BEST PRACTICES IN IMPLEMENTING AN EFFECTIVE RISK MANAGEMENT SYSTEM

Tenth Annual Medical Device Quality Congress
June 4 – 6, 2013
Bethesda, MD

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• Intent of Risk Management
• The Risk Management process
• Effective Risk Management
• Conclusion
Intent of Risk Management

Concept / Feasibility | Development | Production and Postproduction

Increase Safety & Effectiveness
Reduce / Manage Risk

Probability vs. Time
Launch
Principles of Quality Risk Management

- The evaluation of risk to product, process or quality should be based on scientific knowledge and ultimately link to the protection of the patient.

- Should be implemented throughout the product life-cycle.

- The level of effort, formality and documentation of the Quality Risk Management process should be commensurate with the level of risk of the products to patient, end-user and other stakeholders.
Risk Management and the Product Life-cycle process

<table>
<thead>
<tr>
<th>Concept / Feasibility</th>
<th>Development</th>
<th>Production and Postproduction</th>
</tr>
</thead>
</table>

- Risk Management Plan
- Risk Analysis
  - Use FMEA
  - Design FMEA
  - Software Risk Analysis
  - Process FMEA
  - Fault Tree Analysis
- Risk Management Report
- Risk Reviews
  - Production, post-production, post-market data sources

Risk Management and the Product Life-cycle process

- Example

Intended Use
- Safety-related characteristics
- Other data sources

Time
§ 820.30 (g) – Design Validation:

- *Design validation shall include software validation and risk analysis, where appropriate.*

- Pre-Amble to 21 CFR Part 820- Quality System Regulation

  - Comment 4:
    - ...gives the manufacturer the flexibility to determine the controls that are necessary commensurate with risk.

  - Comment 83:
    - When conducting risk analysis, manufacturers are expected to identify possible hazards associated with both normal and fault conditions. The risk associated with the hazards, including those resulting from user error, should then be calculated in both normal and fault conditions. If any risk is judged unacceptable, it should be reduced to acceptable levels by appropriate means, for example, by redesign or warnings.
    - Risk analysis must be conducted for the majority of devices subject to design controls and is considered to be an essential requirement for medical devices under this regulation...
ISO 14971:2007 - Terminology

- Risk Management Plan
- Risk Analysis
- Risk Evaluation
- Risk Control
- Evaluation of overall residual risk acceptability
- Risk Management Report
- Production and Post Production Information

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

- Risk control option analysis
- Implementation of risk control measures
- Residual risk evaluation
- Risk / benefit analysis
- Risks arising from risk control measures
- Completeness of risk controls

Risk Management

Risk Assessment

Risk Management

Hazard
Exposure ($P_1$)

Hazardous situation

$P_2$

Harm

Severity of the harm

Probability of occurrence of harm

Risk

$P_1 \times P_2$
Hazards, Hazardous Situations and Harm

HAZARDS
Electrical, Mechanical, Energy, Biocompatibility, Operational, Labeling

Initiating Event

Step 1
Step 2
Step 3
Step 4
Step 5
Step 6

Hazardous Situation

SEVERITY (S)

Risk = S x O where O = (P₁ x P₂)

P(1)

P(2)

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• Type of device and use in a clinical setting
• Life sustaining / life supporting evaluation
• Historical complaint data and MDR files
• Historical production / NCR / CAPA data
• Data of similar devices from public sources
• Current standards and regulations
• End-user requirements and expectations
• Societal norms
• Best available technology and / or product maturity
• Consumer versus producer risk
Residual Risk and Overall Residual Risk

<table>
<thead>
<tr>
<th>Hazard Analysis</th>
<th>Pre-mitigation</th>
<th>Post-mitigation</th>
<th>Severity of Harm</th>
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Severity of Harm

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<td>Cumulative Risk</td>
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From Procedures to Execution and Documentation

- Policies and Procedures
- Work Instructions, Forms and Templates
- Execution
- Records
Ineffective Risk Management Processes

- Poor understanding of risk assessment and risk management per ISO 14971:2007
- Inappropriate use of the term risk, risk analysis and risk assessment
- Conducting risk assessment in a vacuum
- Unqualified, inexperienced and untrained personnel conducting risk assessments
- Ignoring the “unusual events” and the “that will never happen” syndrome
- Business priorities over quality and due diligence
- Poor communication of risk assessments and results to production, purchasing, servicing, installation etc.
Effective Production and Post-production Activities

- Risk-based decisions and activities commensurate with the level of risk:
  - Production
  - Purchasing controls and supplier controls
  - Servicing
  - Installation
  - CAPA
  - NCRs
  - Complaints
  - MDRs
  - Change control
- Determination of **true root cause** for alleged deficiencies
- Confirm, validate risk assessments
- Update, revise, modify risk documents
- Early identification of problems and rapid response

Closed-loop Quality System and Risk Management System Effectiveness
• Design in the quality; design down the risk
• Cross-functional teams
• Defined roles and responsibilities
• Effective links and communication between the various quality system elements and functions to risk management
• Updates to risk files based on changes and periodic reviews of post-production data and information
• A learning organization → to ensure continued effectiveness of the risk management system
• Appropriate metrics to measure the effectiveness of the risk management system
• Management leadership, commitment and involvement
Compliance, Quality and a Company’s Maturity Level

Level 1 (Procedures)

Level 2 (Processes)

Level 3 (Culture)

Integral part of the company’s DNA
A quality-based culture

Management of Change

Quality and Risk based processes

Amount of Effort

Time

Maturity Level

Compliance

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The Cost of Poor Due Diligence

Project Time Line

Cost of Poor Quality
Cost of Poor Compliance
Cost of Poor Due Diligence
Conclusions

A effective Risk Management System:

- An organization where risk management is infused into their processes and operations

- Designing in quality; designing down risk

- Use of risk-based decisions

- Closed-loop processes to establish and maintain an effective Quality Management System

STATE OF CONTROL

COMPLIANCE WITH REGULATIONS AND STANDARDS
REDUCED PRODUCT AND PROCESS ISSUES AND COMPLAINTS
INCREASED PRODUCTIVITY AND PROFITABILITY
WINOVIA® LLC (www.winovia.com) is a consulting company that provides customized, sustainable solutions and strategies in product life-cycle management, quality management and high performance materials.

WINOVIA® LLC provides consulting and training in:

- FDA and ISO Quality Systems Regulations for Medical Devices and Pharmaceuticals
- Quality Systems Assessment and Implementation
- Design Controls
- Production Controls and Process Validation
- Design for Six Sigma and New Product Development
- Operational Excellence and Six Sigma
- Technology Roadmaps
- Risk Management
- Corrective Action and Preventive Action (CAPA)

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