Risk Management Applications in Quality

ASQ Food, Drug, and Cosmetic Division MidWest Conference

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Overview/Outline

- Foundation/Applications
- ISO 14971 - Risk Management
- Risk Analysis Techniques
- Risk Analysis Applications
- HACCP
- Risk Application in Manufacturing
- Risk Control

Foundation

- Risk Management is increasing in interest in all FDA regulated industry (and non-regulated)
- Applications exist in each FDA regulated group
  - Devices/IVD's
  - Foods
  - Pharma
  - Biotech

Applications

- Devices/IVD's
  - Required in design by QSR-would have been more widespread except for timing of the regulation
  - ISO 14971 is required for certification (MDD, IVDD)
  - 6-sigma and other techniques use risk integrally

Applications

- Food
  - HACCP use risk and is required for Food processing
  - ASQ has a certification for HACCP

Applications

- Pharma/Biotech
  - Process Analytical Technology
  - Risk and Quality System integration
    - Scientific advancements are "encouraged"
    - Match level of effort against risk
    - Science has advanced, regulation hasn't
    - Quality systems (and markets) are international

Applications

- FDA Inspection
  - Risk is used to schedule inspections
  - Seattle district inspects 20% of its firms annually - high risk is every year - low risk is seldom if at all

Risk Management Requirements.. An Overview

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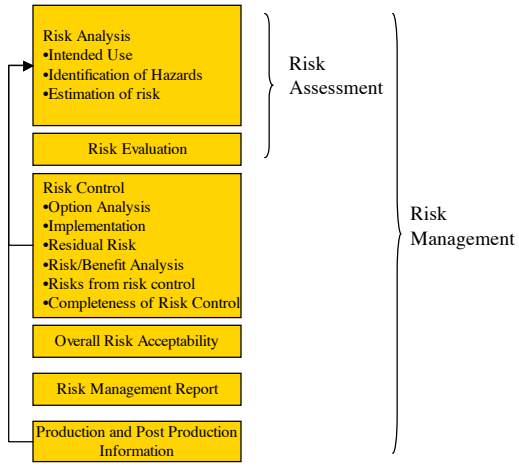
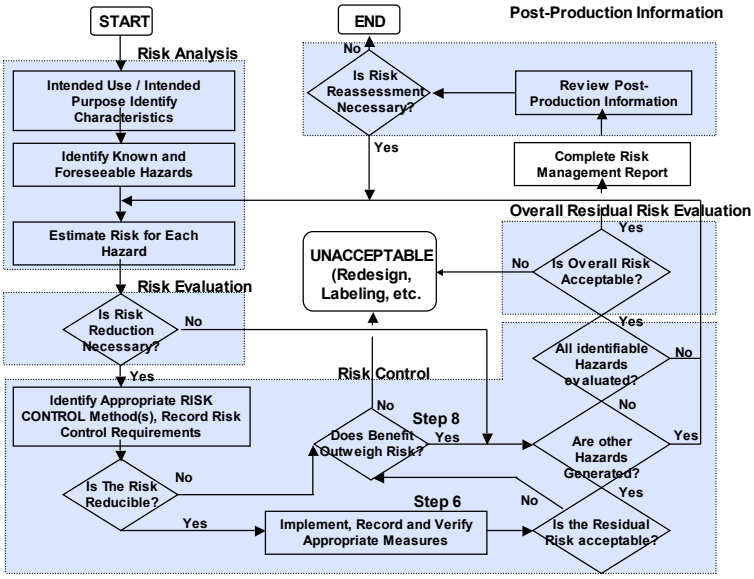
ISO 14971
General Requirements for Risk Management

- ISO/CD3 14971 is latest version
- Risk Management Process
  - Risk Analysis
  - Risk Evaluation
  - Risk Control
  - Production and post-production information

Schematic of Risk Management Process



Overall Risk Management Process (ISO/EN 14971)



ISO 14971 Management

- Management Responsibilities
  - Ensure the provision of adequate resources
  - Ensure the assignment of qualified personnel

