document reviews and approvals by third parties not on the client network, with full audit traceability, template management and user management. Users have access to a database of some 15,000 templates from a variety of equipment, systems and facilities validation projects, including Validation Master Plans (VMP), Validation Plans (VP), Design Qualification (DQ), Installation Qualification (IQ) and Operational Qualification (OQ) protocols. The software also allows users to adapt and input their existing document and validation work flows and processes into the system for greater efficiency, as well as use any global templates or document templates already developed.

The ValMan module sits on the g-docs™ GLP 21 CFR Part 11 compliant platform from Good Products and allows users to store electronic documents in one secure area with full tracking of the document, including version history. Using the software, laboratory workers can be assured that their computer systems, equipment and analytical method validation projects are fully compliant at all times. ValMan is easy to install and is easy to use as it is based on Microsoft systems regularly used by laboratory staff. Project managers can easily configure the software to allow access to data libraries for individual users depending on their job title, job description and their level of responsibility, without the need to utilize additional programs. All customers benefit from complimentary unlimited training for users and administrators and the software can be integrated into Outlook where re-validation dates, document approvals, and project changes can be notified via email, prompting user action.

Conclusion

Using a designed validation project management tool offers laboratories a standard and uniform method of managing all validation projects, documentation and data by eliminating the need for multiple computer systems. By storing all validation artefacts in one secure reposi-

tory, companies can benefit from standardized validation projects, best practice proliferation across the group and be confident that all projects are fully compliant with industry regulations and guidance. Such secure systems are easy to use and can be swiftly implemented to increase efficiencies in validation projects, thus saving time and costs over traditional validation processes.

1. <http://www.labcompliance.com/tutorial/glp/default.aspx>

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YOU NEED TO CREATE AN SOP...

NOW WHAT?

The SOP development process is an excellent way for managers, workers, and technical advisers to cooperate for everyone's benefit. Standard operating procedures used in combination with planned training and regular performance feedback lead to an effective and motivated workforce.

The following eight steps describe a method that will produce excellent procedures and generate maximum buy-in from the workforce.

1 Plan for Results

Standard operating procedures work best when they are designed to achieve specific results. Decide what business goals will be achieved through better management with SOPs and how those goals will be measured. Many benchmarks exist in the industry to help measure quality and efficiency in specific areas.

2 Produce First Draft

Select a format for the procedure. If you choose to use simple steps, hierarchical steps, or the graphic format, first make a detailed list of the steps in the order that they are done. A simple way to get started is to observe someone performing the process as it now exists and write down everything that the person does. This list is now a draft of the procedure. If the procedure needs to appear as a flowchart, start with the most reasonable beginning point. Draw the decisions that a worker will need to make and the actions that follow each decision. Don't try to be perfect with the first draft, because it is very likely that you will need to make many revisions.

3 Conduct Internal Review

Provide each worker who performs the procedure with a copy of the draft SOP. Ask the workers to review and suggest changes that will make the procedure easier to understand or more accurate or will improve performance. Assure the workers that their input is important and will be used. People are much more likely to accept and use an SOP if they feel a sense of ownership in it. Another reason to involve the workers is that they are likely to have good ideas. Highly successful managers actively engage their work teams in a continual quest to become more efficient, increase cost-effectiveness, and improve quality.

4 Conduct External Review

Managers increasingly rely on advisers outside their own organizations. The SOP writing process is an excellent way to tap the expertise of your advisers. Provide them with a copy of the SOP draft. Ask them to suggest any changes that will make it clearer and more effective. Revise the procedure as necessary to incorporate their input.

5 Test

For procedures to be effective, they must perform in the workplace. There is only one way to be absolutely certain that a procedure is well written and performs as expected. Have someone test the procedure by performing each step exactly as it is described while the procedure writer watches. Have a person not familiar with the work follow the procedure. Any steps that cause confusion or hesitation for the test worker should be revised.

6 Post

Make a final draft of the procedure and post it in the appropriate locations. The workplace is one essential location. A master SOP file should be kept in a central location so workers can review little-used SOPs when necessary. It is essential to keep SOPs up to date.

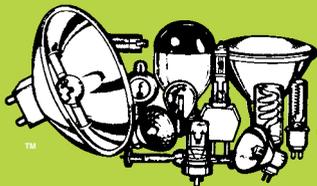
7 Train

One of the last steps in the SOP writing process is often the most neglected. Train or retrain everyone as necessary to follow the procedure exactly. Even with very detailed steps, it is necessary to train all workers. Otherwise, individuals will interpret the meaning of procedures in different ways, leading to inconsistency in work routines and performance.

An effective SOP training program first will make the worker aware of what training activities will take place and what the trainee will be able to do when training is complete. The trainer will explain and demonstrate both why and how each step in the SOP is performed and then give the learner a chance to practice. The trainer will provide positive feedback as the learner masters parts of the procedure and patiently revisits those parts that need improvement.

