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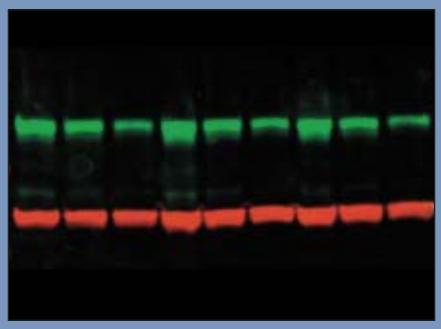

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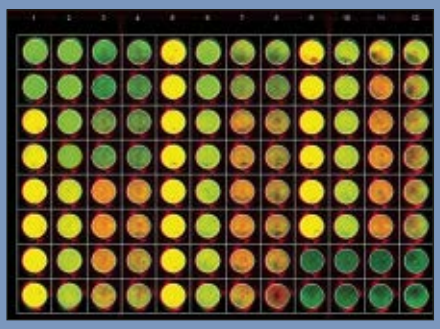

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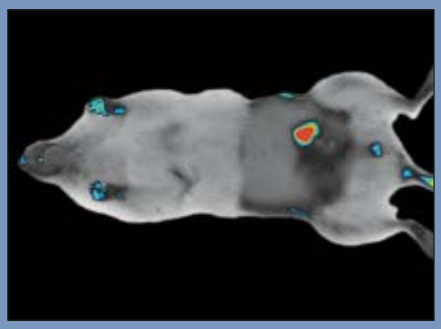

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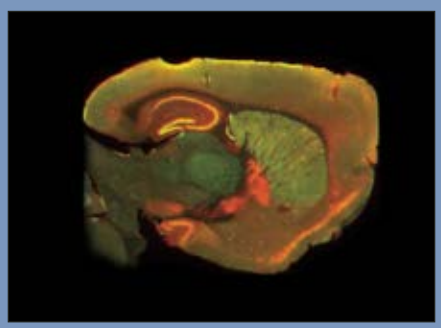

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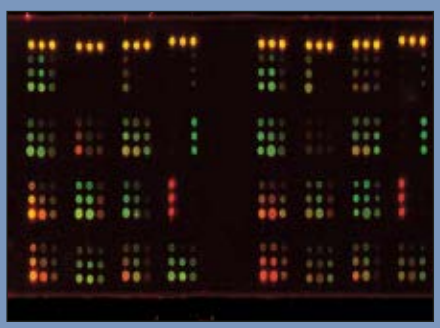

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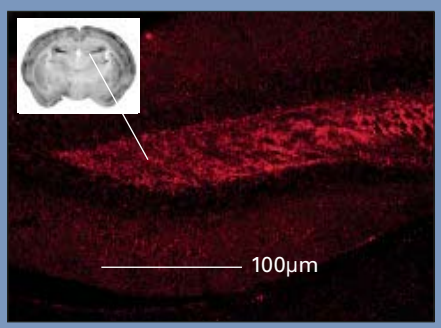


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Lab Manager MAGAZINE®



## Author Guidelines

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

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

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# Are job titles indicative of management responsibility?

I don't think so. If your title is not "laboratory manager," does that mean that you have nothing to manage? At all levels of the science lab hierarchy, management tasks abound. Just because you are a post-doctoral fellow and don't influence the hiring and firing practices of your PI, it doesn't mean that you aren't honing your management skills.

Are you a radiation safety officer in the lab? Do you help maintenance equipment? Do you serve on a committee in charge or placing orders for reagents and equipment? Do you ever supervise others on a project, such as technicians or students? Then you have lab manager responsibilities.

The same can be said of scientists in the industrial sector. Just because you aren't the head of a department or individual lab, it doesn't mean that you aren't responsible for managing certain tasks in that department or laboratory. Often, the management workload is shared or rotates between lab members so that each one can take part in the prideful responsibilities (translation: time sink away from your primary job function) that make the laboratory function smoothly, safely, and efficiently.

*Lab Manager Magazine*® addresses the needs of ALL managers within the laboratory, not just those at the top of the chain. Certainly we cover personnel and budget issues, but we also are a resource for purchasing products, managing contracts, and forming collaborations. Everyone benefits by discussions of time management and job interviewing tips, as well as some lighthearted stories of management processes that perhaps don't work so well. We want to be your "turn to" guide for questions about how to bring all the laboratory management tasks together in a way that allows you to focus on what is most critical in the lab: generating data and disseminating those results to others.

We want to provide information about proven management strategies that work, particularly in a scientific laboratory environment. We've all experienced bad managers and have seen what DOESN'T work; now it's time to give you tools that DO work and have been shown to work well.

We welcome the readership of not only those heading up the lab, but also those who are just getting started with management responsibilities. Don't wait to unlearn bad management practices; learn to do it right from the very beginning.

*Barbara VanRenterghem*

*"The most exciting phrase to hear in science, the one that heralds the most discoveries, is not "Eureka!" (I found it!) but "That's funny…"*
Isaac Asimov

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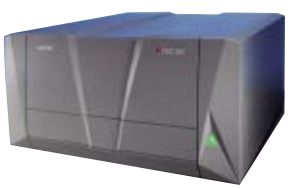

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# HUMOR in Laboratory Management (Seriously!)

"IF YOU'RE NOT ALLOWED TO LAUGH IN HEAVEN, I DON'T WANT TO GO THERE"— MARTIN LUTHER

Scientists are very serious people engaged in very serious work. Or at least that is the perception of the general public. But those of us who have made our living as scientists know better — it's just that our sense of humor can be a bit off-beat and can seem eccentric or peculiar to the layperson. While some scientists enjoy inane slapstick comedy (think "The Three Stooges") or ribald jokes outside of work, humor in the lab tends toward a more subtle variety. For example, technical workers are clever people who may be adept at wordplay (you might say they are punny people), enjoy satirical humor, or appreciate creative ruses. Since humor is part of the lab environment, an inquisitive mind might wonder if it serves any useful business function and if it has a place in the lab management toolbox. Thus, we take a serious look at humor to answer the question "Is there a useful role for humor in laboratory management?"

## UNDERSTANDING HUMOR

We begin by developing a better understanding of our subject — so, first, a few facts and figures. The Merriam-Webster dictionary defines humor as "that quality which appeals to a sense of the ludicrous or absurdly incongruous; the mental faculty of discovering, expressing, or appreciating the ludicrous or absurdly incongruous." While this definition addresses some aspects of what amuses us, our sense of humor is more complex and nuanced than implied in this formal definition; humor is one of those terms that everyone knows intuitively but can't quite express in words. We also know that humor has individual and cultural components so that it is not something that can be universally shared — what amuses one may offend another. And, both the type and quantity of our humor tends to change over our lifetime. Did you know that the average child laughs or smiles 400 times a day but the number drops to only 15 for the average 35 year old adult? That a hardy laugh releases endorphins into the body to produce an exhilarating effect while burning 3 ½ calories? That laughter increases oxygen intake to invigorate the body and release stress? The bottom line is that whatever your definition of humor, it is good for you and we don't have enough of it.

**The bottom line is that whatever your definition of humor, it is good for you and we don't have enough of it.**

It is not surprising that humor has evolved an academic discipline that constructs theories to explain how it works. The leading theories fall into the category of "Superiority Theories" which maintain that humor comes at the expense of human failings, defects, disadvantages, or misfortunes.[1] According to this view, all humor is derisive. Other popular theories are "Relief Theories" which maintain that humor comes from venturing outside the constraints of social norms and "Incongruity Theories" relating to mingling of two ideas that are felt to be utterly disparate or degrading something exalted by bringing it into contact with something disreputable.[1] There are all sorts of variations on these themes but none account for the inexplicable subtleties of what amuses us — for example, I know a scientist who always laughs at the mere mention of the number "four" (???). Undoubtedly, many more research grants are needed before the academics figure it out.

Wayne Collins, Ph.D.

## BENEFITS OF HUMOR

While understanding the basis for humor may be an important intellectual exercise, the more practical issues are around its value in business. Again there have been studies performed by researchers from prestigious universities to answer these questions. In one experiment to determine if humor interferes with work and wastes time,[2] participants were asked to complete tasks with "another person" over a networked computer. Actually, the comments were from a preprogrammed computer and differed only in whether they contained humor. The study found that the task time and amount of effort were unaffected by the humor and that the participants receiving the humorous comments rated the "other person" as more likeable, more cooperative, more social, and had a higher satisfaction rating for their work than those who received no humorous comments. A survey of CEOs found that 98 percent preferred job candidates with a sense of humor to those without and that 84 percent thought that employees with a sense of humor do better work.[3] Humor is said to facilitate communication, build relationships, reduce stress, and provide perspective when used correctly in the workplace. It can break the tension or emotional anxiety of mistakes, enhance team building, reduce aggression, and generally promote a feeling of well-being and contentment.

In addition to the cultural benefits, humor can also have cognitive effects. It changes one's mindset from a serious, rational, and objective frame to a more playful and creative one. It can allow teams to break out of cognitive "ruts" and stereotypical thinking to arrive at more creative solutions. One technique used in brainstorming is to ask the participants to suggest their most ridiculous ideas knowing that they will not work. In addition to serving as a fun icebreaker, the ideas often contain new perspectives on the problem that stimulate unexpected, out-of-the-box solutions that actually will work. Humor facilitates brainstorming and innovative thought and unlocks serendipitous genius.

