Combining HACCP and FMEA

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FMEA as state of the art

Where it came from

FMEA was formally introduced in the late 1940s for military usage by the US Armed Forces. Later it was used for aerospace/rocket development to avoid errors in small sample sizes of costly rocket technology. An example of this is the Apollo Space program. It was also used as application for HACCP for the Apollo Space Program, and later the food industry in general. The primary push came during the 1960s, while developing the means to put a man on the moon and return him safely to earth. In the late 1970s the Ford Motor Company introduced FMEA to the automotive industry for safety and regulatory consideration after the Pinto affair. They applied the same approach to processes (PFMEA) to consider potential process induced failures prior to launching production

(www.wikipedia.org)

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FMEA as state of the art

General principles

FMEA is a sequential and disciplined approach

- Working bottom-up; i.e. starting in the detail design/process and ending up at the user/patient
- establishing preventive measures to avoid failures reasonably likely to occur

FMEA consists out of the following steps

- Identify smallest design elements / process steps and their funtion
- Brain storm causes of failures
- Define potential failure modes
- Determine effects and their severities
- Determine the likelihood of occurrence (and detection)
- Identify controls and evaluate residual risks

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FMEA as state of the art

An example

Process Steps	Potential Causes of failure	Potential Failure Modes (Hazardous situations)	Potential Harms	Severity of Effect	Probability of occurrence	Risk Control measures	Risk Evaluation
Incoming Inspection Sterile packaging	sterile bags damaged (pinholes or sealing) at supplier sealing of sterile bag not welded properly (temperature, pressure, time during sealing)	Product is not sterile due to defective sterile packaging	**Infection**	4	2	Supplier qualification program and Incoming inspection of sterile bags Process Validation of sterile bag welding (temperature, pressure, time during sealing) Calibration and maintenance of welding equipment	ALARP
Final Packaging Shipping	sterile bag damaged during final packaging or shipping				2	Operator training (sterile welding, final packaging, shipping) 100% final visual control Transportvalidation as per ISO 11607-1	ALARP
Storage Handling	Storage of products outside specified storage conditions (temp, shelf life) sterile bag damaged during handling				1	Labeling of products containing warnings about proper storage and handling	ALARP

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HACCP as another tool

Where it came from

In the 1960's, Pillsbury created Space Food Sticks to capitalize on the popularity of the space program. Space Food Sticks were developed by Robert Muller, the inventor of the HACCP standards used by the food industry to insure food safety. Since then, HACCP has been recognized internationally as a logical tool for adapting traditional inspection methods to a modern, science-based, food safety system. Based on risk-assessment, HACCP plans allow both industry and government to allocate their resources efficiently in establishing and auditing safe food production practices. In 1994, the organization of International HACCP Alliance was established initially for the US meat and poultry industries to assist them with implementing HACCP and now its membership has been spread over other professional/industrial areas (www.wikipedia.org)

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HACCP as another tool

General principles

- HACCP focuses on three key areas:
  - identifying critical safety hazards in advance
  - establishing preventive measures to control hazards reasonably likely to occur
  - monitoring each critical control point for the hazards identified
- HACCP consists of the following steps:
  1. Conducting hazard analyses
  2. Determining the critical control points
  3. Establishing the critical limits for each control point
  4. Establishing procedures to monitor each critical control point
  5. Establishing corrective actions
  6. Establishing recordkeeping and documentation procedures
  7. Establish procedures for ensuring the HACCP system is working as intended

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HACCP as another tool

An example

Medical Hazard Analysis Worksheet

www.medicalhaccp.org

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

Firm Name: _____

Firm Address: _____

_____

_____

_____

Prepared by: _____ Date issued: _____

Approved by: _____ Date: _____

Effective date: _____ Revision #: _____

Product Description: _____

_____

Method of Storage and Distribution: _____

_____

Intended Use and Consumer: _____

_____

Design ref. #: _____ Revision #: _____ Date: _____

(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 a critical control point? (Yes/No)

HACCP as another tool

An example

Medical HACCP Plan Form

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

www.medicalhaccp.org

Firm Name: _____

Firm Address: _____

Product Description: _____

Method of Storage and Distribution: _____

Intended Use and Consumer: _____

Prepared by: _____ Date issued: _____ Design ref. #: _____ Revision #: _____ Date: _____

Approved by: _____ Date: _____ Effective date: _____ Revision #: _____

(1) Critical Control Point (CCP)	(2) Significant Hazards	(3) Critical Limits for each Preventive Measure	(4)	(5)	(6)	(7)	(8) Corrective Actions(s)	(9) Verification	(10) Records
			Monitoring						
			What	How	Frequency	Who			

Combining HACCP and FMEA

Is HACCP useful for medical devices?

