

Lab Manager[®] MAGAZINE

Where Science and Management Meet[™]

June 2007

Volume 2 • Number 6



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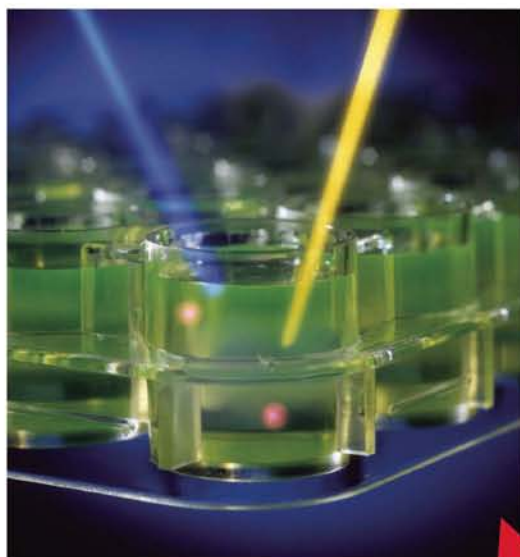
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The article review process should begin with a query by e-mail or phone followed by a brief abstract or outline. Please state your topic and objective, and indicate your perspective as well as your professional relationship to the topic. Content must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

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As a publishing company, we use a lot of paper in our office. But over the last five years, we use dramatically less. The advent of new computer software and internet capabilities has changed the way we receive articles, proofread, edit, layout the magazine, and work with the printer. Even as little as a few years ago, the magazine was printed out on a copy machine at our office, shipped overnight to our printer who would in turn make a paper mock-up of the magazine and ship it overnight back to us. If there were corrections and changes, we would try to do as much as possible using ftp sites and sending pages electronically but there were times when the process had to be repeated over again. Advances in software, data sharing, and storage have made the publishing industry significantly less reliant on paper. Now, we simply upload pdfs to a website and review the pages electronically. It not only saves paper but cuts days off the publication schedule. Going with less paper has been an improvement in process and in dollars.

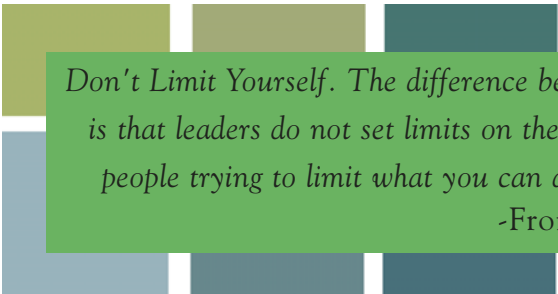
Not that the transition was all that easy. There were new programs to learn (what it could do and what it couldn't), problems with the software, a few upgrades that we had to initiate to be compatible, and many changes in process. We had to rethink and adjust our work flow to accommodate the software and to trust it to do what they said it would (it did). Some parts were easy and we said "Hallelujah! At last we have the capability to do this!" And at other times, we found ourselves mourning the loss of a process that kept us connected. (Our art director never sent a box to the printer without making sure it contained candy for our customer service reps. They adored her for the treats and even more for her thoughtfulness. We had to find news ways of staying their favorite customers.)

In the end, we work more efficiently, have as much or more control over the process as ever, and have gained time in the turnaround from concept to publication. The investment has been worth it and we have actually reached the stage where we tell stories of the "old days" — less than five years ago — of how we used to put out the magazines. It almost sounds quaint.

In this issue, there are several articles that address the benefits of reducing dependence on paper and how to incorporate electronic methods into daily processes. Though there is often little doubt that a computerized version will improve efficiency, changing habits and creating new routines are often the toughest parts.

The incorporation of software to improve workflow, data sharing, and storage is an ongoing process. There will always be the next great idea or upgrade, so a software solution is not always a one-time initiative — it's a continual process. However, reliance on paper is a thing of the past and the changeover to more and better software solutions and paperless processes is worth the effort.

Patrice Galvin

A decorative graphic consisting of several overlapping squares in shades of olive green, teal, and grey-blue, arranged in a stepped pattern.

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Web-based LIMS: Right for Any Sized Lab

LET'S LOOK AT HOW THE COMBINATION OF A LIMS WITHIN THE INTERNET ENVIRONMENT WILL ENHANCE THE EFFICIENCY OF THIS POWERFUL CORPORATE TOOL FOR LABS OF ALL TYPES AND SIZE.

The internet has had an enormous impact on our lives by allowing quick access to information, expediting business transactions and providing communication from anywhere in the world. Even your children and parents are using email, instant messaging, on-line banking, Google™, ebay®, Amazon, and bevy of other sites on a day-to-day basis. In essence, the internet provides a trouble-free way to save time and add convenience to our lives, so why not provide these same benefits to your laboratory information?

In its most basic terms, a LIMS is software that is used to promote an accurate flow of sample and associated test data to and through the laboratory to transform it into information that is used to make critical business decisions. Modern LIMS also provide self-auditing capabilities and easy access to historical data through interactive queries and/or reports. The benefits of a LIMS vary based on the size and charter of the laboratory. Let's look at how the combination of a LIMS within the internet environment will enhance the efficiency of this powerful corporate tool for labs of all types and size.

We'll first explore the general benefits of implementing a web-based application compared with traditional software applications and then describe how efficiencies are achieved within several day-to-day LIMS tasks through the implementation of a fully web-based system.

ARCHITECTURE AND MANAGEMENT

The beauty of a true web application is its architectural simplicity. To run any true web application, all you need is a PC with a web browser internet (or corporate intranet) access. There is absolutely no software installed on your PC, so you don't have to worry about the software's configuration, computer's disk space, memory, and, most importantly, conflicts with other software (often referred to as "dll hell"). All modern PCs come equipped with a browser and internet connectivity is now so prevalent that you can use web-based applications from anywhere at any time.

The use of a ubiquitous web-based LIMS extends the LIMS far beyond the walls of the lab in a secure manner to become a boon to labs of any size.

Web-based software actually resides and runs on a remote computer (or web server) and the data is stored within a database that may be installed on the same or different computer (or database server). Your browser simply displays formatted data that is located on the remote computers. This architecture reduces local IT desktop support duties to the single task of maintaining the internet (or intranet) connection and the application support consists of managing a set of files on the web server and managing the database. The IT manpower savings experienced will be very large relative to the size of the organization.

Web-based applications have far more reasonable demands on the client PC's memory than locally installed programs. By residing and running on servers, web-based applications use the memory of the servers instead of the desktop PC. This leaves more RAM available to run multiple applications simultaneously without incurring frustrating performance hits so you'll make more effective use of your desktop computers or purchase less expensive computers.

A wide degree of cross-platform compatibility is provided via web applications because the browser is the only software needed on the client PC. Cross-platform compatibility means that your desktop computer can be traditional Windows-based PCs running internet Explorer or Firefox, a Macintosh PC, or a Linux PC. In virtually all cases you'll be able to make use of all of your existing hardware.



Wayne Verost

Sooner or later software needs to be fixed or updated. When using a web application all software updates are managed from a single location so all users will always be using the most recent release of the software. More importantly, there is no need to disrupt users by having new software installed or downloaded. In fact, many organizations don't even allow end users to install any software on their computers in order to protect the integrity of the company's computers and network. The painful and time-consuming process of updating software is virtually eliminated when using a web application.

System crashes and other technical problems that result from software or hardware conflicts with other existing applications, protocols or internal custom software are greatly reduced through the use of web-based applications. In addition, since applications are not installed or downloaded on your PC, there is no fear of corrupting your PC with viruses. With web-based applications, everyone uses the same version, and all bugs can be fixed as soon as they are discovered; hence, web-based applications have far fewer bugs than traditional desktop software so end-user satisfaction is much better.

To summarize, the savings in IT and computing costs that are derived through the implementation of a web-based application is enormous by virtue of its simplicity. You no longer need to have a resident 'PC expert' available to install and update desktop software or diagnose and repair the problems that will always exist when using traditional software, so your IT headcount can be reduced or redirected. The system requirements of the desktop computer will be lower and more diverse so your hardware costs will be lower since you can use existing PCs or purchase less powerful PCs. All system management is performed on one or two computers which lowers management cost and adds a great amount of convenience. Finally, there will be far fewer disruptions to your operation due to system downtime. These general features are beneficial to any organization of any size. You can take the reduction in IT support one step further and have the web-based LIMS 'hosted' at an external site at a very low cost in order to have highly professional IT staff members administer their application.

FUNCTIONAL BENEFITS

It is well-documented that the proper implementation of a LIMS improves the bottom line of a business both directly through the measurable savings that are derived through the reduction in time required by the lab staff to manage data and indirectly through production and product development efficiencies. The specific benefits that are derived from LIMS are dependent on your laboratory size and function, but in all cases, it is the combination time reduction and providing accurate data to its consumers that makes a LIMS a powerful business tool. The use of a ubiquitous web-based LIMS greatly enhances these benefits by extending the LIMS far beyond the walls of the lab in a secure manner to become a boon to labs of any size.

A one-time installation of the software makes it instantaneously available for use by anybody who is granted access to use it by virtue of being provided the web site and assigned a login id and password and associated security privileges. Once installed, a web application reduces the time it takes to implement the software to a simple matter of training the users in the more complex aspects of the software. Since many of the functions will be self-explanatory, many people won't require training at all.

At first glance, the benefits of a web-based system seems geared towards large organizations with multiple facilities located throughout the world as opposed to a single laboratory with a handful of chemists and technicians, but this isn't really a true assumption. Small labs may wish to provide their customers with real-time access to the system as an added level of customer service while employees may need to access the system while home or travelling at any time of the day or night to prepare for meetings or service customers in a convenient manner.

We've now established that the web-based software is easy to install, maintain and access, but all of this is for naught if it isn't used. With this in mind, we'll now concentrate on why it is the right approach for any sized lab and why it will be more effective than a traditional LIMS by answering a few questions.

Training is not needed on the web sites that I use to bank, shop, and surf, do you need extensive training to use a web-based LIMS?

