Business Continuity During the COVID-19 Pandemic Era: Surviving and Improving the Quality Process Management System

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Abstract: Worldwide health and the global economy have been heavily damaged by the COVID-19 pandemic, with business continuity being the primary issue of every company operating in the health industry. A critical instrument for enterprise survival is the establishment of a business continuity management system that enables them to manage risks, discover opportunities created by the pandemic, and secure their continuity. The purpose of this paper is to examine how a pharmaceutical firm may ensure business continuity by adopting ISO 22301:2019 in parallel with the existing ISO 9001:2015 quality standard, as well as the similarities and differences between the two management standards. According to the results, the pharmaceutical company, whose case was studied, managed to create an effective action plan in order to mitigate at an acceptable level the identified risks, to maintain its business continuity and to ensure the quality of the product and the health of the patients and its employees.

Key-Words: Business Continuity; Quality; Business Process Management; System; ISO; COVID

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1 Introduction

Pandemics are a natural occurrence throughout history, and the question is not whether one will occur, but when one will (Huremović, 2019). The worldwide community faced a pandemic similar to those that occur every ten to fifty years owing to viral mutations in the early years of 2020, the COVID-19 pandemic (Djalante et al., 2020). COVID-19 sickness began spreading in China in December 2019 and was declared a pandemic by the World Health Organization (WHO) on March 11, 2020, due to the disease's rapid expansion in the majority of the world's countries (Jebril, 2020). Coronavirus disease is caused by the SARS-CoV-2 virus, which causes a respiratory infection and is spread from person to person via the respiratory tract or by touch if proper hand hygiene is not practiced. Fever, dry cough, and discharge are the primary symptoms, which typically last between two and fourteen days (Larsen et al., 2020). The rapid spread of the virus, the resulting complications in patients' health, and the disease's high mortality rate have compelled the world community to take fast action to safeguard human lives and, secondarily, the economy (Ioannidis, 2021).

To halt the pandemic's global spread, country leaders have proposed universal or individual measures such as blockades, curfews, social isolation, and forced stay at home, all of which might have a catastrophic impact on a global business level (Donthu & Gustafsson, 2020; Leite et al., 2020). The COVID-19 pandemic has forced the closure of numerous businesses, causing enormous disruptions in various industries. Most businesses worldwide are currently struggling to stay afloat, owing to dwindling sales and rising levels of uncertainty about the future. Therefore, it is critical for businesses to conduct a thorough evaluation of their business strategy in order to ensure business continuity (Donthu & Gustafsson, 2020).

Businesses' continued operation in the face of serious health crises, such as the COVID-19 pandemic, has prompted them to design and implement customized Business Continuity Management Systems (BCMS) based on management standards, not only to deal with current events, but also to deal with future ones (Torabi et al., 2016). With the development and implementation of a BCMS, which can also be referred to as a risk management system, businesses gain an efficient and effective tool for dealing with any catastrophic event

that could have an irreversible impact on them (Sahebjamnia et al., 2015), for increasing their operational resilience, but also for identifying potential opportunities (Torabi et al., 2016). A critical component of implementing an effective SDR is identifying, analyzing, evaluating, and responding to risks that may influence the business, as well as recognizing any opportunities that may develop (Torabi et al., 2016).

In the remining of the paper, the most significant ISO standards, ISO 9001: 2015 and ISO 22301: 2019, related to risk management and business continuity will be discussed and compared. ISO 9001: 2015 "Quality Management Systems-Requirements," is studied given that risk management is a critical component of the structure of the revised management standards and that the primary objective of businesses is to produce and offer high-quality products to their customers while taking individual risks into account. ISO 22301: 2019 "Security and Emergency Recovery-Business Continuity Management Systems-Requirements," is studied to assist businesses on the difficult path to survival based on the requirement for an immediate response to the COVID-19 pandemic of business operations, as well as the requirement for immediate and unrestricted access to information.

After discussing the standards ISO 9001: 2015 and ISO 22301: 2019, as well as their similarities, common points, and differences, the paper will examine how applying management standards and risk analysis tools can ensure a pharmaceutical company's business continuity by adopting ISO 22301: 2019 in parallel with the existing quality standard ISO 9000. The paper will also present the results of an analysis of the effectiveness of management standards in sustaining a pharmaceutical business's operations and viability during a pandemic, as well as the level of preparedness of a company that already uses quality systems. Finally, a summary of the structure of the current work will be presented, together with the most significant themes that were addressed, forming the conclusions section.

2 ISO 22301:2019 vs ISO 9001:2015

The International Organization for Standardization's (ISO) initiative to harmonize management standards by establishing the "New High-Level Structure" to assist enterprises in simultaneously adopting many management systems is now a given. The ISO 22301 management standard was structured according to this innovative method from the start, which was enhanced in the revised edition of 2019. The same was true with the modification of the ISO 9001 quality standard, which clearly reflected the new methodology in its revised 2015 edition. The comparison of ISO 22301 and ISO 9001, as shown in Table 6 at the Appendix, demonstrates the new structure's implementation in both standards. Also, a key common point in the structure of the standards is that they should follow the Improvement Cycle, as shown in Table 7 at the Appendix, having the same basic structure with some common requirements and differences depending on the subject matter. Comparing the requirements of the two standards for the main sections (§4) to (§10) we can observe the following similarities and differences.

2.1 Section 4: The Organization's Operational Framework

As illustrated in Table 6 at the Appendix, both standards adhere to the same structure in terms of the organization's operating framework, adjusting their criteria according to the subject matter. ISO 22301: 2019 specifies in sub-section (§4.1) the identification of external and internal BCMS issues, the comprehension of stakeholders' needs, expectations, and requirements (§4.2), and the legal and regulatory requirements by separating them into a separate sub-paragraph (§4.2.2), which does not exist in ISO 9001. Sub-section (§4.3) discusses establishing the scope of the BCMS by defining its limits and application and concludes with the requirement for introducing, implementing, maintaining, and continuously improving BCMS (§4.4). In comparison, ISO 9001: 2015 refers in sub-section (§4.1) to the identification of external and internal Quality Management System QMS parameters, to the comprehension of stakeholders' demands, expectations, and requirements, as well as to applicable legislation and regulatory requirements (§4.2). Sub-section (§4.3) also refers to the definition of the QMS's scope, taking into account the limits and application of the QMS. ISO 9001: 2015 sub-section (§4.3) goes into further depth about the establishment, implementation, maintenance, and continuous development of QMS and makes specific reference to QMS processes, which is not the case in ISO 22301: 2019. Finally, both standards emphasize the importance of having recorded information to support the operation of the BCMS (§4.3.1) or QMS (§4.4.1).

2.2 Section 5: Leadership

ISO 22301: 2019 sub-section (§5.1) refers to the management's responsibility to take a leading role in demonstrating its commitment to the BCMS by ensuring all aspects of its successful implementation, including the establishment of an appropriate

business continuity policy for the organization (§5.2.1), communication within the organization but also with stakeholders as needed (§5.2.2), and finally, ensuring that roles, responsibilities, and responsibilities are sufficient. In comparison to ISO 9001: 2015, the sub-section (§5.1) is further analyzed in the sub-sections (§5.1.1), which refer to the management's responsibility to play a leading role in demonstrating its commitment to the QMS by ensuring all aspects of its successful implementation with reference to the process approach and the risk approach, and (§5.1.2), which refers to the management's responsibility to play a leading role in demonstrating its commitment to the QMS by ensuring all aspects of its Due to the fact that ISO 22301: 2019 deals with a different subject area, there are no references to the process approach, risk approach, or customer focus. Additionally, ISO 22301: 2019 refers to management's responsibility to ensure that roles, responsibilities, and responsibilities are appropriately defined and accessible throughout the organization in sub-section (§5.3). Finally, both standards make reference to sub-section (§5.2.2), which states that a quality policy or company policy must exist as proven information.

2.3 Section 6: Programming and Planning

ISO 22301:2019 and ISO 9001:2015 section (§6) both pertain to the design and programming of BCMS and QMS. ISO 22301: 2019 specifies the requirements for defining (§6.1.1) and addressing threats and seizing opportunities (§6.1.2), emphasizing that threats and opportunities are related to the efficacy of the system. The risk associated with a disorganizing incident is mentioned in section (§8); this is a note that is absent from ISO 9001: 2015. Additionally, sub-sections (§6.2.1) and (§6.2.2) examine the establishment and characterization of business continuity objectives. Finally, there is the addition of a new sub-section (§6.3), which did not exist in the previous (§2012) version, which specifies the requirements for managing changes in the planning and scheduling of the SDES in accordance with ISO 9001: 2015 section (§6.3). In comparison to ISO 9001: 2015, sub-section (§6.1) defines the requirements for identifying (§6.1.1) and managing threats and seizing opportunities (§6.1.2), describing in greater detail what should be included in the risk management choices, which is not the case with ISO 22301: 2019. Additionally, it refers to the formulation and defining of quality targets, which are discussed in sub-sections (§6.2.1) and (§6.2.2). Finally, sub-section (§6.3) specifies the procedures for handling modifications to the QMS's design and planning. Finally, both standards emphasize the importance of maintaining current information on business continuity and quality targets (§6.2.1).

