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Toot Your Own Horn

The stage beckons more scientists now. Scientific promotion was once an oxymoron. But as the global economic storm toys with the career dreams of many scientists, promotion is emerging as a 21st-century survival skill for the scientific community.

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Perspective On: A Cell Culture Lab

Though small, the cell culture lab at global product supplier Akron Biotech in Boca Raton, Florida plays a critical role in the company as a whole. The company specializes in the manufacture and supply of cell biology and cell culture products, so everything relies on cell culture to ensure those products are the best quality they can be.

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Even industrial R&D giants are finding they often lack all the necessary expertise in-house and are reaching out to suppliers, customers, universities, and government laboratories to establish partnerships in order to access the expertise and equipment they need to develop innovative new products and processes.

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Many companies have systems to deal with the alphabet soup of agencies and regulations that govern the handling and transfer of products and technology in the U.S. Yet few biotechnology companies have the compliance systems necessary to handle export control risks involved in their international operations.

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The mass spectrometry (MS) market continues to be one of the fastest-growing areas of analytical instrumentation. MS's growing popularity can be explained by its ability to provide, in many cases, verifiable molecular weights and thereby positive identification of known molecules.

Angelo DePalma, Ph.D.

HEALTH & SAFETY

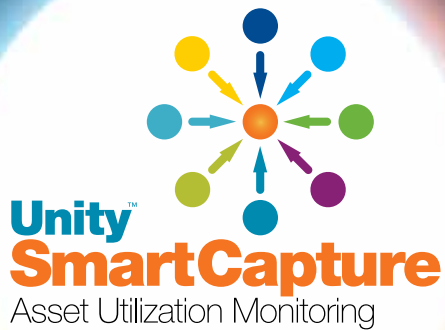
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Our Safety Guy guides you through conducting a meaningful laboratory safety survey with the intent of helping you set up and implement a successful in-house safety audit program in your lab.

Vince McLeod

LAB MANAGER SECTION GETS AN UPGRADE

Our December 2012 issue will see the last installment of the "Right Choice" section in *Lab Manager Magazine* as that feature will be replaced, beginning in our January/February 2013 issue, with a new piece called "Time to Upgrade?" Here we will focus on one specific technology each issue, interviewing experts about when lab professionals absolutely need to upgrade a piece of equipment in their labs and situations when it's best to stick with the model they currently have. We hope this new feature will help clear things up for lab managers who are uncertain about whether or not it's worth it to upgrade their current equipment and make their final decision a little easier. Our very first "Time to Upgrade?" will focus on fume hoods, so if you're considering purchasing a new model, you'll definitely want to check out that article in the new year.



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

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Boasting for dollars

In many quarters, bragging about oneself or one's accomplishments is considered bad form. Modesty and humility are the virtues most ascribe to. However, things have changed. Think of the dance some football players do in the end-zone after scoring a touchdown. And while watching such displays might make us wince, we have come to accept it from professional athletes. But for scientists to engage in such a display of hubris is unthinkable. However, that may need to change. This month's cover story makes the case that in challenging economic times, tooting one's own horn may be crucial to an individual's and a research institution's success. "Marketing, selling, promoting, positioning, branding — to some, these smack of vulgar business methods breaching and sully the sacrosanct integrity of science. But as researchers consider their options in a time of tight money and a job market where supply exceeds demand, the utility of promotional and marketing techniques exerts considerable appeal," says author Key Kidder.

Another long-accepted image of the scientist is someone alone in the lab, hunched over his or her bench or microscope, singularly toiling away to solve some scientific riddle or heretofore undiscovered mystery, with the operative word being "alone." So much for stereotypes. In this month's management article, "Teaming Up," author John Borchardt makes a case for partnering with other research institutions or with academia to improve individual research outcomes and business success. "Cross-pollinating various styles of thought, problem-solving approaches, and training is a powerful driver of breakthrough innovation," says Bernard Munos, an adviser in corporate strategy at Eli Lilly & Company.

Lab managers who don't understand the importance of lab safety compliance should probably rethink their career choice. And Vince McLeod should not need to — but does — remind us of that in this month's Lab Safety column: "A lab safety audit is a serious undertaking and preparation beforehand is paramount to success and ensuring your findings are ultimately useful." However, a less familiar compliance issue, and one that affects mostly U.S. biotechnology companies, is that of export control. "The U.S. government has national security interests in certain types of information and goods that may cross borders and exercises those interests through export controls. Understanding the export control rules related to products, equipment, and know-how is critical for U.S. biotechnology companies, and proper compliance is the only way to protect the company and its employees." Turn to page 26 to find out the consequences of non-compliance as well as what's required to change that.

This month we publish our second annual laboratory spending trends report in which academic, government and industrial lab professionals share their expected budget growth rates for 2013 as well as where those budget dollars will be going. While the picture is not entirely bleak, there is some cause for concern. "Survey participants are pessimistic about 2013, in good part because federal fiscal policy may become restrictive at a time that the economy still needs stimulus." But on the other hand, "While many respondents cite tight budgets and rising costs as negative factors affecting their labs, some positive factors also are cited. These include demand-generating factors such as emerging markets, green initiatives, increased emphasis on quality, legislative and regulatory issues, and an aging population." Turn to page 14 for the whole story.

With the threat of federal cuts to science and research, what does your lab anticipate and how are you preparing? Please share your thoughts and, yes, don't forget to vote.

Pamela Ahlberg
Editor-in-Chief

Correction: On page 90 of the October issue, we misidentified Proteintech's url. That should have been <http://whyitworks.ptglab.com/>

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Subscription Customer Service

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TOOT YOUR OWN HORN

AGGRESSIVE SELF PROMOTION JUST MIGHT BE THE SCIENTIFIC COMMUNITY'S SAVING GRACE by F. Key Kidder



A scientific star was born when the rover Curiosity descended through the Martian atmosphere in August. Viewers watching NASA's live feed were captivated as flight director Bobak Ferdowski guided the rover through "seven minutes of terror" to its final touchdown on the Red Planet. Bobak was dressed to kill—his Mohawk hairstyle sported red and blue highlights, offset with white stars bleached into the sides of his head.

"The Mohawk guy" was an overnight sensation. Tens of thousands of Twitter followers hung on his every tweet. President Obama hailed him for a job well done. In one fell swoop, he had achieved recognition and acclaim that can seem as unreachable as the furthest galaxy to scientists who labor in anonymity in labs around the world.

You don't have to be a rocket scientist to recognize a great career move when you see one. In his moment onstage, the Mohawk guy delivered. It was a surpassing stroke of self-promotion.

The stage beckons more scientists now. Scientific promotion was once an oxymoron. But as the global economic storm toys with the career dreams of many scientists, promotion is emerging as a 21st-century survival skill for the scientific community. University endowments are down and furloughs are up. Congress continues to tighten the purse strings of agencies funding research. There's an oversupply of post-docs and grad students chasing fewer jobs while senior scientists struggle to attract grants. The competition has never been fiercer.

Enter the "M" word

"In today's economic climate, lab managers regularly do great research that somehow fails to attract funding and support," says Marc Kuchner. "Marketing is often the tool they are missing."

Marketing, selling, promoting, positioning, branding—to some, these smack of vulgar business methods breaching and sully the sacrosanct integrity of science. But as researchers consider their options in a time of tight money and a job market where supply exceeds demand, the utility of promotional and marketing techniques exerts considerable appeal.

Kuchner is an astrophysicist and author of *Marketing for Scientists*, a practicum that spans the gamut of promotional methods old and new—standbys such as conferences, presentations, and posters, and the recent wave of social media and Web technologies such as blogging, Facebook, Twitter, etc.

Want to spruce up that old poster?

Try adding a bar code that re-directs scientists to your web site when scanned into their cell phone; several websites generate barcodes for free. Don't forget to use good visuals, which are retained much better than words. Timid about using Web 2.0 social media technologies? About one-third of scientists avoid the blogosphere at all costs, but it's a great venue for self-citation. Interested in knowing "Nine Scientifically Proven Ways to Get Re-tweeted on Twitter"? It's one sure sign of successful self-promotion.

"Scientists do things that are marketing, but we don't label it as marketing."

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Like others scientists, Kuchner was conditioned to reject promotional impulses and initially found marketing “bewilderingly nonintuitive.” Then he discovered that the practice “already threads its way through the fabric of today’s scientific and academic institutions.”

“Scientists do things that are marketing, but we don’t label it as marketing,” says Marlene Winkelbauer-Hurt, manager of the Reed cell biology lab at Harvard Medical School. “We don’t take marketing classes or learn about it from that point of view, but when we write a grant proposal, we need to state the results to fit the goals of the funders.”

“If it’s the worst of times for scientists in terms of funding, it’s the best of times to be of a mind to promote oneself.”

Kuchner contends that marketing is essentially the stuff of routine interpersonal commerce—nothing more than satisfying one another’s wants and needs, making connections. And as the funding bind continues to vex the scientific community, he believes his book will embolden lab managers to adopt a promotional, proactive approach to free up financial support and more—to attract talent, develop relationships and collaborations, and even shape public debate.

As director of marketing for Thermo Fisher Scientific, a leading laboratory supplier, Bill McMahon serves the global universe of lab managers. “There’s been a shift, in some ways generational and some ways by necessity,” he says. “More lab managers are curious about how to present themselves. They ask me about marketing, how to put some message out there.”

Others say the situation is reaching a tipping point: promote or perish.

If scientists “want projects to go forward... we have to learn how to ‘do’ marketing,” says John Mather, senior project scientist on the James Webb Space Telescope, named one of the 100 most influential people in the world in 2007 by *Time* magazine. “We have to learn it on the fly,” acknowledges Mather, “and don’t really know what we’re doing.”

That’s where Kuchner comes in, and he’s not alone in suggesting that scientific enterprise would benefit from a more aggressive promotional posture. Other books in a similar vein include *Am I Making Myself Clear?* by Cornelia Dean, *Don’t Be Such a Scientist* by Randy Olson, *Unscientific America* by Chris Mooney and Sheril Kirshenbaum, *Escape from the Ivory Tower* by Nancy Baron, and *Explaining Research* by Dennis Meredith.

If it’s the worst of times for scientists in terms of funding, it’s the best of times to be of a mind to promote oneself, says consultant and author Meredith. The Internet has “immense power to make each person a media outlet,” capable of readily creating and dispensing print, video, and audio content. There’s even The Science and Entertainment Exchange, a National Academy of Sciences program that mainstreams research by hooking scientists up with Hollywood as consultants for TV and films.

Not so fast, says Jim Austin, editor of *Science Careers*, a publication of *Science* magazine and the American Association for the Advancement of Science.

“On the one hand, a certain kind of self-promotion is critical to anyone who is ambitious in science,” says Austin. “But it’s not a matter of saying ‘hey, look at me.’ It’s a matter of trying to be a part of things. The right approach, in my opinion, is a particular kind of networking that scientists have long taken part in, but maybe amped up a bit.

“You need to use the classic science dissemination tools to promote yourself. Go to conferences, present your work, attend other people’s talks at those conferences and ask questions, and introduce yourself and tell people what you’re interested in scientifically. Seek collaborations with other scientists and seek letters of support for grants and projects.

“These things involve you in science and also establish a social connection. If you are perceived as someone who promotes your science outside the normal channels, on your blog or wherever, then you run the risk of having some important and rather conservative scientists decide that you are a pretender.”

Fear of repercussions often inhibits self-promoters. The decision to take research outside the normal peer-review channels can be “deeply personal” according to author Nancy Baron, outreach director of the Communications Partnership for Science and Sea, and invites backlash. “Interdisciplinary work is especially prone to such conflict” because of turf battles. The new kid on the block can evoke jealousy, and when science interferes

with corporate or special interests, it can provoke a reaction “which only pretends to be about the data.”

Observers can disagree about what constitutes proper promotion, but they’re inclined to coalesce around the notion that scientists have their work cut out for them. To advance in their careers, scientists formerly only needed to explain their work to other scientists. Now they have to tell it to the world. But scientists didn’t take classes like Communicating Science 101, and even routine presentations can leave much to be desired. “I’ve been at so many seminars where you can’t follow what they’re trying to present because (presenters) are in their small corner of the research world,” says Winkelbauer-Hurt. “Scientists don’t think about helping their audiences understand the significance of their work.” To develop empathy, Kuchner advises scientists to heed the acronym WIIFM (what’s in it for me) when considering what to say.

How to say it is another matter, and one of Kuchner’s favorite tips is about the power of props. Skip the elevator speech, and pack a memento instead. He begins his book with a story of how a scientist employed a mint plant cutting to convince a congressional kingpin to make a 180-degree turn on an issue. Speaking of storytelling, Kuchner says scientists should do a whole lot more of it, because it injects life into the tedious expositions of data that the profession is prone to.

As more scientists begin to throw around marketing terms like positioning and branding, Kuchner addresses their facility to attract the support of perfect strangers and pull in distant collaborators. Borrowing from the seminal writings of Al Ries and Jack Trout, he covers Ries and Trout branding law # 1—get there first in the prospect’s mind, because nobody remembers who finishes second. And if you can’t be the first in some category, move to law # 2—invent some new category where you can stake your claim to be No. 1.

“To launch a brand, it really helps to own a word,” says Kuchner. “A big part of owning a brand is coming up with a word that names it. The crazy thing is that scientists can achieve both goals at the same time—making up a brand name and owning a word. That’s because society gives scientists special license when it comes to making up words.”

“Fear of repercussions often inhibits self-promoters.”

The tricks of the marketing trade are well and good, says Kuchner, but at its heart, science marketing is about building relationships—“a new pillar of marketing.” Relationship building is not a trick—it turns on being real and authentic. “As corporate America is learning, you need to provide products and services that can withstand criticism all across the Internet, or they won’t come back.” He urges scientists to keep the marketing focus on ideas and research, not themselves.

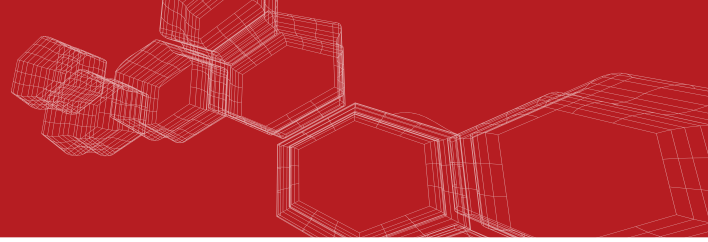
An Internet site is not optional—for promotional purposes, there’s nothing better, assuming it is maintained and updated. “Like it or not, a lab manager’s identity (depends on) their Web footprint,” says McMahon. “If you have good content, and it’s fairly current, you’ll be higher in the search (results) and get more frequency. What I always say is... what do you want people to find on Google two years from now?” The best web sites have the right mix of research, outreach, and personnel, says McMahon; to attract other scientists, Kuchner says sites need to show “captions, passion and generosity.”

McMahon urges lab managers to develop their networking footprint as well. “Scientists are often very bright people who don’t like to talk about themselves, so this can be intimidating. But just being present at 10 different places over the course of a year—such as panel discussions or your former college—helps talent acquisition.”

McMahon recalls an incident from a former job when a new hire wanted to return to his university for a panel discussion. “One of my partners said, ‘That’s a silly expense; he doesn’t know anything about our company, and why do we want to fly him back when he just wants to go party?’”

I said, “That might be true, but he’s someone who loves our company and will say nothing but good things about it to 200 people. And if nothing else, he’ll leave behind the impression that our company is willing to let people leave the lab and interact, which is a neat thing to do.”

F. Key Kidder left journalism to pursue a career in government relations, politics, and PR, but he still likes to keep his hand in writing. He can be reached at k2@keykidder.com or by phone at 410-963-4426.



THE SECOND ANNUAL LABORATORY SPENDING TRENDS REPORT

**ANOTHER YEAR OF LOW-GROWTH
LABORATORY PRODUCT BUDGETS
ANTICIPATED IN 2013**

by Joerg Dittmer and Jonathan Witonsky

Outlook for 2013

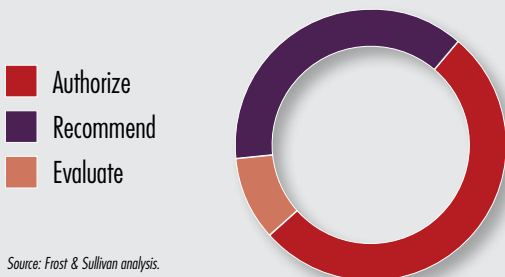
With the “fiscal cliff” looming—the possibility that substantial portions of the U.S. federal budget will be trimmed in 2013—laboratories that depend on government money are anticipating sharply constrained budgets. Other labs may also be affected due to the negative impact that lower federal spending and higher taxes would have on the overall economy. Thus, instead of the once-typical growth of 3% to 5%, overall growth of just 1.2% is anticipated for 2013, after 1.0% growth in 2012.

This conclusion is based on a survey of 170 laboratory workers with knowledge of their lab’s budget. Survey participants include lab managers, directors, group and project leaders, scientists, technicians, principal investigators, researchers, and graduate and postdoctoral students. They represent academic, biopharmaceutical, industrial, patient care, and government labs. Most respondents work in North America, although the survey was open to respondents anywhere in the world.

Survey participant demographics

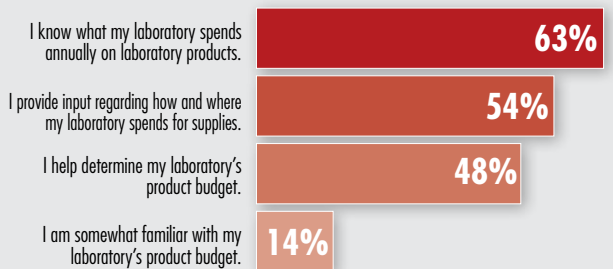
The demographics of survey participants are graphed below. Slightly more than half authorize purchases, others recommend or evaluate purchases. Most—86%—indicate substantial familiarity with their lab’s budget, while 14% indicate that they are “somewhat familiar” with it.

Purchasing Authority: Global, 2012 (n=170)



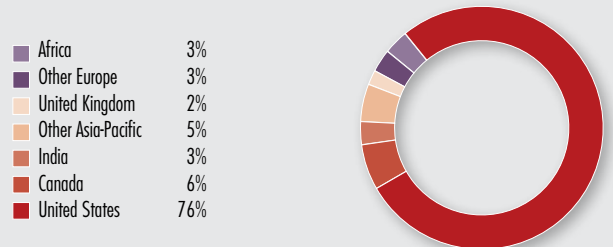
Source: Frost & Sullivan analysis.

Familiarity with Budget: Global, 2012 (n=170)

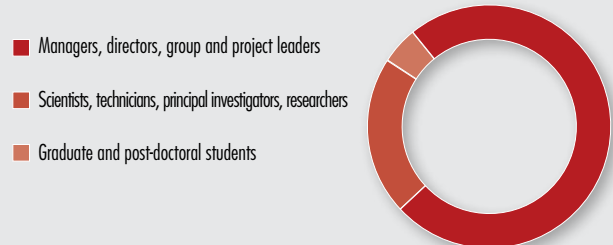


Three-quarters of survey participants are from the United States, with Canadians the second-largest group by country. Almost three-quarters are managers, directors, or group or project leaders.

Respondent's Country: Global, 2012 (N=170)

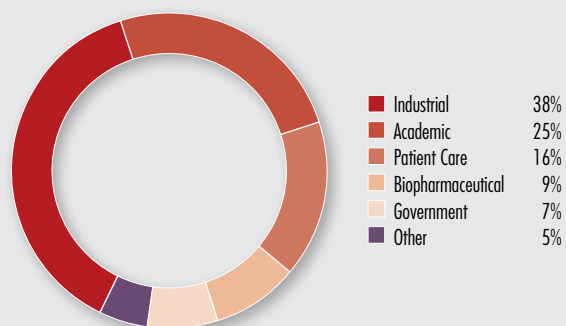


Respondent's Job Title: Global, 2012 (N=170)

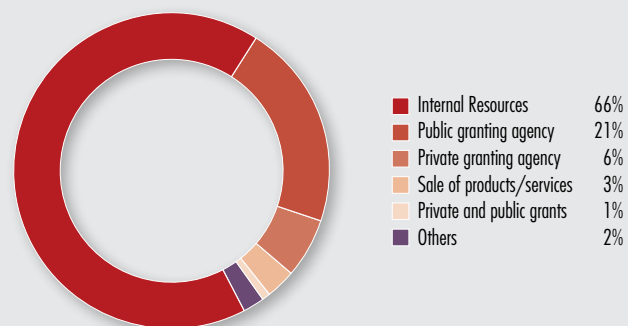


Industrial and academic are the most prevalent lab types. Most labs fund their product purchases primarily through internal resources.

Type of Institution: Global, 2012 (n=170)



Primary Funding Source: Global, 2012 (n=170)



Anticipated budget growth in 2013

Budget growth rates realized in 2012 and anticipated for 2013 differ substantially across laboratory and product types, as illustrated in the table below. Academic labs expect budget growth of 3.1%, after a 1.6% decline in 2012. All other lab types expect slower growth in 2013 than in 2012. However, because of the large share of academic labs in the sample, overall budget growth across all lab and product types is expected to increase slightly, from 1.0% in 2012 to 1.2% in 2013.

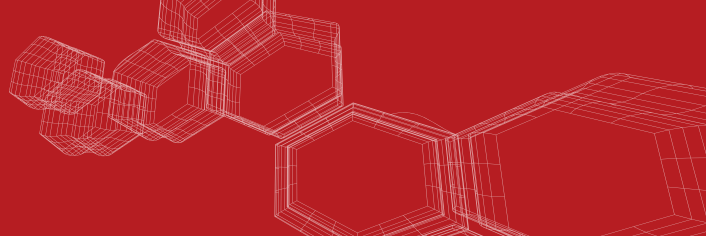
Average Anticipated Budget Growth Rates, 2013 relative to 2012

Lab type/ product type	Academic (%)	Biopharmaceutical (%)	Industrial (%)	Patient Care (%)	Government (%)	Overall (%)
Instruments	6.4	-2.2	1.4	-0.8	-3.5	1.1
Equipment	2.8	-0.5	0.1	-4.5	-8.9	-0.7
Chemicals	2.5	1.8	2.3	-0.9	8.2	2.2
Life science reagents and kits	3.0	3.1	-4.4	-0.4	7.9	1.5
Glassware	1.6	-1.0	0.7	-3.7	0.3	-0.1
Plasticware	2.5	-0.3	-0.6	-1.6	5.0	0.6
General lab supplies	2.8	2.0	1.7	0.8	1.2	1.9
Overall	3.1	0.6	1.1	-0.6	0.1	1.2
n=	43	15	62	25	12	164

Memo: Average Budget Growth Rates, 2012 relative to 2011

Overall	-1.6	2.0	2.8	0.2	4.3	1.0
n=	35	33	36	36	8	151

Readers are cautioned that the 2013 relative to 2012 biopharmaceutical and government results are based on small numbers of observations. A small number of 'Other' lab types is not shown.
Source: Frost & Sullivan analysis



Average 2012 budgets by laboratory and product type

To indicate the relative sizes of these market segments, the following table presents 2012 estimated average budgets. Budgets of academic laboratories are seen to be relatively small, while patient care labs have the largest budgets on average. Instruments, chemicals, and general laboratory supplies are the largest product categories, followed closely by life science reagents and kits. The relatively large average budget for the latter category is significant, since 46% of respondents indicate that their labs do not use life science reagents and kits at all (have not purchased and do not expect to purchase in the 2011-2013 period). The next-highest value for this statistic is 19% for glassware. This suggests that labs that do purchase life science reagents and kits spend substantial sums on them.