This question is answered by Sid Besmertnik, the Global Quality Control Improvement Manager from Rhodia Novecare who implemented a system that supports 15 quality control labs in 8 countries.

"The user-friendly structure and format allowed plant technicians who are responsible for sample login, data entry, and data transfer to the ERP systems to accomplish training in only 45 minutes per lab. Training for a system of this nature and scope can otherwise take days to complete."

But training can be reduced even further or even totally eliminated by restricting each user's access to the pages that are germane to their needs in order to reduce confusion and make the software as simple and straight-forward as possible to operate. The pages can be designed to guide users through their use in much the same way shopping sites do. In addition, up to date on-line help and 'flash movies' can be embedded within the web pages to provide immediate instruction on how to use the software to greatly reduce training costs and ensure that the software is used by as many people as possible.

If people can order products over the internet, why can't they order testing using the LIMS?

The answer is; they can. The sample login (or registration) process is one of the most time-consuming and error-prone tasks that are performed within a LIMS. The traditional workflow for initiating a sample consists of having the submitter fill-out some type of paper form by hand and deliver it to the laboratory along with the sample. A clerk or chemist transfers the

information into the LIMS by logging the sample(s) into the system. This workflow wastes a lot of time as the task of registering and identifying the sample(s) is actually performed twice and is fraught with error because hand-written submission forms can be misread or lost. Simply replacing the paper form with a web page of similar content will eliminate duplication of effort and eliminate transcription error while providing the lab with the added benefit of advance notice that samples are on their way allowing more efficient scheduling of resources. Clearly printed labels and submission forms can be printed by the LIMS to accompany the sample to the lab to confirm receipt and avoid the illegible 'chicken-scratch' on hand-written forms.

Consider the possibilities to the self login approach. Plant operators can log in quality control samples and print labels from the control room. Environmental field samplers can register their samples using internet-connected laptop PCs. Analytical service labs can have their customers log in samples and print labels and submission forms for delivery with their samples. Whether your lab is large or small, the benefits are of equal importance. In fact, the image of smaller analytical service labs will be greatly enhanced by providing this level of service and sophistication to their customers.

I can track the location of my FedEx or UPS package and bank transactions via the internet, can I track my samples the same way?

Of course you can, but like your on-line bank account, the security system is structured to ensure that you only have access to information that is associated with your data. Each sample is assigned a specific sample identifier (or tracking number) so you'll be able to track the progress of testing and see data as it is released by the laboratory. By providing this level of secure access, the lab can concentrate on performing analytical work instead of answering phone calls with the constant question "have you tested my sample yet?" The sample and request information can automatically be emailed to the submitter upon final authorization by the lab to provide the consumers of lab data with instantaneous 'just in time' delivery of information. Regardless of the size of your lab, the immediate access to information in a manner provides a level of self-service that cannot be made more convenient for the lab or the customer and is especially helpful in making smaller labs appear big.

Most LIMS make it hard to find information, can we have a simple search tool to make it easy for infrequent or novice users to retrieve information?

If the web-based application is designed correctly, it will provide a Google-like search tool in order to make it easy to locate historical information with little or no training. This type of tool will allow customers and lab users



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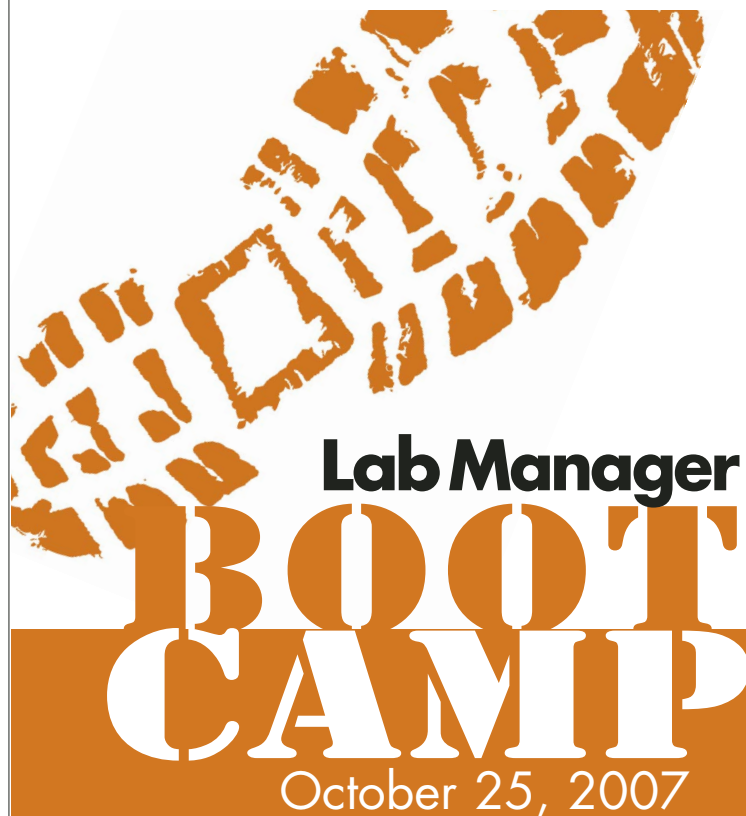
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alike to simply enter key phrases into a field and the LIMS will find all information that matches the entered criteria. The idea of any web-based application is to make it so easy to use that it becomes less convenient to contact the lab than to retrieve the information from the browser.

When travelling, I can quickly respond to issues via email to make critical business decisions, will I be able to review and release critical data while on the road?

A fully web-based LIMS will provide all functions including the ability to review and release information so you don't need to be chained to your office in order to perform your managerial duties while travelling or working from home. In addition, you can respond to emergencies faster and as a result, you are able to immediately react to data anomalies and respond in real time.

I can retrieve a statement from my bank account in order to get a clear picture of my finances, is it possible to get managerial information while out of the office?

The report generation features will allow you to extract consolidated information from your LIMS from anywhere at any time. For example, sales people will be able to interactively access COAs, SPC charts, and other informative data while performing presentations to customers. In fact, you can even allow your customers to retrieve the reports on their own. Management reports can be generated during business meetings or in the comfort of your own home. The possibilities are endless and can result in a better image for you and your organization.

These are just a brief listing of the advantages that a true web-based LIMS will add to any organization, but like all changes to 'the way we do things', you may encounter some initial resistance when introducing this concept, but once they get accustomed to it, they will absolutely love it!

The implementation of a web-based LIMS is a win-win-win situation for labs of any size. The lab wins through efficiency gained by offloading tasks through the self-service aspects of the software. The consumer of lab information (both internal and external customers) wins by giving and getting more accurate information faster. The organization as a whole wins by greatly reducing cost and improving the corporate image and providing better working conditions for its employees.

Wayne Verost has a B.S. in Chemical Engineering from Lehigh University; his experience with LIMS began in 1989 as product manager for Beckman Instruments. He is the President of QSI Corporation and can be reached at 201-251-2101; wayneverost@qsius.com.

A Well-defined Vision: the key to driving a hybrid laboratory to success

THE HYBRID MODEL IS A SUCCESSFUL AND PROFITABLE ONE IN THEORY. HOWEVER, THIS SUCCESS LIES IN THE PROPER MANAGEMENT OF THE LAB — WHICH HAS PROVEN TO BE PROBLEMATIC.

The majority of basic medical research labs in universities and non-profit research institutes share one common goal: the noble pursuit of knowledge, seeking to expand our understanding of diseases and afflictions of the body and mind. Research is vigilantly pursued with the goal of publishing any findings, thereby sharing it with other researchers, hoping to ultimately discover the cause and, by association, a cure. While these laboratories serve a valuable purpose in their fields, they are not independently able to draw in monies and so rely heavily upon government and private foundation funding. The current funding for these laboratories, however, is becoming rare. The funding rate of the National Institute of Health (NIH) this year is less than 10%, making industrial funds the most significant part of research and development funding.¹ In order to support their research, many laboratories have had to diversify their efforts to include commercial research and application, changing the structure of the lab and its ultimate purpose. These hybrid labs have merged with a business world where they seek to patent and market their research while they continue to apply for grant funding, a rather “schizophrenic” approach and the newest trend.

The training of most Principle Investigators (PIs) is solely focused on science rather than organizational behavior. When these PIs find themselves thrust into the managerial role in a business sense, the hybrid lab can be easily mismanaged and the members left confused and frustrated. With low lab morale, there comes high member turnover, inefficiency, and low productivity, and the lab quickly flounders in a business world where it has no experience. In order for the hybrid model to succeed, it is imperative that the PI be able to construct and communicate a clear, well-defined vision.

In order to support their research, many laboratories have had to diversify their efforts to include commercial research and application, changing the structure of the lab and its ultimate purpose.

DEFINE A CLEAR VISION

One of the most confusing aspects in a hybrid laboratory is the ultimate goal of the organization. I once heard a graduate student in a lab I worked in ask simply, “Are we here to make a product in science or to make a difference in science?” The answer, not so simple, is “both.” The real problem with these models is finding the balance between what is academically notable and what is marketable. The mission of a hybrid laboratory might seem contradictory with this schizophrenic approach and would likely cause confusion and frustration among the lab members. It is important that they get published, but they must also focus on turning a profit. The fatal mistake for several of these types of labs is the PI’s changing of the scheme from one to the other and back again. For example, if a PI’s training is in science, he would push for publication of research, telling the lab members to write more, stretching out of the market realm. Then, realizing that the commercial side is neglected, he would refocus the lab’s efforts on product, reigning in the members’ enthusiastic research into the unknown. Then, again, feel the pull of the academic when the possibilities begin to imply more than what their product is really aiming for, exciting the PI into further research areas. This constant shifting results in a loss of excitement



for a project that may be dropped or changed in the course of a week, a weakening of dedication towards the lab as a whole, and a lack of respect and trust for the PI.

