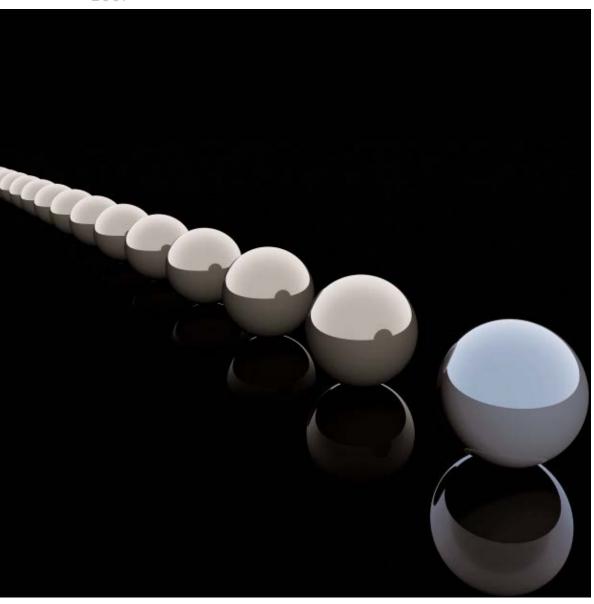
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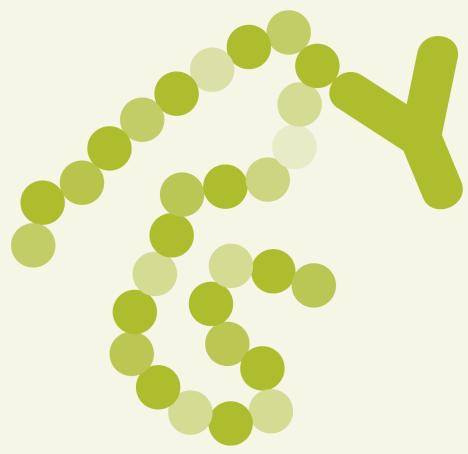
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upfront

Leading versus Managing

I recently delivered a leadership course to laboratory managers and one of the pieces of feedback I received was about the necessity for acquiring a leadership skillset in the first place. The question was, "If I am a trained and experienced manager, why do I need to learn about leadership?"

The simple answer to that question is really: "You don't. Unless..." And this is where it gets tricky.

We have all read something of Peter Drucker's regarding the science of management. He is the modern day guru and it is primarily because he pushed it into the realm of a learned/acquired set of rules that we are able to quantify what it takes to manage something. I define management as "the science of planning, organizing, directing, and controlling resources to achieve an organizational goal." This is a very straightforward definition and combines most of elements used by many very knowledgeable folks

I define leadership as "the art of motivating people to achieve a common goal." I am not certain if most people can appreciate the differences between these two definitions but, for me, the science deals with resources and the art deals with people. In my opinion, people are not resources; they are people.

Under an approach using management science, we will consider people (human resources) as another set of variables and resources to apply to the project we have been assigned. If we treat people as resources we may get maximum "use" of them, but we will not get maximum "benefit" from them. And that is the single biggest reason why the management approach may not be good enough for managers.

Maximum use is not the same as maximum benefit.

I can already hear some managers ringing up cost/benefit analyses from this statement and I guess that is OK, but those that do may run into some resistance from the people on their teams. People can sense when they are being sized up to produce more with less.

The real paradigm shift that managers should experience at this point is the realization that, just like themselves, the people on their teams can "contribute" to the success of the team or organization whereas resources can only be used in attaining such successes. Resources do not contribute to such successes, only people can do that.

Managers who do not understand this believe that the only person who is contributing to group success is his or her self—and no other. For these folks, people truly are "resources." I think such managers should consider restricting the practice of their science to processes, plant, and other inanimate resources.

But what should a person do, if they really want to get maximum benefit from the folks on their team — the team they have been appointed to "manage?"

If such a manager understands that people are not resources, they have taken the first emotionally-risky step in becoming a true leader. They will learn to concentrate on providing motivation to their team members, individually and collectively. They will learn that team success is dependent on the success of everyone else on the team. They will learn that their own personal success is based on the success of everyone else on the team. They will be practicing the art.

In short, when we switch our concentration away from our own resource allocation work to the work of our team members — we are changing from managers to leaders. When we understand that leadership is more about how we (personally) do things and management is more about how resources are aligned, we can start to get more from the people who are our team members.

People do not really need to be managed, but they really want good leadership from us. If we give them what they need, they can provide the real contribution to the success of the team and our organization. The approach we use is entirely up to us, but the results will depend on our team members.

J.E.J. (Ned) Gravel, P.Eng., CA-LS, CAE, is the Manager, Quality and Training for the Canadian Association for Environmental Analytical Laboratories (CAEAL). www.caeal.ca

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Guide to Selecting an In Vivo **Optical Imaging System**

WHAT ARE THE KEY QUESTIONS YOU SHOULD BE ASKING TO PRIORITIZE CAPABILITIES BASED UPON YOUR NEEDS?

In vivo optical imaging is a powerful technology that allows researchers to monitor biological processes taking place in living mammals — non-invasively and in real time. By capturing light emitted from within living organisms, an optical imaging system provides a "window" into the organism and makes possible the real-time tracking of biological activity at the molecular level.

There are two major types of optical imaging reporters: bioluminescent and fluorescent. In vivo bioluminescent imaging utilizes luciferase — the enzyme that makes certain insects, jellyfish, and bacteria glow. The luciferase gene is incorporated into cells, microorganisms, and animals and, when active, causes a reaction that emits light. In vivo fluorescent imaging utilizes a fluorescent reporter — a molecule that emits a photon when excited by a particular wavelength of light. Fluorescent reporters can be fluorescent proteins, dyes, or nanoparticles.

By measuring and analyzing the light emission, in vivo optical imaging systems can help researchers monitor cellular or genetic activity and use the results to track gene expression, the spread of a disease, or the effect of a new drug candidate.

With all of the different technologies available, examining specification sheets can be confusing and may not be the best way to compare systems.

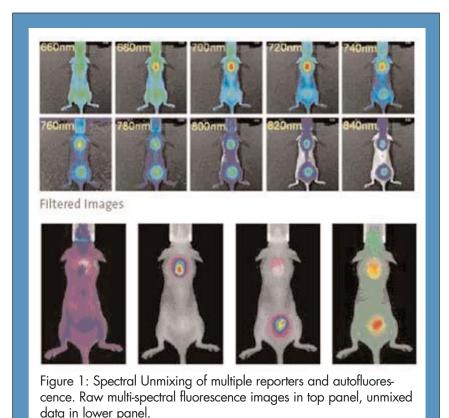
GENERAL IMAGING CONSIDERATIONS

There are multiple optical imaging systems available on the market today, making it difficult to determine which optical imaging system is best suited to your needs. With all of the different technologies available, examining specification sheets can be confusing and may not be the best way to compare systems. There are some key questions you should be asking and help you determine how to prioritize capabilities based upon your needs.

KEY INSTRUMENT CONSIDERATIONS

CCD Camera

The CCD camera is the heart of an optical imaging system. Performance variables to evaluate are: camera sensor, CCD chip size, pixel count, cooling temperature, spectral sensitivity, quantum efficiency, sensor readout noise, dark current, dynamic range, signal to noise ratio, spatial resolution, and frame rate. All of these are key considerations when selecting an imaging system since these specifications will have a dramatic effect on sensitivity, especially for bioluminescent applications. A back thinned, back-illuminated CCD is designed to increase the absorption of photons by the detector which results in a much higher quantum efficiency of greater than 90% vs. less than 50%. The CCD chip size determines the field-of-view and the amount of photons the CCD can collect (larger chip = larger field of view and more photons). The number of pixels will affect resolution and dynamic range; smaller pixels allow for a higher resolution but lower dynamic range. Binning combines pixel charges mathematically, thus increasing sensitivity but decreasing resolution. The dynamic range is a measurement of the minimum and maximum intensities that can be simultaneously detected, correlates to the numbers of bits required to digitize the signal, and determines the charge capacity (the number of counts) a pixel can hold before saturation. Sixteen-bit digitizers are recommended. Dark current is thermal noise generated by the camera in absence of light. Cooling the operating temperature will significantly reduce this background noise. To guarantee proper cooling of the sensor, a sealed vacuum is essential. Readout noise generated by the camera electronics such as the output amplifier is the limiting factor for low light images. CCDs only have one amplifier; cooling the CCD will slow the transfer rate and increase charge transfer efficiency, reducing readout noise.



Optics

In conventional photography, the lens often separates a good camera from a great camera. This also holds true for optical imaging. Lenses are important for maximum light collection, but it is also important to consider the flexibility of the lens. A system that has a lens capable of multiple fields of view will allow the researcher to balance sensitivity and throughput, depending on the application.