Show the "Rules of the Lab" (see sidebar) to an accountant, salesman, or member of any other profession that is not familiar with life in the lab and they may miss the point and fail to appreciate the humor. The same material usually evokes at least a chuckle from scientists and lab staff that recognize a small grain of truth in the exaggerations and have personally experienced the frustrations captured in the jokes. Sharing this insider humor in a team can build social bonds to bring the members closer together and build a feeling of affiliation. Some of our professional magazines include this type of insider humor — for example, the occasional humorous twist on chemical nomenclature or molecular structure that we enjoy would be totally incomprehensible to the average person just as accountant humor (an oxymoron?) might be lost on us.

Within psychology, there is a concept known as mirroring where people working closely together tend to synchronize both physiologically and emotionally after about 15 minutes. Thus, managers who bring humor and joy to their job will have it reflected in the attitudes of their staff. Managers with a good sense of humor are more socially popular, approachable, and are people magnets; the gap between management and staff is narrowed and interactions are more relaxed. Adding light humor when giving negative or sanctioning feedback conveys the message that improvement is expected but the misstep will not seriously affect the future relationship. A manager's ability to "take a joke" also opens an important back door through which peers and subordinates can pass valuable feedback without risk of offending. Humor gives the speaker the right to deny that he meant anything by his comment, and it gives the listener the right to act as if nothing has been conveyed. Thus, this type of

### RULES OF THE LAB

When you don't know what you're doing, do it neatly.

Experiments must be reproducible; they should fail the same way each time.

First draw your curves, then plot your data.

Experience is directly proportional to equipment ruined.

If an experiment works, something has gone wrong.

Always keep a record of your data. It indicates that you have been working.

If you can't get the answer in the usual manner, start at the answer and derive the question.

In case of doubt, make it sound convincing.

Do not believe in miracles — rely on them.

Team work is essential, it allows you to blame someone else.

No experiment is a complete failure. At least it can serve as a negative example.

From: http://www.officehumorblog.com/

humor should never be ignored or taken casually — be aware of any underlying truths or hidden messages that are being conveyed in these jokes.

## HUMOR AND MANAGEMENT

It is important for the manager to adopt an appropriate level of humor to avoid being regarded as a clown rather than as a leader. First and foremost, the staff needs to trust that the manager has the competence to lead them to their destination and the stability to guide them through stormy issues. Using humor without first establishing this credibility exacerbates a difficult situation and undermines the manager's ability to lead. Managers wishing to improve their sense of humor should start slowly and trust their intuition — use humor as the icing and not the cake. Risk increases as more humor is injected so the manager must find the degree that matches his/her comfort level. The safest approach is to take yourself lightly and laugh at your own foibles — in moderation.

Just as some businesses have a dress code, it is appropriate to also have a humor code to spell out the limits of propriety. Certain types of humor should not to be tolerated in the workplace under any circumstances. This includes humor that is of a sexual nature, profanity, put-down, racial, religious, or harassing. Likewise, any humor ridiculing an employee or that makes anyone feel that they are not part of the team is unacceptable — humor must be inclusive, not exclusive. Making an assumption that a questionable joke is safe within a homogeneous group or at a gathering outside of work can spell trouble for a manager — you don't leave your leadership role at the office. And remember, the preface "I hope this doesn't offend anyone" will not let you off the hook in a work environment.

Practical jokes are not bad per se but have the potential to lead to harmful consequences if allowed to get out-of-hand. First and foremost, they must be totally harmless and pose absolutely no safety risk. I still chuckle when I recall arriving at work early one morning to find my office barricaded with crime scene tape and the outline of a body drawn on the floor. This was a totally harmless prank that the laboratory staff thoroughly enjoyed playing on "the boss." This type of activity is part of an open collegial culture but boundaries must be set to prevent it from going too far. For example, a quick search of the web finds such lab products as snake-in-a-reagent-jar, grinding centrifuge noises, the spilled experiment gag, and the dribble beaker advertised for sale. These types of jokes can easily backfire and

endanger or cause harm to the lab staff; strict rules must prevent this type of humor from entering the lab.

Scientists are serious people in a serious business but we are still entitled to have fun at our work. Humor makes for good business and for good science when used appropriately. It helps to create a relaxed culture where the staff enjoys their jobs and communication flows freely. Creativity and productivity can thrive in this type of open environment. The lab manager is the role model in demonstrating just the right level of humor appropriate for the organization. Good, effective leaders are able to combine communications and persuasion skill with an appropriate touch of humor to get their message across and win support for their ideas. If you have a good sense of humor, bring it to work with you to share with your staff and be prepared to reap an abundance of physical, cultural, and business rewards. There really is a role for humor in laboratory management — seriously!

*This article was based upon a presentation given at Pittcon 2007, Chicago, IL.*

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# The Role of Defensive Publications in Intellectual Property Protection

IT IS BECOMING INCREASINGLY EXPENSIVE TO BOTH OBTAIN PATENTS AND DEFEND THEM IN LAWSUITS SHOULD THE NEED ARISE. AN ALTERNATIVE IS PROTECTING YOUR RIGHT TO COMMERCIALIZE AN INVENTION THROUGH THE STRATEGY OF DEFENSIVE PUBLICATIONS.

Justin Hasford, an associate with the law firm of Finnegan, Henderson, Farabow, Garrett & Dunner LLP (Washington, DC) explains that a defensive publication places the knowledge that your lab has developed in the public domain, enabling it to serve as prior art preventing other companies from obtaining patents on the same technology. For a document to be an effective defensive publication, it must describe, anticipate, or make obvious all the elements of the claimed invention.

This is embedded in U.S. Patent and Trademark Office (USPTO) regulations and patent law, particularly 35 USC 102 (a) and (b), which states "A person shall be entitled to a patent unless,

a) The invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States…"

Using defensive publications must be done within the context of your company's goals according to Dr. Sandra Thompson of the Buchalter Nemer law firm (Irvine, California).[1] These include:

- To prevent competitors' patents from issuing
- To create technology licensing and sales opportunities
- To either stop or facilitate patent litigation
- To protect one's patent portfolio without spending patent application funds
- To save money

**How can you prevent competitors from using patents to block your own firm commercializing its innovative products and services?**

A printed document is considered a defensive publication "upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinary skilled in the subject matter of the art, exercising reasonable diligence can locate it."[1,2] In particular, Hasford notes that a firm should issue defensive publications when "it perceives a competitive threat from another company likely to apply for a patent."

Before discussing the various types of defensive publications, let's demonstrate their value by considering various strategies for using them.

## STRATEGIES

How can you prevent competitors from using patents to block your own firm commercializing its innovative products and services? The key is to bring your technology into the public domain where it may be used as prior art to prevent other firms being issued blocking patents that prevent your firm from commercially practicing the technology. One way to prevent blocking patents is to file your own patent applications. These are now published eighteen months after filing. However, this is an expensive strategy due to the costs of filing patent applications. Keeping your technology a trade secret, while feasible in some areas of chemical process technology, does not bring your innovation into the public domain.

John K. Borchardt

If all you desire to do is to protect your firm's ability to commercialize and profit from technology your lab has developed, strategically publishing the technology may be a cost effective way to do so. According to Thompson, defensive publication can be used to lay the groundwork for challenging U.S. patents.[3] Hasford notes that the procedure involves submitting a request for the USPTO to re-examine an issued patent that includes citations of the defensive publications. These defensive publications are evidence that your technology was publicly available before a competitor applied for a patent and thus can prevent issuance of a patent, cause the patent to be invalidated, or provide a defense should a competitor sue claiming you are violating their patent.

Even if defensive publications don't completely invalidate a competitor's patent, they may invalidate some of the claims. The result is that the scope of the issued patent is narrowed. Defensive applications also can cause loss of a competitor's foreign rights to patentability or provide support for broad claims in your firm's related patents in foreign countries.[1]

## PROTECTING CORE PATENTS

Defensive publications can protect your firm's core patents. In most cases once a patent is issued on an invention, many incremental improvements are possible. Competitors can "surround" your patented technology with their own patents covering incremental improvements that provide an improved product or a means of manufacturing it more economically. One common solution to this problem is to cross-license patents. Your firm gives a competitor a license to practice the core technology in your original patent while you receive a license to practice patented improvements. However, the net result is that a new competitor enters the marketplace.

Hasford notes that defensive publications describing improvements to your firm's core patent enable your company to practice both the patent and the improvements without licensing the basic patent to others, thereby preventing new competitors from entering the marketplace. To do so, competitors would have to develop completely new technology. On the other hand, if it is your company that has developed completely new technology, Hasford advises that your firm should file a patent application.

## TYPES OF DEFENSIVE PUBLICATIONS

Being in the public domain means that patent examiners and others can find descriptions of your technology. These must enable one having ordinary skill in the described technology to practice the invention. Defensive publications include product literature, white papers, and press releases, which may be in hardcopy form or published on your firm's website.[1] Papers published in research journals or trade magazine articles are also in the public domain. So are papers presented at conferences. However, often the only information available to people who did not attend the conference, which would include most, if not all, patent examiners, are brief abstracts. Only the text of the abstract may be relied upon, not the unpublished information in the full presentation. So it is often be advisable to publish a printed version of your paper or post the slides the presenter used on your firm's website (see below).

