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Failure to communicate

I miss the old rotary dial telephones. When I was a kid, chatting with a friend on the phone was a fairly thoughtful activity, sometimes involving a comfortable chair and a generous amount of time. But more than anything else, I miss the ease with which I could hear and be heard on those old phones. Ironic that with all the various and fast-changing telecommunication technology available today, actual conversations suffer. I find that with mobile and wireless telephones, voices collide, overlap and become garbled. This may explain why "texting" is the preferred medium for teens and 20-somethings. They can't hear each other either.

Whether it's because of flawed technology or some other set of circumstances, failure to communicate is a serious problem for lab managers. The opposite—good and effective communication—is the *most* important, and this month's issue makes that case loudly and clearly. In talking about the Deepwater Horizon oil rig disaster, John Borchardt writes in this month's cover story, "Communication failure is a risk factor in every disaster. Congressional testimony and news media interviews with rig survivors suggest that this was the case in the well blowout." Borchardt uses the Gulf of Mexico disaster to illustrate that "poor communications also can result in ineffective action or no action being taken to manage risk factors in laboratory situations."

The same message can be heard in the Leadership & Staffing article, "Shaky Ground," in which author Stephen Balzac shares some best practices for helping staff deal positively with change in their organizations. Key among them is—again—communication. Referring to one CEO's attempt to change his company's training procedures, Balzac writes, "It was only after talking with both parties, and educating them about the concerns, and fears, each one had, that the organization was able to move forward. The CEO was able to ... solicit input on the best ways to get there; the staff felt they had a voice in the process and were able to come up with several excellent ideas to move the process forward."

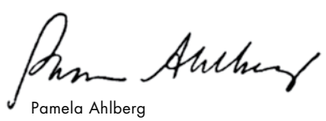
Pamela Jett, in her Lab Manager Academy article, "Words Matter," says, "Communication is the tool by which leaders, managers, and supervisors can create a work environment in which individuals feel valued, connected and actively engaged. In fact, communication is really the only real tool to build relationships leaders possess."

And finally, lab manager Paul Annable tells us in this month's "Perspective On: A Contract Lab," "Communication is the key to success in our industry. You must communicate with both internal and external clients to ensure that everyone is aware of their project deliverables."

So managers, listen up. If you're not communicating well enough, often enough or effectively enough, heed the advice of your peers and experts and begin reinvigorating your communication practices. It might just help you sidestep your own Deepwater Horizon catastrophe.

For anyone in the market for a biological safety cabinet or a new LIMS, you're in luck. In both the Lab Safety article on page 54 and our Product Focus on page 40, authors share a wealth of information on different biohazard levels and the appropriate safety cabinet for each. For LIMS purchasers, we present this month's "expert," Manfred Goebl, who shares with readers the due diligence required before putting a both user-friendly and effective LIMS in place. Gloria Metrick in "Trends in Laboratory Informatics," provides an overview of the latest LIMS developments based on her attendance at two LIMS-specific conferences this fall. All very timely and useful information.

Before I sign off on this last missive of 2010, I would like to take a moment here to sincerely thank you, our readers, as well as our advertisers, for your continued support of *Lab Manager Magazine* and wish you all a joyful holiday season and a very happy and healthy new year.



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MANAGING CRISIS

WHAT THE DEEPWATER HORIZON DISASTER CAN TEACH LAB MANAGERS ABOUT DECISION MAKING

John K. Borchardt, Ph.D.

Making good decisions is perhaps the most important lab management skill. It is essential to managing crises, both big and small. While some may believe decision making is completely innate or only gained through long years of management experience, it is also a skill that can be learned and perfected.

After reviewing some decision-making processes, we'll take a look at the recent Gulf of Mexico oil well blowout and the lessons it offers laboratory managers. The greatest industrial accident in history, it provides useful examples of the same problems that can occur in laboratory environments.

"Decision making... involves applying social psychology, group dynamics and management theory."

Decision making is an interdisciplinary process that involves applying social psychology, group dynamics and management theory. Making decisions is a complex process with psychological, social and emotional components. By understanding and controlling these components, you can make better decisions. An important part of making a good decision is accurately defining the problem; only then can you solve it. Hidden difficulties, not obvious ones, present the greatest challenges in making effective decisions.

Considering case studies is a good way to understand and improve your decision-making processes.

Cut your losses

Early in my first industrial research job, I was fortunate enough to learn (in hindsight) an important decision-making lesson from observing the mistakes of others. A common decision-making error is not to cut one's losses soon enough. A research project had continued for several years and progressed to the point where a pilot plant was built, producing 50,000 pounds of material per year. Two problems became apparent when operating the pilot plant. The first was that the properties of the polymer produced in the plant were inferior to those produced in the lab. The second was that the pilot plant product was too expensive to achieve targeted sales volumes, particularly if the properties could not be improved. The program was continued for approximately three years in an effort to solve these problems.

It gradually became apparent that the company was throwing good money after bad. Millions of dollars were involved. The laboratory manager could not be persuaded to give up on the project and direct resources elsewhere. Finally this manager was replaced by another person and lost his job. Having no emotional attachment to the project, the new lab manager quickly killed it and shut down the pilot plant. Some staff members lost their jobs.

Individual decision making

In making decisions, many individuals do not examine every possible alternative but rely on experience and rules of thumb to make decisions. This can lead to cog-

nitive biases—systematic mistakes when making choices between options. In the case of the example above, it may have been a systematic bias toward optimism—based on previous successes—that resulted in the research program being funded year after year without the critical problems being solved.

Another nonquantitative, nonanalytical tool used in decision making is intuition. Intuition is more than just gut instinct; it is the result of pattern recognition capability. Well-honed intuition can be a useful decision-making tool and is often involved in making breakthrough decisions resulting in the development of revolutionary new products and processes.

The Deepwater Horizon drilling rig burning shortly before it sank last April. Photo courtesy of the U.S. Coast Guard

Group decision making

Decisions are often made by teams or groups. Are teams and groups smarter and more capable of making better decisions than individuals? The answer can be yes if an important pitfall can be avoided: "group think." Group think can occur when the group discussing decision options is pressured into conforming to the view of a powerful individual. This can occur through subtle influence. The powerful individual does not have to be actively pressuring other members of the team.

Another problem occurs if there is little synergy between team members. This results in each team member making a decision independently rather than reaching a consensus. One sign of this occurring is when a group tries to come to a decision by voting on options with little discussion.

Decisions at the organizational level

Decisions made at the organizational level often cannot be attributed to a single leader. The structure and culture of an organization can shape its decision-making process and the decisions made. A small firm owned by an individual usually can reach decisions much more quickly than a large company can. An entrepreneurial organization often reaches different decisions than a large, conservative, well-established company would.

Often decisions made at lower levels of a large organization must be passed "upstairs" for ratification before they can be implemented. This can lead to delays. For the lab manager it means delays in initiating new projects, in moving projects to the field trial stage or in commercializing new products resulting from R&D projects.

In difficult economic times, some managers become afraid of making decisions for fear of making mistakes. This can slow decision making, resulting in "paralysis by analysis," in which potential courses of action are subjected to overly exhaustive study. As a result, new revenues from new products and processes are delayed when needed most.

Sales and marketing personnel can become involved in disputes with lab managers who delay introducing new products and processes. If the new product is successful, this can have severe repercussions for the lab manager. I was involved in a situation like this in the early 1980s, just after the oil boom turned into an oil industry recession. A product I developed was not released to the field despite my optimistic reports to company field engineers. My department manager refused to permit its release. When a vice president attended a division engineers meeting, he received complaints that led him to overrule my department manager and order 30 drums of product be made immediately for field testing. Excellent test results came back, just when new products were badly needed. The research department manager was transferred to a staff position without supervisory responsibilities—a dead-end job. He was laid off in a subsequent staff reduction.

Scenarios can aid decision making

Wise decision making can be encouraged by use of scenarios developed long before decisions must be made.

Shell Oil made the use of scenario planning famous: http://money.cnn.com/magazines/fortune/fortune_archive/2005/10/03/8356715/index.htm (Fortune). Company planners had developed various scenarios of future crude oil prices and developed plans for how the company should respond to each scenario. Shell already had a plan in place before the 1973 Arab oil embargo effectively doubled crude oil prices for its oil refineries, and calmly moved to execute that plan. In a sense, no decisions had to be made. However, frenetic activity characterized the headquarters of some other major oil companies as rush decisions had to be made.

Today many firms in many industries use scenario planning to help guide their decision making.

Scene at the blowout site on July 11, 2010. Two drillships (foreground) drilling relief wells. A drilling rig working on the original well (background) and numerous workboats. Photo courtesy of the U.S. Coast Guard

Avoiding bad decisions

Poorly thought-out decision-making processes usually result in poor decisions. Managers need to think about how to make a decision, try to remove personal biases, collect needed information in advance and determine the diverse perspectives of others. By doing all this, they can greatly improve the success of their decision making.

In a rapidly changing environment such as the recent recession, past decision-making methods that were used in better business conditions may not be best processes to follow.

Risk factors in projects

Mark Abkowitz, a Vanderbilt University engineering professor and author of the book *Operational Risk Management: A Case Study Approach to Effective Planning and Response*, has identified ten risk factors in projects. These are:

1. Design and construction flaws (think laboratory building design, instrument design and project design)
2. Deferred maintenance (a recent problem for some lab buildings due to budget cuts)
3. Economic pressure (project budget cuts)
4. Schedule constraints (which can result in rushing projects to completion prematurely)
5. Inadequate staff training (a problem in some labs due to budget cuts and staff reductions)
6. Not following procedures (usually due to pressure to save time and rush projects to completion)
7. Lack of planning and preparedness (which can occur due to lab managers' heavy workloads)
8. Communications failures
9. Arrogance resulting in overconfidence and a refusal to allow for the possibility of failure
10. Political agendas that exist due to the desire to please major customers or finish projects on budget

The Gulf of Mexico well blowout

These risk factors don't occur only in laboratory projects. Many, if not all, also occurred in the events leading up to the recent Gulf of Mexico well blowout. This led to a disastrous explosion resulting in the loss of 11 lives, the sinking of an expensive drilling rig, an environmental disaster caused by the flow of oil and gas into the Gulf of Mexico, and billions of dollars in economic damage to the Gulf Coast economy.

Abkowitz noted that risk factors often work together to generate an event with disastrous consequences. This was certainly the case in the blowout. BP's own September 8, 2010, report (http://www.bp.com/sectiongenericarticle.do?categoryId=9034902&contentId=7064891) identified eight interacting factors that together caused the well blowout. These were:

1. The cement barrier did not block oil and gas from surging up the well.
2. Downhole tools called shoe tracks did not block oil and gas from shooting up the well.
3. Negative-pressure tests to determine whether oil and gas were entering the well were accepted despite anomalous results.

4. Operators did not recognize the influx of oil and gas into the riser—the pipe between the top of the well and the drilling rig at the ocean surface.
5. Well-control response actions failed to regain control of the well. These included activation of the blowout preventer.
6. Oil, gas and drilling mud were not diverted overboard into the ocean. Instead, these fluids were diverted to a mud gas separator, resulting in natural gas venting onto the rig.
7. Natural gas invaded areas of the rig not electrically classified as spark-free. The rig's fire and gas system did not prevent hydrocarbon ignition from an electrical spark.
8. Three methods for operating the blowout preventer in emergency mode were unsuccessful in sealing the well. The explosions and fire on the rig probably disabled the emergency operation sequence.

Had effective action been taken or effective preventative measures been in place to deal with any of these eight factors, the disaster could have been prevented or its scale substantially reduced. Some experts have suggested an additional causal factor: the well design used by BP, thought by some to be inherently less safe than well designs favored by other oil companies drilling in deep Gulf of Mexico waters.

Abkowitz has also noted that communication failure is a risk factor in every disaster. Congressional testimony and news media interviews with rig survivors suggest that this was the case in the well blowout. Poor communications also can result in ineffective action or no action being taken to manage risk factors in laboratory situations. This is why a busy work schedule shouldn't prevent the documentation of lab results and their communication to all concerned parties in the form of meetings, meeting minutes, e-mails and formal laboratory reports.

Overconfidence can lead to underestimating risk factors, according to Abkowitz. While the facts are in dispute (due to poor and often undocumented communications), BP engineers may have ignored concerns expressed by rig operating personnel and other contractors in the two weeks or so leading up to the well blowout.

Another Abkowitz observation: It often takes a disastrous event to convince people that something needs to be done. This was certainly the case in the Gulf of Mexico well blowout. A six-month drilling moratorium was instituted to allow time to develop improved safety regulations.

Back to the laboratory

Abkowitz also noted that a lack of uniform safety standards in different nations creates an uneven safety risk environment field for international companies. This is certainly the case for laboratories as well as for offshore oil drilling. Laboratory managers, including research managers at the highest levels, need to be sure that safety measures are uniform in all their global laboratories. These have to be effectively communicated to laboratory staff members despite differences in language and culture.

Laboratory managers are fortunate that, while the business risk factors may be great, risks to the health and safety of laboratory personnel and to the environment are less than those of the Gulf of Mexico well blowout are. However, that does not mean that laboratory managers should not take their risk management responsibilities very seriously.

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IMPORTANCE OF PURE WATER IN MODERN ION CHROMATOGRAPHY

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Ion chromatography (IC) is evolving to meet the analytical demands for more rapid analyses using significantly smaller sample volumes. It is essential that sensitivity and reproducibility are maintained. The purity of the water used has a key role to play.

INTRODUCTION

IC a form of liquid chromatography, it uses ion-exchange based stationary phase materials to separate atomic or molecular ions for qualitative or quantitative analysis.

USE OF PURE WATER IN ION CHROMATOGRAPHY

When analyzing samples at such trace levels, the only way to ensure confidence in the data is to have a reliable IC instrument, high-quality reagents and, especially, pure water. Water is used in all aspects of IC, including the dilution of samples, sample preparation or pre-treatment, preparing blanks and standards, the rinsing of equipment and as an eluent. In reagent-free ion chromatography (RFIC) systems the only flow stream is water, therefore, any impurities present in the water can interfere with the analysis in a number of ways and a reliable source of water free of contamination is essential for reproducible results.

So what type of water impurities is a chromatographer at risk of encountering and what effects could they have?

TYPES OF WATER IMPURITIES

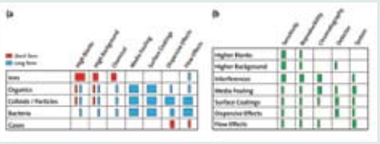
Ultrapure (type I) water is usually produced by the multi-stage treatment of potable mains water but the unique ability of water to dissolve to some extent or other virtually every chemical compound and support practically every form of life means that natural waters inevitably contain a wide range of impurities and contaminants such as ions, dissolved organics, dissolved inorganic compounds, suspended particles, microorganisms and dissolved gases. As the water is rendered potable, many of the contaminants are removed, but some others may be introduced, such as plasticizers from pipework systems or bituminous coatings from tanks.

EFFECTS OF CONTAMINATION

With a sensitive technique such as IC, the effects of contamination of the water could have serious consequences, with the potential to negate experimental results.

But what impact can impurities really have on the reliability and reproducibility of an IC analysis?

As summarized in Figure 1, the effects of contamination from ions, organics, colloids, bacteria and gases can all impact sensitivity and reproducibility to some degree. Contaminating ions tend to have a significant but short-term effect, producing high blanks, high background and chemical interferences that directly degrade results and reduce sensitivity. Varying levels of contaminating ions would result in higher variances in the observed results. While organics, colloids and bacteria will also affect background/blanks, they also tend to have a long-term impact through media fouling and surface coating that can affect parts of the instrumentation, such as the chromatography column, the detector or inner surfaces of the system itself. The net effect of this type of fouling is anomalous baseline shifts, unknown peaks on the baseline, high noise etc.



▲ *Figure 1. The effects of water impurities on the ion chromatography technique: (a) effects on the system and (b) the subsequent potential impact on experimental results. The size of the area in each box indices the significance of each effect (qualitative).*

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TRENDS IN LABORATORY INFORMATICS

THE LATEST NEWS FROM THIS FALL'S INFORMATICS CONFERENCES AND MEETINGS

by Gloria Metrick

I've been invited to speak at and chair more and more meetings in the laboratory informatics industry. While many conferences waive or lower conference fees for speakers, travel costs still add up. Thus, when I was invited to four conferences in the fall of 2010, I knew I would not be able to attend them all. First, it takes too much time away from work. Second, the cost is too high. Third, because some of these conferences are held in Europe, the cost is higher still.

So, I thought I would share some of my conference experiences with you as you're not likely to be attending all these events, either. I wondered, "What would a laboratory manager find interesting or useful from all these laboratory informatics meetings?" I realize that some laboratory managers have entire departments of people to select software for them or inform them about developments in the laboratory informatics industry. But that's not true for everyone. Either way, laboratory managers must wonder at times which informatics products could best help their labs, and how some issues are evolving.

From the two conferences I attended recently, I've identified several topics that either came up at both events and/or provoked quite a bit of discussion. The two conferences were the VIB "Laboratory Data Management USA 2010" in Boston and the IQPC Pharma IQ "ELNs and Advanced Laboratory Solutions" in Amsterdam.

Buying laboratory informatics

For those of you looking to buy software for your laboratory to replace your laboratory notebook or for any other reason, it's still rare for you to simply buy software and just install it. Many of the larger packages still need a full project path to implement them in your lab. You will still need someone specifically dedicated to setting up and/or programming that software before you can fully use it. The word "configuration" is still used to refer to programming activities.

Build versus buy

While our industry has long touted the vast amount of software on the market, there are still areas for which software has to be custom written. One area where labs sometimes buy systems but also write them in-house is drug discovery. So, if you're managing such a lab, just be aware that you can look for solutions in the market, but depending on what you're doing, you might decide that it makes more sense to write software for your specific application.

LIMS versus ELNs

Laboratories continue to ask about the dividing line between LIMS (Laboratory Information Management System) and ELN (Electronic Laboratory Notebook). Which one owns the results, for example? Which exact features should be used when both provide them? The industry continues to change, and both systems continue to encroach on each other's territory. However, at these two conferences, I think our industry finally came to an agreement that the convergence is happening. The terms LIMS and ELN no longer mean anything. More acronyms have come up as vendors try to define the new space, but that just adds to the confusion.

Vendors and customers alike have recognized that traditional roles for LIMS in sample management and for ELN as a replacement for the paper notebook are now outdated. Additionally, other tools, such as SDMS (Scientific Data Management Systems) and ECM (Enterprise Content Management), integrate and tie together the entire laboratory picture and facilitate good document and file management. However, getting all the systems coordinated continues to require good planning and a good bit of work.

