SoHOs oversight system: a focus on inspection and authorisation process at national and European level

SESSION 2 - PREPARATORY TOOLS TOWARDS A EUROPEAN COMMON APPROACH OF THE OVERSIGHT ACTIVITIES

Risk Assessment approach

Rome, March 28th, 2023

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Risk Assessment approach

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How technical rules can be kept up to date at the EU level?

How can we Facilitate the development of a common and optimal approach to assess and authorize preparation processes in blood and tissues establishments?

Risk Assessment approach

The challenge of keeping EU legislation up-to-date in a dynamic sector with changing risks

No accessibility

Non efficacious therapies

No sustainability

Q&S&E Standards and GXP

rternationa accreditation

Harmonized authorization procedure

Let's focus on: **Q&S&E Standards and GXP**

Good Practices (p.e. EDQM) are more and more written in a **risk management mode** instead of in a **requirements mode**, by incorporating ubiquos references and specific risk management tools. For instance: Microbiological risk assessment tool (MiRCA) (already included in the 5th ed of the EDQM Guide) and the EuroGTPII risk assessment methodology (coming to the EDQM platform in 2023).

This implies the need for the CA to be provided of sufficient technical knowledge to guarantee an adequate evaluation and a correct interpretation of the risk assessment outcomes.

Risk Assessment approach

EU T&C Directives already explicitly mention the need of applying Risk Management tools to diverse situations; e.g. change of any new donor selection or testing criteria; or if a exclusion criteria included in the Directives is not applied.

COMMISSION DIRECTIVE 2006/86/EC

ANNEX II

C. STORAGE AND RELEASE OF PRODUCTS

5. A documented risk assessment approved by the responsible person as defined in Article 17 of Directive 2004/23/EC must be undertaken to determine the fate of all stored tissues and cells following the introduction of any new donor selection or testing criterion or any significantly modified processing step that enhances safety or quality.

COMMISSION DIRECTIVE 2006/17/EC

ANNEX I

SELECTION CRITERIA FOR DONORS OF TISSUES AND/OR CELLS (EXCEPT DONORS OF REPRODUCTIVE CELLS) AS REFERRED TO IN ARTICLE 3(a)

Selection criteria for donors are based on an analysis of the risks related to the application of the specific cells/tissues. Indicators of these risks must be identified by physical examination, review of the medical and behavioural history, biological testing, post-mortem examination (for deceased donors) and any other appropriate investigation. Unless justified on the basis of a documented risk assessment approved by the responsible person as defined in Article 17 of Directive 2004/23/EC, donors must be excluded from donation if any of the following criteria applies:

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Draft EU regulation quality and safety of SoHO

Article 58, § 5

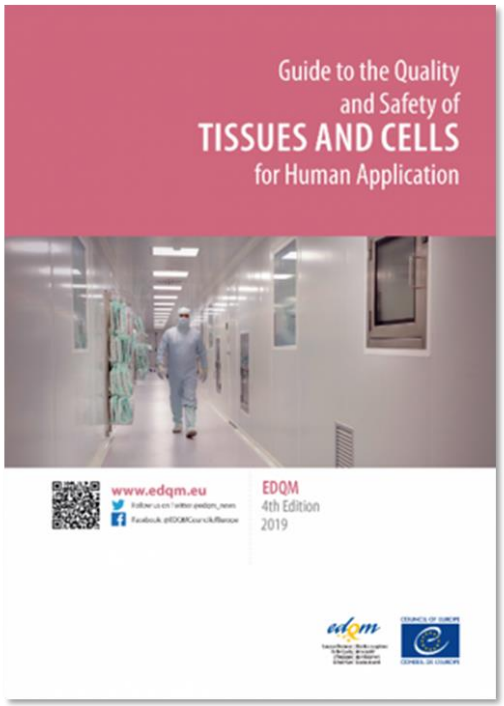
In the procedures referred to in paragraph 1, **SoHO entities shall mitigate risks arising from microbial contamination** of SoHOs from the environment, the personnel, the equipment, materials or solutions coming into contact with SoHOs during collection, processing, storage, or distribution. **SoHO entities shall mitigate such risks by**, at least, the following measures:

(a) specifying and verifying the cleanliness of collection areas;

(b) specifying, **based on a structured and documented risk assessment** for each SoHO preparation, validating and maintaining a defined air quality in processing areas;

(c) specifying, procuring, and decontaminating equipment, materials and solutions such that their sterility is ensured.