Filters

For fluorescent imaging, the excitation light source can be a filtered broadband Tungsten halogen lamp, a tunable laser, or several laser diodes of specific wavelengths. Fiber optics can be used to illuminate the entire subject or to focus the excitation light to a point source. Typically the entire subject is illuminated in the reflectance mode (known as Epi illumination) where the excitation light and the detector are on the same side of the subject. In the transillumination imaging mode, a point source is located on the opposite side of the subject from the detector. Upon integration of data taken at several different transillumination points, transillumination fluorescence imaging can provide sensitive detection, accurate quantification, and signal depth location of deep tissue sources.

There are numerous fluorescent markers available at a variety of excitation and emission wavelengths, and it is important to be able to select appropriate filters for different markers. Check to see what types of filters are available for the imaging system and how easy it is to switch between them. Narrow band excitation and emission filters can be used to detect and separate multiple fluorescent reporters and/or to minimize the detection of tissue autofluorescence using a technique know as spectral unmixing (see Figure 1).

OTHER HARDWARE

Other system features related to subject handling can make an instrument easier to use and less stressful for the subject.

- A fully motorized system secures reproducible data — motor-controlled stage, filter wheels, lens position and f-stop
- Integrated gas anesthesia system providing a delivery system, knockdown box, and a manifold in the chamber simplifies use of gas anesthesia for animal sedation
- Heated sample stage prevents hypothermia during anesthesia
- Laser alignment grid allows subjects to be conveniently and consistently aligned in the field of view
- Anesthesia/cardio monitoring system - non-invasively monitors animal well being
- Isolation box to isolate infectious diseases
- Catheter port for catheters, ECG leads, etc.
- In vitro multi-well plate imaging capabilities — allows for convenient correlation of in vitro cell based assays with in vivo live animal studies

KEY SOFTWARE CONSIDERATIONS

Software is the link between the user and the optical imaging system. It is imperative that the software is easy to use while providing a comprehensive set of analysis tools. Be sure to ask about training, how long it takes to get up to speed using the system, and if a dedicated operator is required.

QUANTIFICATION

Obtaining quantitative data is essential for in vivo imaging. Some imaging systems use a relative light unit (RLU) for their quantification. If this is the case, it is difficult to compare data from experiments performed on the same instrument, and impossible to compare data from different instruments. The only way to achieve high-quality data is to use absolute quantification in physical units. One way to perform absolute quantification is to use the unit photons/cm²/steradi-





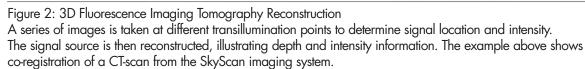












an. This unit accounts for all camera settings such as the location of the source within imaging chamber, imaging time, and other parameters. Only by using imaging standards and calibration tools is absolute quantification possible. Understanding how calibration and quantification is performed, and whether it is "absolute quantification" is essential to obtain high-quality, reproducible data.

SOFTWARE FEATURES

There are some key features that make software easy to use. Most imaging system software packages have a similar set of functions; however, the following features set some systems apart:

- Complete instrument control: all functions of the imaging system should be under control of the software (e.g., camera settings, stage height, and filter selection should all be user-selectable from a computer control panel)
- Data analysis: automatic creation of a "region of interest" (ROI) delivers reproducible data
- Absolute quantification
- Automatic quantification: automatically analyze and quantify a series of images
- Programmed imaging sessions: investigators can run preset imaging sequences; this helps in kinetic and other time course experiments
- Data management: multiple users compiling large amounts of image data can generate a database of enormous proportions in little time. The task of managing the data is an important one. Choose software that provides a basic data management system for organizing and referencing image data, and allows users fast and easy access to their data.
- Software compatible for co-registration with other imaging modalities such as MRI, CT and PET, or SPECT
- GLP compatibility

THROUGHPUT CONSIDERATIONS

Imaging systems can image one or more subjects at a time, depending on the system and field of view. Researchers doing large-scale studies would want to ensure that more than one subject could be placed in the imaging chamber.

Along with the physical size of the imaging chamber and selectable fields of view, it is important to consider the image acquisition time. Some imaging technologies result in long imaging times (up to 30–60 minutes for one subject) and may not yield accurate bioluminescence data, where luciferin kinetics must be taken into account. Imaging systems that can capture a view of the whole subject at one time will yield lower acquisition times and reduce the impact of luciferin kinetics.

ADVANCED INSTRUMENTATION CONSIDERATIONS

3D Imaging Tomography

All of the imaging systems available on the market today can perform 2D optical imaging. However, there have been advances in the technology in the past few years, allowing researchers to reveal 3D tomographic information. The following describes two approaches currently possible using a 3D system.

Single-view Tomography

One way to perform 3D optical imaging is to generate single-view tomographic reconstructions of mouse images. With such as system, a laser scans the surface of the mouse and creates a surface "map" of the animal. The system then performs a "spectral analysis." Due to the light transmission properties of tissue, the imaging system can determine the depth of a signal by taking multiple images of the same subject using different filters. This allows investigators to reconstruct a whole mouse and determine location and depth of a source signal. This feature is the result of both hardware and software-based technologies. For an example, see Figure 2.

Multi-view Tomography

Another approach to 3D imaging is to reconstruct a full 3D tomographic image of a single mouse by taking images at different angles. In the imaging chamber of this type of system, the subject rotates around a movable mirror and up to eight images of the animal are taken. These images allow for a more precise 3D reconstruction and in-depth information pertaining to source signal and intensity — 3D diffuse tomography reconstruction.

Fluorescence Imaging

Fluorescence is a powerful tool with a broad set of applications. It is one of the best ways to detect a target of interest when doing microscopy. When using fluorescence for in vivo optical imaging, an auto-fluorescent background can make data collection difficult. Fluorescence requires the use of a light source to excite the reporter. Unfortunately, the skin of the subject will auto-fluoresce, making it difficult to detect the target signal above the background noise. Be sure to examine how each imaging system removes and/or subtracts auto-fluorescent background.

Two possible methods to subtract background noise are: 1) to use background subtraction filters and image math in order to improve signal-to-background ratio and 2) separating reporter signal from tissue autofluorescence by applying spectral unmixing

algorithms (software) to multi-spectral fluorescence images (see Figure 1).

REFERENCES AND PUBLICATIONS

Be sure to ask for a bibliography list from your optical imaging vendor. Ensure that the imaging system has been used by other researchers in your field and that there are a number of publications in peer-reviewed journals.

CONCLUSION

Selecting an optical imaging system can be challenging; reviewing the long list of specifications can be a daunting task. Knowing which questions are most important — CCD chip size, cooling temperature, lens quality, quantification, software features, throughput, 3D capability, and references — will help you make the best decision for your needs.

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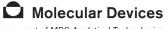
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Laboratory Response Network Part 1: History

CDC HAS BEEN WORKING WITH ITS PARTNERS TO IMPROVE THE PUBLIC HEALTH RESPONSE TO A LARGE-SCALE CHEMICAL EXPOSURE INCIDENT.

In 1999, the Centers for Disease Control and Prevention (CDC) entered into the Public Health Preparedness and Response for Bioterrorism Cooperative Agreement (BCA) with 62 jurisdictions in the United States: the 50 states; the cities of New York and Chicago; Washington, DC; Los Angeles County; Puerto Rico; the U.S. Virgin Islands; Guam; Palau; the Federated States of Micronesia; American Samoa; the Northern Mariana Islands; and the Midway Islands. This cooperative agreement was created to improve both the local and the national public health infrastructures' ability to respond to acts of bioterrorism, which is broadly defined to include toxic chemical exposure resulting from a terrorist act. Because funding was limited in the late 20th century, approximately \$40 million was available for distribution to the jurisdictions' public health laboratories (PHLs) for terrorism preparedness. Of these funds, about \$4 million was reserved to fund four laboratories that would provide surge capacity should a chemical terrorism incident require more than the analytical resources of CDC's National Center for Environmental Health's Division of Laboratory Sciences (CDC/NCEH/DLS). Eventually, five laboratories were funded: the Wadsworth Laboratories at the New York State Department of Health; the Virginia Division of Consolidated Laboratories; the Michigan Department of Community Health Laboratory; the California Department of Health Services Division of Laboratory Science; and the New Mexico Department of Health State Laboratory Division.

created a network in which different members contribute to the program based upon their interests and abilities, which benefits everyone in the network.

This work has

The strategy behind this funding was to equip and staff these labs to serve their states' needs and to provide CDC with additional analytical capability for priority terrorism-related chemicals, such as nerve agents, cyanide, or sulfur mustard, should the need arise. In a chemical terrorism incident or large-scale chemical accident, clinical samples would be delivered to CDC for analysis by the rapid toxic screen, a series of analytical methodologies and instrumentation that would quantitatively analyze the samples for 150 potential agents using highly sensitive target compound analysis methods. Medical toxicologists would interpret the analytical results, which would be presented in 36 hours or less.