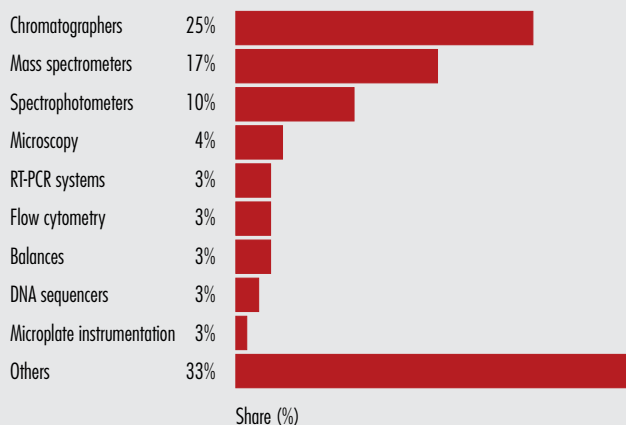
Average Budgets by Laboratory and Product Type, 2012

Lab type/ product type	Academic (\$ thou.)	Biopharmaceutical (\$ thou.)	Industrial (\$ thou.)	Patient Care (\$ thou.)	Government (\$ thou.)	Wtd. Ave. (\$ thou.)
Instruments	9.7	75.4	63.8	106.5	63.1	55.2
Equipment	7.2	54.8	34.8	44.0	30.2	30.7
Chemicals	15.8	99.1	51.1	90.9	25.7	50.7
Life science reagents and kits	18.2	46.8	4.6	216.7	21.0	46.4
Glassware	3.4	16.3	12.9	12.0	21.5	10.7
Plasticware	10.2	26.9	11.5	14.4	16.4	13.3
General lab supplies	17.4	62.0	29.1	164.2	45.3	50.6
Total	81.9	381.2	207.8	648.8	223.3	257.5
n=	43	15	62	25	12	164

Readers are cautioned that the biopharmaceutical and government results are based on small numbers of observations. A small number of 'Other' lab types is not shown. Source: Frost & Sullivan analysis

The survey also asked about budget shares for specific products within the broad categories presented above. A series of graphs with these results follows.

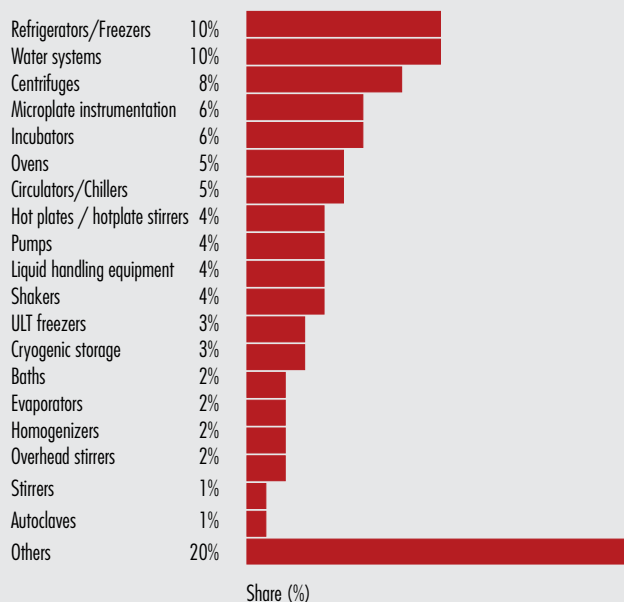
Shares of Total Instrument Spending: Global, 2012 (n=114)



Chromatographers and mass spectrometers hold the largest shares of instrument budgets.

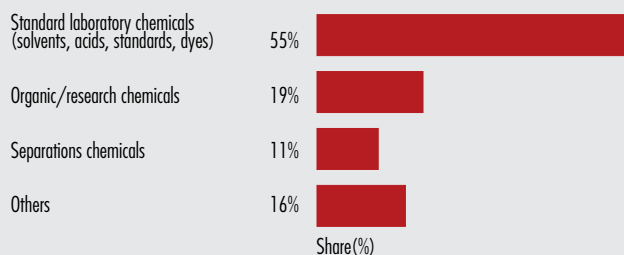
Water systems, refrigerators/freezers, and centrifuges are the biggest segments of the equipment category.

Shares of Total Equipment Spending: Global, 2012 (n=128)



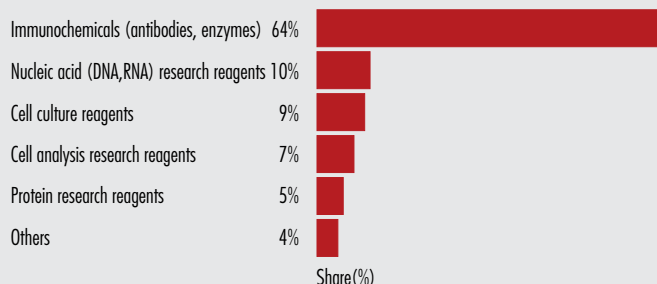
Standard laboratory chemicals (solvents, acids, standards, and dyes) make up the largest segment of the chemicals category.

Shares of Total Chemicals Spending: Global, 2012 (n=154)



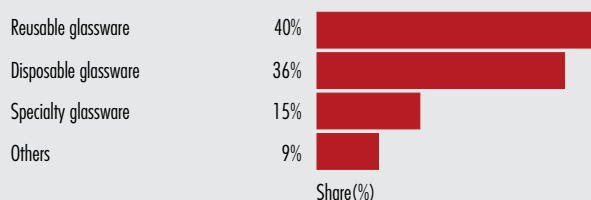
Immunochemicals easily hold the largest share of life science reagents and kits budgets.

Shares of Total Life Science Reagents and Kits Spending: Global, 2012 (n=85)



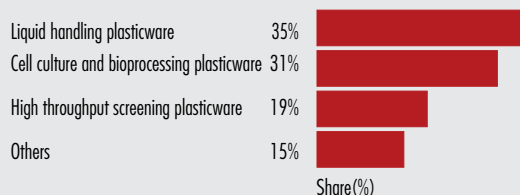
Reusable and disposable products hold almost equal shares of the glassware category, with specialty glassware holding a relatively small share.

Shares of Total Glassware Spending: Global, 2012 (n=113)



Liquid-handling products represent just more than one-third of plasticware budgets on average, while cell culture and bioprocessing products hold a share of just under one-third.

Shares of Total Plasticware Spending: Global, 2012 (n=131)



Academic and government laboratories face greatest uncertainty

Budget cuts at the level proposed by the Sequestration Act would have a tremendous impact on academic and government labs. With sequestration, these labs' budgets could decline by as much as 10%. Cuts to the National Institutes of Health alone would result in 2,300 fewer awarded grants, which would bring grant applicant success rates to an all-time low.

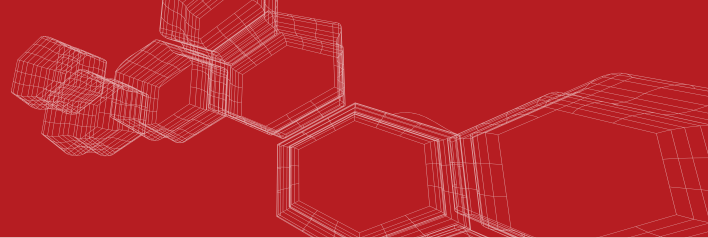
Nonetheless, respondents from both academic and government labs expect their product budgets to increase in 2013. The 43 respondents from academic labs anticipate that their 2013 product budgets will grow by 3.1%; more than that reported by any other lab type. Academic labs' average anticipated budget growth rates for 2013 relative to 2012 showed an increase across all product types. All other lab types reported a decline in at least two product categories. Moreover, academic labs expect to see the greatest increase in spending—6.4%—on instruments, which are generally the most costly lab expense.

Predicting an increase of 0.1%, the 12 respondents from government labs do not expect growth in their 2013 product budget to be nearly as robust as respondents from academic labs do. Even so, the fact that government labs plan to spend slightly more than they did in 2012 is encouraging given the generally bleak outlook for federal funding. While government labs conducting mandated work—such as environmental testing—are likely to be insulated from any budget cuts, government labs performing basic research could be hit hard.

Stable growth in biopharmaceutical, industrial, and patient care laboratories

The 15 respondents from biopharmaceutical labs plan to increase their product budgets by 0.6% in 2013. This increase is rather modest given the anticipated growth of the overall biopharmaceutical market. According to Frost & Sullivan research, in 2013 the global biopharmaceutical market is expected to grow at a rate of 4.6%, from \$939 billion to \$982 billion. However, due to continued industry consolidation, research and development spending has not remained commensurate with revenue growth. Despite consolidation, though, biopharmaceutical labs continue to spend more on lab products—almost \$10 billion annually—than any other lab type does.

LABORATORY SPENDING TRENDS



With a 1.1% increase, the 62 respondents from industrial labs expect their 2013 product budgets to be slightly higher than those anticipated by biopharmaceutical labs. Industrial labs cover a broad range of applications, from chemical and petrochemical to food and beverage. Accordingly, product budgets vary considerably depending on the particular industry segment. In aggregate, though, industrial lab product budget growth rates generally parallel overall economic growth. According to U.S. Federal Reserve officials, 2013 gross domestic product growth is likely to be between 2.5% and 3%. Estimates for 2014 are from 3% to 3.8%, which bodes well for industrial labs.

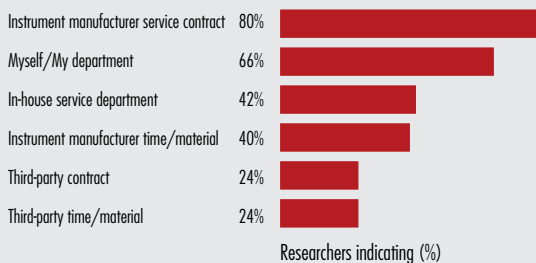
Of all labs surveyed, patient care labs are the only type to report an anticipated budget decline in 2013. The 25 patient care lab respondents expect their product budgets to shrink by 0.6% in 2013. In addition, with the exception of general lab supplies, patient care

labs anticipate cuts to all product categories. In 2014, however, patient care lab product budgets should grow, given the 19.5 million additional patients resulting from the Affordable Care Act. The patient care lab was the only type to report an anticipated decline in 2013, but it is very unlikely that the decline will continue beyond one year.

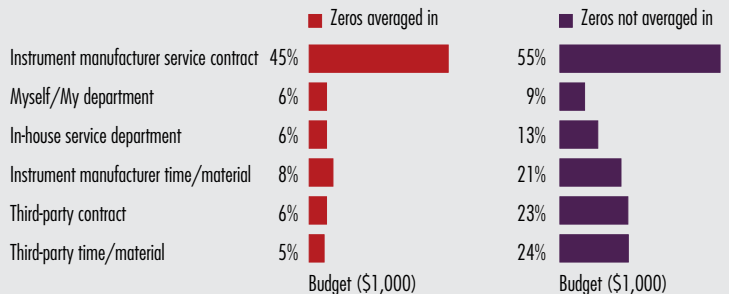
Service and repair of instruments and equipment

Labs have a number of options for the service and repair of their instruments and equipment. For both product types, manufacturer contracts and in-house service (by a service department or by the lab itself) are widely used. However, in revenue terms, manufacturer contracts predominate, indicating that in-house service is cost-effective when feasible. The survey results on these points are graphed below.

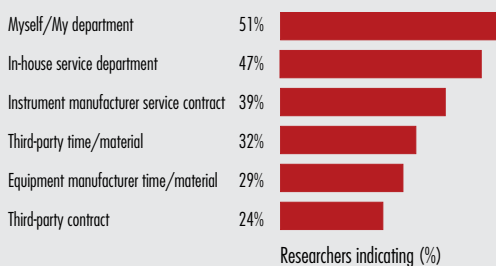
Types of Service Used for Service and Repair of Instruments: Global, 2012 (n=110)



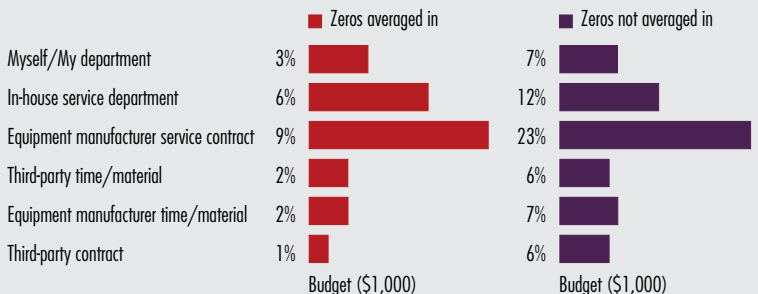
Average Instruments Service and Repair Budget: Global, 2012 (n=110)



Types of Service Used for Service and Repair of Equipment: Global, 2012 (n=119)



Average Equipment Service and Repair Budget: Global, 2012 (n=119)



Conclusions

After the economic collapse of 2008, labs experienced constrained budgets in 2009. Some budget support was provided in 2010 by economic stimulus spending, but in general austerity has continued through 2012. Survey participants are pessimistic about 2013, in good part because federal fiscal policy may become restrictive at a time that the economy still needs stimulus. The fiscal cliff that may hit in 2013 if Congress does not act would both cut federal spending and raise income taxes—a double whammy for the economy.

The total budget growth of 1.2% anticipated for 2013 is weak, particularly considering that this growth follows several years of austerity. Coming out of a trough, growth should be much stronger—perhaps at the upper end of the historical 3% to 5% range.

Demand for consumables is projected to hold up better than demand for other products:

- Chemicals 2.2%
- General lab supplies 1.9%
- Life science reagents and kits 1.5%

Instrument budgets are expected to grow somewhat, while equipment budgets are expected to contract a bit:

- Instruments 1.1%
- Equipment -0.7%

Plasticware has been replacing glassware for many years.

This trend appears to be continuing:

- Glassware -0.1%
- Plasticware 0.6%


These results make intuitive sense. It is easier to defer acquisition of instruments and equipment than of consumables, which are continuously used up in lab operations. Instruments and equipment, on the other hand, can continue to be used even if their technology is out of date. Glassware and plasticware may be consumable or reusable—in times of tight budgets, the incentive is to treat them as reusable as a cost-saving measure. This would be reflected in relatively weak demand for glass and plastic labware.

While many respondents cite tight budgets and rising costs as negative factors affecting their labs, some positive factors also are cited. These include demand-generating

factors such as emerging markets, green initiatives, increased emphasis on quality, legislative and regulatory issues, and an aging population.

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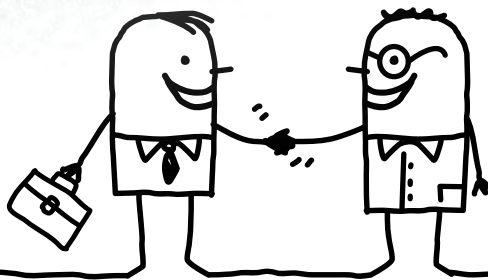
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TEAMING UP

A RESEARCH PARTNERSHIP DONE RIGHT SOLVES TECHNICAL PROBLEMS AND GROWS BUSINESS

by **John K. Borchardt**



Even industrial R&D giants are finding they often lack all the necessary expertise in-house and are reaching out to suppliers, customers, universities, and government laboratories to establish partnerships in order to give them access to expertise and equipment they need to develop innovative new products and processes. While the number and often size of these research partnerships have grown greatly, they are actually not new. For example, in the 1980s when I joined Shell Oil, I was fascinated by coworkers' use of computerized tomography (CAT scanning) to study fluid movement in permeable media (rock). The researchers would go to a hospital very late at night, insert their high-pressure test apparatus in a scanner, and monitor fluid behavior as aqueous fluids were injected into oil-bearing rock. The objective was to learn how to control fluid movement so the aqueous fluid penetrated a larger fraction of the rock, thereby recovering more oil.

Research consortia

Professors and even entire university departments sometimes establish research consortia: partnerships with industrial and government laboratories. Their objective is to fund university research studies of common interest to faculty members and industrial firms. Consortia exist in many fields of science, engineering, medicine, and other disciplines. Consortia offer a way for multiple companies—and sometimes government agencies as well—to work together on projects. The academic consortium members take the lead in defining R&D projects and goals. However, by obtaining input from the industrial members of the consortia, university faculty members can better target their research to provide financially useful results.

The research is funded by the consortium members. In return for providing funding they receive periodic updates on research findings. As they discuss the results with the academic members of the consortium, the companies have opportunities to influence the direction of the research and incorporate the findings into their own R&D programs.

Academic freedom is an important consideration. While the industrial members of the consortium do learn of the R&D findings, they are later presented at conferences and published in research journals so other organizations can learn of the results and possibly build on the researchers' findings.

Another advantage of the research consortium is that graduate students and postdoctoral researchers can learn about the industrial research process. Because the industrial researchers know them, these students and postdocs often have an advantage in obtaining jobs with industrial members of the consortium.

I have been fortunate in participating in several research consortia and academic-industrial research partnerships. My experience has been that the interactions between consortia members produce R&D results whose value substantially exceeds the cost of consortium membership. For example, while working for Shell Chemical Company my employer was a member of the Cooperative Recycle Fiber Studies Program, a consortium focused on paper recycling R&D in the University of Maine Department of Chemical Engineering and led by Professor Edward Thompson. Of the seven industry consortium members, I represented the only chemical company consortium member and was considered the chemistry expert. The other consortium members were

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representatives of paper companies operating paper recycling mills and companies that produced process equipment used in these mills. My participation in the consortium gave my employer considerable credibility with these paper companies, helping to ensure that our chemical products were considered for use in their mills.

Using the Internet for confidential communications

Email and social media can be used to promote communication and sustain research partnerships. Laboratory managers once had assistants to do this work. Now many managers have to do it themselves. While email can be helpful in doing this, negotiation of meeting time and location can require a series of tedious, time-consuming exchanges of emails. Online software such as Microsoft Outlook and SurveyMonkey® enables meeting participants to share calendars and arrange acceptable meeting times while minimizing the time required to do so.

Once scheduled, these meetings may be held in person or be teleconferences or videoconferences. Online meetings may be held using software such as GotoMeeting® or WebEx™.

Social media such as Facebook and Twitter enable scientists around the world to share their findings and opinions. Distance is no barrier to communicating their research results quickly and efficiently. However, social media raises issues for industrial researchers due to the proprietary nature of their work. They are more likely to use social media that are part of their firms' intranets in order to bar access to confidential findings by outsiders.

Given these considerations, it is more often academic scientists who are likely to use the Internet to advance their research. One basic requirement for research is funding. Crowd funding is a fundraising method by which people come together to provide funds for a particular research program. The cumulative effect of individuals pooling their funds can be a substantial sum that makes serious research possible. Some websites that enable crowd funding are Kickstarter.com, Indiegogo.com, and RocketHub.com.

One can also go one step further and actively involve members of the public in the research itself. Social media have been used to establish research partnerships

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between citizen scientists and research institutions in biology, astronomy, and other fields. Groups with interests as varied as conducting bird censuses or detecting and studying comets can set up group pages to request assistance and allow citizen scientists to report their observations.

Besides tweeting, an increasing number of academic scientists are using blogs to discuss their work. These can become vehicles for conversations with other scientists—both academic and industrial.

Geographic proximity

Even in these days of email, social media, and online meetings, geographic proximity can be a strong promoter of innovation. Companies located in close proximity to suppliers, customers, and other companies with technologies they would like to access can realize synergies from this proximity when undertaking joint R&D projects. Increased face-to-face contact often increases communication quality, promoting innovation. Other benefits include reduced travel time and costs for meetings with research collaborators.

These geographic groupings are called Porter clusters because it was Harvard University business professor Michael Porter who popularized the concept in his book “The Competitive Advantage of Nations” and determined many of the advantages of this geographic proximity, even in these days of high-speed electronic communication.¹ Examples include the oil industry in Houston; petrochemical companies on the U.S. Gulf Coast between Houston and New Orleans; the many biotechnology companies located in the greater Boston area, San Francisco, and San Diego; and the numerous pharmaceutical companies in Philadelphia, northern New Jersey, the Boston area, and Research Triangle Park in North Carolina.

What are these advantages, and how do they occur? It was economist Alfred Marshall, author of the influential 1890 book “Principles of Economics,” who offered three major explanations.² The first is “input sharing.” In volatile knowledge-intensive activities, several firms often cooperate to make something. This phenomenon is called vertical disintegration. Vertical disintegration enables firms to reduce the risk of needing some specialized input. Firms in a Porter cluster often have access to more input sharing, thus reducing its purchased input costs. This may occur through direct company interactions or interactions occurring through local sections of science and professional engineering organizations.

Marshall’s second explanation is “labor market pooling.” Clusters can offer better matches between employees and firms. When employees quit or are laid off, it is easier for a worker to find a new position and for firms to fill vacant positions when an industry and the skills it requires are concentrated geographically in a Porter cluster.

The third explanation is “knowledge spillover.” Marshall wrote, “The mysteries of the trade become no mysteries, but are as it were in the air ...”² Provided that knowledge spillover does not become fossilized into rigid, unoriginal groupthink, knowledge spillover can lead to formal and informal partnerships that result in knowledge creation, knowledge spillover, and economic growth for companies and the cluster as a whole. Knowledge spillover depends heavily on the amount and type of knowledge produced locally—hence, research universities are important in the mix of organizations and laboratories constituting the cluster.

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Local professional networks, fostered in part by local professional organizations, can act as knowledge brokers, increasing knowledge spillover. One can meet potential R&D partners at meetings of local sections of professional societies such as the American Chemical Society, American Institute of Chemical Engineers, and Society of Petroleum Engineers. These organizations can promote interactions between researchers at different companies through their local activities.

Intellectual property concerns

Technology licensing is facilitated when the organization selling the technology works with the buyer to be sure all relevant information is transferred. Sometimes the seller will also sell specialized lab equipment and have discussions with the buyer to facilitate commercialization of the licensed technology.