Theses placed in a university library can be used as defensive publications if the public has access to them.[1] If library access is restricted to students, faculty, and other university staff, the thesis may not be considered sufficiently accessible to the public unless people can purchase copies from UMI (formerly known as University Microfilms International).

U.S. legal criteria require that defensive publications qualify as a "printed publication" under the U.S. patent law. To do so, defensive publications must be "sufficiently accessible" to the public interested in the described technology. This means that interested people could obtain a copy of the defensive publication if they desired. Circulation of the document must be sufficient for these people to do so. However, the company issuing the document is under no legal requirement to make sure that interested parties such as competitor companies actually receive copies of the defensive publication.

Careful timing of defensive publications is essential. Publish too soon and competitors may learn about the strategic direction your company is taking in time to make their own timely entry into the marketplace using your technology or their own. Publish too late and your competitor may have already filed a patent and be in a position to argue to the patent examiner that your publication does not constitute prior art due to its later publication date. By submitting a manuscript to journals and trade magazines, firms lose control of the timing of its publication due to the time required for peer review. In the case of trade journals, the date of its publication may be affected by the magazine's editorial calendar with publication of certain subjects scheduled for particular months.

## RESEARCH DISCLOSURES

For over 40 years Research Disclosure has provided a rapid-disclosure mechanism for companies and individual inventors wishing to place their research findings in the public domain. Research Disclosure is the only dedicated rapid disclosure journal included in the PCT Minimum Documentation, ensuring its use during search examination by all leading patent offices or national IP authorities around the world.

## STATUTORY INVENTION REGISTRATION

Statutory invention registration (SIR) is a relatively costly form of public disclosure. It can be used when the USPTO's office action on a patent application reveals insurmountable difficulties to receiving a patent. The USPTO charges a fee for SIR, currently $400 or $800 dollars, in addition to the patent filing fee paid earlier. The firm waives patent rights.[1] The SIR could also affect the patentability of related inventions in divisional or continuation in part applications as well as foreign patent applications.

## INTERNET SOLUTIONS

Documents published on the Internet or online databases are considered to be printed publications within the meaning of 35 USC 102(a) and (b) provided that the publication is accessible to persons concerned with the technology the document describes.[1,4] When the only published information available from a conference is in the form of brief abstracts, online publication is an effective means of making the information presented in a conference available to the general public in the form of a full paper or the presenter's slides.

To control the problem of proper timing of public disclosure, some firms now offer rapid Internet publication of defensive publications. For example, the IP.com website publishes electronic versions of research disclosures. These are searchable using Internet search engines. With proper time stamping and notarization of electronic documents, the original publication date of the document can be verified. Having a publication date is very important in deciding what is and isn't prior art. Anonymous posting of information is allowed and can thwart a competitor's use of the document for competitive intelligence on your firm's plans.

RD Electronic is an online database offering 40 years of non-patent prior art published in the journal Research Disclosure <www.researchdisclosure.com>.

DISCLOSURE, a site on the STN International electronic databases, is produced by Germany's FIZ Karlsruhe and provides the full text, including images of technical disclosure records from the defensive publication journal Research Disclosure. The service may also be accessed directly over the Internet at <http://stnweb.fiz-karlsruhe.de>.

Other media are also considered to be printed documents. These include microfilm, magnetic disc or tape, and handwritten documents.

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

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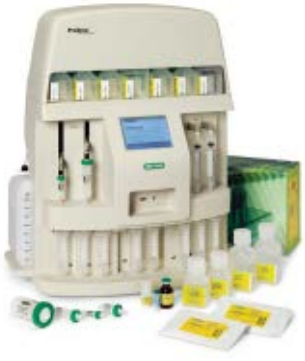

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# Choosing A Good Scientific Mentor

CHOOSING THE RIGHT MENTOR IS AKIN TO CHOOSING A LIFE PARTNER. IDEALLY, IT SHOULD BE A RELATIONSHIP THAT NURTURES THE GRADUATE STUDENT FOR LIFE.

Scientific mentors should stimulate intellectual independence, critical and analytical thinking skills, and foster professional growth in their students. As Eric Parsloe from The Oxford School of Coaching & Mentoring puts it, "Mentoring is to support and encourage people to manage their own learning in order that they may maximize their potential, develop their skills, improve their performance and become the person they want to be." So, given the critical role of a mentor, how should graduate students go about making this decision? Outlined below are some factors the student should consider to ensure their time in graduate school is well spent and well guided.

## MULTIPLE LABORATORY ROTATIONS

Choosing the right mentor requires students do some preliminary homework. Fortunately, most graduate programs facilitate this by requiring first-year graduate students to rotate through at least two to four different research labs before choosing their mentor. These rotations can last either weeks or months and usually culminate in the student giving an overview of their project in either a talk or poster format. For the student, this time is very valuable as it allows them to understand the type of research done in the lab. It also enables them to observe how the potential mentor interacts with the senior students in the lab, and to gage the overall productivity of the lab. At the same time, the potential mentor is evaluating the student's capabilities. Since the rotation is time-restricted, the potential mentor gives the student a well defined project whose experimental aims can be reasonably completed within the allotted time. Depending on the lab size and the prior experience of the rotation student, the mentor may provide minimal to extensive guidance for the student by pairing him/her with a more senior student. Another benefit to these rotations is that it enables the student to compare and contrast different lab cultures and mentoring personalities prior to making a long-term commitment.

**… given the critical role of a mentor, how should graduate students go about making this decision?**

## PERSONALITY CONSIDERATIONS

Perhaps one of the most important things to consider is that the personalities of the mentor and mentee be compatible. This is obviously something that is difficult to gage, but hopefully, the graduate student will get a feel for this during the rotation period. The student will be working very closely with the mentor for a period of, on average, four to six years. During this time, there will undoubtedly be many peaks and valleys in the student's research project that will be much easier to weather if the student's personality is somewhat compatible with the mentor's.

## SCRUTINIZE THE PUBLICATION RECORD

Because the student will only rotate through a handful of labs, they should select only those labs whose research truly intrigues them. Often, the graduate school will hand first-year students a list of "open" labs — meaning these principal investigators (PIs) have the room and time to accommodate rotation students. Students should review this list, read the research briefs for each professor and pre-select a number to investigate further. The next step is to look at each PI's publi-



Jennifer Sbrogna, Ph.D.

cation record on PubMed, the online database of medical literature, and assess the PI's overall productivity (i.e., how many articles/year) and the quality of the journals they publish in. This is one of the most critical steps a graduate student can take in choosing the right mentor. If a PI publishes frequently, but only in bottom tier journals, then it's probably better to go with the PI who publishes a little less frequently but in highly respected journals like Cell or Science.

## EXPLORE THE CULTURE OF THE LAB

Once entrenched in their first rotation lab, students should get a feel for the lab culture. By observing the relationship between the PI and the students, they can predict the type of mentoring they would receive if they chose this mentor. They should assess whether the other students generally seem happy in the lab and if they feel their mentor is adept at teaching and managing them. While these two skills are an integral part of successful mentoring, ironically, mentors are scarcely ever formally trained in either one. The best way to identify those rare mentors who possess both these qualities is to ask their current graduate students. In general, if the graduate students are happy and productive in their work environment, then they're most likely fortunate enough to have mentors who are good teachers AND good managers. Students should also ask the senior students in the lab how they would describe their relationship with the PI. Are they satisfied with their research projects and with the feedback they get from the PI? Are there frequent lab meetings? If so, does each student get a chance to present his/her progress and is the feedback constructive?

A final thing to evaluate during the rotation period is the average amount of time it takes students to graduate from this lab. Do the PI and the student seem to agree on the timeframe for graduation? They should also ask where former students of this PI end up — are they in well placed positions that will serve as springboards for their future careers? Of course, if this PI has a competitive publication record, then one can assume the graduate students will be able to pursue competitive postdoctoral fellowships in either academia or industry.

## DOES THIS MENTOR HAVE LONG-TERM FINANCIAL SUPPORT?

Most potential mentors will tell a graduate student at the beginning of their rotation whether or not they have "space" for them in the long term. The word space may be used to describe whether they can physically accommodate this graduate student (i.e., bench space, desk, and other supplies) and whether or not they can fund this student. If a mentor fails to mention how well the lab is funded, don't hesitate to ask them directly. They expect this question to be asked and will certainly understand if a student does not choose their lab due to insecure funding.

## OTHER CONSIDERATIONS

The overall size of the lab often dictates how much one-on-one interaction a graduate student can expect to have with the mentor. In general, smaller labs enable mentors to spend more time with their graduate students and may even allow the mentor to personally train students on certain techniques. Larger labs often result in fewer and shorter individual meetings with the mentor. Regardless of lab size, students should consider whether or not there are weekly lab meetings where students present the ongoing progress of their projects. If there are regularly scheduled lab and individual meetings, then students will most likely get consistent and frequent guidance from the mentor. This level of interaction between the student and the mentor will significantly enhance a lab's "training potential," a term that is used by NIH review committees to assess the overall level of intellectual stimulation and the breadth of techniques a scientist will be exposed to in a given lab.

A student also needs to consider whether or not the faculty member is tenured. There are advantages and disadvantages that fall on either side of this status. Tenured mentors have seniority and stability. They've already proven themselves to the scientific community and to the university so they're more likely to have clout and will be able to help you network — something that is very important for a budding scientist's career. On the flip side, while non-tenured mentors may lack the security of tenure, they're usually extremely motivated and will push their graduate students to publish in top tier journals since they only have a short period of time to prove themselves before tenure review.

