: In the conducted study a comparison was performed between the requirements towards the risk management in drug manufacturing and the risk management recommendations in medical device manufacturing.

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RISK MANAGEMENT IN MEDICINAL PRODUCTS AND MEDICAL DEVICE MANUFACTURING

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Introduction

The risk-based approach has always underpinned the manufacture and applicable regulation of medical devices and medicines. Quality risk management includes systematic processes designed to coordinate, facilitate and improve science-based decision making with respect to risk. Possible steps used to initiate and plan a risk management process depend on the type of the product. For medicinal products, the main regulation is GMP through ICH Q9 recommendations, which classify the risk management as a systematic process. The medical devices are manufactured basing on ISO 13485 with a separate standard, ISO 14971 that classifies risk management as a systematic application of management.

ISO 14971:2019

ICH Q9

Keywords

Quality system, Risk management Manufacturing, Medical devices, Medicinal products, GMP, ISO

Purpose

The purpose of the study is to provide a comparison concerning risk management techniques and the QRM process used for the manufacturing of medicines and medical devices as the overall steps seems to be similar yet the regulations are different.

Materials and methods

A qualitative research included the examination of internal documentation of a pharmaceutical manufacturing company, and close analysis and comparison of both ISO standarts and ICH recommendations. The obtained data was triangulated hence several methods for the verification of the obtained data were used.

Results

QRM METHODS COMPARISON

ICH Q9	ISO 14971
QRM Initiation	General (Flowchart, maps, Ishikawa)
Risk Assesment: Risk identification; Risk analysis; Risk evaluation	Risk Tools (FMEA, FTA, HAZOP, REM, HACCP)
Risk Control: Risk reduction; Risk acceptance	Mitigation Plans
Result/Output	Risk Summary
Risk Review: Review events	
Product Information	
	Risk Analysis: Safety characteristic; Intended use; Hazards ID; Risk estimation
	Risk Evaluation
	Risk Control: Risk control options; Measure implement; Residual risks eval.; Risk/benefit; Post measures risks
	Risk Evaluation
	Risk Review
	Product info.

Conclusions

ICH Q9 & ISO 14971 are mostly similar in their requirements, even though the QRM steps in the standard are more complex.