Open innovation and open innovation providers³ offer vehicles for technology discovery and licensing. “Prob-

lems in one discipline have often already been solved in another,” observes Bernard Munos, an adviser in corporate strategy at Eli Lilly & Company. “Cross-pollinating various styles of thought, problem-solving approaches, and training is a powerful driver of breakthrough innovation.” Open innovation facilitators such as yet2.com provide a Web-based method for bringing technology buyers and sellers together so that all parties maximize the return on their intellectual assets.

Some organizations have established websites to promote licensing of their technology. For example, the National Institute of Science and Technology (NIST) maintains a Technology Partnerships Office and a section of its website for technology partnering activities between NIST laboratories and industry.

Intellectual property disputes can arise during scientific collaborations. Thus, these collaborations and the obligations and rights of each party need to be specified in contracts. For example, the patent rights of industrial members of a scientific consortium need to be specified.

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Diversity as a collaboration issue

The different nature of the institutions involved in a research partnership can result in problems in institutions working together and can lead to failure of the partnership. This is a diversity problem. Leaders and members of the collaboration must realize that cultural differences exist between research partners: companies, universities, and government laboratories. Challenging cultural differences, even between companies in the same industry, can create challenges to effective collaborations. Multinational companies sometimes find that cultural differences between their laboratories located in different countries can create barriers to establishing effective research partnerships. In addition, cultural differences can exist between and within disciplines. Sensitivity to these cultural differences is required for effective scientific partnerships.

Wrap-up

Whether your innovation partners are located across town or across the globe, they can provide a means for laboratory managers to solve their technical problems and grow their firms' businesses. Every laboratory manager and laboratory employee should be on the alert for interesting technology that can be relevant to current projects in the lab. Current awareness services, provided by your library, your IT department, or an outside provider, can be essential to keeping you aware of when technology solutions to your lab's problems are published or patented.

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Dr. John K. Borchardt is a consultant and technical writer. He is the author of Career Management for Scientists and Engineers and often writes on career-related subjects. He can be reached at jkborchardt@botmail.com.

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RISKY BUSINESS

MANAGING EXPORT CONTROL COMPLIANCE IN THE BIOTECHNOLOGY INDUSTRY

by Eric McClafferty and Brooke Ringel



Many companies have systems to deal with the alphabet soup of agencies and regulations that govern the handling and transfer of products and technology in the U.S. Yet few biotechnology companies have the compliance systems necessary to handle export control risks involved in their international operations.

Why care about export controls?

Most companies work hard to protect their intellectual property and institutional knowledge when collaborating with labs outside the U.S. Beyond the business interests involved, the U.S. government has national security interests in certain types of information and goods that may cross borders and exercises those interests through export controls. Understanding the export control rules related to products, equipment, and know-how is critical for U.S. biotechnology companies, and proper compliance is the only way to protect the company and its employees. As the proliferation of biological and chemical weapons rises, regulating agencies and their enforcement arms are taking a close look at how and where materials and equipment are being sent internationally, how information is shared, where it is stored, and who has access to data. Electronic export records and a new export control certification requirement for new hires make it easier than ever for the U.S. government to track these statistics and find violations.

What if we don't comply?

With over 60 companies in the biotechnology, chemical, and equipment industry penalized in the last five

to six years, more companies are making sure they are compliant with export regulations. Penalties for violating export control rules include criminal charges against companies and individuals (including jail time of up to 20 or more years) and civil penalties up to \$1 million per export or technology release. Beyond civil or criminal penalties, companies that violate the regulations risk being denied all export privileges. Companies put on so-called “denied party lists” can have trouble buying equipment from the increasing number of suppliers who screen their customers against those lists. Companies can also lose the ability to sell to the U.S. government.

Working without an export compliance system is, in many ways, just as risky as not having a health and safety compliance program. And, with some guided effort, a good export compliance system is not difficult or costly to implement.

What do the export control rules cover?

Export control regulations govern shipments of military items and a variety of less-sensitive dual-use chemicals and biological materials, including certain human, animal and plant pathogens; toxins; and genetically modified organisms. The regulations also cover export of equipment (for example, certain storage tanks, reactors, agitators, valves, and pumps).

In addition to physical exports, the transfer of know-how (referred to as “technology” or “technical data” in the regulations) to non-U.S. persons can trigger export controls. Technology sharing can occur by sending documents attached to emails, in-person demonstrations

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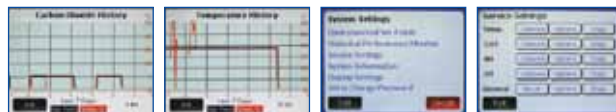
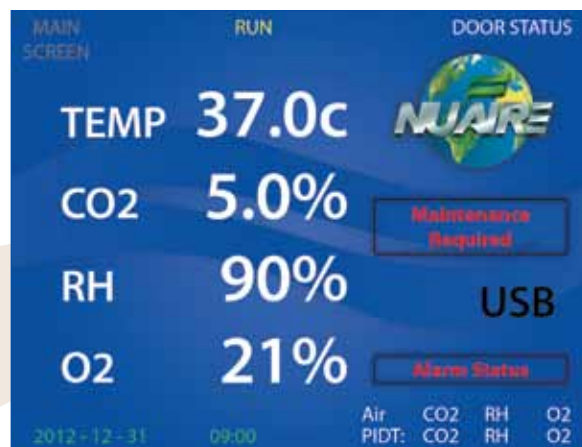
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or lab visits, or oral transmission through a phone call or in-person conversation. Without proper training it is easy to unwittingly share export-controlled technology in violation of the regulations.

Finally, international sales is a key area where export controls may affect your company. Many biotechnology companies are expanding to new sales territories. Places such as India and China are not only becoming popular sites for biotechnology manufacturing and research (and technology exports) but also growing as profit centers due to upward trends in income and population levels.

“Without proper training it is easy to unwittingly share export-controlled technology in violation of the regulations.”

U.S. export control regulations overview

The U.S. Department of Commerce’s Bureau of Industry and Security (BIS) and the U.S. Department of State’s Directorate of Defense Trade Controls (DDTC) are the two agencies primarily responsible for control of most biotechnology goods and technology exports from the U.S.

BIS administers the Export Administration Regulations (EAR). The EAR cover dual-use products, software, and technology that can be used for commercial and military (or terrorist) end uses.¹ For example, a hammer is a dual-use item because it can be used by a construction worker to build a house or by the military to repair a tank. Items requiring BIS authorization for export to a particular destination are indicated on a list of items, software, and technology called the Commerce Control List (CCL). EAR also control exports to certain individuals or entities and for certain end uses, including use of any item for the development of chemical or biological weapons.



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DDTC administers the International Traffic in Arms Regulations (ITAR), which control military products (“defense articles”), software, and technology.² DDTC also maintains a list of controlled items called the U.S. Munitions List (USML), but anything specifically designed or modified for military end use (whether in the U.S. or for a foreign military) is also controlled as a defense article. A license from DDTC is required to export virtually all USML items.

Industry-specific controls: products

BIS regulates certain dual-use microorganisms, toxins, biological equipment, and related technology identified by the Australia Group, an international association that seeks to stem the development of biological and chemical weapons through export controls. BIS also controls the export of select agents. Licenses are required to export these products to many countries.

“Working with foreign employees or contractors can create export licensing requirements.”

Controls affecting the biotechnology sector are primarily found in Categories 1 and 2 of the CCL. Each control is identified by an Export Control Classification Number (ECCN), which comes with specific instructions. Some key ECCNs for the industry include 1C351 (human pathogens), 1C352 (animal pathogens), 1C353 (genetically modified elements containing nucleic acid sequences of CCL-controlled organisms and other organisms containing those sequences), 1C354 (plant pathogens), 1C360 (select agents), and 1C991 (vaccines). The levels of control vary. For example, an export license from the Department of Commerce is required to export an ECCN 1C351 item to any destination. In contrast, ECCN 1C991 items, which are under a lower level of control, can be exported to more destinations without a license. Also, don't forget the equipment controls on pumps, valves, reactors, agitators, piping, fermenters, and a wide variety of other lab equipment found in ECCNs 2B350 and 2B352. These categories provide only a sample of export controls that companies need to know about.



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Industry-specific controls: Technology

Both the EAR and ITAR govern the export of export-controlled know-how (technology) required for the development, production, or (in some cases) use of an item listed on the CCL or USML.³ It is sufficient to know that technology is very broadly defined and can exist in virtually any format, including lab procedures, drawings, calculations, and test procedures. Controlled technology requires a license for export to certain destinations just as does the export of the product that the technology is used to design, make, or use.

Biotechnology companies should focus on ECCNs 1E001 and 1E351, which control technology for dual-use biological materials described above. ECCNs 2E001, 2E002, and 2E301 control technology for certain biological material handling equipment, as noted above. Similarly, USML Category XIV controls any technical data or defense services related to controlled biological agents.

“The U.S. government is paying more attention to the movement of biological materials, equipment, and technical information.”

U.S. export control enforcement authorities vigorously enforce rules relating to technology releases. Think of it this way: Shipping a vial of a controlled toxin gives someone one vial of toxin, but the release of sensitive production technology permits a potential enemy to produce that toxin on a much bigger scale.

Based on this policy, the rules prohibit the unauthorized transfer of technology to foreign persons even if they are company employees abroad or physically located in the U.S. A data release in the U.S. is called a “deemed export” because it is deemed to be an export to the recipient’s home country. The key to deemed export compliance is to consider that *access*—to shared computer network drives, data-sharing programs or websites, meeting and production areas, unsecured technology—by foreign persons must be restricted wherever they are located. Consider access to shared computer network drives, data-sharing programs or websites, meetings and production areas, and unsecured technology.

Human resources professionals in the scientific, technical, and complex manufacturing sectors are seeing the number of foreign-born applicants steadily increase. For a biotechnology company that develops or produces both products and technology likely controlled for export, working with foreign employees or contractors can create export licensing requirements.

The bottom line

Could collaborating with a lab outside the U.S. lead to an export violation with significant penalties? Yes. Could a lab visit by non-U.S. persons lead to an export control violation? Yes.

Could employing a non-U.S. person at a lab lead to technology export violations? Again, the answer is yes, if you are not careful about export compliance.

Certain license exceptions may be available for publicly available technology and “fundamental research.” Be aware, however, that many companies rely too heavily on these limited exceptions. If your company would not share particular know-how with its competitors, these exceptions probably do not apply.

Every company in the industry should implement an export compliance system to prevent violations. Get help from qualified export compliance counsel that can assist on a confidential and attorney-client-privileged basis as you develop your compliance system in the event a potential past issue is discovered.

What steps should we take?

Implement a basic set of compliance tools. Undertake a risk assessment. Use a systematic approach to accurately classify “core” and “noncore” products, equipment, and technologies. It is impossible to know whether an export license is needed without conducting this classification process.

Here are some other select key elements that a solid export compliance system needs:

- Export compliance policy and manual
- Identification of responsible individual(s)
- Technology control plan
- Training
- Internal review/audit program
- Plan to respond to enforcement visits or inquiries (e.g., Commerce, ICE, Customs, the FBI, and Homeland Security)

Conclusion

As the threat of proliferation rises, the U.S. government is paying more attention to the movement of biological materials, equipment, and technical information—not less. U.S. biotechnology companies and laboratories seeking to expand research, manufacturing, sales, and purchasing relationships outside the U.S., or that employ talented foreign nationals must ensure they have export compliance procedures in place to protect their business, managers, and employees.

References

1. 15 C.F.R. § 730, et seq.
2. 22 C.F.R. § 120, et seq.
3. See 15 C.F.R. Pt. 772; 22 C.F.R. § 120.10

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IT'S THE LITTLE THINGS THAT COUNT

CREATIVE IDEAS TO IMPROVE MORALE, ENHANCE PRODUCTIVITY, AND MAKE YOUR LAB MORE FUN!

By Barbara A. Glanz, CSP, CPAE



Studies have shown that what workers want from their jobs is not better benefits or more money. Rather, it is the small things that make people feel commitment to an organization. One study shows the top three things workers want are interesting work, full appreciation for the work they do, and a feeling of being in on things. Baxter Labs recently did a global study in which they asked their employees worldwide what they could do to make things better for them. The resounding answer was to be “respected as whole human beings with a life outside of work.”

What seems critical in labs today is for leaders to respond to workers as HUMAN BEINGS and to foster an atmosphere that is inclusive, caring, creative, appreciative and joyful. People are looking for a deeper sense of meaning and purpose in their work, and above all, they want to be respected and valued.

Let's look at eight of my favorite ideas that any lab can adapt and introduce to make an immediate difference in spirit. Common sense as well as much current research tells us that happy employees are more productive employees, so implementing even a few of these ideas will not only boost morale but will certainly impact productivity and profit.

1. Does everyone in your organization have business cards? If not, that is one of the fastest ways to boost morale. They can be made on the computer for little or no cost and what a meaningful way to tell an employee how valued and important he or she is.

“People are looking for a deeper sense of meaning and purpose in their work, and above all, they want to be respected and valued.”

2. Have a contest with employees—“If our lab/department were a T-shirt, this is what it would say...” Then have them actually design the shirt. Photograph, post, or videotape the results. You will learn amazing things about the way people feel about your organization.

3. Collect drawings from employee's children or grandchildren of “What my Mom/Dad/Grandma/Grandpa/Aunt/Uncle does at work all day.” Compile these into a company booklet or display them for everyone to enjoy. You

are helping to blend work and family by involving workers' family members, and you are also creating memories.

4. When people in your lab turn on their computers, have a message of the day such as a quotation on customer service, personal growth, something humorous, or even the birthdays of employees during that week. If a day begins with inspiration, it will help lift the level of interaction in your workplace

5. Collect lab legends and success stories on video or audio. If possible, interview the employee or the customer to whom they happened. These recordings become a source of pride for current employees and a wonderful addition to orientation for new hires. You will be recording and celebrating the moments of peak performance in your organizational culture.

6. Add a personal signature to your work to differentiate yourself from all the others who do the same work as you. A United Airlines Captain on each of his flights writes handwritten thank you notes to several passengers whom he picks at random from the computer, thanking them for choosing his airline and offering his help in any way they might need. A grocery store bagger always puts a “Thought for the Day” in each person's grocer-

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ies he bags. As employees begin to find ways to express themselves in their work by adding a personal signature, your workplace will become more caring, creative, and much more fun!

7. Have a lab poster party for all frustrated/aspiring artists to create signs and posters that demonstrate the lab's values. Use quotations, graphics, and bright colors. Display them in clear plastic frames throughout the building. Not only will you find talent you did not know existed, but you will also be creating an atmosphere of inspiration and delight.

8. Post "street" signs to name hallways in your building. Choose names that communicate your company's mission or values or relate to your core business. You may also want to name hallways after valued employees. By making these values visible daily, employees will constantly be reminded of the organization's foundation and reason for being.

Remember that it truly is the little things that count. You may decide to try one new idea each month, or form a Spirit Committee and have them design a plan to incorporate some of

these things into your culture, or simply use these ideas to get your own creative juices going to come up with other ideas that your employees will enjoy. Help create an atmosphere that produces peak performers and committed joyful workers and, as a result, creates more loyal customers. Have fun!

Barbara Glanz, CSP, CPAE, is an internationally known speaker, author and a member of the prestigious Speaker Hall of Fame who works with organizations that want to improve morale, retention, and service and with people who want to re-discover the joy in their work and in their lives. She is the author of 11 best-selling books, including The Simple Truths of Service Inspired By Johnny the Bagger; The Simple Truths of Appreciation; Handle with CARE—Motivating and Retaining Employees; CARE Packages for the Workplace—Dozens of Little Things You Can Do to Regenerate Spirit at Work; Building Customer Loyalty and CARE Packages for Your Customers. Barbara can be reached 941-312-9169; bglanz@barbaraglanz.com; www.barbaraglanz.com

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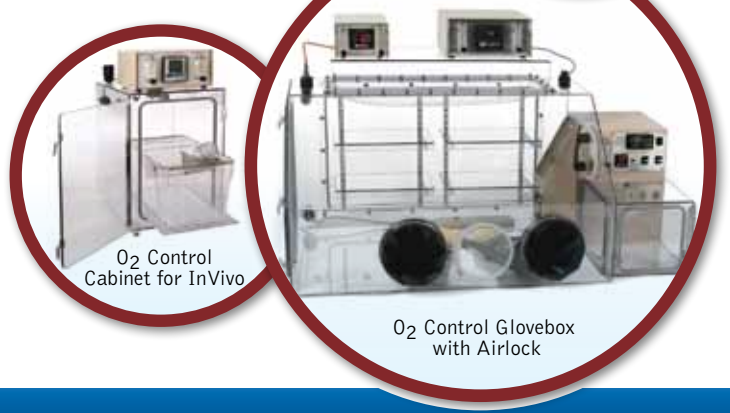
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FIVE NECESSARY ELEMENTS FOR INTEGRATING LAB SYSTEMS

WHERE WE ARE **vs** WHERE WE NEED TO BE
by Joe Liscouski

The lab systems we have today are not built for integration system-wide. They are built by vendors and developers to accomplish a set of tasks, and connections to other systems are either not considered or are avoided for competitive reasons. If we want to consider the possibility of building integrated systems, the following five elements are needed:

- Education
- User community commitment
- Standards—file format and messaging/interconnect
- Modular components
- Stable operating system environment

Education

Facilities with integrated systems are built by people trained to do it. But the educational issues don't stop there. Laboratory management needs to understand their role in technology management. It isn't enough to understand the science and how to manage people, as was the case 30 or 40 years ago. Managers have to understand how the work gets done and the technology used to do it. The effective use/misuse of technologies can have as big an impact on productivity as on anything else. The science also has to be adjusted for advanced lab technologies. Method development should be done with an eye toward method execution—can this technique be automated?

User community commitment

Vendors and developers aren't going to provide the facilities needed for integration unless the user community demands them. Suppliers are going to have to spend resources in order to meet the demands for integration,

and they aren't going to do this unless there is a clear market need and users force them to meet that need. If we continue with "business as usual" practices of force-fitting things together and not being satisfied with the result, where is the incentive for vendors to spend development money? The choices come down to these: you purchase only products that meet your needs for integration, you spend resources trying to integrate systems that aren't designed for it, or your labs continue to operate as they have for the past 30 years—with incremental improvements.

Standards

Building systems that can be integrated depends on two elements in particular: standardized file formats and messaging/interconnect systems that permit one vendor's software package to communicate with another's.

File format standards—The output of an instrument should be packaged in an industry-standard file format that allows it to be used with any appropriate application. The structure of that file format should be published and include the instrument output plus other relevant information such as date, time, instrument ID, sample ID read via barcode or other mechanism, instrument parameters, etc.

In the 1990s the Analytical Instrument Association (now the Analytical and Life Science Systems Association) had a program under way to develop a set of standards for chromatography and mass spectrometry. It was a good first attempt. There were several problems with it that bear noting. The first point is found in the name—Analytical Data Interchange Standard. It was viewed as a means of transferring data between instrument systems

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and served as a secondary file format, with the instrument vendors being the primary format. This has regulatory implications, since the FDA requires storage of the primary data and requires that the primary data is used to support submissions. It also means that files have to be converted between formats as they move between systems.

Ideally, the standard format would be THE format for an instrumental technique. Data collected from an instrument would be in that format and be implemented and used by each vendor. In fact, it would be feasible to have a circuit board in an instrument that would function as a network node. It would collect and store instrument data and forward it to another computer for long-term storage, analysis, and reporting, thus separating data collection and use. A similar situation currently exists with instrument vendors that use networked data collection modules.

“People had to buy systems, and they couldn’t wait for standards to be developed and implemented.”

The issue is further complicated by the nature of analytical work. A data file is meaningless without its associated reference materials—standards, calibration files, etc.—that are used to develop calibration curves and evaluate qualitative and quantitative results. While file format standards are essential, so is a second-order description—sample set descriptors that provide a context for each sample’s data file. A sample set might be a sample tray in an autosampler; the descriptor would be a list of the tray’s contents (standards, sample ID, etc.).

The second issue with the AIA’s program was that it was vendor-driven with little user participation. The transfer to the ASTM should have resolved this, but by that point user interest waned. People had to buy systems, and they couldn’t wait for standards to be developed and implemented. The transition from proprietary file formats to standardized formats has to be addressed in any standards program.

The third issue is standards testing. Before you ask customers to commit their work to a vendor’s implementation of a standard, they should have the assurance through an independent third party that things work as expected.

Messaging/Interconnect standards

Developers and vendors design programs to be self-standing—the software works as though nothing else existed, and it is self-sufficient for all critical tasks. That is a reasonable viewpoint since it may in fact be true. There isn’t any standard suite of lab software. It is also true that software exists and functions in concert with other programs, and they may have the need to exchange data elements. We need a standard for intertask communications. The advent of ELNs only raises the level of complexity. Files can be imported/exported, but if we want integration, we need communication between elements. That includes the modules used in sample preparation as well as in large instrument data systems, LIMS, and ELNs. Some vendors use PDF files as a means of information exchange. While this works, it is not the ideal situation for engineered message transfer.



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Modular systems

The previous paragraph notes that vendors have to assume that their software may be running in a stand-alone environment in order to ensure that all the needed facilities are available to meet the users' needs. This can lead to duplication of functions. A multiuser instrument data system and a LIMS both need a sample login. If both systems exist in the lab, you'll have two sample login systems. The issue can be compounded with the addition of more multi-instrument packages.

Why not break down the functionality in a lab and use one sample login module? It is simply a multiuser database system. If we were to do a functional analysis of the elements needed in a lab with an eye toward eliminating redundancy and duplication—designing components as modules—integration would be a simpler issue.

A modular approach—login module, lab management module, modules for data acquisition, chromatographic analysis, spectra analysis, etc.—would provide a more streamlined design with the ability to upgrade functionality as needed. For example, a new approach to chromatographic peak detection and peak deconvolution could be integrated into an analysis method without having to reconstruct the entire data system.

When people talk about modular applications, the phrase “LEGO®-like implementation” comes up. It is a good illustration of what we'd like to accomplish. The easily connectable blocks and components can be structured in a wide variety of items, all based on a simple standardized connection concept. There are two differences that we need to understand. With LEGO, almost everything connects. In the lab, connections need to make sense.

LEGO is a single-vendor solution that, unless you're THE vendor, isn't a good model. A LEGO-like multisource model (including open source) of well-structured, well-designed, and supported modules that could be connected/configured by the user would be an interesting approach to the development of integrated systems.



Modularity would also be of benefit when upgrading or updating systems. With more functions distributed over several modules, the amount of testing and validation needed would be reduced, and it should be easier to add functionality. This is what systems engineering—laboratory automation engineering—is when you look at the entire lab environment rather than at implementing products task-by-task in isolation.

