2.1 RISK MANAGMENT FOR MEDICAL DEVICES

RISK defines as possibility of loss or injury. There are things that each of us does every day that involves RISK.

- The food you eat, the habits you have, driven your car, your daily routine – all full of risks in some way, shape, or form. But you don't usually think about this being a risk at all. You take it for granted.

Risk per ISO 14971 is defined as the combination of the probability of occurrence of harm and the severity of that harm. The intent behind Risk Management is to identify, evaluate, analyze, assess, and mitigate potential product issues. The topic of Risk Management is one that can be daunting, and at times confusing. Thankfully, ISO 14971 exists and is helpful in providing guidance and direction

2.2 THE IMPORTANCE OF RISK AND MEDICAL DEVICES

The patient, often unknowingly, accepts the risks of the medical device you design, develop, and manufacture. And this is exactly why Risk Management is so important to the medical device industry. You have to know that the medical devices you are involved with bringing to patients and end-users are safe.

The purpose of this guide is three-fold:

1. To leave you with an understanding of what is expected from medical device regulators regarding Risk Management.
2. To help you use Risk Management as a tool to design safer medical devices by providing a few helpful tips and pointers to guide you.
3. To share with you all the steps that you need to define and address within your Risk Management procedures.

2.3 REGULATIONS & STANDARDS

Realize that nearly every medical device regulatory agency has placed the topic of Risk Management front and center. In fact, regulatory agencies, including FDA, are now using risk-based processes throughout their own internal processes when reviewing device submissions and conducting inspections and audits.

Know this: U.S. FDA, Health Canada, EU Competent Authority, Australia TGA, and Japan MHLW all require you to have a Risk Management process defined and Risk Management documentation for your products.

In addition to ISO 14971, there are several other key medical device industry standards requiring risk management. **The partial list includes:** IEC 60601**,** IEC 62366**,** ISO 10993**,** ISO 13485

In both cases, the abstract describing the standard is the same:

- "ISO 14971 is a key standard specifying a process for a manufacturer to identify the hazards associated with medical devices, including:
    - in vitro diagnostic (IVD) medical devices,
    - to estimate and evaluate the associated risks,
    - to control these risks, and
    - to monitor the effectiveness of the controls.
- The requirements of this standard are applicable to all stages of the life-cycle of a medical device."

2.4 DESIGN CONTROLS & RISK MANAGEMENT

There is a very strong correlation and relationship between Design Controls and Risk Management. With Design Controls, you also identify, evaluate, analyze, assess,

and mitigate potential product issues. Design Controls are intended to demonstrate that a medical device has been:

1. Designed to address the needs of users and patients.
2. Designed to meet inputs and requirements.
3. Proven to meet applicable standards.
4. Meets performance criteria.

2.4.1 GOOD DESIGN CONTROLS REDUCE PRODUCT RISKS

- If you are thorough with defining and documenting User Needs, Design Inputs, Design Outputs, Design Verification, Design Validation, and Design Reviews, then you will be on the right track towards ensuring your medical device is safe.
- Prior to clinical use, you have to know without a doubt that the product is safe
- Realize Design Controls and Risk Management are related.
- Realize that your overall goal in medical device product development and manufacturing is to prove and demonstrate that your product meets clinical needs, design inputs and requirements, and is safe and effective.

2.5 RISK MANAGEMENT PROCESS OVERVIEW

The process itself includes:

• Risk Management Planning
• Risk Analysis
• Risk Evaluation
• Risk Controls
• Overall Residual Risk Acceptability
• Risk Management Report
• Production & Post-Production Information

2.6 RISK MANAGEMENT DEFINITIONS

RISK MANAGEMENT – systematic application of management policies, procedures, and practices to the tasks of analyzing, 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

HAZARDOUS SITUATION – circumstance in which people, property, or the environment are exposed to one or more hazard(s)

HARM – physical injury or damage to the health of people, or damage to property or the environment

SEVERITY – measure of the possible consequences of a hazard

RISK ANALYSIS – systematic use of available information to identify hazards and to estimate the risk

RISK ESTIMATION – process used to assign values to the probability of occurrence of harm and the severity of that harm

RISK EVALUATION – process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk

RISK ASSESSMENT – overall process comprising a risk analysis and a risk evaluation

RISK CONTROL – process in which decisions are made and measures implemented by which risks are reduced to, or maintained within, specified levels

RESIDUAL RISK – risk remaining after risk control measures have been taken

2.7 ROLE OF MANAGEMENT IN RISK MANAGEMENT

The cornerstone of a medical device company's risk management process must be executive management.