ISO 14971
Risk Management Plan

- Scope of risk management activities
- Assignment of responsibilities
- Requirements for review
- Criteria for risk acceptability
- Verification activities
- Methods for production and post-production review

ISO 14971
Risk Management File

- Risk Analysis
- Risk Evaluation
- Implementation and Verification of risk control measures
- Assessment of the acceptability of residual risks

ISO 14971
Risk Management Report

- Risk Management Plan has been implemented
- Residual Risk is Acceptable
- Methods are in place to obtain production and post-production information

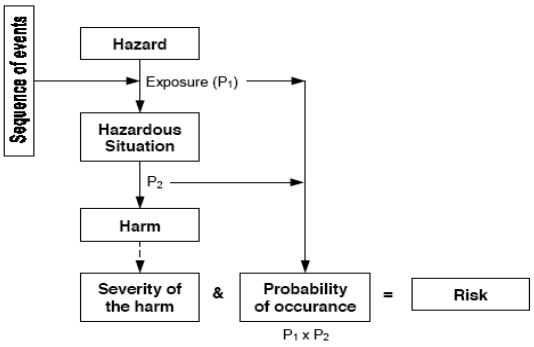
Definitions

- Hazard: *potential source of harm*
- Harm: *physical injury or damage to the health of people or damage to property or the environment*
- Risk: *combination of the probability of harm and the severity of that harm*

Definitions

- Severity: *risk associated with the effect for a given failure mode*
- Frequency/Likelihood: *possibility that the specific cause/mechanism of a failure will occur*
- Detectability: *relative rank associated with the control mechanism for the failure*

Hazard/Harm Relationship



Risk Analysis

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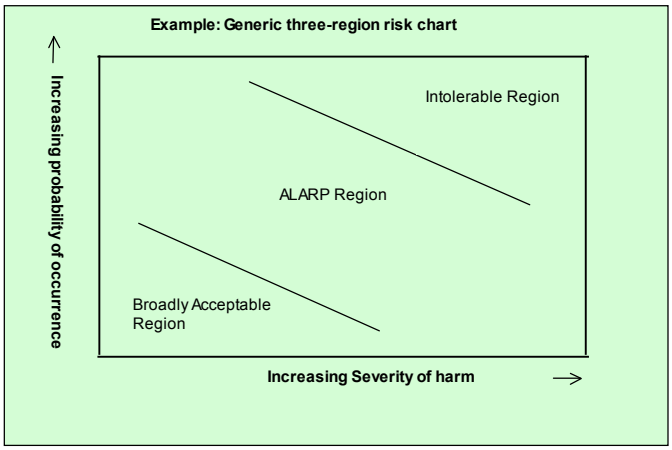
Risk Analysis Tables

- For any product risk analysis we need to determine:
  - Severity
  - Likelihood/Frequency
- Should be in a procedures and needs to be company specific
- A risk level chart for analysis is needed

Concept of Risk Level



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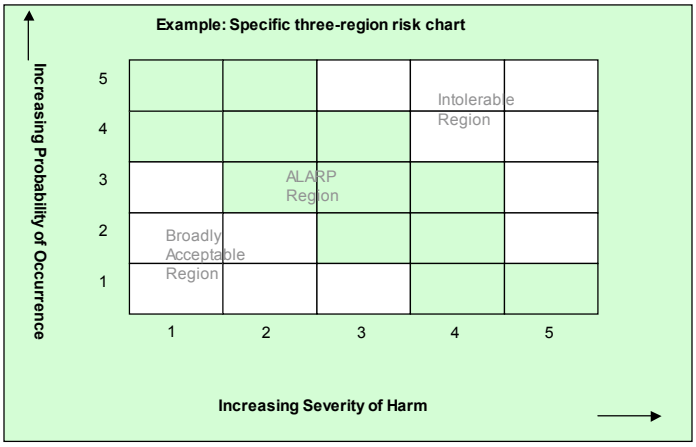
Concept of Risk Level Chart