Stable operating system environment

The foundation of an integrated system must be a stable operating environment. Operating system upgrades that require changes in applications coding are disruptive and lead to a loss of performance and integrity. It may be necessary to forego the bells and whistles of some commercial operating systems in favor of open source software that provides required stability. Upgrades should be improvements in quality and functionality where that change in functionality has a clear benefit to the user.

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Where do we go from here?

At some point the steps described are going to have to be taken. Until they are, labs are going to be committing the results of their work to products and formats they have little control over. The use of proprietary file formats that limit one's ability to work with the company's data should be replaced with industry-standard formats that give users the flexibility to work as they choose with whatever products they need.

We need to renew the development of industry-standard file formats, not just from the standpoint of encapsulating data files but also so that formats ensure that the data is usable. The initial focus for each technique needs to be a review of how laboratory data is used, particularly with the advent of hyphenated techniques, and to use that review as a basis for defining the layers of standards needed to develop a useable product.

“The foundation of an integrated system must be a stable operating environment.”

At a recent ELN and LIMS forum held in Milan, Italy (September 25th – 27th 2012), users expressed continued frustration with the lack of movement. The continued development of the AnIML standard (Analytical Information Markup Language) holds some promise since it addresses both data formats and context as noted above. In addition, a new organization—the Allotrope Foundation—has been funded by pharmaceutical companies and may provide some direction.

Overcoming the barriers to the integration of laboratory systems requires a change in mind-set on the part of lab management and those working in the labs. That change will result in a significant difference in the way labs work, yielding higher productivity, a better working environment, and an improvement in the return on a company's investment in its lab's operations. Waiting for that change to occur isn't going to produce the results needed. The user community needs to take a leadership role and come together and provide direction to developers.

Joe Liscouski, executive director of the Institute for Laboratory Automation, can be reached at liscouski@InstituteLabAuto.org or by phone at 978-732-5122. For more information, visit <http://www.InstituteLabAuto.org>.

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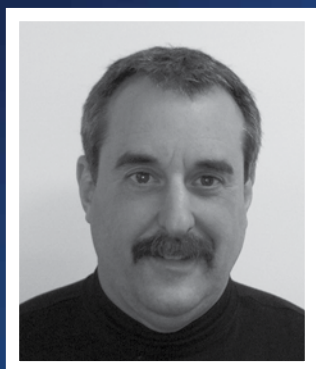
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Steven Wolk, Ph.D.

ASK THE EXPERT

THE IMPACT OF UHPLC ON EFFICIENCY AND OUTCOMES by Tanuja Koppal, Ph.D.

Steven Wolk, Ph.D., associate director of analytical chemistry at SomaLogic Inc., discusses the use of high-performance liquid chromatography (HPLC) and ultra high-performance (or pressure) liquid chromatography (UHPLC) technologies for analytical work with contributing editor, Tanuja Koppal, Ph.D. He reflects on the changes taking place in the liquid chromatography market, on both the hardware side and the software side, and comments on the incremental improvements that can be made.

Q: Why did you transition from a traditional HPLC to a UHPLC?

A: In terms of improving resolution using LC systems, I don't believe there is anything better than a UHPLC, and for us, resolution was the number one priority. The beauty of UHPLC is that along with increased resolution you also get a reduction in run times. As the run times get shorter, the throughput goes up. So it's like getting the best of both worlds. We have seen resolution improve by two to four times and run times reduced by two to eight times, or even more in some cases. At SomaLogic we purify our modified oligonucleotides (proprietary molecules called SOMAmers) via large-scale preparative HPLC purification, and all the analytical characterization is done using UHPLC.

Q: What other advantages have you found using a UHPLC?

A: With UHPLC you use less solvent, so it's a cheaper and greener technology. UHPLC also offers a lot more flexibility. The fundamental principle of UHPLC is that you use a column with

smaller particle size ($<2.5\mu\text{m}$) to give improved resolution. However, the smaller particle size leads to an increase in column pressure, and the pumps have to be designed to handle these high pressures. So now, you have a much broader pressure range that you can operate under. You can use a normal HPLC column and operate it under regular pressures and flow rates or with a UHPLC column, you can operate in the higher-pressure range. Other advantages are that the UHPLC systems have been designed with a much smaller system volume and hardware components that minimize dispersion, which results in lower band broadening and more precise mixing of the mobile phases when generating gradients. These factors also improve resolution.

Q: What is the disadvantage to having an increased back pressure in your system?

A: I haven't found any downsides to the higher pressure. However, there are minor issues like having a smaller column capacity. People who are used to HPLC often

overload their UHPLC columns. With UHPLC columns you have to adapt to smaller sample volumes and smaller amounts of material. Overall, our columns and our systems are very robust and not affected by the high pressure. As the hardware and software for the LC systems get better, there is also better monitoring of the pressure. In our UHPLC system we get a readout of the pump pressures, and once, when we were experiencing a problem, I just took a printout of the monitoring screen and e-mailed it to the service representative. Just by looking at the diagnostic pressure response readout, he was able to tell me that there was a check valve problem on the lead pump, which saved me time in terms of getting someone to come in and fix the problem.

Q: What is involved with routine care and maintenance of these systems?

A: Our company uses service contracts. So we do the basic maintenance ourselves but let the vendors take care of the in-depth maintenance. With the stuff that we do in-house I have not noticed any increased problems when compared to HPLCs. That being said, our people are well trained to take good care of these systems. We don't do anything special but use good common sense that any well-trained chromatographer would use. UHPLC is not that different from HPLC, but there are some minor



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Steven Wolk, Ph.D., is currently the director of analytical chemistry at SomaLogic, Inc., a biotechnology company in Boulder, Colorado, which is developing SOMAmers (Slow Off-rate Modified Aptamers) as a basis for proteomic measurements, therapeutics, and a variety of other applications. He received a Ph.D. in biophysical chemistry from the University of California in Berkeley and has worked in industry as an analytical chemist for 24 years. His research has involved the characterization of oligonucleotides, proteins, polymers, and small molecules, utilizing a wide variety of instrumentation, including HPLC/UHPLC, NMR, and mass spectrometry.

exceptions. For instance, if you leave aqueous buffers in contact with the system for a long time, it will eventually grow bugs and clog the head of the column. This bioburden in the buffer will affect a UHPLC faster than it would an HPLC column because of the smaller packing in the column. Very salty buffers, like those used for size exclusion or anion exchange chromatography, can affect the pumps. Hence, you need to take extra care to make sure that all the salt gets flushed out of the system.

Q: What about sample preparation for UHPLC? Any special concerns there?

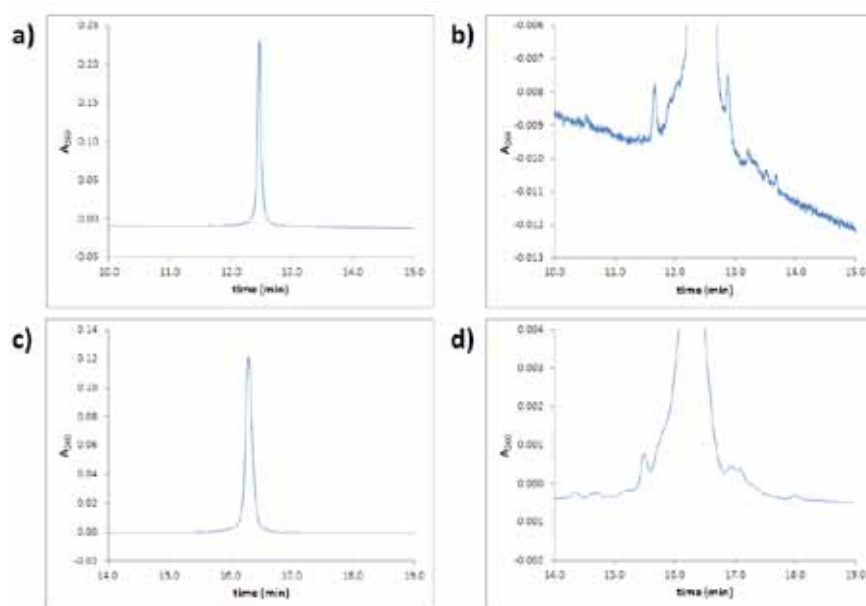
A: You have to be a little more careful about filtering your samples to remove insoluble materials because of the smaller packings, which may cause the column to get clogged. Typical commercial systems come equipped with autosamplers that can handle about 100 vials, and most modern systems can also accommodate 96-well plates.

Q: Where and what types of improvements would you like to see in the UHPLC technology?

A: There is always room for incremental improvements in the particle size, the system volume, and the flow rate. As particle size gets smaller, the resolution gets better but

you have to deal with higher pressure, and there is room for improvement there. There is still some catching up to do in terms of the types of columns and solid supports that you can buy. However, it's getting better all the time, and every few months there are new columns being offered. I'll challenge

the vendors to try and find a way to make cheaper columns, as the columns are still reasonably expensive. Sample prep still requires some work. If there is a way to automate the sample prep, perhaps by filtering samples within the autosampler or something else, that would be an advantage.



▲ Comparison of UHPLC and HPLC analysis of a SOMAmer containing 50 nucleotides, some of which contain benzyl modifications of the DNA bases, as well as modifications necessary for SomaLogic's SOMAscan technology. Figures 1a (full-scale main peak) and 1b (vertical expansion) show the UHPLC chromatogram, and Figures 1c (full-scale main peak) and 1d (vertical expansion) show the HPLC chromatogram. Samples were analyzed using similar columns and an identical gradient. Injections were 5 μ L of a 2 μ M solution for the UHPLC analysis, and 20 μ L of the same solution for the HPLC analysis. Higher resolution of the main peak is observed for the UHPLC analysis (Figures 1a vs. 1c), as well as much better resolution of the small impurities observed on the back shoulder (Figures 1b vs. 1d), allowing for much better understanding of the true impurity profile of the modified oligonucleotide.

Q: How easy is it to justify the return on investment?

A: It depends on what you are trying to achieve. For us, that extra resolution helps us determine the quality of our reagents (SOMAmers). If you are making an oligonucleotide therapeutic then quality is of huge importance. So it's difficult to put a number on the quality of science that you can do. In addition to that, the savings in solvent costs and increase in throughput over time make things easy to justify.

Q: If you had the resources, would you replace your HPLCs with UHPLCs over time?

A: If I were going to buy a new instrument then there would be no reason to buy an HPLC. I would just buy a UHPLC. I don't see any advantage to buying the old-style systems. However, there are instances,

especially in the pharmaceutical industry, where methods need to be validated. If a technology changes then the method has to be revalidated and that can be very time consuming and expensive. That's the only situation I can think of where I wouldn't buy a UHPLC. Or in some rare case where your samples are particularly dirty and there is no way to filter them, then you are likely to continually clog your UHPLC columns.

Q: What advice do you have for lab managers looking to invest in the UHPLC technology?

A: There is no reason to hesitate when looking to invest in a UHPLC. Whenever a new technology comes on the scene, you hear the hype. Then reality sets in and it doesn't quite live up to the hype. UHPLC has been an exception, in that it has lived up to the hype and delivered on all its promises. UHPLC does everything your HPLC did and more.



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SCIENCE MATTERS

LATEST TRENDS SHAPING THE SCIENTIFIC WORKFORCE

MAKING SENSE OF DATA MANAGEMENT IN A DIGITAL WORLD

By Mark Lanfear



The incredible invention of social media and other Web-based technologies has transformed our personal lives in ways we really don't have to think about anymore. Need to get in touch with a long-lost friend? A distant relative? An old colleague? Devote five minutes on the Internet and it's usually done, thanks to all kinds of digital resources. As recently as 10 years ago, however, this task would have been drastically more complicated—that's how fast technology has radically changed the way we live.

The same thing is happening in the life sciences, though in much more complex ways and with far greater implications for scientific companies. We already are aware of how the science business in general has changed, prompting leading companies such as Pfizer, Roche, and Astra-Zeneca to re-evaluate the way they operate, transforming some processes, especially in the collection and use of data, in innovative and highly productive ways. Whereas once these companies used to be considered traditional pharmaceutical organizations that produced the most important therapies of our time, they now have evolved even further into commercial health care providers. As a result, they are now able to

cater to practically every health care trend—from personalized medicine to consumer products to other forms of life-enhancing products—all with a more watchful eye on safety, feedback, and compliance information.

As challenging as this new way of operating continues to be, the welcomed byproduct is that these companies, by necessity, have had to lead the way in being equally personalized and innovative about gathering and analyzing the data required to accomplish their lofty goals. If these companies aren't already well into the process of doing so, they are all certainly headed in the direction of making it easier for patients and research subjects to participate proactively in the health care discussion in much the same way that all of us would participate in a personal discussion with a friend through a variety of social networks.

These open lines of communication—where once they were closed due to regulatory norms, lack of technology, and fear of the unknown—are now positively affecting a great many across the scientific spectrum, from academic research and crowd-sourcing think tanks to the companies that sponsor clinical trials and the patients who will reap

the benefits of life-enhancing treatments and even right down the line to the governmental bodies tasked with regulating product safety and effectiveness claims.

But it also means that data no longer exists in a vacuum—and that the entire scientific industry will continually have to adapt to the infinite number of ways that we are now able to use that data. Not only are the possibilities of analyzing and applying data limitless, but so is the data itself. We are in fact being exposed today to profound amounts of knowledge, representing a true quantum leap forward as science becomes social and people become more and more willing, and comfortable, in sharing their experiences for the greater good and quicker development.

And yet this brilliance will only be able to build off itself if data managers, as well as the organizations that support them, as a whole, are willing to match—and even exceed—the savvy nature of the social media platforms that are allowing us all to move the research and development world forward. In many ways, data management used to be the skeletal system of the industry. By necessity, there was a rigidly defined set of

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goals, standard operating procedures, and compliance standards. It used to be that one case report form (CRF) page, with just one category of data, would be keyed into a database. Next, someone would have to clean and check that data. This process worked well in an age of limited resources, more limited information flow, and a different expectation in timelines. But now that the amount of potential knowledge is so great, previous finite systems fall dreadfully short of current capabilities as well as of the innovative possibilities of the near future. Social media and other technology platforms mean that data management and these leading professionals must now, in fact, operate much more like the nervous system, feeling and responding to all the sensations around them. The inputs are not just from one tactile place as they were in the past, but are from multiple media sources that need to be integrated and adapted to, and ultimately land in the “brain” where data is analyzed and objectively interpreted.

When not only the industry but the scientific community as a whole is able to completely embrace this new frontier in data analytics and the role of the data manager, the advantages will be staggering. We are already seeing the lines blur between electronic medical records and CRFs. Processes that used to be considered highly separate steps, such as clinical monitoring, source document verification, and data entry and edits, will only become more blended and matrixed so the information can be used at faster rates and in more efficient ways. Technology will continue to create a unique synergy between these subject matters that will continue to yield efficiencies in cost, quality, and time. Linkages of all this data will reduce the errors and redundant reporting of years past, while digital channels will continue to evolve and drive the sharing and collecting of data points and experiences that the commercial health providers, biopharmaceutical companies, and the like may not have even thought to collect or

contemplate before. Scientific epiphanies will abound as a result, leading to life-saving medicine and life-enhancing products.

What are the best ways for companies to capture and integrate the knowledge that is discovered in social media, in patient communities, online, and face-to-face in this new digital era? At this speed of development, time will be the final judge. In the meantime, trial and error will likely inform which best practices work today and which ones will come to be accepted community wide.

Regardless of the constant changes in the way these free-flowing digital channels drive information, one thing is certain: an organization’s data analytics team can no longer be content to exist in the background, because their star is clearly rising. The infrastructure of the management of data has become the interactive face of our life science world. These processes will become the key to better science, and the role of the data management professional will no doubt take its new “natural” place at the forefront of this spectrum of collaboration.

Mark Lanfear is a global practice leader for the Life Science vertical at Kelly Services, a leader in providing workforce solutions. He has operated clinical trials around the world for almost two decades. In addition, Mark is a featured speaker at many of the Life Science industry conferences and a writer for its periodicals. He can be reached at MARL773@kellyservices.com or 248-244-4361.

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MASS SPECTROMETRY TODAY

**FAST-GROWING, INNOVATIVE,
BUT STILL SOMEWHAT ENIGMATIC**

by Angelo DePalma, Ph.D.

The mass spectrometry (MS) market continues to be one of the fastest-growing areas of analytical instrumentation. MS's growing popularity can be explained by its ability to provide, in many cases, verifiable molecular weights and thereby positive identification of known molecules. For unknowns, MS fragmentation patterns help scientists piece the molecule of interest together, like pieces of a puzzle. The growing popularity of MS detectors for gas and liquid chromatography, despite adding significant cost over conventional detection modes, underscores MS's utility and accessibility, even to technician-level operators.

As Steven Smith, Ph.D., senior director for MS product management at Waters (Milford, MA), explains, "An increasing number of assays performed as part of a regulated workflow require a mass spectrometer. If you want to sell your product, then you must use MS." In this context, "selling" includes handing off data from one stage of product development to the next, such as pharmaceutical discovery to process development.

MS markets

Mass Spectrometry: Driving the Superhighway of Analysis, a 2011 market study from Strategic Directions International (SDI; Los Angeles, CA), notes that sales of MS instruments fell in 2009 due to the recession, but have picked up briskly since then. SDI estimated 2011 sales at \$3.9 billion; they are projected to hit

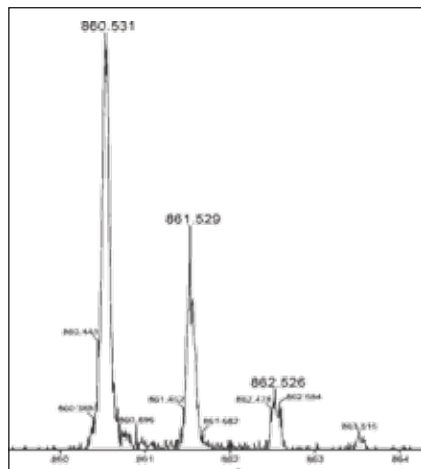
\$4.8 billion by 2014. Including the recession years, compounded annual growth between 2009 and 2014 is estimated at 7.9 percent—significantly higher than most other lab instrument categories.

Innovation and performance enhancements have accelerated as MS instruments have become commonplace, both as detectors for gas and liquid

chromatography and as standalone instruments. "The latest generation of instruments ... significantly outclass models that were introduced as little as a year before," the study authors write. "Over the past 12 to 18 months, resolution performance has improved anywhere from 50 percent for Q-TOF LC-MS to 400 percent for LC-TOF models. Vendors also have been working to reduce or eliminate traditional trade-offs in performance, such as sensitivity versus scanning

speed versus resolution, which have been a major marketing focus for many of the newest systems."

According to the study, the top 2011 markets for MS as a percentage of global sales are the United States and Canada (38.1%), Europe (31.1%), and Japan (13.3%), followed by China and the Pacific Rim (11.5%). Industry sectors with the highest sales activity are pharmaceuticals and biotech (20.4%), government (18.5%), academia (12.6%), and environmental/general testing (9.4%). The remaining end-user markets, in order of importance, are electronics, food/agriculture, chemicals, and hospital/clinical.



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Look Ma, no sample prep!

Apart from the rise of chromatography-MS, laboratories are beginning to adopt “ambient ionization” techniques such as DART® (direct analysis in real time) for applications ranging from forensics to food safety. “In addition, high-resolution MS is becoming much more common with the availability of new, more easily accessible technologies such as time-of-flight (TOF),” observes Robert Cody, Ph.D., mass spectrometry product manager at JEOL (Peabody, MA).

“The overwhelming majority of technicians in regulated ... laboratories are not degreed spectroscopists.”

DART requires no sample preparation or significant method development. DART’s plasma ion source strips surfaces of analyte ions and sweeps them as intact, protonated molecules, into the MS instrument. Another innovative ionization technique for aqueous samples, DESI (desorption electrospray ionization), resembles conventional ESI in that pneumatically assisted charged droplets ionize and remove sample from many nonconventional substrates, also without preparation. LAESI (laser ablation electrospray ionization), which Protea Bio (Morgantown, WV) licensed from George Washington University, is useful for producing 2-D maps of surfaces, including biological samples.

DART’s ability to identify known or unknown contaminants, such as brominated fire retardants, slip agents from polymer processing that wind up in food, adulterated drugs, and active ingredients in herbal products, makes it particularly attractive. The technique’s main weakness, according to Brian Musselman, Ph.D., CEO of IonSense (Saugus, MA), a vendor of DART ionization devices, is it provides little or no physical separation. DART cannot distinguish among the various six-carbon sugars, for example, or cleanly isolate a target analyte from its milieu. “With DART, if you’re not looking for something, you won’t find it.” DART operates most efficiently, Dr. Musselman explains, as a super-fast, definitive screen for specific targets.

Software: The user experience

End-users interact with complex instruments and systems primarily through software that provides data acquisition and processing, instrument control, method development, and other vital functionalities. Whether positive or negative, as the software interface goes, so goes the user experience.

“Software is perhaps the biggest obstacle to its successful deployment of MS,” comments Kevin A. Schug, Ph.D., associate professor, Department of Chemistry and Biochemistry, the University of Texas (Arlington). Vendors, he goes on to say, find it necessary to accommodate an expanding, typically inexperienced user base. “But this too often sacrifices the ability to manipulate instrument parameters for exploratory research.”

While OEMs make up for the lack in this versatility gap with *a la carte* software add-ons, these can significantly add to system costs. “One can hardly fault the manufacturers for this,” Schug adds, “but offering individual research customers consultation on software customization would be a great idea.”

“[Sales of MS instruments] are projected to hit \$4.8 billion by 2014.”

Some academic users, like Gavin Phillips, Ph.D., a research scientist at the Max Planck Institute for Chemistry (Mainz, Germany), take matters into their own hands. “I acquired my system from a small U.S. vendor, and the software was pretty basic, so I’m looking to write our own software using LabView [system design software] to get the instrument to do what we want in a more user-friendly manner.”

In stark contrast to control software, data handling packages are constantly trending toward greater functionality. Earlier this year, MS vendor AB SCIEX (Framingham, MA) and Indigo BioSystems (Indianapolis, IN) agreed to co-market Indigo’s expert system software, ASCENT™, for streamlining data acquisition and automating MS data review in forensic toxicology and preclinical and clinical drug research. The software is expected to simplify and accelerate adoption of new-generation MS technologies, and significantly reduce the manual interaction required for data analysis.

Practical aspects

The variety and diversity of MS can overwhelm the uninitiated. The SDI report identified no fewer than sixteen instrumentation categories, each with its own abbreviations and acronyms. The actual number, when all options are considered, is probably closer to 100; factoring in workflows, applications, and methods drives the number much higher.

“Given the cost of MS instrumentation, purchase decisions have come to resemble those for capital investments.”

