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SAFETY

LEADERSHIP

**EIGHT VALUES TO BE AN
EFFECTIVE SAFETY LEADER**



**Optimizing
EHS Performance**

Risk-Based Programs





THE BENEFITS OF LPA MEMBERSHIP

Exclusive member benefits promote commercial success for LPA members by **Scott D. Hanton, PhD**

The Laboratory Products Association (LPA) enables manufacturers, distributors, and suppliers of lab products and services to consistently improve their global and commercial success through networking, market information, professional education, and government affairs advocacy. The LPA has been supporting member companies for more than 100 years and is focused on growing the vital role played by the laboratory products industry.

The value of the LPA to its members is clearly communicated by Fran Hutson, head of global strategic distributor management from MilliporeSigma: “The value of LPA, found in the strength of the members, continues to provide insightful market reports, relevant scientific and market forums, along with leadership connections that are invaluable. Driving inclusion with diverse companies as members keep engagement rich and launching new programs like the recent Women’s Forum is just another example of adding leadership strength to the organization.”

Today’s competitive global environment places added pressure on companies to gain access to the resources and tools they need to be successful. The LPA provides exclusive member benefits to enable success in the lab products industry, such as:

- **Market data** – surveys and other market reports provide strategic insight into the current business climate and trends impacting laboratory products
- **Business networking** – multiple networking events at LPA meetings and other conferences important to the lab products industry with senior-level executives
- **Government and regulatory affairs advocacy** – reports on ever-changing important legislature that affects members and provides a voice with representatives in Washington, DC to discuss industry issues
- **Professional growth** – leadership development opportunities working with peers in the association
- **Scientific advisory boards** – panel discussions with professionals from laboratories seeking their

expertise to enhance the knowledge, understanding, and strategic thinking of labs for LPA members

- **LPA Reporter** – monthly newsletter that provides timely news on the industry, events, and other members
- **Career center** – online job postings make connections between members and outstanding talent. Positions are also shared with broader aggregate boards
- **Flash Report** – monthly sales survey information, anonymous and informative
- **LPA Engagement app** – access exclusive benefits from any device
- **Industry calendar** – quick and easy access to the industry-specific calendar
- **LPA Women’s Forum** – increasing engagement with women in the industry

The benefits of membership in the LPA are important to Lisa Witte, president, research and safety division of Thermo Fisher Scientific: “The LPA provides its members with an ever-increasing and powerful range of benefits. The market reports are insightful, and the education programs are both up-to-date and useful to personnel at all levels in our member organizations.”

A highlight of LPA membership is participation in the two meetings. In 2022, the LPA Spring Meeting was held May 2-4 in Austin, TX, and the LPA Annual Meeting will be held October 1-4 in Scottsdale, AZ. These are great opportunities to network, learn from, and share with other experts in the lab products industry.

For more information on joining the LPA and gaining access to the exclusive member benefits, please contact Angie Errera, the LPA director of membership, marketing, and communications, at: aerrera@lpanet.org. Go to www.lpanet.org/join to watch a membership video to see how members benefit from being part of the LPA.

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SAFETY FIRST WEBINARS

Looking for more strategies and guidance to keep your lab staff safe? Sign up for *Lab Manager's* Safety First webinars! Held four times per year, these webinars feature expert presenters who are ready to answer your questions and provide action items that you can implement in your lab. Topics for this year include biosafety basics, hazard reviews, preventing common accidents, and effective waste handling. Sign up to watch previous webinars on demand, or sign up for the next one here: www.labmanager.com/events/webinars

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The BIG Picture

TACKLING THE TOPICS THAT MATTER
MOST TO LAB MANAGERS

Host cell proteins (HCPs) are process-related impurities that are produced by the host organism during biologic manufacturing and production. A purification process is necessary to reduce the levels of HCPs in any biopharmaceutical product to ensure it is safe for patients. This is a complex process that requires the right tools, expertise, and strategies. This series explains the process of HCP analysis in biologics development, the benefits of using ELISA kits, how to ensure security of supply for HCP reagents, and solutions for validating HCP ELISAs.

The Big Picture is a digital series produced by the *Lab Manager* editorial team. Each month, the series features a collection of in-depth articles, expert insight, and helpful resources, covering a specific industry, trend, or challenge.

To see the “Develop a Smart HCP Kit Strategy” and other Big Picture series, please go to *Lab Manager’s* website at [LabManager.com/big-picture](https://www.labmanager.com/big-picture).



analyzing your lab's risks

How do you approach risk analysis in your lab? Some risks and hazards may seem obvious, but individual perceptions and biases can influence how different staff members on your team rank potential dangers in their workspace. In this issue, we cover many of the core aspects of developing a culture of safety in the lab.

To ensure safety is top of mind for lab staff, the lab manager needs to accept the leadership role and lead by example. As editorial director Scott Hanton notes in our cover story article, "A robust safety culture won't develop on its own. It requires agile and engaged leadership by the lab manager." Hanton goes on to outline eight key values lab managers need to embrace to achieve an effective safety culture in the lab. Learn more about each of these traits and how to implement these approaches by turning to page 10.

The topic of lab safety is broad, complex, and varies depending on the type of lab in which you work. At *Lab Manager*, our editorial team works diligently to cover all aspects and nuances of laboratory safety. As we continue to broaden the scope of our coverage and deliver on our mission of providing readers with relevant, insightful content to help run your lab like a business—and do so

safely—we recently invited Jonathan Klane, MS Ed., CIH, CSP, CHMM, CIT, to join the team as senior safety editor. While many readers had the chance to meet Jonathan in person at the Lab Manager Leadership Summit in May, it only felt right to officially introduce him here as well, in the pages of our lab safety issue. Jonathan previously worked as director of risk management and safety education for BioRAFT. In this innovative position, he focused on creating opportunities and solutions for the greater EHS community. As part of the Risk Innovation Lab at Arizona State University, he studied how stories, narratives, safety culture, and other dynamics affect our risk perceptions and behaviors. Jonathan will contribute to *Lab Manager's* offerings in a variety of ways—through written articles (like the one on page 30), the Lab Manager Academy, and interactive webinars and other presentations. If you have questions or suggestions of topics you'd like Jonathan to cover, please reach out to him at: jklane@labmanager.com.

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MANAGER  MINUTE

Three Keys to Improve Safety with Inspections

by Scott D. Hanton, PhD

Keeping staff safe in and around the labs is a key responsibility of lab management. There are many different actions lab managers take on a consistent basis to ensure the safety of their labs, and to build an effective safety culture for the lab. One important contribution that lab managers can make to lab safety is to participate in the regular safety inspections. It is important for the lab manager to see and experience exactly what is happening in the labs and get a first-hand appreciation of the efforts to promote safe work. Being seen doing safety inspections is also important. The effort of conducting safety inspections reinforces the message that safety is a high priority for everyone in the lab. It also gives the lab manager an opportunity to talk with people in the lab about safety, to ask questions about specific situations, to follow up on previous inspection action items, and to answer questions related to lab safety. Here are three things lab managers can do to improve lab safety through inspections.

#1 – Actively participate

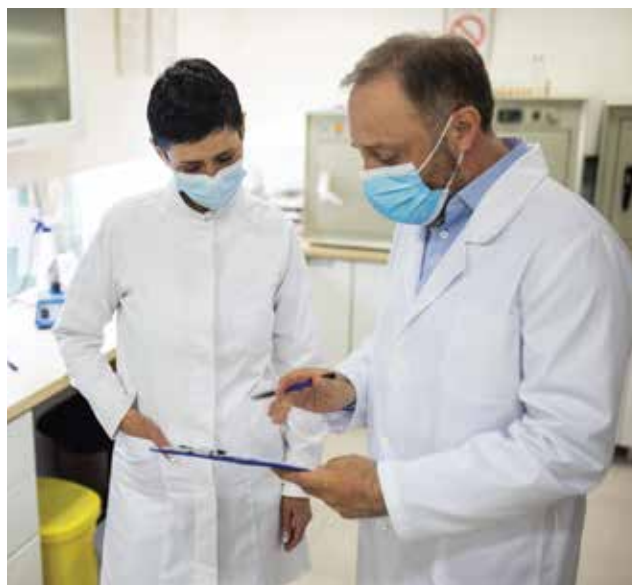
Join the safety inspection schedule. Do safety inspections along with the usual inspectors. Put time and effort into the inspection. Provide sufficient time to do the inspection properly, the way you want everyone else to conduct them. Pay attention to the details in the lab. Work hard to find potential problems, both to ensure ongoing safety, and to spark useful conversations during the inspections.

#2 – Ask good questions

Use your scientific experience and training to ask good questions of lab staff during inspections. Expect lab staff to be present during the inspections. Ask them about any safety concerns or actions that they think need to be taken to keep the lab safe. Get them talking about ways to further improve safety of the lab. Listen carefully to their responses.

#3 – Make decisions

Safety manuals can't address every detail of the lab work. As you encounter different situations and listen to different ideas, be willing to make decisions to improve the safety of the lab. Addressing situations on the spot and making decisions that improve safety will demonstrate the importance of safety in the lab, and the need and the impact of making effective decisions. Management participation in inspections can help resolve some of the gray areas discovered during periodic safety inspections.



Thanks for reading. I hope you can use this information. I am very interested in hearing from you. If you have feedback or comments on this set of tips, or suggestions for future Manager Minutes, I'd love to hear from you. Please reach out to me at shanton@labmanager.com. I'm looking forward to our conversations. Thanks.

EMBRACING

SAFETY

EIGHT VALUES TO BE AN EFFECTIVE SAFETY LEADER

by Scott D. Hanton, PhD

LEADERSHIP

When Ed Donley was the CEO of Air Products (1978–1986), he announced that safety was more important than anything, including profits, sales, production, and research. He instituted practices that made safety the first agenda item in meetings, a condition of employment, and included safety objectives in performance reviews. This demonstration of priority removed excuses and ensured that all safety-related items were given sufficient consideration.

One of the most important responsibilities for a lab manager is keeping everyone—staff, students, scientists, researchers, and visitors—safe while they perform the work of the lab. The best way to improve lab safety is to actively develop a robust safety culture, spot hazards, communicate potential risks to staff, and learn from and adjust to new situations that arise in the lab. A robust safety culture won't develop on its own. It requires agile and engaged leadership by the lab manager.

While there are many aspects to lab safety, there are eight elements over which lab managers have significant impact. Committing time and effort to each component will enable the lab to improve both its safety culture and performance.

Drive safety as the top priority

As demonstrated by Ed Donley at Air Products, keeping lab staff healthy and safe needs to be the top priority for the lab and for the lab manager. People can't focus on the work if they are concerned for their health and safety. Even without such engaged leadership, lab managers can drive safety as the top priority by having

regular conversations and sharing stories with staff about safety, including safety as an item in all lab meetings, and insisting that safety be considered as a foundational aspect of all work.

Ensure safety training and equipment get the priority they need in the lab budgets. A robust safety program requires staff time to read, understand, and create effective documentation, share observations, help each other, and receive training around potential hazards. Ask staff about their needs to improve the safety of the work.

Active participation

Lead by example. Author Ralph Waldo Emerson said, "What you do speaks so loud, that I cannot hear what you say." Staff will learn more from your actions than from your words, especially about lab safety. Ensure you follow all safety and risk policies and practices. Please remember that staff are constantly watching you, listening to you, and learning from you. If you take shortcuts on safety, you are demonstrating that safety isn't always your priority. Engage staff in discussions about safety and risk with everyone. Ask questions about what you observe, and answer questions about priorities and safe practices. Staff understand that the things you discuss with them are the top priorities.

Expect everyone to respect the risks encountered in the lab. Don't tolerate inattentive practices that can lead to incidents, injuries, or exposures. Act when you see inappropriate safety or risk-related behaviors. Address issues promptly and work with staff to resolve them.

Create habits

Part of developing a robust safety culture is creating safe habits in the lab. Unfortunately, most scientists or researchers have little safety or risk training until they join an established lab. They likely didn't bring the right level of safety habits with them when they joined the lab, so those habits need to be created and nurtured.

The Air Products safety program builds self-discipline and a proactive safety culture through a program of enforced activities, leading to habits, building individual values, and ultimately generating their safety culture. The lab manager needs to set priorities and demonstrate expectations and preferred activities to begin developing safer habits. Examples of enforced activities include always wearing proper attire and personal protective equipment (PPE) in the lab, ensuring safety redundancies, consistent safety inspections, no food or drink in the lab, and no chemicals in the office. Risk-reducing habits need to be consistently enforced and reinforced.

Active participation in risk-reducing activities allows lab managers to build more safety habits. Asking questions and being open to answering staff questions about why the safety practices and expectations are in place will facilitate an ongoing dialogue and build the relationships as well as culture. Emphasize the need to take care of one another and be willing to call a timeout on a project to explore the safety of the work by reassessing its risks.

Train staff

There are many ways to train staff on the potential hazards of the lab. Some of the easy ways are making safety data sheets easily available, conducting internal training on common safety issues, providing safe work documentation about materials, equipment, and procedures, conducting hazard recognition exercises, and assessing risks on an ongoing basis.



Document processes

Documentation of processes, policies, and procedures is an important activity to help keep staff safe. Staff need to be trained to follow these guidelines, and the documents need to be reviewed and updated every three to five years.

Safety policies define the expected behaviors and practices around the lab. Many of them describe the required behaviors that form the foundation of the safety program. Defined procedures in the lab can be documented as safe work practices (SWP). These documents illustrate the potential hazards and provide step-by-step instructions to safely perform specified activities. The SWP will also identify any required PPE.

More complex experiments can be safely performed by conducting and following a design hazard review (DHR), which examines the risks of a set of experiments and provides ways to safely conduct them by reducing the risks. The DHR covers the operating procedures, equipment, materials, safety considerations, and PPE required for the experiments. One common component of a DHR is a “what-if” section that asks questions like, “what if the cooling water fails?” The scientists or researchers would then think through the potential hazards and risks associated with those situations and plan for them.

Inspect

Regularly inspecting labs, offices, and storage areas are part of a healthy safety culture. These inspections are intended to be a candid opportunity for skilled scientists and lab management to lead walkthroughs in all parts of the lab, encouraging others to look for potential hazards and reduce risks. Bringing new eyes into the lab can help identify issues that the people working there cease to see. Having the lab manager participate demonstrates the importance of safety to the lab.

Inspections need to cover all aspects of safety, including biological, chemical, radiological, physical, and ergonomic. Inspectors can document potential issues for the lab occupants to repair and resolve. Lab management ensures that all action items are completed in a timely fashion.

Measure

To improve lab safety and risk performances, it is essential to measure important aspects of the program. Some examples of key safety metrics include both leading and lagging indicators. A few examples are injuries, OSHA recordables, near misses, hazard observations, repeat inspection items, late or missing safety documentation, and problems with safety training.

