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Automated BCP for Biopharmaceutical Company under Pandemic Diseases

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Abstract: *This paper examines automated Business Continuity Planning (BCP) for biopharmaceutical companies during pandemics. It analyzes COVID-19's impact on the industry, including sales declines and supply chain disruptions. A risk analysis framework is presented, followed by a comprehensive BCP strategy based on the FEMA model. The study proposes crisis management techniques, monitoring systems, technical support integration, and safety measures. It also reviews industry policies and provides a detailed implementation plan with budget considerations. The research emphasizes the importance of adaptable crisis management, continuous monitoring, and collaborative approaches in developing effective BCPs for biopharmaceutical companies.*

Keywords: *Business Continuity Planning, Biopharmaceutical industry, Pandemic response, Risk management, FEMA model, Crisis management, Automated systems, COVID-19*

1. Introduction

As the pandemic spreads around the world, biopharmaceutical companies are facing unprecedented challenges. In order to ensure the continuity of production and supply, biopharmaceutical companies need to develop business continuity plans. Business continuity planning (BCP) is a preventive and response strategy designed to ensure that an organization can maintain a certain level of operational capabilities when a catastrophic event occurs. In this article, we will explore how biopharmaceutical companies can implement business continuity plans to cope with market changes and challenges under the impact of the pandemic.

Business continuity planning refers to a preventive and response strategy that ensures that an organization can maintain a certain level of operational capabilities when a catastrophic event occurs. BCP should follow some basic principles, such as advance planning, simplicity, operability, and testability. The core elements of BCP include: Analysis, Crisis Management Team, Communication and coordination, Backup and recovery strategy, Training and Exercises [1,2].

In this article, we will explore how biopharmaceutical companies can carry out business continuity planning under the impact of the epidemic, as well as specific strategic guidance for implementing BCP.

1.1 Research background

As the epidemic spreads around the world, many industries and organizations have been severely affected, and biopharmaceutical companies are no exception [3]. In order to ensure the continuity of production and supply, biopharmaceutical companies need to develop a business continuity plan (BCP). BCP is a preventive and response strategy to maintain the organization's operational capabilities when a catastrophic event occurs. Therefore, studying the BCP of biopharmaceutical companies during the epidemic is of great significance to ensure the stability and sustainable development of the global biopharmaceutical market.

1.2 Research content

During the pandemic, biopharmaceutical companies face many challenges in developing and implementing BCPs. For example, supply chain disruptions, employee infection risks, transportation and logistics problems, etc. A case study of a biopharmaceutical company that stopped production due to

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employee infection with the coronavirus illustrates the need for implementing a BCP. The company's BCP team quickly took measures such as temperature testing, personnel screening, and social distancing to ensure the rapid resumption of production at the factory. This paper discusses how biopharmaceutical companies can develop and implement business continuity planning (BCP) strategies to better handle challenges posed by epidemics. 1. Crisis Management Model; 2. Monitoring and evaluation of the epidemic situation; 3. Leveraging technology for resilience 4. Ensuring employee safety; 5. Engaging with the community and local authorities.

2. Analysis of the impact of the epidemic on the biopharmaceutical

Since the outbreak of the COVID-19 pandemic, the biopharmaceutical industry has shown obvious anti-cyclicality [4,5,6]. Every breakthrough in the research and development of COVID-19 vaccines and drugs will cause considerable waves in the capital market, and CDMO companies have also participated in this research and development competition. The pandemic has put pressure on biopharmaceutical production capacity, forcing biopharmaceutical companies to rely on CDMOs to expand vaccine production. Through this approach, a fruitful collaboration has been reached, leveraging the pharmaceutical companies' R&D expertise in vaccine development and the CDMOs' expertise in vaccine manufacturing. However, the biopharmaceutical industry also has regional dependence. Biopharma companies and CDMOs typically have limited manufacturing sites for economic reasons. During the pandemic, the geographic isolation of manufacturing has manifested itself in the supply chain. Currently, biopharma companies and CDMOs are considering building more small-scale local production sites instead of building a few large production sites around the world to better meet and serve population needs.

2.1 Direct impact of the epidemic on the biopharmaceutical

Sales decline: In the early stage of the outbreak, the public health incident had a certain impact on social life. People sought medical treatment less frequently, hospital outpatient visits decreased, and drug sales fell sharply. Supply chain disruption: During the epidemic, the supply chain of biopharmaceutical companies has also been greatly challenged. Factors such as traffic restrictions and overseas epidemic outbreaks have led to obstructions in the transportation of raw materials and finished products, increased logistics costs, and had a negative impact on corporate production and profits.

