Environmental Health & Engineering, Inc.

Biosafety Management: Essential Insights for Every Life Science Developer

INTRODUCTION

The Life Sciences industry has been growing fast, with experts projecting an additional 7% to 13% growth in the sector from 2022 to 2029. As clinical research, product manufacturing, and commercialization stretch beyond traditional industry clusters in biotechnology hubs like the Greater Boston area, San Francisco, and San Diego, more real estate developers and the municipalities in which they operate are navigating the complexities that come with having Life Science companies located in their own communities.

Among these challenges are the stringent requirements in place to protect the individuals who work in laboratory spaces as well as surrounding communities. As developers position their properties to appeal to this fast-growing industry, it's critical that they understand the types of materials used in laboratories, their potential safety risks, and appropriate oversight.

Equally important, developers and municipal agencies need to be able to speak comprehensively and accurately about these potential risks in order to address concerns from their communities. For localities that have not previously been the site of Life Science industry activity, mention of "biological hazards" can cause concern, whether or not it is warranted.

With a clear understanding of the types of hazards present in Life Science laboratories and how to properly manage any associated risks, property developers can better navigate these challenges and offer more attractive properties to Life Science tenants.

RISKS IN THE LIFE SCIENCE LABORATORY

The Life Science industry is a highly regulated industry due to the fact that there are a number of laboratory materials that can cause harm if not properly handled. Regulations at the local, state and federal level ensure that companies within the Life Sciences industry are able to safely operate without negative impact to personnel or their communities.

Some of the concern that surrounds life science laboratories comes from a misunderstanding of how risk is addressed. First, it's important to understand two key terms:

- *Hazard* describes something that has the potential to cause harm.
- *Risk* describes how likely something is to cause harm.

It may help to think of it this way: water is a *hazard* that can cause harm through drowning. However, the *risk* of drowning is much higher in a lake than in a puddle—even though the same hazard is present in both instances.

In other words, Life Science laboratories can contain potential hazards. By implementing appropriate safeguards, their risk can be minimized significantly.

It is never possible to eliminate risk entirely. However, the risks present in the vast majority of Life Science laboratories are minimal. Protections put in place against any potential hazards are primarily geared toward the protection of laboratory staff directly handling potentially hazardous materials—materials that, in some cases, can be found in medical offices and even within homes.

When communities seek assurance that a laboratory will have zero risk, it's important for developers to be able to communicate the unlikeliness of any risk to the community and the many safeguards put in place. Understanding the typical laboratory hazards and risk groups can also help put community members' minds at ease.

TYPICAL LIFE SCIENCE LABORATORY HAZARDS

We'll focus primarily on biological agents in this paper, but other hazards are usually present as well. In general, the hazardous materials found in life science laboratories may include:

- *Chemical*: Chemicals are ubiquitous in laboratory environments, and include things like acids, bases, and flammables. Chemical hazards can range from burns to increased risk of developing chronic illnesses.
- *Radiation and lasers*: Some laboratories use radioactive materials like tritium as tracers. Some equipment emits radiation, both non-ionizing radiation from lasers or ionizing radiation emitted by certain types of imaging equipment. One type of radiation-emitting equipment that many people are familiar with is the X-ray machine found in hospitals, clinics, and dental offices.
- *Animals*: Some laboratories use rodents or other animals to support research. While there are a range of hazards associated with working with laboratory animals, one of the most common hazards is that someone who works with the animals will develop an allergy to the animal's dander or saliva.
- *Biological*: Biological hazards come from potentially infectious agents such as bacteria, viruses, and fungi, as well as from materials that may contain these biological agents, like human tissues or blood. Many of these materials and corresponding risks can also be found in hospitals and clinics. It is also commonplace for laboratories to use recombinant DNA techniques to develop and produce therapeutics such as human insulin and vaccines.

UNDERSTANDING RISK GROUPS

Biological agents are assigned to "risk groups" by agencies like the U.S. National Institutes of Health or World Health Organization. Risk groups are assigned based on a biological agent's capability to infect and cause disease in a susceptible host, the severity of disease it causes, and the availability of preventative measures and effective treatments to minimize harm. There are four risk groups:

- *Risk Group 1* includes agents that are not associated with disease in healthy adult humans. Brewer's or baker's yeast are examples of risk group 1 agents. These one-celled fungi won't make a healthy adult seriously ill but could cause some discomfort if ingested. Some risk group 1 agents may cause illness in an immunocompromised adult.
- *Risk Group 2* includes agents that can cause disease in human, but those diseases are easily preventable or have treatment readily available. *Salmonella enteritidis*, which is implicated in food poisoning, is one example of a risk group 2 agent. Most Life Science laboratories handle materials that fall into Risk Group 1 or 2.
- *Risk Group 3* includes agents that are associated with serious or lethal human disease. Many are transmitted through inhalation. Preventive strategies or treatments may be available. *Mycobacterium tuberculosis*, the bacteria that cause Tuberculosis, is an example of a Risk Group 3 agent.
- *Risk Group 4* agents are likely to cause serious or lethal human disease. Preventive or therapeutic interventions are not usually available. Only a handful of laboratories in the entire country work with risk group 4 agents and they carry an extremely high level of regulatory oversight.