Typically, in chemical exposure incidents, for every affected person, many others will think they might have been exposed and will present themselves at hospitals for assessment and treatment. Samples from people who are worried, but well, and the need for rapid sample analysis require a sample analysis surge strategy. The first strategy model proposed for the CDC/PHL partnership envisioned an Incident Response Laboratory at CDC. At this laboratory, multiple instrument systems and analysts would be prepared to respond to a terrorist attack that used chemical warfare agents (CWAs), such as the 1995 Aum Shinrikyo cult attack on the Tokyo subway. If the extent of the incident should exceed the capacity of the CDC Incident Response Laboratory, additional CDC resources would be converted from their normal environmental health analytical activities to respond to the need for additional CWA analytical capacity. The five funded state PHLs would be included in this expanded laboratory capability. As these state labs developed and demonstrated their expertise in CWA metabolite analysis, they would become primary resources during a chemical terrorism incident for post-rapid toxic screen assessment of people's exposure to

a chemical agent. This surge capacity role was formalized in 2003 when specific funding was dedicated from cooperative agreement funds to support these laboratories in this new role.

CHEMICAL TERRORISM LABORATORY NETWORK

The CDC/PHL partnership proposed that funding from the cooperative agreement would be used between 1999 and 2002 to hire staff and to equip the laboratories for assessing human exposure to CWAs and toxic industrial chemicals. The Chemical Terrorism Laboratory Network (CTLN) was officially formed during Fiscal Year 2002 as a partnership between CDC and the five state public health labs.

LRN provided the ideal mechanism to help expand the chemical terrorism response capability at public health laboratories, and tiny CTLN was assimilated into the newly created Laboratory Response Network – Chemical (LRN-C).

In the CTLN strategy, human exposure to CWAs and chemicals would be assessed by measuring either the chemical itself or its metabolites in clinical samples such as blood or urine. Analysis methods developed at CDC would be transferred to the state public health labs through hands-on training at the CDC/NCEH/DLS facilities. With the funding provided, the PHLs would be required to purchase specific instruments; to hire staff, including one Ph.D. chemist as team leader; and to equip facilities to house the required instrumentation.

CDC would contribute by supplying validated analysis methods, by providing hands-on training for the implementation of these methods, and by establishing a program to demonstrate the network labs' proficiency in producing timely, accurate, and precise results for assessing people's exposure to

toxicants. The program's initial analytical focus was on the transferring methods that were developed to measure metabolites of CWAs. The discussions defining the proficiency testing program determined that both the CWA metabolites and the stable isotope-labeled internal standards were often not commercially available and, when available, were often extremely expensive. This limited availability prompted the creation of a materials program in which CDC would coordinate the preparation of calibration solutions and quality control samples in the appropriate biological matrix and in the properly diluted solutions of internal standards.

LABORATORY RESPONSE NETWORK – CHEMICAL (LRN-C)

After the terrorist events of September 11, 2001, however, CTLN was short-lived. Funding for terrorism response expanded dramatically from \$49.9 million in FY 2001 to \$949.7 million in FY 2002, but this increased funding could not be used for chemical laboratory capability until the following year. In 2003, chemical terrorism response capability was required in all 62 jurisdictions covered by the Bioterrorism Cooperative Agreement. Fortunately, in 1999, CDC's National Center for Infectious Diseases had created the Laboratory Response Network (LRN) to coordinate the activities of the many laboratories being funded to support bioterrorism surveillance and response. LRN provided the ideal mechanism to help expand the chemical terrorism response capability at public health laboratories, and tiny CTLN was assimilated into the newly created Laboratory Response Network - Chemical (LRN-C).

Although LRN had drawn upon an established infectious disease assessment capability in hospital and public health labs, LRN-C found that clinical chemical analysis capability was not common in many public health laboratories. A number of jurisdictions either had insufficient infrastructure to support a chemical analysis program or had no interest in creating such a program, although it was required by the cooperative agreement. LRN-C developed a four-level structure: All 62 jurisdictions would have a Level 3 component; some would have a Level 2 (laboratory) component; and the former CTLN labs, which would continue to be CDC's surge capacity laboratories, would now be designated as Level 1 labs. CDC/NCEH/DLS, with the greatest lab capability, did not have a level designation.

Level 3 activities include reaching out to a jurisdiction's medical facilities to establish the need to collect samples for suspected chemical terrorism incidents, indicate what samples to collect, and give instructions on how to properly package and ship those samples to the nearest lab with adequate analysis capability; in most cases this lab would be CDC. Level 2 activities were targeted to increase the public health labs ability to respond to the most likely source of toxicant exposure,

refined, and restructured like the TR-32 to reflect current regulatory expectations and good practice.

Professionals from the Americas and Europe contributed to the production of GAMP 4 which is intended for suppliers and users in pharmaceutical manufacturing and related healthcare industries. This guide draws together key principles and practices and describes how they can be applied to determine the scope and extent of validation for different types of automated systems.

Benefits of this standard to industry users and suppliers echo those of the TR-32 and others include:

- Cost benefits, aiding the production of systems that are fit for purpose, meet user and business requirements, and have acceptable operation and maintenance costs
- Increased understanding of the subject and introduction of a common language and terminology
- Reductions in cost and time taken to achieve compliance systems
- Clarification of the division of responsibility between user and supplier

While GAMP addresses a broad range of issues related to validation of systems, another document that can assist cleanroom operators in maintaining 21 CFR Part 11

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compliance is the joint PDA/ISPE publication "Complying with 21 CFR Part 11, Electronic Records and Electronic Signatures," a companion document to GAMP 4.3

International standards and the groups that develop, maintain, archive, and promote them are the background for auditing within the regulated environment. Consideration must be given to adjunct drivers in the industry that help us conduct not only audits but daily performance, inspection, and maintenance of various processes.

ICH, or the International Conference on Harmonization, along with ISO 9001 standards, govern certain critical elements of the manufacturing process and how they are conducted. The American Society for Quality has been instrumental in supporting the industry and professionals who perform the operation, maintenance, inspection, and management of any systems within the industry.

ISO, the International Standards Organization, is a network of the national standards institutes of 155 countries, on the basis of one member per country, with a Central Secretariat in Geneva, Switzerland, that coordinates the system.

Between 1947 and the present day, ISO published more than 16,000 International Standards. ISO's work program ranges from standards for traditional activities, such as agriculture and construction, through mechani-



and Sanitizers

completion of their sixth analysis method, Level 2 labs were engaged in 24 PT exercises per year, or two PT exercises each month. The Level 1 labs had an even more crowded schedule with as many as 40 PT challenges per year.

A similar expansion of LRN-C's material program was also required. Instead of preparing materials to stock six labs (CDC plus the five Level 1 labs) for validation, PT, and incident response, the network had to accommodate the now 47 participating labs; as a result, the number of vials required for each analysis increased from thousands to tens of thousands. In addition to the issues associated with the increase in volume, there were also logistics and timing issues. Training the large number of labs in the performance of the analysis method now required months under ideal circumstances and more than a year in reality. Also, with limited shelf life, a single large batch of materials produced for a method would provide early trainees with materials that might last for almost 2 years, while later trainees would have to purchase materials that might have a shelf life of 6 months or less. In addition, the vendors who created and ampoulized these solutions would have to stock these materials for 18 months before they were able to sell everything they had produced. The solution to both of these problems was to create multiple small batches of materials. This solution increased the work for the CDC quality assurance team but solved the problems for both the vendors and the PHL customers.

With the PT program stabilized and the PHLs generating acceptable analytical results, the network realized that being able to hit the analytical target was only part of the mission of a response network; there were other response aspects that a regularly scheduled PT program did not test. For example, the PHLs were required to collect clinical samples, to properly package the samples, and to ship them so that the shipment met shipping regulations and the samples arrived intact and compatible with the required analysis. The labs also had to be able to respond to an emergency. The network considered the following questions: Could the network's emergency contact chain notify the right people of an emergency? Could samples reach the right laboratory? Could a lab respond to the need for a rapid analysis and report the results in a timely manner?

These untested response activities led to new exercise programs: the Sample Collection, Packaging, and Shipping (SCPaS) exercises and the Emergency Response Exercises. For SCPaS exercises, the PHLs were requested, and later required, to ship samples from 10 "patients" to CDC to be evaluated against rules for shipping, evidentiary, and analytical requirements. Participation in Emergency Response Exercises was required for all Level 1 and Level 2 labs. At 10:00 am at the PHL local time on Day 1, a CDC representative would telephone the PHL 24/7 emergency contact and advise him or her that samples would be arriving by a next-day priority shipment for analysis by a method that the laboratory was qualified to

perform. The samples were to be analyzed, and the results reported to CDC as soon as the analysis was completed. These two exercises were thought to be the best assessments of a lab's ability to respond to the emergency situations that the network was created to address.