2.2 Impact of other industries affected by the epidemic on the biopharmaceutical

Tourism: Biopharmaceutical companies often need to cooperate with foreign countries during their research and development, production and sales. The impact of the epidemic on the tourism industry has limited the exchanges between biopharmaceutical companies and foreign companies and institutions, and cooperation projects have stagnated. Export market: Another challenge faced by biopharmaceutical companies during the epidemic is the decline in demand in the export market. Factors such as the shortage of medical resources abroad and the reduction in hospital outpatient visits have led to a decrease in demand in the foreign market, which has had a negative impact on the export business of biopharmaceutical companies.

In response to these impacts, biopharmaceutical companies have taken a variety of countermeasures, such as adjusting the supply chain, expanding the domestic market, and strengthening online medical services. At the same time, government departments have also taken support measures, such as tax reductions and exemptions, and providing loans and subsidies to help companies tide over the difficulties.

3. Risk analysis of resumption of work and production in the biopharmaceutical

Table 1 shows the risk analysis and the percentage of each item, clearly displaying various risk categories.

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Table 1: Risk Analysis

Risk Type	Risk Description	Analytics
Declining market demand	Drug sales fell sharply	20%
Difficulty in sourcing raw materials	Purchase raw materials	30%
Logistics and transportation are restricted	Logistics hindered	25%
Insufficient staff returning to work	Employees return to work	25%
Other	Policy adjustment	10%

4. Biopharmaceutical Sustainability Plan and Measures

To better cope with the challenges brought by the epidemic, biopharmaceutical companies can adopt the following strategies to develop and implement BCP:

Crisis Management Model: Implement a recognized crisis management framework, such as FEMA or an equivalent model, to develop a comprehensive Business Continuity Plan (BCP). These models offer standardized guidelines to facilitate rapid organizational response during disasters. Monitoring and evaluation: Develop a robust epidemic monitoring and evaluation system to track the evolving situation in real-time, enabling timely adjustments to the BCP as circumstances change. Technical support: By using cloud computing, big data, artificial intelligence and other technical means, we can achieve goals such as facility automation and production optimization, thereby improving the organization's resilience. Personnel safety: Integrate employee safety measures into the BCP, including detailed personal protection strategies and health screening protocols, to safeguard the wellbeing of all staff members. Community Engagement: Foster collaborative relationships with local authorities and community organizations, actively participating in epidemic prevention and control efforts to minimize the impact of the outbreak on both the organization and its surrounding community.

4.1 Industry policy guidance

The "Notice on Strengthening the Epidemic Prevention and Control Work of Biopharmaceutical Enterprises" issued by the National Health Commission pointed out that it is necessary to strengthen the epidemic prevention and control work of biopharmaceutical enterprises, formulate a sustainability plan (BCP), increase prevention and control efforts, ensure the normal operation of enterprises, and protect people's health. In terms of local policies, the Shanghai Municipal People's Government issued the "Guiding Opinions on Responding to the New Coronavirus Pneumonia Epidemic and Supporting the Stable Development of Biopharmaceutical Enterprises", proposing 25 specific measures in 10 aspects to support the stable development of biopharmaceutical companies. Industry association documents: The "Guiding Principles for Sustainability Plans (BCP) for Biopharmaceutical Companies to Respond to Epidemics" issued by the Chinese Society for Bioengineering proposes that biopharmaceutical companies should formulate BCPs to ensure the sustainability of the company and the health and safety of their employees. News content: A biopharmaceutical company has developed a business continuity plan (BCP) to ensure the normal operation of the company during the epidemic. The plan includes increasing the reserves of epidemic prevention materials such as masks and disinfectants, establishing a remote working system, reducing the risk of cross-infection among employees, and strengthening employee health monitoring and management.

In addition, there are reports that a certain biopharmaceutical company increased its R&D investment during the epidemic, focusing on the development of new vaccines and drugs to meet the challenges brought to mankind by the epidemic.

In summary, the industry policy guidance for the biopharmaceutical industry sustainability plan (BCP) and measures during the epidemic includes national policy documents, local policy documents, and industry association documents. These documents provide guidance and support for current biopharmaceutical companies to formulate BCPs to ensure the sustainability of the company and the health and safety of employees.