Risk Assessment approach



Free download at: go.edqm.eu/dl

Chapter 2: Quality management, risk management and validation, *page 49*

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EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines

Part I - Basic Requirements for Medicinal Products

- Chapter 1 - Pharmaceutical Quality System (into operation since 31 January 2013)

Part III - GMP related documents

- Site Master File
- Q9 Quality Risk Management

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ICH guideline Q9 on quality risk management

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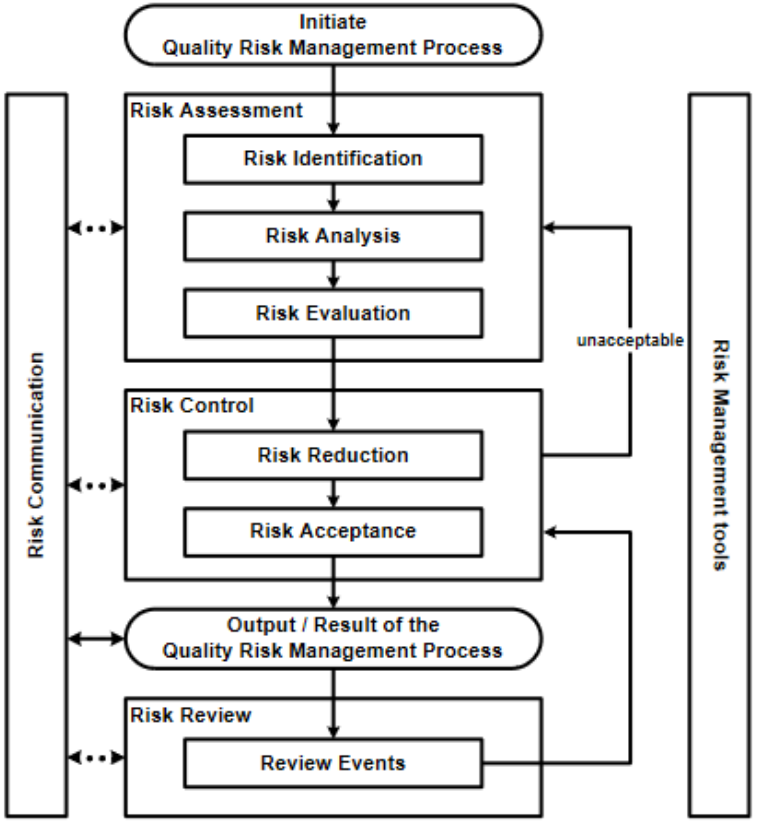
Overview of a typical quality risk management process



ICH guideline Q9 on quality risk management

Applicable to a specific risk management event

- Prospective event; diminish the risk if the event occurs
- Retrospective event; assess risk when the event occurred p.e. deviation from Directives or internal procedures)

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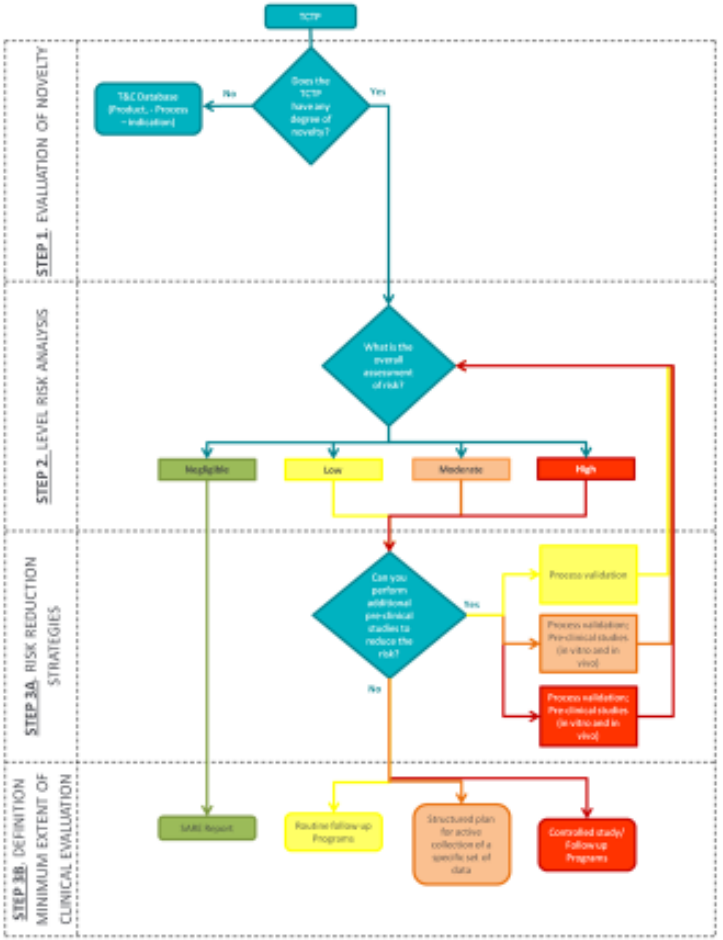
EURO GTP II
Good Tissue & cell Practices

