

An Ounce of Prevention

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Developing relationships with first responders can help life sciences companies keep manageable incidents from becoming costly disasters.

A small electrical fire breaks out in the middle of the night in the lab of a biotechnology company that is developing a promising new therapeutic drug. The building's smoke detector activates a central station alarm and the nearby fire department responds within eight minutes. The fire is limited to a small area, not big enough to trigger the building's sprinkler system, and is poised to be quickly extinguished. But the firefighters are unfamiliar with the facility and cannot quantify the risk their personnel face by entering the building. Biohazard warning signs lead them to first seek information to quantify those risks. By the time company personnel arrive to explain the facility's operations, 40 minutes have passed and the fire has grown.

When the incident is over, the company's cell cultures have sustained smoke damage and spoilage, which set the company's research and development program back nearly two years. The company loses a seven-figure milestone payment, and more than a year later it still has not fully recovered. What could have been little more than an unfortunate but manageable event has turned into a financial catastrophe.

This scenario, although fictional, is all too real. Although most pharmaceutical and biotechnology companies invite the local fire department to tour their facilities at least once a year, many do not realize that the personnel who make these tours are generally code-enforcement officers—not the fire suppression team—and it won't be the code enforcement officers who respond at 3:00 a.m. That's why life sciences companies need to develop deeper relationships with their local utility companies and fire departments to arm them with the necessary information to respond to emergencies in an expeditious and effective manner.

UNIQUE CHALLENGES

Following a significant adverse event—such as a fire, flood or explosion—a pharmaceutical facility or biotechnology company may be faced with the loss of raw materials and finished product, damage to its physical plant and, in some cases, lost lives. The life sciences industry, however, has its own set of unique challenges. The loss of validation and compliance with regard to good manufacturing, laboratory, and clinical practices is foremost among those issues. Following a significant event, it can take 6 to 18 months before a plant is revalidated and can begin manufacturing product. During that time, the company faces an interruption of research and development activity resulting in the delay of market approvals, the loss of market capitalization as customers or investors flee to companies in more robust health and, often, the interruption of investment income. For small, start-up companies that rely heavily on investors, a marketable product may still be a distant goal. For such companies, missed milestone payments can often spell the end.

Following a fire, flood, power failure, or other event, a life sciences business is not just confronted with sodden walls, carpets, and product. Even when the

water is gone, there are unwanted bio burdens, such as mold and other biological contamination, left behind. Smoke can blacken offices, labs, and storage areas, and it can also kill large numbers of lab animals or damage cell cultures. And a change in environmental controls, such as a loss of refrigeration, can destroy years of research.

WORKING WITH LOCAL FIREFIGHTERS

Firefighters protect life first and property second. It is their job to evaluate danger to employees as well as special hazards to responders. A primary goal of establishing a relationship with your first responders is to provide them with the information necessary to confidently enter your facility. Be sure they understand the actual hazard level in each area. Required hazard warning signs do not always indicate the level of risk. A biosafety level 1 agent presents a fairly low hazard as compared to a highly infectious pathogen. You don't want the fire department to refrain from extinguishing a lab fire for fear of pathogens that are, in fact, a low-risk biological agent such as the common cold.

It is also important to explain the potential effects various perils might have on your operation. For example, for their own safety, firefighters will often request that power to a building be cut. If they are aware, however, that the loss of refrigeration can affect cell cultures or that the loss of power can reduce the pressure gradient in a clean room allowing contaminants in, they can first attempt to cut power to the affected area only. Alternatively, they can make every effort to restore power to critical areas promptly. And instead of removing smoke through the nearest exit, when that exit is through a clean room, firefighters can preidentify alternatives, with those details built into the facility firefighting plan.

Give first responders an overview of operations and familiarize them with what chemical, biological, radiological, or mechanical hazards exist. Take firefighters on a tour of critical production and lab areas, vivariums, and mechanical spaces. Explain your HVAC, water, steam, and smoke-control systems. If possible, provide floor plans for firefighters to keep and

review at the firehouse so they can refresh their memories periodically. Though utility company personnel will work primarily outside the facility during an adverse event, field supervisors should have extensive information about facility electrical and water systems that will help them restore service as soon as possible. The infrastructure of most utilities is owned by the utility company up to the point where it penetrates a building. Therefore, it is also important to work with your power and water companies on preventive maintenance to be sure that in an emergency, when they are most needed, transformers, pumps, and gas and water mains will be in good repair.

First responders should understand your in-house emergency contingency plans and should have contact information for key personnel to get support on site quickly. For firefighters, there is nothing better at 3:00 a.m. than knowing the facility manager is only 10 minutes away, or that there are others to call if the phone in the facility manager's home goes unanswered.

The safety of personnel is paramount to all first responders; they can't help others if their own people are in peril. Accordingly, the local fire suppression team and utility companies should be pleased to receive a call from your facility manager, and you can expect a request for a facility tour to be welcomed as a positive event, not an imposition on their time. A tour should be organized at least once a year, or whenever there are significant changes to your operation, with representatives from each shift who might be called upon to respond. With the fire department, a tour by the actual fire suppression team would supplement the usual tour by code enforcement officers, not replace it.

NEW FACILITIES

Companies that are building new facilities have the opportunity to engage their local fire departments, utility companies, and insurance carriers in plan reviews during the preconstruction phase and get the special support they need from those third parties during construction. From a risk management point of view, the goal in facility design is a high level of compartmentalization

so that critical areas can be isolated from fire, smoke, and contamination, along with proper design of protection systems that will contain adverse events. Particular attention should be paid to smoke control, utility reliability, and utility redundancy, such as back-up generators to ensure uninterrupted power supply.

It's also wise to meet with field supervisors from your utility companies and local fire suppression teams early in the construction phase. They will want you to maintain adequate water supply for fire suppression, and to minimize combustible loading during the critical stage when fire protection systems have yet to be installed. They should also advise you to install and activate those systems as early as possible. Keep in mind that one of the simplest safety measures on a construction site is often the most overlooked—no matter how quick the response to an alarm, if first responders cannot make their way to the building, they cannot put out the fire, control the flood, or restore power. All it takes to keep help from arriving in time to prevent a minor incident from turning into a major one is a muddy, unpaved road into the building site, construction materials partially blocking a road, or a bulldozer left in the wrong place.

Geographic and regional events such as tropical storms or floods are times when fire departments and power companies are stretched thin and competing priorities can lead to a slower response. You should understand that the emergency operator on the phone in the middle of the night when a regional event is already in play is not in a position to make an assessment of your greater level of need. Establish a strong relationship with your first responders now, and be sure that you are permanently near the top of their priority list.

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