In sum, graduate students should take the responsibility of choosing a mentor very seriously. They should rotate in labs whose research and productivity impress them, familiarize themselves with the different mentoring techniques of each PI, and survey other students for feedback on the lab and the PI. If they approach this process with their eyes wide open, they should be able to find a mentor who will inspire them to ask important scientific questions and will empower them to achieve intellectual independence and success throughout their scientific careers.

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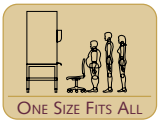


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# Dangers of Mycoplasma in Cell-Based Assays

WHILE OTHER COMMON TYPES OF CONTAMINATION ARE USUALLY QUICKLY IDENTIFIED AND/OR TREATED, MYCOPLASMA CONTAMINATION OFTEN PROVIDES NO CLEAR SYMPTOMS BUT CAN WREAK HAVOC ON ASSAY RESULTS.

Cell-based assays have become a vital tool for drug discovery and an emerging trend in other markets as they allow scientists to study true cellular responses and behaviors under conditions that mimic the cell's natural environment. Much attention has been focused on further miniaturization and increased sensitivity of these assays; however, one critical and basic element of cell-based assays must not be overlooked or underestimated — the dangers of mycoplasma contamination.

Treatment for mycoplasma contamination is laborious, costly, and at times ineffective; in fact, many choose to dispose of the cells completely and start with a new culture. In order to effectively prevent and contend with this threat, it's important to understand what mycoplasma is and how it affects cell cultures.

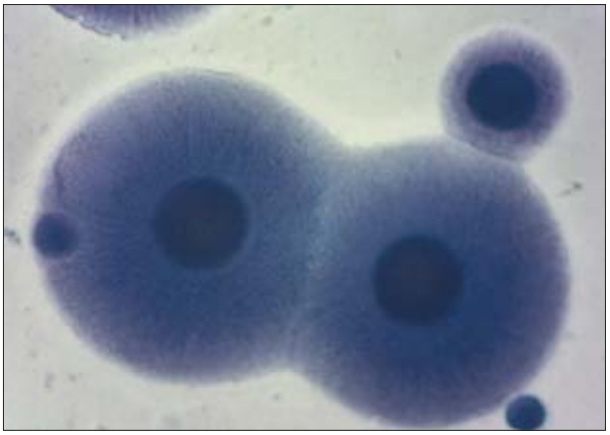
**Even in the protective environment of a laminar flow hood, airborne particles and aerosols can result from pipetting, dust in protective garments, dry, flaking skin, or even talking or sneezing while working around cell cultures.**

## DEFINING MYCOPLASMA

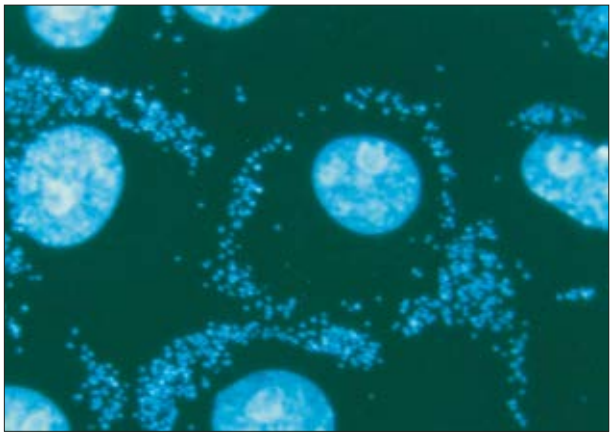
Mycoplasma are classified as prokaryotes with several unique properties that distinguish them from other prokaryotes. They lack a cell wall, instead using sterols, especially cholesterol, from vertebrate hosts to maintain their plasma membrane. Therefore, they are unaffected by antibiotics that interfere with the murein formation of cell walls. It also means that mycoplasma do not overgrow their host cells but in fact bind with cell walls to obtain nutrients. As they are extremely small (0.15–0.3 μm), these organisms are difficult to filter out of suspension, and can grow to particularly high concentrations in mammalian cell cultures without producing turbidity or other obvious symptoms.

Mycoplasma grow very slowly as they infect the cell culture. Nonetheless, this can have a serious effect on the host cell's metabolism. Unexpected alterations can develop in growth, metabolism, function, secretion and synthesis, and expression of the host cell. Additionally, damage can occur to the host cell's membranes, DNA and RNA, and other intracellular organelles. All of this can lead to skewed and/or inaccurate data and, if not recognized as a mycoplasma infection, can seriously compromise the validity of the final product or study results.

Paul Held, Ph.D.



Direct culture method of mycoplasma colonies on agar. Courtesy of Bionique Testing Laboratories.



DNA Fluorochrome (Hoechst) staining assay binds to and reveals the large nuclei of cells in culture as well as the small mycoplasma surrounding the cells. Courtesy of Bionique Testing Laboratories.

## METHODS OF TRANSMISSION

The most widespread methods of mycoplasma contamination are cross-contamination of healthy cells with infected cultures and poor aseptic technique.

Cross-contamination can occur when untested, infected cells or media materials come into contact with a clean cell culture. Previously infected cells can come from other research laboratories as shared research, donations or gifts, or from commercial suppliers. Cross-contamination can also occur in conjunction with poor aseptic technique via aerosolization during routine handling of cells. Even in the protective environment of a laminar flow hood, airborne particles and aerosols can result from pipetting, dust in protective garments, dry, flaking skin, or even talking or sneezing while working around cell cultures. Mycoplasma contamination can often be recovered from equipment and media bottles used in a hood and even the internal surface of the hood several weeks after exposure to the contaminants.

Another example of poor aseptic technique that can result in mycoplasma contamination is the handling of supplies and equipment. Improperly sterilized or stored consumable supplies, media, or other materials may become contaminated before or during use. Materials and equipment stored in laminar flow hoods can disrupt air flow patterns, and increase surface area for potential mycoplasma contamination. Incubators with integrated fans and air currents created during opening and closing of the internal incubator door may spread mycoplasma-containing particles. Water baths, waste containers, and even cooling coils on refrigerators and freezers are major and often overlooked sources of mycoplasma contamination.

While sera and other animal-derived products, historically a common source of mycoplasma contamination, have improved dramatically in quality, they cannot be automatically eliminated as a source of contamination, especially if they are from an unknown or questionable manufacturing source.

## PREVENTION

The single most important factor in prevention of contamination is proper aseptic cell culture technique. This reduces the risk not only of mycoplasma infection, but bacterial, viral, chemical, and other contaminants as well. The following guidelines can help to reduce the risk of contamination.

## REDUCE AEROSOL GENERATION AND AIR-FLOW PATTERNS

Wear dedicated personal protective equipment to shield cells from aerosol and debris contamination caused by street clothes, skin, hair, and even breathing. Clear work surfaces and laminar flow hoods of all clutter and storage boxes, and thoroughly clean with a suitable disinfectant between uses, and only use these surfaces and hoods for one cell line at a time. Laminar flow hoods should continually run unless they won't be used for extended periods of time. To

reduce turbulent airflow in the laboratory, the number of people in the laboratory should be as few as possible.

## INCREASE ATTENTION TO DETAIL

Maintain and separately store media and reagents for each cell line and clearly label to eliminate any doubt or confusion. Clearly label the cell lines as well and test prior to and after freezing in a cryogenic cell repository to ensure that they are free from mycoplasma contamination. Additionally, rotate the frozen stock periodically to reduce dependence on the active cell culture. Clean, service, and calibrate incubators, water baths, environmental monitoring tools, and other equipment at regular intervals. Similar attention to care and cleaning should apply to the surrounding environment, including areas behind and underneath equipment, storage shelves and cabinets, and even low-traffic sections of the laboratory.

## PERFORM ROUTINE TESTING

Test, test, and test again! Cell cultures should be tested for mycoplasma contamination on a regular basis, depending on the needs of each laboratory. Media and reagents should also be subject to rigorous testing prior to use. Any new cells, media, or reagents should be quarantined until they have tested free from mycoplasma contamination. Even equipment and work surfaces should be monitored and tested for exposure to mycoplasma.

## CONSIDER THE HUMAN FACTOR

Unwavering perfection is just not practical; accidents due to human nature are often unavoidable. Mistakes are much more likely to happen when operators are inexperienced, feel stressed, overworked, distracted, or rushed. Proper and repeated training sessions educate personnel on correct aseptic technique in cell culture, and also keep the lessons and skills learned top of mind. Additionally, being mindful of and focusing on

the tasks at hand can prevent countless errors.

## USE OF ANTIBIOTICS

Subject to occasional controversy, antibiotic use in cell culture can provide a benefit to preventing or eliminating bacterial contamination. However, when overused, antibiotics can provide a false sense of security and mask mycoplasma contamination. It can also promote resistance, even to antibiotics specifically targeted for mycoplasma infections. Antibiotics should be used with great care and only when absolutely necessary.

## MYCOPLASMA DETECTION METHODS

There are a number of mycoplasma detection methods that fall into two broad categories: direct testing and indirect testing for specific mycoplasma characteristics. Direct culture testing is the most sensitive method of cultivatable mycoplasma detection but also the most cumbersome and time-consuming; results can take up to four weeks. As it requires live mycoplasma controls, many laboratories prefer to reduce risk by using an outside testing facility.