That is why assessing “generic” maintenance, cost of ownership, return on investment, and learning curves for MS is nearly impossible. Nevertheless, JEOL’s Robert Cody believes a lot more could be done to educate users at all levels, with all instrument types. “Mass spectrometers are being treated as a black box, which is risky if the operator lacks the understanding to critically evaluate the answers the data systems provide.” The ability to recognize good answers from bad, Cody adds, is “priceless.”

“Industrializing” instruments has become a critical component of the business case for upgrading to or acquiring MS capability. The overwhelming majority of technicians in regulated food, chemical, and medical laboratories are not degreed spectroscopists. Instrumentation must be accessible and their outputs readable in industry-relevant units and not “instrumentaleze.”

“These are not markets where you simply present someone with a spectrum or chromatogram,” says Waters’ Steven Smith. Waters spends “a lot of time” working with customers on the business impact of their

“As the software interface goes, so goes the user experience.”

MS instruments—something they would not have done five years ago. Among the considerations are power consumption, throughput, assay value, cost per test compared with alternatives (if they exist), sample preparation, and solvent consumption. Given the cost of MS instrumentation, purchase decisions have come to resemble those for capital investments.

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LET'S HAVE A LOOK

**PREPARING FOR AN EFFECTIVE LAB
SAFETY INSPECTION** by Vince McLeod

The typical research facility contains a multitude of hazards. Most facilities will have a mix of research laboratories, instrument rooms, chemical storage areas, waste handling areas, and busy receiving/loading docks. The focus of this column will be on conducting safety audits in research laboratories, but the steps and the process can be applied to all the different areas of the facility. This Safety Guy's column will step you through conducting a meaningful laboratory safety survey. Our intent is to stimulate you to set up and implement a successful in-house program.

A great starting point for any lab using hazardous chemicals is the OSHA Laboratory Standard,¹ an excellent resource and the current regulation for private-sector facilities. Appendix A of the standard recommends performing inspections at least semiannually or quarterly for labs with high personnel turnover.

Personally, we feel there is no substitute for face-to-face interviews and a physical walk-through of each laboratory. The crucial thing here is that the inspector or auditor must have specific training and/or experience. He or she must possess specialized knowledge about the type of research performed in the laboratory undergoing the safety inspection. Checklists can help guide the process, but you need to know what you are looking for and what questions to ask if something does not appear right. You need to look for and spot the same health and safety issues that the regulating agencies would cite if they visited the lab. The different agencies potentially involved could include OSHA, EPA, USDA, CDC, DEA, and NIH, depending on the research focus of the lab.

Therefore, a complex lab may require more than one visit and/or inspector.

We prefer unannounced safety inspections, as this methodology can provide insights into true day-to-day lab operations. However, there are drawbacks to this approach. If the lab is very busy, the principal investigator (PI) or lab manager might not be available. Or some areas might not be accessible due to ongoing experiments. Flexibility is needed, and a mix of scheduled visits and unannounced inspections is the best option.

In reality, a lab safety survey involves performing a walk-through inspection and trying to spot obvious safety hazards while observing overall conditions in the lab. One goal of the inspection is to ensure that regulatory requirements are met and the lab is in compliance with all applicable rules.

Obviously, special research labs such as those dealing with radiation, select agents, or biosafety level 3 and above must receive focused inspections. These specialty labs contain more serious potential safety and health issues and require a closer look as well as experienced and knowledgeable inspectors.

We suggest you start the inspection with a records review, or as we call it, the paper trail. Seek out the lab manager or PI and identify yourself and the purpose of the visit. Opening with the paperwork gives you an opportunity to begin the interview while becoming familiar with the focus of the lab. We usually request the chemical hygiene plan, chemical inventory with safety data sheets (aka MSDS), and lab SOPs (standard operating procedures).

Prior to entering the lab, make note of any signs, hazard indicators, and warnings. Lab entrances



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SAFETY TIP



MAINTAIN A CHEMICAL INVENTORY TO AVOID PURCHASING UNNECESSARY QUANTITIES

By James. A. Kaufman

One school accumulated 20 five-pound bottles of mercury. Each year they ordered from the same list that they had used the year before! Not a good idea. You need to know what you have, where it's located, and who's responsible for it.

Whether you decide to do it with sheets of paper, index cards, or computers, you need to have a chemical inventory. It's pretty hard to comply with OSHA, EPA, and state right-to-know regulations without one. It's also difficult to know what to order without one.

If you decide to use a computer to keep your records, you can use any word processor, spreadsheet or database software program you like. Or, you can buy a program from one of the several vendors that offer the software packages. Programs are available that run on either IBM or Apple/Macintosh type systems.

Look at the features and see what meets your needs. How easily can additional chemicals be added to the database? Can the total list be sorted or indexed? How fast does it search? Can extra fields of information be added? How many?

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

should have appropriate signage to alert those preparing to enter about the hazards present. Most important, emergency contact information for after-hours incidents should be listed. Double-check this again when exiting to note if all hazards are represented and that any newer ones have been added.

After the records review, it is time to begin the walk-through. A quick Google search will produce myriad checklists available on the Web; the University of Florida has a good example.² We recommend using one. There are just too many things to cover. You will want to tailor your checklist to cover the majority of your labs. However, leave plenty of space to expand, as labs are dynamic and change from year to year, especially in an academic setting. For the technologically astute, you may want to use electronic lists on touchpads, net books, or notebook computers that record data directly to a database. However you choose to do it, we suggest that you take some time before the audit to read over your checklist and the previous year's findings to focus on all the different areas involved, such as:

- General lab signage and safety equipment such as hoods, eyewash stations, and safety showers
- Personal protective equipment that is appropriate for the task: lab coats, aprons, gloves, eye protection, etc.
- Overall lab housekeeping and organization
- Chemical safety and proper storage
- Electrical safety (this is a big one)
- Basic fire safety (another major category)
- Lab waste disposal

A lab safety audit is a serious undertaking and preparation beforehand is paramount to success and ensuring your findings are ultimately useful. If there is a golden rule for lab safety audits it is "do not rush." Take your time and look carefully at each counter, each shelf, and each cabinet. Do not be afraid to ask lab personnel if you are not sure about equipment setup or function, or any potential hazards. It will add to your knowledge base for the next inspection. Discuss all discrepancies and needed corrections with the PI or lab manager during a brief exit interview. That way any questions can be addressed immediately. Finally, do not forget to follow up with a written report, or you could find out the hard way that if it is not documented, "it did not happen." One last suggestion is to include a certain time or date to complete the corrections in your follow-up report. This will encourage quick action and help all parties involved make safety a priority.

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



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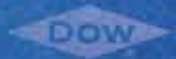
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THE HEART OF A GC SYSTEM

by Angelo DePalma, Ph.D.

Gas chromatography (GC) has experienced significant changes over the past 40 years, some technology based and others driven by specific applications. “While hardware and software improvements have made acquiring and processing data easier and more reliable, columns remain the heart of GC systems,” says Jack Hubball, Ph.D., technical director at Quadrex Corporation (Woodbridge, CT), a manufacturer of capillary GC columns and a distributor of gas generators, portable GCs, and consumables.

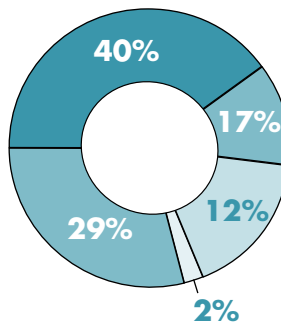
Close to 200 individual GC stationary phases were characterized by the mid-1970s. The advent of bondable polyethylene glycol phases reduced the number of identifiable phases to approximately 15, but according to Dr. Hubball, “This was short lived.”

Today, the number of distinct phases has grown due to the specialization of methods in the environmental, pharmaceutical, and petrochemical industries; differentiation of stationary phases beyond the standard chemistries; the realization that thick films exhibit different selectivity than does the same stationary phase at standard thickness; and the introduction of new materials such as ionic liquids.

Doing more with less

“GC is a mature market,” observes Kory Kelly, GC product manager at column specialist Phenomenex (Torrance, CA), “but with the economy being what it is, users are looking to do more with less, to optimize columns for higher performance.”

TYPES OF GC COLUMNS OUR READERS USE IN THEIR LABS INCLUDE THE FOLLOWING:



ONE MIXED BED/LINEAR/MULTIPORE COLUMN	29%
ONE SINGLE POROSITY COLUMN	40%
TWO OR MORE MIXED BED/LINEAR/MULTIPORE COLUMNS	12%
TWO OR MORE SINGLE POROSITY COLUMNS	17%
MIXED BED/LINEAR/MULTIPORE COLUMN WITH OLIGOMER COLUMN	2%

A typical user’s wish list might include:

- Columns that last longer, with improved initial peak shapes and more inert stationary phases
- Lower detection limits, with the capability for large-volume injections of more dilute samples
- Faster GC and/or optimized run times through shorter columns

and smaller internal diameters

- Specialized stationary phases for “strenuous” applications, particularly with chemically active analytes

The main column characteristic providing longer life and better performance is chemical inertness with minimal column bleed. Columns that leak during the stationary phase result in noisy chromatograms, or in some cases a gummed-up detector. “Columns with good initial peak shape, high efficiency, and low bleed last longer,” Kelly says. “They can take more abuse while delivering performance that is equal to or better than lower-performing columns.”

Factors affecting low detection limits are, in order: detector, inlet parameters, and column capacity. The right detector can make an ordinary column look like an all-star; inlet parameters relate to how much analyte reaches the column. Innate capacity becomes problematic, particularly for dilute samples, as column diameters shrink from 1 mm ID to 0.50, 0.25, 0.18, and 0.10. Capacity is proportional to the column diameter and length, but it also depends on the thickness of the stationary phase. Some manufacturers have compensated for smaller IDs with a thicker stationary phase coating, but this affects the magnitude of chemical interactions between analytes and columns.

Fast GC

Faster elution times—“fast” or “rapid” GC—are a function of column dimensions and stationary phase thickness. Other techniques include switching carrier gases (e.g., from helium or nitrogen to hydrogen) and vacuum outlet operation. The most significant contributor to faster elution has arguably been temperature programming, typically used alongside shorter, narrower columns and thinner stationary phases. Kelly likens the rapid ramp-up of oven and column temperatures at hundreds of degrees per minute to mobile phase gradients in high-performance liquid chromatography. Several vendors sell specialized ovens or columns encased in thermally conductive material connected to an electrically generated heating source.

But what goes up must come down: Cycle times can only be shortened by rapidly cooling the column back to its standard operating temperature. For this, Kelly advises, chromatographers need to select their upper and lower temperatures judiciously. “Some columns take longer to cool than they do to heat up. Choosing the optimal temperatures can cut 25 percent or more off cooling time and significantly shorten the analysis.”

Selling “solutions,” not columns

As with GC systems, what the marketplace is looking for from columns are “solutions,” says Chris English, manager for Restek Corporation’s (Bellefonte, PA) Innovations Lab. For columns, this means products related to and designed toward a specific method, e.g., pesticides. “Many manufacturers are building columns named after the intended application. The ‘solution’ consists of the column bundled with standards, an application note, plus hints not found in the official method but that users nevertheless need to get the method to work,” he explains.

This “secret sauce” consists of advice one might normally gain from experience, for example the length of a dry purge or the pros and cons of 1-microliter vs. 2-microliter injections. “Much of this information is not explicitly spelled out in the method,” English says.

“Solutions” need not be targeted to cutting-edge analysis. Most, in fact, address shortcomings in established methods. Restek’s Rtx®-CLPesticides and Rtx®-CLPesticides2 columns, for example, were developed for legacy pesticides, introduced decades ago, and their persistent degradation products. A lot of work continues as well on polyaromatic hydrocarbons, of interest to environmental and food safety, and the fluoranthenes, which are polyaromatic byproducts of burning coal and diesel.

While recognizing the desire for faster chromatography, English believes the trend will only go so far. “Not that many labs are going down to 100-micron ID columns because of the very high pressures involved. Plus their dynamic range is quite small and their calibration curves very short.” While 0.18-mm columns do provide faster separations, users may run up against scan speed issues when using a mass spectrometry (MS) detector. “A typical quadrupole MS should scan each peak at least eight times, which is why standard column diameters for this detection mode are 0.25 mm and higher.”

This discussion has so far been limited to capillary columns, but as English points out, packed columns are not going away anytime soon. “Many users don’t even know they’re still on the market.” Packed columns are ideal for large injections of liquids or gases in the petrochemical industry, or for back-flush applications. Many methods, such as ASTM 3606, for analyzing ethanol in gasoline, also call for packed columns.

Angelo DePalma is a freelance writer living in Newton, NJ. You can reach him at angelo@adepalma.com.

FOR ADDITIONAL RESOURCES ON GC COLUMNS, INCLUDING USEFUL ARTICLES AND A LIST OF MANUFACTURERS, VISIT WWW.LABMANAGER.COM/GC

MILLS AND GRINDERS

IMPROVED ACCURACY AND SPEED CREATE NEW POSSIBILITIES

by Mike May, Ph.D.

To grind something solid, many of us might think of a mortar and pestle as the original grinding machine. In fact, that technology goes back at least to 1550 BCE, when one was described in Egyptian writing. Many other hand-powered mills and grinders followed, leading to powered devices in today's many forms.

In describing mills and grinders, Joe Porcelli, regional sales manager at IKA (Wilmington, NC), says, "There are two traditional methods: wet and dry approaches." Wet milling uses a high-shear mixer on solids in a liquid suspension. "Wet milling helps minimize dusting, reduces heat degradation of the particles, and promotes improved flow characteristics through the mill," says Porcelli. In the dry technique, "particles are reduced through impact on tooling surfaces or particle collision. Examples include jet mills and pin or hammermills," he adds.

Both versions of this technology appear in many applications. "Some classic examples include wet milling of APIs—active pharmaceutical ingredients—slurries, size reduction, deagglomeration of cellulosic material in biofuels or bio-based chemical conversion,

and specialty pigment milling in the cosmetics and coatings industries," says Porcelli.

Getting the right grind

Consumer concerns often impact the use of laboratory equipment. For example, recent media attention to arsenic in rice and *Salmonella* in peanut butter drives enhancements to food safety processes. "This work requires high quality results from the sample process," says Kyle James, vice president of sales at Retsch (Haan, Germany). "So they are really focused on getting a grinder that produces accurate and reproducible results."

"Some grinders can store protocols—up to nine in some machines."

The accuracy involves particle size and homogeneity of the particles. "With a coffee grinder," says James, "you can get particles that range in size from 300 microns to 2 millimeters, but food safety researchers want something with more focused particle size." To get that consistency, a researcher needs to know that a specific configuration—grinder, rotor, sieve, timing, speed and so on—will always produce the

same or similar results. "Then, if you have a problem with your analysis, you know it's not because of the grinding of the sample," James explains.

To help users run different tests, James points out that some grinders can store protocols—up to nine in some machines. "If you need to report the procedure, you have all of the parameters available to you," James says.

The right grind also plays a key role in making pharmaceuticals. For example, Porcelli says, "In API wet-milling applications, as new drug materials are discovered, they are often insoluble in water. Wet milling these drug materials increases their efficacy and dissolution in the body and ease of formulation into a tablet matrix." He adds, "A new trend in the pharmaceutical and chemical industries is the controlled crystallization and subsequent wet milling of new compounds to control particle size and material performance."

Milling yeast

Mills also appear in modern molecular biology research. Tim Hopkins, president and CEO of BioSpec Products (Bartlesville, OK), and his colleagues started working with yeast about 30 years ago. "We worked with hundreds of gallons of yeast, and tried to find ways to break it open," Hopkins says. "It occurred

to me that we might add sand to a bar blender and throw in some yeast.” The experiment quickly destroyed the blades on the blender, but it disrupted the yeast. That led to the so-called BeadBeater approach.

Hopkins also wanted to make a machine to work with smaller volumes. For that, he says, “We moved toward the same bead mill but with 2-ml microvials with screw caps, and we shake the heck out of them.”

At Rutgers University (New Brunswick, NJ), George M. Carman, Ph.D., Board of Governors Professor in the department of food science and director of the Rutgers Center for Lipid Research, uses mills to break open yeast cells to make extracts. He uses these extracts to get enzymes from inside the yeast cells. “There are other ways to do it,” Carman says, “but this is the easiest and most efficient way.” In short, Carman uses the mill to break open the yeast to release its intracellular contents, and then he purifies the enzymes.

“A portable mill can be used in a cold room to help keep the samples from getting too hot, and therefore damaged.”

It might sound easy enough to break open yeast cells, especially since the cells are usually only a few micrometers across—maybe a few tens of micrometers for the largest yeast. But as Carman explains, “Yeast has a cell wall, and that’s not easy to open. It’s a very rigid wall—harder than a plant cell wall.” He adds, “The force from the beads allows shearing to break the cell wall into fragments.”

In looking for a mill, Carman seeks several features. It must break open the cells efficiently and quickly. “It has to happen in a pretty quick manner, because too much heat would destroy the enzymes that we’re trying to extract,” Carman says. Besides breaking up the cell walls quickly and efficiently, the sample must be kept cold in other ways to protect some of the components. So Carman uses some mills that include a jacket that can be filled with

ice. On the other hand, a portable mill can be used in a cold room to help keep the samples from getting too hot, and therefore damaged.

Beyond the basic technology in a mill, Carman also appreciates other features. For example, he likes that his mill lets him simultaneously process multiple microvials. “We do six, eight, 32, maybe more samples at one time,” he says. He also likes a mill with a timer. “We might shake a sample for 20 seconds, and then stop for 10 seconds to let it cool down a little before the next round of shaking,” Carman says.

From APIs to yeast, today’s mills change the possibilities of research and medicine.

Mike May is a freelance writer and editor living in Texas. You can reach him at mike@tecbtyper.com.

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ROTARY EVAPORATORS

ALL-IN-ONE VERSIONS AND OTHER OPTIONS ENHANCE EFFICIENCY AND SAFETY

by Mike May, Ph.D.

In 1950, the late biochemist Lyman C. Craig of The Rockefeller University developed a simple rotary evaporator. The first commercial version came from Walter Buchi in 1957. A rotary evaporator is a lab instrument that allows people to do chemical separation or purification by using heat and agitation—or stirring—under vacuum. “You’ll find one in any chemistry lab,” says Jim Dawson, president of Heidolph North America (Elk Grove Village, IL).

As Jeff Reid, product specialist at BUCHI Labortechnik AG (Flawil, Switzerland), points out, “You can use a rotary evaporator to separate a solvent from a compound of interest.” He adds, “Solvent recycling is big as well.” This technology can also be used in other applications, such as crystallizing samples.

Evolving evaporators

“There used to be just a few configurations of rotary evaporators,” says Dawson, “but now there are more options—different configurations to choose from and more manufacturers.”

Enhancing safety is a key trend in this technology. “Many researchers want the ability to safely control a rotary evaporator outside the fume hood or away

from the chemistry,” Dawson says. “This doesn’t mean a remote such as a TV remote, but a small wired operating panel that allows the chemist to control the process going on inside the hood at a safe distance.” He adds, “It basically helps to protect the scientist from the chemistry.” Still, chemists often want to watch the process. “Chemists still do lots with their eyes, like visualizing [whether] something is changing,” Dawson explains.

“An all-in-one system can save 75 percent in energy.”

Beyond safety, users want very low maintenance. “All researchers now have to run at higher levels of productivity, and downtime has to be minimized,” Dawson says. “So price isn’t always the game.” He adds, “The keys are the total cost of lifetime ownership and productivity.”

All-in-one control

Beyond controlling a rotary evaporator from outside a hood, some users want additional control with the technology itself. When asked about recent trends, Reid says, “Researchers want a system where you can control all

of the components—the chiller, the vacuum pump, and the rotary evaporator itself—together.” He adds, “An all-in-one system can save 75 percent in energy. In such a system, for example, the vacuum pump produces the needed level of vacuum and then holds it, instead of running continuously.”

Users can also build a system from various vendors and run them all from one controller. John Pollard, vice president of sales at BUCHI, says, “Our controller and some of our competitors’ controllers can control other brands, but you lose the green functionality.” When building a system from various components, for instance, the controller might display the vacuum but not turn off the pump when it reaches the desired level. “It’s more automated when it all comes from a single manufacturer,” Pollard says.

An all-in-one system also enhances the simplicity of using a rotary evaporator, which Pollard says is near the top of the list among customer desires. “In an academic market, you could have 100 users of one rotary evaporator.” So that machine needs to be easy to use.

In some cases, the use is easy enough but, as Reid says, “The trick is to find the right parameters.” He adds, “So we provide those for the most common solvents.”

From the field

For a rotary-evaporator customer, two questions should be considered. First, will the rotary evaporator work as the manufacturer says it will? Second, if something goes wrong, will the customer have support to get it running again? “Chemists know things will go wrong,” Dawson says, “because they are using volatile chemicals and acids.”

Alfred Bacher, Ph.D., of the department of biochemistry at the University of California, Los Angeles, teaches lower-division organic laboratory courses and the upper-division inorganic/organometallic laboratory course. He says, “In all of these courses, we use rotary evaporators very heavily, particularly in the lower-division courses, because the solvents being used are flammable.” Based on working largely with undergraduate students, Bacher would like a range of improvements in rotary evaporators. For one thing, he’d like lower-cost versions because, he says, “The cost of the rotary evaporators is too high to be used in larger numbers in undergraduate laboratory courses.”

“In an academic market, you could have 100 users of one rotary evaporator. So that machine needs to be easy to use.”

In addition, Bacher desires some design improvements. “Overall, the design seems to be very intimidating to many of my undergraduates,” he says. He’d also like the design to “allow for an easier disassembly of the setup for maintenance.” In fact, he’d like less maintenance overall. For example, he says the seals that connect the condenser unit with the motor are “not as robust” as they could be. Maybe, Bacher suggests, a rotary evaporator could include fewer joints in general to reduce the sources of leaks. For example, he says, “While I do understand why the receiving flask is attached with a ball joint, I feel it generates a significant



▲ IKA RV 10 Series rotary evaporator

problem as well because most round-bottom flasks used in the lab have normal ground glass joints.” Even adding a simple pressure gauge would be nice, Bacher notes.

Some problems can even be costly. As Bacher says, “The speed of lowering the assembly is too high in some models or a low point cannot be set to avoid the destruction of the vapor duct, which happens frequently in undergraduate laboratories.”

Nonetheless, Bacher realizes that many factors come into play in device design. So he describes his suggestions as “some of them being realistic, others probably not so much.”

Beyond the lab, rotary evaporators also appear in new markets. For example, some chefs use a rotary evaporator to distill liquids that they use over foods, like pouring on a high-tech reduction. The increasing simplicity of using this technology, such as the availability of all-in-one systems, should lead to even wider circles of use.