To those of you who may be a bit confused about what to select, industry vendors and end-user companies that have already gone through the process can tell you that it is more important than ever to know your requirements. It's pointless to decide you need one system or another. What you need isn't based on some acronym; it's based on what you actually need.

TRENDS IN LABORATORY INFORMATICS

The cloud

Your IT department might have told you that you're going to use "the cloud." You may be wondering what that refers to. It just means that someone else is storing your data and/or hosting your application. Actually, there can be private clouds run by your own company that make it possible for you to get access to heavy computing power or large amounts of data storage. Those of you managing small labs may already be using cloud computing for intense computing power to compete with larger companies that have access to the supercomputers. But that's not what your IT group is probably talking about. They probably mean they're thinking of storing things like your e-mail, management data, product data, laboratory data and other information in one of these cloud spaces.

The problem is that privacy issues do need to be worked out before such data gets stored in the cloud. If your company decides that you can store e-mail outside the company (such as with Amazon or Microsoft), but not critical product data, that means you need to have policies in place to make sure you're not using e-mail to send your critical product data to others, even within the company. So, a decision to use the cloud to store such communication may have an impact on how you will share your data, depending on how you currently do that as well as how you intend to do it in the future.

Legal issues

While laboratory managers don't often get involved in legal issues, some are frustrated with company lawyers regarding the use of ELNs. Cheer up. More and more company lawyers are becoming comfortable with these systems; more companies are allowing digital signatures, rather than printing the paper and signing it; and there are even companies starting to discuss machine witnessing, and it appears that some have already implemented it. With machine witnessing, instead of having a notebook witness review things and sign off, the machine (i.e., your computer via the software running the ELN) checks that everything is finished and witnesses it. This is more likely to occur in truly structured areas, however. Thus, if you are doing early research, where processes are less rigid, this is unlikely to be automated. If your work is in a later stage of the process, such as Development or Quality Control, where the processes tend to be less flexible, it is more likely to be a candidate for early machine-witnessing.

Projects and data

At the conferences I attended, many customers gave presentations about project issues or discussed details of managing or coordinating their data. No single strategy seems to work for everyone, as these presentations attested, but some good ideas were put forward. For those companies about to embark on new and large laboratory informatics projects, these conferences are useful, if only for to find out how other companies handle issues that arise with just about all projects. Additionally, attending conferences enables participants to speak with the other companies' representatives and ask them questions. Laboratory managers who will buy or influence the purchase of these systems should consider attending one of these meetings. If your IT department will be handling the purchase, you should encourage them to attend so they gain an understanding of the choices available and the issues your company will face.

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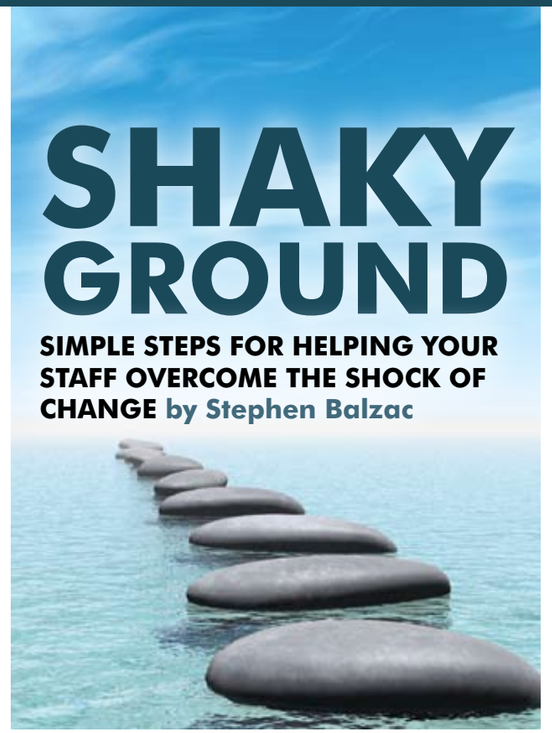

When I arrived in northern California in 1989, I was just in time for the Loma Prieta earthquake. The experience of having the earth start moving under one's feet is an unsettling one. When the quake doesn't stop immediately, the unsettled feeling increases much faster than might seem rational to someone not experiencing the event. Even after the quake is over, many people report jumping whenever the ground shakes from a subway going underneath or a large truck going past; the first night after the quake that the cat jumped on the bed, I just about shot through the ceiling. Fundamentally, having something whose solidity we take for granted suddenly stop being solid is a very disturbing occurrence.

Despite this, businesses subject employees to the metaphorical equivalent of earthquakes all the time. No, the building doesn't shake; the job does. When a business decides to make a significant change, some aspect of the job suddenly becomes uncertain. Even, or perhaps especially, when management insists that the change is a good one, employees are still nervous and uncomfortable. The less their concerns are dealt with in a constructive way, the worse it gets. This translates into reduced job satisfaction, lower performance, and decreased loyalty. In other words, the result of poorly managed change is lower revenues for the company.

At one company I worked with, the new CEO's vision involved very substantial changes to the way training was conducted. Existing trainers went ballistic. They saw the new policy as undermining their authority, compromising the mission of the company, and reducing the quality of the classes. It wasn't long before both parties were so busy screaming at each other that neither one could hear what the other was saying. It was only after talking with both parties, and educating them about the concerns, and fears, each one had, that the organization was able to move forward. The CEO was able to step back, focus more on the outcomes, and solicit input on the best ways to get there; the training staff felt they had a voice in the process and were able to come up with several excellent ideas to move the process forward.

The fact is, when a company decides to make a change, employees immediately wonder how that change will affect them. Even when things are going well and most changes do not involve people being laid off, benefits being cut, or salaries being reduced, change makes people nervous. They wonder how they'll fit into the new world order; whether the company will still meet their needs; whether the company will still hold to the ideals that attracted them in the first place; whether they will feel proud or ashamed of working for the company; even whether the company will survive the change. If those questions are not addressed, people will start to focus on them to the exclusion of getting work done. Rational argument is surprisingly ineffectual, even when dealing with people who are seen as, and consider themselves, extremely rational.

I worked with one software organization for which we needed to change the way defects were tracked and reported to engineering. The assurances that the new process would be easier, take less time than the old one, and result in a higher quality product didn't matter. Even the fact that a weekly, all-day bug-tracking meeting was eliminated and replaced with a brief status meeting didn't matter. What mattered to people was that something that they saw as inviolate was being changed, and thus their whole image of the company was being changed as well. Engineering had always had the final say over which bugs were fixed and who fixed them. Changing that made the engineers feel that their competence

> "The result of poorly managed change is lower revenues for the company."

and autonomy were being threatened. The initial response was one of continual, passive resistance. Dealing with that resistance involved helping all parties recognize that they had the same goals for the company, the product, and each person's ability to manage his or her own time. It meant addressing fears, rational and irrational. Once it became clear that the goal wasn't to assign blame, but to enhance the customer experience without increasing demands on engineering, the engineering team became an enthusiastic supporter of the new process.

I frequently hear that people "do not like to change." In fact, that's not really true. What people don't like is being changed by someone else. When people are confronted with the prospect of change, there is a window of opportunity while they take in the news and evaluate the situation. During that window, most people are initially ambivalent. It's when they are told how great the change will be, how there's nothing to worry about, and how they should just go along because there really isn't any choice, that they start resisting. When people are trying to make up their minds how they feel about something, pushing them tends to produce an immediate, and opposing, reaction.

"Leave the door open, invite opinions, and recognize that enthusiasm takes time to build."

So how do you defuse this natural resistance before it becomes active or passive rebellion, or a mass exodus of employees?

Start by recognizing that resistance is not something to smash through; as in the practice of jujitsu, resistance is a signal that you are moving too quickly. Slow down and acknowledge employee concerns; don't try to minimize them or ignore them. That only sends the message that the concern must be really serious because you aren't willing to discuss it. Acknowledging their concerns also helps reinforce the feeling that you're all in this together: quietly reinforcing a sense of community is critical in reassuring people that you really do have their interests at heart.

Involve the employees in identifying the disadvantages of not changing. Present the situation to them and ask them to tell you why doing nothing may be a bad idea. Ask open-ended questions: "What are the biggest threats we face if we do nothing?" is better than "Do you think there's a problem with our doing nothing?" Once they've identified the problems with doing nothing, then you can transform those problems into the advantages of making a change.

Especially if your firm is large, periodically summarize and repeat back the feedback you're getting. Make sure employees know they're being heard.

Create a compelling, vivid vision of the brave new world. Once people are thinking about the advantages of change and the disadvantages of staying put, it becomes important to give them a place to go. Don't present the vision as set in stone but as a work in progress.

"If you praise success, people are less willing to take risks than if you praise the process."

Invite your employees to become part of the change process, but don't try to force them. At one company, each employee was ordered to come up with two ideas to move the company forward. While that may sound like a great way to include everyone, in fact it was seen as just another way to undermine autonomy and get people to eliminate themselves. Leave the door open, invite opinions, and recognize that enthusiasm takes time to build.

Brainstorm with employees on how to change and what changes will be best. Forge agreement on the ultimate goals of the change process. Treat objections as opportunities to develop innovative solutions, not as signs of argument or disloyalty.

Look for opportunities to give each employee as much autonomy as possible in implementing the changes. Remember, your goal is to get everyone to the same place at about the same time; it doesn't necessarily matter how they get there. Furthermore, the more actively people are involved, the less they'll feel like they're being changed and the more they'll feel like competent, respected members of the team.

Praise the behaviors you want to reinforce. If you want people to contribute ideas, praise those who come up with them, whether or not those ideas end up being used. It takes a lot of unworkable ideas to produce one really good one. If you praise success, people are less willing to take risks than if you praise the process.

While fighting through resistance may feel like the natural way of doing things, in the long run it's not only counterproductive, it's also painful, unpleasant, and exhausting for all concerned. What are you doing to make change easy?

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WORDS MATTER

UNLEASH A MAGIC LEADERSHIP PHRASE

by Pamela Jett, CSP

Did you know that nearly one-quarter of U.S. employees (according to a recent Gallup Management Journal survey) would fire their bosses if given an opportunity to do so? Yikes! The reason these employees would opt to fire their boss is because they feel "disengaged" and "disconnected" at work.

Communication is the tool by which leaders, managers, and supervisors can create a work environment in which individuals feel valued, connected and actively engaged. In fact, communication is really the only real tool to build relationships leaders possess. As such, leaders would be well served to remember that words matter and use communication to strengthen as opposed to sabotage professional relationships.

Here is a technique leaders can use to build relationships and connect. This technique will help people feel like their opinions, ideas, and insights matter; which, in turn, helps people feel like they matter. Great communicators are comfortable using a version of "that's interesting, tell me more".

1. If you are a leader and you notice an employee engaged in a behavior that seems, at first blush, to be inappropriate or wrong, you can either ask something defense producing (and thus counter-productive) such as "what are you doing?" or "why are you doing that?" or you can opt to be more savvy and try "that's interesting, tell me more." This frees the employee up to provide more information, without them becoming defensive. As a leader, you just might discover that what they are doing, although different than what you would do, is actually smart or innovative. Or, you might discover that they are engaged in something wrong. However, you can then provide correction and they are likely to be more open to the correction because you allowed them to explain themselves first.
2. If you ever need to buy yourself some time because you have been blindsided or caught off guard, "that's interesting, tell me more" is a great way to gather more information and simultaneously buy yourself some time to gather your thoughts. And, you appear professional and composed in the process.
3. This technique also works when you suspect someone is being less than completely candid. By saying "that's interesting, tell me more" you are sending someone a subtle signal that you are on to them and they will think twice about stretching the truth or being less than honest with you in the future.

These are just some of the scenarios in which "that's interesting, tell me more" can be beneficial. It is a power phrase leaders can use to improve their communication and enhance employee engagement.

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TECHNOLOGY & OPERATIONS

GAS ON DEMAND

MAKING A CASE FOR IN-HOUSE GENERATION OF CARRIER GAS FOR TOC ANALYSES

by Jack Mahan and Peter Froehlich

Total organic carbon (TOC) analyzers are commonly used in applications including the determination of organic matter in water in municipal water supplies and sewage facilities, the monitoring of water used in semiconductor manufacturing and nuclear power plants, and the clean-in-place procedures used in pharmaceutical manufacturing.

TOC analysis includes three discrete steps:

1. Acidification of the sample to remove inorganic carbonaceous material and purgeable organic carbon (e.g., methane)
2. Oxidation of the organic matter in the sample (typically via persulfate in a heated quartz tube) into CO_2
3. Detection of the CO_2 (typically by non-dispersive IR)

"A TOC analyzer can be coupled with a nitrogen analyzer... so that the level of both elements can be determined."

High-purity air or N_2 is used to drive the CO_2 from the oxidation process to the detector, and its purity is a critical issue in the optimization of the sensitivity and operating range of the system. The gas must be free of CO, CO_2 and hydrocarbons (e.g., compressor oils), and is typically supplied to the analyzer at a pressure of 80 to 100 psig and at a flow rate of 400 to 800 mL/min to provide a broad operating range; as an example, organic carbon can be detected over the range from 4 to 25,000 mg/L using the Shimadzu TOC-V_{CSH} Analyzer (Shimadzu Corporation, Tokyo, Japan) shown in Figure 1. In addition to analysis of organic carbon in water, a TOC analyzer can be coupled with a nitrogen analyzer (which converts organic nitrogenous compounds to NO followed by measurement of the chemiluminescence of the NO) so that the level of both elements can be determined.

Figure 1. Shimadzu TOC-V_{CSH} TOC analyzer

Although carrier gas for TOC analysis can be provided by a cylinder obtained from an external source, many laboratories employ an in-house generator to supply the gas. In this article, we will describe how carrier gas for TOC analysis can be generated in-house from laboratory air and show that this is a safer, more convenient and less expensive approach than the use of a cylinder.

Design of an in-house gas generator for TOC analysis

The initial steps in generating TOC carrier gas involve filtration of the compressed air and oxidization of hydrocarbons. The compressed air is then passed into a pressure swing adsorption (PSA) system to remove water vapor and CO_2, and a final filtration step is employed to remove all particulate matter >0.01 micron. An overall schematic diagram of a typical in-house generator designed to generate high-purity gas for TOC is shown in Figure 2.

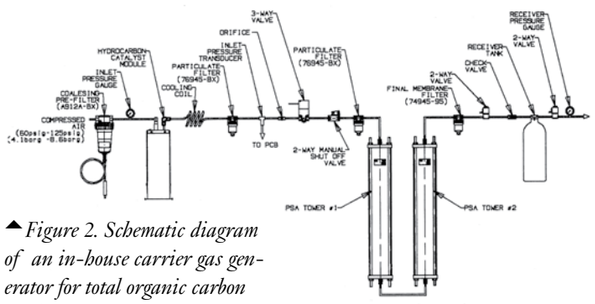

Figure 2. Schematic diagram of an in-house carrier gas generator for total organic carbon analyses

The heart of an in-house gas generator for TOC analyses is the PSA system. This system involves pressurizing air and passing it into a chamber that contains molecular sieves that are specially designed to retain the gases that are not desired while allowing the product air to be passed into a storage tank for use with the TOC analyzer. The undesired gases are purged from the molecular sieves on a periodic basis by heating the sieves and reducing the pressure.

A molecular sieve such as activated carbon (charcoal) is used in the PSA system because it has a very large surface area available for adsorption, is extremely porous and can retain a significant amount of the undesired gases before it must be purged. Due to its high degree of micro porosity, 1 g of activated carbon may have a surface area in excess of 500 m_2 (which is equivalent to the area of about two tennis courts), as determined by nitrogen gas adsorption experiments.

The carrier gas supplied by an in-house generator contains extremely low levels of CO_2 and provides superb sensitivity with a TOC analyzer. As an example, the composition of the gas generated by the Parker TOC-1250 TOC gas generator (Figure 3) is presented in Table 1. Although the gas contains approximately 1 percent Ar (Ar is not retained by the molecular sieve), this is not a problem for TOC analysis since Ar is not detected at the wavelength used to monitor the CO_2 that is generated by the oxidization of the organic compounds. If the compressed air supply contains halogenated hydrocarbons, a scrubber should be installed upstream from the generator, as halogenated hydrocarbons will render the molecular sieves inactive.

Gas	Composition
Nitrogen	99.9999%
CO	<1 ppm
CO2	<1 ppm
O2	<1 ppm
H2O	<1 ppm (Dew Point <-100oF [-73oC])
Hydrocarbon (as methane)	<0.1 ppm
Argon	0.9%

Table 1. Composition of nitrogen provided by a typical in-house generator

The TOC-1250 TOC gas generator shown in Figure 3 can generate gas at flow rates as high as 1,200 mL/min (at an inlet pressure of 150 psig). The total hydrocarbon and CO_2 concentration of the gas from this generator is extremely low and provides an extremely stable baseline for extended periods of time (Figure 4).

Figure 3. Parker Balston TOC-1250 TOC gas generator

Benefits of in-house generation of TOC-grade gas

Safety considerations

In-house generation of TOC-grade gas readily provides the required volume of sufficiently pure gas for superb sensitivity with a TOC analyzer. The gas is available on demand and is present at a lower pressure than the gas from a cylinder, increasing laboratory safety.

A cylinder contains a considerable amount of gas at high pressure; if a leak occurs (e.g., if the valve is compromised), a large quantity of N_2 would be released into the laboratory and would displace the air, leading to the potential of asphyxiation. Since an in-house gas generator typically has a maximum output of 600 to 1,200 mL/min at a pressure of approximately 100 psig, the volume of gas that could escape in the laboratory due to a leak in the system is very small and presents a minimal hazard.

An additional safety concern with the use of cylinder gas involves potential hazards inherent in transporting it from the storage location to the instrument. As an example, if the individual moving the cylinder loses control of it during transport and the valve is damaged, the cylinder can become a guided missile. A typical user, Dr. Michael Lockney, a chemist at Momentive Performance Materials (Sistersville, WV) who uses a TOC analyzer to monitor plant waste water, indicated that they obtained an in-house TOC gas generator to minimize the safety issues and eliminate the concerns involving the handling of gas tanks.