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Severity Classification

Patient Risk	Definition
Negligible	Little or no potential of injury. Inconvenience to operator. No effect on safety or efficacy.
Marginal	The product is operable but degraded. Potential injury or non-serious injury may result. (Generally not MDR reportable)
Critical	Serious Injury, product is inoperable or ineffective. MDR Reportable
Catastrophic	Death or potential for one or more deaths. MDR Reportable

Likelihood Classification

Classification	Definition	Likelihood
Frequent	High probability of occurrence during use	Probability >50%
Probable	Moderate probability of occurrence during use	Probability 5% to 50%
Occasional	Occasional probability of occurrence during use	Probability 0.5% to 5%
Remote	Unlikely probability of occurrence during use	Probability 0.1% to 0.5%
Improbable	Probability of occurrence is so low that it is not expected to occur	Probability 0.01% to 0.1%
Incredible	Possibility of the event is not conceivable	Probability <0.01%

Risk Level Table

Severity				
Likelihood	*Negligible*	*Marginal*	*Critical*	*Catastrophic*
Incredible	Broadly Acceptable	Broadly Acceptable	Broadly Acceptable	ALARP
Improbable	Broadly Acceptable	Broadly Acceptable	ALARP	ALARP
Remote	ALARP	ALARP	ALARP	ALARP
Occasional	ALARP	ALARP	ALARP	Intolerable
Probable	ALARP	ALARP	Intolerable	Intolerable
Frequent	ALARP	Intolerable	Intolerable	Intolerable

Risk Analysis Techniques

- Other techniques can and should be used, they include:
  - FMEA
  - FTA
  - HACCP
  - Others

Failure Modes and Effects Analysis (FMEA)

- "Bottom-Up Analysis"
- Analyzing each component or subsystem
  - Potential low level failures
  - Impact on Local, Larger System
  - Estimation of Severity, Frequency, Detectability
  - Determination of Threshold:
    - Failure Modes needing Risk Reduction
    - Failure Modes not needing Risk Reduction

FMEA Example

- (Component) Pump motor parametric failure
- (Local) Higher current for step(s) required
- (System) Pump fails to deliver set volume/time
- Device Mitigation: Alarm created alerts attendant
- Medication regime: Immediately adjustment

- Lowest Level - Component Evaluated
- Component - Local - System - Risk - Mitigate?
- Failure Impact Impact Evaluation

FMEA Worksheet

Subsystem: CPU and data related items

Item ID.	Item Functions	Potential Failure Mode	Potential Causes of Failure(s)	Potential Local Effects	Potential System Level Effects	Asumtions/ Comments	Current Conditions					Recommended Actions / Safety Measures / Rationale for Retention	Effectiveness Of Risk Control / Safety Measures	Person Responsible For Activities Status/ Date Proof of Closure
							Current Controls	Severity	Frequency	Detection	Risk Index			
Microprocessors including memory														
CPU1														
CPU2														
Communications														

FMEA Worksheet Example

Subsystem: CPU and data related items

Item ID.	Item Functions	Potential Failure Mode	Potential Causes of Failure(s)	Potential Local Effects	Potential System Level Effects	Asumtions/ Comments	Current Conditions					Recommended Actions / Safety Measures / Rationale for Retention	Effectiveness Of Risk Control / Safety Measures	Person Responsible For Activities Status/ Date Proof of Closure
							Current Controls	Severity	Frequency	Detection	Risk Index			
Microprocessors including memory														
CPU1	User interface, database, comm with CPU2	No processing	Power Interupt, Clock Failure	CPU Fails	No display, no touchsreen, no data storage, no comm with CPU2. Corrupt database.		Communication timeout detection on CPU2	4	2	1		CPU2 detect CPU1 failure and safely shutdown system. Use transaction-oriented DB. RAM test at powerup. Checksum on ROM.	Test R015 to verify CPU2 detects forced CPU1 failure with VDD, VCC low, addresses to 0(32), and Clock to V0	J. Jones verified with R015 on 15June05
		Incorrect processing	Software Failure, Interrmtnt event	CPU Performnc Cmprmsd	Unpredictable Communicati on. Possible corrupt database.	*Hardware side failures are detectable; Software side an issue*	*CPU2 Alarms*	5	2	3		Monitor Output to Patient and Design Safe Shutdown	Test R022 to verify CPU1 3 random data lines at V0 to cause CPU2 to alarm and safe stop.	J. Jones verified with R022 on 19June05
CPU2	System Monitoring & Control	No processing	Power Interupt, Clock Failure	CPU Fails	Unpredictable Control		Communication timeout detection on CPU1	5	2	1		Determine Safe Shutdown Sequence, Intermtent Motor signal to con't running. RAM test at powerup. Checksum on ROM.	Test R016 to verify CPU1 detects forced CPU2 failure with VDD, VCC low, addresses to 0(32), and Clock to V0	J. Jones verified with R016 on 17June05