TRAINING

While expanding the scope of laboratory support, the network determined that the transfer of analysis methods from CDC to the PHLs had to change in many ways but still needed to be conducted as hands-on training by subject matter experts. To maximize the effectiveness of the transfer and optimize the use of the limited training facilities, each PHL was required to send two trainees at a designated time; CDC would train two PHL staffs per week. Each PHL team would have a dedicated instrument and associated equipment in the training facility. In addition, each PHL staff would be taught by a team of three instructors so that a 2:1 student-to-instructor ratio could be maintained during the lab sessions even if one instructor was not available.

Many PHLs encountered difficulties in hiring qualified staff, and the experience and expertise level of the different laboratories varied greatly. To provide a minimum level of expertise with the specific instrument platform and analysis technique, a PHL had to perform a series of three steps before it could send students to CDC for analysis method transfer training. Step 1 was including instrument installation and familiarization as part of every instrument purchase; this step would assure that the instrument was properly installed and that the PHL staff had received fundamental exposure to the operation of the system. Step 2 was taking the instrument vendor's standard operation course, delivered by the vendor to all potential operators at the PHL site. Step 3 was delivering a technique course, in which the capability of the analysis technique, instead of the operation of the instrument, was explored. This course was developed by CDC staff and delivered at the PHL site by the vendor's technical support staff. After completing 3 weeks of preliminary training, PHL staff were permitted to enroll in their first CDC analysis method transfer course.

EXERCISES

The validation exercises that began with CTLN have been continued as LRN-C has expanded. These exercises have been critical to trainees' technique development when learning to perform the analysis; the exercises have provided an opportunity to integrate the analysis requirements with the resources of the laboratory infrastructure. Reporting results for the validation exercise has provided the basis for reporting other analytical results, whether PT, Emergency Response Exercises, or real-world response samples.

The ultimate exercise in the program is the full-scale Rapid Toxic Screen/Surge Capacity exercise, in which all major parts of the chemical terrorism incident response plan are exercised. In conjunction with a Level 3 or Level 2 PHL, a CDC/NCEH/DLS team creates a scenario for either a covert or overt exposure incident. Part of the team — usually the PT program staff — creates the required number of patient samples that are spiked with the appropriate agent or metabolite and ships these samples to the Level 2 or 3 PHL to distribute to participating hospitals. At a time selected by the PHL, the PHL calls the CDC Director's Emergency Operations Center and describes the exercise incident. The relevant persons are notified, and the CDC Lab Response Team is scrambled and flown to the incident site for sample collection. The team collects the samples, either from the hospitals or from the PHL; packages the 40 samples required for the Rapid Toxic Screen; and returns to CDC.

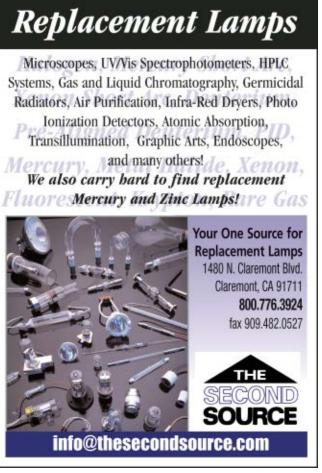
At this point the rapid toxic screen process begins by accessioning the samples, dividing the blood and urine samples into the hundreds of aliquots required for the various tests, and delivering those aliquots to the analysts. The results of the tests are assembled and interpreted, and a report is issued to the PHL that requested CDC assistance. At this time samples can

be analyzed for the causative agent if the Level 2 lab is qualified for the analysis, and additional samples are shipped from the incident site to the Level 1 labs to exercise their surge capacity role. All participating labs report their analysis results to CDC through LRN website capabilities, and a final report is issued. These hands-on, real-time exercises have been critical in identifying gaps in the response process and in building experience and confidence in the PHL staffs.

Since the early days of the Bioterrorism Cooperative Agreement, CDC has been working with its partners in public health labs, initially numbering five and now numbering 62, to improve the public health response to a large-scale chemical exposure incident. Partly by plan and partly by trial and error, a network has been created in which different members contribute to the program based upon their interests and abilities, which benefits everyone in the network.

Over the past 5 years, CDC and its partners have not only created a functional chemical incident response network but have also learned a number of important lessons, which will be covered in the next issue.





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Online Resources for Experimental Design

THE INFORMATION HERE IS PROVIDED AS A SERVICE TO THE SCIENTIFIC COMMUNITY ABOUT SEVERAL ONLINE RESOURCES THAT CAN ASSIST WITH YOUR DAILY WORK AND THAT ARE FREELY AVAILABLE.

Life science and systems biology research requires the integration of a number of information resources. Recognizing this challenge, scientists have come together to develop a growing number of websites and communities that aim to solve this puzzle. This online guide at www.invitrogen.com/linnea can assist lab managers with their own research needs as well as needs within their laboratories.

SPECIFIC AREAS OF FOCUS INCLUDE:

- Gene & Protein Resources: LINNEA™ Genes is a powerful search engine that allows lab managers to quickly search through over 245,000 gene and protein based products from both human, mouse, and rat. This information resource also provides direct access to over 200 validated signal transduction pathways and contains scientific gene and protein information. The information in LINNEA™ Genes is sequence standardized and uses internationally recognized gene IDs and symbols within the reference ontol-
- Vector Sequence Software: Vector NTI® Software is freely available to lab managers through an open access policy for academic researchers. This application allows them to design, annotate, and store vector and primer sequences in the laboratory and effectively manage vector inventory.
- \bullet Protocol Resources: LINNEA $^{\text{\tiny TM}}$ Protocols provides over a 1,000 validated protocols from both Invitrogen and Current Protocols™ from John Wiley and Sons to assist them in lab training and experimental design.

Simplifying the task of gathering product and reagent information, LINNEA™ Genes provides a very powerful search engine that allows researchers to rapidly search through over 245,000 gene and protein products from human, mouse, and rat to find the right reagent. Search results can be filtered by a number of features including product category, application, and species. Supporting drug discovery, product lists organized by gene symbol and direct links to products by gene family within many of the common druggable gene classes are also provided. Behind these functionalities is a custom-designed relational database that holds standardized product information and gene and protein information relationships.

Understanding the complex dynamics and relationships within cell signaling is core to biological discovery. The search engine provides access to 248 signaling and metabolic pathway maps [maps provided by GeneGo (www.genego.com)]. Each map allows direct access to associated products and reagents to allow rapid investigation of pathways for important cellular processes.

Having desktop software and online resource to reliably facilitate reagent design and information management of DNA primers, RNAi molecules, and DNA vectors is key as data integration within the lab inherently saves time,



As we look to the future, we foresee an even greater need for access to centralized scientific information...

allowing more time for research. Software solutions containing informatics analysis packages also allow researchers to gain new experimental insights and improve experimental designs prior to testing them at the bench.

Vector NTI® software is a powerful desktop tool for DNA and protein sequence analysis that has become a standard resource for a number of scientists within the life science industry. It is available free of charge to scientists from non-profit institutions directly through the Vector NTI® User Community (www.invitrogen.com/

VectorNTICommunity). Commercial researchers can also access this site to obtain free trial licenses to evaluate the software.

Providing solutions for molecular biology and genomics, this tool allows users to design, construct, and analyze a number of biomolecules within the lab. Each new sequence or vector can be easily designed and viewed in silico prior to testing in the lab and new reagents can be ordered online from Invitrogen directly through the software. Integrating bioinformatics algorithms with real experimental data in their design, these resources are optimized for each reagent to provide the best solution.

To ensure the design of more successful, accurate experiments, a freely available, centralized, online collection of the best research practices and methods across life science research have been created. LINNEATM Protocols houses a targeted selection of over 900 proven methods from Current Protocols[™] by John Wiley & Sons, as well as over 1,000 validated experimental protocols developed by Invitrogen scientists. The protocol library supports common research workflows and quickly connects scientists to detailed experimental methods, supporting documentation, and recommended products for each experiment. This will allow lab managers to more easily find new protocols and reagents when the laboratory is moving into new areas or when new experimental approaches are required.

As we look to the future, we foresee an even greater need for access to centralized scientific information and will be expanding the online guides in the coming years as science advances and new bioinformatics algorithms are developed. As many of these freely available resources support the integration and sharing of scientific information as

well as streamlining reagent selection for the lab, they significantly simplify researchers' day to day work and free up more time for biological discovery — the end goal.

Michaeline Bunting, Ph.D., is the Director of eBusiness Sciences at Invitrogen. She received a Ph.D. in Biochemistry from the University of Utah.