Mike May is a freelance writer and editor living in Texas. You can reach him at mike@tecbtyper.com.

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LAB WASHERS

ADVANCED FEATURES MAKE THIS TECHNOLOGY MORE EFFECTIVE AND MORE GREEN

by Mike May, Ph.D.

Once when helping a friend do the dinner dishes, she said, “You wash them so thoroughly.” I laughed and said, “I wash dishes like lab glassware.” And why? Because I was the ‘lab washer’ more than once during my science education. Now, modern machines handle that task.

For today’s lab washers, in general, “Scientists look for under-the-counter lab washers that have added features that make life a little easier and offer green capabilities,” says Odette Nolan, product specialist at LABCONCO (Kansas City, MO).

Those features include sustainability. For example, Deborah Ruriani, manager of marketing communications at Miele Professional (Princeton, NJ), says several factors contribute to machine longevity, such as fast cycle times, heating rates, and product construction. “Our glassware washers are tested to perform 15,000 operating hours and 90 percent of the machine is recyclable, constructed of high-grade stainless steel with plastic components clearly marked to facilitate recycling,” Ruriani says. “Baskets and inserts also need to be made of high-grade material and should be interchangeable.”

She adds, “Sustainability is not just about saving energy and water, but also about making sure that a lab washer does not end up in a landfill.”

Advanced options

Many advances in today’s lab washers involve special features. For instance, lab washers include capabilities to wash specific pieces of glassware. “In a pipette washer,” Nolan says, “an attachment forces water through the pipettes and then forces air through to dry them, so you don’t need an oven later.” The air, though, only dries the glassware. It doesn’t sterilize it. For that, researchers still need an autoclave.

“Several factors contribute to machine longevity, such as fast cycle times, heating rates, and product construction.”

In some lab washers a rack includes spindles for glassware with long necks, such as volumetric flasks. These features wash and dry, by forcing water and air through the spindle, respectively. “This cuts down the handling time of

the glassware, and anytime you handle glassware, your odds of breaking it go up,” says Nolan.

Manufacturers are looking to be solutions providers rather than just sell products. For example, there are labs that have high volumes of glassware to wash. If space allows, a user can buy a larger capacity glassware washer or two under counters. Likewise, says Ruriani: “A user can get twice the washing capacity in the same footprint with our stackable machines.”

Efficient cleaning

To make glassware washing efficient, machines must use fewer resources. “Green is always on the mind of everybody,” Nolan says. To make a lab washer more resource efficient, manufacturers take several approaches. For instance, a washer’s controls can include the ability for delayed washing, just like a home dishwasher. This lets users run the machine at off-peak hours, when electricity costs less.

The efficiency also depends on the speed of washing. For instance, Ruriani points out that powerful heating elements get water up to temperature quickly and powerful circulation pumps require less water per fill to provide a rigorous but gentle wash. These features reduce the overall wash time.

When it comes to water, the value of savings comes from how often a lab runs its washer. “It depends on the lab,” Nolan says. “We had a call from someone who was running a washer four times a day for BOD [biochemical oxygen demand] bottles, and a lab washer can take one and a half to two hours per cycle.” In such a situation, going from an older lab washer that uses 20 gallons per cycle to one that uses just 13 can save considerable water—140 gallons a week in the case of the BOD bottle washer.

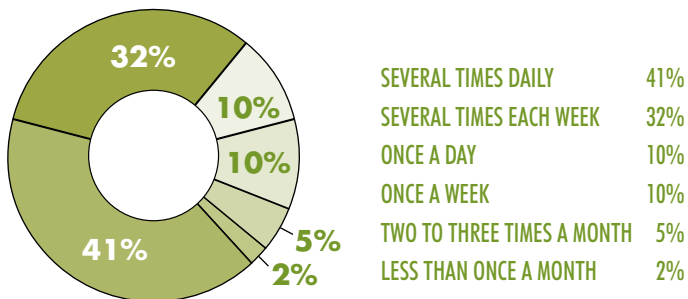
From the field

The benefits of a lab washer arise largely from how it gets used. For example, Monica Zatarski, PharmD, of MD Custom Rx (Brookfield, WI), says, “We use our lab washer to wash laboratory equipment and glassware used in prescription compounding.” Typically, that use results in running the lab washer once—sometimes twice—a day Monday through Friday. When asked what features she likes most about her lab washer, Zatarski says, “Primarily, I like the fact that we installed it to be able to provide a rinse cycle with purified water, which allows us to be USP [United States Pharmacopeia] compliant without relying on my staff to rinse everything.” She adds, “It gives great peace of mind knowing that the washer is able to steam clean and cleanse our equipment [at a level] unsurpassed by manual or residential dishwashing.”

“When it comes to water, the value of savings comes from how often a lab runs its washer.”

The features needed in a lab washer depend on budget and usage. As Ruriani says, “You have to really understand what someone is washing in the lab and their requirements [in order] to match them to the right system.” For example, she says, “People performing drug compounding tend to have confined budgets so they are limited in what they can spend, but they want a good washer that will last.”

MOST OF OUR READERS USE THEIR LAB WASHER SEVERAL TIMES EACH DAY:



High-end options

In cases where a researcher needs to validate cleaning, such as in a pharmaceutical environment, even more features can come in handy. For example, some users require secure controls and cycle documentation, fail-safe cycles and program monitoring, as well as validation documentation and execution. “This requires programmability,” says Ruriani. “Delivering repeatable wash results requires superior technologies, such as sensors on rotating spray arms that alert the user of a problem with the wash cycle, for example, if glassware is blocking an arm.” This allows the user to stop the process and rerun the wash.”

Some lab washers also provide maintenance-free conductivity monitoring that keeps track of the cleanliness of the rinse water leaving the washer. Likewise, some lab washers include HEPA filtered forced-air drying.

To get reliable cleaning, even seasoned and thorough hand washing of glassware fails. It takes an automated lab washer—one with modern capabilities.

Mike May is a freelance writer and editor living in Texas. You can reach him at mike@tecbtyper.com.

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REFRIGERATORS & FREEZERS

by Rachel Muenz

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APPLICATIONS

- Academic
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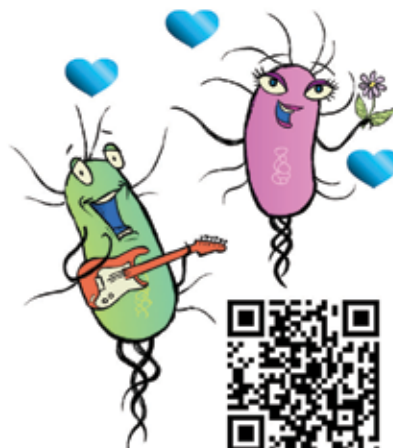
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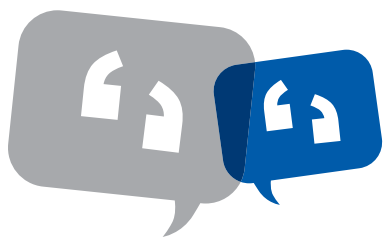


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Water jacketed	63%
Air jacketed	41%
Stacked units	41%
HEPA filtered	38%
Passively humidified	35%
Benchtop	24%
Thermistor-controlled CO ₂	23%
Actively humidified	17%
Infrared-controlled CO ₂	17%
Auto-decontaminating	16%
O ₂ Controlled	12%
Other	15%

Incubator components currently being used by our respondents:

High temperature disinfection	20%
Infrared CO ₂ control	17%
O ₂ control	14%
RH control	12%
Data logger	11%
Other	7%

ARE YOU IN THE MARKET FOR A... CO₂ INCUBATOR?

Top 6 Questions You Should Ask When Buying a CO₂ Incubator:

1. What measures have been taken in the design to avoid contamination and what features are included to remove (sterilize versus decon) contamination?
2. How does the CO₂ sensor contribute to optimal cell growth?
3. How does the humidity contribute to optimal cell growth?
4. Ask for the uniformity and accuracy data versus asking for a water jacket or air jacket.
5. Do you need O₂ control to simulate the environment for your experiment accurately?
6. Calculate the total cost of ownership on the product over one year including product price, install, regular cleaning labor, material like HEPA filter, etc.

Top ten factors/features that influence our readers when buying a CO₂ incubator:

Low maintenance/easy to clean	98%
Stable CO ₂ control	98%
Value for price paid	98%
Performance of product	96%
Warranties	96%
Ease of use	94%
Audible & visible temperature alarms	93%
Service and support	93%
Minimal temperature control	91%
Safety and health features	91%

Most common incubator operation issues being experienced by our readers:

Presence of contamination in the unit	23%
CO ₂ level is unstable	21%
Condensation	18%
Unstable temperature	12%
Humidity display	6%

Most common maintenance checks being performed by our respondents:

CO ₂ tank regulator pressure gauge inspection	72%
Humidity pan/pan level check	71%
Temperature display check with internal thermometer	71%
Interior disinfection and removable parts autoclaved	62%
CO ₂ inspection with an independent analyzer	52%
CO ₂ regulator and gas lines leak check	50%
CO ₂ and temperature calibrated using factory procedures	35%
Filter discoloration/replacement check	28%
Power cord wear inspection	27%
Proper CO ₂ tank switcher operation inspection	25%
Air flow and fan blade rotation/discoloration inspection	18%

➔ For more information on CO₂ Incubators, including useful articles and a list of manufacturers, visit www.labmanager.com/incubators

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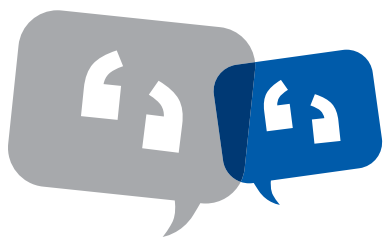
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ARE YOU IN THE MARKET FOR A... BIOLOGICAL SAFETY CABINET?

Biological safety cabinets (biosafety cabinets or BSCs) are enclosures that protect users and the environment from biohazards and samples from contamination. Whether performing research or production activities, the proper degree of protection should be maintained and is required based on the biosafety containment level of the lab or application.

Types of biosafety cabinets being used in our readers' labs:

Class I Biological Safety Cabinet	9%
Class II Biological Safety Cabinet	83%
Class III Biological Safety Cabinet	3%
Other	4%

Respondents using Class II biosafety cabinets are using the following sub-types:

Type A Class II	51%
Type B Class II	22%
Unsure of sub-type	26%

Top 5 Questions You Should Ask When Buying a Biosafety Cabinet:

1. Do the samples/specimens/cultures need to be protected from environmental particulates? Answering this question determines what type of BSC you require.
2. Are chemicals involved in your application? Hazardous (toxic or volatile) vapors are not filtered by the HEPA/ULPA filters found in BSCs. Different BSC designs are available.
3. What are your size limits? Know your maximum space allotment so that you don't end up with equipment that is too big for your lab, or so small that you can't work.
4. Does your procedure require modifications to the equipment that are uncommon? BSCs should be built to an appropriate standard and listed by a testing agency. Some modifications can lead to the equipment being unsafe. Reputable manufacturers will not provide such alterations.
5. Cost is always a concern. Avoid looking at the sticker price of a BSC; Inquire instead about the lifetime cost of each BSC. This includes energy savings, service life, and a proven product track record.

Top ten factors/features considered by our readers when purchasing a biosafety cabinet:

Durability of product	97%
Safety and health features	95%
Low maintenance / easy to clean	93%
Ease of use	91%
Performance of product	91%
Controlled airflow	86%
Low operating costs	83%
Service and support	82%
Warranties	82%
Value for price paid	79%

Containment level of our respondents' labs:

Containment level 1	35%
Containment level 2	55%
Containment level 3	9%
Containment level 4	1%

Respondents' agreement with the following safety statements regarding biosafety cabinets:

Test labels are properly affixed to all BSCs tested	91%
Storage in BSCs is kept to a minimum & doesn't impede proper airflow	90%
Workers using biohazards, toxins & regulated carcinogens have received the proper training	90%
BSCs containing regulated carcinogens, biohazards & radioactive materials are properly labeled	90%
Samples/specimens/cultures are protected from environment particulars	50%
All BSCs in the lab have been tested within the past year	18%

➔ For more information on biological safety cabinets, including useful articles and a list of manufacturers, visit www.labmanager.com/biosafety-cabinets **COMPLETED SURVEYS: 223**

protection

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and performance



**1300 Series
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Exceptional efficiency, safety
and value



DOCUMENTATION, DOCUMENTATION, DOCUMENTATION

KEEPING A RECORD OF EVERYTHING IS CRITICAL TO THIS SMALL BUT MIGHTY LAB

by Rachel Muenz

Though small, the cell culture lab at global product supplier Akron Biotech in Boca Raton, Florida plays a critical role in the company as a whole. The company specializes in the manufacture and supply of cell biology and cell culture products, providing raw materials to the stem cell and biotools industries, so it relies on cell culture to ensure those products are the best quality they can be.

“Our target market needs stem cells, needs cell culture,” explains Claudia Zylberberg, Ph.D., CEO/CSO of Akron Biotech. “So every product that needs to have some quality, [it] is the objective to have them fully developed, fully tested and be able to be fully compatible with any specific cell line for specific projects. Those projects require a lot of cell culture and qualification of those products for specific cell lines. That’s what we do.”

The lab has three employees who work on about four to five projects

per month and those workers need to have at least a year of experience with handling a tissue culture and two years of experience in lab technology, Akron’s lab supervisor, Andrea Pena, adds.

“Everything is pretty much a trial and error [process], so everything has to be documented each day.”

Aseptic technique and documentation practices are also key skills staff at Akron need in order to work in the cell culture lab.

With cell culture Ms. Pena explains, lab workers are, seeing which different aspects and different variables can change the product in making it better or making it

worse, which is why documenting everything is so important.

“Everything is pretty much a trial and error [process], so everything has to be documented each day,” she says. “It’s very detail-oriented type of work.”

Staff education must also be updated on a regular basis.

“As far as specific techniques—for example aseptic technique—that needs to be retouched every year,” she says. “The aseptic technique basically just details that everything that they touch is for the production of the product itself so it eliminates all possibility of contamination.”

Anyone interested in working in a cell culture lab like Akron’s should also make sure they have a solid grounding in biology, “So they understand the fundamental aspects of cell culture, like specific phases of the cell and how they grow, ways they can be agitated to express different types of proteins,” Ms.



Pena says. “Basically a good education in biochemistry and biotechnology, specifically cell culture.”

Managing the cell culture lab

As lab supervisor, Ms. Pena is responsible for making sure the cell culture facility’s equipment is up-to-date and properly calibrated, as well as making sure the employees are comfortable in the cell culture environment.

“I find that if they’re uncomfortable, they get nervous and mistakes can be made,” she says. “So if they’re comfortable and confident then things go a lot smoother.”

Ms. Pena also keeps an eye out to make sure the proper techniques are being used and is also responsible for “making sure that we use the best product for our cell culture, making sure that [staff members] document absolutely everything that they do from the time they start to the time they leave. It’s very essential that all data is collected.”

Making herself available to staff in case they have any questions is also important for Ms. Pena in managing the lab.

“If they have any type of questions about anything technical, [it is important] that they come ask instead of staying quiet and letting things progress,” she says.

In terms of keeping staff motivated Ms. Pena says that while different people are motivated in different ways, it

mainly comes down to being supportive, in addition to making sure staff have all the training they need.

“A lot of the staff that we employ need to have the confidence and the reassurance of their superiors, so if they have good feedback and positive feedback from their superiors and they go into the project with a positive mindset, then everything pretty much [builds] from there,” Ms. Pena says. “In order to keep them on point, [you] just have to make sure that if you ask them specific questions, that they’re able to answer you and ... that they are involved and in tune with the work they are doing.”

Dr. Zylberberg adds that giving employees a sense of the big picture also helps.

“I think that once they have responsibility for the project, then you give them [an idea] of where that project belongs in the big picture, what the impact that project will have ... I think sometimes that is a good motivation for the work,” she says.

Documentation is especially important in keeping the lab organized. Annual equipment maintenance and calibration records are kept on file and similar documentation is needed for employee training and quality control.

On top of that, employees must document everything they do in the lab each day and the data they collected in their own lab binder so that they can go back and review

what they did for the whole cell culture procedure they are working on.

“We’ve gone through ISO training, which is extremely stringent as far as documentation practices are concerned,” Ms. Pena adds. “It is essential that every single thing that comes in and goes out, that we touch ... has to be documented.”

Things that need to be documented include materials and equipment used, any incidents that occur and any time employees use the fume hood or do any maintenance or cleaning.

“Everything needs the documentation just to ensure that if something does go wrong or something comes back contaminated, we can trace it back to find the actual cause and the culprit and we can address it and fix it at that point,” Ms. Pena explains.

Forgetting to document one thing isn’t always the end of the world, but it’s usually better to be safe than sorry.

“That one thing could be extremely detrimental or the one thing could be overlooked,” she says. “If, for example, the data that they need to input is missing, that could be detrimental in the final results of the project.”

A day in the life of the lab

The average day in the Akron cell culture lab starts with a lot of paperwork scattered on the table that needs to be gone through before the day’s experiment begins. Once that experiment starts, it involves a lot of walking back and forth between instruments, getting materials and anything else needed for the work.

“You have to keep in mind that within the tissue culture lab, everything is based in one room to not have so much contamination in the area,” Ms. Pena explains. “Basically, you’ll see people in body suits, you’ll see them in shoe covers, hair nets, you’ll see them in full face masks, sleeve covers—a completely aseptically clean area to make sure that the final product isn’t contaminated.”

The day also involves checking on the growth and viability of the cells with microscopes and other equipment as well as cleaning and freezing the cells to supply more samples for the next experiment— aliquoting the cells, drying the cells, and making sure the cell banks are documented with all the company’s cell lines.

Dr. Zylberberg says cell culture technology has come a long way since the beginning, making that daily work much easier.



▲ A look inside the Akron cell culture lab.

“It always was very classic; [it] didn’t have very many pieces of innovation,” she says of how cell culture used to be, adding current advances on the disposable side, scaffolding, and 3D cell culture materials are bringing new products to the cell culture field.

“The applications have expanded a lot,” Ms. Pena adds. “It was very basic and simple and you couldn’t really manipulate it so much before but now there’s so many ways that you can do different types of testing to make sure the cell culture is actually viable. A lot of techniques have changed—they’ve improved over time.”

For Akron specifically, that means tasks such as running a gel take 45 minutes rather than three hours and technology is also much more precise.

“For example in the mycoplasma testing, it’s becoming more and more advanced and able to detect in the very initial stages so you can treat it properly. The technology has advanced quite rapidly in that sense,” Dr. Zylberberg says, adding that tighter quality control regulations and better contamination control have also had a big impact on the cell culture field. “I think there has been a big improvement in the industry and now that we have more cell therapies and cell culture becomes more a part of that, I think more stringent regulation makes the work a little more stressful but we realize we have all the elements in place right now to do better work, even if you compare with the biotech and biopharmaceutical companies,” she explains.

The most interesting project the lab is working on right now involves stem cells.

“It’s been a challenge, but we’ve been trying to build some embryonic stem cells for some work that we’re doing,” Dr. Zylberberg says.

That level of difficulty is due to the sensitivity of the cells, Ms. Pena explains, but it also makes them more interesting than other cells.

“They’re [stem cells] different from other cell cultures because they’re very sensitive and the way that they grow is different,” she says. “It’s cool in the aspect of, visually, you can see them clumping, you can see them split. Normally it’s difficult with other types of cell lines to see that type of growth. The science is cool from a nerdy, geeky standpoint, but it is cool.”

Time tight, but work rewarding

“Time is my biggest challenge,” Ms. Pena says of her biggest obstacle in the lab. “There’s not enough of it—”

“To finish all the things we need to finish,” Dr. Zylberberg chimes in. “I think adding more personnel would be the way to go but a lot of things have to happen at the same time, unfortunately.”

However, that time crunch is also part of what Ms. Pena enjoys most about her work at Akron.

“I like challenge and pressure, the reason being because I feel a sense of accomplishment once I’m given a task that’s very difficult and I have to find thousands of ways to overcome obstacles,” she says.

Finally getting the product done and finding out it works the way it is supposed to is another plus of the job, Ms. Pena adds.

“It’s very, very pleasing once we finish, as far as my point in the lab,” she says. “So working from the very bottom all the way to the top, seeing how things progress and get better—I just like the challenge and the fact that I can make a difference, whether it’s a positive or a negative... I feel very accomplished.”

Rachel Muenz, assistant editor for Lab Manager Magazine, can be reached at rachelm@labmanager.com or by phone at 888-781-0328 x233.

MAIN INSTRUMENTS:

- Revco by Thermo Scientific incubator with CO₂ tank for cell flask incubation
- Labconco Purifier class II biosafety cabinet
- Beckman Coulter cell counter
- Sorvall Legend RT centrifuge by Thermo Scientific
- Two BioRad thermocyclers (PCR machines)
- ND1000 NanoDrop spectrophotometers
- PerkinElmer 96-well plate spectrophotometer
- AKTA System mass spectrophotometer
- Agilent HPLC



▲ Though it is small, the cell culture lab at global product supplier Akron Biotech in Boca Raton, Florida plays a critical role in the company as a whole.

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BEYOND SAMPLE DIGESTION

TWO NEW MICROWAVE SYSTEMS BRING NOVEL SAFETY FEATURES AND CONTROL TO CHEMISTS

Anton Paar's recently released microwave digestion systems—the Multiwave PRO and Multiwave ECO—aim to address the limitations of legacy digestion techniques.

The Multiwave PRO is designed to go beyond simple digestion while the ECO is a low cost microwave digestion system designed for quick and convenient preparation of well-defined samples for routine environmental and food testing applications.

"Older open vessel techniques for digestion such as hot blocks or oil baths are limited by the method—the temperature could only go as high as the boiling point," said Eric Fox national sales manager of analytical and synthetic chemistry at Anton Paar.

He added that although safety features have come a long way since kitchen microwaves were used when scientists first started exploring microwaves as an energy source for chemical reactions, problems still exist.

"Over time, laboratory microwave manufacturers have been adding safety features to control these reactions but control is limited because temperature and pressure feedback are provided from only one 'control' reaction vessel," Mr. Fox said. "The Multiwave PRO has continuous, proactive monitoring on all sample positions which allows the user superior control of their sample digestion as well as unparalleled safety in closed vessel digestion techniques."

Mr. Fox added that current users of both systems find the precision on the control of temperature and pressure especially beneficial as it provides them with higher yields, fewer reworks, and smaller solvent quantities.

Among other benefits, there are also many different options for users, such as a comprehensive Installation Qualification package for regulated industries.

"Anton Paar now makes it even easier for you to integrate a new Multiwave PRO microwave system into your laboratory environment," Mr. Fox said.