In-house generators include a variety of safety features to minimize the possibility of injury to personnel and facility damage. As an example, if an overpressure or a pressure loss is observed, gas production is immediately terminated and a diagnostic

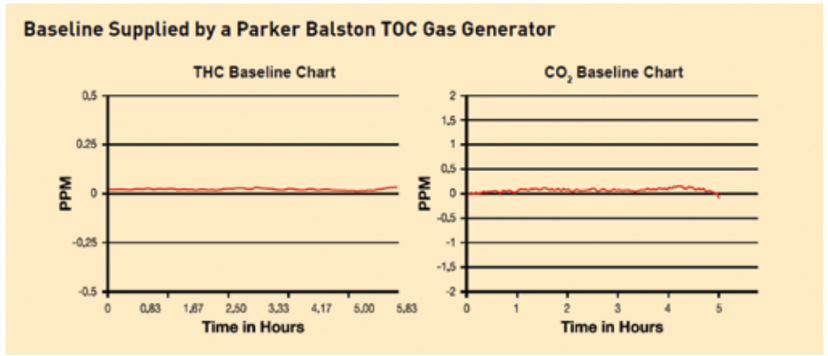

Figure 4. Baselines observed on a TOC analyzer from carrier gas from a Parker Balston generator. Left: total hydrocarbons; right: CO_2

message is generated. If desired, an audible alarm and/or a signal can be sent to an external controller or to the operator. In addition, these systems meet the requirements of a broad range of safety standards, including NFPA and OSHA (1910.103), and of regulatory agencies such as the IEC, CSA, UL, cUL and CE.

"The heart of an in-house gas generator for TOC analyses is a pressure swing adsorption (PSA) system."

Convenience

When an in-house gas generator is employed, the TOC-grade gas is readily available on a continuous (24/7) basis or can be generated as required with a short system warm-up. In contrast, when a cylinder is employed, the operator must make certain that the cylinder contains a sufficient amount of gas for the desired operation. In many facilities, replacement cylinders are frequently stored in a remote (outdoor) location for safety reasons, and specially qualified personnel may be required to perform cylinder replacement (replacing a tank is inconvenient in inclement weather). When bottled gas is employed, it is necessary to maintain a supply of spare cylinders and order/return cylinders on a periodic basis.

In contrast, when an in-house generator is employed, very little maintenance is required. Once the system is set up, gas is readily available for an extended period of time with no effort on the part of the analyst. As an example of this point, Dr. Charles Weatherford, the QA supervisor at Metrex Research (Romulus, MI), a division of Sybron Dental Specialties, Inc., reports that their TOC air system has been in use for over eight years with only a minimum of annual maintenance. Similarly, Dr. Lockney indicates that the system at Momentive Performance Materials has been in use for three years with no service issues, and it is not necessary for them to monitor the usage of the generator.

Elimination of contamination

When a cylinder is used to deliver TOC gas, the connection between the source of the gas and the TOC analyzer must be broken when a cylinder is replaced. This can lead to the introduction of contaminants such as water vapor, O_2, CO_2 and other materials that may be present in the laboratory atmosphere into the system. These may have a deleterious effect on the TOC measurement. In contrast, when an in-house generator is employed, a permanent direct connection is made between the generator and the TOC system, thereby practically eliminating the possibility of contamination.

Cost

The overall cost of operation of an in-house generator is considerably lower than the cost of cylinders to provide gas. The only costs for an in-house generator are for electricity and periodic service. The power consumption of the TOC-1250 system is 2 A, so if the generator is used for a 40-hour cycle on a 52-week basis, approximately 500 kWh would be used. At 10c/kWh, the annual operating cost would be approximately $50 and the cost of maintenance and replacement of an in-house generator would be about $500/yr. While the payback period of the generator clearly depends on the amount of gas that is consumed and the local cost of the gas cylinders, the generator can pay for itself in a year in many facilities. When cylinders are used to supply the gas, many other expenses must be considered, including the time cost of ordering the gas and bottle demurrage. These costs are not relevant when an in-house generator is used.

"In-house generators include a variety of safety features to minimize the possibility of injury to personnel and facility damage."

Conclusion

In-house generation of carrier gas for total organic carbon analyses provides the lab with a number of significant benefits compared to the use of cylinders. An in-house generator is safer, as it produces the necessary gas on demand and eliminates the need to handle high-pressure tanks. An in-house generator can provide gas on a 24/7 basis with essentially no maintenance and has an operating cost that is significantly less than the cost of obtaining pressurized cylinders. Since an in-house generator eliminates the requirement for transporting heavy cylinders from the production facility to the point of use, significant environmental benefits are obtained.

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BEST PRACTICES MADE BETTER

ADVANCES IN VISCOSITY INSTRUMENTATION ENHANCE RESULTS AND SPEED TESTING TIME

by Robert G. McGregor

There are 30 samples to run for viscosity analysis and the boss wants the results by 5 p.m. Without having to think twice, the lab tech knows that this is a near-impossible task, given that each sample can take up to 15 minutes, due to the temperature conditioning that's required and the messy cleanup afterward. The only possibility is to work through breaks and lunch and hope that nothing goes wrong. This is the dilemma for any lab tech in a business that has weathered the economic recession, been reluctant to hire, and loaded additional responsibilities on existing staff.

Saving time on each test in order to do more is the mantra of all analytical labs today, whether in R&D or QC. What easy-to-implement things in viscosity testing could make an improvement over current practice, enhance the results, and actually reduce the time a lab tech must spend running the test? This article reviews advances in viscosity measurement instrumentation and shows how lab managers can use these to increase productivity.

Sample size

Viscosity tests are most often performed on samples in a standard 600mL beaker with the traditional disc spindle. This is a lot of sample material, perhaps more than is really necessary to run a meaningful test. Add to that the requirement for temperature control, which is becoming a recommended best practice, and you can see the test minutes per sample piling up. Consider the possibility of reducing the sample size to save on both test time and cost of material.

The Small Sample Adapter provides a ready means of reducing sample size to less than 20mL. As shown in Figure 1, the sample goes into a cylindrical chamber, which fits inside a water jacket that is connected to a circulating water bath. The obvious advantage is that it takes significantly less time to reach temperature equilibrium. This automatically saves precious minutes when running a viscosity test.

Figure 1. Small Sample Adapter requires < 20mL for viscosity test.

Another potential option is to use the disposable chamber for the Small Sample Adapter, which can save time on cleanup. This is a practical choice for samples that are either highly viscous or make the sample chamber difficult to clean. Compare the small cost of the disposable chamber against the labor time and expense of cleaning the 600mL beaker, and you may have taken another important step toward increased efficiency in viscosity testing.

> "Consider the possibility of reducing the sample size to save on both test time and cost of material."

Temperature control

This need was mentioned above. Some materials are highly temperature sensitive, so it's best to make sure that sample, chamber, and spindle are at equilibrium temperature. But how long do you wait for equilibrium? Experience with your material usually establishes this time period, which can take from several minutes up to an hour. Select viscometers in today's market actually integrate the temperature control function as part of the built-in test capability. Otherwise, use of a benchtop timer is required. The inherent advantage of having this control capability in the viscometer is that the test will commence automatically as soon as the required temperature set point is achieved.

Connecting the spindle

The long-established method for connecting the spindle is to screw it onto the viscometer. One slight catch is that the direction of rotation is the opposite of what you might think. This in and of itself sometimes causes problems for the technician, who momentarily forgets to rotate the spindle clockwise as he or she looks down on the instrument. Potential damage, not to mention momentary frustration, can result.

Another detail of proper handling of the disc spindle is that it has to be cocked at an angle during immersion so that the disc does not trap air on its bottom side (Figure 2). The consequence of having air bubbles beneath the disc is the creation of artificially high viscosity readings. This naturally supports use of the Small Sample Adapter, which prevents this type situation from occuring.

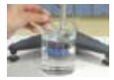

Figure 2. Recommended technique for immersing disc spindle into beaker.

So regardless of spindle choice, there are new connection mechanisms for attaching the spindle that may save time and minimize potential damage. For existing viscometers, there is an inexpensive device called Quick Connect that can be attached to any spindle (Figure 3). When subsequently connected to the viscometer, the sleeve on the Quick Connect is raised to remove the spindle. The same movement of the sleeve allows the technician to reattach the spindle.

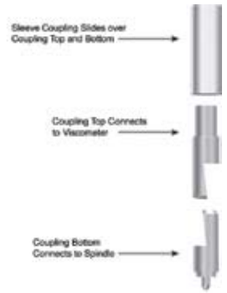

Figure 3. Quick Connect permits rapid spindle attachment.

An alternative mechanism is called EZ-Lock, and operates similarly to Quick Connect. The difference is that the mechanism is built into the instrument. The advantage of EZ-Lock is that it provides inherent protection to the sensitive suspension system inside the instrument.

Accurate test time

Once the test setup is ready, how long do you allow the spindle to rotate before capturing the viscosity reading? Most test methods specify a time interval, which ensures that the spindle has rotated at least five complete revolutions. This allows the measurement system within the instrument to stabilize and guarantees better repeatability of the viscosity reading. At 10 rpm, the technician waits 30 seconds before recording the reading, while at 1 rpm the test takes 5 minutes.

But what if the technician becomes distracted and forgets to set a timer? Can this affect the final reading? If the material is time-sensitive, the answer is yes; most likely, the reading will be lower than expected. If there is no time sensitivity, then there is nothing to worry about.

TECHNOLOGY & OPERATIONS

Is there a foolproof way to be sure that test time is managed correctly? One practical approach is to use the built-in time clock that resides in today's continuous-sensing digital viscometers. As stated above, viscosity tests require that the spindle rotate for a certain period of time or for a fixed number of revolutions. The time spent waiting for the spindle to complete its work can be wasteful, especially if the tech has to attend the instrument for several minutes. The adventurous tech who attempts to get other tasks moving during this lull sometimes misses the appointed time for completion of the test, and writes down whatever value is displayed upon his or her return to the instrument. How much easier it is to let the embedded clock in today's new viscometers automatically stop the spindle rotation when the time is up, and record the final viscosity reading.

> "Select viscometers in today's market actually integrate the temperature control function as part of the built-in test capability."

Perhaps this simple, but effective, procedure can save 1 to 2 minutes per viscosity test. For a lab that needs to run 30 tests per day, the time saved can be 30 minutes to an hour.

Documenting the viscosity reading

Many technicians write down the viscosity reading at the conclusion of the test. There is always the possibility that the number is copied incorrectly. Wouldn't it be a lot simpler to have the viscometer send the data to a PC or printer? In R&D, availability of a PC is seldom an issue. For QC, the use of PCs is normally limited to a lab environment. On the production floor, use of a printer makes more sense. In either case, choice of the proper digital viscometer permits automatic transmission of data to an external device or network. Today's digital instruments are designed with this capability and can save valuable seconds with each test, not to mention eliminating potential copying mistakes due to human error.

Delivering the results on time

The above recommendations will save enough time to complete the initial assignment of getting 30 samples tested within a day. Equally important, the results will be correct. One side benefit not mentioned before is the spare time that can be used to deal with other tasks while the viscometer is running. Since each test executes automatically without further operator involvment, the tech has newly found free time to get other things done.

Advanced viscosity testing

Single-point viscosity tests are commonplace. This means using one spindle at a defined speed to run the test. Hopefully, temperature control and time of spindle rotation are considered and taken care of in the test method. If the viscosity reading falls between two established values, then the test passes and the material is deemed acceptable.

The ability to take two or more viscosity readings on the same sample, but at different rotational speeds, offers a better methodology to evaluate materials for shear thinning behavior. Most fluids and semisolid materials are pseudoplastic to some extent, and the ability to measure this property may provide more meaningful data for QC. Programming a viscometer to perform this type of test automatically is possible with the advanced viscometers available in today's market.

Use of math models to analyze the data from this more detailed test gives potentially new useful information not possible with the single-point test. The chocolate industry, for example, uses the Casson equation to compute a consistency index and yield stress value (Figure 4). The former value characterizes the degree of pseudoplasticity while the latter value quantifies the ability of the chocolate to hold its shape.

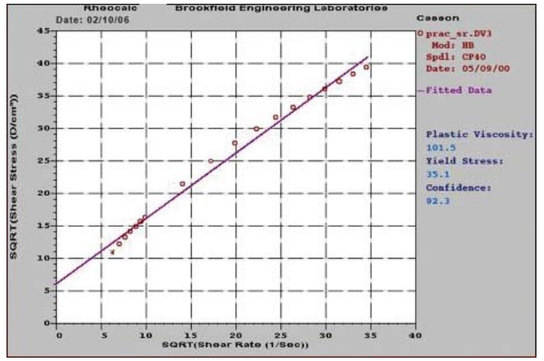

Figure 4. Casson equation applied to chocolate viscosity data.

Conclusion

Proper selection and use of viscosity instrumentation can bring valuable time savings to test programs in today's busy labs. Increased data throughput, coupled with detailed analysis, is a new horizon that has potential to offer enhanced quality control. Take the time to talk with viscometer manufacturers before making your next investment and map out the test strategy that will keep your company ahead of the pack in viscosity testing.

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THE "DO'S AND DON'TS" OF CELL CULTURE

Given below are a few of the essential "do's and don'ts" of cell culture. Some of these are mandatory, e.g. use of personal protective equipment (PPE). Many of them are common sense and apply to all laboratory areas. However, some of them are specific to tissue culture.

THE DO'S

1. Use personal protective equipment, (laboratory coat/gown, gloves and eye protection) at all times. In addition, thermally insulated gloves, full-face visor and splash-proof apron should be worn when handling liquid nitrogen.
2. Always use disposable caps to cover hair.
3. Wear dedicated PPE for tissue culture facility and keep separate from PPE worn in the general laboratory environment. The use of different colored gowns or laboratory coats makes this easier to enforce.
4. Keep all work surfaces free of clutter.
5. Correctly label reagents including flasks, medium and ampules with contents and date of preparation.
6. Only handle one cell line at a time. This commonsense point will reduce the possibility of cross contamination by mislabeling etc. It will also reduce the spread of bacteria and mycoplasma by the generation of aerosols across numerous opened media bottles and flasks in the cabinet.
7. Clean the work surfaces with a suitable disinfectant (e.g. 70 percent ethanol) between operations and allow a minimum of 15 minutes between handling different cell lines.
8. Wherever possible, maintain separate bottles of media for each cell line in cultivation.
9. Examine cultures and media daily for evidence of gross bacterial or fungal contamination. This includes medium that has been purchased commercially.
10. Quality Control all media and reagents prior to use.
11. Keep cardboard packaging to a minimum in all cell culture areas.
12. Ensure that incubators, cabinet, centrifuges and microscopes are cleaned and serviced at regular intervals.
13. Test cells for mycoplasma on a regular basis.

THE DON'TS

1. Do not continuously use antibiotics in culture medium as this will inevitably lead to the appearance of antibiotic resistant strains and may render a cell line useless for commercial purposes.
2. Don't allow waste to accumulate, particularly within the microbiological safety cabinet or in the incubators.
3. Don't have too many people in the lab at any one time.
4. Don't handle cells from unauthenticated sources in the main cell culture suite. They should be handled in quarantine until quality control checks are complete.
5. Avoid keeping cell lines continually in culture without returning to frozen stock.
6. Avoid cell culture becoming fully confluent. Always sub-culture at 70 to 80 percent confluency, or as advised on ECACC's cell culture data sheet.
7. Do not allow media to go out of date. Shelf life is only 6 weeks at +4ºC once glutamine and serum is added.
8. Avoid water baths from becoming dirty by using Sigma Clean (Prod. No. S5525).
9. Don't allow essential equipment to become out of calibration. Ensure microbiological safety cabinets are tested regularly.

The above information can be found in the "Fundamental Techniques in Cell Culture Laboratory Handbook" published by Sigma® Life Science and European Collection of Cell Cultures (ECACC), A Health Protection Agency Culture Collection. Visit sigma.com/cellculture or hpacultures.org.uk to view the entire Cell Culture Laboratory Handbook. Sigma is a registered trademark belonging to Sigma-Aldrich Co. and its affiliate Sigma-Aldrich Biotechnology, L.P. ECACC is a registered trademark of the Health Protection Agency in the UK.

ASK THE EXPERT

« EXPERT: Manfred Goebl, Ph.D.

ASK THE EXPERT

CHOOSING THE RIGHT LIMS FOR YOUR LAB

by Tanuja Koppal, Ph.D.

Manfred Goebl is the senior European technical development applications analyst at Mundipharma Research GmbH & Co. Goebl studied chemical engineering and then switched to studying chemistry at the Technical University in Berlin, focusing on physical chemistry. He earned his Ph.D. at the Nuclear Research Center Hahn-Meitner Institut in Berlin in radiation chemistry. He worked for six years at Dionex, starting out as an application chemist and ending up in sales. In 1989 he switched completely to LIMS, starting out with VG Instruments, which was bought by Fisons and later became a part of Thermo Instruments. It still exists under the name Sample Manager. He joined Mundipharma GmbH in Limburg, Germany, in 2000 and was hired to implement a LIMS for the analytical and formulation departments, from scratch. In 2004 the research department of Mundipharma GmbH was split and merged with Napp Pharmaceuticals in Cambridge, UK, and became a new company called Mundipharma Research. The LIMS he had up and running in Limburg in the German language was then switched off, and the company started using a common system running in English from LabWare. Goebl's job now is to maintain the system and develop new features as required, depending on the workflow. He is still the only one in Limburg responsible for implementing LIMS, but he works closely with his colleagues in the UK.

Manfred Goebl, Ph.D., senior European technical development applications analyst at Mundipharma Research GmbH & Co., talks to Tanuja Koppal, Ph.D., contributing editor at* Lab Manager Magazine, *about the due diligence that needs to be done before putting in place a Laboratory Information Management System (LIMS) that is both user-friendly and effective.

Q: How did your involvement with LIMS begin?

A: I started working on LIMS in 1989. I was in a sales position then and had the opportunity to work on a few different LIMS that were available then. LIMS at that time was all server based, since personal computers were still young. The servers were expensive and memory was very limited, with ~300 MB hard disk drives. After a decade in sales I switched to the other side of the table and joined Mundipharma to help them implement LIMS in their laboratories.

Q: Can you share some of your experiences setting up the LIMS at Mundipharma?

A: When I joined Mundipharma there was no LIMS in use at the company. So the first thing I did when I got here was to get user requirements. First you have to make clear what it is that you need. LIMS is usually not implemented for just one laboratory, but spread within and across different departments. So you have to find out about the workflow within and between departments. This user requirement specification has to be written down in a clear and structured way so that potential vendors can read and understand it. The vendors can then demonstrate how their system best fits your needs. In my sales position we had to make such presentations to prospective customers based on their user requirements and then make modifications to our system to make sure it worked for them.

