

Contingency Planning: Preparation Is the Key to Recovering from Disasters

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ABSTRACT

Businesses in any industry can reel from the repercussions of electrical outages, fires, computer hackers or the ravages of Mother Nature. When such disruptions occur, these companies may be forced to halt operations for days, weeks or even months. These businesses can and do recover, but in some sectors, like biotechnology, business interruptions that result from such events are potentially catastrophic. This article provides an overview of practical items that should be considered by all life science companies as part of contingency planning.

INTRODUCTION

Businesses in any industry can reel from the repercussions of electrical outages, fires, computer hackers or the ravages of Mother Nature. When such disruptions occur, these companies may be forced to halt operations for days, weeks or even months. These businesses can and do recover, but in some sectors, like biotechnology, business interruptions that result from such events are potentially catastrophic.

That's because biotechnology, pharmaceutical and biopharmaceutical operations are particularly sensitive to any disruptions in their operations. For example, even simple changes in temperature and humidity in a laboratory can destroy colonies of microbes or ruin experiments with animals, resulting in potentially ruinous operational delays as replacement colonies or suitable animals are found so that operations can resume. These delays can be exacerbated because of rigorous regulation of the biotechnology industry by governmental agencies at various levels.

Consider, first, that the Food and Drug Administration (FDA) has the final call on when—if ever—these firms can resume operations following a business shutdown due to smoke, fire, flood or some other event. The approval process can take months, maybe even years. The FDA's scrutiny often results in biotechnology firms returning to square one, when they first needed to satisfy applicable facility- and supplier-qualification requirements and, in some cases, perform lengthy validation exercises. If a significant interruption occurs at a start-up company relying on funding from venture capitalists or angel investors who deem the cost of further involvement too risky, the company

may never recover. For larger, more established companies, such an event may prohibit the company from receiving the FDA's approval on time, which can allow competitors to gain the edge to market.

Given these realities, insurance is not enough. Biotechnology companies seeking to survive a disaster or other business shut down should combine their insurance portfolio with an effective disaster-recovery plan that will act like a road map, showing the direction the company will take if a disaster or other business interruption strikes.

A COMMONSENSE APPROACH

Developing a disaster recovery plan is as commonsense as writing a basic business plan—and just as demanding. It requires an intensive, companywide effort, putting on paper all the events that could occur, deciding how to address them, and then determining if the right controls are in place.

Typically, the life cycle of a biotechnology company begins at the virtual, or conceptual, level, moves to the emerging stage, and then progresses to clinical trials and manufacturing. For all four stages in this cycle—as in project management—a whole host of criteria must be met before passage to the next phase. Unfortunately, too many firms neglect to include disaster recovery as one of these criteria at each stage of growth. That is a big mistake. Biotechnology companies would be well advised to integrate disaster recovery into their business development planning, making it a line item throughout their conceptual and operational review process. However, many firms wait until they are up and running, when they have good

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cash flow, to even consider drawing up a contingency plan.

Unfortunately, an interruption can occur at any point during the development process, and a disaster-recovery strategy should exist for each stage of a company's life cycle. Businesses in the midst of research and development spend years conducting chemical or microbiological analyses to identify an agent or compound for use in a potential product. During this process, a master cell line of unique, temperature-sensitive biological material may be developed. If, because of a power failure, the temperature changes significantly, and the materials are destroyed, the R&D disruption could be devastating. It took years to develop the cell line of the material, and it now must be recreated.

Without adequate planning to protect those materials, perhaps duplicating and storing them in another location, a firm could be ruined. Biotech firms are not alone in failing to go the extra mile to secure their business futures. A 2005 AT&T survey conducted by Opinion Research Corp. found that despite the prospect of terrorist attacks or other disasters, business-continuity planning was not a high priority at four in 10 companies surveyed nationwide. Respondents hailed from the services, manufacturing, wholesale and retail trades, financial services, transportation, communications, utilities and construction sectors. "Many companies are placing their confidence in the systems they already have in place or, in effect, crossing their fingers that their companies won't be victims of a disaster that cripples their ability to do business," the report concluded.