2.4 Section 7: Support

ISO 22301: 2019 and ISO 9001: 2015 section (§7) both relate to the support required for the BCMS and QMS to be implemented successfully. More precisely, in sub-section (§7.1) of ISO 22301: 2019, reference is made to the resources required for establishment, implementation, maintenance, updating, and continuous improvement, without going into greater detail, in contrast to ISO 9001: 2015, which analyzes the requirements for internal and external resources (§7.1.1), personnel (§7.1.2), infrastructure (§7.1.3), and the environment in which processes operate (§7.1.4), resources for monitoring and measuring compliance with requirements for products and services (§7.1.5), resources for tracing measurements (§7.1.5.2), and the essential operational expertise for operating processes and achieving product and service conformity (§7.1.6). The following sections of the two standards outline a common structure and requirements for staff professional competence (§7.2), staff awareness of the organization's policies and objectives (§7.3), and the requirements for internal and external communication (§7.4), all of which are adaptable to the needs of each management system. Finally, both standards make reference to the requirement for substantiated information to exist (§7.5), to be created and updated (§7.5.2), and to be verified (§7.5.3), with a particular emphasis on the identification and verification of substantiated externally generated information.

2.5 Section 8: Operation

ISO 22301: 2019 section (§8) and ISO 9001: 2015 both refer to the standards for the organization's operation. Due to the fact that each management model has a distinct subject matter, the requirements for this part and its structure are entirely unique, with no commonality between the two standards. ISO 22301: 2019 sub-section (§8.1) details the requirements for planning and controlling the operation of processes, with specific reference to sub-section (§6.1), as well as the actions for addressing dangers and capitalizing on opportunities. Sub-section (§8.2) discusses the requirements for operational effect analysis and risk assessment in relation to ISO 31000, which is a common denominator for both standards. Sub-section (§8.3.2) details the requirements for the definition of business continuity strategies and solutions, while sub-section (§8.3.3) details the requirements for the selection of business continuity strategies and solutions, as well

as the resource requirements (§8.3.4) for their implementation (§8.3.5). Sub-section (§8.4) covers the requirements for business continuity plans and procedures, the requirements for the response structure (§8.4.2), and the requirements for warning and communication (§8.4.3), all of which are accomplished through documented business continuity plan procedures (§8.4.4) as well as the criteria for reorganizing the organization following a disorganizing event (§8.4.5). Finally, sub-section (§8.5) discusses the requirements for implementing and maintaining an effective exercise and testing program to validate the effectiveness of business continuity strategies and solutions, as well as the requirements for evaluating business continuity documentation and capabilities (§8.6).

2.6 Section 9: Evaluation of Performance

ISO 22301: 2019 and ISO 9001: 2015 section (§9) both refer to the requirements for evaluating BCSM and QMS. More precisely, in sub-section (§9.1) of ISO 22301: 2019, reference is made to the requirements for determining what needs to be monitored and measured, for monitoring, measurement, analysis, and evaluation methods, as well as for when and by whom monitoring, measurement, analysis, and evaluation are performed. The requirement to identify the staff or team responsible for monitoring, measuring, and analysis is new, and does not appear in the ISO 9001: 2015 standard. In comparison, ISO 9001: 2015 maintains the same general requirements for monitoring, measurement, analysis, and evaluation (§9.1.1), but adds requirements for monitoring the degree to which customer needs and expectations are met (§9.1.2), as well as for the analysis and evaluation of relevant data and information on product and service compliance, customer satisfaction, the performance and effectiveness of SBS, and the effectiveness of threats and opportunities (§9.1.3). Both standards establish a common framework and procedures for conducting internal audits (§9.2), management review (§9.3), incoming information to be considered (§9.3.2), and management review outcomes (§9.3.3), which are correctly customized to each management system. Finally, both standards make reference to the necessity to retain substantiated information as proof of management review results (§9.3.3).

2.7 Section 10: Improvement

ISO 22301: 2019 and ISO 9001: 2015 sections (§10) both refer to the requirements for improving the BCMS and QMS. More precisely, sub-section (§10.1) of ISO 22301: 2019 refers to the identification and utilization of opportunities, non-compliances and the requirements for dealing with them, as well as the management, monitoring, and evaluation of corrective actions taken as a result of non-compliances (§10.1.1, 10.1.2, 10.1.3). In comparison, ISO 9001: 2015 refers to the identification and exploitation of opportunities, but it goes into greater detail regarding the improvement actions, which include the enhancement of products and services, the correction, prevention, and reduction of adverse effects, as well as the enhancement of the performance and effectiveness of the QMS (§10.1). Additionally, non-compliances and the requirements for dealing with them are discussed, as is the method for managing, monitoring, and assessing corrective measures performed in response to non-compliances (§10.2.1, 10.2.2). Finally, both standards require the existence of validated information demonstrating the type of non-compliances and the outcomes of corrective efforts, as well as the continual improvement of the business continuity (§10.2) or quality (§10.3) management system.

2.8 Conclusions from the Comparison

Considering the comparisons made between the two standards, some critical conclusions may be drawn. It is evident that by applying the "New High-Level Structure" to the two ISO standards 22301: 2019 and ISO 9001: 2015, the standards can be harmonized in terms of their structure and the common requirements they share for the bulk of their sections. A critical point of convergence in the construction of management standards is that they are all based around the Improvement Cycle, as illustrated in Table 7 at the Appendix, with a similar fundamental structure but with some common requirements and changes depending on the subject matter. The two standards now share even more requirements than in previous versions, including the operational framework of the organization in relation to the BCMS or QMS, the leadership position and commitment, the planning and scheduling of the BCMS or QMS, the treatment of threats and opportunities, the resources required for successful implementation of the BCMS or QMS, the evaluation of the performance of the BCMS or QMS processes, and finally the requirement to keep substantiated information for all individual requirements, always taking into account the different subject matter.

In light of the various points, we can deduce the following:

- ISO 9001: 2015 includes a more extensive sub-section (§4.3) on the establishment, implementation,

maintenance, and continuous improvement of QMS and makes specific reference to QMS processes, which is not included in ISO 22301: 2019.

- The sub-section (§5.1) of ISO 9001: 2015 is further analyzed in sub-sections (§5.1.1) with reference to the management's responsibility to play a leading role in demonstrating its commitment to the QMS and ensuring all aspects of its successful implementation, with reference to the process approach and the risk approach. Due to the fact that ISO 22301: 2019 deals with a different subject area, there are no references to the process approach, risk approach, or customer focus.
- ISO 22301: 2019 sub-section (§6.1.1) identifies the requirements for identifying and responding to threats and exploiting opportunities (§6.1.2), noting in particular that the threats and opportunities relate to the effectiveness of the BCMS, as the risk associated with the disorganizing event is mentioned in section (§8) – a note that is absent from ISO 9001: 2015. ISO 9001: 2015 sub-section (§6.1) details the standards for defining (§6.1.1) and managing threats and seizing opportunities (§6.1.2), outlining in greater depth the risk management solutions available, which is not the case with ISO 22301: 2019.
- ISO 22301: 2019 sub-section (§7.1) makes reference to the resources required for establishment, implementation, maintenance, updating, and continuous improvement, but without going into detail, in contrast to ISO 9001: 2015, which analyzes the requirements for internal and external resources, personnel, infrastructure, the operating environment for processes, and resources for monitoring and measuring product and service compliance resources for the traceability of measurements as well as and the necessary operational knowledge for the operation of its processes and the achievement of the conformity of the products and services (§§7.1.1-7.1.6).
- Both ISO 22301: 2019 and ISO 9001: 2015 refer to the requirements for the operation of the organization in section (§8); however, due to the distinct subject matter of each management model, the requirements for this section and its structure are completely different, with no overlap between the two management standards.
- ISO 22301: 2019 and ISO 9001: 2015 sections (§9) both refer to the requirements for evaluating BCMS and QMS. However, ISO 22301: 2019 includes a new requirement for identifying the staff or team responsible for monitoring, measuring, and analysis, which is not included in the ISO 9001: 2015 standard. ISO 9001: 2015 adds requirements for monitoring the degree to which customer needs and expectations are met, for analyzing and evaluating appropriate data and information about the conformity of products and services, the degree of customer satisfaction, the performance and effectiveness of QMS, the effectiveness of threats and opportunities, and the need for SBS improvement (§9.1.2–9.1.3).
- Finally, ISO 22301: 2019 and ISO 9001: 2015 sections (§10) both allude to the standards for BCMS and QMS improvement. ISO 9001: 2015, however, goes deeper than ISO 22301: 2019 in terms of improvement actions, which include product and service enhancement, correction, prevention, and reduction of adverse consequences, and enhancement of the QMS's performance and effectiveness (§10.1).