Increase the awareness of safety observations, which are things that staff see around the lab that might cause a safety incident, to improve the safety performance of the lab. By noticing and addressing these seemingly small things, the work environment is safer with less risk. The same is true for addressing near misses, which are events that occur in the lab, but no one gets hurt and no equipment is damaged. Studying, understanding, and implementing preventive actions can mitigate more serious issues in the future.

“Emphasize the need to take care of one another and be willing to call a timeout on a project to explore the safety of the work by reassessing its risks.”

Provide for emotional and psychological safety

Most labs do a good job of addressing the physical safety of staff. Another way to improve the safety culture and work environment is to include emotional and psychological safety. These involve the ability of lab staff to bring their whole best selves to work. Promoting this kind of safety environment will enable lab staff to be freer to contribute their ideas, ask questions, seek help, and be more creative in their science.

Lab managers can improve this kind of safety by ensuring mutual respect among the staff, using gratitude, being humble, and listening to everyone. To learn more, look into the books *The Culture Code* by Daniel Coyle, and *The Fearless Organization* by Amy Edmondson.

Lab managers can make a significant impact on the safety of their labs by actively and purposely participating in the different aspects of the safety program. Through effective leadership, lab managers can promote safer work habits that reduce risk while raising expectations around expected behaviors in the lab. By stressing and demonstrating mutual respect, lab managers can extend the safety culture to include emotional and psychological safety.

Scott D. Hanton, PhD, editorial director for Lab Manager, can be reached at shanton@labmanager.com.

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Intertek York

SAFETY TESTING LAB FOCUSES ON STRENGTH AND DURABILITY OF BUILDINGS AND CONSTRUCTION MATERIALS
by Katie Ellsworth

When you think of lab safety, the first things that may come to mind are personal protective equipment, chemical containment, or safety protocols. But what about the safety of the lab building itself? Modern buildings need to be built to several strict safety standards, ranging from fire safety to natural disaster resistance, and the materials and structures must be tested and certified to industry standards. This is where safety testing laboratories like Intertek York come in.

From evaluating how well buildings can withstand natural disasters to checking how long windows and doors can hold up to various threats, Intertek York has the facilities to assess a wide range of safety concerns. With labs in more than 100 countries, Intertek serves a wide variety of industries. Their Building and Construction division

▲Dynamic wind and water tests can be conducted in the lab or in the field.

has grown significantly over the past decade, and the York, PA lab (previously Architectural Testing Inc.) is one of their more recent acquisitions, having joined the company in 2013.

The existing facilities at the York lab added to Intertek's fenestration, thermal, and acoustic testing capabilities, which they have since expanded to incorporate a larger number of safety testing methods.

Serving building product manufacturers all over the world, Intertek York provides assurance testing, inspections, and certifications to meet a variety of regulatory and code requirements, such as

the International Building Code and North American Fenestration Standard. Clients can make use of the York lab facilities to test products ranging from small material

“Clients can make use of the York lab facilities to test products ranging from small material samples to full building mock ups.”

samples to full building mock-ups. As one of 17 North American Intertek labs, the York lab has several safety testing domains that overlap with other labs, but there are a few unique services they provide.

Water, wind, and fire hazards

Environmental hazards, both natural and manmade, are one of the main areas of focus for Intertek's York lab. Hurricane safety testing was not standard prior to 1990's Hurricane Andrew, but it is now one of the most popular services offered by the York lab. The unique combination of wind, water, and airborne debris created by a hurricane poses a distinct set of challenges for buildings. Intertek York offers two types of tests that address this specific category of hazard: dynamic water testing and windborne debris testing.

While many building materials have established water resistance ratings, dynamic water testing takes things a step further by assessing how materials and structures fare in simulated storm conditions. Tom Lawlor, project testing manager at York, explains that the storm conditions are created by continuously spraying water onto the exterior of the structure being tested while also using a four-meter propeller powered by a large aircraft engine to produce the effect of wind-driven rain. With the additional ability to set the test chamber to specific cyclic and static air pressures, the dynamic water testing allows the lab to determine if there are any sections of the structure that could cause problems in stormy weather. "The dynamic test will force water into/onto these areas, even holding water in specific locations due to the turbulent characteristics of the enclosure design," adds Lawlor.

Windborne debris is another safety issue present in storms with high

winds. The Intertek York lab simulates the possibility of debris impact damage using their Missile Impact Cannon. This compressed air cannon fires 8-foot lengths of 2x4 wood at up to 34 miles per hour into the building product being tested, be it a window, wall, door, or structural mock-up. Depending on what type of standard the client needs to meet, the products can either be graded on a pass/fail system, or they can be given a rating based on how well they hold up. Like the dynamic water testing,

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this type of testing is especially popular with building product manufacturers who are selling their products in hurricane prone areas.

Intertek York also offers a wide range of fire testing services to help customers verify that their building products or systems meet designated fire safety requirements. In addition to basic fire resistance and flammability testing, the lab can test for a number of more specific fire-related qualities in materials and structures. One specific test assesses how flames spread from the propagation source on different materials, including the speed at which they spread and the distance or depth of material that gets burned. This type of testing can be especially useful for walls or other structures that are made of multiple layers of materials, as it can help identify if the specific components, such as internal insulation or external cladding, still meet required safety standards in combination. Testing can also be done to establish how long structures maintain compartmentalization and to see how much smoke or heat is given off during burning. As fire safety is a universal concern, such testing is always in demand.

External threats to buildings

The other key area of safety assessments performed by the Intertek York lab is threat resistance testing. Their Security Research Center (SRC) is one of only five labs in the US that is approved by the Department of State for forced entry and ballistics resistance testing. “Generally, the customers for these tests are producing products for government buildings or military bases,” explains Travis Hoover, Intertek’s SRC program manager. “They



are also utilized by clients selling products to the Department of State for embassies, schools/universities, banks, and courthouses.”

One of the most unique types of safety testing offered by Intertek York comes in the form of their pneumatic shock tube. This large tube is used to test how different building materials and products hold up to shock waves, like those that would be made by explosions. But how exactly does this work? Hoover describes the process:

“Using compressed air, the blast tube produces a shock wave that is subjected on the specimen, which is secured downstream within the tube. The test is conducted at a specific blast pressure and impulse duration, and then based on the performance of the product a blast rating is determined.”

This pneumatic shock tube test is not a type of test that is widely available, meaning that this service is



1. Blast resistance testing is shown here using a shock tube per ASTM F1642, F2927, and GSA-TS01. 2. Windborne debris testing for hurricane prone areas per TAS 201 and ASTM E1886/E1996–Large Missile Impact Test. 3. Lab staff demonstrate ASTM F3038 time evaluation of forced entry resistant systems. 4. Safety glazing testing per North American and European standards (picture is European standard). 5. Ballistics resistant testing per UL 752, NIJ0108.01, EN 1063, and DOS SD-STD-01.01.

Credit for all images: Intertek York's Building and Construction division

in high demand. The test requires a building that can withstand the pressure exerted from the shock tube, as well as numerous safety protocols. “The shock tube is inside the lab so when a blast test is being performed, sirens, alarms, and flashing lights are set off to alert anyone that may be in the vicinity that a blast test is occurring,” adds Hoover. “Everyone within the building needs to remain inside the office area or control room during the blast test.”

Another popular type of threat resistance testing performed at the lab is forced entry resistance (FER) testing, which evaluates how well a window or door withstands attempts to break through. “FER tests are performed either individual or mob style,” says Hoover. “Personnel make a concentrated assault using hand tools in an attempt to create an opening in the product for access.”

Essentially, a group of people are given tools like sledgehammers and told to try to break through a product such as a door. The product is then evaluated based either on the time it takes to break through or the degree to which it could be penetrated, depending on the test method and standard that the client requires. Of course, Hoover adds, “Proper PPE must be used by individuals partaking in the attack, as safety is the number one priority.”

Expanding into the future

The Intertek York lab offers a wide variety of other safety testing for the building and construction industry, including safety glazing testing, NYC fall prevention, curtain wall testing, and ballistics testing. They also work closely with other Intertek labs to provide one of the most comprehensive safety testing catalogues in North America. While they have faced challenges over the past few years due to the pandemic and the slowed economy, the variety of services they offer allows them to be adaptable. “Our lab in York has been around since the 1970s,” says Jose Colon, regional sales director. “We are proud of our technical expertise and our test equipment.”

In keeping with Intertek's expansion and growth as a company, the York lab is sure to continue to expand and refine their testing offerings. Just as hurricane testing didn't come about until the 1990s, there has been a recent surge in demand for ballistics and school security testing and they have taken that shift in stride. “[Intertek York is] always testing new building product technologies,” says Colon, “and there are some interesting new products coming into the market.”

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Optimizing EHS Performance in Your Lab

EHS MANAGEMENT FOCUSES ON FOUR CORE ASPECTS OF THE LAB ENVIRONMENT **by Dan Scungio, MT(ASCP), SLS, CQA (ASQ)**

Environmental health and safety (EHS) in the laboratory encompasses a variety of topics that should be integrated into the overall lab safety program. EHS focuses on the physical environment aspects of the lab, like ventilation and air flow, engineering controls, and life safety (fire prevention) regulations. Prioritizing EHS elements in the laboratory creates an environment where fewer incidents will occur and where employees will be safer.

Laboratory ventilation

Monitoring the ventilation in the lab workspace is a key safety initiative that every EHS program should include. Many laboratories are designed to have a specific number of room air exchanges as well as directional air-flow (from uncontaminated areas to contaminated areas). Many older air handling systems may not perform as well as when they were installed, and in some lab spaces, the air exchanges no longer meet industrial guidelines. Anatomic pathology areas, for example, should have 12 to 16 air exchanges per hour. Fewer than that can lead to unwanted staff exposure to chemical fumes. A solid EHS program will include regular (at least annual) monitoring of the lab's air handling systems and room air exchanges to ensure safe and optimal performance.

Another important method for checking the lab ventilation is the use of vapor badge monitoring. The Occupational Safety and Health Administration (OSHA) requires laboratories that use hazardous chemicals such as xylene and formaldehyde to monitor the exposure of their employees. If baseline vapor readings are within established limits, no further recordings are necessary

unless there are process changes, instrument changes, or complaints involving the use of these chemicals. However, performing at least annual monitoring of exposure to these chemicals can be a good secondary way to ensure room ventilation and other engineering controls (like chemical fume hoods) remain adequate.

“Prioritizing EHS elements in the laboratory creates an environment where fewer incidents will occur and where employees will be safer.”

If proper room ventilation cannot be achieved or if specific lab tasks create high hazards to the employees, then respiratory protection must be implemented. Respirators protect the employee from contaminated or oxygen-deficient air. Two classes of respirators are common; air-purifying respirators, which use filters to remove contaminants from the air you breathe, and atmosphere-supplying respirators, which provide clean air from an uncontaminated source. These types of respirators can also be classified further as tight-fitting or loose-fitting. Tight-fitting respirators need a tight seal between the respirator and the face and/or neck of the user to work properly. Make sure staff are properly trained to select and use the correct type of respirator based on the needs in the department.

Ergonomics

Oversight of an ergonomics program is another vital function of laboratory EHS management. Preventing staff musculoskeletal disorders from poor work practices and inappropriate work bench arrangements can save managers from employee absences and injuries. Perform ergonomics assessments of departmental work areas and whenever there are employee complaints involving ergonomics issues. Be sure microscope and computer workstations are arranged for good body mechanics, and train staff to take numerous breaks from repetitive or long-term tasks.

Noise studies should be included in the laboratory ergonomics monitoring. Baseline noise studies should be taken initially and when instrument or process changes occur that can affect sound levels in the department. Decibel levels can be measured using a noise meter, and the time weighted average (TWA) is calculated using multiple readings throughout the workday. If the noise TWA is greater

than 85 decibels, OSHA requires the employer to institute a hearing conservation program that includes ongoing noise monitoring, hearing testing, the use of hearing protectors if needed, and training for staff about the program itself. Most laboratories, however, are not environments that produce noise that exceeds OSHA's limit. If high noise levels are encountered, it is likely that the source of the noise can be determined and mitigated. Fixing broken equipment or installing sound absorbent barriers can often solve high noise issues in the department.

Life Safety

Life Safety (fire safety) is part of EHS management, and it is also a required element for any laboratory safety program. Regulations regarding fire safety in the laboratory come from multiple agencies, including OSHA, the National Fire Protection Association (NFPA), and the International Fire Code (IFC).

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NFPA 45 (Standard on Fire Protection for Laboratories Using Chemicals) lists guidance for the storage of flammable chemicals in the lab. This guidance requires that any flammable liquids that must be stored at cool temperatures be placed inside of a unit (refrigerator or freezer) that is designated by the manufacturer as explosion-proof or safe for the storage of flammable liquids. These special units must be labeled with signage indicating that flammables may be stored within. The standard even requires that refrigerators and freezers that are not safe for such storage should be labeled as well. The signs might say, “Danger: not for flammable material storage.” This means that every unit in a lab where flammable chemicals are used should have some sort of label on it indicating what type of storage is allowed. Cold storage units may be modified for safe flammable storage, and these need special labels as well.

The use of flammable storage cabinets is addressed in NFPA 45 as well. In general, if a lab has more than one gallon of a flammable liquid in each 100 square foot space of the department (two gallons if there is an automatic fire extinguisher system), those chemicals should be kept inside of a flammable cabinet. Chapter 57 of the International Fire Code (IFC) requires that these cabinets have well-fitted, self-closing doors.

The IFC has not been adopted in every US state (although it has been adopted in 42 of them), and your local fire authority has the final say in the requirements. It is a good idea to purchase flammable cabinets with self-closing doors. There are door-closing adapter that can be purchased, but in some cases, the use of these adapter may damage the cabinet door and inactivate the function and warranty for the cabinet.

Firefighting equipment should be available in the laboratory, and OSHA requires staff to have training to use that equipment if it is provided. The best training includes a regular hands-on return demonstration and periodic fire drills. Confirming staff can use fire extinguishers and know how to respond to a fire situation may be one of the most important safety training policies you can implement. Fire blankets are typically not required per local fire code, but if they are in place, be sure staff is aware of how to use them should the need arise.

When an uncontrolled lab fire event occurs, staff will need to evacuate and prevent the spread of the fire. It is important to keep aisles clear and wide in the department for safe travel, and all exit routes and stairwells should be checked to make sure no obstructions exist. Staff should be aware of their primary and secondary

evacuation routes, and all exits should be adequately marked. Make sure employees know to close fire and smoke doors during a fire situation.

“Confirming staff can use fire extinguishers and know how to respond to a fire situation may be one of the most important safety training policies you can implement.”

The laboratory environment

The laboratory is a dynamic environment. Different people work in many areas during different shifts. If the area is not set up properly and monitored for ongoing safety, accidents will happen. These lab accidents can cause damage, cost money with fines and repairs, and worst of all, can hurt people.