Risk Control/ HAACP

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HACCP

- Technique for determining control points
- Used in the food industry
- Has application in medical devices but is not an FDA requirement

Seven Principles of HACCP

1. Conduct hazard analysis and identify preventive measures.
2. Identify critical control points.
3. Establish critical limits.
4. Monitor each critical control point.
5. Establish corrective action to be taken when deviation occurs.
6. Establish record-keeping system.
7. Establish verification procedures.

HACCP Worksheet Steps

- Component and Process Steps
- ID Hazards
- Hazards Significant?
- Justify "significance"
- Preventive measures
- Establish as Critical Control Point?

HACCP Matrix/Worksheet

Hazard Analysis Worksheet

Firm Name: PMA/510(k) #: _____ Class: _____

Firm Address:

Product Description: Method of Storage and Distribution:
Intended Use and Consumer: Delipidated.
Prepared by: Date issued:
Approved by: _____ Date: _____ Design ref. #: _____ Revision #: _____ Date: _____
Effective date: _____ Revision #: _____

(1) Materials/Components/ Processing Step	(2) Identify potential hazards introduced, controlled or enhanced at this step	(3) Are any Potential safety Hazards Significant? (Yes/No)	(4) Justify your decision for column 3	(5) What preventative measure(s) can be applied to prevent the significant hazards?	(6) Is this step an essential Control Point? (Yes/No)

HACCP Matrix/Worksheet - Example

Hazard Analysis Worksheet

Firm Name: LSI - Greenslopes PMA/510(k) #: _____ Class: _____

Firm Address: Level 2, Administration Building, Greenslopes Private Hospital, Newdegate Street, Greenslopes, QLD 4120

Product Description: Delipidated Plasma via triple solvent PDP Method of Storage and Distribution: Storage in refrigerator, transportation by car in insulated container
Intended Use and Consumer: Delipidated plasma will be reinfused into donor healthy volunteer to verify safety of process.
Prepared by: B. Craner and J. Johansson Date issued: 13Dec01
Approved by: _____ Date: _____ Design ref. #: _____ Revision #: _____ Date: _____
Effective date: _____ Revision #: _____

(1) Materials/Components/ Processing Step	(2) Identify potential hazards introduced, controlled or enhanced at this step	(3) Are any Potential safety Hazards Significant? (Yes/No)	(4) Justify your decision for column 3	(5) What preventative measure(s) can be applied to prevent the significant hazards?	(6) Is this step an essential Control Point? (Yes/No)
Transportation Wesley to Greenslopes and back to Wesley	Dropping container	Yes	If plasma bag does ruptures, plasma may be contaminated. If no rupture, insulated and rugged Igloo container should maintain sufficient integration for remainder of trip	Prevent damage from fall can be mitigated by carrying at lowest level with pendulant handle. e.g. Igloo carrier has handle that allows carrier bottom to be at 2-2.5 feet off ground. Carrier can be trained to be wary of possible contributors to dropping container.	No, rare and mitigated No, rare and mitigated
	Transportation stalled	Yes	Plasma can warm with excessive time and failed blue ice	Have courier take mobile phone to contact alternate carrier if delay is expected to be significant.	No – rare, and mitigated

