Challenges for Applying FMEA Tools into the Medical Device Development

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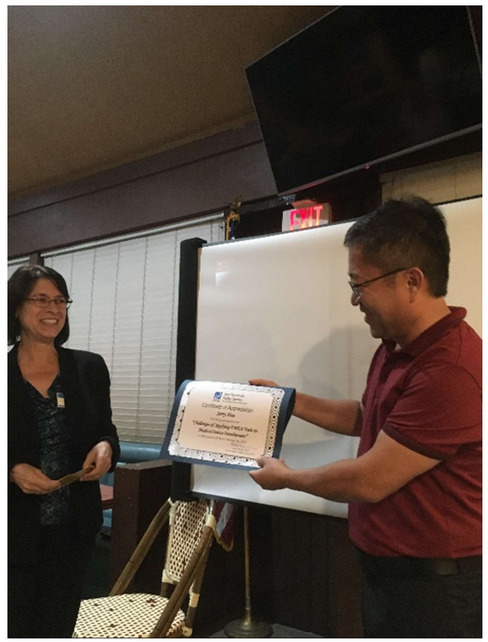


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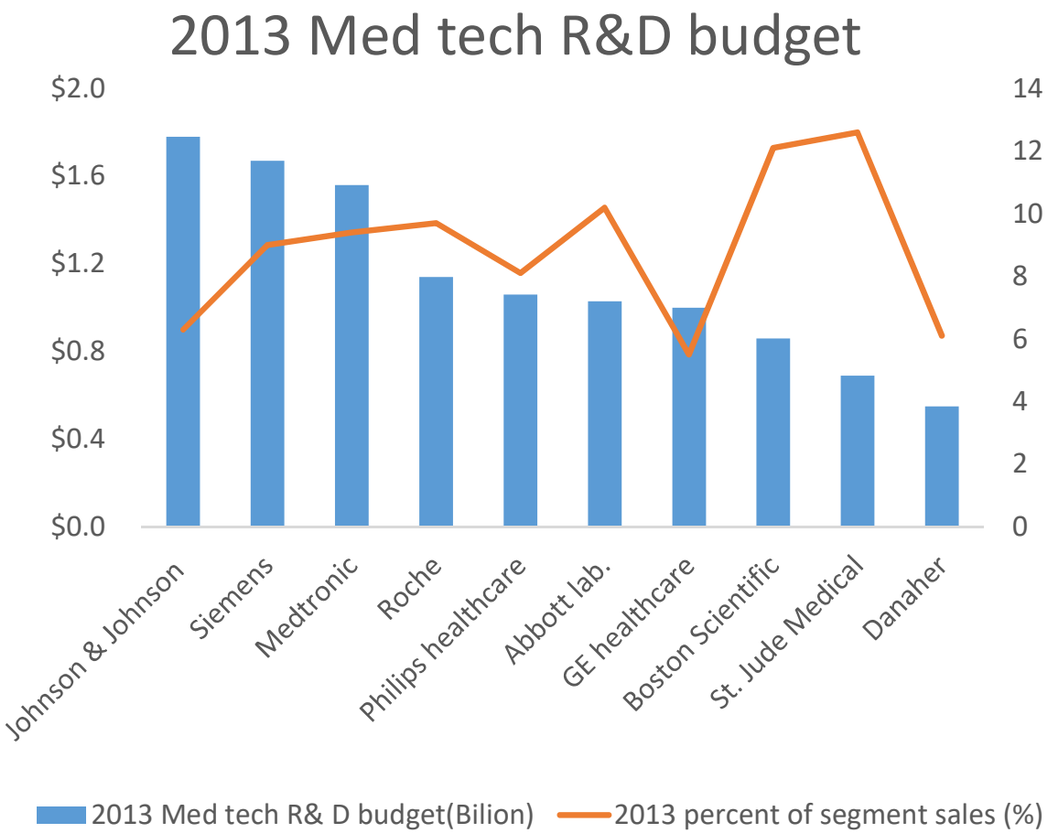
Jerry Xiao
For his presentation on:
"Challenges of Applying FMEA Tools to
Medical Device Development"
to ASQ Section 0706 on October 16, 2018
Jamie Marks, Chair
San Fernando Valley Section 0706