For more information, visit <http://www.anton-paar.com>



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PRODUCT SPOTLIGHT

REDUCING THE TIME TO RESOLVE CRIMES NEW DNA KITS SPEED UP THE PROCESSING OF DNA SAMPLES IN FORENSIC LABS

Back in September, Life Technologies launched its new GlobalFiler™ and GlobalFiler™ Express DNA kits, which the company says will revolutionize how crime labs perform forensic testing around the world—making it faster, easier and cheaper to process DNA samples.



By increasing the number of genetic markers by over 30 percent to 24, GlobalFiler™ allows users to recover more information from forensic samples and increases discrimination power by up to nine orders of magnitude. This results in faster and more powerful comparisons of forensic data to resolve crimes.

The kits feature a new, proprietary chemistry that enables 48 samples to be processed in under two hours when combined with Life Technologies' forensic testing systems—five times faster than other solutions currently on the market.

"Enabling labs to go up to 5 times faster will decrease labor costs dramatically," said John Gerace, head of applied sciences for Life Technologies, about the new kits. "Also, if labs have not implemented direct amplification for reference/database samples yet, they will save time and money by eliminating up front processing time/costs (sample extraction, normalization). These up front processing steps can add significant costs to the overall process of DNA testing, so eliminating the step eliminates the cost."

He added that the kits deliver additional information faster to analysts and the company's improved buffers also make the kits more robust than older technologies.

"GlobalFiler also facilitates quicker and improved amplification of challenging samples, such as degraded human remains," Mr. Gerace said. "This is because this kit includes 10 mini-STRs, which are basically small sized markers that make it much easier to recover results from challenging samples."

For more information, visit www.lifetechnologies.com/globalfiler

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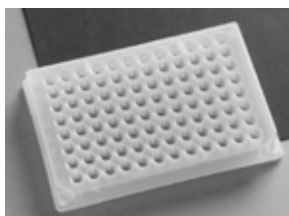


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An HPLC/UHPLC Column Protection System

Problem: In most UHPLC/ HPLC applications, the buildup of sample and mobile phase contaminants at the head of the chromatography column can cause detrimental effects. Particulates may enter the HPLC from many sources, including system wear and tear, sample preparation methods, or from the buffers and solvents used. Sample particulates and contaminants will build up on the column inlet frits or even migrate into the media itself. Increased system backpressures can result, along with degradation in chromatography, resulting in significantly shortened column lifetimes. Method sensitivity, quantitation and peak identification may all be adversely affected.

When columns have to be replaced more often costs go up, as does system downtime; chromatographers are forced to purchase, install, calibrate and condition a new column, thus impacting laboratory throughput. UHPLC columns packed with sub-2 micron particles tend to clog even more easily and rapidly than traditional HPLC columns packed with larger 3- or 5-micron media. This is because the UHPLC columns have smaller interstitial spaces between particles and the frits used have smaller pores. The restricted flow path makes it easier for particulates to build up, hindering both column and system performance.

Solution: Column protection systems, such as Phenomenex's SecurityGuard and SecurityGuard ULTRA, can protect columns and detectors from microparticulates from the sample or solvent. Column protection systems trap particulates and chemical contaminants with inexpensive replaceable cartridges. The cartridges are designed with a short bed length to ensure that they do not alter the chromatography while still protecting the column. Some advanced column protection systems like SecurityGuard ULTRA are specially designed for sub-2 micron, core shell technology (such as Phenomenex's Kinetex and Aeris) columns and < 3-micron particle columns (< 20,000 psi / 1,378 bar).

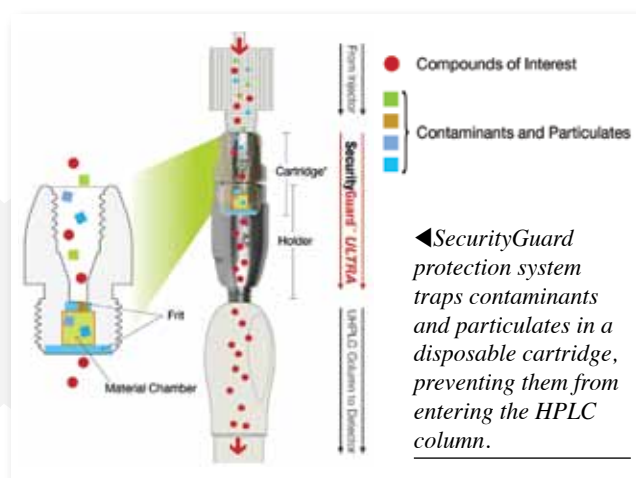
SecurityGuard and SecurityGuard ULTRA feature a direct-connect cartridge holder with a floating outlet nut that automatically adjusts to the precise port depth of almost every analytical column. This ensures a leak-free and low-dead-volume connection, without adapters or couplers. The cartridges, which are packed with matching column media, are designed for easy replacement when the current cartridge is expired.

An accelerated lifetime test, using an endogenous biological matrix injected onto a core-shell column, was conducted and results with and without column protection were compared. The results clearly showed that sequential injections of the matrix using an unprotected column lead to a steady and irreversible increase in backpressure, where the increase becomes logarithmic. This increase in backpressure ultimately leads to degraded chromatography, including band broadening and possible peak splitting. System pressure limits may also be quickly reached, at which point the

instrument automatically shuts down. Unattended runs may stop prematurely, requiring significant rework by the analyst.

Column lifetime is greatly extended by using the SecurityGuard ULTRA. In this case, sequential injections of the matrix will still lead to an increase in pressure, but this is due to the particulates being captured in the cartridge itself, rather than in the UHPLC/HPLC column. Thus, by simply replacing the cartridge at regular intervals, backpressure returns to starting levels and effective column lifetime can be greatly extended.

For more information, visit <http://www.phenomenex.com/SecurityGuard>.



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Absolute Quantification with Droplet Digital PCR

Problem: Basic research and clinical research labs have long relied on real-time PCR (qPCR) for its speed, sensitivity, specificity and ease-of-use. Common applications include gene expression analysis, mutation detection and identification of copy number variation to better understand inherited disorders, cancer and infectious disease. While qPCR is a viable strategy for detection, numerous challenges—ranging from errors associated with using a standard curve to imperfect amplification efficiencies—limit the accuracy of this technique for absolute quantitation. Real-time PCR is unable to reliably distinguish copy number differences below 50 percent.

Solution: Droplet Digital PCR (ddPCR) provides a new approach to target DNA quantification. Bio-Rad Laboratories' QX100™ Droplet Digital™ is one example of a PCR system that provides an absolute measure of target DNA and RNA molecules offering far greater sensitivity, accuracy and precision than qPCR (see chart). It works like qPCR with one big difference: it first partitions the sample into 20,000 droplets, providing greater precision and resolution for detecting small concentration differences. Due to the digital nature of the assay and the fact that no standard curve is required, ddPCR can discriminate between ± 10 percent differences in target DNA concentration.

The QX100 in particular partitions samples and reagents into 20,000 droplets with target and background DNA randomly distributed among them. This reduces background interference for more reliable and sensitive measurement of low concentrations of nucleic acid that may not have been detectable using qPCR and other technologies.

After PCR amplification occurs, droplets from every sample are streamed in single file on the system's droplet reader to determine which droplets contain a target and which do not. Using Poisson statistics, the reader calculates the concentration of target DNA from the fraction of positive reactions, providing researchers with an absolute quantification of target DNA.

The ability to detect and count single DNA molecules using droplet digital PCR opens new disease research and diagnostics applications including copy number variation, single cell and miRNA analysis, rare allele detection and next generation sequencing. In fact, researchers using the QX100 for mutation detection have reported that they can now detect a point mutation at 0.0005% to 0.001% of wild-type, which is more than 1,000 times more sensitive than qPCR. The system also discriminates small-fold differences in copy number, enabling researchers to measure 1, 2, 3, 4, 5, 6, or more copies. Researchers in Harvard Medical School professor Steve McCarroll's lab used the QX100

to precisely and reproducibly measure copy numbers greater than four, offering new ways of analyzing complex genome structures and relating them to human disease.

For more information on ddPCR, please visit <http://www.bio-rad.com/ddPCR> or e-mail Frank Bizouarn at Frank_Bizouarn@bio-rad.com.

	PRECISION	SENSITIVITY	ACCURACY
REAL-TIME PCR	Discriminates 2-fold differences in target DNA concentration	Limited sensitivity due to background interference	Requires standard curves or reference genes to estimate concentration of unknown
DIGITAL PCR	Discriminates $\pm 10\%$ differences in target DNA concentration	100x greater sensitivity by massively partitioning away the background	Absolute

▲ Digital PCR compared to real-time PCR.



hTERT-Immortalized Cell Lines

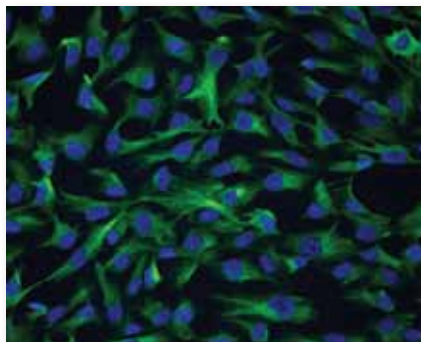
Problem: Choosing an *in vitro* model system that faithfully represents the natural physiology of the cell being studied is fundamental to understanding its *in vivo* function. Cultures of primary cell isolates retain their physiology and karyotype after isolation, but cultures may be difficult to prepare and are susceptible to contamination. More importantly, primary cells, with few exceptions, do not express telomerase. Without telomerase to maintain them, the telomere ends of the chromosomes shorten with each cell division, leading to telomere-induced replicative senescence. Thus, although primary cells are good models of cellular physiology, they become senescent *in vitro* before they can be expanded to provide the number of cells needed for biochemical or genetic assays.

Continuous cell lines, on the other hand, are not encumbered by telomere-induced replicative senescence and can be expanded indefinitely, making them ideal for performing biochemical and genetic assays. Continuous cell lines, however, are often derived from malignant tissue. As a result, they contain numerous genetic mutations, exhibit an unstable karyotype, and have protein expression patterns that may not represent the normal parent cell. Moreover, continuous cell lines representing normal, healthy tissue or non-malignant, genetic diseases like Cystic Fibrosis or Parkinson's disease are difficult to obtain. Consequently, continuous cell lines represent a narrow range of *in vivo* cellular function. Therefore, the ideal *in vitro* model must combine the physiology and stable karyotype of primary cell isolates and the indefinite propagation properties of continuous cell lines, while avoiding the replicative senescence of the former and the spurious genetics and limited reach of the latter.

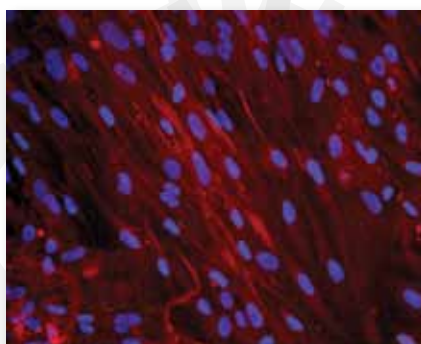
Solution: ATCC offers a wide variety of primary cells that have been immortalized through the forced expression of the hTERT component of the Telomerase gene. Expression of hTERT allows human primary cells to maintain the telomere ends of chromosomes and repress replicative senescence. Analysis of numerous hTERT-immortalized cell lines indicates these cells have a stable karyotype and retain many of the physiological characteristics of the primary cell, including normal phenotypic marker expression. Further, they exhibit normal p53 cell cycle checkpoint control, are non-malignant, contact inhibited, and anchorage dependent. Furthermore, they retain normal growth responses to serum and mitogens, require growth factors for proliferation, and do not show changes associated with transformation, such as tumorigenicity or growth in soft agar.

Importantly, hTERT technology allows for the straightforward development of matched cell lines from normal and diseased tissue. For example, ATCC offers hTERT-immortalized lines with non-malignant, genetic disease origins, such as those derived from the lung epithelium of Cystic Fibrosis patients (ATCC® CRL-4013™, -4015™, -4016™, -4017™). Additionally, these lines may be used experimentally with hTERT-immortalized lung epithelium from normal, healthy control subjects (ATCC® CRL-4011™). Thus, investigators no longer need to settle for primary cell isolates or continuous cell lines and their respective flaws. They now have the option of using hTERT-immortalized primary cell lines to provide a physiologically relevant, continuous cell culture model to build powerful experiments and advance their research.

For more information, visit <http://www.atcc.org>



▲ hTERT Immortalized Retinal Pigmented Epithelial Cells ATCC® No. CRL-4000™ stained with a monoclonal pan-cytokeratin antibody (green) and Hoechst dye (blue)



▲ hTERT Immortalized Hepatocyte Epithelial Cells ATCC® No. CRL-4020™ stained with a monoclonal pan-cytokeratin antibody (green) and Hoechst dye (blue)

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The system comes standard with an integrated feed water monitor, which protects and maximizes the life of your cartridges and filters by alerting you when a drop in feed water quality occurs.

The GenPure xCAD system can be mounted in numerous configurations: on the wall, on the bench or under the bench – up to 9 feet away from the xCAD remote dispenser. The remote dispenser can also be mounted on the bench or on the wall. With this improved mounting flexibility, you can remove the need for bench space for a water system, providing more space to do your science. The xCAD remote dispenser also has an adjustable angle display and swivel arm with extendable handle to increase visibility and working range.

Convenience is ideal when you are maximizing your work output. The remote dispenser can be set to dispense to a pre-programmed volume of water, creating hands-free operation and preventing over-filling of vessels.

Additionally, changing cartridges is easy with the aqua-stop quick connections, which eliminate the need to shut down or depressurize the system. Simply remove the old cartridge and insert the new cartridge. The aqua-stop connections prevent air from entering the system and water from exiting the system.

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ABSTRACT: Increasing the sensitivity and resolution of LC/MS instruments has been an ongoing focus for instrument manufacturers. As a result of this increased sensitivity of today's analytical instrumentation, the choice of high purity solvents can greatly influence the test results that are achieved.

INTRODUCTION: To meet the needs of the most demanding ultra-high pressure liquid chromatography (UHPLC) and mass spectrometry research and analytical testing applications, such as proteomics, drug discovery, pharmacokinetics, and clinical research, instrumentation is not the only parameter to be considered. Solvent design and selection is also very important. Performance of three specific solvents, (1) Acetonitrile, (2) Methanol, and (3) Water was examined in detail and the solvents were assessed for their suitability in selected LC/MS applications. In particular, the impact of packaging materials on the quality of LC/MS solvents was evaluated. The performance of LC/MS grade solvents was compared using LC/UV/MS gradient, MS infusion, and trace metals analysis. One way to ensure that high purity LC/MS grade solvents meet stringent purity requirements is by improving the packaging associated with the storage and delivery of these solvents. For example, certain containers can leach metal ions during storage, and lead to the formation of metal adducts, which can adversely impact test results.

EXPERIMENTAL CONDITIONS:

Materials:

- LC/MS grade Acetonitrile, Methanol, and Water from various suppliers

- J.T.Baker® ULTRA LC/MS™ solvents
- Standards (Sulfadimethoxine, Chlorophenicol)

Methods:

- LC/MS gradient (Waters ACQUITY UPLC® System/LCT TOF mass spectrometer)
- Positive/Negative ESI (electrospray ionization)
- Direct infusion to mass spectrometer (Waters Quattro Micro)
- Trace metals (Perkin-Elmer ICP-MS)

RESULTS: Results indicate that J.T.Baker® ULTRA LC/MS™ solvents and solvent packaging show better performance than other traditional LC/MS grade solvents. The J.T.Baker® ULTRA LC/MS™ water packaged in the borosilicate bottle maintained sodium levels < 9 ppb in two months while material packaged in amber glass bottles presented sodium levels > 150 ppb. Sodium metal adducts (m/z 333) were also reduced. The J.T.Baker® ULTRA LC/MS™ grade exhibited adducts of 40% compared to 150% for the material packed in amber glass bottles.

CONCLUSIONS:

Based on the data compiled for the study, the test results indicate that J.T.Baker® ULTRA LC/MS™ solvents are more suitable for use on UHPLC and high sensitivity

mass spectrometry instrumentation. J.T.Baker® ULTRA LC/MS™ solvents also offer better performance than the other brands tested by delivering:

- Lower trace metals
- Reduced adduct formation
- Minimal suppression

REFERENCES / TRADEMARKS

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Figure 1: ULTRA LC/MS Water—Sodium level (Borosilicate vs Amber Bottle)

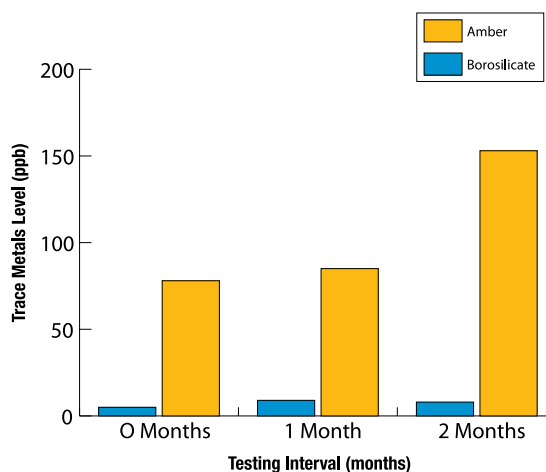


Figure 1a contrasts the sodium leaching for water packaged in amber bottles to borosilicate bottles over a two month time interval.

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The durable, easily maneuverable animal transfer station features an ergonomically engineered, adjustable work surface and slanted viewscreen on three sides for increased worker comfort. The well-lit workspace significantly reduces eyestrain, and low noise level improves operator comfort and reduces effect of ambient noise on animals.

The AniGARD e3 provides 14" high access openings and a flat, spacious work surface, so a variety of sized cages can be pulled in and out quickly, plus its hinged viewscreen opens to almost 22" for moving large items in and out of the workspace prior to working in the cabinet.

SUPERIOR PERFORMANCE IN CLEANLINESS, PROTECTION AND CONTAINMENT

The AniGARD e3 is designed to protect animals from particulate exposure and cross-contamination and reduce users' exposure to allergens by providing HEPA filtration in a recirculating air system. Its recirculating air design eliminates air discharge near the floor that could kick up dust and dander from the floor and into the environment.

The innovative animal transfer station also employs a unique high-velocity momentum air curtain to help ensure product and personnel protection without restricting access. This unique airflow design generates a strong air barrier along the perimeter of the work surface, working to prevent room particulates from entering the work area. Backed by rigorous testing in the Baker laboratory, the AniGARD e3 animal transfer station achieves stellar results for containment and protection, and minimizes cage-to-cage cross contamination. It provides ISO Class 4 (Class 10) air cleanliness and can help reduce user exposure to allergens.

EASY TO CLEAN AND MAINTAIN

The AniGARD e3 features a moveable, two piece work surface for easy access to spill tray and pre-filter. The unit has a welded, full perimeter drain pan under the work surface, with a 1" drain valve to catch liquid or spills and protect electrical components. The HEPA filters are easily accessed at the top of the cabinet with an easily removable pre-filter just below the work surface.

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ECONOMIZING ON VISCOSITY TESTING

ROTATIONAL VISCOMETERS ARE THE MOST WIDELY USED TOOL IN TODAY'S QC LABS FOR MAKING VISCOSITY MEASUREMENTS. MANY SMALL CHANGES, LIKE REDUCTION IN SAMPLE SIZE AND SHORTENING THE VISCOSITY TEST TIME, CAN LEAD TO SIGNIFICANT INCREASE IN QC LAB PRODUCTIVITY.

Rapid turnaround time in viscosity testing is fundamental to Quality Control's role in improving product consistency and minimizing batch rework or outright rejection. There are four factors to consider as lab manager that can reduce test time and/or improve the usefulness of test results:

1. Reduce sample size to the minimum necessary
2. Control sample temperature as quickly as possible
3. Reduce the time required to run the viscosity test procedure
4. Automate the entire test if feasible

EXPERIMENTAL CONDITIONS

SAMPLE SIZE: QC viscosity test methods have been in existence for ages. Many do not get reviewed to see if they still make sense or are being done in the most practical way. Grab samples from the production floor may be up to a half-liter or more in size, when perhaps much less will do. The test apparatus used to make the viscosity measurement can be selected to work specifically with small sample sizes. Disposable chambers for use with accessories like Small Sample Adapter (see Figure 1) require 16mL or less, depending on spindle used, and can be discarded after the test is run.

TEMPERATURE CONTROL: One reason for variability in viscosity test results is absence of temperature control when making the measurement. All fluids and semi-solids are temperature dependent. R&D should provide an assessment of the viscosity-temperature profile and decide whether temperature control should be practiced during the QC test. If yes, then the choice of small sample size above makes even more sense. The time needed to bring 16mL of sample to temperature is relatively small compared to a half-liter. The Small Sample Adapter comes with a water jacket that brings the sample to temperature equilibrium in a matter of minutes.

VISCOSITY TEST TIME: Once the spindle is immersed in the test sample and temperature equilibrium is achieved, the test may last a few minutes. Regardless of the rotational speed(s) used, there is the possibility that the time of rotation before the viscosity measurement is recorded is longer than necessary. What guideline should you use? Once the

viscosity reading stabilizes, this is a good indication that a valid reading has been obtained. QC should report this observation back to R&D for consideration in shortening the test. Precious seconds, if not minutes, can be saved by using good judgement.

AUTOMATING THE VISCOSITY TEST: Today's benchtop viscometers have the capability to run tests automatically. The instrument shown in Figure 1 can monitor sample temperature until equilibrium is achieved, then start the spindle rotating for a defined time interval, and finally record the measured viscosity value. Data capture can be automated as well if the instrument is connected to a printer or PC.

RESULTS

Busy QC labs that run dozens of tests every day look to economize whenever possible. Saving a half minute on every test can bring significant returns toward boosting lab throughput. The QC Lab Manager can easily make this calculation once the viscosity test procedure has been reviewed and analyzed.

CONCLUSIONS

Small changes in viscosity test procedure for QC Lab operation can lead to big improvements. Time saved per test brings immediate return to the bottom line. The investment in the equipment shown in Figure 1 is minor compared to the financial savings that result from reduced test time. Perhaps it's time to reconsider your viscosity test method and economize.



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THE ANALYSIS OF 1,4-DIOXANE FOR EPA METHOD 522 AND UCMR 3

This Application Note will demonstrate the extraction of 1,4-Dioxane from an aqueous matrix using Option 1 of EPA Method 522 for 500 mL initial volume sample. It will make use of the SmartPrep Cartridge Extraction System to produce a valid Initial Demonstration of Precision (IDP) and Initial Demonstration of Accuracy (IDA).