Indirect methods, including biochemical and fluorescent assays, nucleic acid hybridization, immunoassays, and polymerase chain reaction (PCR) can detect both cultivatable and noncultivatable mycoplasma strains in much less time than direct methods. Biochemical and fluorescent assays are quick and user-friendly tests that measure mycoplasma enzyme activity. Results can be easily analyzed and documented via a multi-mode microplate reader in 30 minutes or less. Nucleic acid hybridization uses a chemiluminescent label to detect ribosomal RNA from mycoplasma; tests take over an hour to complete. Fluorescent assays require a microscope with particular UV filters to detect mycoplasma DNA, results are provided within 24 hours. Immunoassays measure specific mycoplasma antibodies, and deliver responses within hours, but must be type-specific. Finally, PCR protocols using primers to amplify ribosomal RNA from mycoplasma are highly sensitive and rapid, with results in about two hours, but involve complex handling protocols and may produce false positives.

The combination of a direct culture with an indirect test is recommended to ensure accurate results.

## REMEDIATION FOR CONTAMINATED CULTURES

If a culture is inadvertently contaminated with mycoplasma, two solution options are available. The first option, quick and easy, is simply to autoclave the culture, dispose of it, and start with a new culture. The second, riskier option is to treat the culture with specific antibiotics or other chemicals that are toxic to mycoplasma but safe for cells.

Proper antibiotic treatment should kill mycoplasma rather than inhibit growth. Unfortunately, complications can arise due to antibiotic resistance, cellular toxicity, or cytotoxic side effects to the cell culture itself. Most typical cell culture antibiotics are not effective against mycoplasma contamination but other types have shown success in eliminating mycoplasma from cell cultures. Ciprofloxacin, BM-Cyclin and quinolone derivatives provide reasonable mycoplasma elimination rates but none are proven to be 100% effective.

Non-antibiotic treatments can target mycoplasma by damaging the plasma membrane. However, they may also have cytotoxic effects to the cell culture, and to be effective must come in direct contact with the mycoplasma organism; reduced effects may be seen in adherent and clustered cells.

## SUMMARY

Cell-based assays are increasingly valuable as they offer more functional information than any other methods to date. As researchers strive to produce more effective results in less time, focus must not be diverted away from the hazards of mycoplasma contamination. As the most significant cell culture contaminant in the world, prevention, early detection, and successful eradication of this hazard is crucial to accurate and streamlined research.

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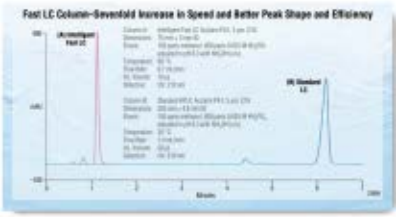


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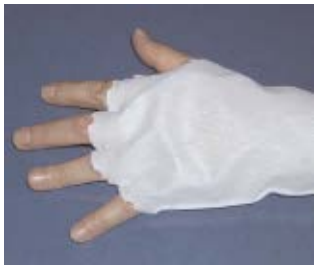

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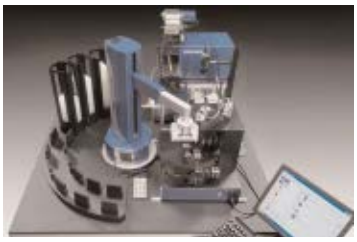

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Molecular Devices
www.moleculardevices.com

# lab agenda

MAY 16–17, 2007
IMACS 2007
International Meeting on Automated Compliance Systems
Princeton, NJ
www.imacs-world.com

MAY 17, 2007
"How to Discipline Employees—Comfortably" Web Conference – 1:00 PM EST
www.viconpublishing.com/audio.asp

MAY 21–25, 2007
ASM 107th General Meeting
American Society for Microbiology
Toronto, Canada
www.asm.org

JUNE 3–7, 2007
55th ASMS Conference on Mass Spectrometry
American Society for Mass Spectrometry
Indianapolis, IN
www.asms.org

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

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

JULY 15–19, 2007
AACC Annual Meeting & Clinical Lab Expo
American Association for Clinical Chemistry
San Diego, CA
www.aacc.org

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

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

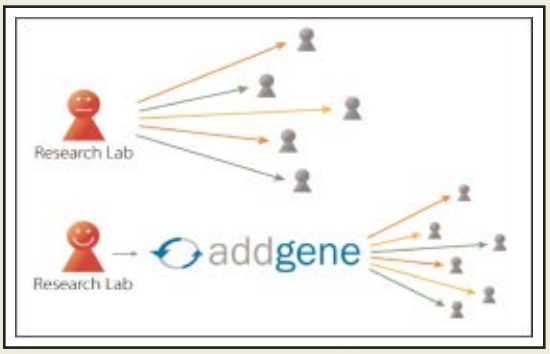
AUGUST 20–24, 2007
Forum on Laboratory Accreditation
Joint Meeting of The NELAC Institute and the National Environmental Monitoring Conference
Cambridge, MA
www.nelac-institute.org

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

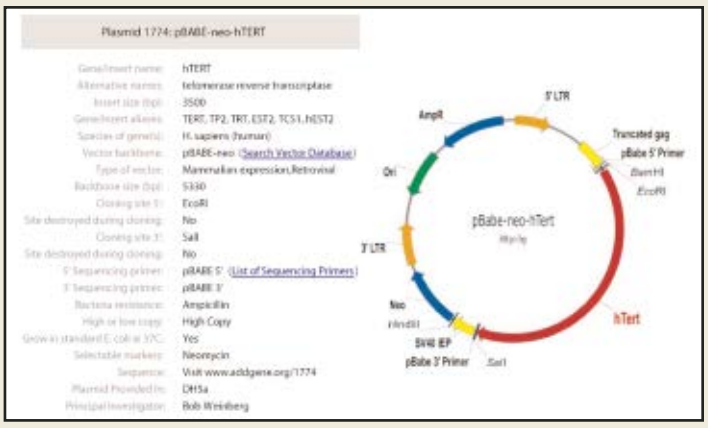
OCTOBER 25, 2007
Lab Manager Boot Camp
Lab Manager Magazine®
Waltham, MA
www.labmanager.com

# How it Works

## Save Time Sharing Plasmids




**Addgene distributes a lab's plasmids to requesting scientists.**




**Sample page of a plasmid deposited at Addgene.**

**Problem:** A research lab must send its plasmids to other labs upon request, but the task is often time-consuming for lab managers. It can be difficult to locate plasmids and their information, and the process takes time away from other tasks.

**Solution:** Addgene is a non-profit organization dedicated to the sharing of plasmid constructs described in published literature. Addgene collects plasmids and distributes them on behalf of labs.

Depositing plasmids at Addgene can save time. Once plasmids are deposited, the lab manager will no longer have to spend time finding, packaging, and shipping plasmids. Instead, the principal investigator can simply respond to plasmid requests with an email directing them to Addgene's website. Members of a lab can track which researchers have requested their plasmids. There is no cost to deposit plasmids.

Addgene makes all plasmid information available through its website, so scientists have easy access to the data they need. Published plasmids are linked to the article in which they were described, so further information is easy to find. Scientists who obtain plasmids through Addgene are asked to acknowledge the depositing lab in publications arising from the use of the plasmids.

For plasmid requests, Addgene charges a $65 fee in order to cover operational costs. Scientists usually receive their plasmids within a few days of placing a request. Addgene aims to make their plasmids as widely available as possible, so discounts are available for labs that cannot afford the fee.

Since its inception in 2004, Addgene has received overwhelmingly positive support. Scientists from institutions around the world, including Harvard, Stanford, the NIH, Kyoto University, and EPFL (Switzerland), have deposited plasmids. Addgene satisfies the NIH resource sharing requirement and is recommended by over 20 top-tier journals. Addgene has already received over 4,500 plasmids from depositing scientists and shipped over 30,000 plasmids to requesting scientists.

For more information, visit www.addgene.org or email deposit@addgene.org.

# news notes

## CHEMISTRY LAB EXPERIMENTS USING MICROWAVE

CEM announced the release of a new undergraduate chemistry laboratory manual, *Clean, Fast Organic Chemistry*. This manual teaches students the methods and more complex chemistries that they will use after graduation, including reactions that cannot usually be run in undergraduate classes due to time constrictions.

*Clean, Fast Organic Chemistry*, written by Cynthia B. McGowan, Ph.D., Associate Professor of Chemistry at Merrimack College, and Nicholas E. Leadbeater, Ph.D., Assistant Professor of Chemistry at the University of Connecticut, contains eleven experiments that will guide students through the execution of organic reactions under faster, safer, environmentally friendly microwave conditions. Experiments that originally took hours or even days now only take minutes. Reducing reflux times gives students more time to design, optimize, characterize, and analyze reactions processes and products.

Microwave energy also serves as an environmentally friendly alternative. Most reactions in the manual can be performed in aqueous solutions, rather than organic solvents, resulting in "greener" chemistry. The manual is available at www.cem.com or by calling 800-726-3331.



## NAOSMM HOSTS SUMMER MEETING

The 34th Annual National Association of Scientific Material Managers (NAOSMM) meeting will be held in Cleveland, OH, July 30 – August 3. Seminars are geared specifically towards lab managers, material managers, and purchasing managers. Visit www.naosmm.org for more details or contact Joanne Brown at jcbrown@haverford.edu.

