



**Risk Management**  
**Plan of Paperless GMP**  
**Software**

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## 1 Introduction

### 1.1 Document overview

This document covers the risk management plan of XXX device, designed in Paperless GMP software development project.

It contains:

- The risk management organization and process during the software development project,
- The risk management organization and process during maintenance, after final delivery of the software development project.

Note: most of times, risk management organization is very different before and after design. You may split the risk management plan in two documents, the first one before end of design, the second one after the end of design.

### 1.2 References

#### 1.2.1 Project References

#	Document Identifier	Document Title
[R1]	ID	Add your documents references. One line per document

#### 1.2.2 Standard and regulatory References

#	Document Identifier	Document Title
[STD1]		Add your documents references. One line per document

Add the standard references to the table above. It may include ISO 14971, ISO 13485, IEC/TR 80002-1, IEC 62304, amongst others.

## 2 Risk management during software development

This chapter covers the risk management process and organization during the software development.

### 2.1 Organization and Responsibilities

Describe the organization of the team responsible for risk management during design. You may add an organization chart or add a reference to your project management plan, where the organization of the project should be already described.



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Person	Responsibility
Project Manager	<ul style="list-style-type: none"> <li>Overall management process responsibility</li> </ul>
	<ul style="list-style-type: none"> <li>Risk Management Plan development</li> </ul>
	<ul style="list-style-type: none"> <li>Creation and update of Risk Analysis Table</li> </ul>
	<ul style="list-style-type: none"> <li>Creation and update of Risk traceability matrix</li> </ul>
	<ul style="list-style-type: none"> <li>Creation and update Risk Analysis Report</li> </ul>
Quality Manager, for example	<ul style="list-style-type: none"> <li>Independent review of Risk Management File</li> </ul>

### 2.2 Qualification of personnel

Describe the qualification of personnel responsible for the risk management and risk analysis activities. Example:

The personnel who participates to the risk analysis is composed of:

- Experienced staff who was involved in the design process of similar products
- The expert practitioners who participate to the design process

### 2.3 Objective of risk management activities

The objective of risk management activities is to deliver a risk analysis report, which contains:

- The device characteristics that could impact on safety (ISO 14971),
- The software safety classification (IEC 62304),
- The risk analysis table,
- The risk traceability matrix with design requirements,
- The overall assessment of residual risk.

The risk analysis table and risk traceability matrix will be created and updated as necessary during software development, according to tasks described in §2.4.

Data on the risk analysis table includes:


- List the columns, according to your risk analysis table in your risk analysis report,
- ...

Data on the risk analysis table includes:

- List the columns, according to your risk traceability matrix in your risk analysis report,
- ...

See the risk analysis report template for columns samples.

Note: The Risk analysis may be performed with the help of the table B.1 in IEC/TR 80002-1.

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The risk analysis report will summarize whether identified and mitigated risks meet the acceptable values defined in this plan. It will also include a statement indicating whether all known hazards have been identified.

The Risk Management File gathers this document and all documents quoted above.

## 2.4 Tasks, Planning

Describe how the risk management activities are planned during the project.

The planning of risk activities shall be coherent with the planning of the project found in §2.2 of the project management plan.

Insert a table or list or diagram describing the planning.

Important, list the deliverables and reviews of each phase of the project

### 2.4.1 Task n

**Optional**, add a sub-section for each task with:

- Inputs of the task
- Content of the task
- Outputs of the task
- Task reviews (in, if necessary, and out)
- Relationship with development planning.

Note: The tasks may group sets of activities found in §4 to §7 of ISO14971.

Examples of tasks below:

### 2.4.2 Risk analysis initialization


During this phase, the following activities are performed: identification of intended use, identification of characteristics affecting the safety, assignation of safety class, identification of hazards, evaluation of hazards, and identification of foreseeable mitigation actions.

- Inputs: publications, clinical data, any information prior to design phase
- Two meetings with clinicians involved in the design process
- Outputs: intended use, safety characteristics and hazards, creation of risk analysis
- Relationship with development planning: Output data of this task is input data for specification
- End of Task review: review of risk analysis in draft version.

### 2.4.3 Risk analysis update

During this phase, the following activities are performed: identification of mitigation actions, evaluation of hazards after mitigation and analysis of risk/patient outcome ratio.

- Inputs: publications, clinical data, any information prior to design phase
- Two meetings with clinicians involved in the design process and system architect
- Outputs: Update of risk analysis

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- Relationship with development planning: this task is performed during specifications
- End of Task review: review of risk analysis in first revision.

## 2.5 Criteria for Acceptability of Risk

Warning: recommend to read carefully §3.4 of IEC 80002-1 to understand how probability of occurrence is determined for software failure.

Risks will be evaluated in accordance with Risk Management Procedures for:

- Probability of occurrence
- Consequence of hazard
- Any other criteria of your choice, like probability of detection ...

