



Risk Management Processes & Tools to Know

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January 14, 2009



Presentation Overview

1. What is Risk Management?
2. Review of Risk Management Principles according to ISO 14971:2007
3. Tools for Managing Risk
4. Integrating Risk Management with your Quality Management System (QMS)
5. Living with your Risk Management Program
6. Open Discussion / Q&A (*and throughout!*)



What is Risk Management?

- Risk Management is a continuous process from product conception through obsolescence
- It is an integral part of the Quality Management System
- Risk-Based vs. Risk Management
- ISO 14971:2007 “Medical Devices - Application of Risk Management to Medical Devices”



What is Risk Management?

- Hazard - potential source of harm
- Harm - physical injury or damage to health, property or environment
- Risk is a function of
 - The severity of the harm
 - The probability of the harm occurring
- Risk management is a structured approach to managing potential and known risks by:
 - Assessing and evaluating potential hazards
 - Developing strategies to control identified hazards



What is Risk Management?

- Risk = severity × probability
- Defining levels of Severity
 - Quantitative: 3? 1-5? 1-10?
 - Qualitative: Negligible, Minor, Serious, Catastrophic?
- Defining levels of Probability
 - Quantitative: Less than 1 in a million? 1 in 100? 1 in 10?
 - Qualitative: Improbable, Remote, Occasional, Probable?
- Risk = severity x probability x detectability



What is Risk Management?

- Risk = severity × probability

Highly unlikely event with severe impact to patient health/safety

VS.

Likely event with slight impact to patient health/safety

- Risk = severity x probability x detectability
 - Severity (5), Occurrence (4), Detection (2) = 40
 - Severity (9), Occurrence (2), Detection (2) = 36
 - Severity (8), Occurrence (1), Detection (8) = 64

How Much Risk is Acceptable?

		SEVERITY				
O C C U R R E N C E		Negligible (1)	Minor (2)	Serious (3)	Critical (4)	Catastrophic (5)
	Frequent (5)	5	10	15	20	25
	Probable (4)	4	8	12	16	20
	Occasional (3)	3	6	9	12	15
	Remote (2)	2	4	6	8	10
	Improbable (1)	1	2	3	4	5



Unacceptable





As Low As Reasonably Practicable (ALARP) / Consider further risk reduction







Insignificant (Acceptable)

How Much Risk is Acceptable?

		SEVERITY				
		Negligible (1)	Minor (2)	Serious (3)	Critical (4)	Catastrophic (5)
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	Remote (2)	2	4	6	8	10
	Improbable (1)	1	2	3	4	5

 Unacceptable
 Insignificant (Acceptable)

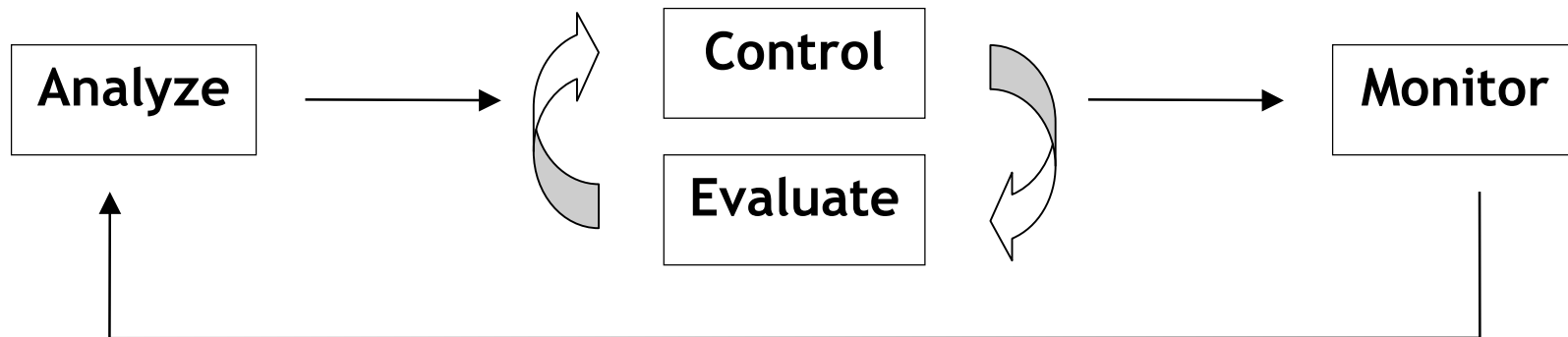
 Unacceptable
 Significant
 Potential Concern
 Insignificant (Acceptable)

