



BUSINESS CONTINUITY PLAN



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1.0 INTRODUCTION

BioSpectra is a US based manufacturer of Active Pharmaceutical Ingredients, Excipients and Process Chemicals manufactured in accordance with current Good Manufacturing Practices. BioSpectra’s manufacturing facilities are located in Bangor, Pennsylvania and Stroudsburg, Pennsylvania. Critical Business Functions at BioSpectra include Operations, Manufacturing, Quality Unit, Laboratory Controls, Supply Chain Management, and associated administration. This Business Continuity Plan (BCP) will be used for the evaluation of key areas necessary for the successful continuity of operations and will focus on the following:

Crisis Management

Disaster Recovery

Business Resumption



The goal of this BCP is to provide a guide to ensure that BioSpectra’s Critical Business Functions continue during a time of crisis, emergency, or disaster. This BCP will provide reference to procedures for the immediate response to an emergency, the necessary means to provide notification of a major event, and the steps for the most timely restoration of data and resumption of business functions.

2.0 ACRONYMS AND DEFINITIONS

ACRONYMS:

- BCP –Business Continuity Plan
- BRP – Business Resumption Plan
- cGMP – current Good Manufacturing Practices
- CMP – Crisis Management Plan
- DRP – Disaster Recovery Plan
- EAP – Emergency Action Plan
- PPC – Preparedness, Prevention and Contingency Plan



DEFINITIONS:

- **Business Resumption Plan:** This resumption plan details the specific steps necessary to enable the critical business functions.
- **Crisis:** A major event due to an emergency or disaster that causes business disruption requiring the execution of an impact assessment to ensure critical business decisions are made accordingly.
- **Crisis Management:** The process by which BioSpectra deals with a disruptive and unexpected event that threatens to harm the Critical Business Functions.
- **Crisis Communication Plan:** A policy driven approach for providing information to BioSpectra's Business Partners, Customers, Suppliers, and Staff as related to a major event due to an emergency or disaster that causes business interruption.
- **Critical Business Functions:** BioSpectra's Organization, Staff, and Business Partners that compose BioSpectra's Operations, Manufacturing, Quality Unit, Laboratory Controls, Supply Chain, and associated administration.
- **Disaster Recovery Plan:** The documented process or set of procedures established by BioSpectra to protect and recover BioSpectra's Information Technology Infrastructure to enable resumption of Critical Business Functions.
- **Emergency:** An actual or impending situation that may cause injury, destruction of property or disruption of business operations to such an extent it poses a threat and requires immediate action.
- **Incident:** An event that may be, or may lead to, a business interruption or disruption, loss and/or crisis.

3.0 REFERENCES

- Preparedness, Prevention and Contingency Plan (PPC Plan)
- Bangor Emergency Action Plan
- Information Technology Security
- Stroudsburg Emergency Action Plan
- Process Specific Emergency Procedures
- Process/System Failure Modes Effects Analysis
- Bangor Emergency Telephone Numbers



- Stroudsburg Emergency Telephone Numbers
- BioSpectra Bangor Site Quality Overview
- BioSpectra Stroudsburg Site Quality Overview
- Business Impact and Risk Assessment Form

4.0 PURPOSE

The purpose of this Business Continuity Plan (BCP) is to maintain Critical Business Functions during a time of crisis, emergency, or disaster.

5.0 SCOPE

This plan applies to any BioSpectra facility and will be enacted only for the purpose of continued business activity in the event of a crisis, emergency, or disaster. This plan will be applicable to the necessary measures to be taken in response to a crisis, emergency or incident that may threaten major business disruption defined as the following:

- Loss of Buildings and Facilities
- Loss of Equipment
- Loss of Utilities
- Loss of Supply Chain
- Loss of Records and Reports
- Loss of Manufacturing
- Loss of Laboratory Controls

6.0 CONSIDERATIONS

The business continuity plan will be utilized in the case of major business disruption. BioSpectra has prepared for events in which there is a minimal disruption or interruption to systems, utilities or equipment. This includes the following:

- A spare parts list of process tools and select equipment
- Supply chain security through, alternate suppliers, established inventory levels and secondary warehousing.
- Generator for each facility for critical equipment and instrumentation.
- The main water supply and sewage services may be interrupted with service from the alternate BioSpectra Facility and approved service provider.



- BioSpectra has Data back-up and recovery systems to ensure data access through VPN. In the event of a partial failure of a server, BioSpectra could experience a server outage of up to 4 hours based on an approved third-party service provider agreement. During that four-hour period, the IT Department will follow the IT Security Procedure to minimize operational down time.
- If the server suite in the Bangor Facility were to be completely lost, a secondary back-up server in the Stroudsburg facility will be activated to minimize disruption. BioSpectra's operational facilities are connected by direct, dedicated fiber optic communication lines.
- Availability of internal telephone communication may fail and there could be a loss of service. However, BioSpectra's phone system allows for direct transfer to mobile communication.
- In the case of a major incident the existing buildings and facilities could be out of use for multiple days. Contract customers are protected with safety stock in accordance with approved agreements.

