

Streszczenie w języku angielskim

Demonstrating the possibility of implementing a comprehensive risk management system in a pharmaceutical plant is an extremely difficult task. Mainly due to the fact that such systems are only at the design stage, and their implementation, even in leading innovative pharmaceutical companies, is currently (at most) partial.

Risk management in a pharmaceutical company in particular refers to the description of the way pharmaceutical plants operate at the operational level, restrictions of the legislative environment (GMP legal requirements) and to the description of specific techniques of risk analysis with the use of recognized methodologies.

At the same time, a comprehensive and exhaustive description of such systems should answer questions:

What is risk management in pharmacy and what will be its practical aspect, and, therefore, what tools and methodologies should be characteristic of such systems?

Where do the greatest risks in the pharmaceutical process reside and how are they considered?

What is the difference between a real time risk analyst informing about future risks (*ex ante*) and risks that already exist, analyzed on the basis of historical data (*ex post*), and what are their interactions?

What is the company's main objective in risk management, i.e. how to define the process element that is subject to the greatest protection against threats, in addition to business KPIs?

How to distinguish between the main approaches to the implementation of the risk management process - expert risk management systems (documentation approach) and systems based on algorithms and statistics, partly automated (approach based on the risk data warehouse)?

Risk management systems in pharmaceutical companies are not yet widespread. In many establishments, they are currently in the process of developing extensive quality assurance systems (with some management functions) and still have a long way to go.

The proposed methods of analysis for calculating and sorting risks are not yet a comprehensive approach to the subject of management in a pharmaceutical company, but they are a binding proposal, because they are based on the experience of using them in operational practice.

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At the same time, promising paths of development and development of similar systems are a good forecast for the future. Machine learning and artificial intelligence algorithms are currently the most dynamically developing field of knowledge, in terms of data processing, and this trend is likely to continue to develop significantly.

Considering the importance of an appropriate and innovative approach to building risk management systems in pharmaceutical plants, the use of such advanced methods may be the answer to the urgent needs of these special enterprises. Together with several borrowings from others (more experienced in risk management) sectors of the economy (such as the banking and insurance sectors), pharmaceutical companies can develop dedicated methodologies and technologies more dynamically.

Risk management in pharmaceutical companies is a constantly evolving subject requiring further research. The continuing lack of comprehensive risk management tools and methods is also a unique opportunity to propose solutions, such as the risk management discussed here with the use of a common database, as a complement to a number of recognized expert management methods.

Risk will always be an important criterion for assessing the situation in a pharmaceutical company.

Therefore, sooner or later the industry, in cooperation with scientists, should develop the most universal, holistic and at the same time coherent approach, combining the knowledge about risk in the pharmaceutical company into one useful and effective system.

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