Management by Walking Around

This communication style is wonderful for managers who are actively engaged in the day-to-day activities of the business. This approach works well when a manager has made a commitment to spend a dedicated amount of time on the floor with the employees or in various employee offices each day. This approach must be compatible with your style; it should not be forced or just a charade. Employees will see through you if you are "just doing this to do it." In effect you are being yourself walking throughout the organization looking for opportunities to make positive comments and/or receive input and feedback. This approach allows you to see everything going on, and it allows you to listen directly to the employees. It is especially effective in an organization with many management layers. The approach permits all employees direct access to the boss and frequently generates high levels of spontaneous, creative synergy while employees and the boss exchange ideas.

> (From http://www.businesstown.com/ people/communication-walking.asp)

How it Works

Precise Dispensing of Bulk Liquids in Microplate Format

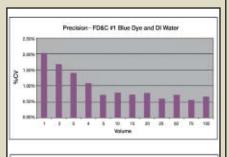
Problem: By design, peristaltic pumps use rollers fixed to a rotor to compress liquid-filled flexible tubing at regular intervals, forcing full volumes of fluid (based on the tubing diameter and distance between rollers) to be dispensed. At larger volumes, a high degree of precision and accuracy can be achieved, but at micro-volumes, cohesive forces in the liquid require most peristaltic pumps to dispense in fractions rather than full volumes, resulting in poor precision accuracy. Additionally, users are often limited by volume range, labware choice, or the need for frequent cumbersome calibrations.

Solution: The proprietary design of multiple cassettes provides full and reproducible volumes of liquid in a familiar peristaltic pump format. Complete dispensing flexibility, a high degree of precision and accuracy, and simple calibrations save time and reduce has-

The MicroFloTM Select Dispenser was created by BioTek Instruments to provide a high degree of dispensing flexibility and accuracy in a compact unit. Liquid may be dispensed into microplates from 6- to 1536-well formats with a variety of plate heights, as well as microtubes and other tubes up to four inches tall. Three selectable cassette sizes (1 µL, 5 µL, 10 µL)



MicroFlo™ Select Dispenser



Volume	Expected	Actual	%Error
1	0.096	0.098	2.29%
2	0.192	0.189	-1.46%
2 3 4 5	0.288	0.292	1.22%
4	0.384	0.392	2.03%
5	0.480	0.473	-1.48%
10	0.960	0.955	-0.52%
15	1.440	1.441	0.05%
20	1.920	1.925	0.27%
25	2.400	2.408	0.33%
50	4.800	4.833	0.69%
75	7.200	7.246	0.63%
100	9.600	9.547	-0.55%

MicroFlo™ Select offers superior dispense precision and accuracy

dispense liquid in a wide volume range from 1 µL to 10 mL. The proprietary cassettes incorporate the appropriate tubing, tip properties, and accurate dispensing technology to deliver full and reproducible incremental volumes of liquid within its specified volume range, even after numerous autoclave cycles.

The cassettes can be autoclaved without time consuming and difficult calibrations and both the cassettes and tubing can be quickly and easily replaced as needed. Suitable for high throughput applications, the MicroFlo Select's dispense height is automatically adjusted and up to eight reagents can be dispensed at one time with a low dead volume and without need for preconditioning.

A full range of flexibility is now united with accuracy and precision when bulk dispensing microvolumes with a peristaltic pump for optimal assay integrity. The MicroFlo Select Dispenser is both precise throughout a range of volumes and easy to operate with simple, low maintenance needs.

For more information, go to www.biotek.com.

How it Works

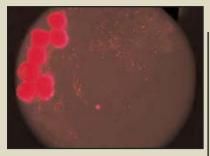
Whole Well Cell-based Screening

Problem: High Content Analysis instruments that use CCD image capture offer high optical resolution and provide high information cellular data for secondary screening. However, these systems are limited for primary screening for certain assays because microscope objectives are unable to fully visualize each well. They typically capture only a 1 mm x 1 mm area per image using a 10x objective (2.5% of well area for a 96well plate). CCD imagers are impractical for applications requiring multiple image capture such as rare event detection, tissue scanning, or colony counting, where they generate very large quantities of data (up to terabytes) and offer limited throughput.

Solution: TTP LabTech's

Acumen range of microplate cytometers, launched in 2001, use laser scanning to excite fluorescence which is then detected by a series of photo multiplier tubes and displayed as 3dimensional object profiles. Acumen microplate cytometers do not generate image files which require analysis by complex algorithms but instead apply cytometry principles to offer a rapid and user friendly approach to high content analysis. Importantly, they also give a greatly increased scan area of 20 mm x 20 mm (or 4 wells of a 96 well plate). This wide field of view allows the Acumen ^eX3 to report data for all cells in each well at throughputs of ten minutes a plate.

Whole-well scanning has many advantages over restricted reporting



Spheroids are cultured cells which have a three-dimensional structure and some tissue-specific functions. They are used as an in-vitro model for studies in oncology as the ability to form spheroids is a characteristic trait of malignant cells. Here an ^eX3 has been used to scan seven spheroids in a 96 well plate.



Autofluorescence scan of rat testis tissue using an Acumen microplate cytometer.

from a small well area:

- It gives statistically robust data from a truly representative cell population — essential for rare event detection assays.
- It can overcome problems of variable stimulation and random cell distribution often observed in screening plates.
- It enables normalization of biological responses to total cell number, offering a simple toxicity or proliferation readout with every test.
- It allows easy analysis of large

objects such as C. elegans, tissue sections, or cell colonies, without the need for image stitching which is required by microscope based systems.

To exemplify the benefits of whole well scanning, cell colony formation assays traditionally involve laborious and subjective analysis by hand using a microscope. The Acumen ^eX3 offers a new approach through the application of a volume algorithm. This assay readout is more representative of cell colony formation in vivo since it correlates well with the growth of higher stage and higher grade tumours, not supported by simply counting the number of colonies above a certain size.

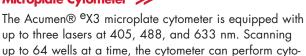
In some cases a cytometric approach to analysis is inappropriate, for example cell segmentation within monolayers. Here, the Acumen ^eX3 offers the flexibility of exporting whole well TIFF images for subsequent batch analysis by third party image analysis software, increasing the instrument's utility in certain biological areas.

Whole well scanning can be used to generate reproducible and robust screening assays, with small data files and speed advantages over image-based technologies, ensuring the Acumen ^eX3 is entirely suited to a screening environment.

For more information, go to www.ttplabtech.com.

product focus: Imaging

Microplate Cytometer >>>



metric analyses at throughputs of up to 200 plates — or 300 data points — per day.

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Imaging Software

HCSExplorer uses proven Web-based technology to enable rapid enterprisewide data access and analysis. This software offers powerful analytical, data visualization, and image comparison tools that can be used with any data store. Additionally, the software provides users with the ability to annotate data and customize reports. Thermo Fisher Scientific

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Benchtop Imaging System

The personalDV is a benchtop highresolution imaging system for the budget-conscious or space limited facility. It is customizable, with many options available for features. Each system is high-quality, from the precision stage control and proprietary illumination to the optional DMS lab server, multiplexed wavelengths imaging, and more.

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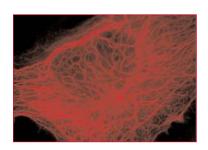
Molecular Devices www.moleculardevices.com



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Leica Microsystems www.leica-microsystems.us



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product news



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tools of the trade



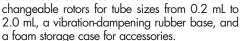
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Mind Mapping

Last month we said that "a picture is worth a thousand words," well this month we'll continue with that theme. With flowcharting we showed that an outline for an SOP could be developed using a set of symbols. But what if our process isn't linear or sequential or if it involves a number of different pieces of equipment or activities? What if we really don't know or understand how the process will flow? Solution — mind mapping.

A mind map is a diagram used to represent words, ideas, tasks, or other items linked to or arranged radially around a central key thought, word, or theme. Mind mapping is simply a visualization tool (and yes there are automated tools) which helps you think and get organized more proficiently. Mind maps are the one of the most effective, "brain-friendly" ways to turn unorganized, linear, fleeting ideas and thoughts into a structured, visual "map." Mind maps are image-centered diagrams that represent connections between portions of information. By presenting these connections in a radial, non-linear graphical manner, mind mapping encourages a brainstorming approach to any given organizational task.

A mind map uses words, lines, logic, colors, and even images. Elements of the mind map are arranged intuitively according to the importance of the concepts and they are organized into groupings, branches, or areas.

MIND MAPPING — AN EIGHT STEP PROCESS

After being introduced to mind mapping, one of my colleague's told me that mind mapping should be done before flowcharting. I tried it and I agree! So is there an SOP on mind mapping? Well not exactly. There are several approaches that can found in books and on the web. I'll present one approach and relate it to one of my first mind maps, which is shown in Figure 1.

