Business Continuity for Biopharmaceutical Companies

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Business Continuity Planning is working out how to stay in business in the event of a disaster.

Business continuity is the activity performed by an organization to ensure that critical business functions will be available to customers, suppliers, regulators, and other entities that must have access to those functions.
Topics Covered

• What is Business Continuity Planning
• Planning Process
• Business Continuity in Biopharmaceutical Industry
• Why is it more important now?
• Key Considerations for Bio-Pharmaceutical Industry
• Typical Solutions
Business Continuity Planning
Why Business Continuity Planning?

• Businesses are affected by many external variables
• Business Interruptions
  – Cause Loss of Products
  – Delay in New Product Launching
  – Loss of Revenue & Profit (Financial)
  – Tarnished Brand Image
  – Loss of Reputation
  – Loss of Clients
  – Can cause product shortages of products that are of national or military importance, etc.
The creation of a strategy through the recognition of threats and risks facing a company, with an eye to ensure that personnel and assets are protected and able to function in the event of a disaster.

**Business Continuity Plan (BCP)** involves defining potential risks, determining how those risks will affect operations, implementing safeguards and procedures designed to mitigate those risks, testing those procedures to ensure that they work, and periodically reviewing the process to make sure that it is up to date.
Business Continuity Plan

- Plan is individualized for each area
- Activities that would need to occur during and after a disaster
- Identification of Roles during a disaster
- Assures that business continues despite major disruption in operations
Planning Cycle

Quarterly Review Plan Creation

Quarterly Update

Analysis

Maintenance

Drills

Testing & acceptance

Solution design

Business continuity planning lifecycle

Education & Training

Implementation

Plan Creation
Continuity Planning

Goal:

Define, develop, and implement plans that will allow your ORGANIZATION to:

1. Prevent disruption from occurring or,

2. If disruption does occur, continue to operate following disruption and

3. Recover in rapid and efficient manner.
<table>
<thead>
<tr>
<th>Business Impact Analysis</th>
<th>Recovery Strategies</th>
<th>Plan Development</th>
<th>Testing &amp; Exercises</th>
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</thead>
<tbody>
<tr>
<td>• Develop questionnaire</td>
<td>• Identify and</td>
<td>• Develop plan</td>
<td>• Develop testing,</td>
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<td>• Complete the BIA</td>
<td>document resource</td>
<td>framework</td>
<td>exercise and</td>
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<tr>
<td>• Receive completed</td>
<td>requirements based</td>
<td>• Organize</td>
<td>maintenance</td>
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<td>BIA questionnaire</td>
<td>on BIAs</td>
<td>recovery teams</td>
<td>requirements</td>
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<td>forms</td>
<td>• Conduct gap</td>
<td>• Develop Relocation</td>
<td>• Conduct training</td>
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<td>• Review BIA</td>
<td>analysis to</td>
<td>Plans</td>
<td>for business</td>
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<tr>
<td>questionnaires</td>
<td>determine gaps</td>
<td>• Write business</td>
<td>continuity team</td>
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<td>• Conduct follow-up</td>
<td>between recovery</td>
<td>continuity and IT</td>
<td>• Conduct orientation</td>
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<tr>
<td>interviews to validate</td>
<td>requirements and</td>
<td>disaster recovery</td>
<td>exercises</td>
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<tr>
<td>information and fill</td>
<td>current capabilities</td>
<td>procedures</td>
<td>• Conduct testing</td>
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<td>any gaps</td>
<td>• Explore recovery</td>
<td>• Document manual</td>
<td>and document</td>
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<tr>
<td></td>
<td>strategy options</td>
<td>workarounds</td>
<td>test results</td>
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<tr>
<td></td>
<td>• Select recovery</td>
<td>• Assemble plan;</td>
<td>• Update BCP to</td>
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<td></td>
<td>strategies with</td>
<td>validate; gain</td>
<td>incorporate lessons</td>
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<td></td>
<td>management</td>
<td>management</td>
<td>learned from testing</td>
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<td>approval</td>
<td>approval</td>
<td>and exercises</td>
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<tr>
<td></td>
<td>• Implement</td>
<td></td>
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</tr>
<tr>
<td></td>
<td>strategies</td>
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</table>
Basic Planning Elements

Hazards | Consequences | Vulnerabilities

Risk Analysis

Planning | Resources

Emergency Operations Plan
Mitigation Strategies
What is Different in Bio-Pharmaceutical?