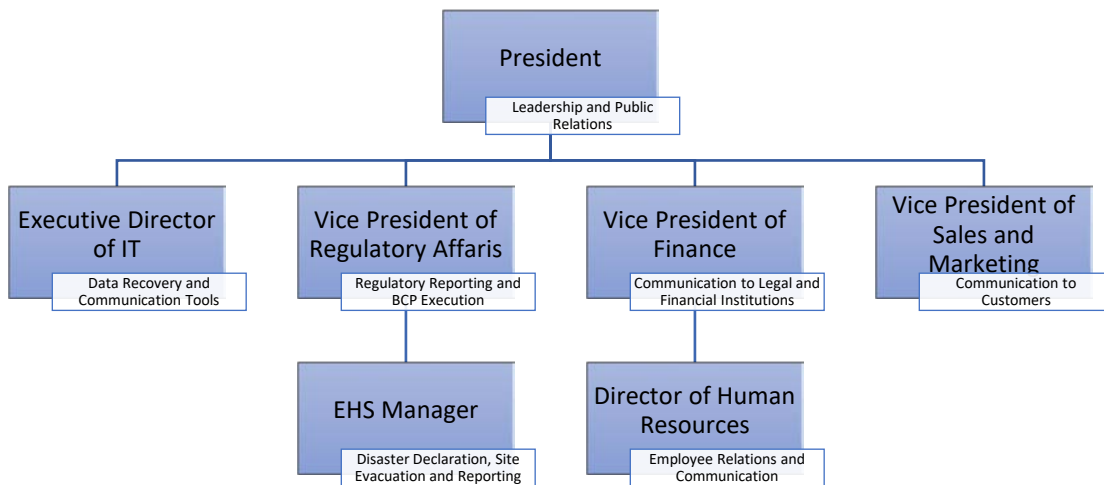
If an incident or event causes disruption beyond the listed considerations, BioSpectra will enact the business continuity plan and will document the events using the tools established within the plan.

7.0 RESPONSIBILITIES

- It is the responsibility of the Vice President of Regulatory Affairs to ensure this plan is current and the appropriate training on this plan is conducted.
- It is the responsibility of each respective department leader to ensure the necessary actions or references mentioned in this plan are enforceable, achievable, and attainable.
- It is the responsibility of the Environmental, Health and Safety Manager to ensure that each site specific EAP, the PPC and the Site-Specific Emergency Telephone Numbers are current.
- Crisis Control Members:
 - President
 - Leadership and Public Relations
 - Vice President of Finance
 - Communication to Legal and Financial Institutions/Insurance
 - Vice President of Sales and Marketing
 - Customer Communication



- Vice President of Regulatory Affairs
 - Regulatory Reporting and BCP Execution
- Executive Director of IT
 - Data Recovery and Communication Tools
- Director of Human Resources
 - Employee Relations and Communication
- Environmental, Health and Safety Manager
 - Disaster Declarations and Evacuation of Site, Site Specific EAPs and Incident Reporting





8.0 STAGES OF BUSINESS CONTINUITY

8.1 Stage 1: Crisis Management



- The Crisis Management Plan is established as a response plan to a current environmental or Electronic/Digital crisis.
 - The Site-Specific Emergency Action Plan will define the action plan to respond to an immediate environmental crisis.
 - When this occurs, the steps that will be followed will be based on the approved process emergency procedures, and at the direction of the Emergency response team and local emergency responders.
 - The Information Technology Security Procedure provides the means for Crisis Management and response to electronic/digital crisis management.
 - The IT department will initiate the approved internal procedures necessary for the rectification of the crisis and establish the action plan for data recovery.
 - Crisis Management outside the scope of internal documented procedures that occur due to natural disasters or global events will require adherence to the applicable government enforced policies.
 - The policies will be reviewed by the Crisis Control Members and internal plans will be established as necessary by law.
 - If business disruption occurs, Crisis Control Members will communicate the Crisis event to BioSpectra’s Business Partners, Customers, Suppliers, and Staff in accordance with applicable policies and agreements using the available communication tools such as approved memos via email, phone messaging or documented posting.



8.1.1 Crisis Management Communication

- Communication for Employees
 - The employee call list will be established and maintained by the Human Resource (HR) department.
 - An employee communication email list will be established and maintained by the HR department.
 - Stakeholder communication will be maintained by Crisis Control Members and provided to the HR department for use as directed.
 - A quarterly evaluation of each contact list will be conducted by the Crisis Control Members to ensure the list is current.