		SEVERITY				
		Negligible	Minor	Serious	Critical	Catastrophic
O C C U R R E N C E	Frequent	Potential Concern	Significant	Unacceptable	Unacceptable	Unacceptable
	Probable	Potential Concern	Significant	Significant	Unacceptable	Unacceptable
	Occasional	Potential Concern	Potential Concern	Potential Concern	Significant	Significant
	Remote	Insignificant	Insignificant	Potential Concern	Potential Concern	Potential Concern
	Improbable	Insignificant	Insignificant	Insignificant	Potential Concern	Potential Concern

What is Risk Management?

- 4 key concepts:

- Analyze
- Control
- Evaluate
- Monitor





Analyze

- Product description
- Intended purpose and users
- Characteristics related to the safety & performance of the product
 - What is the product's role relative to diagnosis, prevention, monitoring, treatment, etc?
 - What factors have an effect on results?
 - How is the product treated before and after use?
- Criteria for risk assessment & acceptability
- Identification of potential hazards
- Risk estimation



Analyze, cont.

- Things to remember:
 - Risk analysis should be a CROSS-FUNCTIONAL TEAM APPROACH!
 - Criteria for acceptability must be set PRIOR to any evaluation activities.
 - Consider product use AND manufacturing
 - Helpful tools to assist with the analysis:
 - Failure Mode and Effects Analysis (FMEA)
 - Fault Tree Analysis (FTA)
 - HAZOP, HACCP, PHA



Evaluate

- Which hazards have risk levels that are unacceptable?
- Is risk reduction necessary?
- Is risk reduction practicable?
- What is the benefit to using this product?
- Can this benefit be used to justify any unmanageable risks?
- What is the overall product risk? Is it acceptable?