- HACCP is more a Quality management tool (or system) than a risk analysis
- It was invented for Seafood, where no quality systems as such were present
- Just applying HACCP in medical devices in addition to ISO13485, 21CFR820 or ISO 14971 would add duplications.

1	Conducting hazard analyses	requested within ISO 14971
2	Determining the critical control points	requested by 21CFR820 and ISO 13485 (e.g. Design Controls, Process Validation)
3	Establishing the critical limits for each control point	requested by 21CFR820 and ISO 13485 (e.g. Design Controls, Process Validation)
4	Establishing procedures to monitor each critical control point	requested by 21CFR820 and ISO 13485 (e.g. Process Validation)
5	Establishing corrective actions	requested by 21CFR820 and ISO 13485
6	Establishing recordkeeping and documentation procedures	requested by 21CFR820 and ISO 13485
7	Establish procedures for ensuring the HACCP system is working as intended	requested by 21CFR820 and ISO 13485 and ISO 14971

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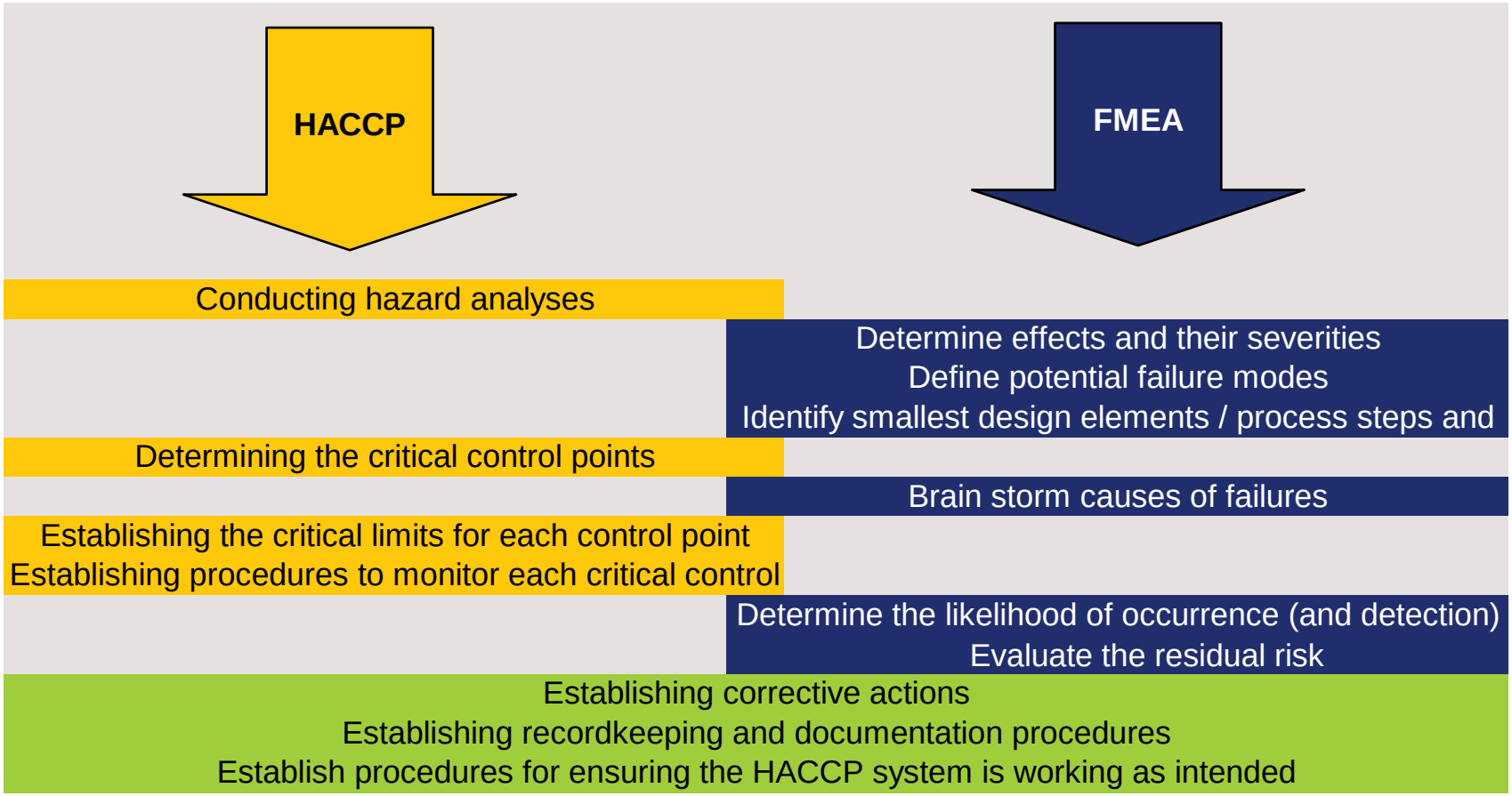