- Highly Regulated Industry
- Global & Complex Supply Chain
- Regulations Vary in Different Countries
- Quality is Extremely Important: Could be Fatal
- Cost of Branded Products are very high: Government Pressure on Pricing
- Political Pressures
- Products Save Lives: Continual Supply is Essential
- Cold Chain
Pharmaceutical Business Processes

**Product Creation**
1. Discovery  
2. Development

**Demand Creation**
3. Launch  
4. Sales and Marketing

**Order Fulfillment**
5. Supply  
6. Manufacturing  
7. Logistics
Causes of Business Interruptions Bio-Pharmaceutical Industry

- Natural Disasters: Flood, Storm, Earthquake, Fire, etc.
- Regulatory Issues (Warning Letters, etc.)
- Product (Medicine) Quality Issues
- Global Manufacturing Sites
- Global Supply Chain
- Political Situations; Unrest in Various Countries
- Terrorism
- Pandemic Outbreak
- Data Integrity/Hacking
- Counterfeits
Why are we Talking About it?

• Seems to have more frequent havoc created by natural disasters
• Global Business: Global Consumers; Global Supply Chains
• More Pandemic Outbreaks
• Heightened Regulatory Scrutiny
• Changing Global Regulations
• Complex Supply Chains from all parts of the world
• Economic Pressure on the Industry: Cost Based Decisions
REGULATORY & QUALITY INTERRUPTIONS
Quality & Regulatory

- Global Regulations: Still not Harmonized
- Consent Decrees & 483 Regulatory Warnings
- Very Costly
- Disruptions in Manufacturing
- Drug Shortages
- Reputations/Brand Images
- Why does it happen?
- Solutions: Outsourcing; Remedies/Fixing

- **Space between 483 & Consent Decree:** Why can’t we do better?
So, Where are we today?

*Business Interruptions are Pervasive.........*

“Company A says Temporary Production glitch Affecting Supplies”
Fierce Pharma Manufacturing  l  May 3, 2012

“Obama to order new FDA Action on Drug Shortages”
October 31, 2011

“Company B halts production of two drugs”
Bloomberg News  l  June 17, 2009

“FDA Places Import Alert on Two Company C Facilities”
In-Pharmatechnologist.com  l  Sept. 9, 2009

“Doctors Decry Lack of Company D Vaccine”
Newark Star-Ledger  l  May 30, 2004
So, Where are we today?

Customers can’t always get the Products they need ..........

“Company E pulls OTC Meds made at Troubled Plant”
   Jan 9, 2012

“Company F can’t say when crucial cancer drug will be available”
   FiercePharma Manufacturing  l  Feb 12, 2012

“...... shortage drags on, with Company G Execs. citing Limited Options
   Nov. 11, 2011

"Company H Drug Shortages leaves users feeling betrayed
   NY Times  l  April 16, 2010
So, Where are we today?