## EXTREME PIPETTING EXPEDITION

To demonstrate the impact of environmental conditions on pipetted volumes, ARTEL launched the Extreme Pipetting Expedition. During this year-long scientific study, ARTEL will visit locations with extreme ranges of common laboratory conditions, such as high and low temperature, humidity, and barometric pressure. Pipette performance will be measured at each location to identify the resulting volume variability. At Mount Washington (altitude 6,288 feet) in the White Mountains of New Hampshire, the pipettes were found to under-deliver by up to ten percent. The data highlight the importance of verifying and calibrating pipettes in actual environmental conditions for optimal laboratory liquid handling operations and accurate data. Log onto www.artel-usa.com/extreme to view the data and to suggest locations and environmental conditions to be explored in the next phase of the study.

## NEW METABOLOMICS WEBSITE

Agilent Technologies announced a metabolomics initiative featuring a new website, the METLIN Personal Database and a portfolio of metabolomics systems. The site, www.metabolomics-lab.com, features resources for researchers around the world, including audiocast scientific talks and links to key scientific databases, seminal journal papers, and fellow researchers' sites.

"According to recent market surveys, it's estimated that the metabolomics market will increase in size and revenue from $38 million in 2002 to an estimated $225 million by 2010," said Agilent's Rick Carberry, senior director, LC/MS Marketing. "Future growth will be driven by biomarker discovery services, the application of bioinformatics/chemometrics, and the development of technology platforms, leading to a market size of over $2 billion by 2012."

## WATERS AND HITACHI COLLABORATE ON CHROMATOGRAPHY INTERFACE SOFTWARE

Waters Corporation and Hitachi High-Technologies Corporation announced their intent to develop a software interface for Hitachi's Liquid Chromatograph Instruments "LaChrom Elite" Control for Waters® Chromatographic Data Station Software Empower 2. It is anticipated that HHT will develop and sell an interface for the Waters Empower® 2 chromatography data software (CDS) in combination with its own line of liquid chromatography systems in the North America market.

# Search Firms: Transition-Minded Lab Managers Pounce On Opportunity

These are good days for executive recruiters. And these are also good days for lab managers who aspire to more responsibility and higher pay.

That's because, in the words of one search firm executive, exceptionally qualified senior-management candidates are a precious resource akin to "the new oil," because they remain "hard to find, difficult to extract and difficult to deliver."

But aside from that anecdotal evidence of the remarkable resurgence of executive-level recruiting activity, consider the fact that U.S. search firms posted their third consecutive year of double-digit revenue growth in 2006, and that, according to recent ExecuNet research, more than one-half of them are hiring more professional staff to keep pace with corporate demand for executive talent.

The forces of sustained globalization and increased competition for the world's best lab and management talent are applying upward pressure on executive search firm fees. They're also escalating pay packages, which itself is fueling the growth of headhunters' revenue because of how their fees are tied to placed candidates' first-year compensation.

And given the increasing competition for top talent, executive recruiters' fortunes appear to be poised for significant growth for a long time to come.

Demand for management talent is beginning to outstrip supply, and search consultants' influence on corporate performance is growing. Recruiters are exceptionally confident in the U.S. economy's ability to fuel additional management-level hiring over the next several months. So this looks like another banner year for executive recruiters and any lab manager who has been contemplating a career move.

It might also be a good year for any hiring organization looking to expand the depth of its lab talent, but as always, the engagement of search firms is all about caveat emptor. That's because there is a lot about the business of executive recruiting that deserves a second look, if not complete transformation.

The fact is that, despite their broad acceptance as a necessary business partner to many of the world's largest and fastest growing companies, search firms' corporate clients are no more satisfied with the outcome produced by their external search engagements than they were decades ago.

Executive recruiters have long profited from hiring organizations' lack of succession planning and unsophisticated approach (in many cases, I'd call it utter incompetence) when it comes to selecting, engaging and evaluating their executive search partners.

Today, more companies are indeed beginning to wake up to the realization that they would be better served by a well conceived management succession process, programs to develop "high potential" lab leaders from within their ranks, but they're generally still in the dark when it comes to maximizing their return on investment in external lab talent recruiting.

Smart executive recruiters will take time from their busy work these days to educate their corporate clients about how to effectively approach executive recruitment, how to be a good client and how to successfully integrate a new lab manager into their organization.

**What It Means For Your Career:** The bottom line here is that because of



Joseph Daniel McCool

the confluence of baby-boomer retirements, a general lack of succession planning and an economy that points to continued economic expansion, it's quite possible you may get a call from an interested recruiter between now and the end of the year. But would you know how to respond to such an overture? First, it's important to realize that few recruiters would actually call to offer you a job. Far more likely is their expression that you have surfaced — along with several others — as a potential 'good fit' to a new lab management opportunity they may have been contracted to fill. If you do get the headhunter's call, don't get too excited. Just figure out whether they're trying to recruit you, use you as a reference, or simply glean information from you. And don't expect too much from the process, since not every recruiter knows to treat the job candidate with sufficient goodwill, tact, and dignity. But do try to learn something from the experience, because if you're as good as others say you are, you can expect a lot more calls from recruiters in the years to come.

***Joseph Daniel McCool*** *is a sought-after writer, speaker and independent consultant on talent management, executive recruiting best practices, and corporate leadership succession. He is currently writing a book about the global executive search consulting business and its impact on corporate performance, culture and profits. He is the former editor of Kennedy's Executive Recruiter News and Recruiting Trends, and his perspectives on recruiting best practices have been cited in BusinessWeek, The Economist, The Financial Times, The Wall Street Journal and other media around the world. Contact him at JoeMcCool@comcast.net.*

# Applying Universal HPLC Detection in Pharmaceutical Development and Manufacturing

Pharmaceutical development and QC scientists have utilized a mixture of older technologies (low wavelength UV, refractive index, ELS, and mass spec) in attempts to come up with an HPLC detection scheme that would give the universality, sensitivity, dynamic range, consistent response, and reproducibility necessary for handling the wide range of detection problems they face on an on-going basis. Development of a truly universal HPLC detection scheme was not possible due to detection technology limitations (dependence on chromophores for detection, lack of dynamic range, problems with measuring weak or non-UV chromophore molecules existing as impurities or degradents, APIs, product intermediates, or formulation components). Coupled with the need to measure classic non-UV absorbing molecules, such as lipids, phospholipids, and sugars for excipient packages, detergents, and surfactants for cleaning validations, many pharmaceutical development groups struggle with unsolvable analytical problems given their existing analytical capabilities.

A universal HPLC technology, charged aerosol detection, is being used to overcome these analytical problems for:

- analytical method development and method transfer for APIs
- degradation studies
- impurity testing
- formulation and excipient characterization
- cleaning validations

## METHOD DEVELOPMENT AND TRANSFER

Most pharmaceutical development laboratories rely on two types of HPLC detectors for the bulk of their method development — UV and RI detection. However, virtually every laboratory has encountered an API with weak or non-existent chromophores necessitating the use of low wavelength UV methods (absorbance at 205–230 nm). While methods to measure poor chromophore molecules can be developed, they are relatively insensitive and can suffer from high background or poor signal:noise ratios. When the molecule has no chromophore, typically only RI can be used which has limitations in terms of sensitivity, chromatography compatibility (no gradients), and detector equilibration. With current detection technologies, poor or non-chromophore API molecules lead to the development of sub-optimal detection methods, which in turn lead to poor results in a development and manufacturing operation.

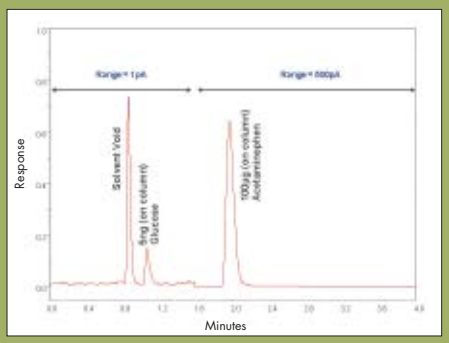



Figure 1. Analysis of poor chromophore steroids by charged aerosol detection.

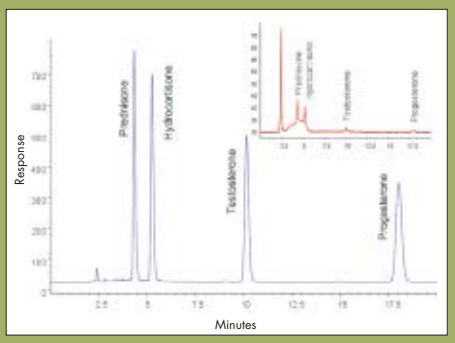



Figure 2. Changing attenuation to measure low level impurty (0.005%)

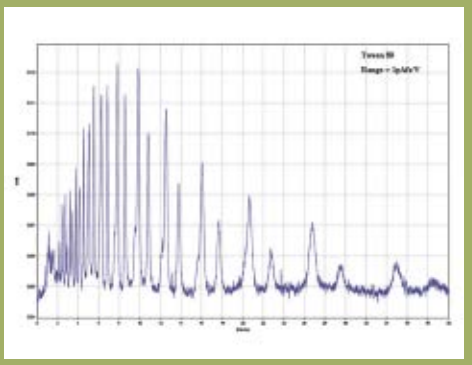


Figure 3. Detection of Tween 80 at 1:1000 dilution by charged aerosol detection. (Tween 80 range = 1 pAfs/V)

Darwin Asa, Ph.D.