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INSTRUMENTATION

- Horizon Technology
- SmartPrep™ Automated Cartridge Extractor
- 6 mL Cartridge Configuration
- 20 mL Tray
- Restek
- ResPrep 6 mL, 2 g Coconut Charcoal Cartridges
- Rxi®-5Sil MS; 30 m x 0.25 mm x 0.25 µm
- Agilent Technologies
- 6890N GC
- 5975C MS – Operated in SIM mode

METHOD SUMMARY

1. Prepare 500 mL of deionized water using 0.5 g of Sodium Bisulfate to lower the pH to approximately 2.
2. Add 2.5 µL of a 2000 µg/mL surrogate solution containing 1,4-dioxane-d8 and 7.5 µL of a 200 µg/mL spiking solution containing 1,4-dioxane (for blank samples, add only surrogate solution).
3. Attach Sip Tube number 1 to the sample container.
4. Place a 20 mL VOA vial in position 1 of the tray.
5. Place a 6 mL, 2 g Coconut Charcoal cartridge on position 1 of the carousel.
6. Program and run the EPA 522 method using an N2P1 pressure of 5 psi and an N2P2 pressure of 10 psi.
7. Bring the final volume of the extract to 10 mL.
8. Add internal surrogate (tetrahydrofuran-d8) to the full 10 mL extract and run on a GC-MS.

RESULTS

Once a calibration curve was generated on the GC-MS, the extraction process was programmed into the SmartPrep system as it appears in Method 522. Each extract took approximately 1.5 hr to complete on the SmartPrep. During this time, the SmartPrep delivered all reagents, gases, and sample automatically allowing the user to streamline the preparatory process by performing the extractions overnight.

To obtain a valid IDP and IDA study, four to seven extracts must be prepared near the midrange of the calibration curve. It should be noted that the same extracts may be used for both quality tests. The relative standard deviation (RSD) must be less than 20 % and the average recovery must fall within ± 20 %. The studies performed for this Application Note had the surrogate and internal standards spiked at 10 µg/L while the target analyte was spiked at 3 µg/L. This corresponds to a midrange concentration of the calibration curve that was run on the GC-MS. The data obtained for this study is given in Table 1. With the recovery of both the surrogate and target analyte being 99 and 98 % respectively, and the RSD being less than 10 %, the IDP and IDA studies pass Method 522 criteria.

CONCLUSIONS

The SmartPrep Cartridge Extractor demonstrated that it is able to obtain a valid IDP and IDA study with excellent precision and accuracy for EPA method 522. In addition to this, the SmartPrep Cartridge Extractor has the ability to extract up to 12 samples automatically while the user is otherwise occupied. The SmartPrep's features combine together to streamline the sample preparation process and allow for it to keep up with the rigorous demands of today's methodologies.



Table 1. Initial Demonstration of Precision and Accuracy for 1, 4-Dioxane

	Blank	LCS 1	LCS 2	LCS 3	LCS 4	LCS 5	LCS 6	LCS 7	Average	St Dev	RSD
Recovery as ug/mL											
	(ug/mL)	(ug/mL)	(ug/mL)	(ug/mL)	(ug/mL)	(ug/mL)	(ug/mL)	(ug/mL)	(ug/mL)	(ug/mL)	(%)
1,4-Dioxane-d8	8.64	10.81	9.22	9.83	10.39	10.15	9.73	9.49	9.94	0.54	5.47
1,4-Dioxane	ND	3.17	2.60	2.98	3.13	2.94	3.00	2.71	2.93	0.21	7.13
Recovery as %											
	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
1,4-Dioxane-d8	86.44	108.06	92.16	98.32	103.86	101.48	97.34	94.86	99.44	5.44	5.47
1,4-Dioxane	ND	105.53	86.53	99.40	104.27	98.07	100.00	90.33	97.73	6.97	7.13

CONCENTRATION OF SOLUTES

OPTIONS FOR THE REMOVAL OF SOLVENTS FROM SAMPLES

Solvent removal from solutions is commonly performed in laboratory and production processes. There are a number of different methods that can be used for solvent removal, including evaporation, vacuum concentration, lyophilization, reverse extraction, solute precipitation, and dialysis (solvent exchange). The objective of solvent removal may be to preserve solutes, as is routinely performed on protein solutions, to concentrate solutes for analysis, or as a step in the synthesis or modification of solutes.



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EVAPORATION

Solutes that are not volatile can be concentrated by drawing the solvent into a gaseous headspace. Two approaches can be used for solvent removal, one being by boiling and the other by directing a stream of (inert) gas over the solvent. In this latter approach, the gas essentially extracts solvent from the liquid phase by dissolving it into a gaseous stream (followed by dilution into the atmosphere). This is the basis of gas chromatography. As the gas flows, the decreased concentration of vapor-phase solvent molecules shifts the vapor/liquid phase equilibrium, drawing more liquid solvent into the vapor phase. By streaming the gas, the evaporation rate is increased. Systems such as the RapidVap® Evaporation Systems, direct a gas stream, usually of inert nitrogen, over the sample. The RapidVap evaporators have the option of applying heat and agitation to the sample to help quicken the evaporation process.



◀ *RapidVap®
Evaporation System*

VACUUM CONCENTRATION

The removal of solvents can be effectively accomplished by boiling. Unfortunately, many solutes such as proteins, are destroyed by the heat required to drive off solvents. However, solvents can boil by either applying heat or by lowering the atmospheric pressure. In both cases, the energy of molecular motion is greater than the intermolecular forces holding the molecules in solution. The result is that solvent molecules escape from the liquid phase

to the gaseous phase. The difficulty with applying a vacuum (or applying heat) is that the force by which molecules move from liquid to gas causes the solution to splatter. This causes sample loss and/or cross contamination between samples when multiple tubes are positioned together. In vacuum concentration devices, such as the CentriVap® Centrifugal Concentrators, a vacuum pump is attached to an airtight, low speed centrifuge that prevents "bumping" by forcing the liquid down into the tube. The system can then run at high vacuum levels to speed solvent removal. The CentriVap Centrifugal Concentrators also have the option of regulating the centrifuge chamber temperature, which is useful for regulating sample temperatures at lower vacuum pressures.



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LYOPHILIZATION (A.K.A., FREEZE DRYING)

Similar to vacuum concentration, the process of lyophilization goes one step further by lowering sample temperature to the point where the solution freezes and solvents are removed by sublimation. The freezing step can be done in the same preparation step or caused by the application of a vacuum, which, in the process of removing the atmosphere, also removes heat. Normally the solution is always frozen before the vacuum is applied. Lyophilization can be a relatively complex process that is usually performed in multiple stages. The first stage is sample freezing, which is critically important to the overall process. Slow freezing of

a sample causes large ice crystals to form which makes freeze drying easier, but may denature many temperature sensitive proteins. Freezing a sample rapidly results in small ice crystals which can impede freeze drying, but many proteins retain activity when flash frozen. The second stage, primary drying, occurs when the sample temperature is raised sufficiently to allow heat to flow into the frozen solution and drive the sublimation process. However during primary drying, if the temperature increases too much, the sample can thaw and "collapse." Primary drying removes 90% or more of the solvent, at which time secondary drying, the third stage, can commence by increasing sample temperature. Secondary drying is feasible once the bulk of the solvent is removed during primary drying; the risk of melting is lessened. Secondary drying drives out residue solvent by applying greater amounts of heat. For instance, mannitol undergoes primary drying at temperatures below -23°C (depending on the formulation) while secondary drying is as high as 40°C. Lyophilizers, such as the Labconco FreeZone® Freeze Dry Systems, are an extremely effective tool for removing relatively large volumes of solvents while retaining activity of sensitive solutes. Freeze drying is very effective for concentrating and preserving biologically active proteins.



◀ *FreeZone® Freeze
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DETERMINATION OF MERCURY IN NUTRACEUTICAL SAMPLES USING A DIRECT MERCURY ANALYZER

With the expansion of the global nutraceutical market, the spotlight on the analysis of its raw materials is ever increasing. Testing of nutraceutical products for heavy metals like lead, arsenic, cadmium and mercury has gained utmost importance. Extremely low levels of these heavy metals like mercury, in nutraceuticals make its analysis challenging. Analytical chemists have to rely on techniques like CVAA and ICP-MS which involve a time consuming and a labor intensive sample preparation step. Direct mercury analysis, as described by EPA 7473, is an alternative method to traditional techniques that requires no sample prep and with results in as little as ~6min per sample. This makes it significantly faster with comparable or better recoveries than CVAA and ICP-MS.

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The nutraceutical industry covers a broad spectrum of products including botanical extracts, vitamins, minerals and dietary supplements. A rise in the level of health consciousness among consumers has led to an exponential growth of the nutraceutical market. However, the industry has come under scrutiny to ensure control over toxic heavy metals such as mercury. Given the volatile nature of mercury and the industry's need to test it regularly at low concentrations, sample preparation can often become complicated and confusing.

Traditional techniques used to analyze mercury in nutraceuticals involve a sample digestion step after which they are analyzed on CVAA or ICP-MS. Although effective, sample preparation requires man power, equipment, handling and disposing large amounts of acid and takes hours for completion. Alternatively, the US EPA developed a method 7473 for rapid determination of mercury in solids and aqueous samples without sample prep. This method uses an integrated sequence of thermal decomposition followed by catalytic conversion, amalgamation and atomic absorption spectrophotometry.

INSTRUMENTATION

A direct mercury analyzer (DMA-80 Tri-Cell) from Milestone Inc. was used for this experiment. The instrument was configured to sequentially process up to 40 samples placed on the auto-sampler. The auto-sampler automatically aligned and accommodated quartz (1500uL) and nickel (500mg) sample boats. All the components of the DMA-80 instrument were contained in a closed system to ensure that the samples were not exposed to outside interferences. Oxygen is used as a carrier gas at 65psi pressure and a flow rate of 7L/hour.

CALIBRATION

The DMA can be calibrated using aqueous standards or Standard Reference Materials (SRM). The DMA-80 used for this experiment had a tri-cell spectrophotometer and covered a dynamic range of 0.0015-1200ng Hg. Each cell was calibrated using different volumes of 1ppm and 0.1ppm stock solutions, prepared from an NIST traceable 1000ppm stock solution (VHG Labs).

EXPERIMENT AND RESULTS

To test the efficiency of the DMA-80, three commonly available nutraceutical samples – Valerian root, Ginkgo Biloba and Glucosamine chondroitin were spiked by a solution having a mean mercury concentration of ~10.2ppb and were run in the instrument to test for spike recoveries. Also, Ginkgo SRM 3248 was analyzed to test if its mercury concentration falls in the NIST certified range.



The spike concentrations obtained for the Ginkgo SRM – 3248 were 0.2544 ppb and 0.2673 ppb. These concentrations were not only in the certified range of mercury concentration but also had an RSD of 0.05% which represented the accuracy and reproducibility of the DMA-80 at low mercury concentrations. The recovery data mentioned in the table above suggests efficient spike recoveries.

A nutraceutical testing laboratory is required to analyze different matrices accurately and quickly while keeping operating costs under control. The DMA-80 is an excellent tool as it yields results in ~6min/sample and proves to be proficient, matrix-independent and cost effective while completely eliminating the challenges of sample preparation posed by conventional mercury analysis techniques.

SAMPLE	CONC. (PPB)	EXPECTED CONC. (PPB)	RECOVERY %
VALERIAN ROOT	4.7447	--	--
GINGKO BILOBA	2.0537	--	--
GLUCOSAMINE CHONDROITIN	1.5817	--	--
SPIKE	10.2750		
VALERIAN ROOT SPIKED	15.5589	15.0197	103.59%
GINGKO BILOBA SPIKED	12.8810	12.3287	104.48%
GLUCOSAMINE CHONDROITIN SPIKED	12.4578	11.8567	105.07%
GINGKO SRM 3248	0.2609	0.271 +/- 0.034	96.27%

▲ Table 1.

The concentrations mentioned in (Table 1) are mean values obtained after running duplicates for each sample.

EXHAUSTING OF A CLASS II, TYPE A2 BIOLOGICAL SAFETY CABINET (BSC)

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VFC INTEGRATION INTO A LABORATORY MECHANICAL DESIGN

Traditionally, exhaust canopies using a fixed slot area provided a fixed exhaust volume requirement that was added to the cabinet exhaust volume for the total exhaust volume requirement used for the laboratory mechanical design. However, now the VFC has variable slot areas, so the exhaust requirement that is added to the cabinet exhaust volume for the total exhaust volume requirement is also variable for the laboratory mechanical design. With the VFC offering a range of exhaust volume possibilities, the question becomes, what exhaust volume should be designed into the laboratory mechanical system? Traditionally, exhaust canopies were designed to exhaust approximately 25% more air volume than the cabinets exhaust volume. The VFC now can be used with as little as 5% more or up to 100% more in some cases depending upon

cabinet size. The answer to the above question becomes one of what produces the optimal mechanical design. Laboratory size, pressure, air change rate, heat load and other exhausting devices can all have an impact on the designed exhaust volume of the VFC.

If it is found that there is not a specific exhaust requirement, then it is suggested to use a target canopy air volume (i.e. 100 cfm plus cabinet exhaust volume) that offers the ability for on-site adjustment (slot area on canopy) for optimal capture velocity (i.e. 200 fpm). If energy efficiency is desired, then use the minimum canopy air volume (i.e. 25 cfm plus cabinet exhaust volume). The real benefit of the VFC is the adjustability both through the design and installation phases. It will provide the mechanical designer flexibility to specify to the optimal exhaust flow volume for the application. It will also let the installer/certifier field adjust to assure the proper capture slot velocity.

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- Integrated audible and visual low exhaust alarm.
- Provides a safety operational tolerance range for normal exhaust system fluctuations.



For full information on how to apply the VFC to your BSC Contact NuAire at: 800-328-3352 or visit www.nuaire.com.

MEASUREMENT OF GOLD NANOPARTICLE SIZE AND CONCENTRATION BY SPECTROPHOTOMETRY

By Andrew F. Page Ph.D.

Although gold nanoparticle production can be controlled to yield specific size ranges, both the concentration and size of nanoparticles must be checked following production. UV-Vis spectrophotometry is an established QC method for this; however cuvette spectrophotometers often require dilution of the nanoparticle solution before measuring, and volumes up to 3 mL. The Thermo Scientific NanoDrop 2000 spectrophotometer presents the advantages of variable pathlength and low sample volume, circumventing the problems of traditional spectrophotometers.

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INTRODUCTION

The ease, speed and cost of UV-Vis spectrophotometry make the technique frequently the first used to judge the success of nanoparticle (NP) production. The use of traditional spectrophotometers is still inconvenient, however, as the use of cuvettes presents several inherent drawbacks.

Nanoparticles are often produced in high concentrations, and have large extinction coefficients, resulting in the need for dilution prior to measurement. In addition to this, the concentration of solutions may vary widely, requiring measurement of multiple dilutions in order to find one within the spectrophotometer's dynamic range. Colloidal metal NP size can also be assessed using UV-Vis spectrophotometry, as the wavelength of the absorbance peak is dependent on the size and shape of the particles because of the surface plasmon resonance effect as light strikes them.

Recent work¹ has shown that a NanoDrop™ 2000 presents a low volume alternative to the use of cuvettes. The pedestal technology used requires only 2 µL, saving samples which may be especially precious following a lengthy functionalization. The variable pathlengths (0.05 - 1.0 mm) also negate the need for dilutions by extending the instrument's dynamic range.

EXPERIMENTAL PROCEDURES

Gold NPs with diameter 13 nm were synthesized via a sodium citrate reduction of gold (III) chloride.² The NanoDrop 2000 was first used to determine the approximate NP size by verifying the wavelength of the absorbance peak (fig. 1a).

The NPs were then purified and concentrated before a serial dilution was created and measured (fig. 1b). Between measurements, the NanoDrop 2000 optical surfaces were simply cleaned using a standard laboratory tissue.

RESULTS

As shown in figure 1a, spectra are highly reproducible, with high signal to noise ratios. Peak absorbance was measured at 520 nm, as previously reported.^{3,4} The solutions were successfully measured over a wide concentration range (1–150 nM, fig. 1b).

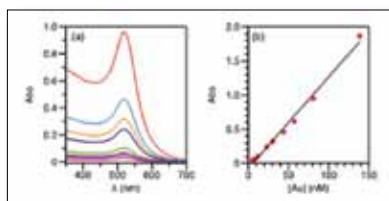


Fig. 1 (a) UV-Vis spectra for a dilution series of gold NPs; (b) corresponding 1 mm Abs vs concentration plot showing the linearity over a large concentration range.

CONCLUSION

The NanoDrop 2000 was found to be very versatile in the analysis of gold NP size and concentration. Given the ability to measure NP concentration over large concentration ranges, as well as the small volumes required, the NanoDrop 2000 is an ideal instrument where very small amounts of concentrated particles are produced.

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The 2010 Geno/Grinder® offers analysts a versatile high-throughput tissue homogenizer for plant or animal tissue homogenization. The patented design with a true linear grinding motion provides the most efficient bead milling mechanism for tissue homogenization and cell lysis for extraction of DNA, RNA, proteins or enzymes. The powerful and compact design enables complete disruption with or without buffer in about 1-3 minutes with high yields. The 2010 Geno/Grinder® has also been successfully used for pesticide residue extraction from fruit and vegetables as well as other organic contaminant extractions from food samples using the QuEChERS technique.

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- Supplied with height-adjustment spacers to handle titer plates, racks, vials, and other configurations
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The bead milling method is one of the few that totally avoids possible cross-contamination between samples because both vials and grinding media are disposable. Speed and effectiveness of disruption can be increased dramatically by increasing the density, form and amount of grinding media in the sample vial or titer plate. Tough tissues may require precooling to embrittle the sample and this also serves to preserve any temperature sensitive components such as RNA or Proteins.

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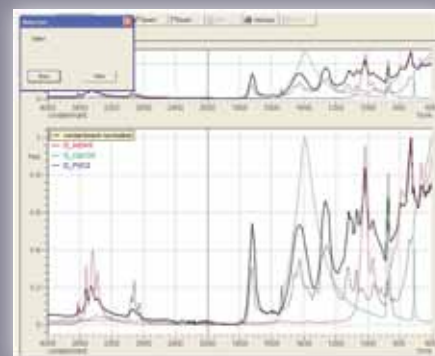
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PARTING POINTS

Takeaways from this month's issue:



TOOT YOUR OWN HORN

The stage beckons more scientists now. Scientific promotion was once an oxymoron. But as the global economic storm toys with the career dreams of many scientists, promotion is emerging as a 21st-century survival skill for the scientific community. Keys to scientific marketing include:

- The Internet
- Communicating to people how the research will benefit them in an understandable way
- Building relationships
- Developing a networking footprint

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THE SECOND ANNUAL LABORATORY SPENDING TRENDS REPORT

With the looming possibility that substantial portions of the U.S. federal budget will be trimmed in 2013, laboratories that depend on government money are anticipating sharply constrained budgets. Major points in our lab spending report were:

- Overall growth of just 1.2% is anticipated for 2013
- Chromatographs and mass spectrometers hold the largest shares of instrument budgets
- Academic and government laboratories face greatest uncertainty
- Stable growth in biopharmaceutical, industrial, and patient care laboratories



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TEAMING UP

Even industrial R&D giants are finding they often lack all the necessary expertise in-house and are reaching out to suppliers, customers, universities, and government laboratories to establish partnerships. Ways organizations are doing this are:

- Establishing research consortia
- Using the Internet for confidential communications
- Taking advantage of geographic proximity
- However, team members must address IP concerns and diversity issues in partnerships



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ASK THE EXPERT: THE IMPACT OF UHPLC ON EFFICIENCY AND OUTCOMES

Steven Wolk, Ph.D., associate director of analytical chemistry at SomaLogic Inc., discusses the use of high-performance liquid chromatography (HPLC) and ultra high-performance (or pressure) liquid chromatography (UHPLC) technologies for analytical work. He says:

- UHPLC is a cheaper and greener technology and offers higher resolution
- There is now better monitoring of the pressure due to hardware/software improvements
- Users must be careful about filtering their samples
- Sample prep and types of columns available are areas that could use improvement

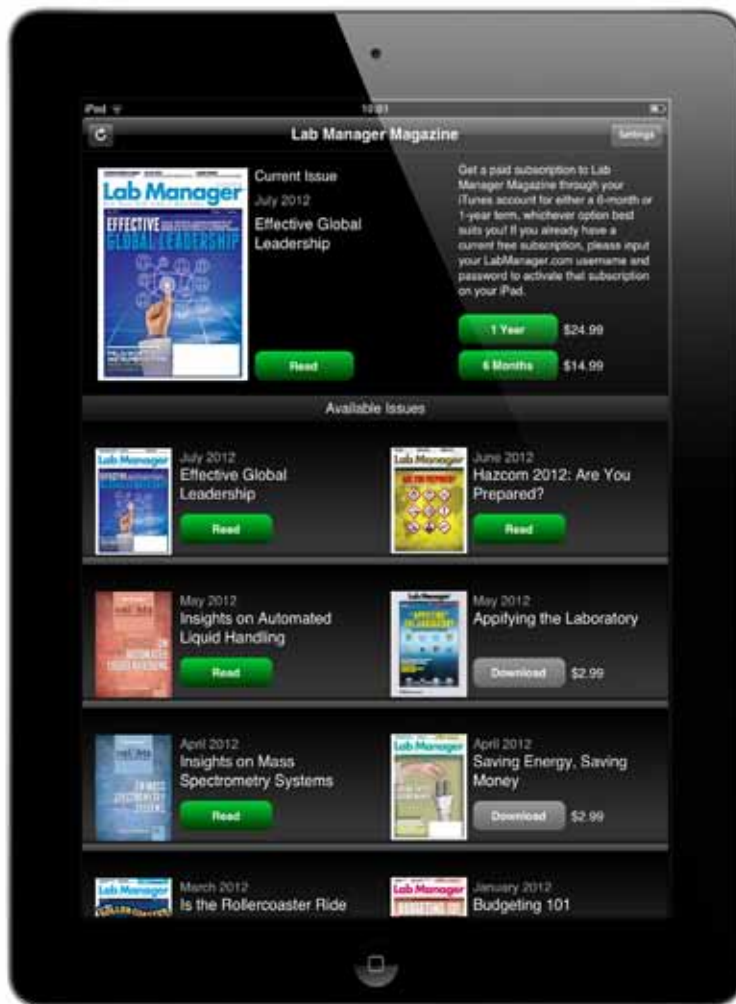


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LET'S HAVE A LOOK

This month's safety column focuses on conducting safety audits in research laboratories, but the steps and the process can be applied to all the different areas of the facility. The main steps of a safety audit include:

- Starting the inspection with a records review
- Making note of any signs, hazard indicators, and warnings before entering the lab
- The lab walk-through with a safety checklist tailored to the specific lab
- An exit interview with the PI or lab manager



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