

Risk Management and Business Continuity of Alkaloid AD Skopje

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Introduction

Risk management is one of the foundations of a pharmaceutical quality system and is an integral part of the processes in a company. The purpose of quality risk management is to provide evidence-based information and analysis to make informed decisions and improve processes in the pharmaceutical quality system.

The risk management process is an essential element for establishing a proactive approach that will ensure continuity of operation and readiness of the company to anticipate, detect and respond to negative impacts that have the potential to prevent the execution of critical processes of the company, achieving its goals and meeting the requirements of stakeholders for quality.

Risk Management at Alkaloid AD Skopje

Risk management in Alkaloid AD Skopje is based on Good Manufacturing Practice, guidelines and examples of risk management tools defined in the ICH Q9 Risk Management Guide, requirements of the ISO 31000 standard Risk Management System, application guides and other standards that the company applies. The risks managed by Alkaloid AD Skopje are integrated in all business and production processes.

Risk and continuity management is under the authority of the Risk Management, Crisis Management and Continuity Management Board, the Risk and Continuity Management Team and the Heads of Organizational Units / Process Owners.

Continuity management is established by the standard ISO 22301 Continuity system requirements. The main

elements according to which the process of continuity of work is based are the following:

- operational planning and control,
- business impact analysis and risk assessment,
- strategy for business continuity,
- business continuity plan,
- programs for testing and practicing the effectiveness of the strategy for continuity of work and
- evaluation of the established documentation and the ability of the established continuity in operation.

Company activities related to risk management

Risk management is a systematic process for identifying, analyzing and assessing whether the risk should be modified, eliminated or reduced to an acceptable level. This process requires a defined communication, ongoing monitoring and verification of the risks identified to establish control of the modified risks and avoid/reduce negative effects.

All activities in the company /organization include risks. Risk management can be applied throughout the organization in all areas and at all levels, at any time and for specific functions, projects and activities.

Risk determination in Alkaloid AD is performed at the level of organization, PC / program (in terms of context), process level, and activity/product. Types of risks processed in Alkaloid AD are strategic risks, process (operational) risks, and quality risks specific to the purpose of the product, process, equipment and more.

All applicable methodologies described appropriately in the quality system can be used for risk evaluation. According to the established Risk Management Procedure,

the methodologies used and recommended in the risk evaluation are FMEA and HACCP methodologies.

The FMEA methodology is based on three parameters: severity, probability and detection. Risk priority categorizes into four categories: low, medium, high, and critical risk. Each category has defined how to take measures to prevent and reduce risks.

The HACCP methodology is based on two parameters: severity and probability, and defining critical control points according to the decision tree. The categorization and the manner of taking measures are identical to the FMEA methodology. The Strategic Risk Register and the Quality Risk Register (process operational and product-specific risks) are used as a tool to support the process. The registers provide a comprehensive overview of risks, timely identification and management of factors that may affect the realization of the goals and strategy of the company. By continuously reviewing the risks, the probability of occurrence of risks is reduced, the severity of the consequences of risks is reduced, and measures are taken to raise awareness, readiness, management and maintenance of risks at an acceptable level.

In 2021, at the Alkaloid AD Skopje level, 1778 risks were re-examined, of which 169 risks were reduced (30%), and 249 new risks were identified.

For PC Pharmacy in 2021, a total of 851 risks from 46 production processes were re-examined, 135 additional measures were defined, 51 risks were reduced (30%), and 41 new risks were identified.

Specific risks to the pharmaceutical industry that have been challenging in operation are the potential presence of N-Nitrosamines in the finished product, the Covid-19 pandemic, and the disrupted political, security, and economic situation in Ukraine and Russia.

For all affected products of Alkaloid AD Skopje, a risk analysis was prepared through a decision tree and a risk report by the regulatory requirements.

At the beginning of the Covid-19 pandemic, Alkaloid AD Skopje developed a Business Continuity Plan, a pandemic with a clearly defined plan of activities and measures that are taken to ensure continuity of operations. According to the Business Continuity Plan, each service illustrates its List of actions according to the processes, employees and location.

A new strategic risk has been opened for the disturbing political, security and economic situation in Ukraine and Russia. A Risk Plan has been prepared with a defined plan of activities and measures taken to ensure safety and continuity of operations.

Conclusion

Risk management is a part of the quality management processes, products and pharmaceutical quality systems.

The output/results of the risk management process should be reviewed at least annually and take into account the information from other processes as context (weakness, threats), internal/external audits/inspection, the change control, product quality review (PQR), post-marketing surveillance of medical devices, clinical studies results, pharmacovigilance, medical device vigilance, complaints and recalls of the product from the market.

The identification and analysis of risks are performed until their complete reduction/elimination to an acceptable level and have a special significance in the processes related to the stakeholders.

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