Risk Application to Manufacturing

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Process Evaluation Steps

- Product Risk Analysis
- Process Map
- Determine Process Validation Requirements
- Prepare a Process FMEA
- Validate Processes with FMEA as guideline
- Prepare Control Mechanisms (Quality Plan)
- Evaluate Risk Periodically

Process Flow

- First step in the risk management process
- Describes each manufacturing step in detail and provides the output of each step
- Can be done in many ways
  - Flow Chart
  - Word Description
  - Excel Spreadsheet

Process Validation

Verify or Validate

- **Validate if:**
  - **No verification**
  - **Verification doesn't provide high degree of assurance**
  - **Low yield**
  - **High variation**
  - **100 % test/inspection**
  - **High level of training**

Process Validation Requirements

Process Validation Requirements Table

	Sub-Process Name	Process Output	Test Methods	Is Process Output fully verified by subsequent inspection or test	If validation is required check off category			Process Evaluation	List Major Equipment	Validation Requirements					No validation required rationale, or validation plan, validation documents, comments
				Yes/No If yes list verification step	Special process/Method	Software	List reference number	PC Required?		Method Qualification	EIQ	EOQ	Process OQ	PQ	
1															
2															
3															
4															
5															
6															

Process FMEA

- Estimate the severity of failure (based on design FMEA)
- Estimate the frequency/likelihood of the failure.
- Estimate detectability of the failure

Process FMEA

					PROCESS FAILURE MODES AND EFFECTS ANALYSIS											
	Project #	Test														
	Description	FPMEA														
	Team	Number One														
	Severity = (1) lowest, (10) highest									Major = 125 and higher	Actions must be implemented that reduces the risk to preferably a minor level but in					
	Frequency = (1) Least (10) Most often									Moderate = 28-125	Action to address the potential shall be implemented and effective at reducing the					
	Detection = (10) Unlikely detected, (1) will be detected									Minor = 1 - 27	No further action is necessary					
REFERENCE PROCESS FLOW DIAGRAM STEP	PROCESS FUNCTION	POTENTIAL FAILURE MODE	POTENTIAL EFFECT(S) OF FAILURE	SEV	POTENTIAL CAUSE(S) OF FAILURE	OCC	CURRENT PROCESS CONTROLS	DET	RPN	RECOMMENDED ACTIONS	RESP. & TARGET COMPLETION DATE	ACTION TAKEN	SEV	OCC	DET	RPN
1	START															
2									0							0
3									0							0
4									0							0
5									0							0
6									0							0
7									0							0
8									0							0
9									0							0

Manufacturing Example

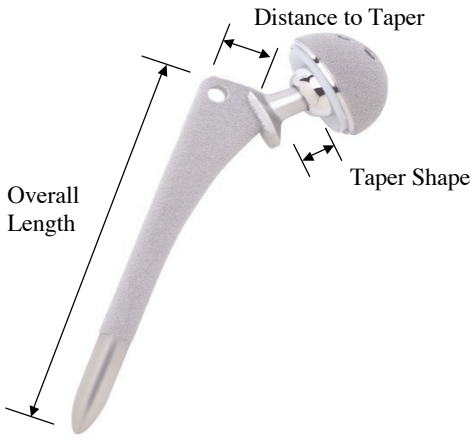
- Some examples of processes that require validation
  - Sterilization
  - Heat Treating
  - Package Sealing
  - Plating
  - Injection Molding

Manufacturing Example

- Guidances recommend the use of risk management as a technique for determining the cause of failure modes and establishing control mechanisms. Risk management can begin with FMEA or FTA techniques.

