

BIOTECHNOLOGY, PHARMACEUTICAL AND LIFE SCIENCES CLUSTER

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Overview

Companies in the Biotechnology, Pharmaceutical, and Life Sciences Cluster in New Jersey felt the effects of Hurricane Sandy directly, through their supply chains, and interruptions in production and transportation due to infrastructure issues. Businesses in this Cluster generally fall under three main categories:¹

- Pharmaceuticals
- Biotechnology
- Medical Devices

Business Continuity Overview for the Biotechnology, Pharmaceutical and Life Sciences Cluster

Business Continuity is the creation of a plan to resume critical business processes after a disruption. Having a plan in place before a disruption, and practicing the plan, will enable a business to resume critical processes much more swiftly, efficiently and cost-effectively than an improvised

response. According to FEMA, 75 percent of businesses that do not have BCPs fail within three years of a natural disaster.² Encouraging suppliers to demonstrate their continuity capabilities can also be a competitive requirement for future business – to provide more confidence in the suppliers’

¹<http://nj.gov/state/bac/pdf/2013-win-bio-life-Sci.pdf>

²<http://www.usfa.fema.gov/pdf/efop/efo47103.pdf>

Business Continuity Overview continued:

capacity to deliver on their orders. Integrating continuity planning up and down the supply chain can help identify efficiencies in “peace time” and build surety in production during disruption.

The level of interdependence of the transportation infrastructure and the supply chains of goods and services that these industries rely on can affect both the companies themselves, and the people who rely on the drugs and devices this cluster produces. Suppliers are strategic partners for these companies, and the selection of vendors to support the supply chain management model is critical. As such, companies in this cluster should attempt to ensure those suppliers have a business continuity plan in place. Companies in this cluster often manufacture products that are time and/or temperature sensitive, and failure or expiration of these products could

jeopardize the mobility, health, or even lives of those depending on them.

It is important to remember that whatever the level of operational efficiency achieved, should any link in a BP&LS company’s supply chain break it will likely wreak havoc on the entire operation of those companies. Remote suppliers, original design manufacturers and key vendors should have the same level of business continuity preparedness that the dependent company maintains internally. Companies should work with both their vendors and clients to craft the supplier’s timeline for recovery, including the ability to recover production volumes within a reasonable timeframe. More information on developing BCP for life sciences industries can be found at <http://www.bio.org/search/node/disaster?page=2>.

Establish a Supply Chain Risk Management System³

A leading disaster risk management strategy is for companies to more closely collaborate with suppliers. Risk management practices should be embedded into all mission-critical points along the supply chain. The process should be a continuous engagement with the supply chain process for ongoing assessment of the constantly changing supply chain environment.

The three key objectives of an effective supply chain risk management strategy in the Biotechnology, Pharmaceuticals, and Life Sciences Cluster are:

- Identifying and prioritizing critical business elements
- Mapping the entire supply chain to show interdependencies
- Identifying potential failure points along the supply chain

³<http://www.automationworld.com/energy-management/automation-tools-managing-supply-chain-risk>

**Common risks and potential actions to reduce those risks for
Advanced Manufacturing companies are identified below:**

Risk	Potential Protective action
Denial of access to facilities	<ul style="list-style-type: none"> • Continuously update status on social media sites, website, and the press to let customers and employees know the current status and plans to get running, find temporary space if needed. • Work with local emergency management to participate in any available re-entry programs.
Loss of critical supplier capacity to complete orders	<ul style="list-style-type: none"> • Establish hard copy and electronic contact lists of primary and alternate suppliers (and competitors). • Establish contingency contracts with alternative suppliers in disparate locations.
Denial of access to key information systems (e.g. computer systems, databases)	<ul style="list-style-type: none"> • Establish robust off-site data replication of key information systems and databases • Acquire alternative communication methods to support technology and transaction requirements. • Integrate remote access into operations whenever possible. Ability to work from home for employees could decrease staffing problems during/after a disaster. • Utilize cloud technology to store critical data remotely.
Lack of communication to suppliers and vendors	<ul style="list-style-type: none"> • Keep status of business updated on social media and the business' website; inform both suppliers and customers that the business survived the event. Reach out via email blasts. • Reach out to current customers via email blasts and courtesy calls (if possible). If the location is no longer accessible, search for a temporary location nearby and publicize that address. • Consider using more than one telephone provider, again in separate locations • Multiple redundant services and especially proximity of vendors to the area are critical for this cluster.
Vandalism and/or theft	<ul style="list-style-type: none"> • Develop plans with local law enforcement and emergency management to maintain security during a prolonged absence. • Invest in remotely accessed security and surveillance equipment.
Physical damage	<ul style="list-style-type: none"> • Develop contact lists of construction contractors, roofers, plumbers, landlords, building management etc. who can reliably respond to physical damage.
Disruption of customers operations	<ul style="list-style-type: none"> • Work with customers and suppliers to understand their continuity plans to appropriately set expectations for when and how those key links will be restored.