Monitoring the lab EHS program as well as the entire physical environment creates value for the overall lab safety program, and it helps to create a strong safety culture among the staff. Have staff actively involved in the EHS monitoring. Check for clear passageways, proper storage of flammable materials, and the ergonomic set up of the various workstations. Other items should be checked as well; look for frayed electrical cords, and check that tanks of compressed gas are individually chained or prevented from tipping. Look for ceiling tiles that show signs of leaks, and make sure lights are working and that fire doors are not propped open. Solid oversight of the lab environment and proper management of the EHS safety program can optimize the work of lab leaders and it can help to keep the valued employees safe as well.

Dan Scungio, MT (ASCP), SLS, CQA (ASQ), has more than 25 years of experience as a certified medical technologist and a bachelor's degree in medical technology from the State University of New York at Buffalo. As a laboratory safety consultant and a safety officer, Dan provides onsite education and safety training for labs of all sizes with a mission to help organizations create safety savvy laboratories.



Three Ways to Address Safety Risks from Aging Analytical Equipment

WHEN IT COMES TO SAFETY, IT'S BETTER TO BE PROACTIVE THAN REACTIVE

by **Holden Galusha**

When one thinks of the safety hazards of laboratory equipment, they may recall the horror stories of unbalanced rotors destroying an ultracentrifuge or fingers getting snagged in the gears of a robotic arm. But analytical equipment with zero moving parts can pose risks as well, albeit such hazards aren't typically so severe, which makes them easy to overlook. Here are a few ways you can proactively address some potential safety issues that may arise in your lab's instruments.

1. Dedicate time to reviewing instrument service logs

With all the competing priorities that you have as a lab manager, it can be easy to overlook something as simple as reviewing your instruments' service logs. Be careful not to ignore them for too long, however. Reviewing your maintenance logs allows you to be confident that all your lab's equipment is being serviced and calibrated regularly, which goes a long way in preventing both inaccurate analyses and hazardous malfunctions.

Repair logs should not be neglected, either. These documents may reveal trends that can help you foresee problems on the horizon. Dan Scungio, a laboratory safety consultant, recommends looking specifically for more frequent additions to an instrument's repair log. If the log is being updated more often as time goes on, it could indicate that the instrument is approaching its end of life and could develop more severe issues—some of which may potentially hurt you or your staff.

To ensure you do not forget to review your instrument logs, try scheduling a recurring reminder on your phone or digital calendar.

2. Consider ergonomics

Our understanding of ergonomic design has improved considerably over the years. The past decade alone has seen a surge of interest in the subject, and manufacturers have

capitalized on this interest by releasing ergonomics-focused versions of everyday tech like computer keyboards.

These advancements have carried over to laboratory equipment as well. For instance, some modern cryostat microtomes now have motorized height adjustment to properly accommodate users of any height. Additionally, many analytical devices have angle-adjustable touchscreens that allow for more comfortable operation. Thanks to these improvements, lab technicians won't be as prone to developing repetitive strain injuries as they operate this equipment day in and day out.

Unfortunately, countless laboratories are still relying on decades-old analyzers that do not offer decent ergonomics. In such cases, lab managers can find ways to adapt the instrument for more ergonomic usage. For example, analyzers driven by a computer and software could be outfitted with a higher-resolution display to minimize eye strain, mounting that display on a height-adjustable VESA mount, and adding an ergonomic keyboard and mouse.

3. Establish a regular instrument replacement program

While not an option for every facility due to budget constraints, it is ideal if you are able to replace your analytical equipment consistently. Not only will this minimize repair downtime, but it will allow you to have greater confidence in the accuracy of your instruments. After all, compromised data can also be a danger. While bad data can't pose a physical risk, it can adversely affect processes downstream. A diagnosis formed on bad data could negatively influence a patient's treatment plan and manifest health risks.

Holden Galusha, associate editor for Lab Manager, can be reached at hgalusha@labmanager.com.



A Practical Approach to Understanding and Addressing Poor Performance

EVERYONE ON THE LAB STAFF NEEDS TO CONTRIBUTE THEIR HIGHEST-LEVEL WORK

by **Olena Shynkaruk, PhD**

Poor performance can be detrimental to the lab culture and workplace well-being. It negatively impacts team morale, leading to loss of human capital, productivity, and profitability. In this article, Ronald A. Williams, a leadership coach with 40 years of public and private sector experience and the creator of the LinkedIn online course, “How to Handle Poor Performers,” shares his insight on managing poor performers—from how to identify and approach them to how to improve their performance and when it’s time to let them go.



▲ Ronald A. Williams

Q: How does a manager spot poor performance?

A: Without the standard in the work environment, it is hard to identify poor performance. So, we need to set a standard. For example, if the standard is one mistake, and someone is making zero mistakes, they are an above-average performer. If someone is making one mistake, they are an average performer, and if they are making two or more, they are a poor performer. Moreover, poor performers have four identifiable characteristics: 1. They consistently don't produce results that the manager expects or wants. 2. They make more mistakes than others. 3. The manager spends more time handling them than anybody else, and 4. If the manager is not consistently handling them, there are ongoing issues.

Q: What does a manager need to overcome challenges with poor performers?

A: As managers, you need data and data analytics to deal with poor performance. Performance is related to people’s behavior. You do not hire people and tell them to be nice; you hire nice people. One question you need to ask yourself as a manager is, “Knowing what you know about the employee today, would you hire them again for this position?” If your answer is no, then this is an unacceptable situation that you need to deal with.

Q: What are the negative impacts of not addressing a poor performer?

A: Poor performers impact morale, and morale is critical in the organization. Suppose you have a poor performer that you haven’t addressed on the team. The following situation can happen: The manager will engage a high performer more, leading to unequal work distribution, a sense of unfairness, and dissatisfaction with the workplace. Why? Because high performers are highly engaged. They give you discretionary effort and high intent to stay, but if you put them in the situation mentioned above, the discretionary effort goes away, and the intent to stay diminishes. Most people leave not the company but a manager. In this case, high performers won’t tolerate a manager who allows poor performance. They lose respect for the leadership, and they leave. So, if you have poor performers, they can increase the turnover, drive the high performers away, and decrease productivity, which will ultimately affect the profitability of the lab. [Author’s note: For additional information, please see *Lab Manager’s* article³ discussing the negative impacts of ignoring poor performers.]

Q: How does a manager successfully deal with poor performance?

A: The manager needs to know three critical Ts: Train, Transfer, and Terminate. In dealing with poor performance, a manager has a responsibility to discern if a person doesn't know how to do the job or doesn't want to do it. If the former is true, the manager needs to train them. If the latter is true, it is probably a people issue, and the manager needs to identify and evaluate the issue. This is where transfer or termination comes in.

Q: How do you approach a poor performer? What are the key elements to having a difficult conversation?

A: Poor managers may not want to engage with poor performers for a variety of fear-based reasons, including the risk of an EEOC (The US Equal Employment Opportunity Commission) complaint filed against them, a lack of confidence to initiate the difficult conversation with the employee, or the fear of the unknown that comes with hiring and onboarding a replacement for the poor performer. But good managers do not manage or lead out of fear. When dealing with poor performers, good managers have the managerial courage to act. This action starts with a difficult conversation, and there are five key elements for its success: 1. Do not confront a poor performer in anger, so you do not create an emotional situation. 2. Do it immediately. If you wait to give the feedback for too long, you will hurt the workplace well-being. For example, waiting for an annual performance review could be too long of a wait. 3. Do it in private. 4. Have the performance standard outlined. However, if there was no standard when an employee started, these conversations could become even more difficult. 5. Be specific and clear and have the evidence or data for their performance or behaviour. You cannot use anecdotal information. While being specific, be cautious of softening the evidence: “If you give them too much sugar, they might not taste the medicine.” The good news is that once confronted, a poor performer either improves or moves.

Q: What strategies and tools can you use to motivate or improve an individual's performance?

A: A good manager gives a poor performer opportunity to change and sets many employee touchpoints for informal feedback beyond formal mid-term and end-of-year reviews. Improving an individual's performance is a progressive discipline, and you need to document

every step. The process starts with a verbal reprimand, followed by a written reprimand and a performance improvement plan (PIP). With verbal reprimand, you acknowledge their less than stellar performance and identify specific areas they need to improve. The written reprimand is similar to the verbal reprimand, but it is kept in the employee's file. You hope that when you give them verbal or written reprimand, an employee will ask how they can improve and what they need to do better. Next comes a PIP. The main difference between a reprimand and PIP is that the latter identifies actionable items, performance indicators, training responsibilities, and timeframes. PIP also holds an employee accountable to improve to a certain standard within the outlined timeframe and includes follow-up.

Q: When does a manager need to terminate a poor performer?

A: If the employee did not improve, you need to terminate them. You need to know that you did not fire them, but they fired themselves by showing an inability to change their performance. Keeping them on the team enables poor performance and hurts the team, and then the manager becomes a part of the problem.

Lab Manager has previously discussed a variety of digital tools to boost a lab's productivity¹. These tools can also be used to obtain employee performance data by allowing staff and managers to arrange check-ins, give feedback, and set goals. For more guidance on how to set clear, achievable goals, see Sherri Bassner's Lab Manager article² on managing lab employee performance.

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EXAMINING THE CO₂ INCUBATOR MYTHS

Persistent myths surround CO₂ incubator technology, pervading advertisements and leading purchasers astray

Cell culture is integral to the biological, biomedical, and biopharmaceutical sciences. CO₂ incubators, in turn, are integral to cell culturing.

Incubators, at their core, maintain optimal growth conditions. They offer carbon dioxide control (five to 10 percent helps regulate pH using standard buffers), constant temperatures (37°C for most mammalian cells), and humidity control (95 percent prevents evaporation). They may also come with optional features around contamination prevention, space-savings, and establishing hypoxic or other extreme physiologic conditions.

When choosing a CO₂ incubator, certain myths and misinformation surface. A clear look at the technology behind incubators helps distinguish fact from fiction and better informs purchasing decisions. What features does an incubator actually need? Here we explore the three most common myths alongside familiar lab scenarios.

MYTH: FAN-ASSISTED INCUBATORS PROVIDE MORE UNIFORM GROWTH CONDITIONS

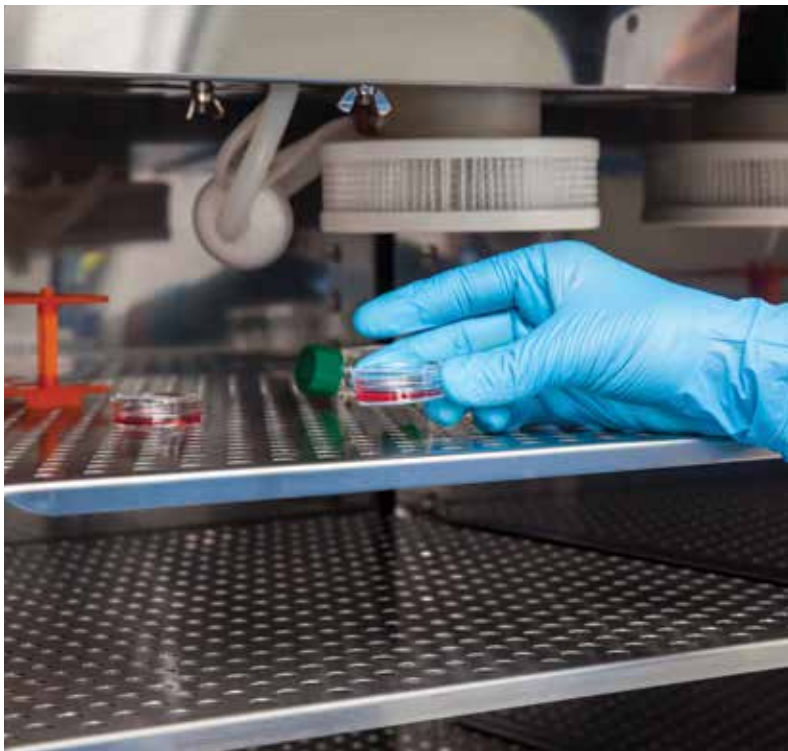
Maia was noticing a pattern. There had been clear variation in the performance of different cell cultures, but she was beginning to nail down the culprit. Performance seemed to depend on where her vessels were kept in the incubator, despite it being a recent purchase. Those on the bottom back left of the incubator were slower to hit confluency, while most of those in the top were unstable. Those along the back of the chamber seemed patchy in distribution as well.

Her first thought was that the door must be getting left slightly ajar, though that didn't correspond to the pattern she saw. Yet, it had to be external. Didn't it? She'd already confirmed that everything was still working. This model was supposed to be the one of the best for maintaining fully homogenous conditions within the incubator, advertising rapid recoveries with gentle, fan-assisted airflow. So how could this be happening?

Temperature uniformity across and between shelves within the incubator is critical to producing consistent, reproducible results. A difference of just one degree Celsius can impact cell morphology and colony density¹. Like Maia, you may have heard that you need a fan to achieve that level of uniformity, including rapid recovery following door openings, from top to bottom and side to side in your incubator.

Strong, directional airflow, however, can disturb cell cultures, increase evaporation of media, and aid the spread of contaminants. Fans also introduce vibrations that may affect cell distribution and attachment. Published guidelines for best practice in cell culture maintenance recommend fanless incubators for these reasons².

So, how does one achieve even conditions throughout the incubator chamber without a fan? It comes down to heating element and sensor design. Well-designed fanless units are capable of circulating air gently through natural convection currents. In a comparison of the fanless Cel-IXpert CO₂ incubator and fan-assisted incubators using 27 temperature sensors, the fanless unit offered the greatest temperature uniformity across the incubator¹. It also demonstrated recovery within five minutes after door openings without overshooting the target temperature.



MYTH: HEPA FILTERS ARE THE BEST OPTION FOR PREVENTING CONTAMINATION WITHIN INCUBATORS

The turbidity was a dead giveaway—the cultures were contaminated once again. Hector swallowed his annoyance, tossed the cultures and reagents, and scrubbed everything down. Again. He was fairly certain this was a technique issue with two new students. His incubator was top-of-the-line for contamination control with copper interior, a HEPA filter, and built-in decontamination features. This should be easy. Additional training and reminders would be needed.

A few months later, things were sailing smoothly in Hector's lab with no signs of contamination since the previous incident. Something was bothering him though. Had the cultures been slowing down? The latest results seemed slightly off. Diluted, compared to earlier work. The cells looked fine, though. He searched back through the archives. Yes, definitely a gradual decline in signal. It was difficult to tell for sure, but he thought certain conditions started weakening later. Almost like it was catching. With a

sinking stomach, he dug out a mycoplasma PCR test kit. Positive. Another reset. Another delay. He'd seen huge improvements in technique, so where was this coming from?

Mycoplasma contamination is a concern in cell culture labs around the world. A suite of assessments in the 1990s estimated its prevalence to 10 to 80 percent of cell line cultures in various countries. While it's expected that infection rates have trended down over the years with increased testing and awareness, one 2015 study found mycoplasma sequences present in 11 percent of 884 published RNA-seq datasets³. Further, they found the expression of 61 genes was associated with mycoplasma contamination levels.