BIOSAFETY OVERSIGHT

Biosafety is the use of specific practices, safety equipment, and specially designed laboratories to ensure that laboratory personnel, other building occupants, the surrounding community and the environment are protected from biological agents.

Biosafety oversight is governed by local, state and federal regulations and guidelines, as well as institutional rules. The purpose of this oversight is to ensure the safe storage, use and disposal of biological agents and materials in a laboratory setting. Understanding the regulations that apply to your region is critical for ensuring appropriate safety precautions are in place in your facility.

BIOSAFETY REGULATIONS

Broad regulations governing biological agents and biosafety oversight exist at the federal and state level. However, not all biological materials will trigger state and federal regulations, and that is where local ordinances may be enacted to fill safety gaps. Many Life Science companies find that their local agencies are more likely to conduct in-person inspections of compliance activities than state or federal agencies, often on an annual basis.

Local Health Departments typically require a permit to work with biological materials and may have permitting requirements that must be addressed prior to and/or after contracting with tenants. In addition, many of the municipalities that are home to growing Life Science clusters require evidence that equipment and procedures have been designed safely and have planned maintenance to ensure safe ongoing operation.

While requirements will vary from city to city, one common requirement is for a floor plan that clearly delineates laboratory space from equipment rooms, materials storage locations, waste handling areas, and office space. Other examples include requirements for proof of equipment validation, plans for and contract partners involved in maintaining equipment certifications, and pest control.

BIOSAFETY LEVELS OF CONTAINMENT

Once a Life Science company has identified the biological hazards they want to work with in their facility and conducted a risk assessment, it is possible to assign appropriate biosafety levels. A biosafety level identifies the containment measures that must be put in place to mitigate the risks presented by the biological hazards so that they can be used safely. Containment measures for personnel include laboratory practices and techniques, training, safety equipment, personal protective equipment like lab coats and gloves, disinfection and cleaning protocols, and facility design.

Containment measures are focused on protections for the laboratory workers who are in direct contact with biological agents rather than the surrounding communities. As we'll explain below, it is exceptionally rare for laboratories to work with materials that present any hazard to the surrounding communities. In all instances, laboratory design in accordance with biosafety level requirements prevents the flow of biological agents into the outside environment.

As with risk groups, biosafety levels go from 1 to 4.

- *Biosafety Level 1 (BSL-1)* containment is suitable for work involving well-characterized agents that are not known to consistently cause disease in immunocompetent adult humans. There is minimal potential hazard to laboratory personnel or the environment. A high school science lab working with non-pathogenic strains of E. coli is an example of a BSL-1 lab.
- *Biosafety Level 2 (BSL-2)* containment is suitable for working with agents that pose moderate hazards to laboratory personnel and the environment. Personnel in these environments should have specific training in handling pathogens. Access to the laboratory is restricted when work is being conducted, and any procedures in which infectious aerosols or splashes may be created are conducted in specialized equipment known as biological safety cabinets or other physical containment equipment. Microbiology teaching labs at universities and clinical labs in hospitals are considered BSL-2 environments.
- *Biosafety Level 3 (BSL-3)* containment is suitable for work with indigenous or exotic agents that may cause serious or potentially lethal disease through inhalation. Many of the components of a

BSL-3 laboratory are designed to minimize or eliminate hazards from aerosol exposure. BSL-3 labs are not common, as these activities are rare and the facilities themselves are expensive to design, build and maintain.

- *Biosafety Level 4 (BSL-4)* is the highest level of containment, often taking place in a separate building or dedicated zone. These facilities must meet special engineering requirements, including shower in/out facilities, supplied air respirators, and extensive security. There are fewer than 10 BSL-4 labs operational in the United States, according to Global Biolabs, a collaboration of researchers from The Bulletin of the Atomic Scientists, George Mason University, and King's College London.

Biosafety levels are based on a risk assessment of the materials and procedures being used in the facility. The biosafety level describes the amount of containment that is needed to achieve biosafety goals and ensure that biological hazards are handled appropriately and safely. Risk assessments should also be an ongoing process, conducted in the event of any changes to activities at the laboratory and on a regular basis to account for changes in scientific knowledge and laboratory activities. Typically, a biosafety consultant or tenant representative with sufficient biosafety knowledge participates in the risk assessment process.