Methodologies



Applicable to risk management

- for new preparation processes or indications
- Changes in consolidated therapies

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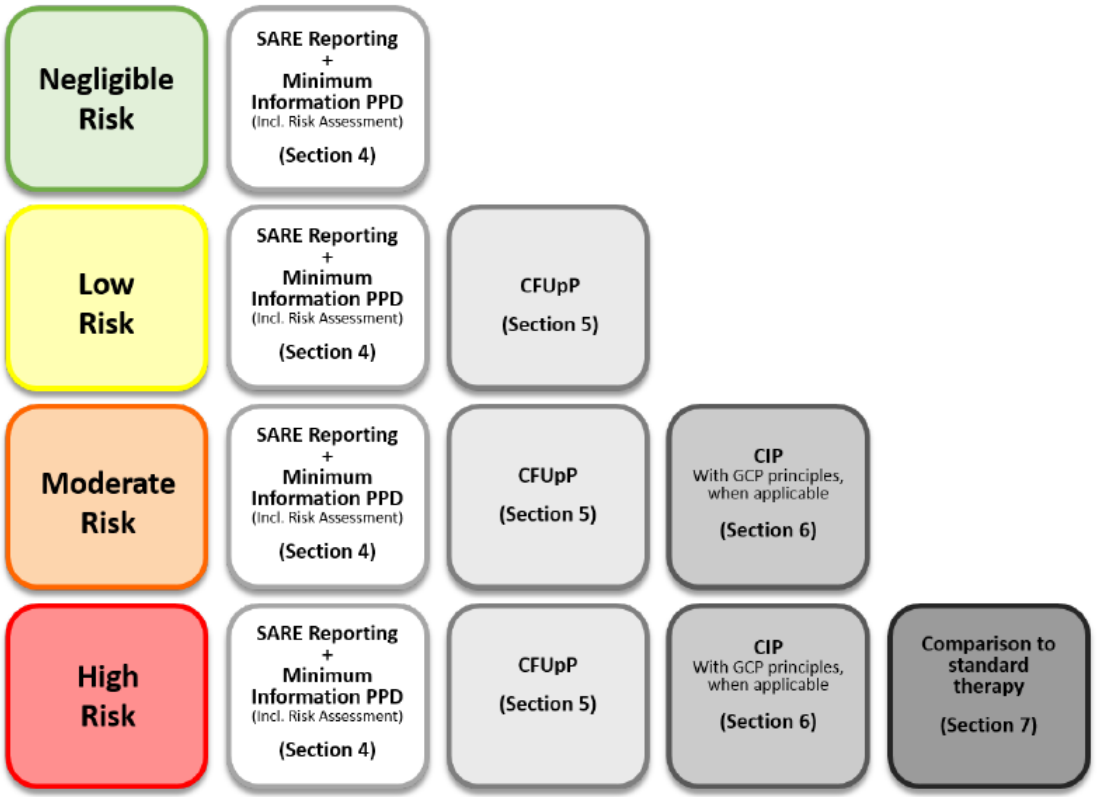

Figure 1. The extent of plan for collecting clinical data included in the clinical component of the PPD is based on the risk level.