At Mundipharma we have three sites functioning in three different countries—in Germany, the U.S. and the U.K. In 2000, representatives from all three sites got together to discuss user requirements and to identify issues that were important to them. We needed a system that was clear, convenient and understandable and that had an interface to our chromatography systems, which generated a lot of data. Being a pharmaceutical company, we also had to take into consideration what the regulatory authorities needed for validation and audits. We met with different vendors and finally settled on LabWare.

Q: What is the driving force behind implementing LIMS?

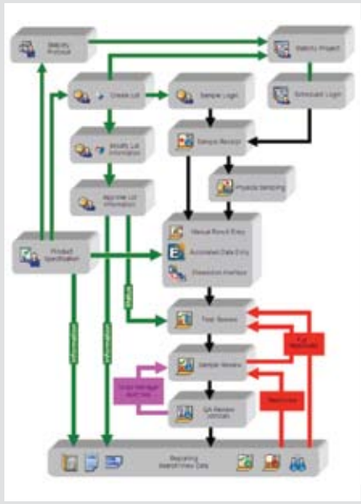
A: The reason for the growth of LIMS is similar to why we are seeing the growth in electronic laboratory notebooks (ELNs) today. There are a lot of people working on different projects and everyone works out of notebooks. Bringing all the data together for generating reports, for instance, becomes very problematic and takes time. LIMS probably first started out in a quality control lab because everything there is fixed, based on product specifications. You know your analytical methods, your instrumentation and your people. LIMS was mainly designed for the analytical labs, not only for generating reports but also for managing the instruments. Its use is still mainly in this area, but with new modules being introduced, it's expanding into other areas as well.

Q: How do ELNs differ from LIMS?

A: When compared to LIMS, ELNs are not structured. In LIMS you have to define beforehand what is going to happen, but with ELNs you can write things as they happen. It is like a piece of paper where you can add your notes, any chemical structures and reactions, equations, spectra, and anything else that is needed. In early research, for instance, not everything is fixed and things have to stay flexible. Hence, this data fits better into ELNs than into LIMS. However a link is needed between ELNs and LIMS, and being in just one system is easier. Also, with LIMS you can track everything. People often use Microsoft Word or Excel, but you can't use that for an audit, since you can't track information back. Our vendor, LabWare, now offers ELNs integrated into LIMS. We haven't invested in ELNs yet, but we are discussing it.

Q: How easy is it to customize LIMS to suit your needs?

A: I would buy what I need today based on my user requirements and see how flexible the system is for expansion. I did all our customization myself, but others who don't have the technical expertise should consult with the vendor. LIMS is a system that is never set in concrete. The workflow and user requirements are changing all the time, and hence the system has to change, too. If you can fit the processes into the system as it exists, then it's cheap, but if you have to make a change, it's not cheap. Sometimes the vendors make the modifications for an extra fee or you can hire a consultant. There is a user acceptance issue, too. Hence, we built a team to get all the user specifications together. They talked to the people in the labs to see who communicated with whom in what way, to find out what they wanted, and what the LIMS should look like. All this has to be done beforehand, and in my opinion it's very important.



▲ *A chart depicting the user workflow at Mundipharma that is incorporated into their LIMS. (Source: Manfred Goebl)*

Q: Can you elaborate on the types of user training needed?

A: We separated our users based on their roles, depending on what they do. We set up different menus for different users. For instance, a user who worked in the lab was trained to enter data or sample information. A lab manager was trained to generate reports or to authorize protocols or samples. Our system administrators received training from the vendor on how to program and use the software, how to generate and integrate reports, how to enter new users, and so on.

Q: How easy is it to switch from one system to another?

A: Transition is never easy. Sometimes you can get old data into the new system and can see it but cannot do anything with it. It's difficult to fill old data into new database fields with a different structure since databases are all different, depending on the vendor. Sometimes vendors stop manufacturing their systems and discontinue all the technical support. That's tough. All the data is gone when people can't switch.

MEASURING A FUNDAMENTAL PROPERTY OF MATTER

by Angelo DePalma, Ph.D.

Since size dictates so many properties of materials, particle size measurement is critical for many industries. Particle size governs dissolution rates of solids, absorption and suspension properties of drugs, the homogeneity of mixtures, color properties of paints, and much more.

One of the emerging applications for particle sizing is nanomaterials, a subset of nanotechnology. Nanomaterials—defined as particles smaller than 100 nm—has been the subject of much research in materials, electronics, chemistry, and biology. In the pharmaceutical industry, developers are investigating nano-sized drug particles as a strategy for making insoluble drugs more accessible to metabolic processes.

Wire mesh sieves are stacked, with the largest diameter sieve at the top, and placed atop a shaker. At the end of a run, particles are counted or weighed within each size range. Sonic sieving, wet sieving, and air jet sieving are variations of traditional sieving that accommodate powders with particles significantly finer than 100 microns.

Gilbert Vial, product manager at Shimadzu Scientific Instruments (Columbia, MD), notes that sieving is widespread in industrial labs that need answers quickly about product quality. "Sieving is imprecise but can be used as a quick check and followed up with more sophisticated methods if needed."

Microscopy is another old but reliable sizing technique. Microscope sizing detection of about 200 nm introduces sampling anomalies. "You can't do a microscope sizing run in two minutes as you can with light scattering systems," says Mr. Vial.

> "Particles larger than about 100 microns in one dimension are often sized by sieving through woven mesh screens."

Particles larger than about 100 microns in one dimension are often sized by sieving through woven mesh screens. Sieving provides approximate values for particle size distributions between certain values, for example 200 and 300 microns, 300 and 400 microns, etc. provides a great deal of information about particle size, shape, aggregation, and crystalline or noncrystalline state. But despite advances in automation and digitization, microscopy remains tedious and slow and requires human intervention, and its lower limit of

Let there be light

Modern particle sizing is based on light scattering (LS) techniques, of which there are several variants.

Joe Wolfgang, diffraction product manager for the Americas at Malvern Instruments (Westborough, MA), estimates the sweet spot for light scattering in particle sizing to be from 1 nm to around 2 millimeters.

Malvern specializes in LS measurements for particles ranging in size from about 1 nm to 2,000 microns. Within this category, diffraction or low-angle light scattering is suitable for particles measuring from about 20 nm to several mm and may substitute for sieving (and vice versa, although LS generally provides more information).

Diffraction works with either dry powders or liquid suspensions. Suspension measurements employ ultrasound, surfactants, or other chemical agents to prevent particles from aggregating, and are straightforward provided the particles are completely insoluble. "Wet" measurements take between

> "Modern particle sizing is based on light scattering (LS) techniques, of which there are several variants."

two and three minutes, dry samples about 30 seconds.

Dynamic light scattering (DLS) measures a larger scattering angle and operates at 1 nm to about 10 microns. DLS is typically used to measure suspensions or solutions of particles or molecules in a liquid—for example, dissolved proteins, polymers, micelles, and carbohydrates in solution or as particles (aggregates), as well as emulsions or dispersions of molecules or nanoparticles.

DLS's primary measurement is not actually size. As a result of Brownian motion, smaller particles move more rapidly through liquids than do larger particles. DLS measures this motion and translates it to particle size.

Within the size overlap region of the instruments, DLS characterizes more concentrated suspensions or emulsions than does diffraction, but the latter works better for larger particles.

Some interesting properties may be gleaned from light-scattering-based particle sizing:

- Zeta potential—electrical potential of colloids, indicating the likelihood that they will aggregate or remain suspended
- Hydrodynamic radius—the apparent size of the hydrated particle
- Molecular weight, conformation, and state of aggregation
- Second virial coefficient—a measure of weak protein-protein interactions

Overlap in size domains for instrument lines is necessary if suppliers wish to cover the range of particles that their customers are likely to encounter. It is not unusual for vendors to offer systems that measure, for example, from 0.5 nm to 200 nm, 10 nm to 250 microns, and 0.1 micron to 3 mm.

What to look for

Diffraction instruments have been available for more than three decades, and all those currently marketed perform basic measurements fairly well. Mr. Wolfgang therefore recommends that customers pay particular attention to an instrument's ease of use, and the level of customer support they can expect from their vendor. "These factors are particularly important as companies downsize, and highly skilled workers become scarcer."

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PROTECTING WORKERS AND THE ENVIRONMENT FROM BIOHAZARDS

by Angelo DePalma, Ph.D.

Biological safety cabinets (BSCs) are enclosures that protect users from biohazards by cleansing the work space air through HEPA filters. By contrast, laminar flow hoods are designed to protect samples from users. The third major type of safety enclosure, the fume hood, vents work space and laboratory air to the environment, usually without filtering it.

The U.S. Centers for Disease Control and Prevention lists three major classes of BSCs: Class 1 protects the user and environment but not the product; Class 2 protects the user, product, and environment; and Class 3 provides the maximum protection from extremely virulent pathogens.

Within Class 2 are four major categories, A1, A2, B1, and B2, which differ in terms of air flow but not degree of protection. A2-type BSCs make up about 90 percent of all units sold in the United States. Users are not likely to keep track of the sometimes fine distinctions between models, but vendors are more than happy to help match workflows with cabinets.

BSCs are to biologists what fume hoods are to chemists, but the two devices work completely differently. Fume hoods, which protect users from chemicals, vent work space and laboratory air to the outside environment; BSCs remove particulates and aerosolized pathogens from the work area through HEPA filtration, then recirculate or exhaust the purified air. Laboratories always choose BSCs for biologics, and fume hoods for chemicals and radionuclides, because exhaust does not nullify pathogens and HEPA filtration does not remove chemicals.

> "Vendors are more than happy to help match workflows with cabinets."

Most of the time, that is. A2 canopy BSCs are a type of hybrid: designed as BSCs, they exhaust rather than recirculate.

What to look for

According to Brian Garrett, product manager at Labconco (Kansas City, MO), ongoing trends in BSCs include improvements in the user interface, cabinet usability, and ergonomics, and lower operating cost.

Motors that run the air-handling systems of BSCs were traditionally of the PSC (permanently split capacitor) type, which are relatively inexpensive but are energy hogs with a relatively short operating life. PSCs also throw off a lot of heat, which increases air conditioning costs and makes workers uncomfortable during long work sessions.

Today, most labs select either an electronically commutated motor running on direct current or a three-phase AC motor. Both designs cost more than a PSC motor but run more efficiently and have an operating life of about 50,000 hours, compared with 10,000-15,000 hours for a PSC.

Energy-efficient motors don't just save money on the electricity bill, says John Peters, assistant marketing director at NuAire (Plymouth, MN). "They improve the product."

HEPA filtration affects operating costs directly. The more life you can get out of the filters, the lower your operating costs. HEPA usable life is based on the torque or reserve capacity of the blower and the size of the HEPA filter. Safety-conscious purchasers tend to go with powerful blowers, but Mr. Garrett urges users to consider energy efficiency as well and balance the two needs, because "otherwise you're compromising one in favor of the other."

Ergonomics plays into purchase decisions for BSCs much more so than for fume hoods. Due to the nature of their work, chemists often set up experiments, close the hood sash, and walk away for hours, while biologists spend many hours glued

to BSCs. Mr. Garrett suggests that buyers take special note of a BSC's height, arm support, heat generated from the cabinet (less is better), and internal/external dimensions. The cabinet should be large enough to accommodate all anticipated reagents and equipment, which users should be able to reach comfortably.

"The more life you can get out of the filters, the lower your operating costs."

John Peters agrees that ergonomics are a prime consideration when selecting BSCs. He adds to the wish-list factors that enhance seating and posture during long work sessions, cabinet layout, and glare-free lighting.

Controls and feedback should be accessible at all times. Preferably, these should indicate key operating and safety parameters constantly, and in real time. "Users need to know the HEPA filter loading, which tells them if the air coming out of the cabinet is safe, on a moment's notice and not just once or twice a year," Mr. Garrett tells *Lab Manager Magazine.*

Unlike most other lab equipment and instrumentation, options on BSCs are often tailored to specific applications and workflows. "A lot of customization goes into cabinets that benefit end users," Mr. Peters says, "from features and functions to materials of construction."

The long-term look

Since BSCs last 15 years or more, customers might be concerned about replacement parts. Some vendors keep these on hand, and parts may be salvaged from used cabinets, but "just-in-time" mentality suggests that critical replacement components like motors will probably not be available much beyond normal service life. But according to Mr. Peters, older units may be difficult to service as standards change, "so users will probably want new products with new technology for ergonomic, safety, and cost-saving features."

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Integrated probes are easier to use but more difficult to replace when they wear out or break. Auto-calibration and temperature compensation are desirable features for sensitive protocols that require frequent calibration.

Metrohm's George Porter advises purchasers to consider how the meter is constructed, particularly if the circuits are galvanically separated. "You're looking for an isolated signal," he says. Another factor is how the instrument handles data. High-throughput labs, particularly those using automated titrators, require meters that upload data directly to a storage device or network.

Purchasers should take a hard look at ease of calibration, says David Minsk, president of Hanna Instruments (Woonsocket, RI), because "there's a wide spectrum of technical astuteness among users." Some methods, particularly in regulated industries or engineering, may call for a three-, four-, or five-point calibration; others are conducted in extreme environments. "You need an instrument you can calibrate easily within your application's operating range."

"Integrated probes are easier to use but more difficult to replace when they wear out or break."

Solid state versus electrode probes

Recently, a team at Oxford University in the U.K. patented a revolutionary type of pH meter. The technology, exclusively licensed to Senova Systems (Sunnyvale, CA), has been touted as the first significant departure from the ubiquitous electrode-based meter.

The Senova product replaces sensitive glass electrodes with a solid-state sensor that is insensitive to temperature changes and may be sterilized. According to the company, the device provides robustness and miniaturization and, perhaps best of all, it never requires calibration.

Over the years lab workers have come to expect more from instrumentation, and pH meters are no exception. Mr. Minsk observes that processor-based features such as calibration data logging, automated uploading, and operational modes for specific industries or situations are highly desirable. "Users are also looking for broader functionality such as conductivity and ion selectivity in one instrument."

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SURVEY SAYS: YOU NEED A pH METER... NOW WHAT?

As part of our Lab Products Survey series, *Lab Manager Magazine* has compiled the responses of 351 lab professionals regarding the use of pH meters in the lab.

It is vital to maintain and control proper pH levels in several agricultural, industrial and environmental processes. Without the proper monitoring and control of pH levels, the quality of products will deteriorate. Like many laboratory instruments, pH meters have evolved beyond all recognition over the past several decades. Today, pH can be measured by various methods including pH paper, digital readout pocket testers, and portable and benchtop meters.

Benchtop meters are found mainly in testing or research laboratories. They are generally more expensive but offer increased accuracy and more testing options. Most portable meters are durable and well-suited for accurate pH readings in the field. Both types of meters use a wide variety of replaceable pH electrodes for individual applications and conditions. The pH meter will continue to enjoy its status as one of the most ubiquitous pieces of laboratory equipment.

For more information on pH meters, please visit www.labmanager.com/ph-meters

If you would like to participate in our laboratory equipment purchasing surveys, please visit www.labmanager.com/surveys

Number of pH meters being used in respondents' labs:

None	5%
1	25%
2	29%
3	15%
4	7%
5 or more	20%

Types of pH meters being used in the lab:

Benchtop	57%
Handheld	27%
Pocket tester	9%
In-line	5%
Other	2%

pH electrodes respondents use in their labs:

Research	47%
Quality control	41%
Clinical	5%
In Vitro Fertilization (IVF)	3%
Other	4%

Primary purpose for these pH meters:

Research	56%
Quality control	16%
Clinical	18%
Production	6%
Other	4%

Respondents' fields of work:

Biochemistry and biology	16%
Chemical	15%
Environment	13%
Pharmaceutical industry	11%
Quality control	11%
Food and beverage	11%
Microbiology	8%
Hospital/Medical center	6%
Other	9%

Satisfaction with pH meters being used in the lab:

Very Satisfied	42%
Satisfied	50%
Not Satisfied	8%

General comments on why a user is not satisfied:

pH electrodes give either unstable or erroneous readings, resulting in increased frequency of calibration.

Annual budget for related equipment, parts, maintenance, service and repairs:

Less than $500	47%
$500 to $3,000	44%
$3,000+	6%
Don't know	11%

Purchasing plans for a new pH meter:

Starting the review process	8%
Plan to purchase in the next 1 to 6 months	13%
Plan to purchase in 6 to 12 months	7%
Plan to purchase in 12+ months	14%
No current purchasing plans	51%
Don't know	6%

Reasons for purchasing a new pH meter:

Replacement of an aging pH meter	43%
Addition to existing systems; increase capacity	27%
Setting up a new lab	18%
New application	8%
First-time purchase of a pH meter	1%
Other	2%

Budget range for the purchase of a new pH meter:

Less than $500	26%
$500 to $1,500	47%
$1,500 to $3,000	19%
$3,000 - $6,000	5%
$6,000+	3%

Factors/features that influence the decision-making process when buying a pH meter:

Resolution and accuracy of the meter	100%
Auto-calibratio	98%
All-in-one probe	98%
Automatic temperature compensation	97%
Low maintenance/easy to clean	97%
Service and support	96%
Ease of use	94%
Detachable probe	94%
Availability of supplies and accessories	92%
Computer interface	74%

MEASURING A CRITICAL PHYSICAL PROPERTY

by Angelo DePalma, Ph.D.

Viscometers measure viscosity, the resistance of fluids to flow or stress. In common terms, viscosity is related to a fluid's "thickness"—a physical property of great interest to manufacturers of liquids, slurries, and pastes. Viscosity is a critical characteristic of foods (e.g., dairy, honey, syrup, soft drinks), paints, cleaners, adhesives, polymers, fuel oils, and pharmaceuticals. Many industries use viscosity as an endpoint in the manufacture of liquid-formulated products.

Dozens of viscometer types are in use in academia, industry, and basic research, and these range in cost from about $100 for simple mechanical viscometers to $15,000 automated instruments. Rheometers, which measure viscosity and related properties, may cost as much as $200,000.

"Many industries use viscosity as an endpoint in the manufacture of liquid-formulated products."

At the low end of the price range are U-tube and Cannon-Fenske tube viscometers found in schools, colleges, and some industries. Other simple designs include falling sphere, falling piston, rolling ball, and oscillating piston viscometers. These are not instruments in the truest sense; some require pourable fluids.