Control

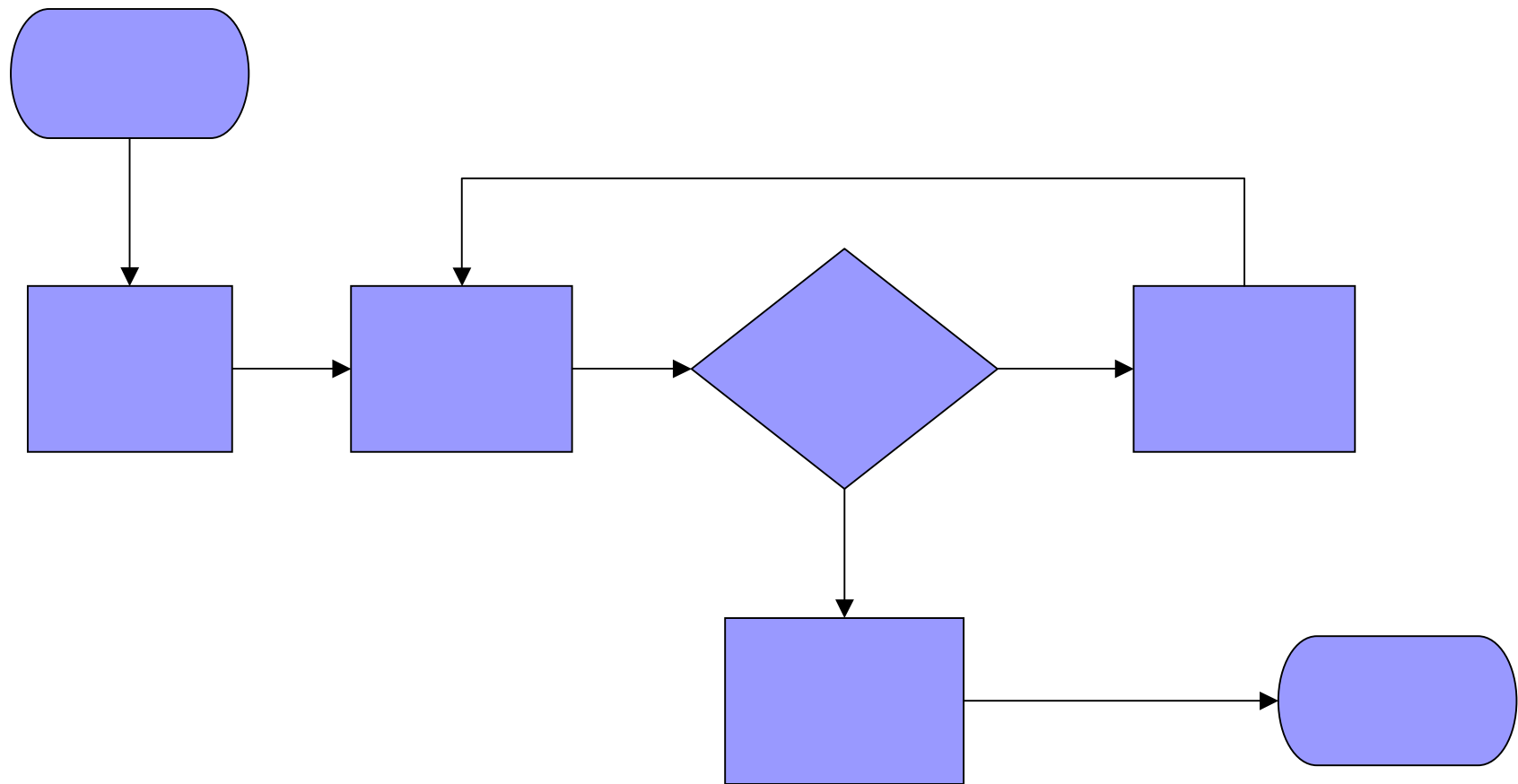
- What can be done to reduce risk?
 - Can the hazard be eliminated?
 - Can the probability of its occurrence be minimized?
 - Can information be shared with the user and/or patient?
- Implementation of control measures
- Verification of control effectiveness
- Reassessment of risk with control measure
- Any new hazards introduced?
- Are residual risks acceptable?
- What is the overall product risk? Is it acceptable?



Monitor

- Review production and post-production information to ensure analysis, evaluation and control efforts were adequate and appropriate
- Information to review includes:
 - Clinical results
 - Customer complaints
 - Internal non-conforming product reports
 - Field Corrective Actions (Recalls)
 - Engineering Change Orders
 - Health and Safety Reports
 - Scientific literature

Review of Risk Management Flow





Risk Management Documentation

- Risk Management File
 - Risk Management Plan
 - Scope
 - Roles & Responsibilities
 - Risk Management Activities Review Requirements
 - Criteria for Acceptability
 - Post-Production Monitoring Method
 - Risk Management Report
 - Risk Analysis/Assessment
 - Supporting information
 - Control effectiveness verification
 - Risk evaluation studies



ISO 14971:2007 Overview

1. Scope
2. Terms & Definitions
3. General Requirements for Risk Management
 1. Process (analysis, evaluation, control, monitoring)
 2. Management Responsibilities
 3. Qualification of Personnel
 4. Risk Management Plan
 5. Risk Management File (plan, analysis, results, final risk)
4. Risk Analysis
5. Risk Evaluation
6. Risk Control
7. Evaluation of Overall Residual Risk Acceptability
8. Risk Management Report
9. Production and Post-Production Information



ISO 14971:2007 Annexes

- Annex A - Rationale for Requirements
- Annex B - Flow Chart of Risk Management Process
- Annex C - Questions that can be used to identify device characteristics that could impact safety
- Annex D - Risk concepts applied to medical devices (hazards, risk estimation, acceptability, control, risk/benefit analysis, overall evaluation)
- Annex E - Examples of hazards, foreseeable sequences of events and hazardous situations
- Annex F - Risk Management Plan
- Annex G - Information on risk management techniques (tools)
- Annex H - Guide on RM for *in vitro* diagnostic devices
- Annex I - Guidance on risk analysis process for biological hazards
- Annex J - Information for safety and information about residual risk (disclosure)