GETTING STARTED

How can a biotech company go about formulating a disaster recovery plan? First, it should review its business plan and, in particular, its stated goals. A start-up company, for example, might be trying for initial discovery on a drug to determine its suitability. A robust enterprise in business for 20 or 30 years with manufacturing facilities throughout the world may be aiming to upgrade its operations.

Secondly, critical risk factors must be identified, especially those unique to a particular operation. For example, in a facility where refrigeration is vital for keeping materials cryogenically frozen, a backup power source should be in place in case electricity is temporarily lost.

Then, there is the issue of employee resource management. Employee exposure to biohazards is a huge consideration for insurers writing workers compensation policies for biotech firms. Although insurance can help protect against these risks, these companies have to understand that their own vigilance is important and that vigorous steps must be taken to safeguard their employees. That

being said, employee health and safety is a separate issue from disaster-recovery planning, and employee health and safety efforts should be well coordinated and given its own careful consideration. At a minimum, evacuation procedures must be outlined. They should also maintain a list of key employees who would be needed to help cope with an emergency.

The best way to gather this information is to solicit input from employees at different levels in the company. Disaster-recovery planning should address all facets of the business and not just the financial aspects. Too often, insurance purchasing is thought to be the end-all, be-all solution, and is relegated to a company's chief financial officer, who may have a narrow take on risks. It's vital that this process include the views of operational, regulatory and legal staff who often hold widely varying opinions on its vulnerabilities.

Ideally, biotech companies should aim to identify their top three priorities for disaster recovery in the first two months of the planning process. For example, in the case of firms that store all electronic media on site, a good first step would be to duplicate this information and store it at a remote location.

The recovery plan also has to be integrated into the company's daily operations. There should be significant planning and active testing so that when an event occurs employees are not playing catch up. It's essential that employees undergo training to know their responsibilities and the actions they will need to take in order to help the company survive a disaster and rebound. It can be a disheartening experience for an insurer to question a biotech company's director of research on his knowledge of the particulars of the disaster recovery plan only to have him draw a blank.

Once a recovery plan is in place, it should be reviewed at least once a year. In addition, recovery plans should be adjusted whenever an operational change occurs, such as altering a manufacturing process; installing new equipment; gaining approval for a new drug or device; or acquiring another company. The same AT&T survey found that among companies with business continuation plans, one in four hadn't updated its plan in the past 12 months, and one in four hadn't tested it in the past year—or ever, for that matter.

If a biotech company has been dragging its feet in developing such a plan, pressure from outside forces may speed the process. For one thing, insurers find it difficult to underwrite the business income exposures of a biotechnology company that does not have effective plans in place to recover from a loss. The research and manufacturing operations of biotech companies are easily disrupted and the recovery time is very long. Without an effective recovery

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plan, a biotech company is simply not a good insurance bet. For another, investors increasingly have been requiring biotech firms to develop continuity plans. Venture capital funds naturally balk at throwing \$50 million or \$60 million at a company, not knowing if they have the tools or the programs in place to deliver on their promise if their operations are disrupted.

PREDICTING WORST-CASE SCENARIOS

By the very nature of the products they offer, insurers are attuned to risks. They are accustomed to asking, "What if?" and imagining the worst-case scenarios. But many biotech businesses don't share that vision. Whether a biotech company is a start-up or an established manufacturer, it often doesn't realize the need for comprehensive contingency planning. Some firms honestly believe they will never incur a loss. Others think their insurance will take care of it. But again, insurance without a contingency plan isn't enough. Typically, these clients work in highly engineered, highly protected and very modern facilities. They just can't seem to envision anything more troublesome than a burst pipe, and thus don't let their imaginations wander much beyond contemplating a fairly simple clean-up and recovery exercise for dealing with water damage.