More sophisticated are vibrational viscometers used in process industries, and rotational viscometers. The latter operate on the principle that energy must be applied to a spindle or disk rotating within a liquid to overcome the resistance of that liquid. That energy is proportional to the fluid's viscosity. Rotational viscometers do not require that the testing sample be pourable. For example, toothpaste cannot be tested in a tube viscometer because it does not "run," but meaningful results can be obtained using paddle- or cylinder-type viscometers.

Higher-end viscometers may be connected to and operated through a computer, or readouts may be taken directly off the front panel display.

Some industries favor one viscometer type. Paint and pigment industries prefer the Stormer viscometer, which uses paddles on a rotor submerged into the product. Similarly, resin labs use bubble viscometers, which measure the time it takes a bubble to emerge from varnishes, and petrochemical companies prefer the Stabinger viscometer, which employs a rotating cylindrical tube.

Viscometry is an old technique, as illustrated by the persistence of mechanical viscometers. But while manufacturers continue to fine-tune more-sophisticated electromechanical rotational viscometers, the underlying technology hasn't changed much.

What is different, says Steven Colo, president at ATS RheoSystems (Bordentown, NJ), is user expertise. "Twenty years ago most users had an academic specialization in viscometry or rheology." Today the specialists are gone and users tend to be generalists.

Mr. Colo views changing user demographics as an opportunity to provide support and expertise in instrument operation, sample testing, and data interpretation.

What viscosity tells you

In biotech and pharmaceuticals, the viscosity of protein and buffer solutions constitutes one of numerous quality checks; in beverages, viscosity is an indicator of sugar content and overall quality. Polymer scientists use viscosity to determine the concentration of plastics in acid solutions.

Viscosity measurements are usually conducted on dilute solutions and at varying concentrations. Measurement of the viscosity of polymer solutions at different strengths, for example,

provides estimates of secondary properties such as intrinsic viscosity, molecular weight, and chain length.

Viscosity is related to solute concentration, which is what makes it one of the most useful physical measurements in research and product development. The viscosity of a liquid tends to rise with the concentration of solid solutes, as with sugar in water. But the viscosity of a blend of fully miscible and nonreacting liquids is usually somewhere between the viscosities of the components.

Rheometers

Rheometers are closely related to viscometers in that they measure viscosity and yield stress. Where viscometers determine a fluid's "thickness" under native conditions, rheometers measure it as a function of applied shear or stress. In addition to viscosity, rheometers provide measures of modulus, shear modulus, "tan delta," gel point, and curing profiles.

Rheology tends to study the mechanics of complex fluids that cannot be fully characterized solely by viscosity. Darren Wilson, product specialist at Anton Paar (Ashland, VA), refers to these materials as "non-Newtonian," meaning their viscosity changes at different shear rates.

"Most samples are Newtonian, which means it doesn't matter if you use a viscometer or a rheometer. But viscosity doesn't tell the whole story with non-Newtonian fluids such as ketchup, mayonnaise, shampoos, and many types of paints and coatings."

"Higher-end viscometers may be connected to and operated through a computer."

Purchase decisions

Useful viscometer/rheometer features that buyers should be aware of are temperature control, spindle rotational speed control, a range of sample holders, and ease of use. Temperature is critical, notes Mr. Colo, since viscosity generally rises as a fluid cools. Spindle rotation may also affect viscosity.

Mr. Wilson notes that sample size may be an issue when analyzing very expensive materials such as drugs or proteins, as is cost of ownership for high-volume applications. Another consideration is the instrument's measurement range. "If you're analyzing petroleum, from crude oil to gasoline, do you want to change out the capillary for each measurement, or use something that works all the way through?"

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SAMPLE SIZE, VISCOSITY ARE PRIME CONCERNS

by Angelo DePalma, Ph.D.

Mixing is ubiquitous in industrial, academic, and industrial laboratories. The choice of overhead or magnetic stirring to achieve uniform mixing is relatively straightforward, based on scale and viscosity of the medium being stirred.

Commercial labs often "scale down" large manufacturing processes that involve mixing combinations of water, organic solvents, and soluble and insoluble materials to create solutions, suspensions, slurries, syrups, pastes, and creams; others work with inherently viscous materials such as polymers.

Then there is the whole other world of small-scale chemistry, biology, and analytical laboratory operations associated with basic research, or in support of production or manufacturing research and development.

These two scenarios closely approximate the domains of overhead mechanical stirrers and magnetic stirrers, respectively. Or as Charles Villano, sales and marketing manager at Kinematica (Bohemia, NY), says, "Overhead stirrers are used when sample viscosity and/or size are issues, or when there exists a concern for significant changes in viscosity."

Overhead stirrers

Overhead units are common in the food, material science, cement, adhesives, polymers, and energy industries.

Basic overhead stirrers consist of a drive mechanism or motor, controller, drive shaft, and stirring fixture or panel. Stirrer configurations include propellers, either x-shaped, anchor shaped, or flat panels, each appropriate for specific applications. Materials of construction are often critical as samples may be acidic, basic, or otherwise corrosive. For example, stainless steel or glass rods are common in the food industry, as are inert materials such as Teflon.

Data- and documentation-hungry labs have demanded feature-rich overhead stirrers, and manufacturers have met the challenge. Most stirrers today sport digital panels that display stirring element rotation and applied torque; many connect to computers, which log this information, via RS232 or USB ports. Torque applied to mix a sample is directly proportional to the sample's viscosity.

These amenities are useful for unattended or automated operations, particularly when viscosity differences indicate endpoints. Mr. Villano estimates that about 20 percent (and growing) of overhead stirrer applications are integrated into processes via computer control.

The principal consideration in acquiring an overhead stirrer is typical sample size and viscosity. But sizing an overhead stirrer for a specific application is part art, part science. "The machines have power ratings that are somehow related to the volumes they can handle," Mr. Villano explains, "or to what volume of an aqueous solution they can stir. But from there it's trial and error. You can buy a 50-watt motor that says it can mix two liters, but if your material is viscous it may only handle 500 mL."

> "About 20 percent of overhead stirrer applications are integrated into processes via computer control."

Magnetic stirrers

While technologically more complex than overhead stirrers, magnetic stirrers are easier to use and set up and possess greater functionality. Magnetic stirrers use a drive magnet that causes a magnetically susceptible stir bar to rotate inside a flask or beaker. The stir bar core is coated with either glass or Teflon for easy cleaning. Most magnetic stirrers incorporate a heating element that operates independently of the stirrer.

> "Magnetic stirrers are easier to use and set up and possess greater functionality."

"Stirrer-hotplates are definitely more convenient than overhead stirrers," Mr. Villano observes, "but they're mostly for smaller-volume organic chemistry labs or aqueous-based processes."

When Germany-based IKA opened a U.S. facility 35 years ago, magnetic stirrers sold in the U.S. were almost exclusively rectangular in shape; Europeans preferred round stirrers. The company slowly introduced U.S. customers to the round design, which now makes up about 50 percent of its sales.

Round stirrer-hotplates more closely match the bottoms of Erlenmeyer flasks and beakers, which are round, and therefore take up less room. "Heat transfer is also better with round models," says Refika Bilgic, managing director at IKA (Wilmington, NC), "but rectangular models can accommodate more labware."

Other improvements followed

Older magnetic stirrers, many of which have been in service for 20 or more years, had two knobs: one each for stirrer and heater. Today the interface has been upgraded with more sophisticated controls and a display panel that provides readouts on plate temperature, run time, and spin-bar revolutions. Some models accommodate the addition of a temperature probe, which, when plugged in, switches the readout from plate temperature to sample temperature.

"Temperature control is a great feature for unattended operation and educational purposes," Ms. Bilgic says.

And where decoupling of spinner and magnet in older units is quite common, redesigns of magnetic drive and stir bars have practically eliminated that issue. Decoupling causes the bar to shake and sometimes jump inside the sample vessel rather than spin.

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STIRRERS:

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

labX AUCTIONS, CLASSIFIEDS & NEW PRODUCTS — IF YOU'RE LOOKING TO PURCHASE A NEW OR PRE-OWNED STIRRER, VISIT **LABX.COM** TO BROWSE CURRENT LISTINGS.

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EVOLUTION OF THE LABORATORY INCUBATOR

BY JOHN BUIE

Incubators are used in modern research laboratories to maintain a stable environment for processes such as growing cells and microbiological cultures and incubating antibodies and cells for fluorescence microscopy.

The simplest incubators are little more than temperature-controlled ovens, capable of reaching temperatures of 60 to 65 °C, but usually used at about 36 to 37 °C. However, most modern incubators are also able to generate refrigerated temperatures, and control humidity and CO_2 levels. Many incubators also offer features such as automatic shaking, measured by revolutions per minute.

Laboratory incubators were first properly introduced during the second half of the twentieth century, when doctors realized that they could be used to identify pathogens from the bodily fluids of patients. In this application, a sample is transferred to a Petri dish, placed on a rack inside the incubator and heated to body temperature (37 °C). The appropriate quantity of atmospheric CO_2 or N_2 necessary for cell growth is then supplied, encouraging the microorganism to multiply, enabling easier and more definite identification.

FUTURE OF LAB INCUBATORS

Laboratory incubators have evolved steadily over the latter part of the twentieth century, and have remained an important piece of laboratory equipment. Experts believe that in the future the incubator market will derive most of its growth from the bio-technology industry. As our medical knowledge and technology improves, and researchers become increasingly exacting, it is believed that growth chamber-type incubators will be required that have an even greater sensitivity in the control of temperature and relative humidity.

Another probable area of growth for incubators is within the field of genetic engineering, in which scientists manipulate the genetic materials in explants, sometimes combining DNA from discrete sources to create new organisms. Although genetic engineering is a controversial subject for many, this technology has already delivered tangible benefits, including the manufacture of insulin and other biologically essential proteins. Genetic engineering has also been shown to improve the nutritional content of fruits and vegetables and to increase the resistance of certain crops to disease. Genetic engineering relies heavily on the use of well-controlled and adjustable incubation, and it is within the field of biotechnology that some experts believe lies the greatest potential of the incubator.

1800 1900 2000 2010

In the **1800s**, researchers began searching for the ideal *in vitro* environment in which to maintain cell culture stocks.

The first CO_2 incubator developed consisted of a simple bell jar containing a lit candle. Cultures were placed under the lid of the jar alongside the lit candle, before the jar was moved to a dry, heated oven. This system may be considered the first "air-jacketed" CO_2 incubator.

During the late **1960s**, the first dedicated, commercial CO_2 incubators were developed. It was during this time that New Brunswick Scientific (NBS) introduced a range of incubator products including the Psychrotherm, the first refrigerated incubator shaker, the Model G25 large-capacity console-style incubator shaker, and the G76 water bath shaker. These models can still be found operating in labs around the world to this day.

A Model G25 Controlled Environment Incubator Shaker from New Brunswick Scientific.

In **1984**, SHEL LAB introduced the innovative general purpose incubator, which proved extremely popular in the marketplace. This incubator offered a unique warm air-jacket design, heated outer door, and five strategically placed heating elements to deliver uncompromising temperature uniformity, with no hot spots.

During the late **1990s**, Torrey Pines Scientific developed the first Peltier-based benchtop incubators capable of chilling and heating. These incubators were marketed under the trade name EchoTherm.

In **2001**, a patent was granted for an ambient-temperature stabilization control system for laboratory incubators. This device was able to effectively maintain the incubator temperature within a desired range and to accurately control the rate of heat loss from the incubator as the ambient temperature rose.

In **2003**, NBS began worldwide distribution of a new line of CO_2 incubators featuring a direct-heat, fanless design. These incubators were lighter in weight than traditional water-jacketed designs, and featured the most advanced CO_2 controllers ever developed, complete with on-board diagnostics, help menu and auto-baseline reset.

Also in **2003**, a patent was issued for a high-efficiency microplate incubator. This incubator offered superior temperature uniformity and stability through a simple construction in which multiple incubation chambers were stacked to conserve laboratory space. The multiple incubation chambers could be electronically controlled by a single temperature control assembly in a master incubator. A water reservoir that could be filled externally was provided inside the chamber.

Caron's second-generation Reach-in IR-CO2 Incubator.

In **2006**, NBS introduced two new CO_2 incubators—the Innova CO-170 and Excella CO-170—which offered greater internal space without increasing external size. In the same year, NBS also introduced 14 new shakers, including four new bench and floor model shakers, two new space-saving stackable I-26 & I26R incubator shakers and the new Excella® line.

In **2008**, CARON introduced the new large-capacity IR-CO_2 incubator, the industry's first and only large-capacity reach-in IR-CO_2 incubator with an automatic moist heat decontamination cycle that cleansed the unit overnight. This incubator also offered a user-configurable interior that could support shakers and cell rollers and an optional environmentally friendly water recirculation system.

The Sterisonic™ GxP Cell Culture CO2 Incubator from SANYO.

In **2009**, SANYO released the industry's first and fastest H_{202} sterilization method available—the Sterisonic™ GxP, MCO-19AIC (UVH) Cell Culture Incubator—described as the most complete cell culture solution for highly regulated applications or conventional incubation. This was considered to be the new standard of incubation technology. This incubator used the industry's first rapid H_{202} sterilization system, an under three-hour decontamination process that is still the fastest method available.

In **2010**, BINDER launched the BINDER gas supply kit which increased user convenience by automatically changing the supply source to a second gas bottle as soon as the first gas bottle is empty. This prevented the need for researchers to come into the laboratory at night or over the weekend to change the gas bottle. The set also had an acoustic and an optical alarm function as well as a potential-free alarm output for external reporting systems.

BINDER's Incubator Gas Supply Kit.

BIOSAFETY LEVELS 1,2,3&4

BIOLOGICAL AGENTS, WORK PRACTICES, SAFETY EQUIPMENT AND FACILITY DESIGN SPECIFIC TO EACH by Vince McLeod

A very specialized research laboratory that deals with infectious agents is the biosafety lab. Whether performing research or production activities, when working with infectious materials, organisms or perhaps even laboratory animals, the proper degree of protection is of utmost importance. Protection for laboratory personnel, the environment and the local community must be considered and ensured.

The protections required by these types of activities are defined as biosafety levels. Biological safety levels are ranked from one to four and are selected based on the agents or organisms on which the research or work is being conducted. Each level up builds on the previous level, adding constraints and barriers. The Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) are our main sources for biological safety information for infectious agents. The publication *Biosafety in Microbiological and Biomedical Laboratories*[1] is a principal reference and the resource for much of the information presented in this month's column. As an introduction, we summarize what the different biosafety levels encompass in terms of the typical biological agents used, safe work practices, specialized safety equipment (primary barriers) and facility design (secondary barriers).

The four biosafety levels were developed to protect against a world of select agents. These agents include bacteria, fungi, parasites, prions, rickettsial agents and viruses, the latter being probably the largest and most important group. In many instances the work or research involves vertebrate animals, everything from mice to cattle. When vertebrates are involved, additional precautions and safety requirements are necessary.

Using the most infectious agents also means extensive security measures are in place, not only because of their virulence but also because of their potential for use in bioterrorism.

Level 1

Biosafety level one, the lowest level, applies to work with agents that usually pose a minimal potential threat to laboratory workers and the environment and do not consistently cause disease in healthy adults. Research with these agents is generally performed on standard open laboratory benches without the use of special containment equipment. BSL 1 labs are not usually isolated from the general building. Training on the specific procedures is given to the lab personnel, who are supervised by a trained microbiologist or scientist.

Standard microbiology practices are usually enough to protect laboratory workers and other employees in the building. These include mechanical pipetting only (no mouth pipetting allowed), safe sharps handling,

LAB SAFETY

avoidance of splashes or aerosols, and decontamination of all work surfaces when work is complete, e.g., daily. Decontamination of spills is done immediately, and all potentially infectious materials are decontaminated prior to disposal, generally by autoclaving. Standard microbiological practices also require attention to personal hygiene, i.e., hand washing and a prohibition on eating, drinking or smoking in the lab. Normal laboratory personal protective equipment is generally worn, consisting of eye protection, gloves and a lab coat or gown. Biohazard signs are posted and access to the lab is limited whenever infectious agents are present.

Level 2

Biosafety level two would cover work with agents associated with human disease, in other words, pathogenic or infectious organisms posing a moderate hazard. Examples are the equine encephalitis viruses and HIV when performing routine diagnostic procedures or work with clinical specimens. Therefore, because of their potential to cause human disease, great care is used to prevent percutaneous injury (needlesticks, cuts and other breaches of the skin), ingestion and mucous membrane exposures in addition to the standard microbiological practices of BSL 1. Contaminated sharps are handled with extreme caution. Use of disposable syringe-needle units and appropriate puncture-resistant sharps containers is mandatory. Direct handling of broken glassware is prohibited, and decontamination of all sharps prior to disposal is standard practice. The laboratory's written biosafety manual details any needed immunizations (e.g., hepatitis B vaccine or TB skin testing) and whether serum banking is required for at-risk lab personnel. Access to the lab is more controlled than for BSL 1 facilities. Immunocompromised, immunosuppressed and other persons with increased risk for infection may be denied admittance at the discretion of the laboratory director.

BSL 2 labs must also provide the next level of barriers, i.e., specialty safety equipment and facilities. Preferably, this is a Class II biosafety cabinet or equivalent containment device for work with agents and an autoclave or other suitable method for decontamination within the lab. A readily available eyewash station is needed. Self-closing lockable doors and biohazard warning signs are also required at all access points.

> "When working with infectious materials, organisms or perhaps even laboratory animals, the proper degree of protection is of utmost importance."

Level 3

Yellow fever, St. Louis encephalitis and West Nile virus are examples of agents requiring biosafety level 3 practices and containment. Work with these agents is strictly controlled and must be registered with all appropriate government agencies.[2] These are indigenous or exotic agents that may cause serious or lethal disease via aerosol transmission, i.e., simple inhalation of particles or droplets. The pathogenicity and communicability of these agents dictates the next level of protective procedures and barriers. Add to all the BSL 2 practices and equipment even more stringent access control and decontamination of all wastes, including lab clothing before laundering, within the lab facility. Baseline serum samples are collected from all lab and other at-risk personnel as appropriate.

More protective primary barriers are used in BSL 3 laboratories, including solid-front wraparound gowns, scrub suits or coveralls made of materials such as Tyvek® and respirators as necessary. Facility design should incorporate self-closing double-door access separated from general building corridors. The ventilation must provide ducted, directional airflow by drawing air into the lab from clean areas and with no recirculation.

Level 4

Agents requiring BSL 4 facilities and practices are extremely dangerous and pose a high risk of life-threatening disease. Examples are the Ebola virus, the Lassa virus, and any agent with unknown risks of pathogenicity and transmission. These facilities provide the maximum protection and containment. To the BSL 3 practices, we add requirements for complete clothing change before entry, a shower on exit and decontamination of all materials prior to leaving the facility.