Before we start, what materials will you need? Not much: a sheet of paper – the larger the better and a pack of colored felt-tipped pens, although a pencil with eraser will work as well.

Step 1: Start at the center of the page

In the center of the paper draw or write down the topic of the SOP. In this case it was Chemical Mixing and Dispensing.

Step 2: Don't be serious!

Write down or draw the first things that come up in your mind when you start to think about an SOP. Put your thoughts related to subject SOP around the central topic. These can be anything and everything. I simply listed the primary chemicals used in our facility.

Step 3: Free associate

As ideas emerge, print one or two word descriptions of the ideas on lines branching from the central focus. Allow the ideas to expand outward into branches and sub-branches. Put down all ideas without judgment or evaluation. As I thought about my SOP, things like mixing and dispensing came to mind of course, but so did records, concentrations, and expiration dates.

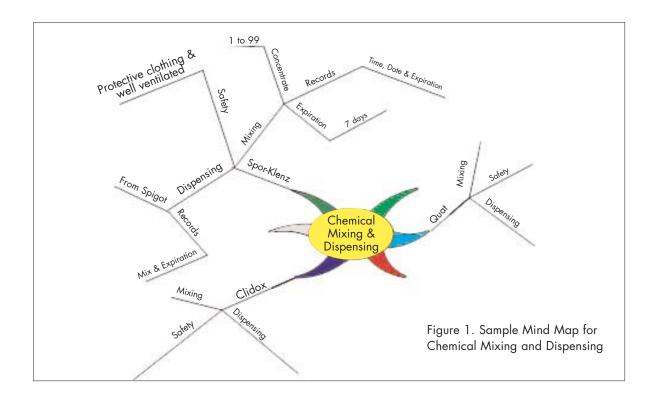
Step 4: Think as fast as you can

Come up with an explosion of ideas. Translate them in words, images, codes, or symbols.

Step 5: There are no boundaries

Think "out-of-the-box," Everything is possible. Use wild colors, fat or skinny colored mark-





ers, or crayons. I'm afraid my mind map didn't have a lot of "out-of-the-box" thinking, but I did have fun!

Step 6: Don't judge too fast

Again, everything is possible. Unrelated ideas might be relevant later on. Think like you are brainstorming. My unrelated idea was protective equipment. I knew it fit in, but wasn't sure how.

Step 7: Keep moving

Keep your hand moving. If ideas slow down, draw empty lines or change colors, and watch your brain automatically find ideas to put on them.

Step 8: Add relationships and connections

Sometimes you see relationships and connections immediately and sub-branches to a main topic can be added. Sometimes you don't, so you just connect the ideas to the central topic. Organization can always come later; the first requirement is to get the ideas out of your head and onto the paper. The relationships and connections shown in the figure represent only one branch of the SOP. To complete this mind map similar relationships and connections would be need to be added.

Ok, so now we have a mind map for a Chemical Mixing and Dispensing SOP, what happens next? Look at the pattern between the three chemicals listed. What

do you see for each — 1) mixing, 2) dispensing, and 3) safety? There's your SOP outline! In the case of Spor-Klenz, some of the subparagraphs are already laid out.

So now we can start writing — yes, and that will be our topic next month.

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



Glenn Ketcham, CIH and Vince McLeod, CIH

Keeping
Cool Under
Pressure:
Working
Safely with
Cryogenic
Materials

Cryogenic materials are used in the vast majority of "wet labs" across the country. On a daily basis we receive shipments packed with dry ice, preserve samples with liquid nitrogen, remove impurities with cold traps or baths, and keep our equipment cooled with controlled internal environments. As with most things in the lab, all of these can be done safely if we recognize the hazards and work diligently to control them. As we look across the literature there is differing opinion for when a substance becomes a cryogenic material. We will consider materials with boiling points below -75°C (so as to include dry ice) as cryogenic for our discussion.

Cryogens are similar to other broad classes of chemicals in that we can divide the concerns into physiological hazards and physical hazards. As with other chemicals in the lab, it should go without saying that the MSDS should be reviewed and SOPs developed for inclusion in your chemical hygiene plan.

PHYSIOLOGICAL HAZARDS

Within the physiological hazards category we can also group the hazards into two main divisions, those that damage tissue from direct contact and those that can cause asphyxiation.

Direct Contact

Protect your skin and eyes. Those of us that are old enough and have spent a lot of time in the sun in our youth are all too familiar with the effects of liquid nitrogen from our visits to the dermatologist. The quick controlled spray of liquid nitrogen freezes and kills tissue in pretty short order. The same effect is true from accidental splashes or contact with these very cold materials. Always wear safety glasses whenever you are near a cryogenic liquid or working with samples recently removed from cryogenic temperatures. In addition, also wear a full-face shield if a cryogenic liquid is poured or if an open container of the cryogen may boil and splatter. To reduce the amount of splatter when transferring cryogenic liquids from one container to another, always start slowly allowing the vaporization to chill the receiving container before filling it. After the vaporization and liquid boiling has decreased, fill the container at the normal rate.²

Cryogenic materials flow freely as do other liquids and as a result can splash and spill. It is important to wear liquid resistant gloves to prevent splashed liquid from being absorbed and freezing the skin.

Asphyxiation

A tremendous amount of potential gas volume is contained in the cryogenic liquids found in the lab. One unit volume of liquid nitrogen, for example, will expand to produce almost 700 unit volumes of gas when vaporized. This raises the concern of oxygen displacement. Normal air contains 19.5% oxygen by volume; one can begin to feel the effects of oxygen deficiency at about 18% and sudden death may occur at about 6%. A leak or vessel breakage can result in an oxygen deficient atmosphere rather quickly, especially in a small room with poor ventilation

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Unfortunately, there are documented cases where incidents with cryogens have resulted in serious injury and death.

Chemical Leak

A laboratory assistant died and four other people were injured in a chemical leak a hospital in Edinburgh. The assistant died after liquid nitrogen spilled in a basement storage room.4

Cryotube Explosion

A university investigator was blinded in one eye when a cryotube exploded while being thawed. The probable cause was the rapid expansion of liquid nitrogen that had entered the tube through a small crack during storage.

Suitable personal protective equipment for thawing cryotubes and handling cryogenic liquids consists of a face shield, heavy gloves, a buttoned lab coat, and pants or a long skirt. Cryotubes should be kept in a heavy, walled container or behind a safety shield while warming.³

N₂ Explosion

A researcher at a university reported that a vial of potentially infectious materials "exploded" when she removed it from liquid

As you may have guessed, the "explosion" occurred when the liquid N₂ leaked into a vial and expanded when removed from the cold. This used to be a fairly common problem with heat-sealed glass ampules, because it was difficult to obtain perfectly fused glass with no microscopic holes.³

(e.g.; an elevator or cold room). An excerpt from an investigation reported by the AIHA stated, "Recently on the campus, a walk-in refrigerator was used to store dry ice. The dry ice was stored in a standard dry ice storage locker but the locker had been placed in the cold box to further reduce the rate of dry ice loss. The dry ice, of course, gave off carbon dioxide (CO₂) gas as it sublimed, causing the refrigerator to build up CO₂ levels of 12,000 parts per million (ppm)! In comparison, outdoor air contains only about 400 ppm CO₂, and OSHA's Permissible Exposure Limit for CO₂ is 5000 ppm." ³ We recommend avoiding cryogen use in these situations and developing specific procedures for transport in elevators.

PHYSICAL HAZARDS

Within the physical hazards category we can group the hazards into those that have an explosion risk from pressure build up and those that have an explosion risk from chemical reactions.

Explosion — Pressure

As we mentioned above the gas volume generated from the vaporization of the liquid phase is very large. Recall liquid nitrogen will expand to produce almost 700 unit volumes of gas when vaporized. If this phase change occurs in a vessel unable to contain the pressures exerted, it can fail dramatically. It is not uncommon to hear of lab-made cryotubes exploding when removed from storage. The liquid nitrogen can get into a cryotube through imperfect sealing and expands upon thawing and conversion to the gas phase. Use tubes specifically designed for cryogenic storage and place them in a heavy-walled container or behind a safety shield while thawing. The tubes are also designed to be in the gas phase and not submerged in the liquid nitrogen in the storage Dewar. Overfilling of a Dewar can cause sample tubes to be stored in the liquid phase allowing liquid nitrogen to enter the tube.

Explosion — Chemical

Cryogenic fluids, such as nitrogen, with a boiling point below that of liquid oxygen are able to condense and accumulate oxygen from the atmosphere. Violent reactions, for example rapid combustion or explosion, may occur if incompatible materials, such as most common organic compounds, come in contact with the oxygen. This might occur in an uncovered nitrogen trap used to condense out low boiling point liquids or a open Dewar. This is why it's important to keep Dewar flasks covered with a loose fitting cap. This prevents air and moisture from entering the container yet allows pressure to escape.