3 Case Study of Business Continuity in a Pharmaceutical Company due to the COVID-19 Pandemic

After discussing the similarities, common points, and variations between ISO 9001: 2015 and ISO 22301: 2019, this section will discuss how a pharmaceutical company manages a disorganized occurrence, in this example the COVID-19 pandemic. Despite the lack of ISO 22301 certification, the company maintained its business continuity through the application of the principles of the business continuity and reclassification management standard and the know-how gained through the successful implementation of

the ISO 9001: 2015 quality standard and the rules of Good Manufacturing Practices (Abou-El-Enein et al., 2013).

3.1 Section 4: The Organization's Operational Framework

The company is engaged in pharmaceutical manufacturing and enjoys a significant market share in the generic pharmaceutical sector. The company's activities span the whole pharmaceutical value chain, from product research to ultimate distribution in more than 85 countries globally. It is equipped with two manufacturing facilities dedicated to the manufacture of Solid Pharmaceutical Forms (coated and uncoated tablets, capsules) and Injectable Pharmaceutical Forms. The Greek National Medicines Agency (EOF) has certified the units for the manufacture of sterile and non-sterile products, their packaging, and chemical and microbiological quality control.

The company's quality management system has been designed to provide customer / consumer satisfaction through the provision of high-quality and competitive products, as well as compliance with Good Manufacturing Practices (GMP) and EOF standards. To accomplish this purpose, the company has implemented an ISO 9001-based quality system that covers all of the company's activities, including export management and product design. Additionally, the organization follows an ISO 14001-compliant Environmental Management System.

As previously stated, the pharmaceutical company is certified to the ISO 9001: 2015 quality standard and the Good Manufacturing Practice (GMP) guidelines. Internal general operating procedures (Standard Operating Procedures, SOP) for risk assessment are implemented in this context. The basic method is established in accordance with the ISO 31000 management standard "Risk Management - Principles and Guidelines" the ISO 9001 quality standard "Quality Management Systems - Requirements" and the European Medicines Agency's (EMA) ICH Q9 «Quality Risk Assessment» guideline. All the company's departments are presented in Table 1.

Table 1: The Pharmaceutical Company's Departments

	Departments
S.M.	Senior Management
P.E.	Planning & Exports
I.T.	Informatics
Q.C.	Quality Control
P.P.	Product Production
Q.A.	Quality Assurance
H.R.	Human Resources
F.M.	Financial Management
H.&S.	Health & Safety
C.S.	Customer Service
I.	Interdepartmental

3.2 Applying the Risk Assessment

3.2.1 Risk Assessment and Identification

At the beginning of the COVID-19 pandemic, the company set up an interdepartmental Crisis Management Team (CRM), which included a representative of the Senior Management, IT (IT), Human Resources (HR), Financial Management Quality Assurance, Planning & Exports, Product Production and Health & Safety. This team was responsible for assessing the risk and operational impact, including the worst-case scenario which was the suspension, but also for all the measures that would be taken during the pandemic period. At the outbreak of the pandemic, CRM applied the brainstorming technique (Brainstorming) and based on the professional competence and experience of the participants proceeded to assess and determine the risk and operational impact by category, as presented below:

1. Disorganization event management
   - Risk of suspension

- Inadequate handling of a disorganizing event
- Inability to meet legal and regulatory requirements

2. Personnel management
   - Risk of spreading the infection to personnel working in production facilities
   - Risk of unavailability of labor due to sick leave
   - Risk of increased contamination by personnel returning from leave
   - Risk of contamination from external collaborators operating in the production unit, laboratories and offices
   - Risk of staff misconduct during a pandemic
   - Risk of insufficient staff information during the pandemic
3. Remote operation and computer security
   - Risk of not providing adequate equipment (laptops, printers, monitors, etc.) to support remote work (work from home) due to lack of market
   - Risk of failing to maintain cybersecurity and productivity when connecting remotely
   - Risk of unsafe access to the network from remote work (e.g., data theft, electronic phishing (phishing), malware attacks)
   - Risk of non-availability of security at network and application level
   - Risk of unsafe mobile devices
4. Facilities
   - Risk of contamination of the product production unit (Suspension of operation)
   - Risk of contamination of offices, laboratories and ancillary premises (Not product production areas) (Suspension of operation)
   - Risk of contamination of warehouses (Suspension of operation)
   - Risk of infection from insufficient social distance
   - Risk of infection from visitors, auditors, contractors and external partners
   - Risk of dependence on service providers (e.g., especially those involved in pest control, facility cleaning, transport companies, etc.)
   - Risk of the health and hygiene of staff
5. Products and services
   - Risk of product safety and quality
   - Risk of patient safety
6. Supply chain management
   - Risk of shortage of raw materials (Actives, excipients, packaging materials) as well as reagents, solvents, etc., to support the production of products
   - Risk of not being able to provide products to customers
   - Risk of insufficiency of transport companies
   - Risk of delivery delays and impact on products and services
7. Financial management
   - Risks related to financial liquidity
   - Inability to fulfill financial obligations
   - Inability to provide required resources
8. Social Responsibility
   - Inability to strengthen society

3.2.2 Risk Analysis

During the risk analysis phase, the Risk Priority Number (RPN) was calculated for each identified threat based on Severity (S), Occurrence Probability (O) and Detection Probability – Detectability (D). In addition, the impact categories were assessed according to the management standard ISO 22317: 2015 "Business Continuity Management Systems - Guidelines for Business Impact Analysis" and the categories as presented in Table 8 at the Appendix. Table 2 demonstrates the categories and examples of impacts at the level of products and services. Table 3 presents the threats that were identified as well as the business sectors they have an impact on. Additionally, the risk and operational impact assessment is analysed in Table 4.

Table 2: Categories and Examples of Impacts at the Level of Products and Services

Category of Impact	Impact Examples
Financial (F)	Financial losses due to fines, penalties, lost profits or reduced market share
Reputational (R)	Negative impact on the company's reputation

Legal and Regulatory (L&R)	Liability and revocation of product production and distribution license
Conventional (C)	Violation of contracts or obligations between companies
Entrepreneurial (E)	Failure to achieve goals or seize opportunities

Table 3: Identified Threats and Business Impact.

No.	Description	Business Impact
Disorganization event management		
1	Risk of suspension	(F)/(E)/ (C)/(R)
2	Inadequate handling of a disorganizing event	(E)
3	Failure to meet legal and regulatory requirements	(L&R)
Staff management		
4	Risk of spreading the infection to staff working in production facilities	(E)
5	Risk of unavailability of labor due to sick leave	(E)
6	Risk of increased contamination by personnel returning from leave	(E)
7	Risk of contamination by external collaborators operating in the production unit, laboratories and offices	(E)
8	Risk from misbehavior of personnel during the pandemic	(E)
9	Risk of insufficient staff information during the pandemic	(E)
Remote work and computer security		
10	Risk of not providing adequate equipment (laptops, printers, monitors, etc.) to support remote work (work from home) due to market shortage	(E)
11	Risk of failing to maintain cybersecurity and productivity when connecting remotely	(F)/(E)
12	Risk of unsafe access to the network from remote work (eg data theft, phishing, malware attacks)	(F)/(E)
13	Risk of unavailability of security at network and application level	(F)/(E)
14	Risk of unsafe mobile devices	(E)
Facilities		
15	Risk of contamination of the product production unit (Suspension of operation)	(F)/(E)
16	Risk of contamination of offices, laboratories and ancillary premises (not product areas) (Suspension)	(F)/(E)
17	Risk of contamination of warehouses (Suspension of operation)	(F)/(E)
18	Risk of infection from insufficient social distance	(E)
19	Risk of infection from visitors, auditors, contractors and external partners	(E)
20	Risk of dependence on service providers (eg especially those involved in pest control, facility cleaning, transport companies, etc.)	(E)
21	Risk of health and hygiene of staff	(E)
Products and services		
22	Risk of product safety and quality	(F)/(E)/ (L&R)/(C)
23	Risk of patient safety	(F)/(E)/

		(L&R)/(C)
Supply chain management		
24	Risk of shortage of raw materials (Actives, excipients, packaging materials) as well as reagents, solvents, etc., to support the production of products	(F)/(E)/(C)
25	Risk of not being able to provide products to customers.	(F)/(E)/(C)
26	Risk of insufficiency of transport companies	(F)/(E)/(C)
27	Risk of delivery delays and impact on products and services	(F)/(E)/(C)
Financial management		
28	Risks related to financial liquidity.	(F)/(E)
29	Inability to fulfill financial obligations	(F)
30	Inability to provide required resources	(F)
Social responsibility		
31	Failure to strengthen society	(R)

Table 4: Initial Risk Assessment and Operational Impact for Each Identified Threat.