Using charged aerosol detection technology, poor and non-chromophore API molecules, such as steroids and -mycin class antibiotics, are easily analyzed (Figure 1).

## DEGRADATION STUDIES AND IMPURITY TESTING

Scientists performing degradation studies or impurity tests on APIs either alone or in combination with an excipient package are currently limited by their use of UV or RI detection methods. One of the most important measurements in a degradation or impurity study is the measure of the relative amount of a degradent in the study. UV detection is commonly used for these types of studies, as RI lacks the sensitivity necessary to see the low-level impurities or degradents present. However, UV detection suffers from a major problem in that many degradents and impurities have extinction coefficients significantly different from the API being considered. Therefore, the UV wavelength selected for the API may not be appropriate for measuring the degradents or impurities produced in a study and some degradents or impurities may lack chromophores entirely. Because of this dependence on a structure/response-dependent detector like UV, scientists can routinely over or under predict the level of degradents or impurities present and have problems determining an accurate ratio of degradent or impurity to API and overall mass balance for the degradation or impurity study itself.

These serious issues in degradation and impurity studies are resolved using charged aerosol detection since the technique's response is relatively independent of chemical structure, so all molecules respond relatively the same. It also has the necessary sensitivity and dynamic range to perform these trace analysis applications which allows for a much more accurate relative assessment of degradents and impurities relative to an API, and a better general accounting of mass balance of the overall sample. The data in Figure 2 demonstrates the ability to accurately measure as little as 0.005% levels of a relative impurity.

## EXCIPIENT CHARACTERIZATION AND CLEANING VALIDATIONS

Another key problem is the need to quantitate molecules, at both low and high levels, that completely lack any UV chromophore. Classic examples are molecules routinely used as excipients in pharmaceutical formulations, such as PEGs, lipids, phospholipids, sugars, oligosaccharides, ions, etc. or detergents and surfactants used for cleaning and sanitizing operations, such as polysorbates, Tween, Triton, etc. Measurement of these molecules is done using RI. RI is limited in sensitivity and limits the chromatography that can be employed as it is not compatible with gradient methods. Other HPLC detection methods, such as ELS, have a limited dynamic range, sometimes inadequate sensitivity, poor reproducibility, and are difficult to deploy in a manufacturing environment due to their considerable calibration and maintenance needs. Using charged aerosol detection, the ability to measure even low levels of these difficult to characterize molecules is possible. The data in Figure 3 demonstrates the detection of low levels of a commonly used surfactant, Tween 80.

## CONCLUSION

Charged aerosol detection provides universal detection of any non-volatile molecule, low ng on column detection sensitivities, a response independent of chemical structure, a 4+ order of magnitude dynamic quantitation range from ng to µg, and excellent reproducibility with RSDs < 2%, even at low detection levels. The combination of these key attributes in a single HPLC detection platform allows scientists in pharmaceutical development and manufacturing QC operations to replace older existing technologies and use charged aerosol detection in key decisions about their samples that can have profound implications for their institutions.

***Darwin Asa, Ph.D.*** *is Marketing Director for ESA Biosciences, Inc., 22 Alpha Road, Chelmsford MA 01824; 978-250-7194; dasa@esainc.com.*

### *Project Planning Checklist*

*Before you start your next project, be sure that the planning stage has really set the stage for success. More of a questionnaire than a checklist, Project Kick Start offers organized groupings of questions that cover the pessimistic ("What mistakes can we learn from? What's the worst that could happen?") to the practical ("What training do we need? Where do we get it?"). While they also offer project planning software for sale, the checklist is free and available to copy, paste, and customize at www.projectkickstart.com/html/triggerlist.htm.*

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*The survey will be sent out via email in the upcoming weeks. Participate in the survey and read the results in the August issue!*

Glenn Ketcham, CIH and Vince McLeod, CIH

# Understanding MSDS — the foundation of safe chemical management

Regular readers will recall our previous article was the first in a series on managing chemicals. And those folks with total recall might remember that a good system for chemical management begins with a complete inventory of the laboratories' chemicals and a collection of MSDS for those materials. This column will explain what an MSDS is, what information it contains, and how to best use that information.

MSDS is an acronym for material safety data sheet. The purpose of the MSDS is to inform chemical users of the hazards that may be encountered with their use. Both the Occupational Safety and Health Administration (OSHA) and the Environmental Protection Agency (EPA) have published regulations dealing with MSDS. However, most chemical products packaged for consumers and general household use are exempt from these requirements. We will focus on the OSHA regulation as it applies to all employers and their workplaces. First a little history.

## MSDS HISTORY AND REGULATIONS

In the 1940s, the Chemical Manufacturers Association (CMA) began producing Chemical Safety Data Sheets for many chemicals used in commerce. These were very detailed in their coverage; the longest of which was some 46 pages. CSDS are no longer produced or supported by the CMA.

In 1985, the OSHA Hazard Communication Standard (29 CFR1910.1200)[1] became effective requiring manufacturers and distributors to provide MSDS to their customers. In 1987, this was expanded to "all employers with employees exposed to hazardous chemicals in their workplaces." The OSHA definition of a hazardous chemical is broad—"any chemical which is a physical hazard or a health hazard." We do not know many chemicals that would not fall into that definition, do you?

Although the HCS does not require a particular format for the MSDS, it does specify what information must be included. This is the focal point of this month's column.

Since the Hazard Communication Standard does not specify a format for MSDS, wide variation existed in the order and completeness of the required information by the many different manufacturers and distributors. Recognizing this problem, the CMA worked on developing a voluntary guidance document in an effort to improve the completeness, accuracy, and consistency of MSDS. In 1993 the "American National Standard for Hazardous Industrial Chemicals-Material Safety Data Sheets – Preparation" (ANSI Z400.1-1993)[2] was published establishing an MSDS format containing sixteen sections.

## MSDS CONTENT

The ANSI Z400.1 format for MSDS incorporates all the information required under the OSHA Hazard Communication Standard (plus a few extras), is listed in a logical sequence, and has gained acceptance by most manufacturers and distributors. Thus, our discussion and comments on MSDS content will follow the ANSI design.

### Section 1: Chemical Product and Company Identification

The contents of this section are obvious; the chemical and/or product are named here along with the manufacturer or distributor and should include the company mailing address and telephone number. A key to this section is that it should relate the MSDS to the container label and shipping documents. Other useful information is a brief description of the chemical or product and its general use. Most companies will also give the date the MSDS was written or the date it was last revised.

### Section 2: Composition, Information on Ingredients

This important section identifies the hazardous components and amounts of each for the product. This is where you look to see what you are dealing with. The chemical abstract service (CAS) number should be given as this number provides positive identification of each component. The CAS number is important with the many different naming conventions and pseudonyms in use. This section also provides information on published exposure limits, if applicable, such as OSHA permissible exposure limits (PEL), American Conference of Governmental Industrial Hygienists (ACGIH) threshold limit values (TLV), and others like IDLH (immediately dangerous to life and health) limits. If any of the components or their amounts are trade secrets that must be stated here.

### Section 3: Hazards Identification

The material's appearance, odor and health, physical, and environmental hazards are listed in this section. The information here expands on the previous section providing details on each component's hazards, routes of exposure, symptoms for both acute and chronic exposures, and target organs for each exposure route. Information on flammability, reactivity, and proper personal protective equipment should also be given.

### Section 4: First Aid Measures

Instructions on emergency and first aid procedures are provided for each potential route of exposure, (e.g., inhalation, ingestion, skin, or eye contact). They should be concise and written in easily understood layman's language. If there are specific medical steps then a "Notes to Physician" section is provided for this information.

### Section 5: Fire Fighting Measures

Described here are the fire and explosive properties of the chemical or product components. The proper extinguishing media is given along with any special protective equipment needed and unusual decomposition hazards. Additional information such as flashpoint, autoignition temperature, and flammable limits in air are helpful depending on the chemical components.

### Section 6: Accidental Release Measures

Addressed in this section are the proper responses to any spill or leak of the material. The information presented is usually intended for emergency response personnel. It describes the personal protective equipment needed, any special precautions such as ventilation or evacuation, clean up methods, and environmental precautions.

### Section 7: Handling and Storage

This section and the following one are very important for laboratory personnel and chemical managers. This section contains guidance for minimizing potential hazards while handling and storing the material. Addressed here are requirements for types of containers and dispensing equipment as appropriate. Conditions to avoid, such as temperature extremes, secondary containment as well as work and hygiene practices should also be covered here.

### Section 8: Exposure Controls, Personal Protection

Discussed in this section are the engineering controls and personal protective equipment (PPE) to be used when handling the material. The need for any ventilation or special exhaust systems is covered along with requirements for eyewash and safety showers. Laboratory personnel should focus on PPE instructions that provide proper eye, hand, and body protection and when respiratory protection is needed.

### Section 9: Physical and Chemical Properties

Of particular interest to chemists, the information presented here assists users in determining proper PPE, handling, and storage. General appearance, odor, and physical state (liquid, solid, or gas) are given in addition to pH, vapor pressure and density, specific gravity, boiling point, and others depending on usefulness. Any warning properties (i.e., how to detect the substance via smell, taste, or feel) should be well noted.