Mycoplasma is an insidious contaminant. It's frequently spread through cross contamination between cultures but can come from almost anywhere. It is difficult to get rid of. It's resistant to antibiotics and, at the 0.1 to 0.3 micron size range, flows right through HEPA filters⁴.

This brings us to our second myth, that HEPA filters clean the airstream in the incubator of all sizes of particles and microorganisms, offering the best protection against contamination within incubators. HEPA filters are only effective at filtering particles and organisms

down to 0.3 microns in size. While HEPA filters are great at filtering out most contaminants—assuming the filters are changed regularly—the fan rapidly circulates the smallest contaminants throughout the chamber.

The addition of the fan and ducts required for air filtration also increase surface complexity within the chamber, adding seams, corners, and nooks that are more difficult to thoroughly clean and disinfect.

Recommended contamination controls—in addition to using proper technique combined with regular cleaning and disinfection protocols—include seamless copper and copper alloy interiors with removable shelving and racking to help with cleaning and disinfection efforts².

Additional features can improve contamination control. UV can be very effective at disinfecting airflow, but its disinfection area is limited to where the light touches. Some incubators also have built-in decontamination capabilities using H₂O₂ or heat disinfection to facilitate cleaning.

MYTH: WATER-JACKETS PROVIDE THE BEST TEMPERATURE REGULATION

Anna was ecstatic to be inheriting a water jacket CO₂ incubator. She'd only used direct heat and air jacket models in the past, but had heard these were the best at temperature regulation, even offering peace-of-mind for power outages. She hadn't thought about how long it would take to reach set temp though. Well, tomorrow would be as good a day as any to move samples.

After a few weeks passed, Anna was not impressed. She'd taken to checking the temperature readouts on the two incubators every time she passed them. The direct-heating incubator seemed to be more consistent, recovering more quickly from openings. She added additional sensors to check accuracy on the readouts. The same. Now, needing to move the incubator just a few feet to the left, she was realizing she'd have to drain the jacket. Anna tried to remember why she'd wanted a water jacket. Squatting in front of the incubator, she opened it to find moisture. Surely not ... yes. It was leaking.

Water-jacketed CO₂ incubators may have been the best option at one time, but current technology enables excellent uniformity using three-dimensional direct heating. The key to temperature uniformity lies with six-sided heating using individual heating circuits and

multiple, fast-feedback temperature sensors⁵. Fast recovery is achieved through fine temperature control that generates gentle convection circulation.

Most models now come with air jacket heating, direct heating, or a combination. Both air jacket and direct heating allow for a slimmer, lighter-weight incubator requiring less maintenance, and both can be self-sterilizing through high heat.

Ultimately, the myths purporting that the best contamination control and temperature uniformity and consistency are provided by fan-assisted, HEPA-filtered incubators with water jackets are just that—myths. Misleading advertising claims have encouraged their persistence, sometimes to the detriment of the purchaser.

When combined with best practices in cell culturing, well-designed, fanless incubators with direct heating, seamless interiors, and high temperature disinfection can offer the best temperature and contamination control.

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Improved Ergonomics through Smart Interior Design

INVEST IN A COMFORTABLE LAB SPACE THAT PROMOTES WORKER HEALTH AND SATISFACTION **by Erin Fogarty, RID, NCIDQ, LEED AP**

A researcher's workspace and work environment can positively, or negatively, affect their personal well-being. In turn, the research they collect can be inadvertently corrupted or inaccurate if fatigue or distraction is present. Protecting researchers and staff from injuries and stress caused by their ergonomic interaction with workbenches, workstations, task chairs, stools, maker tables, carts, lighting, and more is the essence of effective, proactive ergonomics.

Ergonomics is the study of how people systematically interact with their habitat or environment. This environment must foster collaboration, innovation, and enhance their overall performance.

“A successful ergonomic design will keep laboratory occupants comfortable, working efficiently, and support physical and mental health and happiness.”

Designers: Walking in the researcher's shoes (and spaces)

No matter how savvy an interior designer's ergonomic-driven design is, if it is not inspired by input from actual users—researchers and staff—its value is limited. Designers must meet with scientists and other user groups early on, well before pen touches paper in predesign, to intimately

▲Bright and reflective surfaces create an uplifting environment while intentionally placed pops of color highlight areas for collaboration.

observe and understand lab workers' daily tasks, travel paths, and overall workflow. Without this detailed understanding, any design produced will lack the very essence of successful ergonomics. Without seeing and knowing exactly how and where lab inhabitants' function and when, the odds of any ergonomics-driven design will fall short.

Sharing information about daily tasks performed in, to, and from the lab space is a vital conversation that designers and scientists must have early in the process. Discussions of what's working and what isn't working in the existing lab space, potential workplace hazards, inefficiencies, and space needs should all be part of a two-way discussion between those who will design the lab and those who will use it. This dialogue should also include suggestions for how daily lab-centric tasks could be performed in a more efficient, productive manner. At this juncture, designers and engineers may present research and data from previous lab design projects, articulating lessons learned and providing innovative solutions that can positively impact the lab's ergonomic design.

Design inspired by ergonomics

Beyond aligning a task with a person, rather than vice versa, a successful ergonomics strategy decreases fatigue and prevents injuries while improving productivity, safety, and job satisfaction. A successful ergonomic design will keep laboratory occupants comfortable, working efficiently, and support physical and mental health and happiness.

How can ergonomic laboratory design contribute to the productivity and well-being of researchers over the long term and enable employers to retain their best scientists? It's the result of a visual and functional strategy that supports the way lab occupants work—or the optimal way they'd like to function in their space.

In short, successful ergonomics enables researchers to concentrate throughout the workday on discovery, free from the distractions of space inefficiencies and limitations. Here is an overview of aspects to recognize in the design of the space:

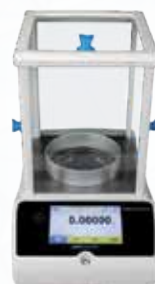
Specify appropriate materials and furniture

Laboratory furniture manufacturers play a crucial role in any successful lab design or redesign effort. Selecting a shortlist of quality manufacturers of lab workstations, benches, maker tables, carts, and lighting spells the difference between successful design versus ineffectively designed spaces that do not achieve users' goals. Working with forward-thinking manufacturers that understand the importance of safety and productivity in their own designs is essential. Manufacturers that are adept in navigating the ever-complex supply chain hurdles can make the project come to fruition on schedule.

Identifying appropriate materials on the surfaces of ergonomic-friendly lab furniture is another crucial facet of ergonomic lab design that designers and users need to master. Chemical-resistant, scrub-resistant, impact-resistant, antimicrobial materials are necessary. Bolder colors in strategic areas of the lab to spur stimulation and attentiveness are key, as are materials that provide the appropriate degree of acoustics.

See the (natural) light

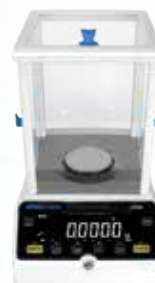
Evidence-based data¹ proves that natural light, or daylighting, is good for staff members' well-being. Today's labs are being designed with views to the outdoors rather than being situated on the inner core of the building. Daylighting not only saves energy, but it also provides a working environment that stimulates creativity and innovation. Daylighting can also help with recruiting and retention of staff.



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Lighting levels are also extremely important in ergonomically inspired design. Providing dimming capabilities and appropriate color temperatures for researchers aids in reducing eye fatigue from working long hours in the lab.

Design and specify furniture and equipment within reach

Height-adjustable benches and workspaces allow for easy access and an ergonomic approach to tools and tasks. Case-work that promotes healthy reach heights is also a lab design must. Providing seating that is adjustable for multiple tasks and positions is essential. Organizing workstations for proper circulation and flow throughout the space contributes toward successful lab design with ergonomics top of mind. Lab layout should promote collaboration between staff members while allowing for easy access to amenities.

Create safety-inspired ergonomic design that reduces injuries

According to OSHA, there are many ergonomic risk factors that cause wear and tear on the body and bear the potential of causing injury. These include repetition, awkward posture, forceful motion, stationary position, direct pressure, vibration, extreme temperature, noise, and work stress. To counteract these risk factors, design should accommodate and support job rotation, warm-up stretching and stretch breaks, proper reaching, lifting, and handling techniques, and more.

Examples of such ergonomic-forward lab safety design accommodations are chairs that provide good back support, adjust easily for workstation height and allow for forward tilting when necessary; adaptable/adjustable benches and workstations to allow workers to keep shoulders relaxed and elbows close to their sides while working; furniture arrangement that discourages repetitive or forceful twisting and turning motions; workstation padding that softens edges and reduces pressure and force while working; and stools with footrests, where appropriate, to relieve back pressure.

Design space to attract, retain lab workers

The advantages of creating good ergonomics in lab design are abundant. Beyond the increased savings realized through a reduction in worker injuries, fewer workers' compensation claims, and increased productivity, ergonomic-forward design increases the morale of individuals and teams. Employees feel valued because their workplace is safer. Without discomfort, pain, or injury as a distraction, safe work environments stimulate productivity. Increased morale and increased safety often lead to



▲ Examples of ergonomic-forward lab safety design accommodations are chairs that provide good back support, adjust easily for workstation height, and allow for forward tilting when necessary. Credit for all images: BSA LifeStructures

overall job satisfaction. Overall job satisfaction translates into reduced turnover, which spells workforce continuity.

Designing a lab space that promotes health, productivity, worker satisfaction, and morale is an investment in people, processes, and outcomes. Ergonomics is the science of matching work environments to fit the physiological, psychological, and cognitive capabilities of the worker. While it's not possible to eliminate hazards in the workplace, a successful, doable ergonomics strategy can identify and minimize the researcher's exposure to them.

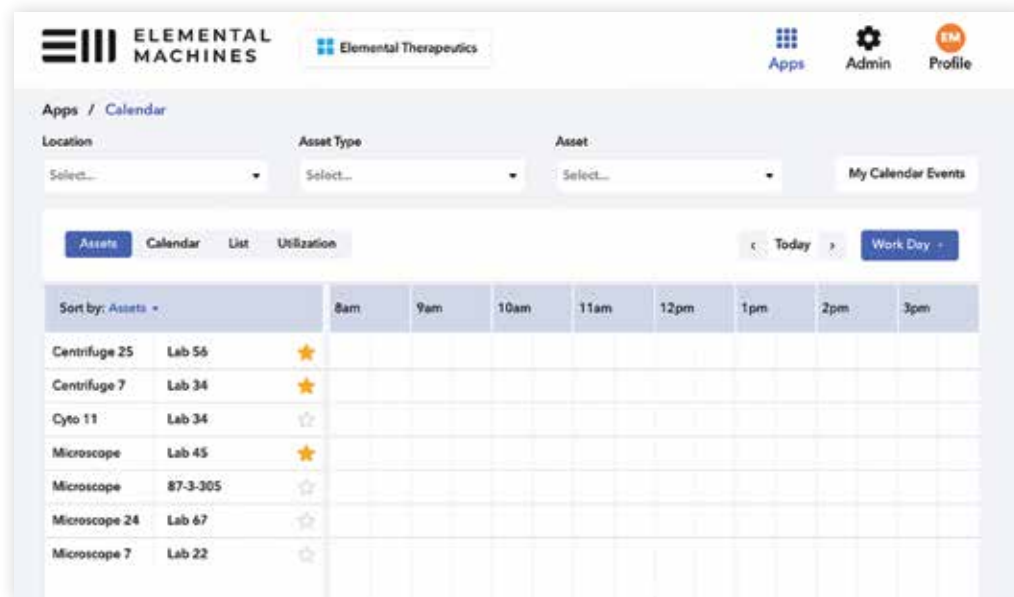
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Erin Fogarty, RID, NCIDQ, LEED AP, is director of interior design with BSA LifeStructures.

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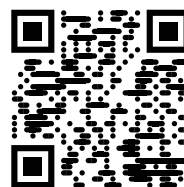
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The Importance of Laboratory Quality and How to Achieve It

LAB MANAGERS AND PERSONNEL PLAY A PIVOTAL ROLE IN ENSURING QUALITY STANDARDS ARE MET **by Aimee O'Driscoll**

Laboratory quality control (QC) and assurance are critical, particularly in highly regulated industries such as food, cosmetics, and pharmaceuticals. There are many definitions of quality, but in a laboratory setting, it generally refers to the accuracy and reliability of results. While inaccuracy is accepted to an extent, a strong quality management system will keep that level to a minimum.

Quality and compliance go hand in hand and can form the backbone of an organization's viability. Lack of QC and assessment can lead to dire consequences for organizations and their customers. Lab staff strive to meet quality and compliance standards to ensure outputs are reliable and conform to regulations.

Here, we examine the importance of lab quality and discuss the key factors managers and staff need to take into account to ensure quality standards are upheld.

“Lack of QC and assessment can lead to dire consequences for organizations and their customers.”

The importance of lab quality

As noted by Ivan Krstic, PhD, head of Chemistry Solutions at Elsevier, lab work underpins all of the R&D life cycle and is vital to its progress. He adds that labs need to ensure scientists are able to capture and store

data accurately and efficiently, and access and share existing data easily. “Lab quality is the approach to ensuring experiments and R&D conducted in a lab deliver accurate, reproducible, and reliable results, minimizing errors and removing duplicates,” explains Krstic.

Anca Ciobanu, Improving the Efficiency and Effectiveness of R&D lead at the Pistoia Alliance, asserts that quality assurance (QA) in the lab is critical for several reasons. “Research organizations firstly need to ensure their output is verifiable and reproducible to advance and support their own projects,” she explains. “Secondly, QA is essential to satisfy strict requirements from regulatory and inspection bodies so that a lab is approved and accredited for research.”

Krstic adds that QA is particularly important in the drug development process where it can take over a decade from discovery to market. “Organizations must be confident in the quality of their lab work and results, or risk losing many years of effort.”

The International Organization for Standardization (ISO) defines a quality management system (QMS) as “coordinated activities to direct and control an organization with regard to quality.” ISO outlines a framework for implementing a systematic and transparent QMS that’s designed to improve performance while addressing all organizational needs. Key principles involve understanding and meeting customer needs, establishing leadership aligned with the organization's objectives, and fully involving all members of the organization. ISO also notes the importance of taking a process approach to quality management and basing decisions on data analysis.

Lab staff must be well-equipped to ensure lab quality

Lab staff are the central driving force in ensuring quality in the laboratory and must be trusted to uphold best practices and adhere to all protocols. Staff should be fully trained in all aspects of their respective roles so that they can confidently fulfill their responsibilities. Within the organization, QC must be embedded into the culture through process and structure, as well as often overlooked components such as team morale and staff autonomy.