Agenda

- ❑ Overview of Medical device development
- ❑ FMEAs Introduction
- ❑ Adapt FMEA tools into medical device development
- ❑ FMEA Software (RdPDM V3.0)
- ❑ References & QAs

Market Research – Medical Device Development

- 350 billion market size for global medical devices (133 billion for U.S.)
- More than 6,500 medical device companies in the U.S.
- Top medical device companies invest on R&D around 6%-12%
- $12 billion on their new product development (U.S.)
- $47.2 billion in Q3 2015 higher than the past 17 years totals (VC)



References:

* Selectusa.commerce.gov
* Market research from MBA project at University of San Diego, 2014
* MoneyTree

Market Research – High Failure Rates in Medical Device Development

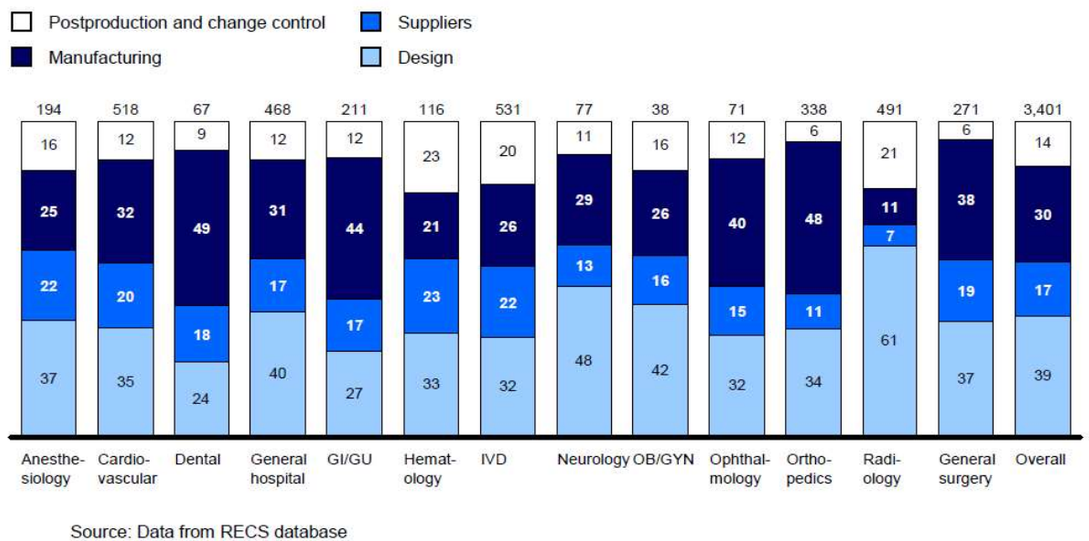
- Over 90% of medical electrical devices have failed on the first submission over the last two years (Intertek, 2010)

  "why 90% of medical devices fail product certification testing in the first time certification testing the first time" Intertek ETL SEMKO

- Design failure ranked as No.1 root cause at 31% on 10980 model recalls between 2003 and 2009

  "Understanding barriers to medical device quality, FDA.gov,

  U.S. Department of Health & Human Devices"



Source: Data from RECS database

FMEA Methodology History

- In 1949, initially formalized by the U.S. military in MIL-P-1629
- In 1960s, contractors for NASA using FMECA, FMEA
- In 1967, civil aviation industry with the SAE adopted FMEA in ARP926
- In 1973, U.S. Environmental Protection Agency applied FMEA
- In 1993, AIAG first published an FMEA standard
- Now, extensively used in a variety of industries including semiconductor processing, food service, plastics, software, and healthcare.