### Section 10: Stability and Reactivity

Although more important for emergency responders, users should also be familiar with the information in this section which depicts potentially hazardous reactions or decomposition products. Examples include evolution of hazardous gases or production of heat if involved in a fire. Any incompatibilities that could lead to hazardous conditions should also be discussed here.

### Section 11: Toxicological Information

Information in this section is drawn from both animal testing and human experience and should include all known toxicities of the material. Included are both acute and chronic effects on skin, eyes, immune system, and reproductive system as well as from inhalation or ingestion. Data on irritancy, sensitization, and carcinogenicity should also be stated.

### Section 12: Ecological Information

Potential impacts should the product be released to the environment are presented here. Data on the expected environmental fate and whether or not degradation occurs is given along with effects on plant, animal, and aquatic life.

### Section 13: Disposal Considerations

Guidance given here is intended for use by technical people in evaluating waste treatment options and those responsible for waste management. Usually reference is made to follow all applicable federal, state, and local regulations.

### Section 14: Transport Information

This section provides information for shipping the material. In general, this means following the U.S. Department of Transportation (DOT) regulations contained in 49CFR172 and includes listing the proper shipping name, hazard classification number and description, UN identification number, proper labeling, and North American Emergency Response Guidebook number as applicable. Information on international shipping may also be given.

### Section 15: Regulatory Information

The chemical or product's regulatory status is presented in this section. Included are the reporting requirements, threshold planning quantities, release reporting quantities, and inventory status under the U.S. Superfund Amendments and Reauthorization Act (SARA); Comprehensive Environmental Response, Compensation, and Liability Act CERCLA; Toxic Substances Control Act (TSCA); and other federal and state regulations as applicable.

### Section 16: Other Information

This section is intended for material that does not fit into any of the preceding sections yet the preparer feels is pertinent. Usually included are the preparer's name and contact information, revision dates, references, and definitions of terms and acronyms.

As you can see now, MSDS are complex and take some work to understand. But if you make the effort to get to know the layout and information they contain, they can provide valuable information and be a reliable asset that you turn to in time of need.

## REFERENCES


1. http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10099 – online OSHA Hazard Communication Standard
2. American National Standard for Hazardous Industrial Chemicals – Material Safety Data Sheets — Preparation, ANSI Z400.1-1993. New York, American National Standards Institute, 1993.



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

***Vince McLeod*** *is a Certified Industrial Hygienist and the senior IH with the University of Florida's Environmental Health and Safety Division. He has 17 years of occupational health and safety experience in academic research with focus in the research laboratory. His specialties are in hazard evaluation and exposure assessments.*

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


***Think writing job descriptions are a waste of time or give employees an opportunity to refuse to do tasks that are not spelled out in black and white?***

*If you are uncertain about the value of job descriptions, About.com offers a few good reasons why it's worth the time to create job descriptions. These include:*

- *Job descriptions provide an opportunity to clearly communicate your company direction and they tell the employee where he or she fits inside of the big picture.*
- *Job descriptions set clear expectations for what you expect from people.*
- *Job descriptions help you cover all your legal bases.*
- *Whether you're recruiting new employees or posting jobs for internal applicants, job descriptions tell the candidate exactly what you want in your selected person.*
- *Well-written job descriptions help organization employees, who must work with the person hired, understand the boundaries of the person's responsibilities.*

*For more tips on writing job descriptions that work, go to humanresources.about.com/od/glossaryj/a/jobdescriptions.htm.*

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# Winning New Customers For Your Employer

What can laboratory staff members do to increase their employer's profits besides developing new manufacturing processes, new products, and new applications for existing products? How can lab managers encourage their staff members to increase their employer's business and provide opportunities for them to do so?

## THE TEAM APPROACH

Doing this often arises out of multi-disciplinary work teams. Product development teams often include more than just scientists, engineers, and technicians. Marketing managers, sales personnel, production chemists and engineers, logistics specialists, patent attorneys, and government regulation specialists often join laboratory staff members on teams. Team focus goes beyond research to include technical service, plant trials, and other issues associated with commercialization of new products.

These teams often include suppliers and customers as well as a firm's own employees. Many companies expect their suppliers to work with them to improve processes and reduce costs.

These R&D partnerships allow each participating firm to concentrate on their core competencies while going to other companies for help in solving problems. This allows each firm to focus rather than dissipate their efforts. Perhaps the highest profile example of this is the new Boeing 787 passenger plane development program. Boeing has gone to firms with expertise in materials science, electronics and other disciplines to form teams capitalizing on suppliers' expertise to expedite this multi-billion dollar product development program.

Often more than one supplier will participate in these teams. For example, a process equipment manufacturer and a chemical supplier may be team members with a mutual customer. Team members will need a variety of team skills (to be discussed in future articles). Supplier members in particular will need good interpersonal skills. Successful joint R&D programs can develop profitable new businesses for both the supplier and the customer.

Goal alignment between customers and suppliers is critical for both to derive maximum benefit from these teams. Customer and supplier must have a mutual understanding of both the joint team goals and the means of attaining these goals. This understanding will determine team membership, division of responsibilities, and team operating practices. These practices include how team members will communicate results, how often they will meet, and how the team will make decisions. These factors can be either determined by team members themselves or by project and laboratory managers.

## LEAVING THE LAB CONFINES

Lab personnel can help bring new products to the marketplace by participating in the first plant runs of new products and processes. This means working on scale-up teams with manufacturing plant engineers, chemists, and operators and often attending these plant runs. Also, lab personnel, particularly product applications specialists, can travel with sales personnel to discuss both new and existing products with potential customers. Such visits often include presenting seminars that describe products and their performance in the customer's applications.

To enable sales representatives to more effectively sell products, lab personnel can work with them to develop promotional materials such as product bulletins and seminars. This often involves coaching sales people so they can both give the presentation themselves and deal with customer questions and concerns without always referring them to lab personnel.

Should the customer decide to evaluate use of the supplier's product in their manufacturing process, both the supplier's and the customer's lab personnel can participate in plant trials. This participation can be crucial in terms of dealing with unexpected problems associated with using the product, optimizing the product's use, and demonstrating commitment to the customer.

John K. Borchardt

## GOING BEYOND SALES CALLS

Laboratory personnel can work with marketing personnel to develop strategies to bring information to potential customers that go beyond customer visits and plant trials. The most common strategy is oral presentations at trade association meetings and other conferences. These presentations describe product performance and are particularly effective when discussing case histories of the product's use. Usually given by lab personnel, these presentations may be prepared by lab staff members who then coach a marketing manager or sales representative in giving the presentation.

Working on conference organizing committees provides supplier personnel opportunities to become acquainted with potential customers and industry leaders. By knowledgeably engaging in technical discussions during these committee meetings, supplier personnel can demonstrate their technical expertise to prospective customers. Active participation in organization programming and governance demonstrates their people skills and commitment to the customer's industry.

Some suppliers staff exhibit booths at trade shows with lab personnel to provide expert answers to customer questions. Lab managers should encourage staff members attending conferences to assist in staffing trade show booths when not attending technical sessions.

Firms can go beyond presenting papers at conferences. They can take advantage of the capabilities of the Internet to present streaming video demonstrations of performance tests and other aspects of products on their websites. Lab personnel can work with programmers to prepare these electronic presentations.

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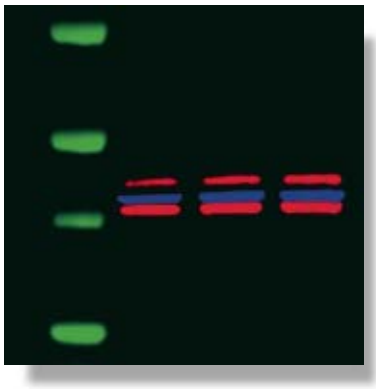


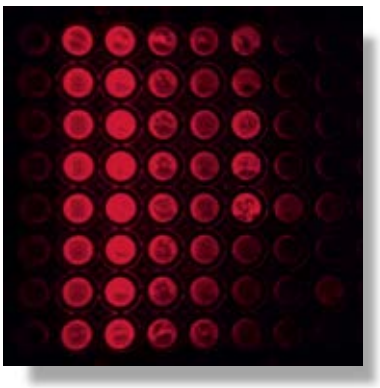


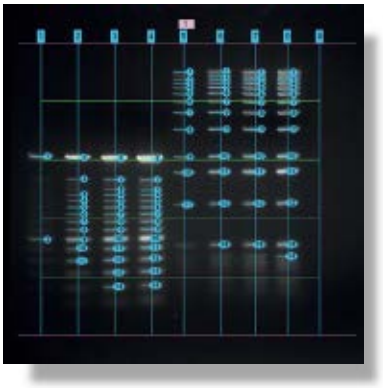

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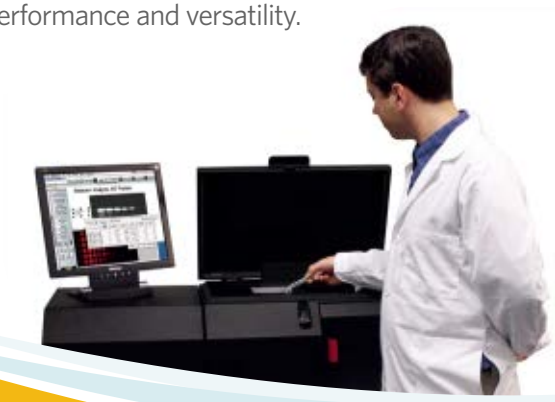

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