# FMEA METOD FOR QUALITY RISK MANAGEMENT IN PHARMACEUTICAL DISTRIBUTION COMPANY

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**Introduction**. As stated in the operating license conditions regarding implementation of manufacturing medicines, wholesale and retail trading of drugs, importing drugs (except for active pharmaceutical ingredients), risk management for the quality of medicines is an integral and very important component of the pharmaceutical quality system.

In the current national Guidance ST-N MOSE 42-4.2:2011 "Medicines. Risk management for quality", harmonized with the ICH Q9 document, the principles and examples of tools of quality risk management that can be applied to different aspects of quality in the activities of pharmaceutical companies. Based on experience from our own practical experience we have found that the identification and analysis of risks in activities appropriate to apply the FMEA method. An FMEA (Failure Mode and Effect Analysis) is a systematic method of identifying and preventing product and process problems before they occur.

**Aim**. Determination processes in pharmaceutical companies for the application of the method FMEA

**Materials and methods.** Was used regulatory documents, ISO specialized standards, ICH regulations and other sources of information. The comparative method of analysis the method of structural-logical modeling, the expert method was applied in the study.

**Results and discussions.** The FMEA process is widely applicable in a variety of settings beyond the product design and manufacturing processes. It can be used to improve support basic processes:

- the transportation of medicine;
- the acceptance of medicine;
- the storage of medicine;
- information systems;
- human resources.

**Conclusions.** The urgency of using FMEA method for quality risk management in pharmaceutical companies distributors. Determination the basic processes for risk management of method FMEA.