No.	**Initial Parameter Calculation**			**RPN**	**Initial Risk Evaluation**	**Responsible**
	(§S)	**(§O)**	**(§D)**	**(§S x O x D)**		
Disorganization event management						
1	High (5)	High (5)	High (1)	25	**Average**	I.
2	High (5)	High (5)	High (1)	25	**Average**	I.
3	High (5)	High (5)	High (1)	25	**Average**	H.R./ Q.A.
Staff management						
4	High (5)	High (5)	Low (5)	125	**High**	H&S/H.R.
5	High (5)	High (5)	Low (5)	125	**High**	H&S/H.R.
6	High (5)	High (5)	Low (5)	125	**High**	H&S/H.R.
7	High (5)	High (5)	Low (5)	125	**High**	Q.A. /H&S/ H.R.
8	High (5)	High (5)	Average (3)	75	**High**	H&S/H.R.
9	Average (3)	Average (3)	Average (3)	27	**Average**	H.R.
Remote work and computer security						
10	High (5)	High (5)	Low (5)	125	**High**	I.T.
11	High (5)	High (5)	High (1)	25	**Average**	I.T.
12	High (5)	High (5)	High (1)	25	**Average**	I.T.
13	High (5)	High (5)	High (1)	25	**Average**	I.T.
14	High (5)	High (5)	High (1)	25	**Average**	I.T.
Facilities						
15	High (5)	High (5)	Low (5)	125	**High**	H.R./ H&S/ P.P.
16	High (5)	High (5)	Low (5)	125	**High**	H.R./ H&S/ Q.A.

17	High (5)	High (5)	Low (5)	125	**High**	H.R./ H&S/ Q.C.
18	High (5)	High (5)	Low (5)	125	**High**	H.R./ H&S
19	High (5)	High (5)	Low (5)	125	**High**	H.R./ H&S
20	High (5)	High (5)	Low (5)	125	**High**	H.R./ H&S
21	High (5)	High (5)	High (1)	25	**Average**	H.R./ H&S
Products and services						
22	High (5)	Low (1)	High (1)	5	**Low**	P.P./ Q.C./ Q.A.
23	High (5)	Low (1)	High (1)	5	**Low**	P.P./ Q.C./Q. A.
Supply chain management						
24	High (5)	High (5)	High (1)	25	**Average**	P.E./Q. C.
25	High (5)	High (5)	High (1)	25	**Average**	P.E./ C.S.
26	High (5)	High (5)	High (1)	25	**Average**	P.E.
27	High (5)	High (5)	High (1)	25	**Average**	P.E. / Q.A.
Financial management						
28	High (5)	Average (3)	Average (3)	45	**High**	F.M.
29	High (5)	Average (3)	High (1)	15	**Average**	F.M.
30	High (5)	Average (3)	High (1)	15	**Average**	F.M.
Social responsibility						
31	Average (3)	Average (3)	High (1)	9	Average	S.M./ H.R.

3.2.3 Risk control

During the control and risk reduction phase for each identified threat, decisions were made on strategies and solutions, based on the evolution of the pandemic, in order to avoid and / or reduce the risk to acceptable levels, according to the results of the RPN calculation for individual threats. Appropriate measures were taken to avoid and / or reduce the risk to acceptable levels for the identified threats whose initial assessment was "High" and "Moderate". For the threats whose initial assessment was "Low" it was not necessary to implement actions to avoid and / or reduce the risk to acceptable levels, however all actions taken were in the context of improving procedures. In addition, actions are classified as "Level A (A) actions" for actions performed immediately at the onset of the pandemic and as "Level B (B) actions" for actions performed at a secondary time during the evolution of the pandemic, as shown in Table 8 of Appendix.

3.2.4 Risk Acceptance

During the risk acceptance phase for each identified threat based on the actions taken to avoid and / or reduce the risk to acceptable levels, the RPN for the individual threats was recalculated. The recalculation was performed to ensure that appropriate risk and operational impact management strategies and solutions were implemented and that the risk was reduced to a company-acceptable level, as shown in Table 5. From Table 5 and the final risk assessment it is clear that based on the actions taken the overall risk was mitigated from "High" to "Moderate", i.e., at levels acceptable by the company.

Table 5: Final risk assessment and acceptance for each identified threat and operational impact.

No.	**Initial Parameter Calculation**			**RPN (§S x O x**	**Initial Risk Evaluation**	**Responsible**	**Risk Acceptance**
	(§S)	**(§O)**	**(§D)**				

				D)			
Disorganization event management							
1	High (5)	Average (3)	High (1)	15	**Average**	I.	YES
2	High (5)	Average (3)	High (1)	15	**Average**	I.	YES
3	High (5)	Average (3)	High (1)	15	**Average**	H.R./ Q.A.	YES
Staff management							
4	High (5)	High (5)	High (1)	25	**Average**	H&S/ H.R.	YES
5	High (5)	Low (1)	High (1)	5	**Low**	H&S/ H.R.	YES
6	High (5)	Low (1)	High (1)	5	**Low**	H&S/ H.R.	YES
7	High (5)	High (5)	High (1)	25	**Average**	Q.A. /H&S /H.R.	YES
8	High (5)	Low (1)	High (1)	5	**Low**	H&S/ H.R.	YES
9	Average (3)	Low (1)	High (1)	3	**Low**	H.R.	YES
Remote work and computer security							
10	Average (3)	Low (1)	High (1)	3	**Low**	I.T.	YES
11	High (5)	Low (1)	High (1)	5	**Low**	I.T.	YES
12	High (5)	Low (1)	High (1)	5	**Low**	I.T.	YES
13	High (5)	Low (1)	High (1)	5	**Low**	I.T.	YES
14	High (5)	Low (1)	High (1)	5	**Low**	I.T.	YES
Facilities							
15	High (5)	Average (3)	High (1)	15	**Average**	H.R./ H&S/ P.P.	YES
16	Average (3)	Low (1)	High (1)	3	**Low**	H.R./ H&S/ Q.A.	YES
17	High (5)	Average (3)	High (1)	15	**Average**	H.R./ H&S/ Q.C.	YES
18	High (5)	Low (1)	High (1)	5	**Low**	H.R./ H&S	YES
19	Average (3)	Average (3)	High (1)	9	**Average**	H.R./ H&S	YES
20	Average (3)	Average (3)	High (1)	9	**Average**	H.R./ H&S	YES
21	High (5)	Low (1)	High (1)	5	**Low**	H.R./ H&S	YES
Products and services							

22	High (5)	Low (1)	High (1)	5	**Low**	P.P./ Q.C./ Q.A.	YES
23	High (5)	Low (1)	High (1)	5	**Low**	P.P./ Q.C./ Q.A.	YES
Supply chain management							
24	High (5)	Low (1)	High (1)	5	**Low**	P.E./ Q.C.	YES
25	High (5)	Low (1)	High (1)	5	**Low**	P.E./ C.S.	YES
26	High (5)	Low (1)	High (1)	5	**Average**	P.E.	YES
27	Average (3)	Average (3)	High (1)	9	**Average**	P.E. / Q.A.	YES
Financial management							
28	Average (3)	Low (1)	High (1)	3	**Average**	F.M.	YES
29	Average (3)	Low (1)	High (1)	3	**Low**	F.M.	YES
30	Average (3)	Low (1)	High (1)	3	**Low**	F.M.	YES
Social responsibility							
31	Average (3)	Low (1)	High (1)	3	**Low**	S.M./ H.R.	YES

3.2.5 Communication and Risk Overview

At each stage of the risk assessment, communication with important stakeholders (e.g., heads of departments, company-wide communication, regulators, customers, and consumers) was maintained to enable the proper and seamless execution of appropriate strategies and solutions for risk reduction. Finally, because the pandemic is a dynamic phenomenon that continues to exist and poses a threat to the global population, the corporation closely watches it and employs every method and measure available to keep it under control. As a result of the pandemic's nature, risk review is a continuing process that requires the company to periodically re-evaluate the risk assessment and operational effect in light of global and national events and the company's commercial objectives.