Krstic places emphasis on using a collaborative approach, noting that the research landscape of today is fragmented and dispersed. “To ensure quality, labs need to have integrated knowledge management. Many projects employ multiple internal and external laboratory partners (e.g., CRO, CMO), each of which may use their own electronic lab notebooks (ELNs) and record information in different file and data formats,” he says. This fragmentation prompts challenges, including difficulty in accessing, sharing, and fully exploring data.

Krstic advises that to ensure high quality lab results, organizations should standardize data capture formats throughout their cheminformatics ecosystem and make them available via various software packages. “Cheminformatics tools should integrate, or have access to, internal and external chemical and bioactivity data, so that researchers don’t have to go to multiple sources and platforms for information to support their use cases.”

Ciobanu recommends that leadership teams also venture outside of the organization to collaborate with other companies in the same industry. “A fundamental step in maintaining quality is good communication internally, but equally, organizations should look outside of their own lab to facilitate sharing best practices with companies facing similar challenges.” She reveals that the Pistoia Alliance fosters a non-competitive approach to establishing and maintaining lab quality, so companies can create common projects that improve quality across an industry. “Current initiatives look at several different aspects, such as naming conventions, enriching lab data, management of processes, consistent methods description, and communication between instrumentation,” says Ciobanu.

The lab manager’s role in quality assurance

QA can take on different forms depending on the industry and individual lab. “Labs can specialize in many different disciplines—chemistry, molecular biology, pharmacology, toxicology—to name just a few,” says Ciobanu. “Within each, there is a different understanding of how quality is implemented and what it should look like.”

But there are similarities within QA that span most types of laboratories. The lab manager is typically responsible for developing and overseeing a strict quality assurance program that enables laboratories to maintain high levels of accuracy at all times. This includes establishing standard operating procedures (SOPs) for every process, defining administrative requirements such as record keeping and audits, and specifying

corrective actions when problems are identified.

Ciobanu explains that the manager responsible for QA must be confident that the lab meets its specific quality standards, not just on paper but in practice, and a key factor in this is proper training. “They must ensure all personnel have adequate training on the lab’s SOPs and work instructions,

any deviations must be documented, and corrective and preventive plans should be implemented.”

Krstic adds that it is the responsibility of the lab manager to select and apply the best tools to help meet quality standards. “There is technology today to make the lab manager’s job easier, ensure that experimentation is less vulnerable to mistakes and human error, and maximize the value and accessibility of data.”

Indeed, many laboratory information management systems and other specialized software offer built-in quality and compliance features. These tools enable staff and managers to monitor and track KPIs and other data, ensuring compliance and providing insight into opportunities for improvement.

Aimee O’Driscoll, BSc, MBA, has a decade of experience as a development chemist and is a seasoned science writer. She can be reached at aimee@aimeeodriscoll.com.

“Lab quality is the approach to ensuring experiments and R&D conducted in a lab deliver accurate, reproducible, and reliable results, minimizing errors and removing duplicates.”

FULLY INTEGRATED LAB MANAGEMENT SYSTEMS ARE KEY TO REMOVING LAB BOTTLENECKS THAT HINDER QUALITY

The modern lab is a digital, integrated lab that centers on effective data management



Modern labs generate vast volumes of data, courtesy of expanding throughputs and information-rich analytical technology. With increasing regulatory requirements, the demands on data management systems are higher than ever as organizations work to reduce risk.

These pressures aren't entirely new—the inefficiencies of paper-based records have been acknowledged and addressed for many decades. The earliest laboratory information management systems (LIMS), used for sample tracking in the lab, are about as old as lab computers. Born of the frustrations of manual sample management, they caught on quickly, and the first commercial solutions were introduced in the 1980s. Since then, software solutions to paper process woes have arisen for all aspects of lab management, including electronic lab notebooks (ELNs), comprehensive scientific data management systems (SDMS), inventory management, and asset management. These solutions have evolved rapidly alongside developing computational and networking capabilities. Most labs now have one or more of these solutions in place to improve workflow efficiency, productivity, and data accuracy and integrity, with growing adoption driven by a simple fact: paper-based lab systems are not sustainable.

These software solutions form a crowded landscape with differing options and functions, interfaces, and management requirements. Addressing lab challenges like bottlenecks one at a time can result in isolated software from multiple vendors, generating new questions. Do you still need an ELN with a LIMS? Are they compatible? What about asset management, inventory, and workstations? Is your data repository compliance-ready, and do you have both adequate backups and complete archives in place? Integrating these systems into a single, central dashboard saves considerable time and effort in lab management, and is key to forming an effective, comprehensive approach. Upgrading and automating lab processes while maintaining integration may seem daunting, but the right tools not only reform current lab processes, they also lay the foundation for future growth while reducing risk.

THE PROBLEM WITH PAPER

The push for paperless workflows is grounded in cost, efficiency, data integrity, accuracy, and regulatory compliance. Data transcription errors abound with paper recording, and it takes enormous amounts of time and

money to adequately maintain records. Data review is onerous with splintered records, searching archives is a nightmare, and audits take weeks of prep.

Moving to electronic data management systems has a dramatic effect on paper volumes. In one example, Vitaquest, a custom contract manufacturer of dietary supplements, overhauled their paper-based processes by implementing a Waters™ NuGenesis™ Lab Management System (LMS) with integrated sample management and scientific data management. They process 3,000 samples per month, and manually transcribed data from output to report, to a hard-copy certificate of analysis form. Not only did automating the process with the LMS improve data accuracy and cut turnaround from weeks to days, it eliminated a ½-inch-thick stack of paper per sample. That's 1,200 feet of paper per year.

Automating data workflows minimizes data handling and drastically speeds up operations and response time for information requests or audits.

“Everything is more efficient.
Our software is validated.
Our workflows just work.”

THE IMPORTANCE OF INTEGRATING INSTRUMENTS

Data form the core of every lab—backups for disaster-recovery and complete, searchable archives are vital to the ongoing success of a lab. Historically, data outputs from analytical instruments have been printed or recorded in a myriad of formats and locations, sometimes in proprietary file types. Frequently, these instruments are managed at the workstation level using native software packages, but broad integration simplifies their management and smooths the data workflow.

Chromatographic reporting, for example, forms a particular concern for many analytical testing labs. In one case, a major generic pharmaceutical company maintained a diverse set of chromatography instruments, each managed at the workstation level with vendor-provided software. Keeping staff fully trained on each interface and ensuring all workstations were current and validated was challenging and resource consuming. Data were stored across various drives, CDs, DVDs, paper, and spreadsheets, hindering data



exchange and creating many points of failure that ultimately increased risk. Their analytical services formed a major bottleneck in product release.

The company needed to harmonize their chromatography data and automated workflows, so they integrated a LIMS with a Waters Empower™ Chromatography Data System (CDS). The CDS provided GMP compliant technical controls for all HPLC and UPLC instruments, vastly improving instrument and data workflows and management.

To consolidate all analytical equipment and data generation across the lab, a full scientific data management system is required. An SDMS should similarly integrate with sample management and execute appropriate backups and data archival. This type of system is sometimes included in a lab management system (LMS), like the Waters NuGenesis LMS which includes an SDMS, an ELN, and sample management to provide a broad, integrated foundation.

A global pharmaceutical CDMO chose the integrated approach with NuGenesis LMS when upgrading its

processes to improve data integrity, allowing them to automatically import data from instruments, scientists, and outside sources. Already running Empower CDS, the network integration and archival improved data accessibility across the company, boosting collaboration and productivity.

Like Vitaquest, the CDMO's new LMS sample management workflow replaced a time-consuming and error-prone manual, paper-based process. According to their quality and regulatory vice president, the automated workflows increased accuracy and "saved an enormous amount of time every day." They deployed barcode labelling for samples, chemicals, and instruments, enabling scientists to quickly input and validate data with automated reporting that dynamically linked both instrument and interpreted data. Buy-in amongst staff was high, with one relieved quality specialist noting that the new workflows "completely revised how we're functioning. The actual launch of the software and changes to how we do things here went so much better than any of us expected."

REGULATORY REQUIREMENTS

Compliance and the need to reduce risk frequently drive changes to data management strategies. The CDMO's transition to LMS described above was triggered by updates to the FDA's data integrity guidance (21 CFR parts 210, 211, and 212). Working with Waters, they brought stand-alone legacy equipment into compliance. The automated electronic data workflows enabled generation, indexing, and storage of scientific data in an environment built for compliance with embedded approval mechanisms and compliant e-signatures.

Compliance was a major concern for the generic pharmaceutical company as well, with facilities across Europe, the US, Australia, and South America. Deploying the solutions as individual networks using the same GxP configurations ensured regulatory compliance in a validated environment while streamlining documentation and validation overhead for a considerable increase in operational efficiency.

Both companies described drastically reduced time, effort, risk, and stress associated with audits and root cause investigations.

FULL INTEGRATION AND THE POWER OF PRODUCTIVITY

Full integration of all workflows and software solutions is becoming increasingly necessary. Deploying multiple solutions that do not interface well adds new bottlenecks and counteracts the efficiencies gained by the individual solutions, dragging overall productivity back down.

The pharmaceutical division of a global healthcare organization experienced precisely that—housing 100 chromatographic instruments in a single quality control lab. The lab used two different CDS solutions, a legacy LIMS, and a third-party solution for the weighing process. The lack of integration across chromatography platforms resulted in a continued reliance on a paper information exchange process.

Needing to improve data integrity, the division introduced NuGenesis LMS and made Empower Software the sole CDS. This solution allowed full integration of all workflows, linking internally generated work lists, LIMS, weighing system, reporting system, e-signatures, and inclusion of an audit trail. The lab is now over 90 percent paperless, has a single, compliance-enabled, searchable repository, and completes analytical processes in half the time.

Moving labs into an all-encompassing and integrated management system with a single dashboard, like the one available with Empower LMS, provides the ultimate solution for efficient, streamlined operations. Choosing a software system with flexible integration and modularity provides considerable room for further growth and development, benefitting both the lab and the business. Waters has found that many of their clients begin by addressing a single problem, then discover that their remaining challenges can be solved with the tools at hand.

The CDMO was one such client, first improving compliance. As other departments searched for software solutions to additional challenges, they realized that their newly implemented LMS could fulfill those needs. A full LMS rollout across the departments effectively streamlined their operations. As their VP reflects, "everything is more efficient. Hundreds of bound paper logbooks where people had to make entries every day are now obsolete. Our software is validated. Our workflows just work. Our review time is a fraction of what it used to be."

Having this foundational management framework in place has since facilitated expansion and new manufacturing initiatives, setting the stage for further growth. Overall, the company has reduced costs, accelerated decision making, and moved clients' products to market faster.

Ultimately, the modern lab must maximize data integrity, efficiency, and flexibility to meet new challenges as they arise. The right integrated lab management software solution can make that task much easier, delivering better data so you can make faster, quality decisions.

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Risk-Based Programs, Tools, and Techniques

ARE YOU AWARE OF THE VARIOUS RISK-ASSESSING METHODS TO KEEP YOUR LAB SAFE? **by Jonathan Klane, M.S.Ed., CIH, CSP, CHMM, CIT**

What’s at stake if you’re not assessing risks in the lab? What if a researcher scales up an energetic compound ten-fold? If this experiment were to kill someone, how would it happen? How can one assess whether they’re using enough controls to mitigate risks?

Things go awry in life and in labs; it’s part of human nature. Conscious of it or not, humans assess risks as part of a process—take driving, for instance. Drivers try to forecast how others will react in the moment. It’s a constant, tiring process. So, the brain creates mental shortcuts and is capable of intuitive, fast thinking to drive without doing it step by step by conscious step. While vital in driving, this doesn’t work as well in labs.

Contributing factors of risk

What is risk, and why is it so critical to assess and embrace its concept and usefulness? Whereas safety is a binary idea (i.e., safe vs. unsafe), risk has two or three factors (depending on context), making it more purposeful and easier to discuss. The three factors of risk are severity of consequence, exposure to the hazard, and probability of outcome. These factors provide plenty of space to have open conversations about risk assessment and our differing views. When failing to discuss or assess risks, lab incidents often occur with poor outcomes (e.g., loss of life or health, broken equipment, lost data and time, etc.).

Research practices that factor into risk assessment include working independently, experimental changes, and a drive toward cutting-edge innovation. All are typical and often necessary, yet they can contribute to risk.

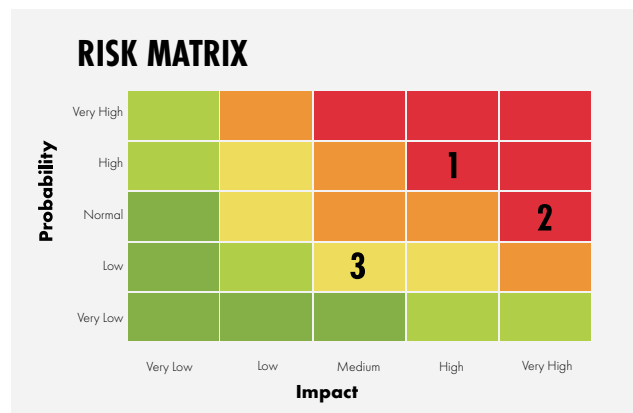
Human decision-making plays a strong role with cognitive biases (e.g., confirmation bias, bias of optimism,

etc.), mental shortcuts (i.e., heuristics), threat to value, and fast-thinking decisions. These are all part of human nature that, along with unawareness, also add to risk.

There are many risk-assessing tools, systems, techniques, and programs you can use. Each has its own purposes, benefits, and limits. Being familiar with several can help make risk assessments easier and clearer. It’s more important to be using at least one than finding the perfect one.

Risk tools

A common approach is the two-factor risk matrix (figure 1). Risk can be as simple as severity times probability. The risk ratings are helpful to discuss and sort risks into low, medium, and high groups. Benefits include its simplicity and visualizing it as a matrix. Two challenges are getting consensus on probability ratings and the omission of the third risk factor—exposure.



▲Figure 1

A three-factor risk formula is risk = severity (of impact) x exposure (to the hazard) x likelihood (of outcome). This adds the third factor of exposure, which can be an individual (e.g., riding a bike) or a group (e.g., all bicycle commuters). One challenge is creating a useful diagram showing three x, y, and z axes. Another is how to assess exposures. Again, using biking as an example, one is much more exposed to the hazard (i.e., traffic) when biking in the road than in a bike lane. Also, one is more exposed on busier streets than on quiet neighborhood roads.

Some risk assessing tools or techniques reverse engineer a root cause analysis (RCA), a common incident investigation technique (not without its own limits). One example of RCA is “Five Whys” in which we keep asking “why?” until we find a root to the incident’s cause. We can work backwards by instead asking “how” it could be caused until we find one or more ways, similar to a “what if” approach.

In “what ifs”, we might brainstorm various aspects going poorly. Examples could be what if the bottle breaks, what if a glove has a pinhole, or what if the eye wash doesn’t work? Each is assessed, rated on severity and odds, and addressed. We might examine how easy the bottle is to hold, check if the gloves have any pinholes, and verify the eye wash working properly with no obstacles in our way.