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Potential Harms	Severity of Effect	Potential Failure Modes (Hazardous situations)	process steps										Potential Causes of failure	Risk Control measures	Probability of occurrence	Risk Evaluation
			incoming inspection	Assembly	Cleaning	Sterile Packaging	Final packaging	Shipping	Sterilization	Shipping	Storage	Handling				
Infection	4	Product is not sterile due to defective sterile packaging	x	-	-	x	-	-	-	-	-	-	sterile bags damaged (pinholes or sealing) at supplier sealing of sterile bag not welded properly (temperature, pressure, time during sealing)	#1 Supplier qualification program and Incoming inspection of sterile bags #2 Process Validation of sterile bag welding (temperature, pressure, time during sealing) #3 Calibration and maintenance of welding equipment	2	ALARP
			-	-	-	-	x	x	-	-	-	-	sterile bag damaged during final packaging or shipping	#4 Operator training (sterile welding, final packaging, shipping) #5 100% final visual control #6 Transportvalidation as per ISO 11607-1	2	ALARP
			-	-	-	-	-	-	-	-	x	x	Storage of products outside specified storage conditions (temp, shelf life) sterile bag damaged during handling	#7 Labeling of products containing warnings about proper storage and handling	1	ALARP

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Risk Control Measure		Work Instruction	Critical parameter / limits	Qualification / Validation	Monitoring / Sampling
#1.1	Supplier qualification program	WIN xx-x-01	Class A supplier	Supplier qualification	Monitoring
#1.2	Incoming Inspection of bags	WIN xx-x-02	Pinholes; sealing strength	Material qualification	Sampling
#2	Process Validation of sterile bag welding	WIN xx-x-03	temperature pressure time during sealing	Validation	Monitoring
#3.1	Calibration of welding equipment	WIN xx-x-04	temperature pressure time during sealing	no	calibration
#3.2	Maintenance of welding equipment	WIN xx-x-05	Sealing bar	no	maintenance
#4	Operator training (sterile welding, final packaging, shipping)	WIN xx-x-06	defect awareness	no	re-training schedule
#5	100% visual control	WIN xx-x-07	Pinholes, wrinkling	Qualification	scrap trending
#6	Transportvalidation as per ISO 11607-1	Design Control	see ISO 11607-1	Validation	sampling
#7	Labeling of products	Design Control	containing warning about proper storage and handling	Validation	Sampling

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So what is new?

Combining HACCP with FMEA would not really add something, but it will change the way doing things

- Hazard Analysis is moved into the center stage and will become the start of each Risk Analysis. All our discussions and doing will be done to ensure safety for patients and users.
- Safety critical points that must be kept under control will become better visible and the need to monitor the limits is inherent to the technique. Traceability is provided
- Safety critical topics can therefore be prioritized versus things not having potential for harm.

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Outputs

Knowledge for/from CAPA

Tests and contents of IQ

Tests and contents of OQ und PQ

Potential Harms	Severity of Effect	Potential Failure Modes (Hazardous situations)	process steps: incoming inspection	Assembly	Cleaning	Sterile Packaging	Final packaging	Shipping	Sterilization	Shipping	Storage	Handling	Potential Causes of failure	Risk Control measures	Probability of occurrence	Risk Evaluation
Infection	4	Product is not sterile due to defective sterile packaging	x	-	-	x	-	-	-	-	-	-	sterile bags damaged (pinholes or sealing) at supplier sealing of sterile bag not welded properly (temperature, pressure, time during sealing)	Supplier qualification program and Incoming inspection of sterile bags Process Validation of sterile bag welding (temperature, pressure, time during sealing) Calibration and maintenance of welding equipment	2	ALARP
			-	-	-	-	x	x	-	-			sterile bag damaged during final packaging or shipping	Operator training (sterile welding, final packaging, shipping) 100% final visual control Transportvalidation as per ISO 11607-1		
			-	-	-	-	-	-	-	-	x	x	products outside storage conditions (temp, shelf life) sterile bag damaged during handling	Labeling of products containing warnings about proper storage and handling	1	ALARP

Sampling plans

Acceptance criteria

Critical Control Points

Need for monitoring of limits

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