3.3 Results Discussion

The company, with its expertise and experience in implementing the ISO 9001 quality assurance system, understood the needs of the ISO 22031 management standard for business continuity and tackled the disorganizing incident using management system fundamentals. The new High-Level Structure aided the company in identifying and meeting the two management standards' shared requirements for:

- the organization's operational structure, an awareness of stakeholders' expectations, and compliance with legal and regulatory requirements. The specific requirements already defined by the application of ISO 9001 were examined in order to incorporate the needs for business continuity management.
- the management commitment, which, aware that one of the most critical elements of successful management system implementation is the management's absolute commitment to this direction, acted appropriately by communicating its policy to ensure business continuity and the necessary resources to all involved.
- the systematic and expedited implementation of the business continuity strategy by identifying, analyzing, assessing, and addressing identified dangers and opportunities.
- the study of operational effect and the design of strategies and solutions necessary to avoid and/or mitigate risks,

but also the necessary changes and improvements to the existing quality management system to assure its quality. product and the health of the patient.
- the performance appraisal, since the organization incorporated points regarding the performance of the business continuity plan's implementation as inputs into the already-existing management review process.
- the company's fundamental policy of continuous improvement of its systems.

The company used a risk-based strategy to assess potential hazards, opportunities, and operational implications related with the COVID-19 pandemic. The risk assessment is regarded as one of the most critical, if not the most critical, steps in developing a business continuity strategy (Păunescu & Argatu, 2020; Torabi et al., 2016). In identifying threats, opportunities, and impacts, the company applied a recognized risk management approach and risk analysis tools to proceed with the identification, analysis, evaluation, control, and reduction to an acceptable level. As demonstrated in the case study analysis, the risk analysis approach has a broad scope and can be applied to any disorganized event due to its universal and reliable application (Jamaludin et al., 2020; Nakat & Bou-Mitri, 2021). The risk strategy is now the beginning point for organizational culture change, both in terms of product and service quality assurance and business continuity.
The Improvement Cycle approach, which is a fundamental principle of both the ISO 9001: 2015 quality standard and the ISO 22301: 2019 business continuity standard, was adopted by the company to implement the design, implementation, and control of the actions necessary to ensure the company's operation, as well as to improve the product quality management system and business continuity.
Along with the risks identified, the company evaluated the opportunities presented by the COVID-19 pandemic, including the following:
- Using remote work as a more flexible and efficient work pattern.
- Using new technologies and improving existing ones
- Improving the company's cybersecurity procedures
- Improving employee care. Possibility of social contribution
- Enhancing client relations
- Boosting the company's reputation and credibility
- Boosting the quality system
- Enhancing business continuity practices.
- Possibility of ISO 22301 certification.

Taking into account the foregoing and the requirements of the business continuity management model, the company established an interdepartmental Crisis Management Team (CRC) at the start of the COVID-19 pandemic manifestation. The CRC was responsible for assessing the risk and operational impact, including the suspension scenario, but also for all actions that would be taken during the pandemic period.
As part of the firm's efforts to avoid and/or mitigate recognized risks, all employees received training on COVID-19 symptoms and prevention by e-mail and SMS from the Human Resources (HR) department, which was responsible for monitoring any health issues affecting company personnel. Additionally, the company has established a telephone medicine consulting service for COVID-19 with the goal of giving accurate information and counseling from healthcare professionals, as well as managing high-risk populations effectively. Employees were urged to practice social distance in their regular tasks through the placement of pertinent educational posters. All necessary infection protection materials (basic surgical masks, surface cleaners, disposable gloves, etc.) and alcohol hand sanitizers have been distributed throughout the company's facilities, ensuring that each employee has access. Weekly disinfection of all facilities was planned and executed in conjunction with daily cleaning and disinfection of all offices and public areas. Despite the preventive maintenance of all air conditioners, the personnel was asked to avoid using air conditioners and instead work with open windows (where applicable). The corporation developed work-from-home policies for a significant portion of its workforce in order to reduce the risk of contamination on the company's facilities. Another mitigation measure implemented by the organization was a meticulously designed shift schedule for all employees working in offices and facilities. To comply with federal requirements about the spread of COVID-19, the company allowed all workers to work either full-time from home or on a flexible schedule while keeping social distance. Additionally, the corporation conducted additional recruitments to ensure that sufficient staff were available in each production unit.
Additionally, the company has implemented mandatory measures that must be followed on a daily basis, including:
- the use of a face mask in all premises,

- thermal scanning at each entry point for all employees / visitors entering the company premises,
- 14 days off work following annual leave, and a free COVID-19 examination prior to returning.

Visitors were denied access to all departments of the corporation, and all business visits inside and outside of Greece were canceled. Visitors were permitted only in exceptional circumstances and upon presentation of a signed "Visitor Identification Statement" attesting to their responsibility for previous travels to countries with an increase in COVID-19 cases or if they had recently contracted COVID-19. Additionally, all internal and external meetings are conducted via video conference or video conferencing. Concerning customer and authority controls, the company established an alternative method of remote / virtual control with the assistance and support of the IT department and the use of appropriate communication platforms. The aforementioned actions are consistent with the practices described in the literature for managing personnel and potentially product quality during a pandemic (Jamaludin et al., 2020; Nakat & Bou-Mitri, 2021; Tuzovic & Kabadayi, 2021), and the World Health Organization's (WHO) guidelines (O'Neill, 2020).

The IT department provided the essential equipment (computers, mobile phones, and VPN access) and VPN access to the company's remote personnel in order to assure each user's safe and productive remote connection. The already-existing IT Support Office (Helpdesk) provided further support to all remote employees. The IT department has integrated modern meeting platforms (MS Teams, Go to Meeting) into its business processes to facilitate collaboration between internal and external stakeholders. Additionally, the IT department hosted online cybersecurity workshops to safeguard the organization from cyber threats, mitigate the severity of attacks, and ensure that business operations continue to run smoothly. Additionally, policies for remote work and internet use have been established, as have measures to defend the organization from hostile attacks. The aforementioned actions are consistent with similar practices mentioned in the literature regarding the actions that must be taken to ensure the company's information systems and cybersecurity (Malecki, 2020; Papadopoulos et al., 2020; Papagiannidis et al., 2020), as well as the WHO guidelines (O'Neill, 2020).

The supply chain is significantly impacted by the pandemic, as it is difficult to prevent the virus from spreading through the flow of commodities. Numerous practices are described in the supply chain management literature (El Baz & Ruel, 2021; Karmaker et al., 2021; Rajesh, 2021; Suresh et al., 2020), and in these the company contacted all suppliers to check delivery of all outstanding orders and to assure the safety of its fundamental raw material inventory (Active substances, Excipients and other raw materials). Additionally, the corporation sought, where possible, early supplies of raw materials and ensured the availability of alternative suppliers while considering any additional expenses associated with transportation, tariffs, and anticipated price hikes. Contact material and service providers to explore any ramifications for their work and how they plan to maintain business continuity during the COVID-19 pandemic.

The financial management department, with the cooperation of top management, has implemented a plan to ensure the company's financial liquidity. To this end, the company reached an agreement with local banks for additional lending facilities, financing a short-term potential increase in the company's working capital, as a practical demonstration of the top management's commitment to securing the necessary resources and ensuring the company's business continuity and compliance with its obligations during the pandemic.

As part of its social responsibility activities, the company has provided free antiseptics to strengthen health institutions, logistical infrastructure (masks, gloves, etc.) to local governments, organized blood donations in accordance with COVID-19 requirements, and supported charities via an online fundraiser and a virtual marathon.

Finally, the company managed based on its experience and expertise in evaluating, implementing, maintaining, documenting, and maintaining a management system, as well as by applying the risk management methodology to respond quickly and efficiently to a disorganizing event, while taking into account applicable legal and regulatory requirements and adapting while maintaining its commitment to continuous improvement of its products and services.

4 Conclusion

The paper demonstrated the methods used by a pharmaceutical company to ensure business continuity during the COVID-19 pandemic. The theoretical foundation for the risk analysis was established by comparing and contrasting the requirements of ISO 9001: 2015 and ISO 22301: 2019. The similarities and variations in the requirements of management standards ISO 9001: 2015 and ISO 22301: 2019 shown the management standards' structural requirements are aligned and

their executive departments are distinct, owing to the subject matter they cover. Finally, a specific emphasis was placed on all aspects of the business continuity management model that link directly or indirectly to the risk approach. The theoretical background analysis was conducted to interpret the approach and methodology used by a pharmaceutical company during the COVID-19 pandemic to ensure business continuity by adhering to quality management and business continuity, risk management standards, as well as its know-how and structured approach to problem solving. Additionally, the study's objective was to emphasize the critical nature of harmonizing the requirements of various management standards in order to make it easier for firms to develop and operate an integrated management system. In this regard, a future study might focus on further developing the method of harmonizing the various management standards, as well as on the risk and operational impact of other disorganizing occurrences. Finally, given the pandemic's unique characteristics and the fact that many of the measures taken to manage this health crisis are heavily reliant on the human factor and individual accountability, it is concluded that the pharmaceutical company studied successfully developed an effective action plan in order to mitigate identified risks to acceptable levels, maintain business continuity, and ensure the product's quality.