In order to avoid these pitfalls, the PI must define a clear, confident vision for the lab to follow and stick to it. This vision should meld the academic and commercial aspects together in the beginning, thereby eliminating the prospect of see-sawing the balance. If done properly, the PI's vision creates the image of what is possible and desirable for the lab, lending great power to create meaning, challenge, and energy within the hybrid lab.² It urges actions, shapes actions, and allows the value of actions to be satisfied. Each experiment and publication should fit within the scope of the vision, even if this means foregoing a potential lead into something academically stimulating in favor of the plan. This vision should be defined by three significant characteristics: achievability, relevance, and prospective.

ACHIEVABILITY

It is imperative — and cannot be stressed enough — that the vision be based in reality, not idealism. This is an important distinction between the vision for a purely academic lab and a hybrid lab. In the world of education, it is acceptable and common to strive toward the dream. For example, a lab may be dedicated to eliminating cancer. This is a noble pursuit to be sure, but when applied toward the commercial world, it is seen as a delusion of grandeur. The members in such a lab may find themselves working tirelessly for what seems like an immeasurable time with little tangible result. They become hopeless and the lab morale becomes low. They no longer take the work seriously. The PI of this hybrid lab must concede to a more short-term, foreseeable goal, such as finding a better treatment for breast cancer or, even stretching a bit, finding a drug to cure breast cancer. This vision could not only attract companies to fund the very marketable research, but it is also worthy of government notice and support. The steps are easily outlined and yield faster and more solid results for the lab members to see and be proud of as well as be excited about. The lab's productivity becomes noticeable. The proper attitude in a lab is a key element to success, and the vision is responsible for bringing it out.

RELEVANCE

College basketball coach Rick Pitino was quoted as saying "People like to be a part of something, something greater than themselves." This is every bit as true in a business arena as it is in sports. It is the PI's goal to provide a vision that satisfies this need for the lab members. His vision needs to create meaning for the members, motivating

them through the importance of their contribution to the project and ultimately the success of the lab. Every member of the lab should feel proud to be part of the process, regardless of the responsibility they fulfilled, from the physical production of a drug to washing of the lab ware. Never should there be a member of the lab who feels unneeded.

This goal is accomplished by simply, yet concisely, communicating the vision. Your lab members cannot possibly feel like an important part of the whole without knowing what that "whole" is. This may sound easy enough and even a bit obvious, but this part of the process is often mishandled or overlooked. It is understandable when we consider that, in an academic lab, the members are students and post-docs who 1) are still training and may not really understand every step in the whole picture, and 2) are not there for the "long term" as they will graduate and move on. In a hybrid lab, however, we must reassess the situation. This is a business now, and each department in a business needs to know where they're going. If they don't, how can they possibly get there? It's like being told to get somewhere without being able to see the map. If you are traveling for days and still see no sign of your destination, would you continue?

Once the vision is communicated to your members, everyone should feel like a part of that "something greater." Each should see the importance of each task. No longer is someone just washing the lab ware. Rather, they are washing the lab ware so that their lab can find the cure for Alzheimer's. The difference is huge.

PROSPECTIVE

A PI for a hybrid lab must take inventory of where the lab is now in order to design the vision for the future. Prospect is important in constructing a workable route toward the end goal. Remember, your lab members have been completely embroiled in either the academic or commercial world where individuals carry on their own projects rather than making a real team effort. Becoming a hybrid is going to bring changes for everyone and it will take some extra time and effort to make those changes. A good vision should make this transition step by step to avoid as much confusion and disruption as possible for your lab. However, these changes must be made. Your vision should impress the importance of these changes for the success of the lab team as a whole.

It is crucial to understand that a vision is not made for "today." A vision is where you want to be in the future. The PI must be able to look ahead at the possibilities that may affect the vision of the lab, bridging the gap between the dream of today and the reality of tomorrow. There

must be more than one route to take on the chance that one may become blocked. For example, a lab's vision should not rely completely on obtaining a certain grant. If that grant is not awarded, an alternate route should already be ready for implementation. The commercial market fluctuates. Grant funding changes. Competition arises. All of these possibilities and more should be considered when mapping out a vision. The future will happen. The PI's job is to plan for it in a way that makes sure the hybrid lab keeps up with it.

CONCLUSION

A hybrid laboratory is a pressure cooker, under constant stress from the academic world as well as the commercial world. Its success relies on its proper management. Defining and communicating a clear vision is imperative in order for the PI to lead the lab and its members effectively around the pitfalls that plague this new type of lab.

The combination of the two worlds, academic and commercial, has become necessary. With the right vision, it can become extraordinary.

Next installment: Building the Vision

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Going Paperless

DONE RIGHT, GOING PAPERLESS CAN MAKE YOUR LABORATORY MORE EFFICIENT — SAVING YOU TIME AND MONEY.

Like a papier-mâché carrot, the promise of a paperless office was dangled before us for decades in our race to computerize our workplaces. Ironically, the idea now sits off-site buried under reports printed by the very machines meant to liberate us. But it's still a good idea. To turn your paper into cash you'll first need to lead your staff into new ways of thinking.

It won't be easy. Paper, after all, is thousands of years old. Its presence in our history is physical, even metaphorical. Still, a laboratory with the newest technology using one of the oldest to store information seems off track, especially when secure, portable, and compact electronic storage is cheaper and faster than the "hard copy" we often prefer.

This anachronism began with the computer age. During the first decade of the personal computer, launched by IBM in 1981 and named "Man of the Year" by Time in 1982, paper use expanded nearly five-fold,¹ continuing to the present in which a typical office worker uses a sheet every twelve minutes,² a four-foot stack at year's end.

Your laboratory may be deluged by reams of reports, required or not, and they all cost you money. One hospital in Portland, Oregon challenged this idea by giving doctors a choice, cutting their output 23% and saving over nine thousand dollars per year.³

Getting rid of paper is good business because it is expensive to handle, sort, and store. But it's hard to imagine a workplace without it, begging the question: do we really want a paperless laboratory?

Of course we do, if it saves time and money. But we work by habits that subvert choice even with a goal within reach. An analogy is computer conferencing technology, available for years yet sidestepped by the persistence of Victorian commuting habits. "The only difference now," as noted in *Inside Knowledge*, "is that people can travel faster and further than they could 100 years ago, thereby creating a lot more pollution and destroying habitats, while suffering from higher levels of stress."⁴

Getting rid of paper is good business....but it's hard to imagine a workplace without it, begging the question: do we really want a paperless laboratory?

RETOOLING THE PAPER PARADIGM

We've been told that the computer will shift our paradigm, or perspective that frames our decisions, from paper to digital media. Old and new paradigms are listed in Table 1.

Our thinking may indeed be changing. Paper sales have recently slowed from seven to four percent annual growth. One reason is nearly half the workers entered the market after computers were introduced. But that's only part of the story. How information is stored is displacing human beings as filing clerks, making digital media not only ubiquitous but permanent.⁵ Trending suggests that paper is becoming a choice.

Before you can help your employees go paperless, there are several obstacles to overcome.

Age, for one. A quarter of our workforce will reach age 50 by 2010.⁶ But nearly a third of clinical laboratory workers are already over age 50.⁷ According to one study they are at least 15% less likely to use computers than coworkers age 30 to 39,⁸ suggesting a link between generation and technology gaps.

Accrediting agencies and individual inspectors may prefer paper, although this is changing. FDA rule 21 CFR Part 11, effective March 20, 1997, considers "paper records to be equivalent to electronic records, and electronic signatures equivalent to traditional handwritten signatures"⁹ By 2003, hospitals such as the Oklahoma Heart Hospital were using paperless charting and order entry with full accreditation.¹⁰



Ironically, the computer itself is an obstacle. Apple designed its 1984 Mac using a paper paradigm¹¹ of black text on a white background that resembles a typewritten page, file “folders,” and a “desktop” adopted as the standard. This imitation perpetuates our notions about the dominance of paper and suggests the adaptation of software rather than a lean flow of information. What was meant to buoy the user above an ocean of paper may now be an anchor.

But our prejudice isn’t simply rote, imposed, or designed. We may be holding onto paper (literally) for good reason. The authors of *The Myth of the Paperless Office* describe “affordances,” qualities that affect how we interact with an object. Paper, being lightweight

and flexible, can be grasped, carried, and folded in a unique fashion. The authors suggest that rather than eliminate paper we integrate it with digital media.¹²

The above makes a “cold turkey” approach risky. But in changing how your employees think about paper you can take practical steps.

REDEFINING PAPER’S ROLE

Assumptions about paper can be redefined as a group, gathering ideas with brainstorming techniques. Asking your staff what paper means to them may make it easier for them to accept new thinking. Suggested new assumptions are listed in Table 2.

If using paper is perceived as a choice rather than an obligation, behavior can change. Envision “information work” instead of “paperwork” and you have the idea. Your employees will see paper as temporary information storage and not permanent in a physical or legal sense. They will realize that unless paper can be quickly retrieved, it is as good as gone.

Once your staff accepts that paper is temporary — more to the point, less permanent than electronic storage — they need to work around this new paradigm. It’s an overwhelming, even terrifying, challenge. After all, your laboratory may be designed around paper or your computer system may have been implemented to supplement, not to replace, paper.

The next step, then, is to redesign your existing processes to be paperless. You’ll need to use paper according to the new paradigm.

What does this mean? It isn’t enough to simply get rid of paper, although the amount of manual work attached to it suggests that any process will be improved by its removal. You may use it to track samples at workstations or record information in paper logs when the same information is in electronic form. Keep in mind that your goal is efficiency. Your processes should be redesigned to

take advantage of electronic storage, saving you space, time, and money.

Using similar techniques used to identify assumptions, your employees can identify a “pilot” project to begin their transition to a paperless laboratory. The group can start by prioritizing their perceptions of where paper causes the greatest inefficiencies. Think of it as the first test of the new paperless paradigm.

After a process is chosen to redesign, the current state is mapped and then redesigned without paper that may involve purchasing or upgrading equipment. If new purchases aren’t immediately possible, make sure you establish it as a ground rule before you begin.

Table 1. Paper paradigms in the laboratory

OLD THINKING

Paper is real Information is real
Paper is evidence Data is evidence
Paper is hard copy Paper is temporary
Paper is mandatory Paper is a choice

NEW THINKING

Table 2. Revised assumptions about paper

PAPER IS (REALLY...)