4.2 BCP and Measures

The FEMA model, or Federal Emergency Management Agency, is a U.S. government agency responsible for coordinating and managing the nation's emergency response and disaster relief efforts. The FEMA model is a crisis management tool that helps organizations stay calm, respond quickly, and

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coordinate actions during an emergency. The FEMA model includes the following stages: Preparation stage: Organizations should make adequate preparations before a disaster occurs, including developing emergency plans, stockpiling emergency supplies, and training employees. Response phase: After a disaster occurs, the organization should respond quickly and take necessary actions to mitigate the impact and resume normal operations. Recovery phase: After the disaster is over, the organization should actively carry out recovery work to restore the original operating state to the greatest extent possible.

Develop a detailed BCP plan under the guidance of the FEMA model. Specifically, the following measures can be taken: Preparation stage: Develop emergency plans, emergency response procedures and responsible persons, reserve sufficient emergency supplies (epidemic prevention supplies, medical equipment), and train employees. Identify possible risks and threats: Before developing an emergency plan, you need to assess the risks and threats that your company may face. Biopharmaceutical companies need to consider the following factors: Outbreaks: infectious diseases such as bacteria and viruses; Policy changes: such as government regulations, taxes, etc.; Natural disasters: such as earthquakes, floods, etc.; Technical incidents: such as power outages, IT failures, etc.; Market changes: such as changes in customer demand, increased competition, etc. Develop emergency plans: Develop specific emergency plans for possible risks and threats. Here are some common emergency plans: Epidemic response plan: including the handling procedures for employees with fever and other symptoms, temporary isolation and disinfection measures, etc.; Supply chain emergency plan: including response measures to problems such as raw material shortages and logistics constraints; IT emergency response plan: including countermeasures for cyber-attacks, system failures and other issues; Market change contingency plan: including response measures to changes in customer demand, intensified market competition and other issues; Contingency plans for policy changes: including response measures to government regulations, taxation and other issues.

Prepare emergency plan manual: The emergency plan should be compiled into a manual to facilitate employees to learn and master it. The manual should include: Emergency response process: clarify the person in charge and time limit for each step of the emergency response; Emergency material reserves: clarify the storage location and quantity of emergency materials, including masks, disinfectants, medical equipment, etc.; Employee responsibilities: clarify employees' emergency responsibilities and contact information; Guide: Provides specific guidelines and instructions for the operation of the emergency plan. Training and exercises: Conduct training and exercises on emergency plans to improve employees' emergency response capabilities. Training and exercises can be conducted in the following ways: Online training: Training is conducted through the company's internal platform, which is convenient and fast; Offline training: arrange professional personnel to conduct training to improve employees' emergency response capabilities; Exercise testing: Regularly organize exercise testing to verify and improve the effectiveness of emergency plans. Update and maintain emergency response plans:

As time goes by and the environment changes, emergency plans need to be constantly updated and maintained to ensure that they are consistent with actual conditions. Here are some suggestions for maintaining and updating emergency plans: Regularly assess risks and threats, and reassess and update emergency response plans; Ensure timely updating and replenishment of emergency supplies; Regularly check the effectiveness of emergency plans and organize experts to review emergency plans and make improvement suggestions.

After the emergency response is completed, record and evaluate the emergency response process, summarize the experience and lessons learned, and further improve the BCP plan. The following are some suggestions for recording and evaluating emergency responses: Establish a recording and evaluation mechanism to ensure that key information during the emergency response process is accurately recorded and effectively evaluated; Analyze the deficiencies in the emergency response process, make suggestions for improvement, and improve the BCP plan; Summarize successful experiences in the emergency response process and enhance employees' skills and quality in emergency response. Response phase: Adjusting operations, implementing remote work, suspending on-site activities, monitoring employee health, and collaborating with stakeholders during the disaster. Recovery phase: Focusing on rebuilding operations, evaluating the effectiveness of the emergency response, and improving the business continuity plan based on lessons learned.