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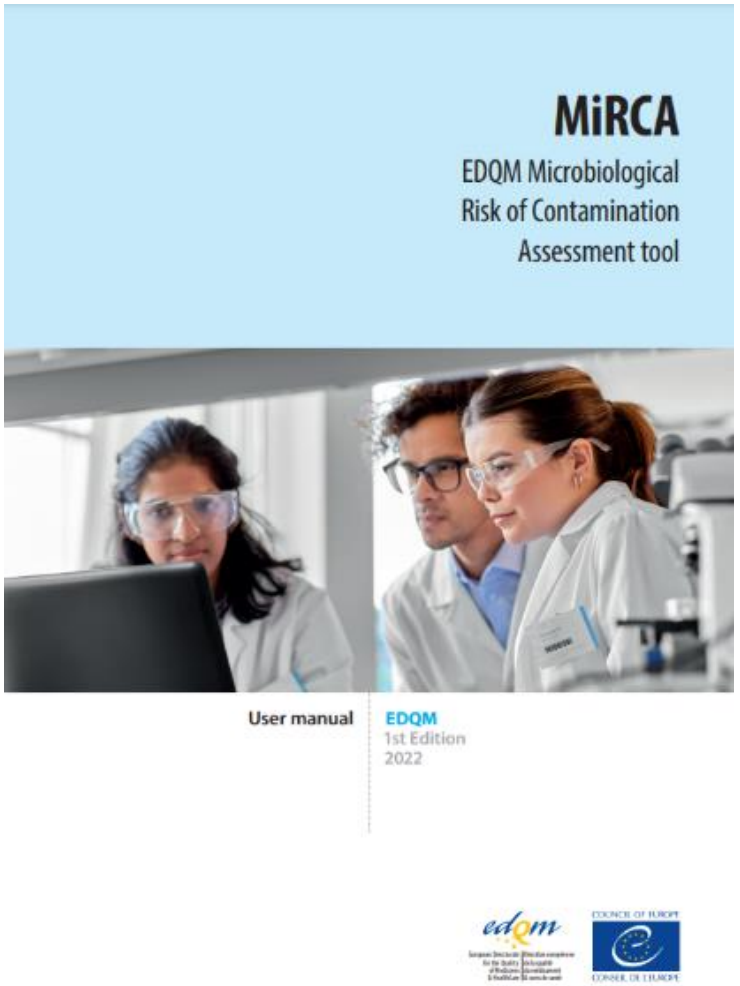
Microbiological Risk of Contamination Assessment tool for tissues and cells (MiRCA)

Applicable to identify risks over consolidated or new processes
Assess probability of generating contaminated products

Risk Assessment approach



A risk informed decision-making tool to assess the overall aseptic (microbiological) risk from procurement to distribution of tissues and cells for human application

What is the aim of the MiRCA tool?

- help users **identify potential risks** in novel, existing, or modified aseptic processes;
- **alert users** to the **degree of risk** of introducing microbiological contamination during the procurement or processing of tissues and cells;
- **support decisions** and changes to mitigate risks during aseptic processes.

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EDQM Standards

SoHO Supply Chain

Risk Assessment approach

EDQM Standards

SoHO Supply Chain

Development Stage

- New therapies
- Improve of established therapies

EuroGTPII methodology

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EDQM Standards

SoHO Supply Chain

EuroGTPII methodology

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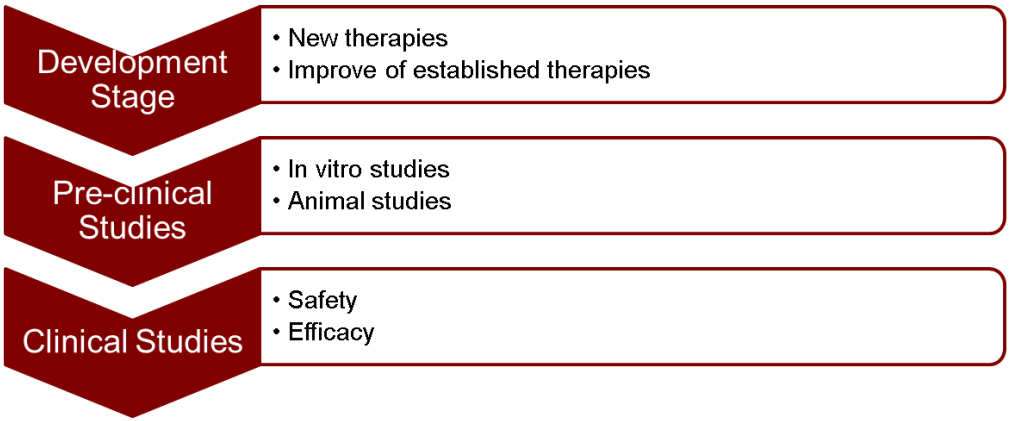
EDQM Standards