References:

[1] Abou-El-Enein, M., Römhild, A., Kaiser, D., Beier, C., Bauer, G., Volk, H.-D., & Reinke, P. (2013). Good Manufacturing Practices (GMP) manufacturing of advanced therapy medicinal products: a novel tailored model for optimizing performance and estimating costs. Cytotherapy, 15(3), 362–383. https://doi.org/10.1016/j.jcyt.2012.09.006

[2] Djalante, R., Shaw, R., & DeWit, A. (2020). Building resilience against biological hazards and pandemics: COVID-19 and its implications for the Sendai Framework. Progress in Disaster Science, 6, 100080. https://doi.org/10.1016/j.pdisas.2020.100080

[3] Donthu, N., & Gustafsson, A. (2020). Effects of COVID-19 on business and research. Journal of Business Research, 117, 284–289. https://doi.org/10.1016/j.jbusres.2020.06.008

[4] El Baz, J., & Ruel, S. (2021). Can supply chain risk management practices mitigate the disruption impacts on supply chains' resilience and robustness? Evidence from an empirical survey in a COVID-19 outbreak era. International Journal of Production Economics, 233, 107972. https://doi.org/10.1016/j.ijpe.2020.107972

[5] Huremović, D. (2019). Brief History of Pandemics (Pandemics Throughout History). In Psychiatry of Pandemics (pp. 7–35). Springer International Publishing. https://doi.org/10.1007/978-3-030-15346-5_2

[6] Ioannidis, J. P. A. (2021). Infection fatality rate of COVID-19 inferred from seroprevalence data. Bulletin of the World Health Organization, 99(1), 19-33F. https://doi.org/10.2471/BLT.20.265892

[7] Jamaludin, S., Azmir, N. A., Mohamad Ayob, A. F., & Zainal, N. (2020). COVID-19 exit strategy: Transitioning towards a new normal. Annals of Medicine and Surgery, 59, 165–170. https://doi.org/10.1016/j.amsu.2020.09.046

[8] Jebril, N. (2020). World Health Organization Declared a Pandemic Public Health Menace: A Systematic Review of the Coronavirus Disease 2019 "COVID-19." SSRN Electronic Journal. https://doi.org/10.2139/ssrn.3566298

[9] Karmaker, C. L., Ahmed, T., Ahmed, S., Ali, S. M., Moktadir, M. A., & Kabir, G. (2021). Improving supply chain sustainability in the context of COVID-19 pandemic in an emerging economy: Exploring drivers using an integrated model. Sustainable Production and Consumption, 26, 411–427. https://doi.org/10.1016/j.spc.2020.09.019

[10] Larsen, J. R., Martin, M. R., Martin, J. D., Kuhn, P., & Hicks, J. B. (2020). Modeling the Onset of Symptoms of COVID-19. Frontiers in Public Health, 8. https://doi.org/10.3389/fpubh.2020.00473

[11] Leite, H., Hodgkinson, I. R., & Gruber, T. (2020). New development: 'Healing at a distance'—telemedicine and COVID-19. Public Money & Management, 40(6), 483–485. https://doi.org/10.1080/09540962.2020.1748855

[12] Malecki, F. (2020). Overcoming the security risks of remote working. Computer Fraud & Security, 2020(7), 10–12. https://doi.org/10.1016/S1361-3723(20)30074-9

[13] Nakat, Z., & Bou-Mitri, C. (2021). COVID-19 and the food industry: Readiness assessment. Food Control, 121, 107661. https://doi.org/10.1016/j.foodcont.2020.107661

[14] O'Neill, R. (2020). WHO Knew. How the World Health Organization (WHO) Became a Dangerous Interloper on Workplace Health and Safety and COVID-19. NEW SOLUTIONS: A

Journal of Environmental and Occupational Health Policy, 30(3), 237–248. https://doi.org/10.1177/1048291120961337

[15] Papadopoulos, T., Baltas, K. N., & Balta, M. E. (2020). The use of digital technologies by small and medium enterprises during COVID-19: Implications for theory and practice. International Journal of Information Management, 55, 102192. https://doi.org/10.1016/j.ijinfomgt.2020.102192

[16] Papagiannidis, S., Harris, J., & Morton, D. (2020). WHO led the digital transformation of your company? A reflection of IT related challenges during the pandemic. International Journal of Information Management, 55, 102166. https://doi.org/10.1016/j.ijinfomgt.2020.102166

[17] Păunescu, C., & Argatu, R. (2020). CRITICAL FUNCTIONS IN ENSURING EFFECTIVE BUSINESS CONTINUITY MANAGEMENT. EVIDENCE FROM ROMANIAN COMPANIES. Journal of Business Economics and Management, 21(2), 497–520. https://doi.org/10.3846/jbem.2020.12205

[18] Rajesh, R. (2021). Flexible business strategies to enhance resilience in manufacturing supply chains: An empirical study. Journal of Manufacturing Systems, 60, 903–919. https://doi.org/10.1016/j.jmsy.2020.10.010

[19] Sahebjamnia, N., Torabi, S. A., & Mansouri, S. A. (2015). Integrated business continuity and disaster recovery planning: Towards organizational resilience. European Journal of Operational Research, 242(1), 261–273. https://doi.org/10.1016/j.ejor.2014.09.055

[20] Suresh, N., Sanders, G. L., & Braunscheidel, M. J. (2020). Business Continuity Management for Supply Chains Facing Catastrophic Events. IEEE Engineering Management Review, 48(3), 129–138. https://doi.org/10.1109/EMR.2020.3005506

[21] Torabi, S. A., Giahi, R., & Sahebjamnia, N. (2016). An enhanced risk assessment framework for business continuity management systems. Safety Science, 89, 201–218. https://doi.org/10.1016/j.ssci.2016.06.015

[22] Tuzovic, S., & Kabadayi, S. (2021). The influence of social distancing on employee well-being: a conceptual framework and research agenda. Journal of Service Management, 32(2), 145–160. https://doi.org/10.1108/JOSM-05-2020-0140

Appendix

Table 6: Comparison of the Structure of ISO 22301: 2019 & ISO 9001: 2015

ISO 22301:2019		**ISO 9001:2015**	
1	**Objectives**	**1**	**Objectives**
2	**Standard References**	**2**	**Standard References**
3	**Terms and Definitions of Concepts**	**3**	**Terms and Definitions of Concepts**
4	**Operating Framework of the Organization**	**4**	**Operating Framework of the Organization**
4.1	Understanding of the Organization and its operating framework	4.1	Understanding of the Organization and its operating framework
4.2	Understanding the needs and expectations of stakeholders	4.2	Understanding the needs and expectations of stakeholders
4.2.1	General	~	~
4.2.2	Legal and regulatory requirements	~	~
4.3	Defining the scope of the business continuity management system	4.3	Defining the scope of the quality management system

ISO 22301:2019		ISO 9001:2015	
4.3.1	General	~	~
4.3.2	Scope of the business continuity management system	~	~
4.4	Business continuity management system	4.4	Quality management system and its processes
5	**Leadership**	**5**	Leadership
5.1	Leadership and commitment	5.1	Leadership and commitment
		5.1.1	General
		5.1.2	Customer focus
5.2	Policy	5.2	Policy
5.2.1	Establishment of business continuity policy	5.2.1	Establishing quality policy
5.2.2	Disclosure of business continuity policy	5.2.2	Communication of quality policy
5.3	Roles, responsibilities and jurisdictions	5.3	Roles, responsibilities and responsibilities within the Organization

ISO 22301:2019		ISO 9001:2015	
6	**Planning and programming**	**6**	**Planning and programming**
6.1	Threats and opportunities	6.1	Threats and opportunities
6.1.1	Identify threats and opportunities	~	~
6.1.2	Dealing with threats and seizing opportunities	~	~
6.2	Business continuity goals and planning and planning to achieve them	6.2	Quality goals and design to achieve them
6.2.1	Establish business continuity goals	~	~
6.2.2	Defining business continuity goals	~	~
6.3	Planning and scheduling changes in the business continuity management system	6.3	Change planning
7	**Support**	**7**	**Support**
7.1	Resources	7.1	Resources
~	~	7.1.1	General
~	~	7.1.2	Staff

