Risk Management for Medical Devices

An Overview of ISO 14971 & How To Apply a “Risk Based Approach” to Your QMS Processes to Address the Upcoming ISO 13485 Changes

September 2015 Presentation
Background

Jon D. Speer

- Founder & VP QA/RA greenlight.guru (Quality, Design Control & Risk Management Software for Medical Devices)
- Founder Creo Quality (Consultancy)
- 17+ Med Device Industry Experience
- @CreoQuality & @greenlightguru
- Email: Jon.Speer@greenlight.guru
Agenda

• Key risk management terms & definitions
• Overview of ISO 14971
• Incorporating risk management throughout the design control process
• Using risk management as a tool during design & development
• Preparing for the coming ISO 13485:201X changes
• Describe relevance of ISO 14971 and the impending ISO 13485 revision
• Applying a “risk-based approach” to all your QMS processes
• Q&A
Risk Management Terms & Definitions
Key Terms & 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
Key Terms & Definitions

- **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
ISO 14971 Overview
ISO 14971 Overview

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

• Scope of the Risk Management activities. Define the product included. It is possible to have multiple products described within a single Risk Management Plan.

• Describe the intended use of the product(s).

• Identify all Risk Management activities planned throughout the product lifecycle.

• Define roles and responsibilities. Identify the Risk Management team and will be reviewing and approving risk documentation.
Risk Management Plan

- Criteria for the product’s risk acceptability. (Note, that often times this is likely to be defined within your Risk Management Procedure.)

- Specify methods to verify Risk Control measures are implemented and reduce risks.

- Define how post-production information will be captured and fed into Risk Management activities for the product.
Free Risk Management Plan Template

6. RISK MANAGEMENT PLAN

The risk management activities coincide with the product development and design control process (refer Design & Development Procedure and Risk Management Procedure).

Table 1 - Risk Management Deliverables by Project Phase

<table>
<thead>
<tr>
<th>Project Phase</th>
<th>Risk Management Deliverables</th>
</tr>
</thead>
<tbody>
<tr>
<td>Planning</td>
<td>• Risk Management Plan</td>
</tr>
<tr>
<td>Design and Development</td>
<td>• System Risk Analysis (hazard identification)</td>
</tr>
<tr>
<td></td>
<td>• System Risk Evaluation</td>
</tr>
<tr>
<td></td>
<td>• Risk Assessment (product &amp; process)</td>
</tr>
<tr>
<td>Design Verification</td>
<td>• Risk Control</td>
</tr>
<tr>
<td></td>
<td>• Residual Risk Acceptance</td>
</tr>
<tr>
<td>Design Validation</td>
<td>• Risk Management Report</td>
</tr>
<tr>
<td>Market Release</td>
<td>• Production &amp; Post-Production Risk Management</td>
</tr>
<tr>
<td></td>
<td>• Revised Risk Management Report</td>
</tr>
</tbody>
</table>

Risk management deliverables are reviewed and approved during design reviews for each project phase. ISO 14971:2007 [ISO EN 14971:2012 for devices entering Europe] shall be used for instructions and as guidelines during risk management documentation. Refer to Risk Management Procedure for the company process.

Risk is defined as the combination of occurrence of harm and the severity of that harm. In order to estimate risks of hazardous situations relating to [insert product family], severity of harm and probability of occurrence of harm are estimated according to the tables below.
Risk Acceptability Matrix

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Negligible</th>
<th>Minor</th>
<th>Serious</th>
<th>Major</th>
<th>Critical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequent 1 in 100</td>
<td>No or negligible risk to patient</td>
<td>Slight customer inconvenience; little to no effect on product performance, non-vital fault</td>
<td>Short-term injury or impairment requiring additional medical intervention to correct (e.g. reoperation)</td>
<td>Severe, long-term injury; potential disability</td>
<td>Loss of limb, life-threatening injury</td>
</tr>
<tr>
<td>Probable 1 in 1,000</td>
<td>Requires RSA</td>
<td>Requires RSA</td>
<td>Requires RSA</td>
<td>Requires RSA</td>
<td>Requires RSA</td>
</tr>
<tr>
<td>Occasional 1 in 10,000</td>
<td>Requires RSA</td>
<td>Requires RSA</td>
<td>Requires RSA</td>
<td>Requires RSA</td>
<td>Requires RSA</td>
</tr>
<tr>
<td>Remote 1 in 100,000</td>
<td>Requires RSA</td>
<td>Requires RSA</td>
<td>Requires RSA</td>
<td>Requires RSA</td>
<td>Requires RSA</td>
</tr>
<tr>
<td>Improbable 1 in 1,000,000</td>
<td>Requires RSA</td>
<td>Requires RSA</td>
<td>Requires RSA</td>
<td>Requires RSA</td>
<td>Requires RSA</td>
</tr>
</tbody>
</table>

ISO 14971:2007
Figure 1 - Risk Management Process

Risk analysis
- Intended use and identification of characteristics related to the safety of the medical device
- Identification of hazards
- Estimation of the risk(s) for each hazardous situation