Not secure
Easily corrupted
Easily destroyed
Easily forged
Easily lost
Expensive to store
Labor intensive

PAPER IS (ALSO...)

Media
Versatile
Portable
Energy Efficient
Cheap

Table 3. Mapping a paperless process

PAPER

1. Paper requisition is received
2. Order is transcribed in system
3. Sample labels print
4. Label is attached to sample
5. Label is attached to work log
6. Sample is loaded on analyzer
7. Sample is analyzed
8. Result prints on analyzer
9. Label is attached to printout
10. Result is sent to the computer system
11. Result is verified by a person
12. Work log is initialed and saved
13. Analyzer printout is initialed and saved
14. Paper requisitions are saved

PAPERLESS

1. Order is placed directly in system
2. One sample label prints
3. Label is attached to sample
4. Sample is loaded on analyzer
5. Sample is analyzed
6. Result is sent to computer system
7. Computer system "autoverifies" if normal
8. Result is verified by a person if abnormal

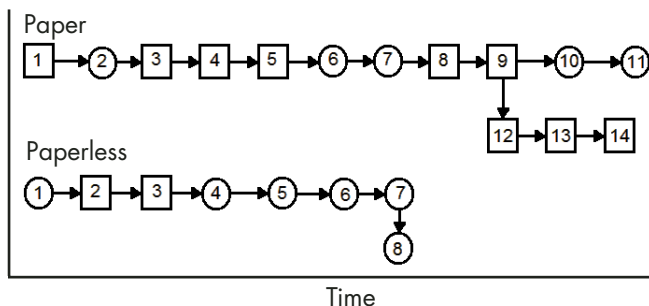


Figure 1: Paper and paperless sample flow schematic

Example: your work group chooses sample flow at a chemistry workstation. The processes are outlined in Table 3. Note that the new process has fewer steps and less chance for error. This paperless process, moreover, by and large isn't waiting for paper to continue.

This concept is illustrated by Figure 1, which plots these processes against time; the blocks represent paper steps. (Note that paper isn't completely gone.) The schematic shows not just a shorter time span, but fewer potential delays, which is what paper steps really represent.

Planning is a good exercise, but how do these ideas work in the real world? The gap between thinking and doing can be wide for some employees. Here are guidelines:

- Reach consensus on the current state. List, map, or flow-chart a process without a particular emphasis on paper.
- Map the "to be" process to highlight the strengths of electronic data storage, rather than simply eliminating paper.
- Give your employees permission to be paperless. "It's OK to get rid of the paper" is quite a different message than "You have to get rid of the paper." Supportive, encouraging language lets your employees know that they are making a choice at their own pace.
- Try incremental implementation to help make change less painful. For example, your employees may first try writing less information on paper or try saving it for less time.
- Expect setbacks. Your employees may find it too uncomfortable to get rid of paper, but they can always try again. Give them the freedom to adapt to a new process in a time span that they find non-threatening, and the change will last.

Your goal isn't to eliminate paper as older technology. Paper has a place in the laboratory, and what remains should be dated, stored, and purged when the time comes. Or it can be inexpensively scanned. A USB drive stores up to 15,000 images, and flatbed scanners cost under \$100.

Changing your paper paradigm can provide the leadership to give your staff permission to use the technology at hand. Once they go paperless, they will never look back.

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USING ICP-MS for Environmental Trace Metal Detection

A CASE STUDY SHOWS HOW ICP-MS PLAYED A VITAL ROLE IN THE INVESTIGATION OF LEAD LEVELS IN A PUBLIC SCHOOL SYSTEM'S DRINKING WATER SUPPLY.

Breakthroughs in atomic spectroscopy, and in particular ICP-MS, have led researchers to a better understanding of environmental pollution and the effects of trace metals on humans. The toxic effects of lead and regulatory toxicity levels have been lowered as new, more sensitive instrumentation has been developed. This case study exemplifies how one water municipality used ICP-MS to analyze over 60,000 drinking water samples for Pb, in an investigation into the impact of the plumbing system on the water supplies of the public schools.

The development of analytical instrumentation over the past 40 years has allowed us not only to detect trace metals at the parts per quadrillion (ppq) level, but also to know its valency state, biomolecular form, elemental species or isotopic structure. We take for granted all the powerful and automated analytical tools we have at our disposal to carry out trace elemental studies on clinical and environmental samples. However, it was not always the case. As recently as the early 1960s, trace elemental determinations were predominantly carried out by traditional wet chemical methods like volumetric-, gravimetric-, or colorimetric-based assays. It was not until the development of atomic spectroscopic (AS) techniques, in the early 1960s, that the clinical and environmental communities realized they had such a highly sensitive and flexible trace-element technique. Every time there was a major development in atomic spectroscopy — such as flame atomic absorption (FAA), electrothermal atomization (ETA), inductively coupled plasma optical emission spectrometry (ICP-OES), and inductively coupled plasma mass spectrometry (ICP-MS) — trace-element detection capability, sample throughput, and automation dramatically improved. There is no question that developments and breakthroughs in atomic spectroscopy have directly impacted our understanding of environmental contamination and the way trace metals interact with the human body.

LEAD

Take for example, the toxicity effects of lead (Pb), especially in young children. It can damage a child's central nervous system, kidneys, and reproductive system and, at higher levels, can cause coma, convulsions, and even death. Lead has no known biological or physiological purpose in the human body, but is avidly absorbed into the system by ingestion, inhalation or skin absorption. Children are particularly susceptible, because of their playing and eating habits. Lead is absorbed more easily if there is a calcium/iron deficiency or if the child has a high fat, inadequate



There is no question that developments and breakthroughs in atomic spectroscopy have directly impacted our understanding of environmental contamination and the way trace metals interact with the human body.

Sam Richardson, Zoe Grosser, and Robert Thomas

mineral and/or low protein diet. When absorbed, lead is distributed within the body in three main areas: bones, blood, and soft tissue. About 90% is contained in the bones while the majority of the rest gets absorbed into the bloodstream where it gets taken up by porphyrin molecules (complex nitrogen-containing organic compounds providing the foundation structure for hemoglobin) in the red blood cells. It is clear that the repercussions and health risks are potentially enormous if children are exposed to abnormally high levels of lead.

The level of lead in someone's system is confirmed by a blood-lead test, which by today's standards is considered elevated if it is in excess of 10 µg/dL (100 ppb) for children and 40 µg/dL (400 ppb) for an adult. However, since 1970, our understanding of childhood lead poisoning has changed substantially. As investigators have had more sensitive techniques at their disposal and designed better studies, the toxicity levels for lead have progressively shifted downward. Before the mid-1960s, a level above 60 µg/dL (600 ppb) was considered toxic and by 1978, the defined level of toxicity had declined 50% to 30 µg/dL (300 ppb). In 1985, the CDC published a threshold level of 25 µg/dL (250 ppb), which they eventually lowered to 10 µg/dL (100 ppb) in 1991. It is well-recognized that the development of flame atomic absorption in 1962 to the detection limit breakthrough of electrothermal atomization in 1971 and the staggering sensitivity and sample throughput of ICP-MS in 1983 have all played an integral part in reducing these toxicity levels.

TOXICITY LEVELS

Even though the majority of sources of lead contamination have essentially been removed from the environment, (e.g. paint, pipes, gasoline, pottery, smelters), there still remains a potential threat from the use of lead plumbing materials used in drinking water supplies. This is definitely the case with older buildings, but can also be a problem with newer homes that use copper pipes and fittings connected with lead-based solders.

This has been recognized by regulatory standards even as far back as the early 1960s, when the Surgeon General under the direction of the U.S. Public Health Service (USPHS) set a mandatory limit for Pb levels in drinking water. Unfortunately at that time, lead assays were carried out using the dithizone colorimetric method, which was very sensitive but extremely slow and labor intensive. It became more automated when

anodic stripping voltammetry was developed but lead analysis was not considered a truly routine method until AS techniques became commercially-available in the early 1960s. It was not until 1974, when Congress passed the Safe Drinking Water Act (SDWA), that the National Primary Drinking Water Regulations set Maximum Contaminant Levels (MCLs) of 50 ppb for Pb. At this point in time, ETA was firmly established as the dominant ultra-trace element analytical technique and even though it could detect these kinds of levels with relative ease, it was extremely slow and labor-intensive. This did not pose a real problem for small numbers of samples, but as a duplicate analysis might take five to seven minutes per sample, it became very time-consuming in high-workload environments.

When amendments were made to the SDWA in 1996, the MCL for Pb was reduced from 50 to 15 ppb. At that time emphasis was placed more on regulating a small number of contaminants that posed the highest risk to public health. It became known as "the lead and copper rule" and, instead of specifying an MCL for both these elements, they had an "action limit," where some action had to be taken if 90% of the drinking waters sampled at the tap or faucet were above 15 ppb for Pb and 1.3 ppb for Cu. In the case of Pb, this meant that some kind of corrosion control procedure had to be put into place, together with a public education and awareness campaign. The result was that state, county, and city water municipalities and public health authorities were mandated not only to monitor lower levels in drinking waters but also to sample them on a more regular basis. This produced a significant increase in the number of samples, which led to a more rapid acceptance of ICP-MS to analyze drinking water samples, not only for Pb, but also for the entire suite of environmentally significant elements. It is no coincidence that the increased acceptance and use of ICP-MS for environmental monitoring has led to the lowering of blood lead levels in children and MCLs in drinking water.

ICP-MS IN ACTION

A recent example of how ICP-MS has met the challenge of monitoring Pb in drinking water samples is shown in a recent investigation carried out by Washington (DC) Suburban Sanitary Commission (WSSC). A study had been carried out by the District of Columbia Water and Sewer Authority (DCWASA) in early 2004, which found elevated levels of Pb in the drinking water supply of many of the schools in the District. Although this was not totally unexpected con-

sidering the age of the schools, it set off alarm bells at the Public Health Departments in nearby Montgomery and Prince Georges Counties in Maryland. Though they were expecting 20-30 drinking water samples per school, the investigation turned out to be far bigger than they ever imagined. The magnitude of the problem soon became evident when one school uncovered some abnormally high Pb levels of up to 40 ppm – approximately 3000 times the U.S. EPA action limit. As a result, it was clear that the frequency and number of samples tested was going to increase dramatically. In fact, in some of the larger schools, the water supply needed to be sampled at over 500 different locations to fully understand the severity of the problem.