SoHO Supply Chain

EuroGTPII methodology



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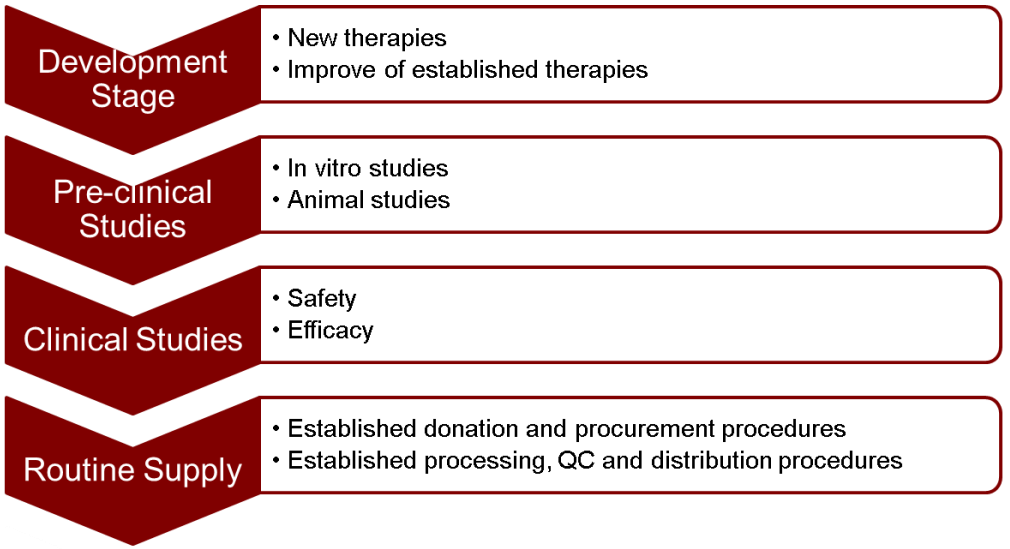
EDQM Standards

ICH Q9 RM tools

EuroGTPII methodology

SoHO Supply Chain



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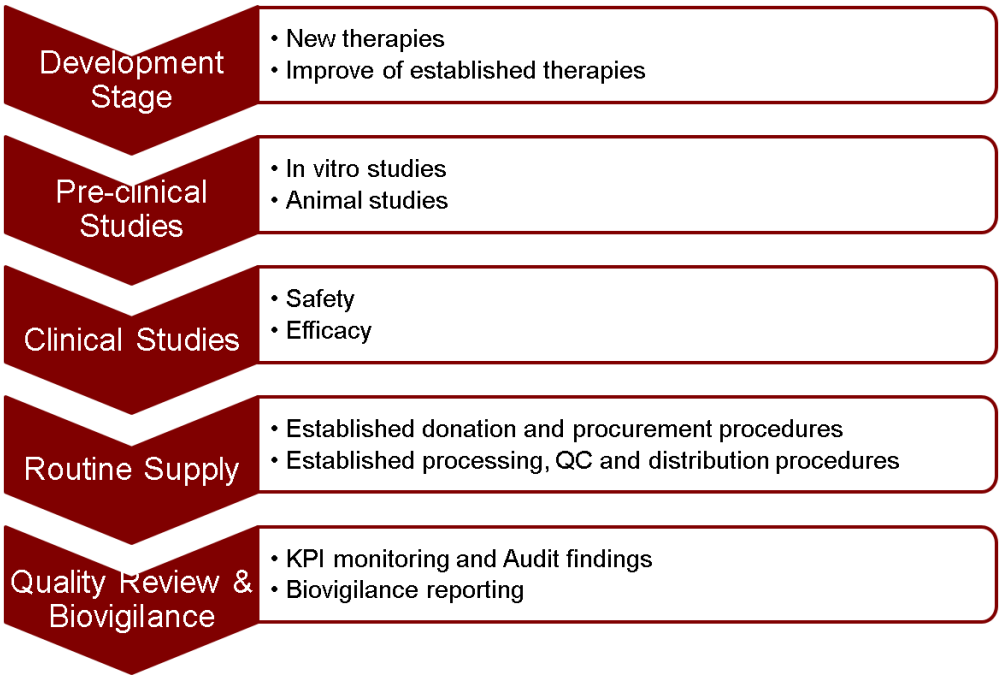
EDQM Standards