Recognize, assess, minimize, prepare (RAMP) is a widely used risk assessing process made up of the four words as a series of steps. Its stepwise approach follows a safety approach to hazards—recognize, evaluate, and control.

Many organizations with labs have some type of Lab Hazard Assessment Tool (LabHAT) or Lab Risk Assessment Tool (LabRAT). Most LabHATs are several pages long with boxes to check (e.g., hazards, PPE, etc.). Some allow helpful descriptions that provide details and context, though how they are analyzed isn’t always evident on the form. Some LabRATs are more decision-based or provide guidance on hazard controls. A better approach can be a brief spreadsheet-based algorithm that helps calculate and add up hazards versus subtracting for controls implemented.

Pre-mortems are a method of pre-determining what might go so wrong that someone (or the project) could die. Ask the question, “If we were to die what would’ve killed us?” It’s an effective tool and question to get people considering the ultimate risk—one’s life.

Failure Mode and Effects Analysis (FMEA) is a method that examines each individual part of a system for its possible failure points. Odds of failures can be broadly used, or numerical ratings can be applied.

“When failing to discuss or assess risks, lab incidents often occur with poor outcomes.”

Fishbone (aka Ishikawa) diagramming is a useful holistic way to diagram differing factors contributing to a process (like an experiment). These often include people, methods, materials, the environment, etc. The diagramming makes it look like a fishbone.

Process hazard analysis is often used in industry to analyze an entire process and can involve several of the other



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COMMON LAB HAZARD TYPES

Lab hazards are often categorized as one of the following:

BIOLOGICAL



CHEMICAL



LIFE SAFETY



PHYSICAL



RADIOLOGICAL



Each is then further divided into many specific hazards. For example, chemical hazards can be corrosive, explosive, flammable, reactive, and toxic, though not often all five together.

methods listed here. It can be in the form of a flow chart, a table, or other graphics.

Fault tree analysis is a diagrammatic approach using logic gates (e.g., if/then, or, and, not, etc.) that helps show and detail how a process will flow based on what occurs within it, and by outside agents such as humans.

Pareto charts use bars and a line to denote how frequently something occurs, such as an error in judgment, measurement, etc. It's common in quality systems, making it a good fit for labs.

A discussion on our risk perceptions is another technique to help lab staff and others engage in useful conversations on how each view the risks differently.

One's risk perceptions are right for them but perhaps don't equate with others' perceptions. Openly comparing differences can make for productive dialogue.

An overlooked yet powerful risk communication tool is storytelling. Stories are sense- or meaning-making tools that originally helped us survive 100,000 years ago. Storytelling, with all its nuances, plot, characters, and emotions, can provide helpful context and greater understanding among lab group members. There are tribes that will tell stories around the fire after the day's work is done to iron out conflicts, bond, relate, and celebrate their challenges and deeds.^{1,2} Sharing stories on lab incidents, close calls, and one's risk perceptions facilitates active engagement like no other technique.

Key takeaways

There are many risks in labs that can be assessed using one or more effective tools or techniques. Our risk systems, cognitive biases, and heuristics cause anyone to make odd and, at times, bad decisions. These risk assessing methods and programs help us be more objective, critical thinkers, explore probabilities, and demonstrate our due diligence.

It's beneficial to review them and decide which one(s) to use. We often need more than one. Choosing to use one or more is key; finding one that works in each case is best. Which one should you use? The ones that you're most likely to use, understand, and benefit from. However, going without any or going it alone is not an option and the probabilities of bad outcomes will eventually catch up in the lab.

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How to Test for New Psychoactive Substances

DETECTING AND QUANTIFYING NPS IS A COMPLEX PROCESS FOR FORENSIC TOXICOLOGY LABS **by Scott D. Hanton, PhD**

The emergence of new psychoactive substances (NPS) provides challenges for most forensic toxicology labs. Drug designers use the chemical structure of existing substances and modify one or more functional sites, leaving the rest of the structure intact. This generates a variety of molecules that produce the desired results but circumvent existing drug laws, which are based on the chemical structures of banned substances. NPS drug designers can synthesize and commercialize new substances much faster than forensic labs can develop and validate new analytical test methods

to identify and quantitate them in seized samples. In addition, with globalization and widespread access to the internet, the online marketing of these substances contributes to their distribution, causing negative public health issues, such as adverse reactions, overdoses, and deaths. As of December 2021, the United Nations Office on Drugs and Crime (UNODC) reports 1,124 NPS have been documented in 134 countries and territories. The two largest classes of NPS are stimulants and synthetic cannabinoid receptor agonists, which account for almost two-thirds of the new substances reported.



COMMON NPS

Synthetic cannabinoids: A class of designer drug molecules that bind to the same receptors to which cannabinoids in cannabis plants attach. Psychotropic effects are much more potent than delta-9-THC



Synthetic cathinones: Also known as bath salts, can give a user a sense of pleasure and euphoria. The chemical structure is similar to that of amphetamines.



Opioids: Include compounds of natural, synthetic, or semi-synthetic origin that interact with agonist receptors in the nervous system. Fentanyl is one of the most potent synthetic opioids consumed in recent years.



Arylcyclohexylamines: Ketamine is one of the most widely used NPS in this category. Ketamine is an anesthetic drug indicated for human and veterinary use, but in recent years it has been used as a drug of abuse due to its hallucinogenic and stimulant properties.



Phenethylamines: The fourth-most consumed NPS group in the US and Canada, with consumption dramatically increasing since 2010 due to online commerce. Adverse reactions can include neuropsychiatric effects and death.



Since NPS are specifically designed to evade legal control based on chemical structure, the UNODC has established the early warning advisory (EWA) on NPS, which shares information on distribution, harm, and drug identification. It also provides law enforcement and forensic labs support on quality assurance, manuals and guidelines, training, and field detection through its lab in Vienna, Austria.

These efforts are helping nations apply the principal of chemical similarity to existing controlled substances to help control NPS. Several countries have applied this concept to address large numbers of NPS.

ANALYTICAL CHALLENGES FOR MONITORING NPS

NPS development is dynamic and occurs quickly. It is relatively easy for NPS drug designers to evade the existing testing methods and databases of banned substances. The process of understanding the toxicological impacts of new NPS, and then detecting, identifying, and quantifying them is expensive, time-consuming, and complex. Despite these challenges, it is essential to learn the health risks associated with consuming

these substances, and to find robust methods to detect these substances. Once understood, it is important to share the methods and the results and incorporate the information in the databases available to forensic labs across the country.

“It is relatively easy for NPS drug designers to evade the existing testing methods and databases of banned substances.”

Analyzing NPS compounds requires methods with sufficient separation, specificity, and sensitivity to be certain of the results. Separation is required to highlight the active agents in a complex matrix, such as blood, urine, or a seized formulated NPS. Specificity is required to identify adulterated functional groups of chemical structures and distinguish between known

drugs, NPS, and other similar structures. Highly sensitive methods are required to detect these substances, which can be effective at very low concentrations. One of the challenges of these analyses is that drug designers are synthesizing new substances, which means that forensic scientists must deconvolute these NPS from the analytical data, and that they cannot rely on published reports to complete the analyses.

Fortunately, innovation in analytical methods and instruments has produced tools and protocols that meet the requirements of forensic labs to characterize the latest NPS products. The most important tools for these analyses are hyphenated chromatography–mass spectrometry instruments, especially those with high performance mass spectrometers.

Gas chromatography with mass spectrometry (GC/MS) is one of the main techniques for researching seized NPS (tablets, powders, seals, herbs, etc.) and their metabolites in blood, urine, hair, saliva, and other samples. GC/MS is a robust lab method that is used to analyze the volatile components of the samples. A key driver to the separation is difference of boiling point of the analytes. Many different sample preparation protocols can help extract and amplify the analytes of interest from a variety of complex samples and increase method sensitivity. Some of the key sample preparation protocols include liquid-liquid extraction (LLE) or deproteinization, solid phase extraction (SPE), solid phase microextraction (SPME), or liquid-liquid microextraction (DLLME).

Liquid chromatography (LC), either high performance liquid chromatography (HPLC) or ultrahigh performance liquid chromatography (UHPLC) is the method of choice for nonvolatile analytes contained in NPS formulations or samples. LC techniques are capable of analyzing NPS and its metabolites in blood, plasma, serum, urine, hair, and saliva samples. LC techniques can also be coupled with effective sample preparation protocols, like LLE, SPE, or DLLME, to increase method sensitivity. LC is a very robust and flexible technique, and its power is often increased by combination with fluorescence and/or mass spectrometry (LC/MS) detectors to increase sensitivity and specificity.

High resolution mass spectrometry (HRMS) is often combined with GC and LC experiments. HRMS combines high mass resolution to clearly identify the compound in question with high mass accuracy, which allows the determination of precise ion masses obtained

from NPS and its metabolites. The exact mass of the ions enables the elucidation of the most probable chemical structures of the NPS compounds. Further analysis by fragmenting ions in the mass spectrometer is available through MS/MS techniques. These instruments add structural information to the data available to scientists to identify and catalog NPS materials. Combining the exact mass and fragment data with a chemical understanding of NPS materials allows for clear assignment of the chemical structures of the new drugs, allowing NPS formulas and their metabolites to be added to databases to enable global sharing of data on new drugs.

“LC techniques are capable of analyzing NPS and its metabolites in blood, plasma, serum, urine, hair, and saliva samples.”

Most forensic labs have GC/MS, LC, and LC/MS instruments and methods available. As new methods are developed to address NPS, these tools can be used to address NPS concerns in those locations. These instruments are very reliable and can be used in both preliminary and definitive analyses.

FUTURE OUTLOOK

The improvement of analytical screening methods such as LC/MS/MS, and definitive detection methods (GC/MS and LC-fluorescence), are fundamental to identify original NPS materials. The rapid introduction of new substances and their metabolites into available databases is essential for forensic toxicology to overcome the current challenges. These more effective tests will contribute to curbing NPS global distribution. To meet this goal, collaborations between laboratories, scientists, governments, and police forces are essential and will help find solutions to the problems generated by NPS.

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Barbara Bessa also contributed to this article.

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ASK THE EXPERT

LEVERAGING AI TO ENHANCE SUPER-RESOLUTION CONFOCAL MICROSCOPY by Damon Anderson, PhD

Yicong Wu, PhD, staff scientist at the National Institute of Biomedical Imaging and Bioengineering (NIBIB), discussed their recent landmark study focused on multiview confocal super-resolution microscopy.

As *Lab Manager* recently reported, Wu and colleagues successfully integrated multiple analytical approaches to increase resolution, spatial scale, duration, and depth of penetration of confocal imaging in a range of sample types. The group went on to apply artificial intelligence (AI) and machine learning (ML) strategies to better predict and resolve challenging images. The combined approach offers significant steps forward for the range, scale, and resolution of biological confocal imaging applications.

Q: Although confocal microscopy is a widely used powerful tool due its contrast and flexibility, there are several significant limitations and areas for improvement. Can you elaborate?

A: Yes, confocal microscopy remains the dominant workhorse in biomedical optical microscopy when imaging a wide variety of three-dimensional samples, but it has clear limitations. These drawbacks include substantial point spread function anisotropy (usually its axial resolution is two- to three-fold worse than lateral resolution, confounding the 3D spatial analysis of fine subcellular structures); spatial resolution limited to the diffraction limit; depth-dependent degradation in scattering samples leading to signal loss at distances far from the coverslip; and three-dimensional illumination and volumetric bleaching, which may rapidly diminish the pool of available fluorescent molecules and lead to unwanted phototoxicity.

Q: Can you summarize the major achievements of the study?

A: The spatial resolution, imaging duration, and depth penetration of

confocal microscopy in imaging single cells, living worm embryos and adults, fly wings, and mouse tissues are improved with innovative hardware (multi-view microscopy, efficient line-scanning confocal microscopy) and state-of-the-art software (super resolution reconstruction, joint deconvolution, and deep learning techniques).

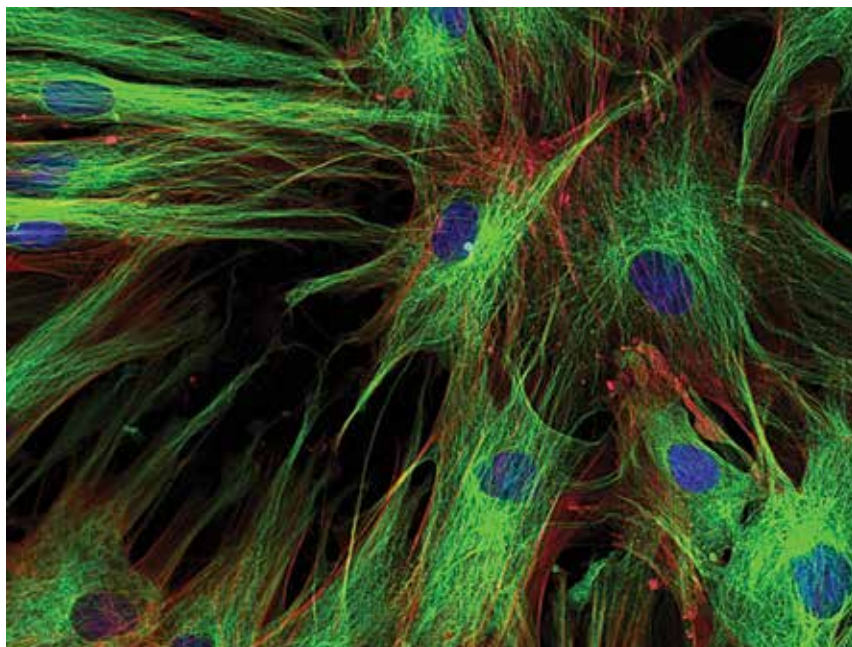
Q: What approaches were used to accomplish these advancements?

A: We achieved our improvements in performance via an integrated approach: 1) we developed a compact line-scanning illuminator that enabled sensitive, rapid, and diffraction-limited confocal imaging over a 175 x 175 mm² area, which can be readily incorporated into multiview imaging systems; 2) we developed reconstruction algorithms that fuse three line-scanning confocal sample views, enabling ~two-fold improvement in axial resolution relative to conventional confocal microscopy and recovery of signal otherwise lost to scattering; 3) we used deep learning algorithms to lower the illumination dose imparted by confocal microscopy, enabling clearer imaging than light sheet fluorescence microscopy in living,

light-sensitive, and scattering samples; 4) we used sharp, line illumination introduced from three directions to further improve spatial resolution along these directions, enabling better than ten-fold volumetric resolution enhancement relative to traditional confocal microscopy; 5) we showed that combining deep learning with traditional multiview fusion approaches can produce super-resolution data from single confocal images, providing a route to rapid, optically sectioned, super-resolution imaging with higher sensitivity and speed than otherwise possible.

Q: Can you discuss the novel triple-view SIM (structured illumination microscopy) image reconstruction technique used in the study and how this compares with tradition SIM in the context of super resolution microscopy?