So here was a large suburban water municipality, with literally thousands of drinking water samples coming into the lab to be analyzed for lead. There were two school superintendents, in charge of almost 400 public schools in the area, who were worried about a potential Pb contamination problem in their drinking water supply... not to mention the thousands of extremely concerned parents. If this was not enough, the local TV station heard about the problem and wanted an interview. An added complication to an already stressful situation was that WSSC did not have a suitable instrument to carry out the investigation.

They knew that their current ETA system and an older ICP-MS instrument would not be able to handle the expected workload and the only way the lab was going to analyze this number of assays was to invest in a new instrument. So the go-ahead was given by the lab director to purchase an ELAN[®] DRC-e (PerkinElmer SCIEX[™]). As a result, they were fully operational just one week after installation — making a dent into the huge backlog of drinking waters, arriving at a rate of 500 samples per day.

In a typical day, they would fill the autosampler and run a QC standard spike sample and blank every ten samples. If the QC standard fell outside the U.S. EPA drift specifications of $\pm 15\%$, recalibration automatically took place. They were able to carry-out unattended, overnight runs and quickly analyzed over 60,000 samples in less than six months.

Unfortunately, the data generated from the investigation have posed almost as many questions as answers to the problem. Evidently, when the drinking water lies stagnant in the pipes for a period of time, it leaches out Pb from the brass pipes, fittings, or the Pb-based solders used in the plumbing joints. That is why some of the older schools in the area that still had lead pipes showed extremely high levels — in some cases as high

as 40 ppm lead. However, when the water system is flushed for a few minutes, the Pb levels are dramatically reduced and resampling has shown that they quickly fall back down to the U.S. EPA “action level” of less than 15 ppb. The long-term solution of the problem will focus on three main areas: adding corrosion inhibitors to the water supply, coating the inside of the pipes with some kind of resin to reduce corrosion, and/or replacing lines/fittings that contain lead or lead-based solders in the plumbing system.

THE FINAL ANALYSIS

It is well-documented that ICP-MS, with its detection capability, has contributed to a better understanding of environmental contamination and the way trace metals interact with the human body. However, in this particular Pb in drinking water investigation at WSSC, it also exemplifies the fact that the technique is now a truly routine analytical tool that can be used for ultra high throughput analysis.

FURTHER READING

For more information about the subject matter in this article, please visit the following websites:

- Montgomery County Public Schools:
<http://www.mcps.k12.md.us/info/emergency/lead/>
- Washington Suburban Sanitary Commission:
<http://www.wsscwater.com/info/leadInformation/LeadInformation.html>
- U.S. Environmental Protection Agency:
<http://www.epa.gov/safewater/lead/schoolandddccs.htm>
- Center for Disease Control:
<http://www.cdc.gov/nceh/lead/factsheets/leadfacts.htm>

Sam Richardson is a member of the Washington Suburban Sanitary Commission, Silver Spring, MD.

Zoe Grosser is employed by PerkinElmer Life and Analytical Sciences, Shelton, CT.

Robert Thomas is with Scientific Solutions, Gaithersburg, MD.

“Make it a habit to ask your employees to propose solutions to the problems they bring you instead of allowing them to dump their problems in your lap and run.”

*From The Rookie Manager
(an e-book at www.amanet.org/online_library/ebooks/rookie.pdf)*

How IT Works

Automating Cell Counting to Produce Fast, Reliable Results



Problem: Laboratories continuously face pressures to produce faster, more accurate results from their research. For this reason, automating manual, tedious processes is critical.

Solution: The Cellometer™ Auto T4 Cell Counter from Nexcelom Bioscience was developed based on requests from scientists and researchers who were routinely performing time-consuming manual steps associated with counting various types of cells. The system includes a compact instrument with advanced image-based cell counting software.

The Cellometer™ counting chamber used with the Auto T4 is disposable; therefore, no washing steps are required after each sample. The instrument does not contain any liquid handling system, which eliminates clogging as well as related maintenance downtime and service charges. Additionally, since the sample is completely contained within the chamber, there is no cross-contamination. The Cellometer™ Auto T4 requires sample volume of 16 to 20 microliters. Its small 3.5" by 4" footprint saves valuable lab space. Only three simple steps are required for results, and it is cost-effective making it an affordable solution for any laboratory budget.

More reliable and more functional than a hemacytometer, the

Image 1: The Auto T4 produces results in three simple steps: (1) pipette into Cellometer™ disposable counting chamber, (2) insert into Auto T4 cell counter, (3) the imaging software automatically analyzes acquired cell images and measures cell concentration and viability.

Cellometer™ Auto T4 is an automated solution to replace traditional manual cell counting with a hemacytometer. Like a hemacytometer, the Cellometer™ system does not require special counting buffer or cell manipulation. Cells in growth media, PBS, or other solutions can be pipetted directly into the Cellometer™ counting chambers. For cell viability measurement, the standard trypan blue method is used.

The Cellometer™ Auto T4 increases lab efficiency by reducing cell counting time per sample from the typical five to ten minutes to less than one minute. A significant benefit of automation is removing subjectivity and person-to-person variation, thus providing a standard cell counting platform for sharing data across laboratories and organizations.

The user-friendly data analysis software automatically captures cell images and calculates cell concentration and viability. Data can be stored for documentation or further analysis.

Size information of individual cells is also saved in a data file and can be further analyzed using familiar methods, such as Microsoft Excel.

Straightforward and user-friendly imaging software, the Cellometer™ imaging software automatically analyzes cell images and measures cell concentration and viability. Parameters can be set to measure specific cells in complex samples. Cell counts are verified using graphic indicators. (Green circles indicate live cells and red circles indicate dead ones.) Changing between different types of cells involves only one drop-down menu selection in the Cellometer™ software, which is very convenient and fast for laboratories with multiple users.

The Cellometer™ Auto T4 is simplifying cell counting for scientists and researchers at major pharmaceutical, biotech, and research organizations. By automating a once manual process, researchers can now focus more time and effort on generating results faster and more reliable than ever before. A live, on-line demo hosted by a member of the Cellometer™ Auto T4 team is available upon request. Contact Nexcelom Bioscience at 978-927-5340 or visit www.nexcelom.com for more information.

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lab agenda

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55th ASMS Conference on
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American Society for Mass
Spectrometry
Indianapolis, IN
www.asms.org

JUNE 17-21, 2007
High Performance Liquid
Chromatography (HPLC) 2007
Ghent, Belgium
www.hplc2007.org

JUNE 24-27, 2007
2007 AAPS National
Biotechnology Conference
American Association of
Pharmaceutical Scientists
San Diego, CA
www.aapspharmaceutica.com

JULY 30 - AUGUST 3,
2007
34th Annual NAOSMM
Conference and Trade Show
National Association of
Scientific Material Managers
Cleveland, OH
www.naosmm.org

AUGUST 6-9, 2007
IBC's Drug Discovery and
Development of Innovative
Therapeutics
(DDT) World Congress
Boston, MA
www.drugdisc.com

AUGUST 19-23, 2007
ACS Meeting & Expo
American Chemical Society
Boston, MA
www.acs.org

AUGUST 20-24, 2007
Forum on Laboratory
Accreditation
Cambridge, MA
www.nelac-institute.org

OCTOBER 2-3, 2007
Joint ELRIG and SBS Meeting:
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European Laboratory Robotics
Interest Group and
Society for Biomolecular
Sciences
Nottingham, United Kingdom
www.sbsonline.org

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

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

OCTOBER 23-27, 2007
ASHG Annual Meeting
American Society of Human
Genetics
San Diego, CA
[www.ashg.org/genetics/ashg/
/menu-annmeet.shtml](http://www.ashg.org/genetics/ashg/menu-annmeet.shtml)

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product focus: meters, monitors, and detectors

Combined Transmitter >>

The PTU300 features digital measuring electronics for pressure, humidity, and temperature, along with several small RH&T sensor heads for different applications and calculated humidity variables. Backlit display shows three-hour graphical trends and up to one year of historical data. Applications include environmental monitoring in calibration laboratories, GPS meteorology, and weather stations.

Vaisala

www.vaisala.com



<< Mercury Vapor Analyzer

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Arizona Instrument

www.azic.com



Portable Gas Detector >>

The SPECTRUM SP portable gas detector with internal pump was developed with a sample draw system required for HF and ozone. The detector features a backlit digital display, dual-level alarms, and a rechargeable battery. This monitor is available for a range of gases including O_3 , HF, HCl, Cl_2 , and AsH_3 .

ENMET

www.enmet.com



Modular Detection Platform

The PARADIGM™ Detection Platform is a modular system featuring a selection of cartridges that can be interchanged in less than five minutes. It is a user-upgradable and -configurable multimode reader. The high-throughput detector reads in formats from 6 to 1,536 wells.

Beckman Coulter

www.beckmancoulter.com

<< HPLC Liquid Flow Meter

The FlowCal 5000 digital liquid flow meter was designed for specialists responsible for HPLC calibration and qualification. The flow meter measures flows accurately to $1 \mu\text{L}/\text{minute}$ with guaranteed linearity from 0.05 to 25.00 mL/min. The flow meter is supplied with a carrying case with foam inserts, a cleaning kit, and a universal mounting kit.