The BSL 4 laboratory should contain a Class III biological safety cabinet but may use a Class I or II BSC in combination with a positive-pressure, air-supplied full-body suit. Usually, BSL 4 laboratories are in separate buildings or a totally isolated zone with dedicated supply and exhaust ventilation. Exhaust streams are filtered through high-efficiency particulate air (HEPA) filters, depending on the agents used.

We have touched on only the main issues and differences between BSL 1, 2, 3 and 4 laboratories. There are many other concerns and requirements addressed in the CDC manual, such as impervious, easy-to-clean surfaces; insect and rodent control; and total barrier sealing of all wall, floor and ceiling penetrations. Our goal was to introduce you to the different levels of biological safety practices and facility design considerations. Hopefully, you now have the knowledge to decide whether you should open that door or not.

References

1. *Biosafety in Microbiological and Biomedical Laboratories*, 5th edition, Centers for Disease Control and Prevention and National Institutes of Health, February 2007. http://www.cdc.gov/biosafety/
2. *Biennial Review of the Lists of Select Agents and Toxins*, National Select Agent Registry, CDC. Atlanta, GA. 2010. http://www.selectagents.gov/

***Vince McLeod** is an American Board of Industrial Hygiene–certified industrial hygienist and the senior industrial hygienist in the University of Florida's Environmental Health and Safety Division. He has 22 years of occupational health and safety experience at the University of Florida, and he specializes in conducting exposure assessments and health-hazard evaluations for the university's 2,200-plus research laboratories.*

SAFETY TIP

SCHEDULE REGULAR SAFETY MEETINGS

By James A. Kaufman

Safety meetings are an integral part of a good safety program. You need to have a time when you and your colleagues can get together and focus on safety issues. Meetings that come as a follow-up on a regular safety inspection provide a good basis for discussion of problems and needs.

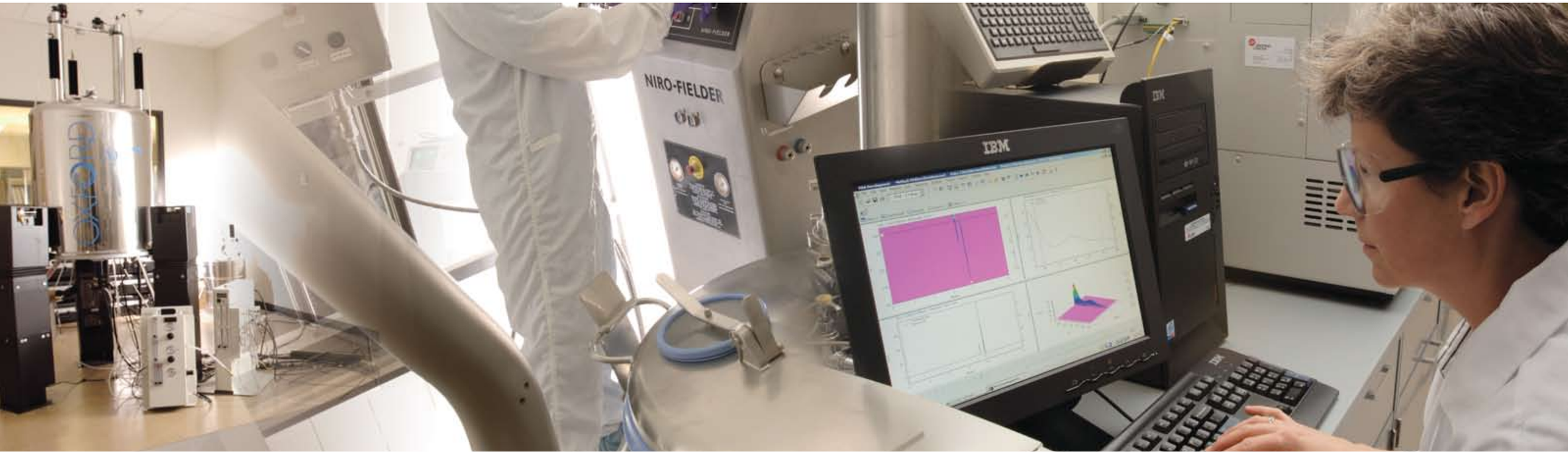
All members of your staff can benefit from participating in these discussions. They become more familiar with safety problems. They see that management is concerned about these issues. They may even contribute some good ideas. Remember, no one's been telling them for years that "it can't be done, it's never happened before, it won't happen here, and it's not in the budget."

Is a whole meeting too much for you to manage? If so, consider having safety as a regular agenda item on your normal department meeting. Set aside 10 to 15 minutes for a safety topic. Ask a member of your staff to pick a safety topic related to his or her particular interests and present a five minute review for the benefit of the rest of the group.

Borrow one of the audio-visual programs from the Lab Safety Institute and show it as part of your meeting. Visit the LSI website to see the list of library audio-visual holdings.

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

PERSPECTIVE ON: A CONTRACT LAB



▲ *Aptuit's 400 mHz NMR spectrometer.* PHOTO COURTESY OF APTUIT INC.

▲ *Aptuit formulation specialist prepares for drug product manufacturing run.* PHOTO COURTESY OF APTUIT INC.

▲ *Aptuit analyst evaluates HPLC chromatographic peak purity.* PHOTO COURTESY OF APTUIT INC.

COMMUNICATION AND ADHERENCE TO SCHEDULES ARE CRITICAL TO SUCCESS

by Sara Goudarzi

Pharmaceutical and biotechnology companies use contract research organizations (CROs), or contract labs, when they need to outsource a portion of their work. Contract labs offer a wide range of services within research and development. Some labs provide a single service, and others are more comprehensive in the scope of their work.

Aptuit Inc., an international contract research organization whose facilities span North America, Europe, India and Asia Pacific, is the latter type. The organization delivers client support from preclinical studies to commercial drug product launches, essentially creating an efficient path for drug development and clinical supply.

"We are contracted by clients to perform various drug development services," says Paul Annable, senior project manager at Aptuit. "Within our specific site here in Kansas City, we support drug development from synthesis of the drug substance all the way to commercialization of the drug product."

> "Individual site groups range from three to fifteen project managers."

Clinical supplies support is the bulk of Aptuit's business in Kansas City, where Annable is based. His team supports traditional molecular weight drug substances as well as large bio-molecular drug substances. The location also boasts a complete concert of drug product packaging capabilities.

"Our clients—ranging from virtual groups with a single molecule or idea all the way to large pharma—are a diversified group from around the world with one common goal: to improve the health of the patients they serve," Annable says.

Lab structure

The Kansas City operational location is a large site that covers well into the thousands of square feet. "The project management group tends to work in a more virtual environment, guiding projects across multiple Aptuit sites with clients from around the world," Annable says.

The site includes about 150 lab personnel involved with supporting drug substance synthesis, clinical trial materials supply, and clinical and commercial packaging. Within the project management group, which Annable is a part of, Aptuit engages

more than 100 individuals in the United States and Europe.

"Individual site groups range from three to fifteen project managers, depending on the services supported by each site specifically," Annable explains.

The expertise of the employees covers a vast range. Within the organization there are analytical chemists, organic chemists, physical chemists, pharmacologists, formulators, packaging experts, clinical trial managers and various diversified business support personnel.

Annable himself is an analytical chemist whose background is in research and development (R&D). He has been in the field for nearly twenty-five years, for half of which he has managed Aptuit's spectroscopy laboratory in Kansas City. Five years ago, Annable moved into project management. His team currently supports about 30 clients.

"As spectroscopists, we support material characterization—reference standards, drug substance and identification of unknown entities presented in various sample matrices," he explains. "Techniques typically employed range from FTIR, ICP, MS and NMR to chromatography's ionic, normal and reverse phases."

Analytical samples originate from multiple sources, including formulation and synthesis development projects, clinical stability, and problem solving situations. Sample counts are dictated by the flow and maturity of the projects they support.

Maintenance, inventory and hiring

Annable's team utilizes myriad analytical instruments. Some of the techniques that get the most use include nuclear magnetic resonance spectroscopy (NMR); mass spectrometry (MS), including both liquid chromatography and gas chromatography; Fourier transform infrared spectroscopy (FT-IR); thin-layer chromatography (TLC); ion chromatography; atomic absorption spectroscopy (AA); inductively coupled plasma emission spectroscopy (ICP); and many other techniques employing large bio-molecular testing instruments. In order to maintain these heavily used instruments and the rest of the equipment, Aptuit relies on highly trained individuals specifically hired for the task.

These individuals, who are also responsible for maintaining the site, are versed in the requirements of documentation in accordance with the industry, Annable explains. "Any changes or improvements in these areas are monitored through a quality assurance change control system."

When it comes to taking inventory, however, everyone in the group lends a hand, while making sure that all industry standards are met.

"Within our industry, an accurate, compliant accountability of all analytical samples is a regulated requirement," Annable says. "We follow best practices in documenting the movement of samples through our laboratories and sample management office. Associates are dedicated to the single task of ensuring accurate and compliant sample tracking during the drug development process."

The facility's smooth operation is partially owed to the careful selection of qualified staff.

"As you can imagine, within the framework described, challenges just from a scientific perspective require a talented and reactive team of specialists," Annable says.

Any department seeking technical associates looks for suitable personnel who are not only well versed in their fields but also possess the skill set needed for that division. Once a person is chosen to work with the team, human resources oversees the rest of the hiring process.

"The facility's smooth operation is partially owed to the careful selection of qualified staff."

Challenges

But as with most labs, it's not always easy at Aptuit. Not only is the road to drug development a nonlinear process, but accuracy, compliancy and timing are all absolutes that constantly affect the work.

"Challenges present themselves daily [and] require team effort to ensure that the goals of our clients and our industry are continually met and delivered," Annable says. "Leading these teams and communicating with our clients is a very dynamic process. Our challenges come from all directions, such as creating the best tablet formulation that will provide the desired dissolution profile or offering packaging solutions for a multicountry clinical trial."

How do Annable and his team meet these challenges?

With client involvement, Annable allows the project team to use its creativity to come up with unique solutions to major snags. Listening to the solutions and ideas of his staff, he says, is the best form of leadership. This type of management, in addition to the type of work that Aptuit conducts, provides Annable with the needed energy and enthusiasm to get through the daily hurdles.

"The most exciting aspect of our work is the support we provide as a drug product moves through the developmental pipeline. As we are all personally touched by medical issues, being part of the myriad drug products and their indications makes our job that much more pleasing and rewarding," Annable says.

"From oncology to neurological indications, we have and are working on all medical fronts and are fortunate to work with our clients and their brilliant ideas, pushing for solutions to improve the health of patients around the globe."

Another factor that lends to the success of Annable's management, and Aptuit as an organization, is the utilization of one of the most, if not the most, important skills in the business.

"Communication is the key to success in our industry," Annable says. "You must communicate with both internal and external clients to ensure that everyone is aware of their project deliverables. Finally, your clients are keener than you are when it comes to their drug and where their project must be at the end of the day."

And at the end of it all, a little bit of levity doesn't hurt either, he adds.

"Communication is the key to success in our industry."

Day to day

As project manager, Annable starts his day very early. With clients and colleagues scattered throughout the world, he has to work with the schedules of many.

"Time zones dictate when I can communicate with my team," he says. "The management of projects of varied maturity in the drug development process requires consummate levels of direct involvement depending on the activities in which we are currently engaged."

He spends many days in team and client meetings to discuss the status of the various projects, anticipated issues and potential solutions. Additionally, because timing is such a major component of his team's daily activities, he ensures that everyone adheres to the initially drawn-up schedule.

"Imagine a clinical study with a very specific patient enrollment process. Our clinical trial materials must be delivered to the clinic as promised in an accurate and compliant state to ensure that the first patient dosing is delivered as required," he explains.

"Think of it in your personal health life: we must deliver as you would expect to be treated for your health concern. That fact is not debatable."

And it is that fact, that promise to the patient he hasn't met, and the promise to his clients and his team, that makes Annable look forward to starting each day.

"Communication and delivery to promise are my daily goals," he says. "I lead by example and expect the same from my talented team. The success of my clients goes right back to the fact we are doing something good for someone who is ill."

Sara Goudarzi is a freelance writer based in New York City. Her Web site is www.saragoudarzi.com.

ATLANTA IS ALRIGHT

IN 2011, PITTCON WILL HOST ITS ANNUAL CONFERENCE AND EXPO IN ATLANTA, GEORGIA. SINCE 1997—THE LAST TIME ATLANTA HOSTED PITTCON—THE CITY'S BIOSCIENCE INDUSTRY HAS BEEN RAPIDLY EXPANDING.

Atlanta can be considered the transportation hub of the Southeastern United States. The Hartsfield-Jackson Atlanta International Airport has been the world's busiest airport for more than a decade, seeing 88 million passengers a year. Though it can be thought of as the international gateway to the U.S., Atlanta's involvement in transportation started even before it became a city.

Founded as Terminus in 1837, the town served as the end of the Georgia railroad line (Western and Atlantic Railroad) and later became incorporated as Marthasville in 1843 in honor of ex-governor Lumpkin's daughter Martha. It was renamed Atlanta in 1845 (based on its location at the end of the Georgia and Atlantic railroad line) and incorporated as a city in 1847. The city became the capital of Georgia in 1868. During the Civil War, the city was burned and almost completely destroyed. After the city was rebuilt, it rapidly grew due to the expansion of the railroads in the southwest.

Today, Atlanta is a major commercial metropolis. The city's economy is led by the service, communications, retail trade, manufacturing, finance, convention business and insurance industries. Atlanta is home to many major corporations, and ranks fourth in the nation among cities with the most Fortune 500 companies, including Coca-Cola, CNN, The Home Depot, UPS and many others.

The city is also home to a number of colleges, technical schools and universities, such as Emory University, Georgia Institute of Technology, Georgia State University, and Oglethorpe University.

The state of Georgia is home to more than 300 bioscience companies, including Centers for Disease Control (CDC), American Cancer Society and the Arthritis Foundation. In 2006, Ernst & Young ranked Atlanta sixth among US cities for the bioscience community. Often referred to as the "Atlanta Technology Loop," this hub of bioscience companies is the home of several industry leaders in the areas of bioinformatics, drug discovery and development, vaccine research and genetic analysis.

While in Atlanta, a great way to experience the city is a Segway tour, which will give you a fantastic orientation and an opportunity to see virtually all of the sites Atlanta has to offer. The world's largest aquarium—Georgia Aquarium, is centrally located next to the convention center. For a complete list of things to do, places to eat and how to get around the city, you can visit the Atlanta Convention and Visitor's Bureau at www.atlanta.net. For more information about Atlanta's bioscience community, visit www.atlantatechnologyloop.com.

See you in Atlanta.

CALCULATING COSTS

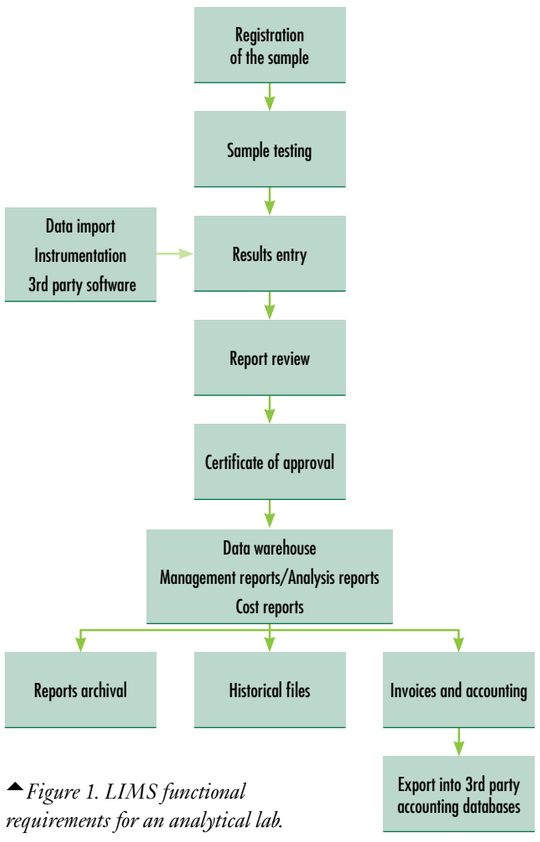
HOW A LIMS-BASED COST RECOVERY MODEL CAN IMPROVE OPERATIONAL EFFICIENCIES AND RESOURCE UTILIZATION

by Vishnupriya Bhakthavatsalam, Ph.D.

Laboratory Information Management Systems (LIMS) serve as the interface to a laboratory's data, instruments, analyses, and reports (Figure 1). For many analytical laboratories, a LIMS is an important investment that assists laboratory management in evaluating the efficiency of the laboratory's operations and reducing costs. In order to understand how low-level services relate to higher-level offerings, we may have to analyze usage patterns and establish metrics that drive costs in an analytical laboratory. We can use LIMS automation to calculate overall costs for base laboratory operations and create invoices on a per-sample basis as well as for batch sample shipments. Every laboratory has its own method of calculating costs for exporting into its accounting database. LIMS reports assist analytical labs not only with their expense budgets, but also with their capital budgets. The invoice created per sample usually includes a factor for overhead costs. These costs typically include depreciation value on the cost of the capital equipment. Payback time for a capital expenditure is obtained by dividing the cost by the annual cash flow (sum of income plus depreciation).

Hence, we need to develop a chargeback strategy for each service rendered and devise a model that pushes forward economical behavior, thus making it possible to charge clients fairly for analytical services. Healthy cost recovery methods in an analytical lab help measure adherence to procedures, as well as help meet time, quality, budget, and safety goals. They also assist in measuring the five facets of innovation, which include developing new methods, improving procedures, keeping up with technology, workplace organization and meeting unique customer needs. The mechanism for cost recovery should be practical and relatively simple to implement. Additional factors are how well it can capture laboratory operations and utilize the functionality offered by the LIMS to prepare monthly invoices for all the samples received. After implementing a chargeback methodology, analytical lab managers should include baseline reporting and key performance indicators (KPIs) in their practices: at fixed intervals, measure and report the savings realized, solicit feedback from upper management, and provide continuous review for ongoing process improvement.