Risk evaluation

Risk control
- Risk control option analysis
- Implementation of risk control measure(s)
- Residual risk evaluation
- Risk/benefit analysis
- Risks arising from risk control measures
- Completeness of risk control

Evaluation of overall residual risk acceptability

Risk management report

Production and post-production information
ISO 14971:2007
Figure B.1 - Overview of Risk Management Activities as Applied to Medical Devices
Risk Assessment = Risk Analysis + Risk Evaluation
Risk Control

Identify appropriate risk control measure(s), record risk control requirements (6.2)

Is the risk reductible? (6.2)

Yes

Implement, record and verify appropriate measures (6.3)

No

Is the residual risk acceptable? (6.4)

Yes

Yes

Do medical benefits outweigh the residual risk? (6.5)

No

Are new hazards or hazardous situations introduced or exiting risks affected? (6.6)

Yes

No

Are all identified hazards considered? (6.7)

No

No

Acceptable

Yes
Risk / Benefit Analysis (RBA)

• After you identify Risk Controls and evaluate residual risks, it is still possible that you will have some risks that are still in the unacceptable level. In these cases, it might make sense to conduct and document a risk / benefit analysis (RBA).

• The RBA must be documented and provided objective evidence and rationale for why the medical benefits outweigh the unacceptable risks. If you are able to do so, the RBA is a special provision for moving forward with unacceptable risks.
Overall Residual Risk Evaluation

Is overall residual risk acceptable? (Clause 7)

- Yes
- No

Do medical benefits outweigh the overall residual risk? (Clause 7)

- Yes
- No

Prepare risk management report (Clause 8)
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 post-production
• Recommend that you have executive management in your company approve the Risk Management Report.
Production & Post-Production Information

- Review production and post-production information (Clause 9)
- Is reassessment of risk necessary? (Clause 9)
  - Yes
  - No

- Normative standard the same
- 2012 added “Z” annexes
- 2012: reduce risk as far as possible
- 2012: risk controls required for all risks
- 2012: risk / benefit analysis required for all risks
Risk Management + Design Controls
Risk Management + Design Controls

• Understand the importance of Intended Use

• Product Risk Management is a cycle—even during product development

• Risk Management & Design Controls have the same purpose
Risk Management As a Tool
Risk Management ≠

• **The Longer You Wait, The Tougher It Gets** – delaying design controls and risk management documentation actually caused lengthy delays in projects.

• **Understanding The Purpose** – design, develop, manufacture, and sell medical devices that are as safe as possible for their intended uses.

• **Value Of Documentation** – FDA inspectors, ISO auditors, and other regulatory bodies and business associates are likely to review your design controls and risk management.
ISO 13485:201X – Major Changes

• **Regulatory Requirements** – not just ISO 13485
• **Risk Management** – entire QMS should involve risk-based approaches
• **Verification & Validation** – plans in place plus supporting documented evidence
• **Design Transfer** – ensure Design Outputs are suitable for manufacturing before becoming production specifications
• **Purchasing Control** – emphasis on purchased product has on safety and performance
• **Supplier Control** – emphasis on suppliers ability to meet regulatory requirements
• **Monitoring QMS** – during production and post-market
ISO 13485:201X – Some Details

• Terms “risk” & “regulatory” used >200 times (vs. ~50 in ISO 13485:2003)
• Align with industry best practices
• Better align with regulations; expectation QMS complies with all applicable regulatory requirements
• Concept of risk-based QMS
  • Previously risk more aligned with D&D
  • Now risk management methods to all QMS processes
• ISO 9001:2015 not aligned with ISO 13485:201X
ISO 13485:201X – Some Details

• More flexible – non-applications of clauses 6, 7, or 8 allowed (with justification)
• “Product Quality” replaced with “Product Safety and Performance”
• Emphasis on traceability during product realization
• Further definition on Design & Development activities (Design Controls)
• More references to software (as a medical device)
ISO 13485:201X – Some Details

• Requirement to address UDI regulations
• Design & Development Transfer now its own subsection
• Effects of purchasing on safety and performance of medical device
• Ensuring suppliers meet regulatory requirements
• Supplier related risks
ISO 13485:201X – Overall Impact

• If you have ISO 13485:2003 and/or 21 CFR 820 compliant QMS, the overall impact of the new standard should be relatively minor

• Should help incorporate use of ISO 14971 throughout QMS

• Improved linkage and integration of all clauses

• Expected to be published in 2016; 3 years to adopt (if already certified)
Risk-Based QMS
Risk-Based QMS

• Greater emphasis on Risk due to ISO 14971 and regulatory bodies
• Manage risks throughout QMS
  • Management Review – What is impact of failing to review critical items?
  • Training – What are consequences of ineffective training?
  • Calibration – What happens if done incorrectly?
  • Purchasing – What effect do purchased products have on safety and performance?
  • Supplier Monitoring – Are suppliers able to meet regulatory requirements?
• Manage risks through entire product lifecycle (like ISO 14971)
Want to Work Together?


Email: Jon.Speer@greenlight.guru

THANKS!