Tovatech

www.tovatech.com



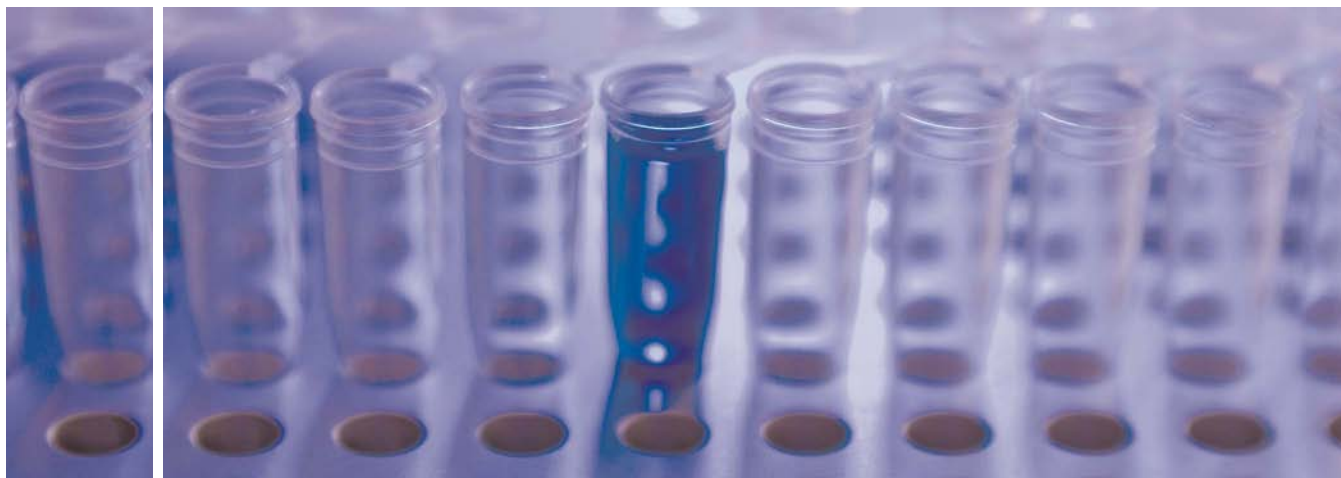
<< pH/ISE Bench Meter

These meters features a 240×320 dot-matrix color display with on-screen help, simultaneous graphing, language selection, and custom configuration. It measures pH using a 5 point calibration with a choice of custom or memorized buffers and provide the user with an electrode diagnostic system. In ISE mode, direct calibration and measurement is allowed with a choice of units, as well as incremental methods.

Hanna Instruments

www.hannainst.com/usa





product news



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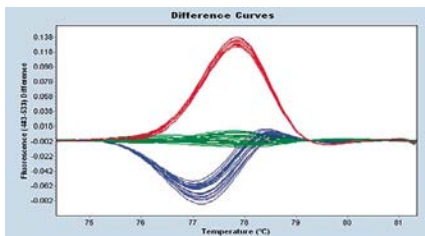


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[Roche Applied Science](http://RocheAppliedScience.com)
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www.kodak.com/go/molecular



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[Leica Microsystems](http://LeicaMicrosystems.com)
www.leica-microsystems.us



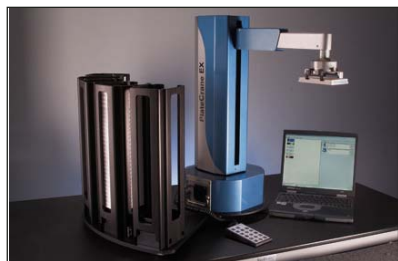
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The bioinformatics Cell accelerates bioinformatics algorithms, such as Smith-Waterman and ClustalW, up to 110 times faster than a desktop computer. The cell is available for a single

computer or for computer clusters. The device is plugged into the USB port of any Intel- or AMD-based computer. Command-line execution is also an option.

[CLC bio](http://CLCbio.com)
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Welcome to the SOP Corner!

THAT'S RIGHT — CORNER — WHERE MANY OF OUR SOPS REST AND RELAX, AND CATCH A FEW "ZZZ"S.

My objective is to get those SOPs out of the corner and up onto their feet. We want them to be effective tools for managing, directing, and inspiring the work of our organization. First, we'll take a look at the basics of an SOP, from why they are needed to the best ways to build them to the best peer review practices. Are you ready? Then let's go.

SOPS — BACK TO BASICS

So, what is a Standard Operating Procedure (SOP)?

Aesop once said, "A sensible man never embarks on an enterprise until he can see his way to the end of it."

Let's look at SOPs in the same light. Never start a new task or project unless you can see your way to the end. Use SOPs as instruments to plan and guide then record and document your journey, from beginning through the middle to the end. Some labs (although the word "many" comes to mind) fail to do those simple, logical things. Their SOPs serve other purposes — meet requirements, satisfy regulations, implement standards. Those labs only update their SOPs just prior to an inspection or an audit. They write their SOPs from an administrative perspective instead of from the user's point of view or they look like a doctoral thesis and not something that a person doing the work can use.

Sure, keeping SOPs current is an administrative task that can siphon away the limited resources we need to run our facilities. Sure, it's easier to update SOPs only when absolutely necessary and, yes, who needs formal training on writing SOPs when "we've always done it this way?" For our SOPs to be useful and effective and serve our needs, we need to take a different approach. We need, in fact, a transformation so SOPs are written and maintained as current, and correct and accurate, for the people who will use them.

WHAT IS A SOP?

The first step in this transformation is to define what an SOP is.

An SOP is a set of instructions or steps someone follows to complete a job safely, without adverse impact on the environment, and in a way that maximizes operational and production requirements.

Our SOPs call out the job steps needed to help us standardize operations and produce work in a safe, top quality fashion, in full compliance with expectations (customer's, regulatory, environmental, and specification). Keeping SOPs current and user friendly is the key to running our facilities effectively, efficiently, and without mistakes or regrettable errors.

WHEN IS A SOP NEEDED?

Develop an SOP for any job that has (or can have) an impact on product or service or personnel. In fact, an SOP can be useful in maintaining the lab's image in the eyes of customers, the public, regulators, and even competitors. Create a SOP for any process that is (or seems) complex or high risk. For example, accounting as a process may seem to have no direct impact of concern but it can certainly be complex and complicated, leading to high risk if done improperly or incorrectly. Consider how a poorly written invoice can cause a direct delay in payment!

We need to have the SOP before the job starts. Postponing development until the next FDA inspection or the annual SOP review deadline is unacceptable; in fact, it puts us at high risk of failure. Build or modify the SOP whenever the job changes, new equipment is installed or changes, or there's a change in facility configuration. Use the SOP as a planning tool for jobs, equipment operation, and personnel protection.

WHO SHOULD WRITE AND OWN SOPS?

Sometimes (the word "often" comes to mind), SOPs are written by the one person in the



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organization with a knack for transferring thoughts to paper. Other times, SOPs are given to the individual with good enough computer skills to format documents and do so within a fairly short period of time. But, a more successful SOP process involves the talents and skills and experience of several people, in particular, those closest to the work (users). This way, there's a true sense of ownership and a better chance of buy-in from everyone. It's also a good idea to make sure there are the right and qualified people to review and evaluate the SOP in terms of quality, health, safety, environmental impacts, operational requirements, and production demands. Together, the developers and reviewers become a SOP team of stakeholders, each individual with an interest in the success of the SOP and the job or task it deals with; for example:

- People who perform the work
- People who will maintain the equipment involved in the procedure
- Technical staff who designed the equipment and processes
- Environmental, health, and safety specialists
- Technical writer
- Equipment manufacturer's user manuals

There, we've reached a good stopping point in our discussion on Standard Operating Procedures for this month. Next time, we'll take a close look at a simple model for planning and developing of SOPs, releasing or implementing them, checking on their implementation, and based on what we find, necessary actions to improve them.

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



**Is your Lab QMS
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**Or are you working
for it?**

The National Cooperation for Laboratory Accreditation (NACLA) has asked CAEAL to present two workshops at the **St. Paul Hotel in St. Paul Minnesota.**

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Workforce Decisions Preordain Client Experiences and Financial Performance

Does your organization make decisions about people with the same due diligence, logic, and confidence as its decisions about investments, customers, products and technology?

That question was posed recently at a human resources conference I attended, and I'll admit to thinking that most board directors and CEOs quite literally spend more time selecting their new plasma flat screen television than they do evaluating their options for promoting and recruiting top management performers.

Today more than ever, the biggest decisions that set the course for future organizational performance and shareholder value are made about people and management, and as more employers struggle to define their own unique demands of leadership, more of those decisions are being made beyond the walls of the HR Department.

Decisions about internal job assignments and promotions, about external recruitment and about other culture-forming elements of the employment proposition like compensation, benefits, training, and succession are being made across the modern enterprise, from the boardroom and C-suite to the division-level and yes, to the laboratory.

But the very best people and workforce decisions about the modern laboratory workforce are made closest to the action and innovation, where science and management meet and where those making the decisions are parties to the customer experience.

The true potential of any modern workforce, the president of a major oil company recently told me, is "its reputation and its ability to bring new talent in." Further, "organization and talent is the basis on which a company has to build its capacity if it's going to do anything successfully."

So how can today's lab manager make more effective decisions about his or her workforce and the pipeline of talent they'll need to sustain it?

For starters, one should examine the organization's employment brand (that is, if it has taken the time to align corporate mission with the employee experience) to understand how the organization is perceived both from the inside and out. Is the organization attracting the right kind of people who put their best into their work and who find compelling reasons to stay?

Also, what's unique about your laboratory, its work and its people? Why should someone aspire to join your team? And what kind of investment do you make in people once they get there? Answering those questions may help you learn whether you're perceived as an employer of choice, or an employer of last resort.

The quality and depth of training programs is also important workforce influencers, because continuous learning and skills development are powerful performance and employee retention enhancers.

Of course, you have to build a laboratory staff that you want to retain and invest in to realize good returns on the company's workforce investments, and you simply can't build those human assets without first starting from a solid recruiting process.

There are so many determinants of recruiting best practice, from communicating an employer brand and reaching qualified candidates to creating a consistent candidate interviewing process and effectively integrating new hires into your laboratory culture.

I once saw an airport advertising billboard that, in the context of making better business decisions about the people side of the laboratory workforce, says a lot about the culture and performance trajectory of your organization: "Success is the



Joseph Daniel McCool

sum of the confident decisions you make.”

