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Risk Management for Medical Devices: Navigating ISO 14971:2019

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Key definitions

Risk Management (RM): systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring risk.

Risk: combination of the Probability of Occurrence of harm and the Severity of that harm.

Hazard: potential source of harm.

Harm: injury or damage to the health of people, or damage to property or the environment.

Hazardous situations: circumstance in which people, property or the environment is/are exposed to one or more hazards.

Check ***section 3*** of the standard ***ISO 14971:2019*** to find all applicable terms and definitions associated to RM.

Management responsibilities

Top Management shall provide evidence of its commitment to the RM process by ensuring:

- The provision of adequate resources; and
- The assignment of competent personnel for RM.

Top Management shall:

- Define and document a policy for establishing criteria for Risk acceptability.
- Review the suitability of the Risk Management process at planned intervals to ensure its continued effectiveness, and document any decisions and actions taken.

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Competence of personnel

Competent persons: education, training, skills and experience appropriate to the RM tasks assigned to them.

This includes knowledge and experience with the specific medical device (or similar), its use, the technologies involved, and the RM techniques employed.

Records shall be maintained to demonstrate compliance with both of the above requirements.

Multidisciplinary team with people from different departments, for example: R&D, Design, Engineering, Regulatory Affairs, Quality Assurance, Production, Quality Control, Clinical, Experts (could be independent reviewers).

RM process

The manufacturer shall establish, implement, document and maintain an ongoing process for:

1. **Identifying hazards and hazardous situations** associated with a medical device.
2. **Estimating and evaluating the associated risks**.
3. **Controlling these risks**.
4. **Monitoring the effectiveness** of the risk control measures.

RM process shall be understood as a continuous iterative process **throughout the entire lifecycle of the medical device**, requiring regular systematic updating.

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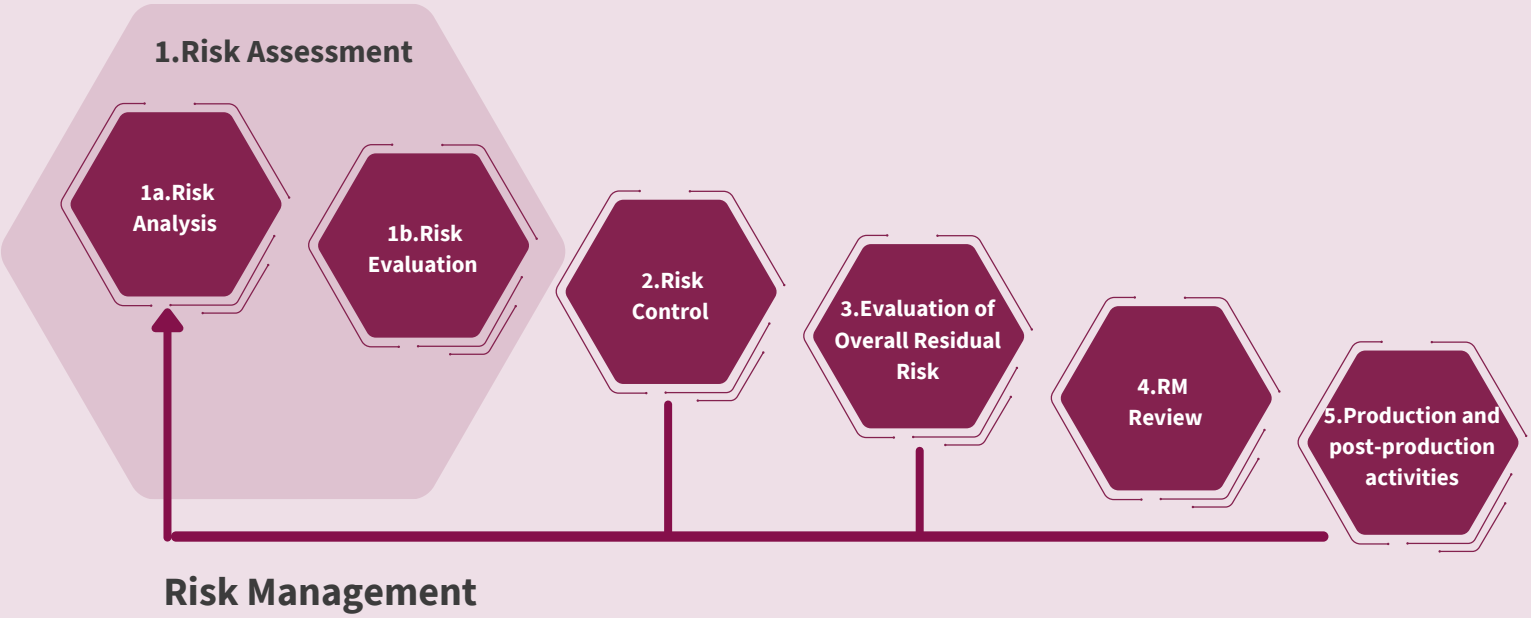
The RM process includes the following elements:

RM Plan



RM Plan: RM activities shall be planned.