ISO 22301:2019		ISO 9001:2015	
~	~	7.1.3	Infrastructure
~	~	7.1.4	Environment for the operation of processes
~	~	7.1.5	Monitoring and measurement resources
~	~	7.1.6	Business knowledge
7.2	Professional competence	7.2	Professional competence
7.3	Awareness	7.3	Awareness
7.4	Contact	7.4	Contact
7.5	Documented information	7.5	Documented information
7.5.1	Generally	7.5.1	General
7.5.2	Create and update	7.5.2	Create and update
7.5.3	Verification of documented information	7.5.3	Verification of documented information
8	**O**peration	**8**	**Operation**
8.1	Design and operation control	8.1	Design, operation and control of processes
8.2	Business Impact Analysis and Risk Assessment	8.2	Requirements for products and services
8.2.1	General	8.2.1	Communication with the customers
8.2.2	Business Impact Analysis	8.2.2	Determining the requirements for products and services
8.2.3	Risk assessment	8.2.3	Review of product and service requirements
~	~	8.2.4	Changes in product and service requirements
8.3	Business continuity strategies and solutions	8.3	Design and development of products and services
8.3.1	General	8.3.1	General
8.3.2	Identification of strategies and solutions	8.3.2	Elaboration of a plan for design and development
8.3.3	Selection of strategies and solutions	8.3.3	Inbound design and development
8.3.4	Resource requirements	8.3.4	Design and development control

ISO 22301:2019		ISO 9001:2015	
8.3.5	Implementation of solutions	8.3.5	Design and development results
~	~	8.3.6	Changes in design and development
8.4	Business continuity plans and procedures	8.4	Control of processes, products and services provided by external parties
8.4.1	General	8.4.1	General
8.4.2	Response structure	8.4.2	Type and scope of control
8.4.3	Warning and communication	8.4.3	Information disclosed to external providers
8.4.4	Business continuity plans	~	~
8.4.5	Recovery or reorganization	~	~
8.5	Pilot exercise program	8.5	Production of products and provision of services
~	~	8.5.1	Control of production of products and provision of services
~	~	8.5.2	Identification and traceability
~	~	8.5.3	Property owned by customers or external providers
~	~	8.5.4	Preservation
~	~	8.5.5	Activities after delivery
~	~	8.5.6	Change control
8.6	Assessment of documentation and capabilities of business continuity	8.6	Release of products and services
~	~	8.7	Control of non-compliant results
9	**Performance evaluation**	**9**	**Performance evaluation**
9.1	Monitoring, measurement, analysis and evaluation	9.1	Monitoring, measurement, analysis and evaluation
~	~	9.1.1	General
~	~	9.1.2	Customer satisfaction
~	~	9.1.3	Analysis and evaluation
9.2	Internal inspection	9.2	Internal inspection
9.2.1	General	~	~

ISO 22301:2019		ISO 9001:2015	
9.2.2	Schedule (s) of inspection	~	~
9.3	Management review	9.3	Management review
9.3.1	General	9.3.1	General
9.3.2	Inbox review by Management	9.3.2	Inbox review by Management
9.3.3	Management results from the Management	9.3.3	Management results from the Management
10	**Improvement**	**10**	Improvement
10.1	Non-compliance and corrective actions	10.1	General
10.2	Continuous improvement	10.2	Non-compliance and corrective actions
~	~	10.3	Continuous improvement

Table 7: Sections of ISO 9001: 2015 and ISO 22301: 2019 and their Correspondence to the Improvement Cycle

Improvement Cycle	Παράγραφος ISO 9001:2015	Παράγραφος ISO 22301:2019
	Section 1 - Subject matter	Section 1 - Subject matter
	Section 2 - Standard Reference	Section 2 - Standard Reference
	Section 3 - Terms and Definitions of Concepts	Section 3 - Terms and Definitions of Concepts
Plan	Section 4 - Operating Framework of the Organization Section 5 - Leadership Section 6 - Plan	Section 4 - Operating Framework of the Organization Section 5 - Leadership Section 6 – Plan & Programming
Execute	Section 7 - Support Section 8 - Operation	Section 7 - Support Section 8 - Operation
Control	Section 9 - Performance Evaluation	Section 9 - Performance Evaluation
Improve	Section 10 - Improvement	Section 10 - Improvement

Table 8: Actions to avoid and / or reduce the risk for each identified threat and to classify them as "Level A- (A)" or "Level B- (B)" actions.

No.	Actions to avoid and / or reduce the risk
Disorganization event management	

No.	Actions to avoid and / or reduce the risk
1	• Recommendation Crisis Management and Replacement Team- (A) • Human Resources Management- (A) • Health and personal hygiene - (A) • Supplier Management- (B) • Inventory Management- (A) • Customer Support- (B) • Remote work- (A) • Irt Virtual audit support - (B) • Activation of internal procedures- (A) • Cleaning and disinfection of facilities- (A) • Infection control- (A) • Human Resources Department Announcements (A) • Frequent updates through the employees corner (Website employees corner) - (B) • Weekly management communication with employees- (B) • Posting of personal hygiene and health care instructions in conspicuous places inside the premises- (A) • Check body temperature before entering the facility- (B) • Free laboratory tests for COVID-19 in staff at a predetermined frequency- (B)
2	• Recommendation Crisis Management and Replacement Team - (A) • Review of the effectiveness of the management of the disorganizing event during the process of the Review by the Management. - (B) • Implementation of internal procedures for dealing with a disorganizing event and maintaining business continuity- (A) • Implementation of internal procedures in order to ensure the quality of the product and the health of the patient- (A)
3	• Ongoing information on current legal and regulatory requirements - (A) • Appointment of staff to monitor legal and regulatory requirements- (A)
Staff management	
4	• Providing free medical advice by phone- (A) • Encouragement to reduce unnecessary travel- (A) • Encouraging social distancing - (A)

No.	Actions to avoid and / or reduce the risk
	• Remote work based on staff rolling schedule- (A) • Special care for vulnerable groups (e.g., teleworking, special purpose licenses without loss of income, free laboratory tests) - (A) • Determination of the maximum allowed number of employees per workplace, in accordance with the existing provisions of the state- (B) • Provided logistics (E.g., masks, gloves, robes, 70% ethanol etc.) - (A) • Coverage of travel expenses of employees to and from work for the purpose of individual movement of staff- (B) • Guest Identification Statement- (B) • Human Resources Department Announcements (A) • Frequent updates through the employees' corner (Website employees' corner) - (B) • Weekly management communication with employees- (B) • Training of staff in matters of personal hygiene- (A) • Posting of personal hygiene and health care instructions in conspicuous places inside the premises- (A) • Check body temperature before entering the facility- (B) • Free laboratory tests for COVID-19 in staff at a predetermined frequency- (B)
5	• Promotion of new recruitments- (B) • Remote work based on staff rolling schedule- (A)
6	• Training of staff in matters of personal hygiene- (A) • Posting of personal hygiene and health care instructions in conspicuous places inside the premises- (A) • Encouraging social distancing - (A) • Determination of the maximum allowed number of employees per workplace, in accordance with the existing provisions of the state- (B) • Provided logistics (Eg masks, gloves, robes, 70% ethanol etc) - (A) • Free laboratory tests for COVID-19 in staff at a predetermined frequency- (B)

No.	Actions to avoid and / or reduce the risk
	• Check body temperature before entering the facility- (B)
7	• Guest Identification Statement- (B) • Encouraging social distancing - (A) • Provided logistics (E.g., masks, gloves, robes, 70% ethanol etc.) - (A) • Prerequisite negative laboratory test COVID-19- (A) • Check body temperature before entering the facility- (B)
8	• Training of staff in matters of personal hygiene- (A) • Posting of personal hygiene and health care instructions in conspicuous places inside the premises- (A) • Encouraging social distancing - (A) • Determination of the maximum allowed number of employees per workplace, in accordance with the existing provisions of the state- (B) • Provided logistics (E.g., masks, gloves, robes, 70% ethanol etc.) - (A) • Free laboratory tests for COVID-19 in staff at a predetermined frequency- (B) • Check body temperature before entering the facility- (B)
9	• Posting of announcements of human resources department in common areas- (A) • Sending newsletters via email and SMS- (A) • Information of the staff by the supervisors- (A) • Frequent updates through the employees corner (Website employees corner) - (B) • Weekly management communication with employees- (B)
Remote work and computer security	
10	• Settlement with IT equipment suppliers- (A) • Needs assessment in IT and technology products- (A) • Placement of required orders- (A) • Additional funding for IT procurement - (A) • Acceleration of relevant implementation processes (Fast track) - (A)
11	• IT Infrastructure- (A) • Online cyber security training for staff- (B) • Continuous IT support- (A)