Wiki: Failure mode and effects analysis

FMEA Standards and Guidelines

- SAE J1739: Society of Automotive Engineers, Design FMEA/Process FMEA, 2009
- AIAG: Automotive Industry Action Group, FMEA Reference Manual, 4th 2008.
- MIL-STD 1629A: Military Standard, cited cancellation in 1994.
- IEC 60812: International Electrotechnical Commission, Analysis techniques for system reliability – procedure for FMEA, 2006

Reference: Carl S, Effective FMEAs

FMEA Successes

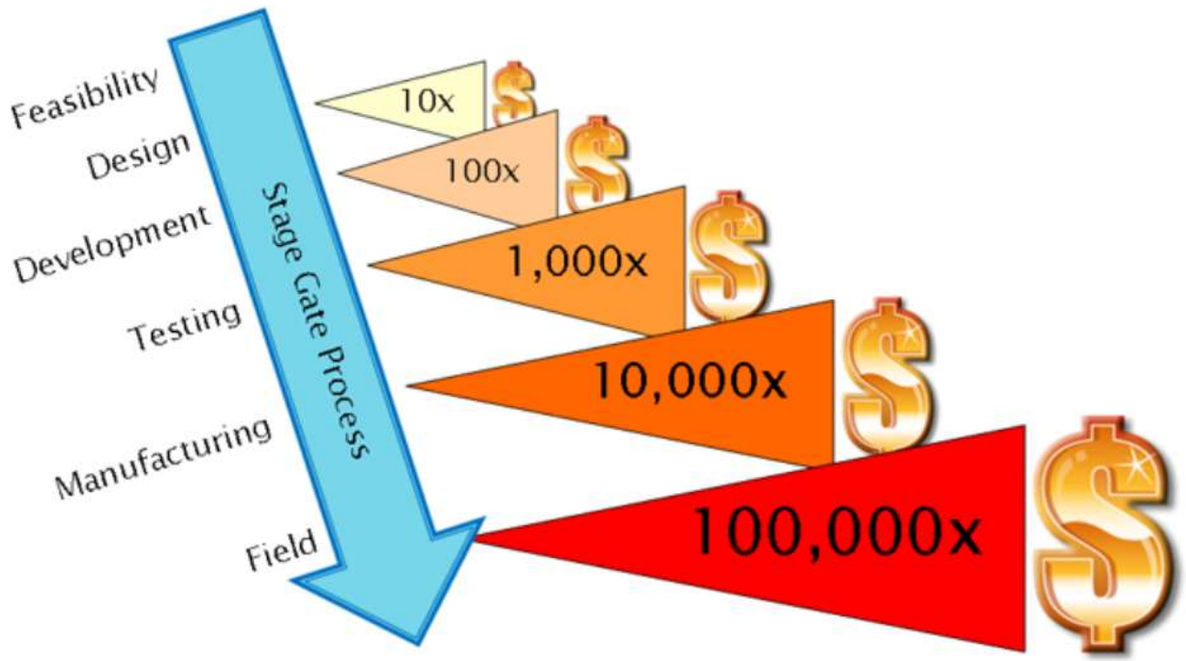
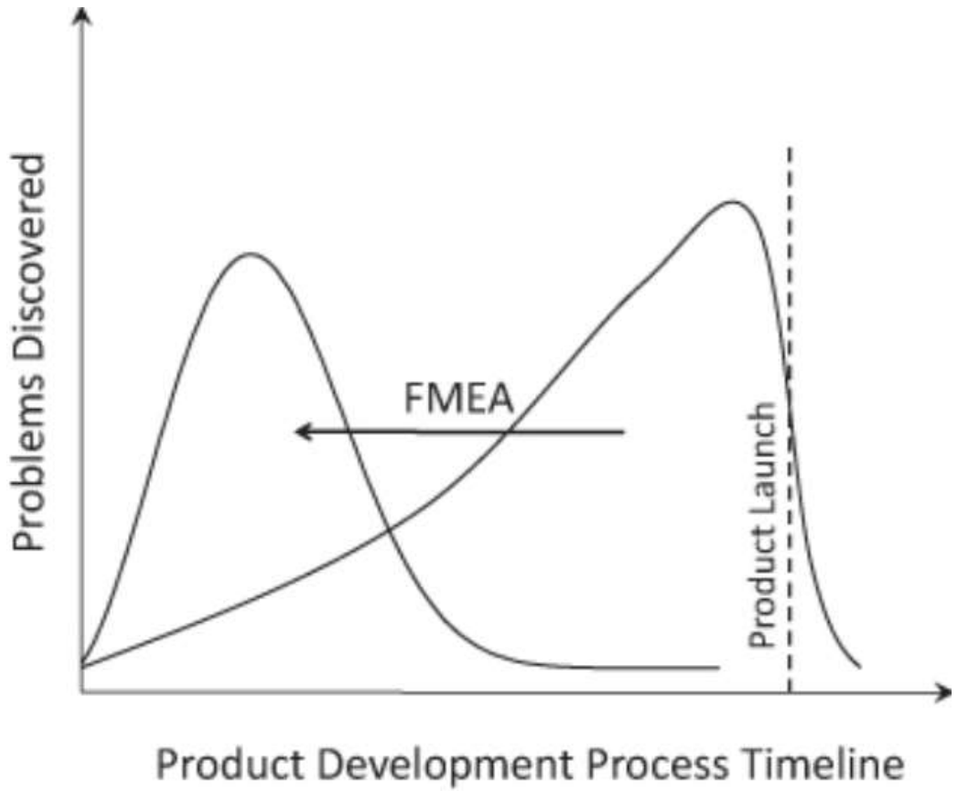