A: In traditional SIM, the 2x resolution enhancement is achieved by reconstruction of multiple interference images. In our triple-view SIM, we obtained super-resolution 1D images using digital photon reassignment and joint deconvolution of the views, achieving triple-view 1D SIM. We also used deep learning to predict 1D



super resolved images at six rotations per view, and jointly deconvolved the views to achieve triple-view 2D SIM. We demonstrated that our triple-view 1D and 2D SIM methods outperformed a commercial 3D SIM system when imaging relatively thick samples.

Q: The multifaceted approach used in this study produced significant enhancements in confocal imaging resolution and performance. Can you describe the imaging improvements as applied to a few of the more than 20 distinct fixed and live samples that were included in the study?

A: The biological results are not only visually striking, but also enable new quantitative assessments of intracellular structures and tissues. For example, we imaged Jurkat T cells expressing H2B-GFP and 3xEMTB-mCherry every five seconds for 200 time points and revealed nucleus squeezing and deformation as the cell spread on the activating surface. For thicker samples other than

single cells, one example was densely labeled nerve ring region in a *C. elegans* larva, in which we obtained superior volumetric resolution in triple-view 2D SIM mode ($253 \times 253 \times 322 \text{ nm}^3$), more than ten-fold better than the raw confocal data ($601 \times 561 \times 836 \text{ nm}^3$).

Q: What were the impacts of AI and ML on the imaging improvements observed in the study?

A: Our work provides a blueprint for the integration of deep learning with fluorescence microscopy. We successfully deployed neural networks to denoise the raw confocal images, enabling lower illumination dose, and thus extending imaging duration. We also showed such networks could predict isotropic, super-resolution images, and improve imaging at depth.

Q: How do you see AI and ML impacting future confocal microscopy investigations, and in particular single cell imaging applications?

A: We believe that the combination of confocal imaging with deep learning allows much better imaging performance than confocal microscopy alone, and has great promise for improving spatial resolution, signal-to-noise, imaging speed, and imaging duration. We suspect the same method could also be profitably applied to other microscopes with sharp line-like illumination for single cell imaging, including lattice light-sheet microscopy, traditional and nonlinear SIM, and stimulated emission depletion microscopy with 1D depletion. Such microscopes are capable of improving spatial resolution in single cell studies, yet this improvement in resolution usually comes at a cost in terms of temporal resolution, signal, or phototoxicity. One caveat, however, is to remember that AI/ML generates *predictions* based on data the network has seen before. Although we obtained significant improvements when using AI, it is always important to remember that it is possible for these networks to generate predictions with artifacts—particularly if the input data differs significantly from the training data the network has already “seen.” More work is needed to make it easier to validate the output of such approaches, but we are very excited about the possibilities for fluorescence microscopy.

Yicong Wu, PhD, is a staff scientist at the NIBIB. Under the direction of Hari Shroff, PhD, in the section on High-resolution optical imaging, Wu’s investigations focus on the development of new imaging tools for use in biological and clinical research.

Damon Anderson, PhD, is the technology editor at LabX.com. He can be reached at danderson@labx.com.

CHEMICALS

WHAT TO CONSIDER WHEN PURCHASING DIFFERENT GRADES OF CHEMICALS

by Aimee O'Driscoll

When it comes to working with chemicals and reagents in the lab, it's important to be aware of the different grades that are available.

Not all chemicals and reagents are created equal, and knowing which grade is right for your needs can make a big difference in terms of quality, safety, and cost.

What lab managers should know about the main chemical grades available

The most common grades of chemicals and reagents are ACS, reagent, USP, NF, laboratory, purified, and technical. The main difference between the various grades is purity, with ACS grade chemicals having the highest purity (95 percent or above) and technical grade the lowest. These grades can be more generally categorized in the following ways:

- **Food and drug grades:** ACS, USP, and NF grades meet or exceed standards set by the American Chemical Society (ACS), United States Pharmacopeia (USP), and National Formulary (NF), respectively. These three grades, along with reagent grade chemicals, are of the highest purity and are typically interchangeable. They are usually acceptable for use in food, drugs, and medicine, and as such, are subject to strict quality control measures. This means they are usually more expensive than other grades, but they're also more reliable.
- **Educational grades:** Laboratory grade chemicals are generally of high purity, but they are not subject to stringent standards and their exact purity is unknown. These chemicals and reagents are ideal for use in educational settings. Purified grade chemicals don't meet an official standard but could still be used for educational purposes and other general applications.
- **Industrial or technical grade:** Technical grade chemicals are the lowest quality products available. They're designed for general use in a variety of applications, and as such, they're not subject to the same quality control measures as other grades. Technical grade chemicals are inexpensive and are often used in industrial and commercial settings, although not where food or pharmaceuticals are involved.

While the grading systems help, lab managers still need to take a close look at each product's specifications before determining its suitability for use.

“For the best quality of data, high quality solvents and reagents are a requirement.”

Why is choosing the right grade so important?

Choosing the right grade of chemical or reagent is vital for several reasons. One is that using a low-purity grade can lead to low-quality results, with the impact depending on your application and how sensitive your requirements are. Chelsea Plummer, PhD, senior product marketing manager, chemistry at Waters Corporation, notes that in LC and especially in LC-MS methods, even small amounts of contamination can decrease sensitivity, leading to incorrect detection limits. “For the best quality of data, high quality solvents and reagents are a requirement.”

As Plummer explains, “there are two main repercussions and complaints that often stem from choosing the wrong grade of chemical or reagent.” First, you could end up with confusing results—for example, a complex MS spectrum—which makes data analysis extremely challenging. You might also find yourself taking additional time to troubleshoot, or worse, adding downtime to clean your system from the contamination that can be left over when using the wrong grade of solvents and chemicals.

Choosing too low a grade can result in noncompliance and safety concerns, particularly in any environment involving food or pharmaceuticals. It can also lead to higher costs due to having to repeat processes or deal with expenses related to equipment damage or replacement. Conversely, using a higher-purity grade than required will lead to higher costs than necessary.

How to choose chemicals and reagents for your applications

When purchasing chemicals and reagents, it's important to consider the intended application, balance cost with required purity, and look to regulatory requirements for guidance. Even if you're not restricted by industry standards, you may decide that other factors warrant the use of high-purity reagents. As Plummer notes, due to the high cost of some lab instruments such as LC-MS systems, getting the most out of the accuracy and sensitivity of these systems should be a priority by using the right solvents and reagents.

Aside from choosing the right grade, you should also look at the intended use for that particular chemical or reagent. For example, in the case of LC-MS, Plummer says using MS-labeled solvents is recommended as HPLC grade will not be pure enough. It's also worth noting that simply checking the label of products is not enough, and you should also consult documentation such as MSDS sheets and certificates of analysis to confirm a product's suitability for your application.

“Choosing too low a grade can result in noncompliance and safety concerns, particularly in any environment involving food or pharmaceuticals.”

Another area to consider is benchmarks. If you're comparing samples to standards, you need to ensure that your chemicals and reagents are of the same grade as those used to produce your benchmark samples, and vice versa. Of course, price is also a consideration when purchasing chemicals and reagents. High-purity products are usually the most expensive and technical grade chemicals are the cheapest. However, it's important to remember that you get what you pay for and choosing the wrong grade can lead to higher long-term costs.



When it comes to choosing chemicals and reagents, there's no one-size-fits-all solution. It's crucial to consider the intended use, the grade of the product, and the price before making a purchase. With these factors in mind, you can be sure to select the best chemicals and reagents for your needs.

Aimee O'Driscoll, BSc, MBA, has a decade of experience as a development chemist and is a seasoned science writer. She can be reached at aimee@aimeeodriscoll.com.

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FUME HOODS

COMPARING DUCTLESS VS DUCTED FUME HOODS

by Aimee O'Driscoll

Many laboratory applications require the use of a fume hood to trap and exhaust volatile vapors and hazardous fumes. Fume hood design has come a long way over the past few decades and there are several different types to choose from. Conventional ducted fume hoods connect to facility ductwork, sending contaminated air outside the facility. Ductless fume hoods are standalone units that filter contaminated air, recirculating clean air back into the room.

Both types of fume hoods have advantages and drawbacks in relation to cost, practicality, and other factors, and it's important to assess these before making a purchase.

Factors to consider when selecting the ideal fume hood

While ductless fume hoods offer several advantages, they are not suitable for all applications. "Industry safety standards require the completion of a detailed chemical assessment before implementation of these products," explains Luke Savage, director of ventilation technologies at Labconco. "If you are not certain that your application and chemical use will remain constant, or if your application has not been approved through a ductless hood manufacturer's filtration provider, these will need to be addressed before entertaining a ductless hood."

Savage adds that another key consideration for ductless fume hoods is anticipated filter life and your organization's tolerance for changing filters at that frequency. "Projected filter life information is always provided in the hood manufacturer's filter assessment," says Savage. From a practical standpoint, because ductless fume hoods don't need to be connected to the ductwork, they are more versatile in terms of placement and can even be moved to different locations if needed.

If environmental concerns are top of mind, a ductless model might be a better option. While some ducted fume hoods contain filters, others don't and send unfiltered, contaminated air outside the facility. Depending on the specific application and resulting fumes, this could have a negative impact on the environment. Ductless fume hoods trap contaminants in filters, which are typically disposed of in a landfill.

Weighing the costs of each option

Purchasing a fume hood can represent a large capital investment, so it's important to carefully consider the costs involved. While ducted units tend to be less expensive than ductless models, the unit cost isn't the only thing to bear in mind. The installation of a ducted fume hood will at least involve connection to existing facility ductwork. "Many existing labs will have capacity in their existing infrastructure in the form of heating, cooling, and ventilation capacity to support the supply and exhaust airflow needs for a ducted hood," explains Savage. "However, if this does not exist, the cost for adding it will certainly exceed the first cost of the fume hood itself."

Aside from the initial installation, you also need to look at ongoing costs, which will vary depending on which model you choose. Savage notes that for ducted models, beyond the first cost of the hood and the mechanical support system is the huge ongoing operating cost of tempering and moving the air. The operating cost is significantly less for ductless units. As Savage explains, "air is simply pulled and recirculated back to the lab, unlike a ducted hood where it's pulled from outside, tempered, introduced to the lab, moved through the hood, and then sent back outside."

Aimee O'Driscoll, BSc, MBA, has a decade of experience as a development chemist and is a seasoned science writer. She can be reached at aimee@aimeedriscoll.com.

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FUME HOODS

THE USER'S IMPACT ON FUME HOOD PERFORMANCE

by Chip Albright

A fume hood is part of the overall laboratory mechanical system and there are a variety of potential causes of failure that can occur, both within and outside the user's control. A cause of failure that is often overlooked is the user's own work practices.

How do you know if your fume hood is working?

The only way to know for sure if a hood is losing containment is to run a test. When doing containment testing, at least 25 percent of failures are caused by user work practices. If a fume hood is performing poorly, the lab manager may not be able to replace the hood or revamp the laboratory ventilation system, but they can educate the user to help protect themselves by ensuring good practices and expanding their knowledge of how fume hoods perform best.

The biggest challenge with fume hood performance is that users cannot see the hazards—most are invisible and odorless. Therefore, there is no easy way to know if your fume hood is working properly and protecting you. Many think that face velocity, which is defined as the speed of the air entering the sash opening, is an indication of safety. The ANSI/AIHA Z9.5 Laboratory Ventilation states: "Studies involving large populations of laboratory fume hoods tested using a containment-based test like the ANSI/ASHRAE Standard 110, 'Method of Testing the Performance of Laboratory Fume Hoods,' reveal that face velocity alone is an inadequate indicator of hood performance." In fact, most hoods that fail containment testing have acceptable face velocity readings.

So, what causes loss of containment in a fume hood? The two biggest causes are turbulence and pressure shifts (room pressure versus fume chamber pressure).

Picture a smooth, flowing river—the surface is only moved by wind. Add lots of boulders, and now there are rapids. The smooth, flowing river has transformed into a raging obstacle course. People do the same in and around fume hoods. Their actions create

turbulence in the airflow that increases the chance of loss of containment.

Components of a fume hood

To the user, the most important feature of a fume hood is the sash. The sash, or sash panels, are the pieces of transparent material—usually glass—that are located at the front of the fume chamber and are movable. The sash position has a huge impact on the airflow within the fume chamber, but the sash is also a barrier between the fume chamber and your breathing zone. It offers protection from other hazards, such as fire and explosion. Using the sash properly is one of the most important things you can do, not only to protect yourself but to also save energy.

The next component to focus on is the baffles. These are normally located in the rear of the hood and, along with the back wall, create the exhaust plenum. The exhaust plenum has the lowest pressure within the hood, so the air naturally wants to flow there. There are slots or holes in the baffles to allow the air to flow into the exhaust plenum. There are many baffle designs, and some perform better than others. The baffles are the most critical component in fume hood performance, so users need to pay close attention to them.

The lower airfoil is also a critical component. The sash normally closes onto this airfoil. It is the nose of the work surface. There are many designs, but they are often constructed of metal and are designed to create a stream of air that sweeps across the work surface rearward toward the baffles.

How to safely work with a fume hood

Even when the hood tests well, your actions at the hood can negatively impact its ability to properly contain.

Let's examine some specific examples of fume hood use.

As a best practice, the lower the sash handle is, the safer the user will be. Hoods should never be used at full open; this is for setup only. Working with an 18-inch opening on a vertical sash is far safer than working at full open.

When you stand in front of the sash opening, your body acts like an airplane wing; the air being drawn into the hood flows over your shoulders and around your sides, creating a low-pressure zone in front of you. This low-pressure area will attempt to pull air from inside the hood outward, creating a loss of containment and possible exposure. This is why you always work at least six inches behind the sash to keep chemicals out of the area of reverse flow.

“When working in the hood, move your hands and arms slowly and deliberately.”

Next, extend your hands and arms into the hood and move them about. What are they doing to the airflow? Picture yourself in a canoe—your arms are the paddles, and just as the paddles can displace large amounts of water, your arms can displace large amounts of air creating turbulence and disrupting the airflow. This is a recipe for loss of containment. When working in the hood, move your hands and arms slowly and deliberately.

Do not place objects directly on the work surface. The airstream flowing over and under the lower airfoil is attempting to sweep chemical fumes back toward the baffles. Placing objects directly on the work surface is like putting boulders in that smooth river. It creates rapids, greatly increasing the chances for loss of containment. Everything in the hood should be elevated off the surface one to two inches.

Baffles have been designed to organize the airflow through the fume chamber into the exhaust plenum. Never tape notes to the baffles or use the hood for storage. Blocking any of the slots or penetrations in the baffles will disrupt the airflow and create turbulence, which increases the loss of containment.