No.	Actions to avoid and / or reduce the risk
	• Remote access via VPN- • Implementing a remote work policy - (B) • Implement internet usage policy- (B) • Integration of meeting platforms- (A) • Daily or weekly department meetings- (B)
12	• IT infrastructure- (DA) • Online cyber security training for staff- (B) • Continuous IT support- (A) • Remote access via VPN- • Implementing a remote work policy - (B) • Implement internet usage policy- (B)
13	• Maintenance of IT infrastructure- (A) • Online cyber security training for staff- (B) • Continuous IT support- (A) • Implementing Remote Labor Policy (B) • Implement internet usage policy- (B)
14	• IT infrastructure- (A) • Online cyber security training for staff- (B) • Continuous IT support- (A) • Remote access via VPN- • Implementing a remote work policy - (B) • Implement internet usage policy- (B)
Facilities	
15	• Application of internal cleaning and disinfection procedures of the premises- (A) • Retraining of staff in the procedures of cleaning and disinfection of premises - (A) • Training of staff in matters of personal hygiene- (A) • Retraining of staff in clothing processes to production rooms- (A) • Posting of personal hygiene and health care instructions in conspicuous places inside the premises- (A) • Encouraging social distancing - (A) • Determination of the maximum allowed number of employees per workplace, in accordance with the existing provisions of the state- (B) • Provided logistics (Eg masks, gloves, robes, 70% ethanol etc) - (A) • Coverage of travel expenses of employees to and from work for the purpose of individual movement of staff- (B) • Guest Identification Statement- (B)

No.	Actions to avoid and / or reduce the risk
	• Frequent cleaning and disinfection of facilities according to the internal cleaning and disinfection procedures- (A) • Check body temperature before entering the facility- (B) • Free laboratory tests for COVID-19 in staff at a predetermined frequency- (B)
16	• Remote work based on staff rolling schedule- (A) • Training of staff in matters of personal hygiene- (A) • Posting of personal hygiene and health care instructions in conspicuous places inside the premises- (A) • Encouraging social distancing - (A) • Determination of the maximum allowed number of employees per workplace, in accordance with the existing provisions of the state- (B) • Provided logistics (Eg masks, gloves, robes, 70% ethanol etc) - (A) • Coverage of travel expenses of employees to and from work for the purpose of individual movement of staff- (B) • Frequent cleaning and disinfection of facilities by external services, in addition to the production areas • Check body temperature before entering the facility- (B) • Free laboratory tests for COVID-19 in staff at a predetermined frequency- (B)
17	• Training of staff in matters of personal hygiene- (A) • Posting of personal hygiene and health care instructions in conspicuous places inside the premises- (A) • Encouraging social distancing - (A) • Determination of the maximum allowed number of employees per workplace, in accordance with the existing provisions of the state • Provided logistics (Eg masks, gloves, robes, 70% ethanol etc) - (A) • Coverage of travel expenses of employees to and from work for the purpose of individual movement of staff- (B) • Frequent cleaning and disinfection of facilities by external services- (A)

No.	Actions to avoid and / or reduce the risk
	• Check body temperature before entering the facility- (B) • Free laboratory tests for COVID-19 in staff at a predetermined frequency- (B)
18	• Training of staff in personal hygiene issues- (A) • Posting of personal hygiene and health care instructions in conspicuous places inside the premises- (A) • Determination of the maximum allowed number of employees per workplace, in accordance with the existing provisions of the state- (B) • Provided logistics (Eg masks, gloves, robes, 70% ethanol etc) - (A) • Coverage of travel expenses of employees to and from work for the purpose of individual movement of staff- (B)
19	• Suspension of the visit by external partners for unnecessary reasons- (A) • Guest Identification Statement- (B) • Determination of the maximum allowed number of employees per workplace, in accordance with the existing provisions of the state- (B) • Provided logistics (Eg masks, gloves, robes, 70% ethanol etc) - (A) • Integration of meeting platforms- (A) • Remote / virtual control procedure (remote audit) - (A) • Prerequisite is the negative laboratory test COVID-19- (A) • Check body temperature before entering the facility- (B) • Visitors are allowed only in special cases and only after providing the signed "Visitor Identification Statement" - (B)
20	• Training of external collaborators in matters of personal hygiene- (B) • Posting of personal hygiene and health care instructions in conspicuous places inside the premises- (A) • Encouraging social distancing - (DA) • Provided logistics (Eg masks, gloves, robes, 70% ethanol etc) - (A) • Visitors are allowed only in special cases and only after providing the signed "Visitor Identification Statement" - (B)

No.	Actions to avoid and / or reduce the risk
	• Frequent cleaning and disinfection of facilities by external services, in addition to the production areas • Check body temperature before entering the facility- (B)
21	• Remote work- (A) • Modified shifts- (A) • Staff encouragement (A) • Training of staff in matters of personal hygiene- (A) • Posting of personal hygiene and health care instructions in conspicuous places inside the premises- (A) • Encouraging social distancing - (A) • Provided logistics (Eg masks, gloves, robes, 70% ethanol etc) - (A) • Coverage of travel expenses of employees to and from work for the purpose of individual movement of staff- (B) • Visitors are allowed only in special cases and only after providing the signed "Visitor Identification Statement" - (B) • Remote / virtual control procedure (remote audit) - (A) • Frequent cleaning and disinfection of facilities by external services- (A) • No air recirculation in all areas of the installation- (A) • Check body temperature before entering the facility- (B) • Free laboratory tests for COVID-19 in staff at a predetermined frequency- (B)
Products and services	
22	• Personnel Management- (A) • Production of products according to GMP- (A) • Implementation and strengthening of the quality assurance system- (A) • Application of internal cleaning and disinfection procedures of production areas- (A) • Retraining of staff in the procedures of cleaning and disinfection of premises - (A) • Training of staff in the clothing processes to the production rooms- (A) • Retraining of staff in clothing processes to production rooms- (A)
23	

No.	Actions to avoid and / or reduce the risk
	• Provided logistics (Eg masks, gloves, robes, 70% ethanol etc) - (A) • No air recirculation in the production areas- (A) • Frequent cleaning and disinfection of facilities by external services, outside the production areas- (A) • Quality control of products during their production and in the final product- (A) • Implementation of internal divergence reporting procedures - (A) • Implementation of internal product recall procedures, if necessary- (B)
Supply chain management	
24	• Precautionary supply chain management with inventory management of raw materials, excipients, packaging materials and consumables- (B) • Timely communication with suppliers- (A) • Availability of stocks to support demand- (A) • Proper stock management- (A) • Hierarchy of orders- (A) • Advance Deliveries - (A) • Alternative suppliers- (B) • Review of management procedures and requirements by suppliers- (B)
25	• Organization of orders in consultation with customers- (A) • Informing the customers about the operations to ensure business continuity- (A) • Preventive supply chain management with inventory management of raw materials, excipients, packaging materials and consumables- (B) • Timely communication with suppliers- (A) • Availability of stocks to support demand- (A) • Proper stock management- (A) • Hierarchy of orders- (A) • Advance Deliveries - (A) • Alternative suppliers- (B) • Review of management procedures and requirements by suppliers- (B)
26	• Timely communication with transport companies to ensure the continuity of their operations, eg strengthening their fleet- (A)

No.	Actions to avoid and / or reduce the risk
	• Maintaining priority for the company's missions- (A) • Update of contracts with transport companies- (B) • Alternative transport companies- (B) • Use of proprietary means for the transport of products, where possible- (B)
27	• Timely communication with transport companies to ensure the continuity of their operations, eg strengthening their fleet- (A) • Maintaining priority for the company's missions- (A) • Update of contracts with transport companies- (B) • Alternative transport companies- (B) • Use of proprietary means for the transport of products, where possible- (B) • Immediate communication with customers in case of delays- (A) • Transport of products by means of which they maintain specific environmental conditions- (A) • Review of product stability studies- (A) • Monitoring of transport conditions (temperature, humidity) using a logger- (A)
Financial management	
28	• Actions to strengthen the financial position of the company by securing additional financial facilities- (A)
29	• Commitment of the top management to ensure the continued fulfillment of its financial obligations to staff and other stakeholders- (PS)
30	• Commitment of the top management to ensure the necessary infrastructure in both logistics and personnel- (A)
Social responsibility	
31	• Free production of antiseptics to enhance state needs- (A) • Provision of logistical infrastructure (masks, gloves, etc.) to local authorities- (B) • Organization of blood donations in compliance with the measures for COVID-19- (B)
	• Supporting charities through online fundraising and virtual marathon- (B)

Contribution of individual authors to the creation of a scientific article (ghostwriting policy)

Georgios Chatzistelios carried out:
Conceptualization, Methodology Development & Project Administration.
Evripidis P. Kechagias carried out:
Writing – Original Draft, Editing and Formal Analysis.
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Review & Model Formulation.
Georgios A. Papadopoulos carried out:
Validation & Supervision.
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