



**GLOBAL DRUG MANUFACTURING
COMPANY, SWITZERLAND**

CASE STUDY

Business Continuity Planning



Business Continuity Planning



Project Overview

CAI was tasked with developing a Business Continuity Planning Strategy and drafting a Business Continuity Plan (BCP) procedure that was aligned with corporate continuity plans but was also a simple program that could be used as a guideline for assessing and recovery from internal or external disruptive events at the site level.

CAI's Subject Matter Experts (SMEs) had the experience and expertise necessary to help the client understand what should be included in the Plan and also provide a customized BCP that satisfied their requirements for a site-level process to mitigate and recover from disruptive events.

Challenge

CAI previously performed a limited Operational Readiness (OR) assessment of their Quality Control and Supply Chain workstreams. Based on the successful completion of the OR assessment, the client requested additional support from CAI for several projects – including development of a BCP.

Departmental continuity plans were already in place – an emergency response procedure and multiple systems recovery procedures. The company has global BCPs – but since manufacturing is currently being performed by CDMOs and CMOs, these BCPs were directed at supplier management and product shortage issues and did not address disruptive events at the new (and first) company manufacturing site.

The challenge to CAI was to provide training, lead workshops on Business Impact Assessment (BIA) and Failure Mode and Effect Analysis (FMEA) and draft a BCP designed to fit the site's specific needs.



CLIENT FEEDBACK

"This BCP project is important for the bioplant because we need to be able to deliver our products to patients in an uninterrupted way.

Therefore, we need to anticipate and map all major threats to our main activities and be prepared to manage major disruptive incidents by putting in place a BCP."

– Client PM



Business Continuity Planning



Solution

When working with a client on processes and procedures that affect such a wide range of stakeholders, there is significant coordination that needs to occur and hurdles to overcome. CAI worked through the following steps and challenges to deliver a comprehensive business continuity strategy and plan:

- **Resource constraints** – the client was preparing for manufacturing of their first commercial batches and department heads – those most likely to be involved in BCP development – were stretched to the limit.
- **Understanding the Scope** – since this was the first manufacturing site for the company, there was substantial learning that had to occur.
- **Business Continuity Policy** – the client did not have a stated policy describing their business continuity strategy or resources experienced in developing a Business Continuity Strategy.
- **Multiple Stand-alone Recovery Processes** – there are multiple systems-related recovery procedures that needed to be reviewed and integrated into the new site BCP.
- **Language** – procedures were written in, but not translated from English, French, and German. Additionally, meetings required translation assistance for clearer understanding.

A key to project success was active sponsorship and engagement by the client Site Head.



POLICY STATEMENT

“The [client] shall create a Business Continuity Plan (BCP) based on an analysis of critical functions within the plant, understanding of biologic processes, and the results of risk analysis and business impact assessments.

The BCP will provide information and instructions in support of business recovery activities.

Senior Leadership at the plant shall participate in development of the BCP, ensure periodic review of the plan, and assess and direct business recovery activities as identified in the plan when a disruption event occurs.”

Business Continuity Planning



CAI and the stakeholders created a site BCP that described a 4-Phase recovery process and provided extensive guidelines and checklists that could be used during an actual event to help in the recovery process.

The 4 Phases:

Phase 1 – Event Occurrence

Phase 2 – Recovery Plan Execution

Phase 3 – Emergency Operations Center

Phase 4 – Return to Bioplant Operations

Key parts of the BCP included:

1. Critical Equipment, Systems, and Resources
2. Business Impact Assessment (BIA)
3. Failure Mode and Effects Analysis (FMEA)
4. Maximum Tolerable Downtime and Recovery Time Objective
5. Recovery Plan Phases
6. Notification to Regulatory Agencies
7. Recovery Teams
8. Emergency Evacuation Plan
9. Preliminary Damage Assessment Checklist
10. Event Impact Assessment Template
11. Recovery Process Flow Diagram
12. BCP Recovery Tasks by Phase
13. Table of Alternative Emergency Operations Center(s) (EOC)s



BUSINESS IMPACT ANALYSIS (BIA) ENABLES THE ORGANIZATION TO:

- Identify the processes and activities necessary to deliver in-scope products and services.
- Identify the resources necessary to deliver these processes and services.
- Recommend recovery objectives for activities and resources.
- Justify activity and resource recovery objectives based on the potential impact of disruption.

THE FAILURE MODE AND EFFECT ANALYSIS (FMEA) ENABLES THE ORGANIZATION TO:

- Assess the likelihood of disruption to the activities and resources that deliver in-scope products and services based on a review of controls designed to “protect” key resources.
- Identify the potential causes or sources of disruption.
- Recommend controls to limit the likelihood or impact of disruption to processes, activities, and resources.

Business Continuity Planning



Client Feedback

"Many thanks ..."

"... thanks a lot, to both of you for your support and hard work on this project!"

Best regards,

[Client PM]

Result

The BCP project was one of several projects performed for this client by CAI SMEs. The client was extremely happy with the deliverables including the training, workshop collaboration, and the final documents.

The client now has its desired result of a procedure in place to guide and support the manufacturing operation during a disruptive event – including a method to assess the impact of the event and respond appropriately. Additionally, the client has identified potential risks, risk mitigation, tasks, and task owners as well as roles and responsibilities during all phases of the recovery process and is better prepared for Business Continuity.

BUSINESS IMPACT ASSESSMENT:

The BIA is executed to identify, at a minimum:

- Potential Risks
- Areas of Impact
- Critical Activities
- Recovery Time Objectives
- Risk Mitigation Activities
- Mitigation Owner

FAILURE MODE & EFFECT ANALYSIS

The FMEA is executed to analyze, at a minimum, the following potential risks:

Internal Risks:

- Resource Unavailability
- Bioplant Damage
- Equipment Failure
- Systems Failure
- Accident / Injury
- Theft / Vandalism
- Adverse Regulatory Findings

External Risks:

- Cybersecurity Threats
- Ransomware, hacking
- Natural Disasters
- Hurricane
- Flood
- Earthquake
- Tornado
- Pandemic / Epidemic
- Power Outages
- Water Shortage
- Raw Material Disruption
- Supplier Failure
- Accident (plane crash) due to airport proximity