It is not just what happens in the hood that matters but what happens around the hood. For instance, just walking past the hood with a raised sash is almost a guarantee there will be

loss of containment. Why does loss of containment matter? The fugitive chemicals escaping the hood contaminate the room air, which means everyone in the lab is breathing these potentially hazardous chemicals.

There is a long list of dos and don'ts beyond what has been outlined here. Remember, users are a critical element of the overall fume hood system.

Chip Albright has spent 40 years designing, manufacturing, installing, and testing fume hoods. He is now the president of Fume Hood Certified, LLC, which promotes testing and training to improve fume hood performance.



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TITRATORS

FINDING THE RIGHT PLATFORM FOR THE JOB

by Mike May

Titration determines the concentration of a specified chemical—the analyte—in a sample by using another chemical or reagent, called the titrant. The reagent reacts with the sample to produce a color, chemical reaction, or change in an electrical property that relates to the concentration of the analyte. The amount of reagent used is measured and converted to concentration.

Analyzing the analytes

“Modern instruments that indicate results of a titration use changes in electrical characteristics,” says Hank Levi, president at Scientific Gear. These instruments are known as potentiometric titrators.

To operate a potentiometric titrator, a sample is added to a container or flask. An electrode is inserted to measure the electrical characteristic, such as the voltage of the sample. The reagent is added from a burette until the electrical changes reach equilibrium or the endpoint. The amount of reagent required to reach that endpoint is measured and converted to concentration. “Scientists use potentiometric titrations for a wide range of chemical concentration analyses, including things like salt and acid/acidity,” Levi explains.

Measuring water content

In the 1930s, German chemist Karl Fischer developed a special reagent to analyze a sample’s water concentration. The methods that use these reagents are called Karl Fischer. A Karl Fischer reagent reacts with the water in a sample to create iodine, a non-electrical conductive chemical.

In volumetric Karl Fischer, the reagent is added to the sample, contained in a sealed container filled with an appropriate solvent, and fitted with an electrode. The

reagent is metered into the container by a burette. The water concentration in a sample is calculated from the amount of reagent used to reach the endpoint.

In 1959, a modification of the Karl Fischer reagent was developed. This reagent combined the sample solvent and the water-reacting reagent in one chemical solution. Levi points out that “this technique uses an electrical current to release the active reagent chemical from the combined reagent/solvent solution.” The system uses two electrodes; one to detect the electrical condition of the sample and a second to provide the electrical current that releases the active reagent. This technique is called coulometric Karl Fischer.

To conduct a coulometric Karl Fischer test, a special sealed vessel, equipped with the two electrodes and a sample insertion port, is filled with coulometric Karl Fischer reagent. A sample is added through the insertion port, and current is automatically applied to separate the active reagent. Here, the amount of current needed to reach equilibrium is converted to the concentration of water in the sample.

Additional options

Other equipment can be added to expand the application of a titrator. To increase throughput, for example, a sample changer can be used to automatically test multiple samples.

The sample itself can also require added equipment. In a Karl Fischer titration, for example, some samples—such as plastics—only release water at higher temperatures. In such cases, a Karl Fischer oven can be used to drive off water into the titration cell. The sample and the desired measurement both play a role in selecting the best titration platform for a particular task. For today’s scientists, many options are commercially available.

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

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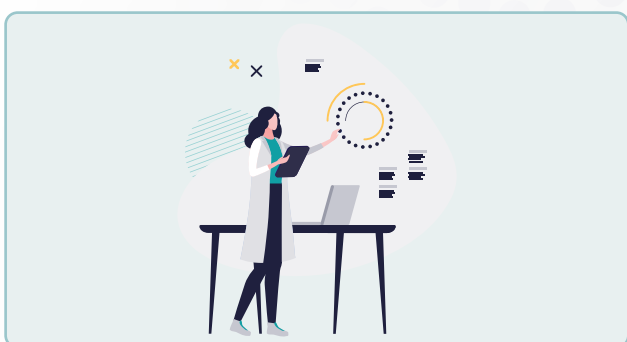
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Innovations in: Personal Protective Equipment

COVID-19 LED RESEARCHERS TO GET CREATIVE IN SOLVING PROBLEMS WITH RESPIRATORS AND OTHER PPE

by **Jonathan Klane, M.S.Ed., CIH, CSP, CHMM, CIT, and Rachel Muenz**



Imagine what it was like being a health care worker or lab employee near the start of the COVID-19 pandemic and not having enough personal protective equipment (PPE). This forced many to come up with creative solutions to stay safe. PPE is now part of everyday life, but problems such as ill-fitting face masks and gowns for health care workers as well as some being forced to reuse disposable PPE due to supply and logistics chain challenges are still plaguing us.

This need to innovate PPE led many researchers and companies to create new products and recraft existing ones, making them more effective and sustainable.

The research roundup highlighted here can't be exhaustive. The few examples of innovations below demonstrate how PPE is advancing and evolving. Note: Face coverings were mostly omitted as they're not technically PPE, though they were used by some for their protection.

“Innovations often stem from great needs while we're under tight constraints...”

PPE PRODUCTION

Access to enough PPE was a major issue over the last couple years, with hospitals and clinical labs running out due to demand outrunning supplies. Many decided to solve this using DIY solutions. Some companies and universities

teamed up with partners to create new PPE designs and 3D-printed face shields and respirator masks. Hospitals innovated too—in one example, a Toronto doctor modified plastic bags to protect health care workers who remove ventilator tubes from patients' throats.

Non-PPE companies opted into PPE innovating. Undergarment manufacturer Hanesbrands and

other clothiers produced three-ply cotton masks approved by the US Food and Drug Administration (FDA) as a substitute for N95 masks in critical needs areas only.

Many followed suit. Spirits producers including Bacardi Corporation, Pernod Ricard SA, Anheuser-Busch

InBev NV, and BrewDog pivoted from potable alcohol to manufacturing hand sanitizer, with many partners helping ensure its safety.

BUILDING BETTER PPE

Along with inspiring PPE innovations, the pandemic fostered research to improve PPE effectiveness and materials. An example involves creating a special fabric using metal-organic frameworks that can deactivate both chemical and biological threats, including the SARS-CoV-2 virus. The material, developed by researchers at Northwestern University, is reusable, requiring a quick bleach treatment after being exposed to various hazards, thus being more sustainable.¹

Research to develop new filters could lead to respirator improvements. Recently, University of California, Riverside researchers and George Washington University colleagues captured 99.9 percent of coronavirus aerosols using nanofibers. The filter is produced via low-cost electrospinning, potentially enabling it to be mass-produced, according to a May 2021 press release.² A year earlier, research in *ACS Nano* from King Abdullah University of Science and Technology showcased improved, replaceable filters for N95 masks. The filter has a self-cleaning, hydrophobic membrane, according to a press release³

Alternatives to N95 masks have also been a key focus area, with one option developed by Brigham and Women's Hospital and Massachusetts Institute of Technology researchers. Their transparent, elastomeric, adaptable, long-lasting respirator uses sensors to ensure a proper fit and let wearers know when filters are saturated. In a small study with 40 participants, the respirator achieved excellent filter exchange, breathability, and fit, and 100 percent fit-testing success. The respirator is greener than current N95s as it can be sterilized multiple times.

Since the pandemic's beginnings, many researchers innovated to solve PPE problems. These solutions include extenders to make surgical masks more comfortable, materials that deactivate the virus, and coatings applied to N95s making them easier to decontaminate and thus antiviral.⁴

DECONTAMINATION INNOVATION

Researchers' work aimed to make PPE easier to decontaminate and developed new devices and methods for PPE decontamination. University of California, Los Angeles researchers and colleagues showed that N95 masks could be safely decontaminated and reused through various

methods, including vaporized hydrogen peroxide (VHP). Other research showed similar results, and VHP is now often used for decontaminating PPE.

Subsequent research confirmed the effectiveness of other decontamination methods. Research from a University of Southampton team published in *AIP Advances* in October 2021 developed a method using low-temperature plasma technology to remove 99.99 percent of coronavirus from face mask respirators while still allowing the masks to be safely reused, cutting costs and reducing waste.

Other work involved developing new devices to decontaminate PPE, such as a compact "portable rack hanging device" created at Florida Atlantic University in November 2020 that uses ultraviolet-C light to sterilize up to six masks at once. The device can decontaminate N95 respirators and cloth masks worn by the general public.

If you were wondering how such decontamination methods change N95 masks, so did researchers. Two national research facilities at the University of Saskatchewan—the Canadian Light Source and the Vaccine and Infectious Disease Organization—International Vaccine Centre—teamed up to use advanced X-ray techniques to explore how different decontamination methods affected mask materials microscopically and what causes the fibers to degrade. The work will help manufacturers improve their products so they can be safely decontaminated by as many methods as possible, and last longer.

INNOVATIONS THAT MAY LEAD TO IMPROVEMENTS

The pandemic also led to research that brought us more insight into how factors such as fit affect how well PPE works and may lead to further innovations. A team at the University of California, Davis found that, despite leakage around the edges, surgical masks still effectively reduced the amount of aerosols produced from coughing or talking. Mask leakage is a significant concern among industrial hygienists. Though the study was small, involving just 12 volunteers, it helped confirm wearing a mask is important, even if you're not wearing it perfectly.

The effects of face shape on PPE performance and improvements have also been a major focus. A team at Florida State University received an \$800,000 grant from the National Science Foundation to better understand the mechanics and flow physics of face masks, how they fit various users, and how protection can be improved. This should lead to better options for all face types.



Developing better PPE materials could also help make masks and other products more effective at protecting people from viruses such as SARS-CoV-2. During the pandemic, hundreds of research projects developed new materials to improve PPE or lead to creating new products. Work from the École polytechnique fédérale de Lausanne involved creating new filter material from titanium oxide nanowires that can trap and kill pathogens. The material could help improve masks worn by the general public. Another filter material developed by Korea Advanced Institute of Science and Technology researchers could also improve face masks, making them reusable while still maintaining effectiveness. In March 2020, the team was awaiting approval in Korea to sell the product, but it's unclear if it's currently being used. Much research has also been done on the effectiveness of current materials used in both cloth masks and N95s, which should lead to improvements.

TACKLING THE PPE WASTE PROBLEM

The increased PPE use was effective at protecting lab workers and others, but it increased PPE waste and pollution. Besides reusable PPE, this led researchers to innovate improved waste management.

A team of researchers from University of York, University of the Sunshine Coast, and the University of Tasmania looked to the past to solve this. They examined it through an archaeological lens to understand cultures by their waste materials. John Schofield of University of York's Department of Archaeology said taking this approach “provides a distinct and helpful perspective on the problem of environmental pollution.”⁵

Research also focused on improving PPE recycling or reformulating it entirely. Research in the journal *Biofuels* shows how PPE could be turned into biofuels using pyrolysis, while similar work from Cornell University scientists in *Renewable and Sustainable Energy Reviews* proposed reverting PPE to its original forms and into fuels.^{6,7}

THE FUTURE OF PPE

Innovations often stem from great needs while we're under tight constraints, as demonstrated above. PPE improvements are likely to continue now that we've seen what we can do. The continued impact of COVID-19 and other challenging risks will create opportunities for more innovation. The need to reuse or conserve PPE will inspire other green, sustainable approaches. It's only a matter of time until the next need for PPE innovations occurs.

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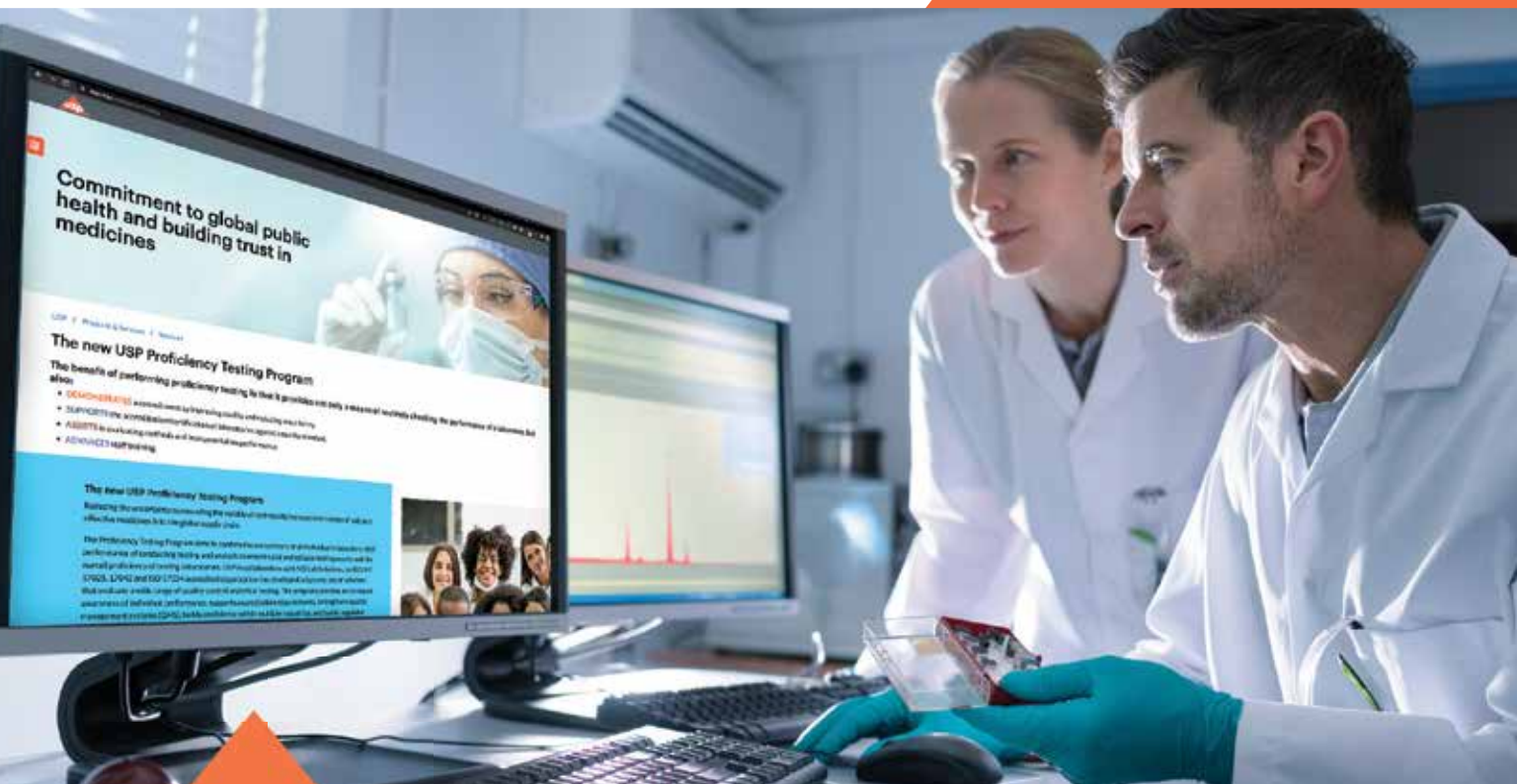


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