Revision history

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| Revision | Date (ddmmmyyyy) | Project / Change Control / CAPA / Complaint | Change description |
| 00 | 30AUG2021 | Project | Creation |
| 01 | 08SEP2023 | Project | Update with clarifications:Section 5.2, sentence added to the proposed phases: “*List the phases appropriated in your situation.”*Section 6.4, tip added:*“Remember that each phase described in section 5.2 should go through the risk analysis process. FMEA in this document is the tool proposed, but feel free to choose another tool if more appropriate (Fault Tree Analysis, Root Cause Analysis, etc.)”*Section 7.1, tip sentence changed to:*“If you choose to perform an FMEA, who will perform the dFMEA… according to which SOP. It is common language to say we use the FMEA tool, even though it is not strictly the tool described in ISO 60812. Usually, FMEAs have been adapted to fit with our industry. If you prefer another tool, feel free to use it.”*Section 8, tip sentence added:*Remember that this document requires to be adapted to the context of your company.**ISO 14971 section 4.2 specifies that risk acceptability criteria is proper to a company policy:**“Top management shall define and document a policy for establishing criteria for risk acceptability.”*Section 8.3, “(hazard)” changed to “(creating an hazardous situation)”. Tip sentence added: *Regarding detectability in the FMEA, some does not want to hear about it, some only for process FMEA, some other use it anyway. It is an eternal debate. The tool has to be adapted to your company SOP.*Section 8.4, tip sentence added:*If you choose not to integrate the detectability, the RPN should be adapted to your choices.*Disclaimer added in the Appendix. |
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# Abbreviations

HCP HealthCare Professional
IFU Instructions For Use

MAH Marketing Authorization Holder

MD Medical Device

NHP Non-Human Primate

PL Project Leader

RCM Risk Control Measure

RMF Risk Management File

RMP Risk Management Plan

RMR Risk Management Report

RPN Risk Priority Number

RT Room-Temperature

SOP Standard Operating Procedure

# Introduction

This risk management plan (RMP) is to serve as the top-level planning document for the *device name* related risk management activities that will be completed.

# Background

*Background of the project to be described here*.

*List CMOs if so, their location, who is owning the design, who will be the legal manufacturer… All relevant information to give a context.*

# Project objective

*Give the objective of the overall project.*

# Scope of the RMP

The aim of the RMP is to ensure safe and effective design and manufacturing of the *device name*. This RMP will be held in the *device name*’s risk management file (RMF).

The RMP encompasses the complete product life cycle, managing risk from the start of the development until the last delivered batch has reached its defined end of life.

## Out of Scope

The following are out of scope:

* Activities related to demonstration material, demonstration non-functional devices and printed material to support marketing activities.
* Drug related risk management activities

## In Scope

The following lifecycle phases for the *device name* will be in the scope of the risk management activities:

1 Storage

2 Transportation

3 Training - Use phase

4 Discard/End of life phase

5 Design

6 Manufacturing

7 Packaging and Sterilization

*List the phases appropriated in your situation.*

The risk management activities are carried out as per ISO 14971.

# Risk management responsibilities

## Quality management medical devices

*Describe the role of quality within the risk management activities, and link with your SOP.*

## Device team

*Describe the role of project lead within the risk management activities, and link with your SOP.*

## Vendor responsibility

*Describe the role of Vendors if relevant within the risk management activities, and link with their SOP.*

## Risk management outputs responsibilities

*List the persons responsible to work on the risk management activities, their required skills and context in the project.*

*Fill the table below with the department in charge for the column “responsibility”, and the roles who will have to work on the documents generated in the column “approval”. The deliverables must be adapted to your company SOP.*

*Remember that each phase described in section 5.2 should go through the risk analysis process. FMEA in this document is the tool proposed, but feel free to choose another tool if more appropriate (Fault Tree Analysis, Root Cause Analysis, etc.)*

| Deliverable | Responsibility | *Company name*’s Approval |
| --- | --- | --- |
| Risk Management Plan |  |  |
| Design FMEA |  |  |
| Process FMEA |  |  |
| Usability Engineering File |  |  |
| Etc. |  |  |
| Risk Management Report |  |  |

# Planned risk assessement activities

Risk assessment activities and documentation will be reviewed in accordance with *Company name*’s SOP (*risks management SOP reference*).

## Design related Risk Management activities

*If you choose to perform an FMEA, who will perform the dFMEA… according to which SOP. It is common language to say we use the FMEA tool, even though it is not strictly the tool described in ISO 60812. Usually, FMEAs have been adapted to fit with our industry. If you prefer another tool, feel free to use it.*

## Usability engineering file

*Who will work on the Usability Engineering File… according to which SOP.*

## Process/manufacturing related risk management activities

*If you choose to perform an FMEA, who will perform the pFMEA… according to which SOP.*

# Criteria for risk acceptability

The criteria for risk acceptability for *final product name* product shall use the criteria defined hereafter, for all FMEAs (use, design, and process).