What they don't envision, alas, is the prospect of excessive smoke with contaminants from burning plastics or other materials, an event that can have truly catastrophic consequences. In the worst case, all lab animals would be killed, the city would condemn the facility and ban reentry until it was deemed safe, all utilities would be shut off, and it would be a week or two before any personnel could get into the building. For established companies, the damage or perceived damage to product by the FDA means that all inventories and work in process may have to be destroyed. When such a picture is painted for senior managers at biotech companies, it's often quite an eye opener.

However, even when biotech firms understand the perils, they still harbor some incorrect assumptions. They may figure that suppliers will always be there for them, or that an alternative facility can be found in a reasonable time. But consider this: The tragic 1995 earthquake in Kobe, Japan, also halted production of the integrated circuit chips that many U.S. firms had been purchasing. When a supply chain is interrupted, biotech companies need to have a secondary source that is validated and ready to go. Some organizations will argue that it doesn't make sense financially to validate a second supplier, because they can't promise that supplier the level of inventory or level of orders needed to sustain the business relationship. But this can be extremely short-sighted. It's incumbent on biotech

firms that are beginning their processes to reach out for information and determine sources for other suppliers and other locations.

Although insurers don't play a direct role in drafting disaster recovery plans for their customers, insurers can provide needed guidance, offer best practices recommendations and present some realistic time frames and expectations. From an insurance company's perspective, smoke and fire protection are critical elements in the contingency plan. Sprinklers alone don't preclude a catastrophic loss. There needs to be more, including smoke detection and abatement equipment and evacuation plans for employees and sensitive laboratory items. Remember, by the time that sprinkler system goes off, animals in a vivarium could be long gone because of smoke inhalation or some other cause.

The first line of defense has to be a series of monitoring procedures to protect sensitive items. Having temperature alarms on refrigerators or freezers containing sample material is important, as are alarms gauging heat and humidity in vivariums. Furthermore, these alarms cannot just ring locally on site; they need to transmit the alarm to a listed underwriter's laboratory central station monitoring service. This is a necessary safeguard in case problems occur when no one is on the company grounds to hear the alarms.

Along with temperature monitoring, insurers also expect a biotech company to have a reliable, back-up power source for electrical systems. The same goes for heating and cooling, so that if one compressor unit fails, it does not take out the entire system.

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BACKING UP FILES

Retention of key records is also a major issue for insurers. Many biotech firms, especially start-ups, tend to keep paper, rather than electronic, documents. Companies that cannot recover these records will have difficulty bringing a product to the marketplace. The FDA is not going to approve the product if they cannot provide proof of quality on a product in their manufacturing and development line.


Companies seeking FDA approval end up with five pallet loads of documentation to ship to Washington. In the meantime, they may store it in a warehouse, and if fire breaks out there, they've lost years of research and development on a product that's nearly ready to be approved. It's critical to build in redundancies for documentation, whether the materials relate to animals, cell lines, lab notebooks or financial records. If something happens at location A, they must be able to recover that information for use at location B.

The need for this degree of preparedness was driven home on a national level by the terrorist attacks of 9-11 and their aftermath. However, just three months prior,

several Houston medical research institutions were among the many flood victims devastated by tropical storm Allison, when more than three feet of rain fell over a five-day period. The loss of transgenic mice and other cutting-edge research took a serious toll on the local biotech community. After 9-11, it became all too obvious that companies needed to back up their work and have contingency plans for off-site operations in the event of a calamity. More recently, Hurricanes Rita and Katrina reminded everyone of the importance of backing up work and contingency planning.

SUMMARY

Make no mistake. Disaster recovery planning, if done diligently, is a long-term effort. When companies claim they can accomplish this in a mere two months, they are not taking the mission seriously or may not understand the complexity of the process. Realistically, it's at least an 18-month project.

But once they formulate an effective recovery plan, and regularly review it, biotech companies can rest assured that if an adverse event does occur at a critical facility, they will be ready. Their foresight will have made all the difference between getting operations up and running in the quickest amount of time possible, or disabling—and eventually shuttering—their business. 



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