Figure 1: Factor of 10 rules

Reference: Reliasoft, DFR Fundamentals



Reference: Carl S. Carlson, Effective FMEAs

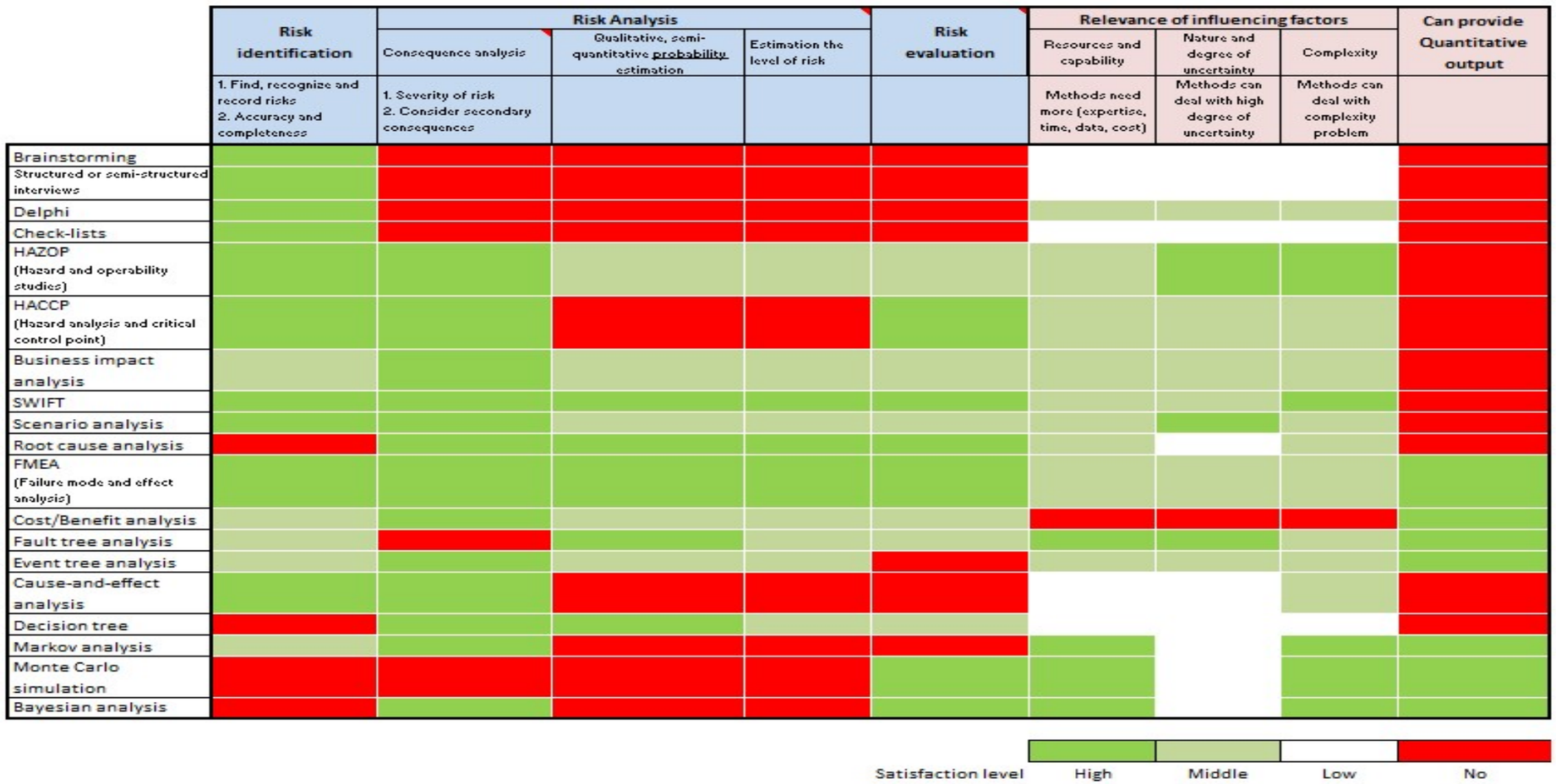
FMEA Procedures

- FMEA is a step-by-step approach for identifying all possible failures in a design, a manufacturing or assembly process, or a product or service.
- Failures: are any errors or defects.
- Failure mode: means the ways, or modes, in which something might fail.