What It Means For Your Career: An increasing number of employers are working to connect organizational strategy to people strategy. That means they're looking at each new promotion or recruiting mandate with an eye toward how each employee will contribute to a bigger bottom line. Lab managers and job candidates at all levels should understand the market challenges faced by their employer or prospective employer and be prepared to explain why their experience is relevant and how their professional skills can flex and adapt as the enterprise tackles new priorities and challenges that may loom just over the horizon.

Joseph Daniel McCool is a writer, speaker and independent consultant on workforce management, recruiting best practices, and corporate management succession. He is the author of a forthcoming book about global executive recruitment and its impact on corporate performance, culture and profits. He is also a senior contributing editor with ExecuNet, a leading executive business, recruiting and referral network, and his perspectives on recruiting best practices have been cited in BusinessWeek, The Economist, The Financial Times, The Wall Street Journal and other media around the world. Contact him at JoeMcCool@comcast.net

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From the Lab to Commercial Production: The Challenge of Scaling Up Homogenization Processes

After successfully creating new formulations in a controlled laboratory environment, innovators in the pharmaceutical, biotechnology, chemical, personal care, and food industries often face significant challenges in scaling up production to commercial quantities.

Unfortunately, instruments designed for the laboratory setting can differ significantly from the equipment required to produce large volumes and withstand the rigors of the manufacturing environment. For certain processes, it is difficult or impossible to adjust and modify production-scale equipment to precisely match the formulations created in the laboratory.

The transition from laboratory to manufacturing can be particularly challenging for the homogenization processes used for cell disruption, particle size reduction, and emulsification. Scaling up conventional homogenization can be as much art as science — a trial-and-error process that can be time consuming and expensive — with results that are difficult to predict and too often fail to achieve the identical product as produced in the lab.

UNPREDICTABLE SCALABILITY OF CONVENTIONAL HOMOGENIZATION

The conventional homogenization process was originally designed for processing milk and other dairy products. Auguste Gaulin received a patent in 1899 for a milk homogenization mechanism that reduced the size of fat globules in order to prevent the formation of a cream layer. It is a mechanical process that forces milk under high pressure through a tiny orifice.

Today, a two-stage homogenization process is typically used for dairy products. The first stage operates at a pressure of 2500 psi and reduces the fat globules to a mean size of 0.5 micrometers (with actual size ranging from 0.2–2.0 μm). Because of a tendency for clumping and clustering of the reduced fat globules, a second stage of homogenization is employed. The second stage valve does not reduce the size, but it does separate the clusters into individual fat globules that are less likely to form cream during two or three weeks of shelf life.

Over the past century, more than 100 additional patents have been awarded for improvements on Gaulin's original design, producing smaller average particle size and achieving higher levels of precision than traditionally required by the dairy industry. For advanced products, conventional homogenizers can be designed to perform a variety of cell disruption, particle size reduction, and emulsification operations by selecting or creating a particular orifice size and valve geometry and by adjusting the pressure.

However, for conventional homogenizers, the orifice size, valve geometry, and pressure settings apply only to a specific flow rate. When scaling up from a laboratory-size homogenizer to a pilot system and from a pilot system to a full-scale production system, completely different valves are used and the pressure may need to be raised or lowered considerably. Sometimes several iterations of equipment design must be tested before an acceptable product is produced, or until the specified flowrate is achieved.

FIXED GEOMETRY OF HIGH SHEAR FLUID PROCESSING

An alternative method of homogenization, high shear fluid processing, is favored by many



companies developing new formulations because production volumes can be seamlessly increased from the laboratory to full commercial manufacturing, while utilizing the same processes and turning out identical product.

High shear fluid processing systems contain an electric-hydraulic system providing power to one or two single-acting intensifier pumps. The pump amplifies the hydraulic pressure to the selected level which, in turn, imparts that pressure to the product stream. Process pressures range from 2,500 to 40,000 psi, resulting in high velocity, high shear process streams.

The intensifier pump supplies the desired pressure at a constant rate to the product stream. As the pump travels through its pressure stroke, it drives the product through precisely defined fixed-geometry microchannels within the interaction chamber. At the end of the power stroke, the intensifier pump reverses direction, and the new volume of product is drawn in. The intensifier pump again reverses direction and pressurizes the new volume of product, repeating the process.

As a result, the product stream accelerates to high velocities, creating shear rates within the product stream that are orders of magnitude greater than any other conventional means. The entire product experiences identical processing conditions, producing the desired results, which include uniform particle and droplet size reduction, deagglomeration, and high-yield cell disruption.

The fixed geometry of the microchannels not only ensures that the processing conditions are identical for all product passing through a single machine but that the processing conditions are also identical for all machines using a particular interaction chamber design and pressure setting, regardless of flow-rate capacity.

Therefore, once a high shear fluid processor achieves a successful result with a small laboratory system producing only a few hundred milliliters per minute, then the same interaction chamber and pressure specifications can be used in the design of a full-scale production system that produces tens of gallons per minute. Because of the ability to scale-up production seamlessly, many users of high shear fluid processors skip the usual pilot stage and move directly from the laboratory to full-scale commercial production capacity.

PRECISION HOMOGENIZATION APPLICATIONS

High shear fluid processors are widely used in two broad categories of applications that require precision processing. The first category is particle reduction and emulsification. For example, drug manufacturers use

high shear fluid processors to make emulsions with high energy lipids that can be administered intravenously, with uniform droplet sizes well below one micron — smaller than the diameter of the capillaries in the human body — all but eliminating the risk of thrombosis.

In the chemical industry, the effectiveness and appeal of high-end coatings for aerospace and automotive applications increase as droplet size decreases and particles become more uniformly dispersed. Manufacturers of the resins, extenders, and additives that are integrated with these coatings use high shear fluid processors to achieve high color strength and gloss. The makers of high quality digital inks use a similar process to ensure that all pigment particles are sufficiently small to avoid clogging tiny ink-jet print nozzles.

The pharmaceutical and cosmetics industries also rely on high shear fluid processors for creating the time-released and depth-released characteristics of lotions and creams. Through uniform micro-encapsulation of active ingredients in liposomes, these products can live up to their promise of delivering benefits to specific sites at controlled and predictable rates.

In addition, the food industry is using liposomes in nutraceuticals to enable the slow release of nutrients that can be more easily ingested. High shear fluid processors enable many other enhancements to the nutritional value, color, taste, and texture of foods and beverages. For example, tiny particles of fiber are added to soymilk and many foods without effecting taste or texture.

The second category of applications requiring the precession of high shear fluid processors is cell disruption for the biotechnology industry: precisely-controlled amounts of shear force are applied to bacteria and other cell structures to safely extract high yields of intact proteins and nano-sized particles. These compounds need to be extracted from the living organisms quickly and without damage or contamination.

Conventional homogenization has served the needs of the dairy industry for over a century. However, the development of advanced products utilizing particle reduction, emulsification, and cell disruption applications now requires a level of precision, uniformity, and predictability that is best achieved with high shear fluid processing.

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Safety Beyond the Lab: Ergonomics in the Office, Part 1



You go home each day with a pain in your shoulder or neck, perhaps you wake up at night with tingling in your wrist or hand. You used to feel good all day long but now you hurt after just a few minutes sitting at the computer. What to do? You have tons of data to enter, you have grant deadlines looming, and it seems you get two emails to respond to for every one you send. This means hours and hours glued to your keyboard and mouse.

Simply put, ergonomics is the study of how people physically interact with their work environment to perform their required tasks. Though we usually focus on hazards within the lab, the office aspect of work should not be overlooked and that will be our focus this issue and the next. More and more, jobs require a substantial portion of the day working with a computer. Very often, pain and discomfort experienced at work or at home can be tied to easily recognized, ergonomic risk factors. Poor ergonomic conditions and practices cause more losses in terms of employee suffering, lost time, and productivity than do most other types of injury in the workplace.

Three fundamental ergonomic risk factors are: position/posture, repetition/duration, and force. These can all be influenced by the work area setup and the activity being performed. The good news is these at-risk conditions that can cause pain and potential injury can often be easily controlled if one understands basic ergonomic concepts and how to apply them. We will take a look at these factors and provide some practical solutions to help get you through the day pain-free.

POSITION/POSTURE

The goal here is to achieve a balanced and neutral position. “Neutral” is typically thought of as the midpoint of range of motion for most joints (e.g., your wrist should be straight in both the up/down and side-to-side axis, your upper arm should hang comfortably from the shoulder, and your back and neck should be straight and not twisted or bent). Balanced in the ergonomic sense is when a posture or position is such that one does not have to fight (much) gravity to maintain that posture or position.

Let's look at some of the most common position-related complaints we see. These are often the easiest to correct and can have very dramatic improvement in discomfort in a relatively short timeframe.

Neck Pain: Your head weighs about as much as a bowling ball. Holding a bowling ball straight upright while resting your elbow on a table takes some effort. Now visualize you are balancing a bowling ball (your head) on a cylinder (your neck). If you begin to tip the cylinder, it becomes harder and harder to support the ball. When you sit upright and are looking directly ahead, your skeletal structure supports most of the weight; if you deviate from vertical, your muscles must come increasingly into play to support your head. Now imagine tipping and lifting that bowling ball hundreds of times a day — that is exactly what you are doing when working from hardcopy placed on your desk. Your head goes up and down and side-to-side each time you look down at the paper and then back up to the computer screen. Similarly, if your monitor is placed on the CPU so you must tip your head back to read (particularly problematic for those of you wearing bifocals), your muscles must support this off-balance posture. A much better approach is to place your hardcopy on a document stand between the keyboard and monitor. The monitor should be directly in front of you with the top of the screen just at or slightly below eye level. This way, instead of repetitive up/down and side-to-side head motions, one can look back and forth between paper and screen almost by using your eyes alone, allowing you to remain



in a neutral, balanced position.

Holding the telephone receiver cradled between your ear and shoulder while doing other tasks is also a classic cause of neck pain if you do so on a regular basis. Hold the receiver in your hand if possible. Use a speakerphone or a headset if you must speak on the phone while working, such as reviewing written materials or computer files while conversing.