Hip Implant Design

Hip Implant Critical Dimensions



Hip Implant Critical Dimensions/Factors

- Overall Length
- Shape
- Taper Location
- Taper Dimensions
- Coating Thickness and Coverage
- Cleanliness
- Sterility

Severity Classification

Patient Risk	Definition
Negligible	Little or no potential of injury. Inconvenience to operator. No effect on safety or efficacy.
Marginal	The product is operable but degraded. Potential injury or non-serious injury may result. (Generally not MDR reportable)
Critical	Serious Injury, product is inoperable or ineffective. MDR Reportable
Catastrophic	Death or potential for one or more deaths. MDR Reportable

Likelihood Classification

Classification	Definition	Likelihood
Frequent	High probability of occurrence during use	Probability >50%
Probable	Moderate probability of occurrence during use	Probability 5% to 50%
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Remote	Unlikely probability of occurrence during use	Probability 0.1% to 0.5%
Improbable	Probability of occurrence is so low that it is not expected to occur	Probability 0.01% to 0.1%
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Risk Level Table

	Severity			
Likelihood	*Negligible*	*Marginal*	*Critical*	*Catastrophic*
Incredible	Broadly Acceptable	Broadly Acceptable	Broadly Acceptable	ALARP
Improbable	Broadly Acceptable	Broadly Acceptable	ALARP	ALARP
Remote	ALARP	ALARP	ALARP	ALARP
Occasional	ALARP	ALARP	ALARP	Intolerable
Probable	ALARP	ALARP	Intolerable	Intolerable
Frequent	ALARP	Intolerable	Intolerable	Intolerable

Hip Implant Risk Analysis

Risk Analysis				**Hip Implant**			
Name	**Sev.**	**Freq.**	**Risk**	**Control**	**Sev.**	**Freq.**	**Risk**
Implant breakage	Critical	Improbable	Alarp	Design Verification	Critical	Improbable	Alarp
Improper fit to bone	Critical	Occasional	Alarp	Surgical Training	Critical	Remote	Alarp
Improper fit of taper	Critical	Improbable	Alarp	Inspection	Critical	Improbable	Alarp
Coating delamination	Marginal	Improbable	Alarp	Process Validation	Marginal	Improbable	Alarp
Foreign material on implant	Critical	Remote	Alarp	Process Validation	Critical	Improbable	Alarp
Instruments not correct for implant	Critical	Improbable	Alarp	Design Verification	Critical	Improbable	Alarp
Implant not sterile	Critical	Improbable	Alarp	Process Validation	Critical	Improbable	Alarp

Hip Implant Process Flow

- Forge
- Inspect
- Machine
- Inspect
- Coating
- Inspect
- Package
- Sterilize

Process Validation Requirements

PVRT								
No.	Sub-Process Discription	Is Process Output fully verified by subsequent inspection or test? yes/no	If Process is fully verified, list step in which verification is carried out?	List Major Equipment (...is any equipment that is not a fixture or a calibrated intrument)	Validation Requirements IOQ	PQ	MQ	Comments (No validation required rationale, or validation plan, validation documents)
1	Receive Raw Material (Titanium)	---	---	---	---	---	---	---
2	Inspect/Verify Certification	---	---	---	---	---	---	---
3	Forge	yes	Step 4	Forge	YES	---	YES	---
4	Inspect	---	---	---	---	---	---	---
5	Machine	yes	step 7	Mill	YES	---	---	---
6	Clean	no	---	Cleaner	YES	YES	YES	---
7	Inspect	---	---	---	---	---	---	---
8	Porous Coat	no	---	Coater	YES	YES	YES	---
9	Inspect	---	---	---	---	---	---	---
10	Package	no	---	Package Seal	YES	YES	YES	---
11	Sterilize	no	---	Sterilizer	YES	YES	YES	---
12	Stock	---	---	---	---	---	---	---

Severity Classification for FMEA

Severity Classification		
Patient Risk Category	Definition	Rank
Negligible	No real effect on performance and does not cause customer annoyance	1
Negligible	No real effect on performance but causes slight customer annoyance	2
Negligible	Customer intervention with no performance degradation	3
Negligible	Customer annoyance with no performance degradation	4
Negligible	Performance degradation with no procedure delay	5
Negligible	Complaints that are not malfunction, injury, serious injury, or death. The nature of the complaints can result in procedure delay.	6
Marginal	Product is operable but operability is degraded. Customer dissatisfied.	7
Marginal	Product is inoperable. Product effectiveness degraded. Non-serious injury or potential for injury. Customer dissatisfied.	8
Critical	Serious injury (MDR reportable)	9
Catastrophic	Death or potential for one or more deaths. (MDR reportable)	10