1. Executive management is the ultimate authority within the company for determining whether the product risks are acceptable or not.
2. Executive management has the responsibility for making sure there are adequate and appropriate resources for conducting risk management activities.
3. Executive management has the responsibility of ensuring the company's risk management processes are adequate and effective.
4. Executive management must review the company's risk management processes for effectiveness. This means that the company's risk management processes are described, documented, and controlled as part of quality system procedures.
5. Executive management also has the responsibility for defining the company's risk management policy. This involves determining the risk acceptability criteria. The criteria should be based on solid, objective evidence, such as industry standards

2.8 RISK MANAGEMENT PLAN

A Risk Management Plan must include the following criteria:

1. Scope of the Risk Management activities. Define the product included. It is possible to have multiple products described within a single Risk Management Plan.
2. Describe the intended use of the product(s).
3. Identify all Risk Management activities planned throughout the product lifecycle.
4. Define roles and responsibilities. Identify the Risk Management team that will be reviewing and approving risk documentation.
5. Criteria for the product's risk acceptability. (Note, that often times this is likely to be defined within your Risk Management Procedure.)
6. Specify methods to verify Risk Control measures are implemented and reduce risks.
7. Define how post-production information will be captured and fed into Risk Management activities for the product.

2.9 RISK MANAGEMENT FILE

A Risk Management File contains evidence of:

- Risk Management Plan
- Risk Analysis
- Risk Evaluation
- Risk Controls
- Evaluation of Overall Risk Acceptability
- Risk Management Report
- Production and Post-Production Risks

2.10 Identification of Hazards

Hazards are potential sources of harm. For your product, you need to identify all the possible hazards. ISO 14971 contains a great list of examples of hazards.

Here are a few examples:

- Electromagnetic Energy
- Line Voltage
- Leakage Current
- Electric Fields
- Thermal Energy
- Mechanical Energy
- Gravity
- Vibration
- Biological
- Bacteria
- Viruses
- Chemical

2.11 RISK EVALUATION

Here are a few very important points regarding Risk Evaluation:

1. For those following ISO 14971:2007, it is very common for the risk acceptability to relate to the risk levels. Items with unacceptable risk levels require risk reduction.
2. For those following EN ISO 14971:2012, all risks identified – regardless of risk level – must be reduced "as far as possible." This means you need to consider risk reductions for all risks – regardless if the level is low, medium, or high.

2.12 RISK CONTROLS

You should consider Risk Control options according to the following priority:

1. Inherent safety by design
2. Protective measures in the actual medical device and/or manufacturing process
3. Information for safety, such as labeling and instructions for use

2.13 PRODUCTION & POST-PRODUCTION INFORMATION

- Risk Management is a total product lifecycle process.
- Your product Risk Management File needs to be a living document.
- Once you begin manufacturing and launch your medical device into the market, you are going to learn a great deal about the product.
- You need to make sure that your Risk Management documentation is current and as best as possible, an accurate reflection of the actual risks your product poses.

2.14 Risk Management Report

- Summarize all your risk management activities
- Include any risk / benefit analyses
- Explanation of overall risk acceptability of entire device
- Discuss your plans for evaluating risks in production and postproduction
- Recommend that you have executive management in your company approve the Risk Management Report.

2.15 SUMMARY

Realize that your Risk Management process must include:

- Risk Management Planning
- Risk Analysis
- Risk Evaluation
- Risk Controls
- Overall Residual Risk Acceptability
- Risk Management Report
- Production & Post-Production Information