

## 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.



### Keywords

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



### Purpose

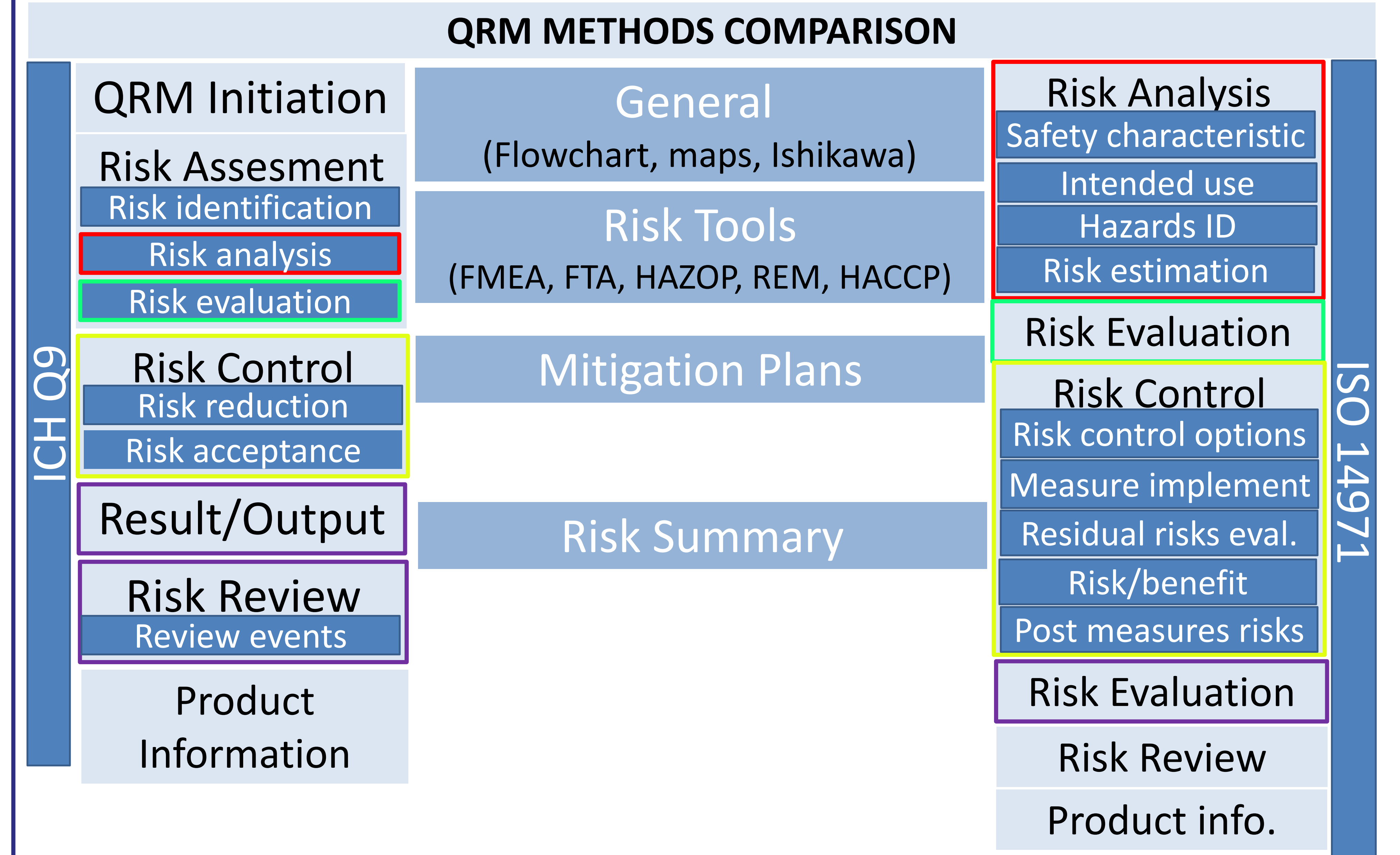
The purpose of the study is to provide a comparison concerning risk management techniques and the QRM process used for the manufacturing of medicines and medical devices as the overall steps seems to be similar yet the regulations are different.



### 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



### Conclusions

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