As every analytical laboratory operates in a unique manner, it will be easier to configure a cost recovery module in the LIMS based on dividing the laboratory's working hours into convenient units based on the appropriate activities. LIMS can capture these



▲*Figure 1. LIMS functional requirements for an analytical lab.*

units of time by individual instruments and personnel. These time sheets are used by LIMS to compute charges against specific client activity. Usually, proposed routine test costs should be benchmarked against the commercial/academic analytical labs. In this manner, the pricing methodology will be structured to promote efficiency and sustainable competition and maximize consumer benefits. Laboratory charges for rush samples are two times the charge of normal samples. For nonroutine tests, costing gets trickier, as the work may range from simple to extensive analytical studies involving additional labor, meetings, report writing, literature searches, etc. This is where we need to provide a best estimate of how much time these tasks will cost and present the estimate to the client. To do that, we can simply add together the analysts' time at their hourly rates, overhead charges, consumables, instrument time in hours, interpretation time in hours, and travel expenses to give the project cost to the laboratory.

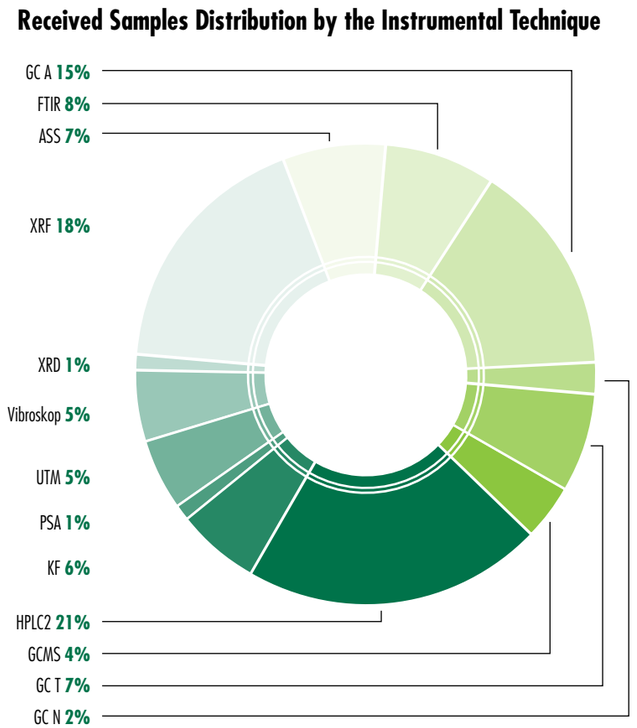


Figure 2. Workload situations in an analytical laboratory captured for a specific period.

Best practices demand that each job requested of an analytical laboratory be identified by a unique project code to which costs can be charged in an R&D environment. The project code names can depend on the clients and their projects, processes, products, etc. We can obtain invoice and account management reports by client project code, sample type, tests performed, number of samples, instrument used, test priorities, etc., in LIMS. Laboratory managers use these reports to study trends in productivity for different periods of time. Usually, after cross training, an analyst has three or four instruments as his first and subsequent responsibilities. Workload situations can vary at times for every instrument; hence, one cannot use the percentage samples received for every instrument alone to evaluate productivity for that period (Figure 2). It would also make sense to capture hard data for instrument utilization time in LIMS. This is because, on an average day, basic activities could account for 50 to 60 percent of the time, which is not limited to instrument time alone. For instance, in HPLC, sample preparation takes several hours inclusive of dilutions, flushing of columns, etc., for routine analysis; nonroutine analysis requires more time for changing of columns, etc. In the case of AAS, sample preparation, lamp setup and cool-down, instrument setting, and calibration require time for every sample. Meanwhile, dead time may involve housekeeping, inventory maintenance, safety meetings, and other laboratory quality measures such as ISO, Six Sigma, and gauge R&R. Separate non-project codes for laboratory's own use can be set up to capture the above activities.

Overall, a technician is 80 percent productive, but the higher-level staff typically have other duties throughout the day (interruptions from other staff to answer questions, customer meetings, monthly reports, yearly and mid-yearly appraisals, vendor meetings, negotiations, conferences and interviews, etc.,) that cannot be charged out. However, it is a challenge to capture above administrative activities in LIMS. LIMS also captures project-related activities, general analytical activities, and non-project-related activities such as installation, training, and maintenance/repair of the instruments. By designing a cost recovery module in LIMS on the basis of the ground rules above, we can produce an effective cost summary through LIMS for any project on that specific instrument for a particular time. Cost reports will enable us to understand instrument load and, therefore, wear and tear on the instrument. The cost recovery for an analytical lab can be proposed by grouping instruments into two categories based on their utilization: 1) instruments utilizing ≥ 50 to 75 percent of capacity and 2) instruments utilizing ≤ 10 to 25 percent capacity, which are called "research instruments" in an R&D environment.

> "Robust cost recovery methods... help measure adherence to procedures, as well as help meet time, quality, budget, and safety goals."

Typical recovery targets, such as 50 percent of the annual depreciation value for 50 to 75 percent utilized instruments and 20 percent of annual depreciation value for < 25 percent utilized instruments within the first five years of instrument life should be comfortable for an analytical lab in a research environment.

The data on repair, downtime, and missed preventive maintenance collected from LIMS can be compiled into reports to reflect instrument performance and allow us to choose between buying replacements and outsourcing. Costs assigned to each piece of equipment can be compared to the actual data collected in the maintenance management system to identify outliers. The costing data from LIMS will be pooled once every quarter and calculation of the recovered cost for every instrument will be carried out. This will help us in setting new cost recovery targets. A report of deviations, if any, can be compiled and presented to top management. Further fine-tuning of the cost-recovery percentage targets can be planned.

LIMS reports on the performance of individual assets (preferably a group of instruments) would shed light on competencies needed for an analytical laboratory and also on resource utilization apart from ROI. An analytical laboratory can be self-sustaining only if it has a sound cost recovery model and proves itself to be a profitable business.

Dr. Vishnupriya Bhakthavatsalam *is the laboratory manager of the analytical science and technology (AS&T) department of Aditya Birla Science and Technology, Taloja, Mumbai. She can be reached by e-mail at vishnupriya.b@adityabirla.com or by phone at 091-22-2740-3164.*

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PRODUCT SPOTLIGHT

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The new TripleTOF™ 5600 System from AB SCIEX is an accurate-mass, high-resolution LC/MS/MS system that combines the quantitative capabilities typically associated with triple quadrupoles with the qualitative capabilities of a high-resolution, accurate-mass system, all on a single platform.

The instrument's Magnetic Levitation (MagLev) turbo pumps provide virtually silent running and superior robustness, while the LINAC® collision cell increases analysis speed and eliminates cross-talk for information-rich, library searchable spectra.

"For the first time, qualitative exploration, rapid profiling, and high-resolution quantitation workflows can be performed on a single platform," said Lydia Nuwaysir, Sr. Product Manager, AB SCIEX. "[This provides] faster and more accurate answers to 'what is in the sample, how much is there, and does it change?'"

With SmartSpeed™ 100Hz Acquisition, users can expect more high-quality information from their samples even when using fast chromatography—up to 100 spectra in one second, or 50 spectra in one second while maintaining intelligent real-time data filtering. In addition, Easy-Mass™ Accuracy provides more than 50 hours of nonstop LC/MS operation for <2 ppm RMS.

The system features a linear dynamic range of 4 orders of magnitude or greater and gives users added flexibility with a software-selectable dual ionization system. Suitable for various applications in areas such as clinical research, forensics testing, biomarker studies, and food and water contaminant screening, the TripleTOF 5600 explores complex samples in great depth.

For more information, visit www.absciex.com.

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308 FPD™

- Designed to analyze the color and relative intensity of individual pixels of even microdisplays
- Attaches to a probe station or microscope to obtain color date and relative intensity
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- Permits simultaneous determination of refractive index and intrinsic viscosity of a polymer solution
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Dorton Analytical www.dortonanalytical.co.uk

Trace Gas Analyzer

VeraSpec™ Trace

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- Also offered in a MS/MS configuration
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Amino and Diol Flash Cartridges

Reveleris®

- Allow fast, easy purification of challenging polar compounds such as carbohydrates and improve selectivity for non-polar compounds such as lipids
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Grace Davison Discovery Sciences www.discoverysciences.com

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- XB-C18 incorporates two iso-butyl side chains at the base of the C18 ligand for reduced secondary interactions with residual silanols
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Solid Phase Extraction System

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- Performs all solid phase extraction steps for aqueous samples directly from their original containers
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- Modularity allows for one to as many as eight extractors to be linked and controlled simultaneously
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www.horizontechinc.com

Permeation Tubes

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- Alpha-polyoxymethylene decomposes to maintain a stable emission rate of formaldehyde
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- Available in 4-, 5- and 8-μm particle sizes

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RKA-5

- Includes Pmove™ interface, consisting of a large color screen, rotary selection knob and a few soft keys
- Available with a full-sized keyboard and barcode scanner for simple sample identification logging
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AMETEK Petrolab Company www.petrolab.com

Stabinger Viscometer

SVM 3000

- Measures dynamic viscosity and density of oils and fuels according to ASTM D7042
- Automatically calculates the kinematic viscosity and delivers measurement results which are equivalent to ISO 3104 or ASTM D445
- Processes up to 30 samples in an hour

Anton Paar www.anton-paar.com

Hotplate

Atlas Hotter

- Achieves temperatures of up to 350°C
- When used with Atlas Lithium system, the hotplate enables automated reactions in a wide range of round-bottom flasks and vials, using dry baths
- The addition of overhead stirring modules forms the Atlas Sodium conformation, which is ideal for more viscous reactions

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- Sends warning reports via e-mail or issues warnings via contact output when a remote unit has entered or recovered from a warning condition

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- Combines a low-noise pump, shatterproof collection bottle and a versatile hand operator

INTEGRA Biosciences www.integra-biosciences.com

PRODUCT SPOTLIGHT

DUCTLESS DEMONSTRATION FUME HOOD

SAFE FOR CLASSROOMS AND INDUSTRIAL TRAINING

The EDU™ Series of demonstration fume hoods from Air Science is ideal for education, vocational training and industrial workforce development. Meeting OSHA, ANSI and other international standards, the hoods are designed to offer 360° visibility for full participation, while protecting the class from any toxic fumes.

The units are mounted on heavy-duty transfer carts, and are designed with a low center of gravity and height so they can be easily wheeled from one lab or classroom to another, fitting through standard doorways. Contaminated air is pulled through the Multiplex™ filtration system, which returns clean air to the room. The filtration system consists of an electrostatic pre-filter, a main filter and optional safety filter. The pre-filter may be changed while the unit is running.

Additional features are available for added flexibility. "[An EDU hood] can be equipped with quick disconnect fittings for water and gas that enable it to be used with various gases and/or water," said Andy Chambre, President, Air Science. "[They can] then be disconnected and put out of the way in a storage area."The EDU™ Series of fume hoods includes four models: EDU-Mobile, EDU-Classic, EDU-Ada and EDU-Junior.

For more information, visit www.air-science.com.

Evaporation System

HT-4X

- An inert purge option allows high safety evaporation of flammable solvents
- An optional facility is available for fast sample lyophilisation
- Chamber cooling between runs protects thermally sensitive samples when run immediately after higher boiling point solvents

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Rotational Viscometers

SMART Series

- Features AUTO-TEST with sound and visual malfunction alarm
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www.fungilab.com

Coulometric Karl Fischer Titrator

AQUACOUNTER® AQ-300

- Features six built-in calculation modes to accommodate solid, liquid and gas samples
- Includes a statistics package with one-touch calculations
- Allows instant recall of data for up to 20 samples
- Choice of ion exchange or fritless cell system and thermal printer or impact printer

JM Science www.jmscience.com

Transfer System

Model 021 LN_2

- Includes a large storage Dewar with a 47-liter capacity that can hold liquid nitrogen or argon for up to 30 days
- Operates at ambient pressure and replaces typical cryogen storage vessels
- Discharge rate is continuously adjustable to a maximum flow of 3 L/min
- Discharge line is insulated to prevent frosting and icing during use

Micromeritics www.micromeritics.com

Microwave Digestion System

UltraWAVE

- Offers higher sample throughput and reduced overall costs with the use of disposable glass vials instead of traditional digestion vessels
- Digests up to 15 samples, of any matrix, simultaneously
- Features Single Reaction Chamber (SRC) technology, removing common limitations of sample prep

Milestone Scientific www.milestonesci.com

Trigas Generator

LCMS-SF5000NA

- Designed to deliver pure nitrogen for curtain gas, pure zero grade air as gas-1/gas-2 source gases and dry -40°F dew point air as source exhaust
- Provides enough gas for a single LC/MS instrument on a continual basis
- Eliminates the need for expensive, high-pressure nitrogen and zero air cylinders

Parker Balston
www.labgasgenerators.com

Digital Manometer

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- Able to simultaneously record temperatures along with pressure and time data
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- PetroNet® software handles online configuration, data transfer and storage on a computer or network

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- Includes three rotors: a 6 x 1.5mL rotor, a PCR Strip rotor and a 1" x 3" slide rotor
- Also includes two adapters for 0.5 to 0.65mL and 0.4mL
- Features a safety interlock which automatically shuts off unit when lid is opened
- Cold room compatible

Scie-Plas
www.scie-plas.com

Flow Controller

Smart-Trak® 50 Series

- Delivers accuracy of ±1.5% FS, repeatability of ±0.25% FS, 300 millisecond response time and 0 – 50 slpm (nmlpm) range
- Includes 316L SS wetted materials, field zero & span adjust and two DB9 connectors located on either side of the enclosure for convenient wiring
- Can be calibrated onsite, avoiding expensive and time-consuming returns to the factory

Sierra Instruments
www.sierrainstruments.com

LIFE SCIENCE

Cell Migration Assay

Oris™ Pro 384

- Uses a non-toxic biocompatible gel (BCG) to form a centrally located and temporary cell-free zone on cell culture surfaces in a 384-well format
- After cell seeding, the BCG dissolves to reveal a detection zone into which the migration of cells can be observed either in real time or after further experimental processing

AMSBIO www.amsbio.com

PRODUCT SPOTLIGHT

EMCCD CAMERA FOR THE LIFE SCIENCES

BROADBAND SENSITIVITY FOR IN VIVO IMAGING

The Evolve 128 EMCCD camera from Photometrics provides extreme sensitivity for demanding low-light applications. Quant-View, one of its advanced camera features, eliminates arbitrary gray levels in favour of photoelectron counts, establishing a basic unit of measurement and making it easier for researchers to compare experimental results.

"There are situations when you're dealing with samples with extremely low expression levels and the time frame of reactions is very small," said Rachit Mohindra, Associate Product Manager at Photometrics. "The sensitivity and high frame rate of the Evolve 128 permit the detection of these signals with sufficient temporal resolution."

The camera's onboard intelligence features maintain precise, accurate and quantitative measurements, as well as improved image quality. Quant-View technology provides a repeatable approach to collecting and interpreting live imaging data by reading out pixel values in photoelectrons—a standardized unit of measurement.

eXcelon™ sensor technology images blue and near-infrared (NIR) wavelengths with higher quantum efficiency. "It takes fringe patterns, or etaloning, and reduces it tenfold," added Mohindra. "This allows researchers to extend their imaging into the longer wavelengths as well as facilitating the development of new fluorescent dyes." Sensitivity across the NIR is vital for imaging studies because of low tissue auto-fluorescence. eXcelon's reduced etaloning facilitates the expansion of NIR fluorescent probes.

Ideal for various applications including calcium and *in vivo* imaging, the Evolve 128 EMCCD camera performs well in low-light applications such as spinning disk confocal microscopy and single molecule fluorescence (SMF).

For more information, visit www.photometrics.com.

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Octet Platform

RED96

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- Includes biosensor re-racking

Fortebio www.fortebio.com

NIR BioProcess Probe

12 mm

- Optimized for real-time in-situ monitoring of mammalian cell culture growth media in bioreactors
- Autoclavable or sterilizable-in-place (SIP)
- Small diameter probe is designed for use in standard instrument ports in benchtop bioreactors and can be adapted for scale up to pilot plant and manufacturing reactors

FOSS NIRsystems www.foss-nirsystems.com

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CpGenome™ Turbo Kit

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AF-rProtein A-650F Resin

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Multiplex Assay Kits

MILLIPLEX® MAP Kits

- Validated, multiplexed immunoassays for measuring 21 biomarkers, including amyloid beta 1-40 and 1-42, serum amyloid P (SAP), total and phospho-Tau (Thr231), PARK7, and alpha synuclein
- Levels of these biomarkers may be predictive of the formation of aggregates that interfere with nervous system functions, resulting in cognitive decline, motor dysfunction, and other symptoms

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Microplate

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- Achieves a storage volume of 1.1 mL/well in a height of 27 mm
- Made from extractable-free polypropylene; certified free from DNase, RNase and endotoxin contamination
- A matching anti-evaporation cap mat, made of thermoplastic elastomer, is also available

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LIMS & SOFTWARE

Flow Cytometry Analysis Software

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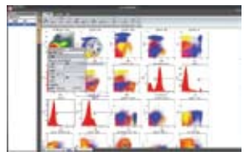
- Processes multicolor files of up to 10 million events in real time
- The NVIDIA Tesla Supercomputer option allows for even faster data processing
- Analyzes data from various platforms, such as MoFlo Series sortersm CyAn ADP and Gallios flow cytometry analyzers, and systems such as iCys and iCyte automated imaging cytometers



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Advanced Remote Monitoring System

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- Portal/Homepage gives the user an expanded overview of the customer enterprise on a single screen, allowing users to easily view alarms, recent events, checkpoints and out-of-range sensors in a consolidated view
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Software Developer Kit

CyMek SDK

- Enables integration of CyMek automation platforms with labs' existing LIMS systems
- Protocols can be issued to the automation without the need for script editing and programming
- Based on standard open interfaces, including XML

eXeTek www.exetek.co.uk

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Version 1.08.3a

- For AC Analytical Controls Reformulyzer Mark 3 (M3)
- Includes support for Chemstation 4.02 SR1 and added reference sample lots
- Integrated diagnostic tool enables automated validation through quality control samples

PAC www.paclp.com

Small Molecule Structural Elucidation Software

Mass Frontier 7.0

- Simplifies the management, evaluation and interpretation of mass spectral data and can be used for metabolism, metabolomics, forensics, natural products, impurities and degradants research
- Features a Fragment Ion Search (FISh) screening tool, including automatic localization of the site of biotransformation through color coding applied to fragments common to the parent compound and its related component

Thermo Fisher Scientific www.thermoscientific.com

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Light-shielding Volumetric Flasks

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- Available in sizes from 10 mL to 1,000 mL

BrandTech
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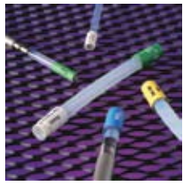
Permeation Tubes

Dynacal®



- Contain a pure chemical compound in a two-phase equilibrium between gas phase and liquid or solid phase
- At a constant temperature, device emits the compound through its permeable portion at a constant rate
- Accurate, stable concentrations range from PPB to high PPM

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- Constructed of low-binding polypropylene to maximize sample recovery (typically greater than 90%)
- Omega™ polyethersulfone ultrafiltration membrane provides high flow rates and is low protein binding
- Available with ultrafiltration membrane, from 3 kD to 100 kD, for rapid concentrating and/or desalting of proteins
- Color-coded for easy visual identification

Pall www.pall.com

Vials for Cryopreservation

Nunc™ Cryobank Vials

- Incorporate 2D barcode tracking for effective sample storage, tracking and retrieval
- Cryobank cap is fully compatible with automated de-cappers
- Sterile, non-pyrogenic tubes are CE-marked and IATA-certified
- Can be used with standard freezer racks and cryoboxes

Thermo Fisher Scientific
www.thermofisher.com

Magnifiers

LED

- Available in powers from 3X to 14X
- LED technology eliminates the need to change bulbs
- Batteries last up to 50% longer than conventional lighted magnifiers
- Bright light enhances aspheric, anti-reflective coated lenses for crystal clear images

Vision USA www.visionusasupplies.com

Business Card Magnifiers

Custom Designed

- Thin, flexible, non-breakable plastic with 3X magnification lens
- Makes small print easy to read
- Custom information can be added (up to 4 lines) in choice of colors
- Comes with clear protective pouch

Vision USA www.visionusasupplies.com

Fume Hood Fire Protection

Problem: Due to the many volatile chemicals and compounds used in laboratories, a fume hood fire can release toxic and/or corrosive vapors and soot into the air. In addition to the fire destroying the fume hood itself, these vapors can destroy chemical or biological research material, damage sensitive instruments and their calibration, and destroy data on laboratory computer hard drives.

