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Business Continuity in the Life Science Industry

Flooding from tropical Storm Allison results in the loss of 60,000 breast cancer tumor samples, estimated to sets back medical research by at least ten years - Journal of the National Cancer institute [1]

How can you justify the integration of business continuity and crisis management programs into your life science operation? This paper is the first in a series of articles that will explain how business continuity programs can be developed, implemented, and used to manage a life science business crisis.

According to the Federal Emergency Management Agency (FEMA), 25% of businesses do not re-open following a disaster, 43% do not recover following a catastrophic data loss, and 60% of businesses do not have a formal disaster recovery plan in place[2]. While these statistics are based on all business industry segments, the critical nature of life science operations increases the potential for negative outcomes during a crisis.

Did you know that laboratory equipment, biological and chemical repositories, and validated manufacturing operations are significantly more sensitive to impact and resulting interruption than most main street businesses?

Much of the national life science foot print lies in areas of the country that prone to natural disasters, including earthquakes, floods, and coastal storms. In reviewing and prepping clinical trial results for regulatory approval, scientific data availability and integrity are critical to the verification of product quality and safety. To complicate the issue further, data often contains both proprietary business information as well as the private data of customers, medical providers, and trial participants.

The Financial Case

There is a financial justification for business continuity planning. Many small to mid-sized life sciences companies are at the beginning stages of creating science and building accompanying product pipelines. Their business cannot rely on sales revenue to operate or, worse yet, cushion the blow of an operational interruption. The impact of a company's loss of scientific and development property can be financially devastating. Lacking of planning can have the following aftermath:

1. Inefficient acceleration of the company's capital burn rate due to unplanned and inexperienced attempts at recovery.
2. Challenges to developing future funding via grants, collaborations, and angel investments.
3. Loss of key personnel in both scientific and administrative departments.

Established life science companies with approved products and sales-generated revenue are also vulnerable to operational interruptions. These companies tend to have more complex exposures throughout the entire supply chain. Without proper crisis management, a company can quickly

expend any remaining inventory not impacted by the crisis, and then lose their customer base as consumers turn to other brands as a result of supply interruption.

Public companies have the additional obligation to protect shareholders from reasonable operational and cyber security risks. Regulations that create a duty to manage continuity risks and protect electronic and financial records include Sarbanes-Oxley, IRS Procedure 86-19, The Consumer Credit Protection Act Section 2001 1X, and Foreign Corruption Practices Act. Inadequate planning and crisis management could fall under the scrutiny of the regulators.

The Ethical and Reputational Case:

Many life science companies provide novel and unique therapeutics or devices that have no alternatives in the marketplace. If there is a loss of inventory or interruption to the production and distribution chain, the lives of the patients could be severely impacted. For example, a biotechnology firm who provides an orphan drug that treats a life threatening genetic disorder in children could be particularly vulnerable to some sort of disturbance in their production capabilities. What if the product requires the production of very small batch volumes under strict validation and environmental parameters? The lead time to make a replacement lot of product can be several quarters and many firms rely on a third-party contract manufacturer to batch the product. If during the course of the crisis it is discovered that some basic planning and mitigation steps could have prevented the disruption and allowed for inventory capacity until the product could be re-campaigned, the backlash may be swift. These are the kinds of stories that can lead the nightly national news. And if during the crisis there missteps in communications with the public and regulators, the crisis can rapidly escalate.

Food and Drug Administration:

The FDA has been proactive in recognizing the value of business crisis planning and addressing the need for appropriate continuity planning in both their regulations and guidance documents. Some examples of these areas include but are not limited to:

1. FDA C.F.R., 21, Part 11;
2. Guidance for the Industry, Computerized Systems Used in Clinical Trials, Section IX Part B, Contingencies Plans.
3. Guidance for Industry, Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products.

The need for an appropriate business continuity and crisis management planning in the life science space is clear. Looking through a financial, marketplace, and regulatory lens, proactively implementing a plan for your organization far outweighs the potential downside.

In the upcoming articles in the Business Continuity series, we will look at the four cornerstones of business crisis management; planning, hazard mitigation, crisis response, and crisis communication; and recovery.

Christopher Dorko has over 20 years of experience in life sciences risk management working in the property and casualty insurance, pharmaceutical development and preparation, and medical device research and production industries. He began his career working for Ethicon, Inc., a Johnson and Johnson company, and then moved to Barr Pharmaceuticals. With both companies Mr. Dorko's responsibilities included site engineering, workplace safety, facility protection, loss prevention, and compliance. Prior to joining Berkley Life Sciences he was a Senior Life Sciences Loss Control Specialist with Chubb where he performed multi-line exposure analysis and client risk services for a large and highly diverse life sciences book of business.

Mr. Dorko has been active in training underwriting and loss control staff in specific exposure identification and mitigation, developing and supporting engineering and underwriting exposure management guidelines, and providing risk management consultation to clients and brokers. He has extensive experience in loss mitigation for critical industry specific operations including research facilities, biologics storage, bio-pharmaceutical, and process flow continuity planning. Mr. Dorko has authored several articles on life science facility loss prevention and disaster recovery planning, and he is a Professional Firefighter in New Jersey. He has a Bachelor's of Science degree from Rutgers University and a Master's of Science degree from New Jersey Institute of Technology.

[1] Bankhead, Charles (n,d,), Tropical Storm Sets Back Research in Houston, Journal of the National Cancer Institute, Vol 93, Issue 18 (pp 1366-1367), https://academic.oup.com/jnci/article/93/18/1366/2519516

[2] Minard, Derik (n.d.), Small Business Continuity Planning Integrated with Fire Department Pre-plans, United State Fire Adminstration, Federal Emergency Management Associations, https://www.usfa.fema.gov/pdf/efop/efo47103.pdf