Here we have just scratched the surface on the hazards and controls associated with cryogens. Anyone who handles or uses cryogenic liquids requires adequate knowledge of the properties of the particular materials they use and the safe handling practices. Specific understanding should include:

- the properties of the cryogen as a liquid, solid or a
- the materials compatible for use with that cryogen (e.g., those that are compatible with the temperatures and pressures of the material)
- the protective equipment required and its proper
- understanding of the equipment being used including its safety devices
- emergency procedures including first aid and treat-

The familiarity of these materials in the lab can lead to complacency but these hazards can result in serious injury if not controlled.

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

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The Evolution of Cool

ULTRA-LOW TEMPERATURE FREEZER TECHNOLOGY IN PROGRESS

From the days of wooden boxes filled with snow or blocks of ice, to the 1800s when mechanical refrigeration systems were invented, people have stored and preserved their food using very archaic methods. It was not until the 1940s that the first free-standing freezer was introduced and since then, the freezer has made huge technological advancements to become an independent unit that plays a more significant role than just storing food.

Today, the freezer is as commonplace in the laboratory environment as it is in the home, and the need for precise refrigeration has grown considerably over the last few years. High performance ultra-low tempera-

ture (ULT) freezers are an essential piece of equipment in the laboratory, providing long-term protection and storage for valuable biological samples on a daily basis in industrial, clinical, and research applications worldwide. Therefore, protecting the integrity of samples is extremely important and can be achieved by combining rapid temperature recovery, temperature stability, and operational efficiency, all in a productive and comfortable lab environment.

However, for lab applications, not just any freezer will do and choosing the wrong one can be costly. A freezer door opened frequently or for extended periods of time could expose your samples to warm ambient air, creating an opportunity for decreased sample integrity. In addition, many lab professionals do not realize the consequences of storing valuable samples and materials, such as DNA, RNA, cells, and protein samples, in conventional household freezers. These units are not designed to maintain critical storage requirements demanded in most laboratory applications; inadequate systems result in wider temperature fluctuations, as well as uneven temperature distribution throughout the cabinet. Choosing a freezer that provides tight tempera-



ture uniformity and delivers rapid temperature recovery is vital in maintaining sample integrity.

KEEPING IT COOL

Freezing is a crystallization process which involves lowering the temperature below 0 °C, resulting in the gradual conversion of water into ice. This freeze-concentration process occurs as water freezes out of solution in the form of pure ice crystals, which causes the freezing temperature of the remaining solution to drop. Freezer cooling systems undertake this process by removing heat from the air in the unit rather than cooling the air in the freezer.

Ultra-low temperature freezers can maintain their internal compartments at temperatures as low as -86 °C (-123 °F) by combining the latest technology advancements to ensure the long-term preservation and storage of valuable samples. These sub-zero freezing temperatures are associated with the extended viability of preserved biological samples by dramatically reducing metabolic activity compared to -20 °C household freezers, thus directly influencing the time during which the samples can be recovered without damage.

COLD STORAGE TECHNOLOGIES

Freezer technology is now a conventional industrial technology that has recently achieved a high level of maturity worldwide due to the increased levels of laboratory pro-



tocol regulations. Minimal fluctuations in temperature are critical to the viability and effectiveness of biomedical products so international regulatory bodies require laboratories to constantly monitor the temperature variation during the storage process. There is also a need for the cooling industry to develop cost-effective and environmentally sustainable solutions to increase energy efficiency. This means focusing on technologies, materials, and solutions that enable new cooling solutions to be delivered in an environmentally responsible manner to enable standards for safety and performance to be met.



As a result, innovative technological improvements have been introduced over the last few years in three key areas — temperature uniformity, recovery, and control. New refrigerant, vacuum insulation, and ultra-low temperature freezing technologies have resulted in the introduction of new products and systems to the market. ULT freezers are now designed to fulfil the toughest environmental and cost-saving targets and incorporate the latest technologies. These design advancements mean that they use less electricity, produce less heat, and make less noise — factors that create a more comfortable laboratory environment, result in cost savings, and operational efficiencies.

SUSTAINABLE COOLING

The basic components of today's modern freezer systems operate on a cooling concept adapted from Faraday known as a vapor-compression system. This involves compressing gas into a liquid that will then absorb heat and in doing so returns to gas. Advanced high performance ULT freezers are now designed with new generation patented refrigeration technology and

use custom-designed compressors to maintain vital operating temperatures up to -86°C to provide the most accurate interior storage conditions possible.

Temperature recovery is an important feature of modern freezers for precise temperature control. Door openings dramatically influence temperature uniformity by creating frost, and prolonged or frequent use increases the temperature of internal compartments very quickly. Therefore, it is vital that freezers recover quickly before the brief rise in temperature and the formation of ice crystals compromise the samples. Forced-air refrigeration provides more heat removal capacity ensuring rapid temperature recovery after door openings. This cooling technology works very differently from household freezers and recovers its temperature much more quickly. This decreases the risk of sample degradation. In addition, highly developed robust electronics platforms feature easy-to-use microprocessor controls and provide real-time monitors and precise temperature settings, power, and other critical parameters, further ensuring the integrity of samples.

One problem with freezing is that it is an exothermic process, and the excess heat needs to be removed in some way in order to maintain controlled cooling. Advanced ULT freezers require less power to efficiently maintain cabinet temperatures which in turn reduces heat emissions into the lab environment, reduces air conditioning and energy costs, and maximizes operational efficiencies.

High performance ULT freezers comprise of an interior storage compartment that uses advanced noise abatement and super insulation technologies for more effective minimal noise output. These technological advancements mean that freezers are now a lot quieter, allowing units to reside directly in the lab. This speeds sample preparation and minimizes sample exposure to ambient air. Researchers, who spend many hours surrounded by lab equipment, also benefit from a quieter and more productive, efficient, and comfortable working environment.

Thermal insulation is achieved inside the freezer using super insulation, a vacuum formed panel consisting of multi-layers of glass fiber. This is encased by a non-gas permeable membrane to insulate the housing, which subsequently reduces freezer wall thickness from traditional foamed in place insulation. This compact footprint means that storage and laboratory space is no longer taken up because of thick layers of insulation. Tight door seals also prevent warm, moist air from entering the freezer so ice builds up more slowly and less defrosting is needed. This design is also effective in preventing energy from re-entering the freezer, thereby improving energy efficiency and in turn decreasing heat injection into the surrounding environment. When opening the doors, it can be difficult for the temperature to restabilize. In order to combat this,

freezers are fitted with inner doors made from an acrylonitrile butadiene styrene (ABS) polymer to reduce cold air loss. This makes it useful for storing material at critical temperatures and to balance cost, size, and capacity considerations.

Other advanced features of modern ULT freezers include a microprocessor temperature control system with digital temperature display, a platinum resistance sensor for extra precision and reliability, a power failure warning system with built-in audible and visible indicators, double insulation polyurethane walls, and hinged outer door latch. Various rack configurations are also available to help ensure the easy retrieval of samples and minimize exposure to ambient conditions.

KEEPING COOL WITH NEW TECHNOLOGIES

Modern refrigeration is almost entirely based on a compression/expansion cycle, which is a reliable and relatively low cost technology. Over the years, all parts of a conventional freezer have been considerably improved due to extended research, and many of the challenges associated with maintaining precise temperature control have been eliminated due to current advancements in control design and technology, as previously discussed.

However, new generation cooling technologies are emerging that are now focused on meeting higher energy efficiency standards and environmental compatibility which also consider criteria costs and functionality while phasing out chlorofluorocarbon (CFC) refrigerants. Freezers are constantly working and can use a lot of energy to achieve a uniform chamber distribution of temperature in well-insulated freezers. In addition, freezers consume the most energy in compensating for the heat that enters the cabinet through the insulation or gaps in the door seals. Energy efficient freezers represent a better investment and new technologies mean that freezers now use less energy and can be operated without ecologically harmful refrigerants and insulation materials. Over the next few years, energy efficiency, green solutions, and the total cost of ownership will be at the forefront. Finding substitutes for greenhouse-effect inducing fluids in energy processes is a major challenge in the struggle to reduce CO₂ emissions. CFCs damage the ozone layer and future cooling technologies lie with safe and effective alternatives such as natural substances that include hydrocarbons, CO₂, and ammonia. Efforts are also being directed to develop other types of refrigerants, which will be even more eco-friendly, cost effective, efficient, convenient, and reliable.