1. Risk Assessment: Risk Analysis + Risk Evaluation

- **1a.Risk Analysis:**
  - **Hazard identification**
    - Intended use and reasonably foreseeable misuse.
    - Identification of safety-related characteristics.

> Refer to the questions in Annex A.2 of the standard ISO/TR 24971:2020 on the Identification of hazards and characteristics related to safety, which can assist you in this phase.

    - Identification of hazards and hazardous situations.

> Many techniques are widely employed across the industry, including **Preliminary Hazards Analysis (PHA), Failure Mode and Effects Analysis (FMEA)**, and **Fault Tree Analysis (FTA)**.

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- **Risk estimation:** process used to assign values to the Probability of Occurrence of harm and Severity of harm.

Hazard

Probability of a hazardous situation occurring (P_1)

Sequence of events

Circumstances affecting severity

Hazard situation

Probability of a hazardous situation leading to a harm (P_2)

Circumstances affecting severity

Probability of Occurrence of harm ($P = P_1 * P_2$)

Harm

Severity of harm

RISK

- **1b.Risk Evaluation:** Assess the estimated risks and determine whether they are acceptable, using the risk acceptability criteria defined in the **RM Plan**.

Check ***Annex C*** of the standard ***ISO 14971:2019*** to find more information about fundamental risk concepts.

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2.Risk Control:

MDR 2017/745 requires reducing risks as far as possible without adversely affecting the benefit-risk ratio.

- **Risk control option analysis:** Control measures for reducing risks to an acceptable level:
  - **Inherently safe design and manufacturing practices.**
  - **Protective measures** into the medical device or the manufacturing process.
  - **Information for safety** and, where appropriate, **user training**.

MDR 2017/745: highlights the need to eliminate or reduce risks **as far as possible through** safe design and manufacture.

- **Implementation and verification of risk control measures:**

A best practice is to include multiple Risk Controls to reduce a risk.

- **Residual risk evaluation:** if a residual risk is not judged acceptable using the criteria for risk acceptability defined in the RM Plan, further risk control measures shall be considered.

- **Benefit-risk analysis:** if some risks remain at an unacceptable level after Risk controls, data and literature may be gathered and reviewed to provide objective evidence and to determine if the benefits of the intended use outweigh this residual risk.

- **Risks arising from Risk Control Measures:** the effects of the risk control measures shall be reviewed.

> Have the risk control measures led to any new hazards or hazardous situations? Are previously identified hazardous situations impacted?

- **Completeness of risk control.**

3.Evaluation of Overall Residual Risk:
After all risk control measures have been implemented and verified, the overall residual risk shall be evaluated:

- If acceptable, users shall be informed of any significant residual risk, and the necessary information shall be included in the accompanying documentation.

- If not judget acceptable, additional risk control measures or modifications in the medical device or its intended use may be considered.

Even all individual risks are acceptable, the medical device may still not be safe.

4.RM Review: the execution of the RM Plan shall be reviewed to ensure that, at a minimum:

- The RM Plan has been appropriately implemented
- The overall residual risk is acceptable
- Appropriate methods are in place to collect and review information in the production and post-production phases.

5.Production and post-production activities: A **system** for actively **collecting and reviewing information** relevant to the medical device shall be established, documented, and maintained.

- **Information collection.**

  Internal audits, CAPAs, complaints, customer feedback, market surveys, scientific literature, feedback form Authorities.

- **Information review.**

- **Actions.**

  Updates to documents, updates to product, Field Safety Notices, Recalls.

RM File

Set of records and other documents that are produced during the whole RM process.

The RM File consolidates all activities:
The RM File compiles everything: RM activities, documentation, and records.
If it is not documented, it did not happen!

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Regulations and standards

Compliance

Required by Regulatory Authorities, including:

- US FDA
- Health Canada
- EU Competent Authorities
- Australia TGA
- Japan MHLW

Additional guidance

ISO/TR 24971:2020 provides additional insights and practical guidance to support the effective application of **ISO 14971,** particularly in the context of medical device risk management.

Supporting standards

- **IEC 60601 series**
- **IEC 62366-1:2015/AMD1:2020**
- **ISO 10993 series**
- **ISO 13485:2016**

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www.asphalion.com

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Author

Koldo García
Medical Device Consultant