# Case for Quality
# Company B

## Risk Management

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# Purpose

- Create a simple, systematic, integrated, sustainable, and compliant Risk Management System

# Risk Management

## What is Risk?

| Standard | Purpose | Definition |
|---|---|---|
| ISO 31000 | Enterprise Risk | Effect of uncertainty on objectives |
| ISO 14971 | Medical Devices – Application of Risk Management to medical devices | Combination of the probability of occurrence of harm and the severity of that harm |

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# Risk Management

Medical device community under scrutiny on the overuse and misuse of FMEA's for risk management

- "I can't tell you how many manufacturers I have seen that have tried to present their risk management system by simply presenting a FMEA. That is NOT a risk management system."

  -Kim Trautman, former QSR expert at FDA, CDRH

  http://www.prweb.com/releases/FDAnews/MDRiskMgmntChicago/prweb12107152.htm

# Risk Management System ISO 14971

- Focus is on Health and Safety
- Consistency, from design to process
- All hazards, hazardous situations and harms must be addressed in the Risk Trace Matrix
- Knowledge management repository
- Flexible use the right tools for input, not just FMEA

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# Risk Management

## Example of Risk Profile

| Severity / Probability of Occurrence of Harm | **Low/Level ≤3** No Impact to Health & Safety | **Medium/Level 4** Non-Serious Injury or Illness | **High\Level 5** Serious Injury or Illness |
|---|---|---|---|
| **High/Probable** ≥ 10E-4 ≥ 1 in 10,000 | | | |
| **Medium/Improbable** > 10E-6 and < 10E-4 > 1 in million and < 1 in 10,000 | | | |
| **Low/Remote** ≤ 10E-6 1 in million | | | |

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# Risk Management

## Example of Risk Table

| Hazardous Situation/ Foreseeable Sequence of Events | Potential Harms | Severity | Rationale |
|---|---|---|---|
| Device is not sterilized and gets shipped to user as unsterile. | Infection | 5 | Device must be sterile. |
| Materials used to manufacture device packaging, labels, do not meet requirements for compatibility with other materials with which they come into contact. | Mild tissue abrasions | 4 | Minor medical condition that resolves itself. |
| User gets dirt on device during handling. User may experience discomfort. | No impact to health and safety | ≤3 | Personal cleanliness for device handling is contained in the package insert. |

# Risk Management

## Example of Risk Matrix

| Hazard Class | Hazard | Hazardous Situation | Risk Control Method | Sev | Prob of Harm | Risk Acc | Source Document for Risk Control | Objective Evidence |
|---|---|---|---|---|---|---|---|---|
| Chemical | Non-conforming limits of process aids in device | User uses device with non-conforming levels of process aids | Bio-compatibility of device is confirmed various issues | ≤3 | Low | | Biocompatibility reports, device specifications, process validation reports | Report numbers and specification numbers |

# Master Product Health & Safety Risk Identification Table

- Knowledge management center
- All known hazards, hazardous situations, potential harms and severity ratings
- Internal Product Health & Safety standard list
- All references to severity determination are traceable

# Product Health & Safety Risk Trace Matrix – Risk Management File

- Matrix containing all identified hazards, hazardous situations, risks controls, applicable product safety standards and references to supporting documentation associated with products
- Ensures that all identified risks have been appropriately analyzed, evaluated, controlled, and documented