SAFE FACILITY DESIGN AND PERFORMANCE

Developers can expect to prepare laboratory spaces that achieve BSL-1 and BSL-2 protections. Many of the controls necessary for ensuring safe operation can be designed into these facilities early on. Because today's laboratory environments are often combined with other activities—such as office space, cafeterias, and even retail areas—developers should pay special attention to potential pathways through which people and hazards can travel.

For example, access control is a safety factor that ensures only individuals trained and qualified to handle biological agents have access to laboratory spaces. A security desk or badge access-only space can protect unqualified individuals from gaining access to potential hazards.

Ventilation is another critical safety factor that prevents chemical fumes, infectious agents, and other potential risks from traveling into non-laboratory spaces. Separate ventilation systems prevent individuals in non-laboratory spaces from being exposed to these hazards.

BUILDING COMMISSIONING FOR AS-DESIGNED OPERATION

As mechanical systems are adjusted over time in response to changes in laboratory activities, system performance can veer significantly from its original design intent. When these systems are adjusted repeatedly, the original design performance can be severely compromised. This is where building commissioning can prove invaluable.

Commissioning conducted by an independent third-party provides proof that all building systems are providing the protection expected. This process includes a review of documentation and verification that systems are installed and performing optimally. Commissioning should be performed initially prior to laboratory occupancy as well as at periodic intervals.

An added advantage of building commissioning is that adjusting system performance back in line with as-designed parameters can preserve equipment for longer and lower its energy usage. Moreover, this process can provide evidence to local municipalities and community stakeholders of ongoing safe operation.

COMMUNICATING RISKS TO YOUR COMMUNITY

Property developers exploring opportunities to support the growing Life Science boom will find that there are a host of stakeholder concerns to address. Community meetings are an excellent opportunity to answer questions and provide education around biological risks and associated biosafety oversight. Many community stakeholders want assurance that the Life Science sector is well-regulated at the local, state, and federal level, and that there are processes in place for establishing and maintaining safe operation.

Local Planning Board meetings are another area where it is critical for developers to be able to clearly address plans for biosafety oversight. Prior to securing a permit to build or renovate at the local level, developers can expect to address questions around planned Life Science activities and protections that will be put in place.

Local first responders may also have questions about biosafety oversight. Emergency responders often find it helpful to tour Life Science facilities in order to plan for any future response. Some facilities address these specific risks by making personal protective equipment available for first responders in a safe, predetermined location at the laboratory. Others might conduct mock drills to plan response in the event of a fire or other potential emergency situations.

A qualified biosafety consultant can be a powerful ally when it comes to addressing these different stakeholders. A consultant well versed in biosafety oversight can provide the necessary detail to stakeholder questions and alleviate concerns around potential risks.

HOW TO QUALIFY A BIOSAFETY CONSULTANT

Not all safety consultants have the same level of insight into biosafety oversight and laboratory protections. Before engaging a consultant, developers should evaluate the following factors:

- *Credentials*: Registered Biosafety Professionals (RBP) have specialized training on how to safely control infectious materials in a range of work environments. Certified Biosafety Professionals (CBSP) meet specific educational and biosafety program management experience requirements. These credentials can be obtained through the American Biological Safety Association (ABSA) International after a biosafety professional meets specific criteria for competency, education, and experience. Few professionals in the world hold both of these credentials.
- *Consistent experience*: Because changes in this field happen incredibly fast, it's important to ensure that any biosafety consultant with which you partner has recent experience in this field. A consultant who last performed a Life Science facility audit five or ten years ago may not be up-to-date on all relevant regulatory requirements.
- *Well-rounded knowledge*: Experience does not just come from spending years in the field. It's also important to work with a biosafety consultant who has experience in the specific area of work in which you need support and not only is well-versed in compliance aspects but can also share industry best-practices for biosafety. Not every safety professional has worked in a BSL-3 laboratory or is well-versed across academic labs, industrial labs, and clinical labs.
- *Support services*: If your building isn't operating as expected, can your biosafety consultant identify why the problems are occurring? Do they offer commissioning services that can help pinpoint problems before they emerge? Consider the full range of services that your consultant can offer to both identify and address problems.

CONCLUSION

Life Science companies are highly motivated to ensure safe operations. It's commonly said in this industry that "safe science is good science." When laboratory processes are lax, companies may find it difficult to receive the necessary regulatory approvals, and years of investing in research and development may leave them without any product in the end. As a result, laboratory personnel generally prioritize safety at every stage.

Safety starts with leadership. When leadership shows that safety is a priority, that attitude is embraced by the rest of the organization. By working with a property developer that shares the company's high regard for safe operations, Life Science companies demonstrate their commitment to safety and lay the foundation for a strong safety culture within the organization.

Property developers will find they can easily put protections in place and clearly communicate this safety oversight to community stakeholders when supported by a knowledgeable partner. This is where EH&E seeks to support property developers as a credible resource on biosafety risks, expectations, and best practices. Together, we can support the life-changing work performed by Life Science companies.