Likelihood Classification for FMEA

Likelihood Classifications				
Classification	Definition	Likelihood	CpK (PFMEA)	Rank
Frequent	High probability of occurrence during the use of the medical device.	Probability > 50%	<0.33	10
Probable	Moderate probability of occurrence during the use of the medical device.	Probability 25% to 50%	0.33 to 0.50	9
		Probability 5% to 25%	0.51 to 0.66	8
Occasional	Occasional probability of occurrence during the use of the medical device.	Probability 1% to 5%	0.67 to 0.82	7
		Probability 0.5% to 1%	0.83 to 0.99	6
Remote	Unlikely probability of occurrence during the use of the medical device.	Probability 0.25% to 0.5%	1.00 to 1.16	5
		Probability 0.1% to 0.25%	1.17 to 1.32	4
Improbable	Probability of occurrence is so remote that event is not expected to occur during the use of the medical device.	Probability 0.05% to 0.1%	1.32 to 1.49	3
		Probability 0.01% to 0.05%	1.49 to 1.67	2
Incredible	Probability of occurrence is so small that possibility of the event is not conceivable.	Probability <0.01%	>1.67	1

Detection Classification for FMEA

Detection Classifications			
Classification	Definition	Probability	Rank
Very Unlikely	Very remote or no chance the design control or process control will detect a potential cause and subsequent failure mode.	No known controls (0%)	10
		< 1%	9
Remote	Low chance the design control or process control will detect a potential cause and subsequent failure mode	1% to 5%	8
		5% to 49%	7
Occasional	Moderate chance the design control or process control will detect a potential cause and subsequent failure mode	50% to 75%	6
		75% to 90%	5
Likely	High chance the design or process control will detect a potential cause and the subsequent failure mode	90% to 95%	4
		95% to 99%	3
Very Likely	Design or process control will almost certainly detect a potential cause and subsequent failure mode	>99%	2
		100%	1

Risk Level for FMEA

Risk Levels for FMEA			
	RPN		
Severity	1 to 71	72 to 391	392 to 1000
1 to 6	BA	BA	ALARP
7 & 8	BA	ALARP	INT
9 & 10	ALARP	INT	INT

Hip Implant PFMEA Severity

	HIP IMPLANT			
REFERENCE PROCESS FLOW DIAGRAM STEP	PROCESS FUNCTION	POTENTIAL FAILURE MODE	POTENTIAL EFFECT(S) OF FAILURE	SEV
1	Receive Raw Material (Titanium)	N/A		
2	Inspect/Verify Certification	Incorrrect Material	Biocompatibility Issue	9
3	Forge	Voids	Implant Breakage	9
4	Inspect	N/A		
5	Machine	Incorrect Dimensions	Poor fit	8
6	Clean	Implant not Clean	Infection	9
7	Inspect	N/A		
8	Porous Coat	Delamination	Foreign Material Rejection	8
9	Inspect	N/A		
10	Package	No Seal	Infection	9
11	Sterilize	Inadequate Sterilization	Infection	9
12	Stock			

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Hip Implant PFMEA Occurence

	HIP IMPLANT			
REFERENCE PROCESS FLOW DIAGRAM STEP	PROCESS FUNCTION	POTENTIAL FAILURE MODE	POTENTIAL CAUSE(S) OF FAILURE	OCC
1	Receive Raw Material (Titanium)	N/A		
2	Inspect/Verify Certification	Incorrrect Material	Manufacturer testing	2
3	Forge	Voids	Process problem	3
4	Inspect	N/A		
5	Machine	Incorrect Dimensions	Machine Defects	3
6	Clean	Implant not Clean	Cleaning process	3
7	Inspect	N/A		
8	Porous Coat	Delamination	Coating process	5
9	Inspect	N/A		
10	Package	No Seal	Sealing process	5
11	Sterilize	Inadequate Sterilization	Sterilization cycle	3
12	Stock			