Risk Management Tools

- Failure Mode and Effects Analysis (FMEA)
 - Examines potential product or process hazards
 - Prioritizes hazards by risk level
 - Helps determine risk control measures to avoid identified hazards
- Fault Tree Analysis (FTA)
 - Relates a “top event” (effect) to lower level failures and basic root causes
 - Uses relationships and probabilities of basic root causes to estimate likelihood of the top event



Other Risk Management Tools

- Preliminary Hazard Analysis (PHA)
 - Translates hazardous situations (not failure modes) into high-level system safety design constraints
- Hazard and Operability Study (HAZOP)
 - Analyzes deviations from design using parameters & guide words
(i.e. flow rate & more/less/partial/none/reverse/etc)
- Hazard Analysis and Critical Control Point (HACCP)
 - Relates hazardous situations (not failure modes) to process points that can either control or eliminate the potential hazard
 - Each control point has associated preventive measures, monitoring procedures and limits

Simple Example FMEA

Process: Walking down the stairs

Failure Modes	Effects	S (1-5)	Causes	Controls	O (1-5)	Risk Index	CAPA	New O	New Risk Index
Trip and fall on 1 st step	Tumble down and break a limb	3	Clutter on stairs	Weekly cleaning service	3	9	Daily cleaning service	1	3
			Unlaced shoes	Double knotted laces	2	6			
			Miss a stair		3	9	Paint yellow stripes on stair lip	2	6
			Dizziness		2	6	Install a hand rail	1	3
	Tumble down and die	5	Harmful (sharp/hard) objects on landing		3	15	Move glass table from landing	2	10
			Bad luck		2	10			



Phases of a FMEA

1. Form a team
2. Learn the process
3. Brainstorm potential hazards & effects
4. Analyze causes & controls
5. Prioritize hazards
6. Recommend control measures
7. Plan & implement controls
8. Reevaluate hazard



1. Form a Team

- At least 4 people
- Cross-functional
- Necessary for the following reasons:
 - No process operates in a vacuum
 - Variety in backgrounds, experiences, familiarity, education, thought processes makes for better brainstorming
 - Buy-in across departments
 - Quicker turnaround time on actions
 - Team building



2. Learn the Process

- Document Review
 - Development/Feasibility data
 - Drafted Package Inserts & Labeling
 - Drafted manufacturing SOPs & Work Instructions
 - NCRs, Investigations, previous failures
- Map it
- Observe it
- Discuss it



3. Brainstorm Hazards & Effects

- 3 questions for each step of the process:
 - “What COULD go wrong here?”
 - “What HAS gone wrong here before?”
 - “What effect would that potential failure have on the product?”
 - Is the result invalid? Incorrect? (IVD)
 - Does production stop?
 - Is product quality compromised?
 - Is the product scrapped?
 - “What effect would that potential failure have on the patient?” “User?”
 - Misdiagnosis? (IVD)
 - Injury?
 - Death?



4. Analyze Causes & Controls

■ More questions:

- What can cause the failure?
- Is there anything in place that prevents this cause from occurring?
 - Design-wise?
 - Manufacturing-wise?
- Is there anything in place that detects when this cause occurs?
- Is there anything in place that detects when the failure or effect occurs?



5. Prioritize Hazards

- Rate each hazard according to:
 - The severity of the effect
 - The probability of the cause
- Ranking system agreed to by the team
- Calculate the Risk Index (if quantitative criteria)
- Prioritize mitigation activity according to Risk Index

6. Recommend Control Measures

- Brainstorm potential controls that:

- Prevent the cause from occurring
- Detect when the cause or failure occurs
- Mitigate consequences of failure
- Demonstrate the acceptability of the failure's current Risk Index (validation)
- Educate user/patient through labeling



- Keeping in mind:

- Risk Index & criteria for acceptability
- Effect of implementation



7. Plan & Implement Controls

- Plan appropriate risk controls with regard to:
 - Patient Risk
 - User Risk
 - Business Risk
 - Feasibility
 - Time
 - \$
 - Resources
 - Future plans



8. Reevaluate Hazard

- Once implementation of control is complete:
 - Evaluate and adjust the Risk Index
 - Review process with new action.
Did we create any new hazards or failures with this change?
- Review hazards when future process changes are being planned.