8 Audit

An audit will show whether the procedure is being adhered to and whether the objectives are being met. It can also help identify areas where improvements can be made. Each SOP should be audited about three months after implementation and thereafter at least annually. In addition, the SOP should be audited when dispensing errors or "near misses" occur, to identify ways of preventing their recurrence.



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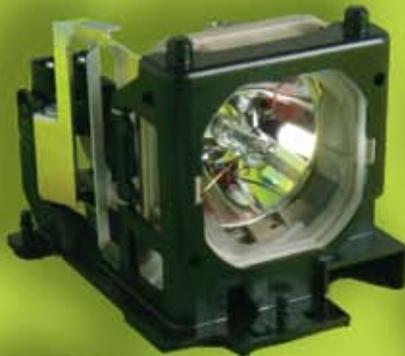
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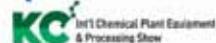


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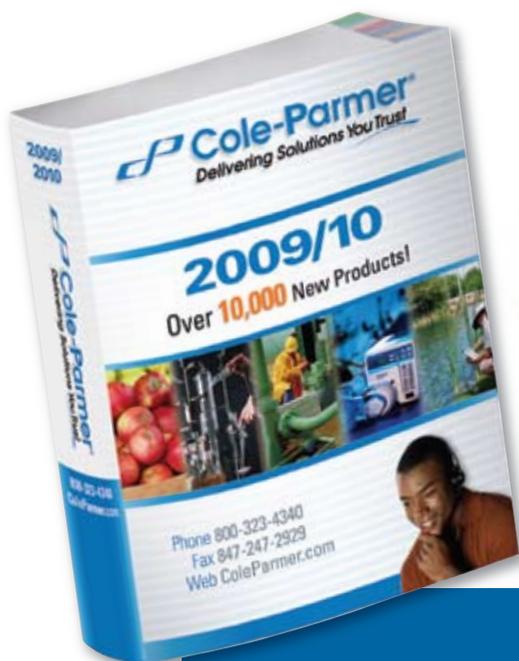
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PARTING POINTS

Takeaways from this month's issue:



Next-Generation Laboratories, p.10

Author Victor Cardona envisions a “laboratory ‘dance floor’ of the future that allows constant change and adapts intelligently to the needs of science.” Features of this best-practice lab include:

- Convertible wet and dry labs.
- Clustered offices for PIs.
- More lab support space per research team.
- “Plug-and-play” equipment zones.
- Adaptable, prefabricated casework systems.
- Fewer underfloor utilities (such as plumbing) and more access overhead (for electrical, data, vacuum and air).
- Improved energy efficiency.
- Sunnier, more transparent spaces with more places to meet and collaborate.



Writing in a Second Language, p. 20

For the increasing number of scientists, engineers and technicians for who English is a second language, John Borchardt offers the following suggestions to help lab managers improve their staff's written communication skills:

- Recommend that students take technical writing and journalism courses.
- Hire consultants to present technical writing workshops.
- Hire consultants to edit their staff members' reports for clarity.
- Assign a “writing mentor” to foreign-born staff members when they are hired.
- Use computer aids to improve writing.
- Coach personnel on the use and limitations of word processor grammar and spell checkers.



Integrated Service, p. 32

When a traditional in-house service model was replaced with an integrated service delivery (ISD) program, benefits included:

- Expert-level, on-site service engineer provided same-day response to service events.
- On-site inventory of high-use parts increased likelihood of same-day repairs.
- Automated, paperless regulatory compliance system provided centralized repository for all protocols across all instrumentation.
- A single, universal protocol replaced OEM-specific compliance protocols for HPLC and GC systems.



Required Maintenance, p.44

A proactive maintenance program demonstrates compliance, keeps audits moving forward and can increase productivity and profitability. Benefits of maintenance monitoring software include:

- Reduced service calls.
- Links to manuals.
- Prompt on-time maintenance actions.
- Increased user productivity from guideline adherence.



Ventilation Strategies, p.80

Two-state or two-position constant volume systems offer many options to ventilation designers. The following four design steps will lead to a system that ventilates a lab efficiently and works with the institution's safety programs:

- Identify the conditions in the room that call for differing flow rates.
- Determine the flow rates for the device and the other flow devices that coordinate with it.
- Select the control system inputs to trigger flow rate changes.
- Design an indicator that informs lab users of the ventilation system's state.

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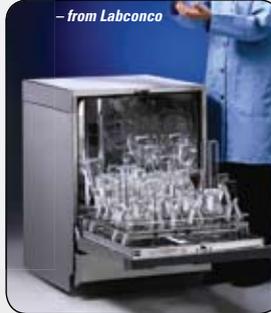
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