In some labs, personnel are trained to fight a fume hood fire using portable extinguishers. However, this is risky as a fume hood fire can grow quickly out of control due to the large volume of air feeding through the sash. Traditional in-cabinet sprinkler-head detection and dispersal systems provide limited effectiveness, as the airflow pattern in the hood can prevent the heat and flames from reaching the top-mounted detection device in time to avoid a major disaster.

To be effective, fume hood fire detection and suppression needs to: provide fast around-the-clock protection; suppress a fire with absolute reliability, even if the sash is open; and prevent the release of fumes. It should not be susceptible to false alarm or interfere with the operation of the hood or its maintenance.

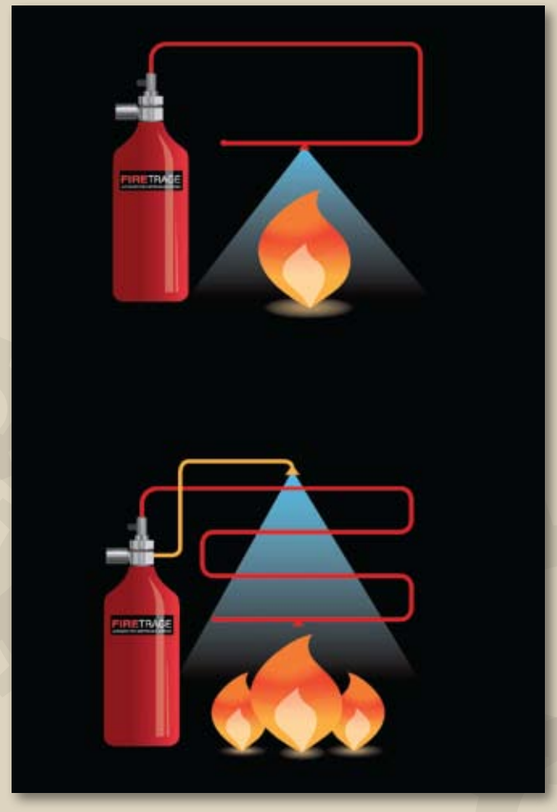
Solution: Firetrace International manufactures a fast-acting and reliable automatic fire detection and suppression system designed to protect against laboratory fume hood fires. The FIRETRACE® system utilizes unique, proprietary pressurized polymer fire detection tubing that is linked to an extinguishing agent cylinder.

The tubing functions as a linear pneumatic heat and flame detector that ruptures or "bursts" at any point along its length where a fire is detected, triggering the release of the extinguishing agent. The flexibility of the detection tubing is such that it allows it to be routed throughout the path that heat and flame will follow—behind the fume hood's baffles and across the exhaust duct openings—ensuring that a fire is suppressed where it starts, and before it can cause major damage.

The operation of the system is unaffected by the sash being open, and the speed of suppression helps prevent the release of fumes that can damage instruments or equipment. The system activates only in the event of a fire, so there is no potential for false alarms or unwarranted suppression activation due to smoke or fumes.

The system is intrinsically safe and requires neither electricity nor external power, and does not demand manual intervention—although a manual release option is available—and so provides constant, unsupervised protection of the fume hood. Firetrace systems are compatible with most commercially available extinguishing agents including CO_2, AFFF foam, dry powder, and the latest clean agents such as 3M™ Novec™ 1230 Fire Suppression Fluid and DuPont™ FM-200® that leave no reside and require no clean-up.

For more information, visit www.firetrace.com.



FIRETRACE® fume hood automatic fire detection and suppression.

Thermo Scientific Polar Series Thermostatic Laboratory Chillers

Thermo SCIENTIFIC
25 Nimble Hill Road
Newington, NH 03801
Phone: (800) 258-0830
www.thermoscientific.com/tc

The new Thermo Scientific Polar series of thermostatic laboratory chillers offers full range cooling for quick ramp-up and cool-down. The Polar Series is ideal for an expansive range of applications, including chemical reaction control, separations, spectroscopy and surface science. Available in 250 or 500 watts of cooling, a force or force/suction pump, and USB communication, the Polar Series is a perfect fit for any temperature control application.

Innovative

The Polar series of thermostatic laboratory chillers offer innovative features

- An internal reservoir minimizes fluid evaporation and optimizes chiller performance.
- An intuitive user interface allows you to choose between 5 temperature set-points.
- Remote temperature control and communication are available on selected models for remote operation, monitoring and data logging.

Reliable

Optimize your performance and productivity with:

- Built-in energy-saving feature limits power consumption
- Ideal for closed loop applications up to 500W
- Temperatures range from -10 to 80°C.

Compact

Its compact size maximizes work space and increases efficiency in the laboratory. With you in mind, all operational and preventative maintenance can be done right from the front of the unit.

Gas Chromatography Analyzers

Problem: The past decade has been painful for most labs with some experiencing staff reductions of 50 percent or more along with significant budget reductions. At the same time, demands for services continue to grow, creating a conundrum for lab managers. How can labs continue to provide new tests needed to support the business when the resources needed for method development have been lost and the remaining staff is sprinting to keep up with the daily workload? Nearly all labs report that a shortage of time and skill has become a major impediment to implementing the enhancements needed to keep them competitive, and is a major obstacle in introducing new services that are being demanded by the business.

Solution: Agilent Technologies now offers a solution for the time and skill shortages that lab managers are facing with pre-configured, factory-tested gas chromatographic analyzers. Rather than simply purchasing a gas chromatograph, lab managers can choose from over 200 analyzers or pre-configured gas chromatographs designed to comply with specific ASTM, UOP, EN or GPA standard methods. Agilent engineers design the complex valve configurations required for many hydrocarbon tests and these instrument modifications are made at the factory. Analytical chemists then complete the method development, including software automation and introduction of advanced technologies to increase test speed while remaining fully compliant with the requirements of the specific standard method. These ready-to-run analyzers include everything needed to produce high-quality data right from day one. A typical analyzer will include the GC instrument, Capillary Flow Technology modules, specialized fittings, all necessary auxiliary hardware such as automated sample handlers, high performance application-certified columns and supplies, powerful, easy-to-use software, installation, performance verification, and any required operator training.

Since in-house implementation of new methods typically takes a week or more of chemist and technician time, these pre-configured workflow solutions tend to provide a very cost-effective solution for lab managers. In addition to solving the time and skill shortage problem, many of the analyzers include productivity enhancements such as automated sample preparation and column backflush for fast analyses that are often not implemented by labs due to time constraints or lack of familiarity with these features. By employing advanced technologies, these analyzers generate continuing cost savings year after year by increasing sample throughput, lowering expendables cost, and deferring purchase of additional instrument capacity. The analyzers also deliver superior data quality by utilizing appropriate passive materials in the gas flow stream for especially demanding analyses where these materials might not be present in the off-the-shelf gas chromatograph. For example, the use of special passive surfaces on tubing and valves minimizes sulfur adsorption on metal parts that can lead to poor chromatography for compounds containing this element, especially at low concentrations.

When ordering new instruments that will require customization to comply with specific standard test methods, lab managers should consider the business case for these custom factory analyzers since they will almost always be the most cost effective and reliable business solution. In fact, Agilent or its partners will develop the custom solutions needed by labs in most cases even when they are not already in the current portfolio.

For more information, visit www.chem.agilent.com

Complex valve configuration typical of customization supplied on some analyzers.

ALPHA

The ALPHA is more than just a compact FT-IR spectrometer. It unites Bruker's years of experience in infrared spectroscopy in a compact, rugged and intuitive design. Quality components and state-of-the-art technology ensure accurate and precise results with short measurement times. The ALPHA delivers excellent sensitivity, x-axis reproducibility and stability. Spectrometer components are continually monitored to ensure operation within their specification. A complete set of mobility options make the ALPHA an independent analyzer that can be used just where it is needed the most: close to the sample to save you time and cost per sample. The ALPHA can be transported easily from lab to lab and can be used in mobile laboratories.

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Bruker's patented, permanently aligned RockSolidTM interferometer incorporates dual retro-reflecting gold coated cubecorner mirrors in an inverted double pendulum arrangement for maximum efficiency and sensitivity. A wearfree flexible pivot bearing is located at the center of mass, which optically eliminates mirror tilt and mechanically prevents mirror shear. It is also resistant to vibrations and thermal effects, ensuring perfect stability and reliability when needed in process environments. The permanent alignment provides consistent high quality results, less downtime and outstanding stability.

Fourier Transform Infrared (FT-IR) spectroscopy is a technique that has been replacing many other expensive and time consuming methods over the years. While it's typically less expensive from consumables perspective, there are still some costs involved with the up-keep and its service over the life of the instrument. The most significant costs for today's many instruments are based on the so-called consumable components of the instrument; such as the HeNe laser and the source. The new ALPHA FT-IR utilizes a solid state laser with a life time of over 10 years. Its infrared source has also been engineered for a lifetime of greater than 5 years. These unique features provide significant cost savings and increases your productivity.

Today's regulated laboratories must comply with extensive regulatory requirements. Bruker Optics offers comprehensive system validation that provides the documentation and procedures needed for an effective compliance. The ALPHA is prepared to fully support your validation needs; from the design qualification (DQ) to daily performance qualification (PQ). Bruker Optics' comprehensive system validation manual provides all related documentation and guides you through all the necessary steps of the validation procedures. Validation, instrument installation and annual certification is offered by Bruker's factory trained, certified service engineers, which further reduce the cost of compliance. The ALPHA incorporates a certified reference standard for fully automated instrument test routines.

The identification of unknown materials is an essential task for all troubleshooting labs. With OPUS IR spectroscopy software for the ALPHA, Bruker developed a new and powerful algorithm to improve the identification process of unknown materials. The new peak based algorithm can be operated in two different modes: searching for a pure component or searching for single component within a mixture. This is only possible, with Bruker's unique peak based search algorithm, where the peak positions are used to find matches in the database. This new approach delivers accurate identification results even when the unknown sample is a mixture. The new peak based search algorithm is a big step forward in FT-IR spectroscopy, specifically for the identification of unknown materials.

The ALPHA offers full sampling flexibility. User exchangeable QuickSnap™ sampling modules allow the analysis of almost any kind of sample (e.g. solids, liquids or gases).

Elemental Impurity Analysis in Pharmaceutical Products

Problem: The United States Pharmacopeia (USP) is proposing two new General Chapters on levels of trace element impurities in pharmaceutical products with the aim of:

- Updating the methodology used to test for elemental impurities in drugs and dietary supplements to include procedures that rely on modern analytical technology; and
- Setting limits for acceptable levels of metal impurities (including, but not limited to, lead, mercury, arsenic and cadmium) in drugs and dietary supplements.

The proposed USP chapters 232 and 233 will place greater emphasis on the use of automated detection methods for analyses.

The current USP chapter is based on precipitation-based detection methods for analyses, however these methods do not deliver the high level of accuracy necessary and can lead to false negative results. As a consequence, trace elements are not being fully detected in pharmaceutical products.

The Thermo Scientific iCAP 6000 Series ICP-OES ensures compliance with the chapters proposed by the USP.

Solution: The USP is proposing a change to legislation that will lower limits for trace elements in pharmaceuticals. New methods of analysis will use instrumentation–based methods rather than the traditional wet chemistry-based techniques, with inductively coupled plasma-mass spectrometry (ICP-MS) and inductively coupled plasma-optical emission spectrometry (ICP-OES) as the technologies of choice.

ICP-OES works on the principle of introducing a liquid sample into the plasma via a nebulizer. The nebulizer then turns the liquid sample into an aerosol. Within this plasma the sample is heated up and as a result emits light which is then measured. Light given off by a specific metal has a discrete wavelength and the intensity of that light is proportional to the concentration of the element within the solution. With the use of this technique, scientists are able to accurately and easily determine levels of trace elements in pharmaceutical products. High throughput is an additional advantage of ICP-OES, which typically takes two minutes per sample analyzed. This is in contrast to wet chemistry-based methods, currently used by the USP, which often require up to 24 hours for sample preparation alone.

The Thermo Scientific iCAP 6000 Series ICP-OES and Thermo Scientific iTEVA Software are ideal for the analysis of trace elements in pharmaceutical products. The instruments are extremely powerful with low detection capabilities and have the ability to resolve complex spectra. In addition, the iCAP 6000 Series ICP-OES has the required wavelength range for the analysis of 167 nm to 847 nm and enables the analysis of all the elements that emit light between these two values. This is significant for a number of reasons. The low wavelength access enables the most sensitive wavelengths for As and Hg to be reached while the instrument also has the ability to access interference-free wavelengths which are critical when analyzing elements that produce a high number of emission lines such as Os, Ir, Pt and Pd. A solid state swing frequency 27.12 MHz RF generator offers robust plasma generation to deal with the most challenging sample matrices. An example of how this is particularly useful is when analyzing parental solutions which contain high concentrations of sugars and salts which can lead to a loss of power within the plasma, resulting in decreased sensitivity.

With the introduction of the new USP chapters on the horizon, the implementation of ICP techniques offers numerous advantages to pharmaceutical laboratories for the detection of trace elements. By using the automated method of analysis provided by the iCAP 6000 Series ICP-OES, laboratories are offered a wealth of benefits including ease-of-use, minimal training, high throughput and the capability to efficiently identify trace elements at lower limits, ensuring compliance with the requirements of this new legislation.

For more information, visit www.thermoscientific.com/trace

ADVERTISER INDEX

Marketplace

PARTING POINTS

Takeaways from this month's issue:

MANAGING CRISIS

Making good decisions is perhaps the most important lab management skill. Making decisions is a complex process with psychological, social and emotional components. By understanding and controlling these components, you can make better decisions. Some tips:

- Examine every possible alternative to avoid cognitive biases
- Intuition: more than a gut instinct, it's the result of pattern recognition capability
- Develop several solutions to various scenarios ahead of time
- Ensure proper communication is in place between all employees

SHAKY GROUND

When people are confronted with the prospect of change, they are initially ambivalent. Pushing them tends to produce an immediate, and opposing, reaction. How do you defuse this resistance before it becomes active or passive rebellion?

- Acknowledge employee concerns; don't try to minimize or ignore them
- Involve employees in identifying the disadvantages of not changing
- Invite them to be a part of the change process, but don't force them
- Look for opportunities to give each employee as much autonomy as possible in implementing the changes

BEST PRACTICES MADE BETTER

Saving time on each test in order to do more is the mantra of all analytical labs today. Lab managers can use the recent advances in viscosity measurement instrumentation to their advantage to increase productivity.

- Consider reducing sample sizes to save on both test time and cost of material; the proprietary Small Sample Adapter can reduce sample sizes to less than 20 mL
- The disposable chamber for this adapter can save time on cleaning, and is a practical choice for highly viscous samples
- The proprietary Quick Connect device, for attaching the spindle, can save time and minimize potential damage

CHOOSING THE RIGHT LIMS FOR YOUR LAB

Manfred Goebl, Ph.D., senior European technical development applications analyst at Mundipharma Research GmbH & Co., talks about the due diligence that needs to be done before installing a user-friendly and effective Laboratory Information Management System (LIMS).

- Buy a system based on user requirements and how flexible it is for expansion
- Dr. Gobel and his team set up different menus for different users: for example, a lab worker was trained to enter sample information, and a manager was trained to generate reports
- It is difficult to switch from one system to another; data can be lost

CALCULATING COSTS

For many analytical labs, a LIMS is an important investment that assists management in evaluating the efficiency of the laboratory's operations and mitigating cost increases. A LIMS-based recovery model can improve operational efficiencies and resource utilization.

- Best practices demand that each job requested of an analytical lab be identified by a project number to which costs can be charged in an R&D environment
- The data on repair, downtime, and missed preventive maintenance collected from LIMS can be compiled into reports to reflect instrument performance
- LIMS reports on individual asset performance would shed light on competencies needed for an analytical lab and also on resource utilization apart from ROI

BioSafe™ Modular Cleanrooms

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Model shown: ValuLine WhisperFlow™ Polypropylene Laminar Flow Hood

ValuLine hoods provide peak performance at lower cost! Available in 36" and 48" widths, with HEPA filtration unit and built-in spill tray.

Starting under $2,000

- Laminar Flow Systems provide particle control to meet cleanliness standards to Class 10/ISO 4
- Ductless exhaust hoods incorporate activated carbon for safe purification of most organic vapors
- Laboratory hoods provide safe ventilation of fumes
- Benchtop models provide space-saving performance and economy
- Full range of optional features includes ionization, UV sterilization, and particle monitoring

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BioSafe™ Pass-Through Chambers feature no-lip, no-seam design for easy sterilization.

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