A CONTINUOUS COOL

Scroll compressors are becoming more common within refrigeration applications due to the reliability and compact size of the compressor's operating mechanism and reduction of moving parts. Instead of utilizing a valve and piston-driven motion to compress gas, the scroll compressor works with two mating parts that literally "scroll" together and rotate around each other. This advanced engineering and flow dynamics efficiently and smoothly compresses the refrigerant gas, and replaces approximately fifteen noisy high-wear parts.

A STIRLING IDEA

The Stirling freezer is based on the reverse of the Stirling engine in cycle and has attracted much attention because it needs less heat energy to generate power and does not require any refrigerant harmful to the environment. Stirling engine technology approaches the limits set by the laws of thermodynamics more closely than any other system and is now being developed for generating low temperature states as low as cryogenic temperatures.

The Stirling engine has been studied and developed as one kind of gas compressor expander because it theoretically has a very high thermal efficiency, allows the use of various kinds of heat sources other than petroleum, and is quiet and harmless to the public.

CONCLUSION

It can be said that these emerging technologies allow for all ultra-low temperature applications and are well suited for use in laboratories and hospitals for the long-term preservation and storage of samples, specimens, and components. These types of valuable samples are protected by combining great rapid temperature recovery, temperature stability, and operational efficiency, all in a productive and comfortable lab environment. These innovations will usher in a new era in ULT freezers allowing for quiet, compact, high efficiency designs to become standard in the industrial and biomedical industries.

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Why An Effective Recruiting Strategy Hinges On A Sensible Retention Plan

HAVE YOU LOST A TALENTED LAB PROFESSIONAL RECENTLY?

If so, the thought of that individual's departure probably conjures visions of all the process and procedure involved in properly facilitating their exit from your organization and the time, effort, and cost of recruiting their replacement. That is, if you can find and attract someone of the same performance caliber.

For far too many employers, effective recruiting has been hampered by ineffectual corporate practices regarding employee retention. Many organizations face a persistent recruiting challenge simply because they have a longstanding retention problem.

And, it's important to point out, when I refer to retention, I'm not talking about the extension of a counter-offer to someone who has just announced their intention to leave.

Rather, a sensible employee retention program is proactive and built with some flexibility to offer compelling inducements for people to stay. It's also designed to help alleviate some of the pressures that the corporate staffing folks invariably face whenever the wider economy is in growth mode and there's a seller's market for good lab talent.

So what can you do to retain your best lab talent? I'm glad you asked, and happy to share some informed opinion about what works:

- Get into the habit of measuring and rewarding performance There is a growing movement with many companies to more effectively benchmark the performance of individuals, teams, labs and overall business units. This way, employers can make smarter, more informed decisions about where to make key investments, and in whom. Talented lab professionals want to work in an environment they can feel good about, and by measuring everyone's performance, you not only identify the people who need to step things up but you also identify those who are consistently delivering the results your lab needs. Sow the seeds of career advancement and many of your best performers will want to stay and grow with your lab team.
- Tell emerging leaders that they have a bright future in your lab Some companies believe that telling a so-called 'high-potential' employee that he or she is indeed destined for success is a mistake because they might change their behavior and/or their attitude, which could hurt wider employee morale. But you owe it to them to share the lab's confidence in their growth potential, so long as you point out they can behave their way right out of the succession plan, too.
- Offer some form of tuition reimbursement Anyone who wants to invest the time and energy to pursue another degree in their limited time outside of your lab obviously has the energy to do great things for your organ-

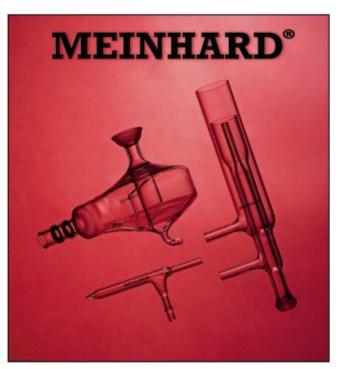
Joseph Daniel McCool

- ization. And you'd be surprised at just how compelling an offer of tuition assistance can be to these career climbers.
- Take action on bad hires before they cause broader morale and productivity issues The business of recruiting new lab talent requires us to make decisions about people, and even those who make a living in recruiting will tell you that there's always the chance for some standard deviation in their hiring decisions. But if you make a poor hiring decision, don't force your best people to live with your mistake, otherwise you'll subject your entire lab team to a potential loss of morale and productivity. You can actually retain your best performers by weeding out your worst performers and the people you should have never hired in the first place.

What It Means For Your Career: Leading labs make recruiting and retaining talented individuals a

real priority, and their winning culture makes you want to stay and be part of the team. If you're not feeling appreciated right now, chances are you'll eventually make plans to leave. So why wait?

Joseph Daniel McCool is a writer, speaker and independent consultant on workforce management, recruiting best practices, and corporate management succession. He is the author of a forthcoming book about global executive recruitment and its impact on corporate performance, culture and profits and will be a featured presenter at Lab Manager's October 25 Boot Camp. He is also a senior contributing editor with ExecuNet, a leading executive business, recruiting and referral network, and his perspectives on recruiting best practices have been cited in BusinessWeek, The Economist, The Financial Times, The Wall Street Journal and other media around the world. Contact him at JoeMcCool@comcast.net.



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Conducting R&D Staff Reductions

R&D staff reductions have become a fact of life in many organizations. Mergers, divestments, and other forms of organizational restructuring plus outsourcing and technological changes have made staff reductions common events even in profitable firms. However, conducting staff reductions remains a very unpleasant duty for most lab managers. Perhaps this is one reason why so many staff reductions are planned and executed poorly. Carefully managing staff reductions can maximize their intended effects: reducing R&D expenses and increasing focus on high growth areas. Careful management also can reduce adverse effects on:

- Employees losing their jobs
- Morale and productivity of the remaining R&D staff
- Workflow disruption
- Quality of customer service
- Your own morale as manager

To accomplish these goals, communication with your staff members must be open and honest. Tell them as much as you can. Admit when you don't know something. However, don't let your sympathy towards employees worried about their job security lead you to disclose confidential information or make promises you can't keep.

DESIGNING THE STAFF REDUCTION

There are two basic options to designing staff reductions. The first is an across the board percentage reduction in each unit of the organization. This design is relatively easy to implement but provides poor control over the need to retain essential skills and minimize adverse effects on R&D programs with the most business growth potential.

The second option is to retain people with essential skills on projects with the most growth potential and focus staff reductions elsewhere. These are more difficult to execute because of the need to prioritize R&D programs and the often different skills of the laboratory personnel staffing these programs. However, when implemented well, this approach provides better control in retaining essential skills and minimizing adverse effects on programs with the most business growth potential.

Managers should base decisions on which employees should be retained on the above design principles: each employee's previous contributions, technical and interpersonal skills, and the need for information retention within the organization. To aid in making good decisions, managers should work with their lower level managers and team leaders. These discussions should be private and the need for confidentiality should be stressed.

There are advantages to executing a staff reduction all at once to end staff members' uncertainty and distraction. However, the second design option permits managers to stage reductions across departments and other units of the organization. By staging the staff reductions rather than performing one massive one, managers can begin reducing R&D spending more quickly and think more deeply about which reductions need to be made in each stage of the process.

THE DEVIL IS IN THE DETAILS

In designing the staff reductions, the devil is in the details. Important questions to answer include:

- What R&D activities can be cut back with the smallest negative impact on current and future business?
- What essential skills must be retained within the organization?
- What skills and programs can be outsourced more cost effectively than retained within the organization?
- What programs and activities can be eliminated with the least harm to the organization?

Before making these determinations, managers must develop a new vision for the organization and redefine its goals. Work processes need to be redesigned to be commensurate with the resources remaining after the downsizing.

EXECUTING THE DOWNSIZING

Having established the design of the staff reduction, which employees will be retained and the shape of the future organization, decisions that have to be made include:

- Designing the severance package
- Financial aspects
- Advance notice
- Outplacement services
- Designing the communications process with both the departing employees and the remaining R&D

Severance pay calculations are usually based on two weeks pay per year of service although three weeks pay is not uncommon. Also common are additions to employees' years of service for the purposes of calculating pensions. Two to four weeks advance notice is most common. However, some firms still prefer to escort employees from the premises immediately after informing them of their job loss. Some managers prefer to have departing employees wrap up ongoing work and write reports before leaving.

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Outplacement services are good for the morale of both retained and departing employees. These services can enable departing employees to update their jobhunting techniques, and identify their most marketable skills.

AFTER THE DOWNSIZING

Instituting redesigned work processes to improve focus and productivity should be done as soon as possible after the downsizing. So should reassigning staff members to projects that will provide the greatest financial reward to the company in a timely way. Low productivity activities should be reduced, eliminated, or outsourced quickly. To aid in implementing these changes quickly after the downsizing, decisions regarding these issues should be made before the downsizing begins.

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

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