Phases of a FTA

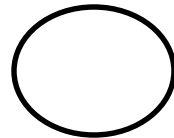
1. Form a team
2. Learn the process
3. Identify the top event (effect)
4. Brainstorm potential causes
5. Estimate probability of basic causes
6. Calculate top event probability
7. Recommend control measures
8. Plan & implement controls
9. Reevaluate probability of top event

Fault Tree Analysis

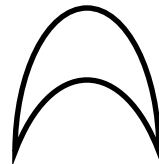
Basic FTA Symbology:



Event

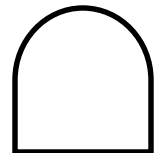


Basic Cause



OR gate

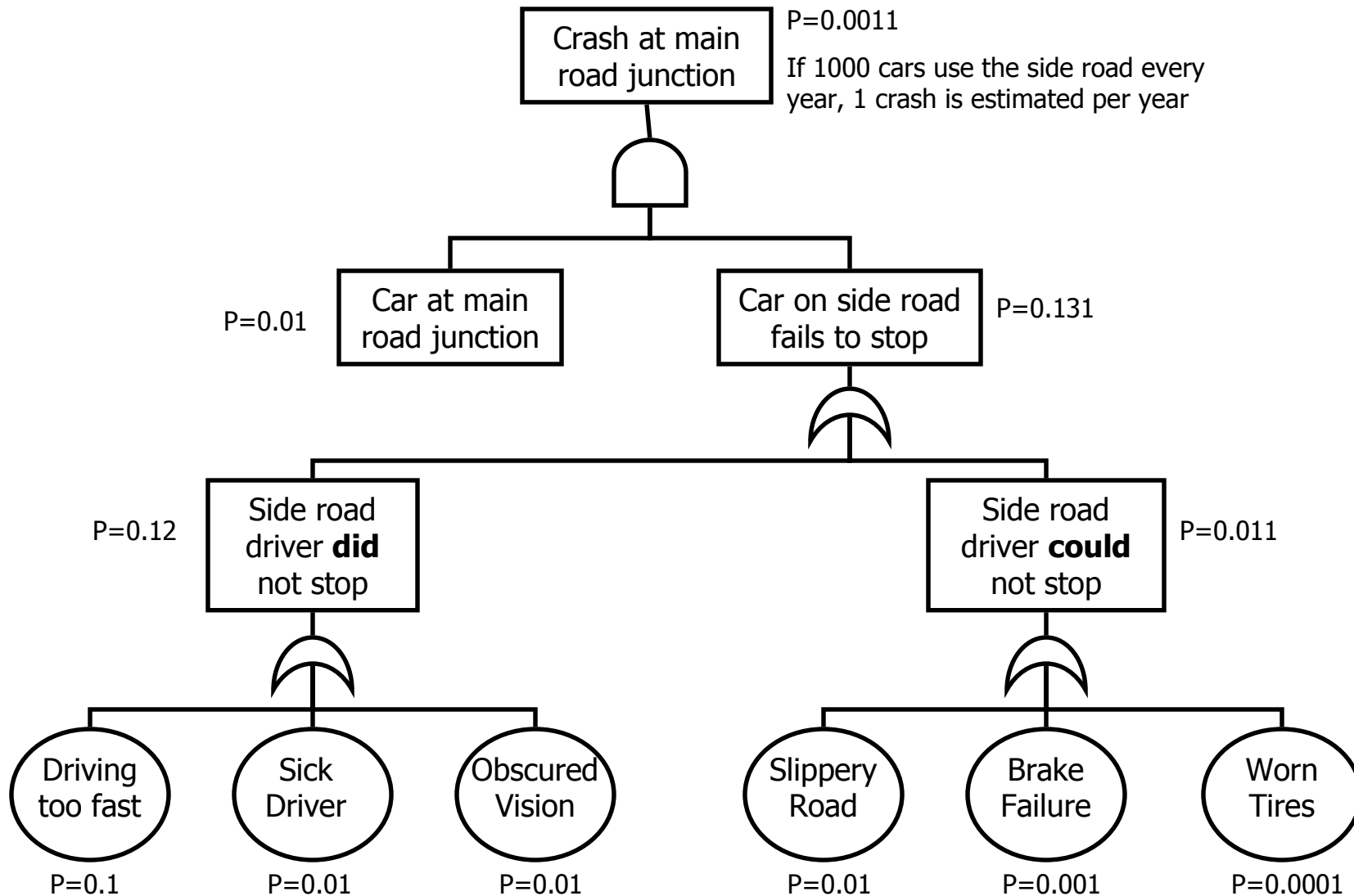
(if ANY input fails, upper level fails)