8.2 Stage 2: Disaster Recovery Plan

- BioSpectra's Disaster Recovery will be performed in multiple phases, specific to the Crisis Event and based on the requirements of the applicable procedures or guidelines for Crisis response.

8.2.1 Disaster Recovery Phase 1 (Containment)

- The first phase of Disaster Recovery will be containment.
 - During this phase, any areas of the BioSpectra buildings and facilities will be contained in accordance with approved internal procedures or as directed by local and federal emergency response depending on the emergency or the crisis unfolding.
 - The incident and containment will be documented by the EHS Manager using the applicable incident reporting form.
 - If this incident causes an impact to BioSpectra's electronic data, data retention or Server, the IT Department will initiate the approved IT procedures to contain and document the incident accordingly.

8.2.2 Disaster Recovery Phase 2 (Process and Systems Risk Assessment)

- The second phase of the Disaster Recovery is Process and Systems Risk Assessment.
 - During this phase, a Risk Assessment will be performed using the Risk Assessment tools that have been established for BioSpectra processes and systems. This Risk Assessment will be performed for any identified area that has experienced a disruption based on an event or incident.



- During this time Data Recovery Assessment will be performed in accordance with the approved IT procedures. If the crisis event causes business disruption, then a Business Disruption Evaluation will be conducted using the applicable Business Impact and Risk Assessment Form.

8.2.3 Disaster Recovery Phase 3 (Business Impact Risk Assessment)

- The third phase of Disaster Recovery will consist of Business Disruption Evaluation and Data Recovery.
 - The Business Impact and Risk Assessment Form will be completed to ensure that all areas of Business Disruption are identified and documented.
 - This evaluation will aid in establishing the most effective business resumption planning.
 - The results of the Business Impact and Risk Assessment will yield information to be used for the respective Business Resumption Plan.
 - During this time complete Data Recovery will be performed in accordance with the approved IT procedures.

8.2.4 Disaster Recovery Communication

- Communication for Employees
 - The employee call list will be established and maintained by the Human Resource (HR) department.
 - An employee communication email list will be established and maintained by the HR department.
 - Stakeholder communication will be maintained by Crisis Control Members and provided to the HR department for use as directed.
 - A quarterly evaluation of each contact list will be conducted to ensure the list is current.
- Additional communication that may be deemed necessary are as follows:
 - Communication to Customers
 - Communication to Supply Chain Partners
 - Communication to Service Providers



8.3 Stage 3: Business Resumption

The Business Disruption Risk Assessment will be used to evaluate the level of disruption based on the event or incident that occurred. The Business Disruption could be deemed temporary or permanent for a given system or process depending on the resources available and the timeline for resumption.

- When a temporary disruption occurs, BioSpectra will evaluate the timeframe needed to resume operations and will ensure that enough resources are available to minimize the time of disruption. These considerations are as follows:
 - Temporary disruption to the manufacture of a product due to an event or incident impacting the process room or raw material supply chain.
 - BioSpectra will refer to the approved customer agreements and forecasts to ensure the necessary material inventory is available to support a temporary disruption in manufacturing.
 - Temporary Disruption to office spaces in a specific BioSpectra Facility.
 - BioSpectra IT has established a server network in which each employee may access the associated documents necessary for work performance. BioSpectra office personnel may use a VPN to access necessary documents from another BioSpectra facility or from a secure remote location.
- Permanent Disruption of a System, Process or Facility may be addressed using the following considerations:
 - In the case where a permanent disruption to business operations at a specific facility occurs, BioSpectra can potentially reestablish operations at its secondary facility.
 - A resumption strategy will be established and approved by the Crisis Control Members with the minimum requirements to be followed in accordance with BioSpectra's quality management systems. The minimum requirements include but are not limited to:
 - Applicable ICH Guidance
 - BioSpectra's Quality Manual
 - Supplier Management
 - Staff Training



- Change Control Management and Notification in accordance with established agreements
 - Inventory Management in accordance with established agreements.
 - Process Validation Master Plan
 - Equipment Qualification Master Plan
 - Recovery of data and compliance to established procedures
 - Analytical Method Validation
- The Business Resumption Plan will be documented and approved by the Crisis Control Members.
 - This Plan will have the following details:
 - Timelines for each action
 - Responsibilities of Staff
 - Plan Details and Expectations
 - Equipment and Manufacturing Restoration
 - Training
 - Communication

Within 60 days of completing the business resumption plan the Crisis Control members will reconvene to review the actions and results and review areas of improvement for future events. This review will be documented in a final report.