Here is a possible detailed description that I have listed at Figure 1, Table 2 and Figure 2:

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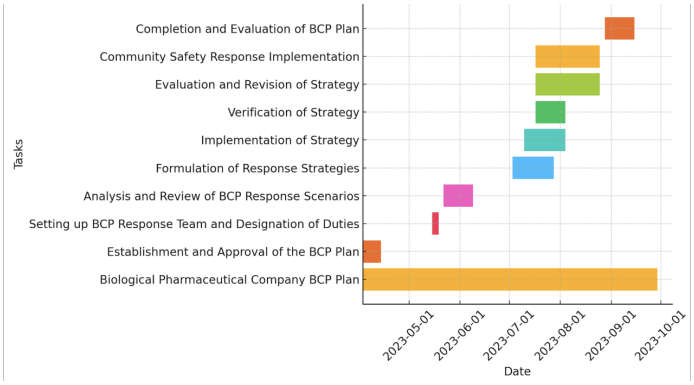

Figure 1: Biological Pharmaceutical Company BCP

BCP formulation and implementation plan for biopharmaceutical companies during the epidemic Objective: To develop a detailed BCP plan for biopharmaceutical companies to address the challenges brought about by the current epidemic.

Table 2: Operational budget

Business Budget	Price (RMB)
crisis management model	7000
epidemic monitoring and evaluation system	140000
Technical support integration and implementation fees	1050000
Personnel safety inclusion and implementation costs	525000
Community participation establishment and implementation costs	70000
BCP plan completion and evaluation costs	35000
Total	1890000

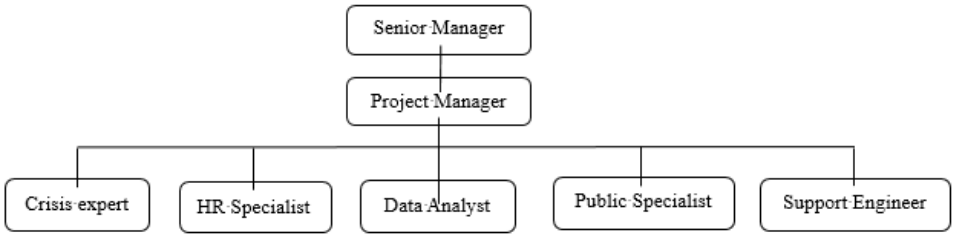

Figure 2: Organization Chart

5. Conclusion

The purpose of the BCP development and implementation plan of biopharmaceutical companies is to respond to the challenges brought by the current epidemic, ensure that biopharmaceutical companies can continue to provide products and services, and protect the interests of employees, customers and suppliers. When developing and implementing the BCP plan, it is necessary to adopt crisis management models and establish epidemic monitoring and evaluation systems. At the same time, it is also necessary to integrate technical support and incorporate personnel safety implementation, as well as establish a community participation mechanism and complete the evaluation of the BCP plan.

1) The adoption of crisis management model is the key to developing and implementing BCP plan. Biopharmaceutical companies need to adopt a crisis management model that suits their industry and adjust and optimize it according to the current epidemic situation. The FEMA model is a commonly used crisis management model that provides a set of general crisis management guidelines and processes that biopharmaceutical companies can flexibly apply based on their actual conditions.

2) The establishment of an epidemic monitoring and evaluation system is also an important part of formulating and implementing the BCP plan. Biopharmaceutical companies need to establish an epidemic monitoring and evaluation system to timely monitor factors such as the health status of

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employees, customer procurement needs, and supplier supply conditions. At the same time, companies also need to formulate response measures and plans for various emergencies, and conduct regular drills and evaluations to ensure the effectiveness of the BCP plan.

3) The integration and implementation of technical support is also key to the formulation and implementation of BCP plans. Biopharmaceutical companies need to integrate various technical supports, including IT systems, communication equipment, remote office, etc., to ensure that they can play the greatest role in the BCP plan. In addition, the company also needs to establish a complete set of technical support processes and specifications to ensure that employees and customers can quickly obtain the information and help they need in times of crisis.

4) The inclusion and implementation of personnel safety is also an important part of developing and implementing a BCP plan. Biopharmaceutical companies need to incorporate personnel safety into their BCP plans and take a series of measures to ensure the safety and health of their employees, including implementing remote work, developing employee travel safety plans, and providing necessary protective equipment.

5) The establishment and implementation of community participation is also an important part of developing and implementing the BCP plan. Biopharmaceutical companies need to establish connections with local governments, community organizations, etc., understand the local epidemic situation, needs and other information, and take a series of measures to participate in the community's fight against the epidemic.

In formulating and implementing BCP plans, biopharmaceutical companies need to fully consider various factors, including the adoption of crisis management models, the establishment of epidemic monitoring and evaluation systems, the integration and implementation of technical support, the inclusion and implementation of personnel safety, the establishment and implementation of community participation, etc. Through the implementation of these measures, biopharmaceutical companies can continue to provide products and services and protect the interests of employees, customers and suppliers.

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