*Remember that this document requires to be adapted to the context of your company.*

*ISO 14971 section 4.2 specifies that risk acceptability criteria is proper to a company policy:*

*“Top management shall define and document a policy for establishing criteria for risk acceptability.”*

## Severity of harm level definition

Severity (S) of harm levels definitions are listed in Table 1.

Table 1 - Severity of harm levels definitions (S)

|  |  |  |
| --- | --- | --- |
| **Ranking** | **Severity of harm** | **Definition** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

## Probability of occurrence of harm

Probability of occurrence (O) of harm is listed in Table 2.

Table 2 - Probability of occurrence of harm (O)

|  |  |  |
| --- | --- | --- |
| **Ranking** | **Probability of occurrence of harm** | **Definition** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

## Detection

Detection is the likelihood that a specific Failure Mode (creating an hazardous situation) will be detected prior to the harm happening.

*Regarding detectability in the FMEA, some does not want to hear about it, some only for process FMEA, some other use it anyway. It is an eternal debate. The tool has to be adapted to your company SOP.*

Table 3 - Detection Ranking (D)

| **Rank** | **Detection** | **Criteria: Likelihood of Detection**  |
| --- | --- | --- |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

## Risk acceptability criteria

### Risk Evaluation

*Explain the ranking of the risks. Rationale must be provided for the choice of specific risk acceptability criteria.*

A Risk Priority Number (RPN) is calculated for each identified failure mode using the formula below and then used to guide the need for additional risk controls (see Table 4).

**Risk Priority Number (RPN) = S x O x D**

*Explain the choices for each category of risk.*

*Refer to section 13.0 for future data collection and update of the FMEA.*

*Fill the table 4 below according to your experience, SOP, etc.*

*If you choose not to integrate the detectability, the RPN should be adapted to your choices.*

Table 4 - Risk Evaluation and Risk Control Measures

|  |  |
| --- | --- |
| **If** | **Then** |
| RPN ≤ xxx |  |
|  |  |
|  |  |
|  |  |

## Risk benefit analysis

*Explain the B/R analysis.*

*The decision as to whether risks are outweighed by benefits is essentially a matter of judgment by experienced and knowledgeable individuals, usually a multidisciplinary team comprising medical, clinical or application experts. An important consideration is whether an anticipated benefit can be achieved through the use of alternative solutions without that risk or with smaller risk. This involves comparing the residual risk for the manufacturer’s medical device with the residual risk for similar medical devices.*

*Note that a clinical investigation might be required to verify that the balance between benefit and residual risk is acceptable.*

# Risk control

Risk Control shall be conducted for *final product name* per *risks management SOP reference*.

## Implementation of risk control measures

*Explain the implementation of the RCM. A link to the ISO 14971 is welcome here for the preferences for the RCM.*

## Residual risk analysis

A comprehensive analysis of the residual risk will be included in each FMEA document.

## Benefit-risk analysis

*Explain how and when the Benefit-risk analysis will be conducted.*

## Risks arising from risk control measures

*Explain how the risks arising from RCM are handled.*

# Evaluation of overall residual risk

*Explain how evaluation of overall risk shall be conducted, by whom. What will be the output.*

# Risk management review

*Explain how the risk management reviews shall be conducted, by whom. Link to your SOP.*

# Risk Management Report (RMR)

*Explain what the Risk Management Report will assess. Explain the output of the RMR, also from a B/R perspective.*

# Lifecycle risk management

*Explain how information will be collected and how it will update the risk management activities.*

## Production Information

*Explain how information will be collected and how it will update the risk management activities.*

## Post-Market feedback

*Explain how information will be collected and how it will update the risk management activities.*

# References

## Internal references

2101UND00 Rev00 User Needs Definition

2101ANL00 Rev00 Applicable Norms List

2101EFA00 Rev00 Functional Analysis

*SOP reference* Risk Management Process for Medical Devices

Etc.

## External references

ISO 14971:2019 Application of risk management to medical devices

NF EN 62366-1/A1 Medical devices. Application of usability engineering to medical devices

# Appendix 1

**Diclaimer:**

This tool is proposed for free by CSDmed. It gives the framework to build a robust Risk Management Plan. It is impossible to propose a RMP that could fit to each SOP or to each device. It must be tailored to your specific situation to be efficient. CSDmed is not responsible for the way the tool may be used. If you need help to build your risk management strategy, feel free to contact us, we will be happy to help.

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