*Resulting in Higher Costs ..........*

“Company I Remediation Drags on longer than expected”
FiercePharma Manufacturing  l April 25, 2012

“Company J Lengthens Remediation Timeline”
FiercePharma Manufacturing  l Jan. 2, 2012

“Company K Lays off 300 at ..... Plant”
Ambler Gazette  l July 16, 2010

“The War Over .... – Company L Quality Problems lead to Market Chaos”
Expert Briefings.com  l May 5, 2011

" Production Quality Control Issues Drag on Company M Q1 Sales”
In-Pharma Technologist.com  l May 21, 2011
INTERRUPTIONS DUE TO NATURAL DISASTER
Examples of Natural Disaster

- Long Term Preclinical Study interrupted could set back product launch in terms of years. Loss could be in terms of billions of $.
- Power Outage due to high wind or big storm stops manufacturing products.
- Natural Disaster in a remote location or a country not capable to deal with a disaster or not having a Quick Disaster Recovery plan can cause severe supply chain interruptions.
- Vaccines were lost due to extended power outage and the cold storage lost its temperature control.
Countermeasures

• Reliability Analysis
• Impact Analysis
• Site Locations susceptible to Natural Disasters
• Identification of Critical Systems, Equipment, Components
• Redundancy of Sites, Systems, Equipment
SUPPLY CHAIN INTERRUPTIONS
Key Elements of the Pharmaceutical Supply Chain

1. Suppliers
   - Active Pharmaceutical Ingredients (API’s)
   - Inactive Ingredients (i.e. excipients)
   - Production Aids (i.e. Filtration)

2. Manufacturing
   - API’s
   - Dosage Form
   - Large Molecules (Biotech & Vaccine)

3. Quality Assurance
   - Standards and Audits
   - Lot Release

4. Logistics
   - Warehousing
   - Product Delivery to Customer
The *Evolution* of the Pharmaceutical Supply Chain

2000 to 2012

<table>
<thead>
<tr>
<th>Global Dosage Form Manufacturing</th>
<th>Costs Reduced</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increased Use of CMO</td>
<td>Outsourced Products Managed More Consistently</td>
</tr>
<tr>
<td>External Supply Departments Established</td>
<td>Customer Service Continues to Decline</td>
</tr>
<tr>
<td>API’s Outsourced from Challenging Locations</td>
<td>M&amp;A Continues at a High Rate</td>
</tr>
<tr>
<td>Huge Focus on Consolidation</td>
<td>“Specialty” Pharma Companies Mature</td>
</tr>
<tr>
<td>Greater Regulatory Scrutiny</td>
<td>Regulatory Actions Rise Exponentially</td>
</tr>
<tr>
<td>Operational Improvement Programs</td>
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</tbody>
</table>
Supply Chain Today

• Very Complex
• More Outsourcing: API; Excipient; CMO; CRO
• Global Suppliers:
  – Political Instability
  – Varying Regulatory Requirements of different countries
  – Varying Reliability
  – Varying Quality Systems
  – Varying Culture
  – Varying BCP
• Cost Pressure: Cost versus Quality Sourcing
• Increased Stringent Regulatory Inspections
• Reliability of Cold Chain
Example of Solutions

- **Natural Disasters**: Proactive Planning; Reliability Analysis; Redundancies

- **Supply Chain Issues**: Contract Manufacturing; Partnering; Sourcing from Stable Countries; Reputable CMOs (Due Diligence)

- **Regulatory Issues**: Proactive Regulatory Reviews/Audits; SOP versus Culture; Global Regulations; Quality Group; Cost vs. Quality
Special Considerations for Biologics Plants
Conclusion

- Business Risk Management: Follow the Right Process
- Specific Risks in Bio-Pharma Industry: **Supply Chain**; Global Regulations; Quality of Product
- Develop Business Continuity Strategy: *Be Proactive*
- Rapid Reaction & Recovery Strategy
- Have proper Disaster Recovery Team with Clear Responsibilities
- Training & Testing
- Facility Design Considerations (site selection etc.)
- Analyze, Plan, Team, Train
Those who cannot learn from history are doomed to repeat it.
-George Santayana

- Companies can no longer say they can’t imagine what could happen – because it just did.
  - Or an earthquake, or a tsunami, or a terrorist attack, or an accident, or a pandemic
- Next time, you may not be watching it on CNN – you may be living it
- Now is the time to think, plan, and take action – later it will be too late