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Hip Implant PFMEA Detectability

		PROCESS FAILURE MODES AND EFFECTS ANALYSIS		
	HIP IMPLANT			
REFERENCE PROCESS FLOW DIAGRAM STEP	PROCESS FUNCTION	POTENTIAL FAILURE MODE	CURRENT PROCESS CONTROLS	DET
1	Receive Raw Material (Titanium)	N/A		
2	Inspect/Verify Certification	Incorrrect Material	Periodic testing	6
3	Forge	Voids	X-ray inspection	7
4	Inspect	N/A		
5	Machine	Incorrect Dimensions	Process Monitoring	6
6	Clean	Implant not Clean	Process Monitoring	8
7	Inspect	N/A		
8	Porous Coat	Delamination	Process Monitoring	8
9	Inspect	N/A		
10	Package	No Seal	Process Monitoring	8
11	Sterilize	Inadequate Sterilization	Process Validation	8
12	Stock			

Hip Implant PFMEA Mitigation

	HIP IMPLANT				
REFERENCE PROCESS FLOW DIAGRAM STEP	PROCESS FUNCTION	POTENTIAL FAILURE MODE	RECOMMENDED ACTIONS	RESP. & TARGET COMPLETION DATE	ACTION TAKEN
1	Receive Raw Material (Titanium)	N/A			
2	Inspect/Verify Certification	Incorrrect Material	Supplier audits	QA	audit
3	Forge	Voids	Process Validation	MFG	PV
4	Inspect	N/A			
5	Machine	Incorrect Dimensions	SPC monitoring and 100% inspection	MFG	Monitoring
6	Clean	Implant not Clean	Process Validation and monitoring	MFG	Monitoring
7	Inspect	N/A			
8	Porous Coat	Delamination	Supplier audits	QA	audit
9	Inspect	N/A			
10	Package	No Seal	Process Validation and monitoring	MFG	Monitoring
11	Sterilize	Inadequate Sterilization	Process Validation and monitoring	QA	Monitoring
12	Stock				

Processes Requiring Performance Qualification

- Cleaning RPN=216
- Porous Coating RPN=320
- Packaging RPN=360
- Sterilization RPN=216

Note that all were ALARP on the risk analysis

Determining Validation Sample Size

- BA 90% Confidence, 90% Reliability
- ALARP 95% Confidence, 95% Reliability
- ALARP with high severity
  - 99% Confidence, 99% Reliability

Risk Control

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Determining Control Techniques

- CpK > 1.8 Monitor Infrequently
- CpK 1.33 to 1.8 Monitor Regularly
- CpK 1.0 to 1.33 Monitor each production batch
- CpK <1.0 Sample monitor each part

Hip Implant QC Plan

REFERENCE PROCESS FLOW DIAGRAM STEP	Control Point	Possible Causes	Monitoring		
			What	How	Frequency
Forge	Process monitoring and control	Material, Mold, temperature	SPC	Control Charts	Hourly
Inspect	N/A				
Machine	Inspection process	Wear, programming, material	SPC	Control Charts	Lot
Clean	Cleaning solution monitoring	Process failures	Sampling	Analysis	Daily/Lot
Inspect	N/A				
Porous Coat	Inspection process	Lack of process control	SPC	Destructive Samples	Lot
Inspect	N/A				
Package	Periodic samples	Material variability	SPC	Control Charts	Daily/Lot
Sterilize	Process Monitoring and Control	Vendor failure	Process Review	Chart Review	Batch
Stock	N/A				

ASQ
Risk Management Applications In Quality

Risk Application in CAPA

Adding Value…
Period

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www.medqsystems.com

CAPA Evaluation

- Review Risk Analysis
- Evaluate based on Risk
  - Coating Defect - RPN 320
  - Non-Sterile product - RPN 216
  - Each require investigation
- Trending
  - Number of "problems" of each type

Time for ...
Q and A

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Thank You!

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