Shoulder and Neck Pain: Hold your arm straight out in front of you for a couple of minutes. Now try drawing your shoulders up a couple inches towards your ears and hold them there for a minute or two. In both cases, you should begin to feel discomfort and fatigue relatively quickly. Both examples illustrate stresses that can occur when one is working with a keyboard and/or mouse on a surface that is either too high or too far away from an ergonomic standpoint. For many people, this is the result of using a keyboard and/or mouse on top of a standard height desk or having an older keyboard tray that doesn't have room for the mouse (this also can cause contact stress issues we will discuss later). You must reach up, over the edge, and out in front to use the input devices. This may not be an issue for really tall individuals but we see that it is problematic for many average and shorter people. Ideally, when using a keyboard or mouse, your upper arms should hang comfortably at your side. The approach we most often take in a case such as this is to recommend installation of a combination keyboard/mouse tray.

A word of caution, a cheap tray will often not solve any problems, it may create new ones. We often see poorly designed trays collecting dust in storerooms because they just didn't help. Look for a tray that has a tilt to lift or a large release button to move it up and down. In our opinion, one should stay away from units with twist knobs to lock and release as these can be troublesome, especially for people that are already having wrist and hand issues.

The surface on which the mouse is used should be in about the same plane as the keyboard, even better when it can rotate over the keyboard or move towards you to reduce your reach and allow you to keep your elbows in while working. The keyboard platform should be kept level or sloped slightly away from you so your wrists are straight (neutral) while typing.

We have begun to explore the ergonomic risk factors associated with the use of computers. The take-home message in this issue is "balanced" and "neutral." Your monitor should be directly in front of you with the upper edge at eye-level or slightly below. Any hardcopy should be placed in front of you on a document stand either between the keyboard and monitor or immediately to the side of the monitor. The keyboard and mouse should be in front of you and as close as practical to prevent over-reaching. Your wrists should be straight in both axes. OSHA provides an excellent review through their eTool on ergonomics.¹ The State of Washington also has some very good self-evaluation checklists and guides.²

Look for Part 2, where we will discuss repetition and force, and solutions to get you through the day pain-free.

References

1. <http://www.osha.gov/SLTC/etools/computerworkstations/index.html>
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Glenn Ketcham is a Certified Industrial Hygienist with 22 years experience in the health and safety field. He is currently the Risk Manager for the University of Florida with responsibility for the loss prevention, ergonomics, disaster preparedness, and the occupational medicine surveillance programs. He has managed the laboratory safety programs for both the University of California, San Diego (UCSD) and the University of Florida. In addition, he served as an industrial hygienist with federal OSHA compliance and has a masters degree in environmental engineering sciences with a health physics concentration.

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The Safety Guys welcome your comments and questions. You can email them at thesafetyguys@labmanager.com.

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Hiring the Right Job Candidates Takes Patience and Care



To hire candidates who will be productive employees, lab managers should begin by clearly defining the work that needs to be done but not narrowly defining who can do it. Too narrow a job description can result in a position that is very difficult to fill. Instead, look for proven problem solvers who have the key skills critical for job success.

The sooner candidates talk to someone who can clearly describe the job requirements, the faster they will understand your company's abilities and needs. Candidates can lose interest if they have to work through poorly informed intermediaries before you have a chance to describe your needs and, in the right situation, persuade a candidate to interview for the position. By contacting candidates early in the process, you and your team help candidates form a positive image of your company.

This means turning your team members into recruiters. Many companies encourage this by paying bonuses to employees who recommend people who later are hired. By doing so, the candidate pool is not limited to individuals who have contacted the employer or leads that a headhunter submits.

In addition to using résumés to identify candidates to interview on-site, many firms increasingly rely on telephone screening interviews to reduce the number of expensive, time-consuming on-site interviews to only the most promising candidates. On-campus interviews and interviews at activities such as the ChemJobs Career Center at American Chemical Society national meetings can also serve as useful screening interviews.

PREPARING FOR THE INTERVIEW

Talking with references is often the best way to verify credentials. Because many of the issues raised during reference checks are chemical or technical ones, the hiring manager should be the person who contacts the references.

Professional recruiter Nick Corcodilos (managing director of North Bridge Group in Silicon Valley and author of "Ask The Headhunter," Penguin/Plume, 1997) notes that references are more likely to be open and honest when talking to peers than human resources representatives. Managers should consult with human resources representatives to assure that questions they plan to ask during a reference check raise no legal concerns.

One question is particularly critical, "If you were me, would you hire this candidate?" Any hesitation before answering this question and the enthusiasm and brevity of the answer are as important as the content of the answer itself.

It's in the hiring manager's best interest to help candidates prepare for the interview. Describe the job requirements and challenges your team and your employer face. This helps candidates focus on their most relevant skills and experience.

Corcodilos advises, "Treat the interview as an open-book test and give the candidate the book before the test."

DURING ON-SITE INTERVIEWS

On-site interviews provide employers with opportunities to get beyond the facts listed in résumés and assess candidates' compatibility as co-workers. Important attributes such as interpersonal and teamwork skills, oral communication skills, and the ability to think quickly on one's feet can be evaluated. Asking candidates how they would respond in certain workplace situations can help you assess how the candidate would fit in your workplace culture.

Without overly dominating the conversation, describe the methods you employ in managing R&D and how your team works with other groups within your company, customers, and suppliers. This will help candidates determine if the workplace culture is compatible with their own ways of doing things.

Be sure the interview schedule includes conversation time with future peers and a workplace tour. If the position will require the candidate to work closely with members of other departments, include their representatives on the interview schedule. Your co-workers will learn things you don't and will be able to aid your decision on whether to make the candidate a job offer.

If candidates present an employment interview seminar, make sure you have read a couple of their published papers or a review of the technology field in question. Candidates often grade employers by the quality and number of questions asked them during these seminars. However, the candidate's host or the hiring manager should moderate the question period to assure that it does not turn into an inquisition.

THE DECISION PROCESS

The longer organizations take to make employment decisions, the more likely candidates will accept job offers from other firms. So don't delay informing the candidate when you've made up your mind. Not yet ready with details associated with salary, family relocation, and other concerns? Then tell the candidate that you will be making an offer although some of the details still have to be worked out.

Well-organized and managed hiring processes enable hiring managers increase the odds of being able to hire the applicants you really want on your team.

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Yu-Hui Rogers

Scientific Director & Director of New Technology Development
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So what's unassuming Yu-Hui Rogers doing with iconoclast Dr. Craig Venter?

Yes, himself. The maverick geneticist and so-called Bad Boy of Biology, still in the fast lane after all these years, ever since he famously challenged the U.S. government to catch him if they could in a match race to first sequence the human genome. That duel ended in a draw in June, 2000.

Venter put the lie to F. Scott Fitzgerald's observation that there are no second acts in life. In 2004, he announced he'd made the first step toward his goal of building a synthetic genome that could change pharmaceutical and energy production as we know it. Then, he embarked on an extended voyage aboard his yacht turned research vessel, trolling the world's oceans for samples of seawater. His reported yield tripled the number of known proteins, and discovered a mother lode of new microbial species.

Rogers admittedly has a low tolerance for the humdrum. "I cannot stand staying in a single place. I get bored. So this is the perfect environment for me."

She has gone the distance with Venter, together lurching across the frontiers of science to crack the code of life. Rogers is Scientific Director and Director, New Technology Development, of Venter's Joint Technology Center in Rockville, MD, which supports research at the not-for profit organization, the J. Craig Venter Institute.

As a leader of Venter's ambitious DNA sequencing operations, she is on the cutting edge of the convergence of entwined technologies that now seem most likely to dominate 21st century scientific endeavor — IT and biotechnology.

"Technology is driving everything," she said. "To survive in this business, you can't get too comfortable. You have to be forward-looking and constantly re-invent yourself, because every two or three years, there's technology refreshment, both in sequencing and IT. I get worried when I see my people getting too comfortable with the status quo."

Change can't come soon enough for stakeholders waiting for genomics to deliver on its dream. Even as advances in computing and bioinformatics continue to reduce sequencing time and cost, Rogers says the day of the \$1000 genomic analysis — which many believe will usher in the golden age of personalized medicine — is "at least five years out. Ten years might be a reasonable expectation.

"We have a very good control and understanding of our processes, how to optimize it, and where the limitations are. In that sense, managing technology is very much a science. As far as managing people, there's more art involved; although there are some key principles I do follow faithfully. I believe deeply in open communication, honesty, fairness, and respect. Other than that, I'm reluctant to talk about any specifics of my management style. With some people, you have to provide constant guidance; with others, you can just let them go. The best way to describe how I manage is to say I'm a very results or goal-oriented person. I apply that to everything I manage — people, projects, and budgets."

Growing up in Taiwan, chemistry seemed natural for one who "always liked to analyze things at their most basic level." She immigrated to America in 1990, earning a masters degree in organic chemistry from the American University. "It was my choice not to get a PhD. I was tired of school. I wanted to get out and work."

Her ascent up the industry ladder began on the bench at Molecular Tool, a small Maryland-based biotech situated near a racetrack whose first commission was to develop genotyping to verify the parentage of thoroughbreds. Initially, Rogers was an accidental manager. "Somehow," she says, "I gradually became involved more in Molecular Tool's management, going out to represent the company at presentations and interacting with potential collaborators and clients." But, when the firm was bought by Orchid BioSciences in 1998, Rogers balked at re-locating to Princeton, N.J.

That same year, ex-surfer and entrepreneurial scientist Venter entered the gene-sequencing business. Rogers signed on as a research scientist at his company, Celera Genomics, and was soon managing an R&D team establishing sequencing pipelines.

When Venter left Celera in 2002, Rogers followed him. "I wanted to work for an organization where I could really make a difference. My career growth with Dr. Venter has not been limited by anything — not by my background, or my degree, or my gender, or my race.

"All my days are good," said Rogers, who manages a staff of 100. "But I have a selective memory, too. Actually, nothing really fazes me."

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

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