More information on business continuity can be found at these sources:

- [FEMA Preparedness for Businesses](#)
- [SBA Disaster Planning](#)
- [FEMA: Ready.gov](#)
- [Red Cross Ready Rating](#)
- [Institute for Business and Home Safety](#)

Many businesses will likely need a more complex BCP; examples of such BCPs can be found in the following links:

- [IBHS Decision Track](#)
- [IBHS Advanced Tack Resources](#)
- [IBHS Supply Chain](#)
- [IBHS Logistics](#)
- [IBHS Incident Management and Crisis Communication](#)
- [IBHS Vulnerability Assessment](#)
- [IBHS Financial Controls and Resiliency](#)
- [IBHS Employee Awareness, Training, and Exercises](#)

A reliable Business Continuity Plan (BCP) should be developed using a systematic, orderly approach. The questions below include processes any BCP should address.

Key Questions	How to proceed
What are our most critical processes?	Think of processes that are customer-facing, employee-facing or facilitate cash-flow.
Who performs these processes?	Create an employee call tree or employee accountability and notification system.
What do they need to perform these processes?	Create a list of critical tools, supplies, data sources, etc.
Where can the people who perform our critical processes work if our business-as-usual facility is unavailable?	If possible enable employees to work from home, put in place an agreement with similar businesses to reciprocally provide emergency workspace, create a list of local realtors who have appropriate space to lease.
How well do you and your employees know your plan?	Have all involved walk through the steps of the plan in a tabletop exercise. Identify gaps in the plan and fix them. Document fixes. Do this annually and this basic plan will be kept up-to-date and will improve over time.

Hazard Mitigation for the Biotechnology, Pharmaceuticals and Life Sciences Industry Cluster

Hazard Mitigation is the assessment of the hazards that are most likely to strike a particular business type or location, and the creation of a plan to lessen the effect of those hazards before they strike⁴. The most common example of hazard mitigation is a fire alarm: the vast majority of all construction is vulnerable to fire, and advance warning of a fire hugely diminishes the risk of loss of life or property.

Each business should plan for the hazards they are most likely to face for example, a business in the Midwest is not likely to experience storm surge from a hurricane, so hurricane mitigation should be a lesser priority. Hazard mitigation is distinct from business continuity planning; hazard mitigation activities are undertaken before a disruption to physically reduce the effect or damage on the business. Hazard mitigation tools and resources are available from the following link to [FEMA](http://www.fema.gov).

Examples of Potential Hazards	Examples of Mitigation Actions
Flooding	<ul style="list-style-type: none"> • Build with flood damage resistant materials: http://www.fema.gov/media-library-data/20130726-1503-20490-6330/fema15.pdf • Raise electrical system components: http://www.ready.gov/floods • Anchor fuel tanks • Install sewer backflow valves • Elevate buildings in low lying areas • Consider utilizing the National Flood Insurance Program (NFIP): http://www.fema.gov/national-flood-insurance-program
Loss of Power	<ul style="list-style-type: none"> • Invest in and regularly test an emergency generator: http://www.emd.wa.gov/preparedness/GeneratorSafety.shtml • Have battery-operated light sources on hand, keep stock of batteries: http://www.ready.gov/blackouts • Invest in an Uninterruptible Power Supply (UPS): http://www.energystar.gov/index.cfm?c=new_specs.uninterruptible_power_supplies, http://en.wikipedia.org/wiki/Uninterruptible_power_supply • Plug computer and electronic equipment into surge protectors: http://www.disastersafety.org/blog/surge-protector-and-power-strip-know-the-important-difference/ • Unplug any sensitive electronic equipment in advance of severe storms

⁴<http://www.fema.gov/what-mitigation/federal-insurance-mitigation-administration>

Hazard Mitigation continued:

Examples of Potential Hazards	Examples of Mitigation Actions
Strong Winds	<ul style="list-style-type: none"> • Utilize Exterior Insulation and Finish System (EIFS): http://www.fema.gov/media-library-data/20130726-1627-20490-4852/how2027_eifs_walls_4_11.pdf • Elevate items in house/business that could flood; bring in items from outdoors that could become projectiles: http://www.ready.gov/severe-weather • Protect windows and doors with covers: http://www.ohsep.louisiana.gov/factsheets/avoidingwinddamage.pdf • Reinforce or replace garage/loading doors • Secure metal siding and metal roofs • Secure built-up and single-ply roofs • Secure composition shingle roofs • Brace gable end roof framing
Fire	<ul style="list-style-type: none"> • Eliminate electrical outlet overloads: http://www.usfa.fema.gov/citizens/home_fire_prev/ • Test smoke detectors regularly: http://www.ready.gov/fires • Replace long-term use of extension cords with permanent wiring • Replace broken or frayed electrical cords • All employees now how and where to shut off electrical power • Separate incompatible materials (flammables and corrosives): http://www.lbl.gov/ehs/chsp/html/storage.shtml • Keep flammables in approved safety containers: https://www.osha.gov/dte/library/flammable_liquids/flammable_liquids.html • Use flammable liquids only in well-ventilated areas
Hazardous Materials	<ul style="list-style-type: none"> • Implement plans for special handling procedures in the event of power loss • Implement protocol for securing materials, such as drugs or drug ingredients, that may be subject to abuse https://www.usfa.fema.gov/nfa/coffee-break/hazmat.shtm

Insurance Considerations Specific to the Biotechnology, Pharmaceuticals and Life Sciences Industry Cluster

Businesses in this cluster can purchase bundled coverage, like the Commercial Package Policy (CPP). The CPP combines Commercial Liability and Commercial Property and some additional policies designed for industries within the cluster. An example may be liability insurance for a medical device manufacturer in the case of a recall. Another type is the Commercial Package Policy, which provides both property and liability coverage but has more flexibility to tailor the insurance coverage to the specific needs of a specific type of business.

Commercial Property Insurance will provide coverage for any building owned or leased, including improvements and permanent fixtures and equipment, business property on premises and personal property of others in the 'care, custody or control' of the company.

BP&LS Industry Cluster business may want to undertake the following steps to assure that insurance coverage is adequate for disaster:

- Evaluate the sufficiency of insurance coverage for physical and financial losses. Consider as well the limitations of the liability insurance policies in situations where lack of production may incur liability due to consequences to patients and healthcare providers.
- Even if the business purchases business interruption coverage, it should allow for sufficient funds for the business to operate

Common Questions to Ask an Insurance Provider

Firms should have an annual insurance policy review with their providers. Included below are some common questions to ask during those reviews:

1. Which perils are or are not covered under the current policy?
2. What insurance regulation changes are coming in the next year?
3. What increases in coverage should be considered?
4. What is the provider's biggest concern with current insurance coverage?
5. Are there any additional options?
6. Are there any incentives or benefits available to businesses that have undertaken mitigation or continuity activities?

Questions Specific to the Biotechnology, Pharmaceutical, and Life Sciences Cluster to ask an Insurance Provider

The following questions are specific to the Biotechnology, Pharmaceutical, and Life Sciences Industry and should be asked during an annual (or more frequent if circumstances change) insurance policy review:

1. Is coverage available to offset the costs of finding, transporting, and/or communicating key staff members, particularly those with unique skills?
2. Does coverage include very specialized or customized equipment and fixtures?
3. Can financial risk due to supplier interruption be covered?
4. Is there provision or financial risk instrument available for liabilities that may result from lack of production of a critical drug or device due to the effects of a disaster?

for the first few days. Interruption coverage is not activated for a specified time period after a disrupting incident occurs. The time period will be listed in the policy.⁵

- It should also be noted that perils not covered under the policy will not be covered in the event these same perils occur. For example, if wind is not a covered peril, any business interruption caused by wind will not be covered. Companies should check with their insurance provider on how to get specific perils covered by insurance.
- Adequate coverage should be requested for products in development, including new formulas and chemical compounds that are damaged or destroyed in disasters.
- Liability for employees injured by exposure to specific chemicals, other materials, and/or equipment in disaster should be covered
- Liability caused by disruptions to supply chains for both raw materials and finished products should be addressed either directly with the insurer or through supplier coverage
- Delays in discoveries of new drugs or devices due to disaster should be covered.
- The National Flood Insurance Program (NFIP)⁶ was created by Congress in response to increasing costs of floods, primarily due to disasters. At the time NFIP was enacted, flood insurance was not readily available or affordable through the private insurance market. Congress agreed to subsidize the cost of the insurance so premiums would be affordable. NFIP was recently changed, and the following links provide critical information on the program and those changes.
- [Flood Insurance Issues in Recovery](#)
- [National Flood Insurance Program and Reforms](#)
- [National Flood Insurance Program](#)
- [Building Higher](#)

⁵ http://www.insureuonline.org/smallbusiness/topic_bus_prop_liability.htm#tips_prop

⁶ <http://www.fema.gov/national-flood-insurance-program>