ICH Q9 RM tools

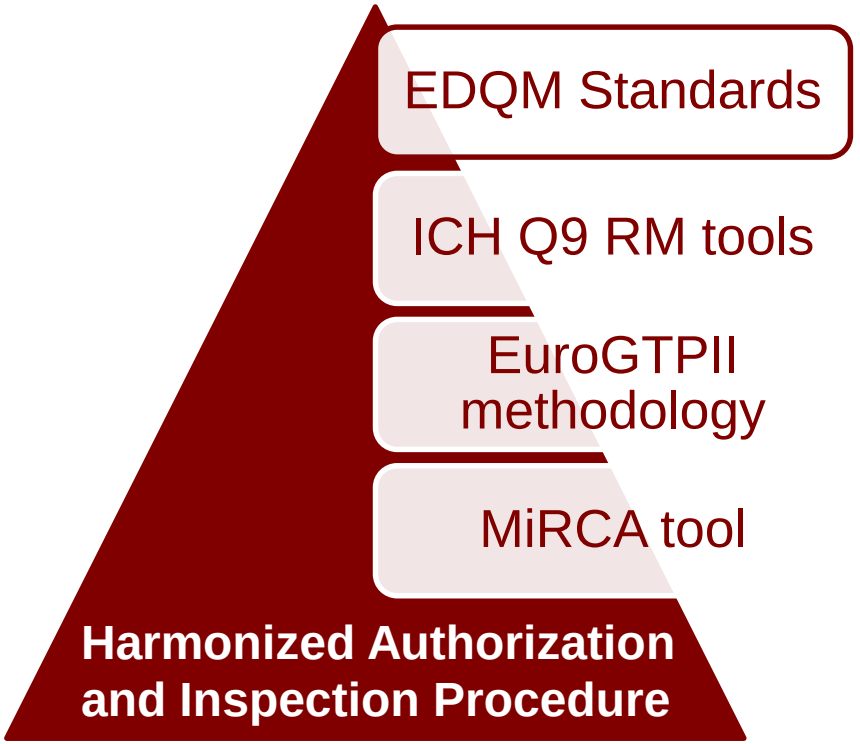
EuroGTPII methodology

MiRCA tool

SoHO Supply Chain



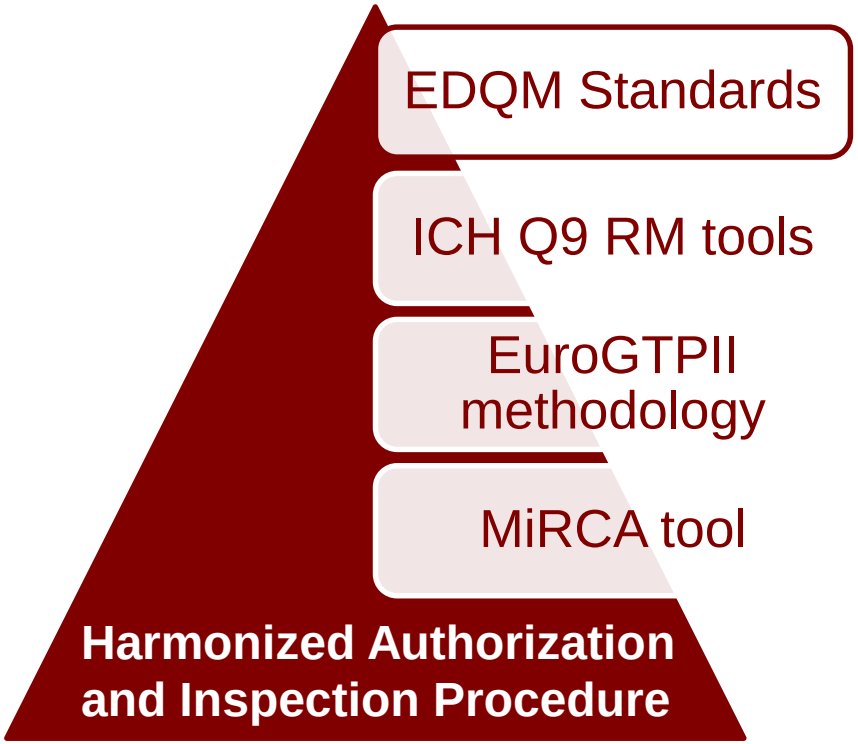
Risk Assessment approach



SoHO Supply Chain

Development Stage	• New therapies • Improve of established therapies
Pre-clinical Studies	• In vitro studies • Animal studies
Clinical Studies	• Safety • Efficacy
Routine Supply	• Established donation and procurement procedures • Established processing, QC and distribution procedures
Quality Review & Biovigilance	• KPI monitoring and Audit findings • Biovigilance reporting

Risk Assessment approach



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We can use RM tools to authorize and inspect, in a harmonized manner, the full process

Take home messages

- The Risk Management exercises help to harmonize legislation and Good Practices across the EU

- The Risk Management exercises allow the Legislation to be closer to the scientific advance

- The Risk Management exercises ease the CAs and professionals to enlarge the knowledge

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