Based on the risk priority number, for each hazard analyzed for XXXX, the Residual Risk will be considered Acceptable if the risk priority number value is less than **<fix your number>**.

Based on the risk priority numbers, the Overall Residual Risk for a device will be considered acceptable if the following conditions are satisfied:

1. None of the identified hazards leads to an unacceptable risk (i.e., no risk priority number above **<your number minus 1>** is identified); and
2. Another quantitative criterion of your choice
3. Another one ...

Any risk priority numbers above these values need to have actions taken to reduce the risk.

## 2.6 Verification and Risk traceability matrix

Verification testing activities will be cross-referenced in the risk traceability matrix, as applicable.

## 2.7 Approvals

The Risk Management Plan must be reviewed and approved by XXXX prior to the start of the risk assessment process.

The Risk Analysis Report will be reviewed and approved by XXXX to ensure completeness and conformance to this Risk Management Plan.

## 2.8 Location of Risk Management File

The Risk Management File is located in XXX (for example a document management tool defined in the software development plan or project management plan). This file contains all the documents related to the management of risk for the device and is kept for the life of the product.



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### 3 Risk management after software development

#### 3.1 Organization and Responsibilities

Describe the organization of the team responsible for risk management after software development. You may add an organization chart.

Discard if unchanged and during and after software development

Maintenance Manager	<ul style="list-style-type: none"> <li>Overall management process responsibility</li> </ul>
	<ul style="list-style-type: none"> <li>Annual Risk Management File Review</li> </ul>
	<ul style="list-style-type: none"> <li>Update of Risk Analysis Table</li> </ul>
	<ul style="list-style-type: none"> <li>Update of Risk traceability matrix</li> </ul>
	<ul style="list-style-type: none"> <li>Update Risk Analysis Report</li> </ul>
	<ul style="list-style-type: none"> <li>Independent review of Risk Management File</li> </ul>

#### 3.2 Qualification of personnel

Describe the qualification of personnel responsible for the risk management and risk analysis activities.

Discard if unchanged and during and after software development

#### 3.3 Production and maintenance information

The Risk Management File is systematically reviewed and updated in the maintenance of the device, especially when:

- The product is modified (software patch, minor updates),
- Analysis of data of post marketing surveillance triggers a reevaluation (internal defects, customer requests, maintenance, vigilance bulletins, of field information from any source)


#### 3.4 Annual Audit

Reviews and updates to the Risk Management File will be done annually (choose your periodicity)

Reviews and updates to any risk related document will be documented, approved, and included within the Risk Management File.

### 4 Ranking System for Risk Analysis

This section describes how the risk priority number is deduced from the characteristics of the risk:

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- List the criteria defined in §2.2.

Describe in sub sections how you quantify your criteria, like these:

#### 4.1 Probability of Occurrence

Use quantitative criteria. Here is an example.

Ranking	Definition	Frequency (F)
5	Every month	Frequent (very high probability)
4	Once every year	Probable (high probability)
3	Once in last 5 years	Occasional (moderate probability)
2	Once in last 10 years	Unlikely (low probability)
1	Zero occurrence in the past 10 years with similar products	Very Unlikely (very low probability)

#### 4.2 Consequences of Hazard

Use criteria based on damages on patient and/or user

Ranking	Definition	Clinical and Process End Effects
5	Catastrophic	Serious injury (irreversible) or death of the patient or user
4	Critical	Serious injury (reversible) to the patient or user. New treatment required.
3	Moderate	Moderate injury to the patient or user. Longer treatment time or new minor treatment required.
2	Minor	Minor injury to the patient. Longer treatment time
1	Negligible / Cosmetic	No injury to the patient or user.


#### 4.3 Add your other criteria

Your definition

#### 4.4 Determination of risk priority number

A rule of your choice, like.

$$\text{Risk priority number} = \begin{array}{l} \text{criterion 1} \\ \times \text{criterion 2} \\ \dots \\ \times \text{criterion n} \end{array}$$

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Example of cross-table of RPN with two criteria:

**CROSS TABLE OF RISK PRIORITY NUMBER**

Frequent 5	5	10	15	20	25
Probable 4	4	8	12	16	20
Occasional 3	3	6	9	12	15
Unlikely 2	2	4	6	8	10
Very Unlikely 1	1	2	3	4	5
	Negligible 1	Minor 2	Important 3	Critical 4	Catastrophic 5

#### 4.5 Criteria for acceptability

Acceptability per risk priority number is: (choose your own)

- If the risk priority number is 1 to xx the risk is **acceptable** - No recommended actions are required.
- If the risk priority number is xx to yy the risk is **tolerable** - Some actions may be used, where possible, to lower the level.
- If risk priority number is above yy the risk is **unacceptable**. Mitigation action must be implemented to lower the level.