AND gate

(if ALL inputs fail, upper level fails)

Simple Example FTA





Example Medical Device Risk Analysis

- See Handout



Integrating Risk Management with the QMS

- ISO 13485:2003 requires RM Program:
 - Clause 7.1 - The Organization shall establish documented requirements for risk management throughout product realization. Records arising from risk management shall be maintained.
 - Clause 7.3.2 - Inputs relating to product requirements shall be determined and records maintained. These inputs shall include... e) output(s) of risk management (see 7.1).
 - Refers to ISO 14971 for guidance related to risk management.



Integrating Risk Management with the QMS

- Both Systems/Standards apply to the product lifecycle.
- Yin/Yang Relationship
 - RMS works through the QMS
 - QMS needs RMS to operate effectively and efficiently
 - The what and the how
 - The PB and the J



Integrating Risk Management with the QMS

- Design Control
 - Design inputs come from RM activities
 - Development of appropriate test methods
 - Prevent failures as early as in the feasibility phase (\$\$\$)
 - Labeling & process documents with risk reduction built in

- Validation of Processes
 - Material, Equipment, Operations, Test Methods
 - What & How to validate - Master Val Plan, protocol designs

- Purchasing/Supplier Management
 - Supplier selection
 - Prioritize audit plans



Integrating Risk Management with the QMS

- CAPA - complaints, nonconformities, recalls, etc.
 - Failure mode missed?
 - Severity or Probability underestimated?

- Change Control
 - Product and process changes - Do they create new risk? Do they change existing risk?
 - How risk mitigation is reviewed and implemented

- Equipment Control
 - Calibration and PM requirements

- Internal Auditing
 - What & How to audit
 - Auditing the RM Program itself



Integrating Risk Management with the QMS

- Training
 - One of the most critical manufacturing risk controls!
 - What and how to focus training
- Product Traceability
 - Which product components require traceability?
- Environmental Control
 - Where to monitor
 - Acceptable limits
 - Frequency of testing
- Production & Quality Planning
 - Planning & RM go hand in hand
 - Reactive vs Proactive




Living with your Risk Management Program

- Maintaining the Program
 - Management Support
 - Build awareness through education
 - Prove its value - Cost of Quality (failures, CAPA, variation)
 - Resources & Skills
 - Keep it alive!
 - Integrate fully with QMS - Proceduralize risk management activities through policies, SOPs, meetings, language
 - Trigger RM file updates with CAPA and change control
 - Instill the value of RM company wide
 - Everyone has a role
 - Define roles/responsibilities in policies and procedures



Living with your Risk Management Program

- Meeting development project timelines
- Kicking off RM activities early
- Managing the level of detail of Risk Analysis
- Receiving input from all perspectives
- Defining criteria for acceptability
- Quantifying severity and probability
- Justifying benefit/risk for unacceptable risks
- Analyzing overall risk 
- Planning for resources for control measure implementation



Living with your Risk Management Program

- Avoiding redundancy in similar products/processes
- Dealing with legacy products (old vs new)
- Assessing risk from suppliers & OEMs
- Finding time for proactive work
- Additional Benefits
 - Reduce process variation
 - Reduce corrective action
 - Increase customer satisfaction
 - Work efficiently using risk-based approaches



In closing...

- Risk Management is critical to every business!
- Recipe for success:
 - Management Support (Objectives, timelines, resources)
 - A seamless relationship with Quality Management System (QMS) is critical to its success
- The more work you do in design/dev, the easier post-market life will be
- It requires a bit of faith and planning
- You get what you give
- It is a culture change
- Keep it value added!



Questions & Answers

Open Discussion

?