- Effects analysis: refers to studying the consequences of those failures.
- RPN: risk priority number S x O x D.
- 13 steps

Process step/ input	Potential failure mode	Potential failure effects	SEV	Potential causes	OCC	Current controls	DET	RPN	Actions recom-mended	Resp.	Actions taken	SEV	OCC	DET	RPN

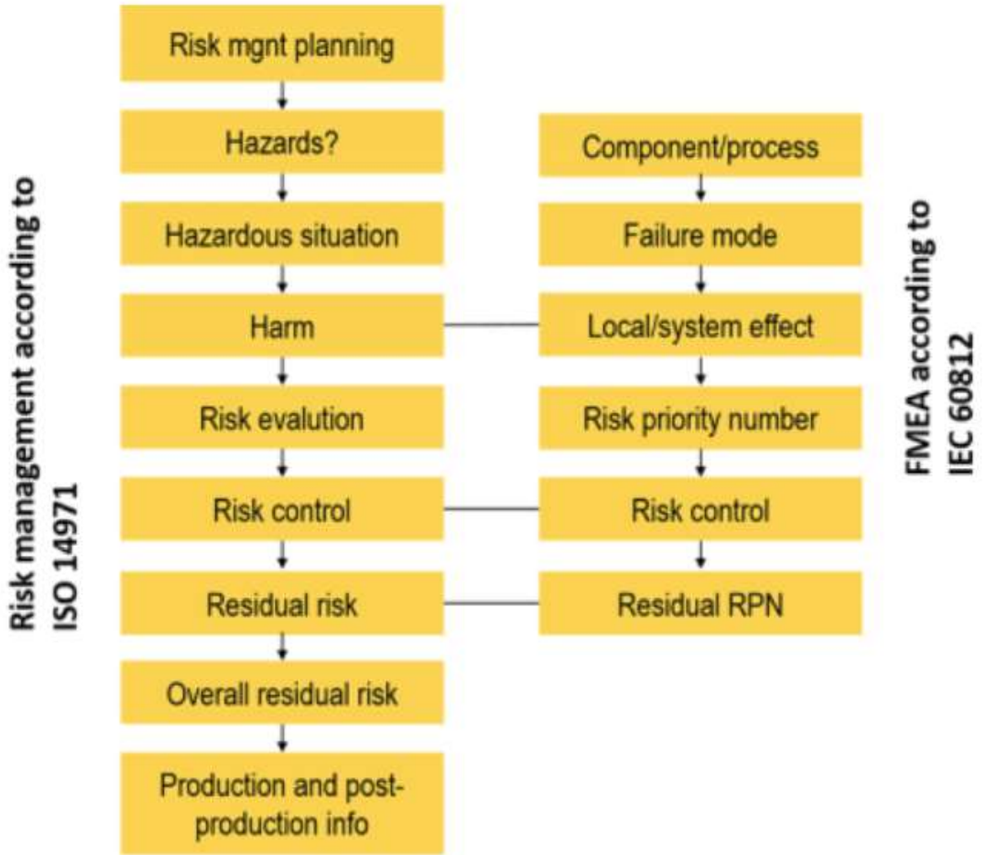
ASQ: Failure mode effects analysis (FMEA)

FMEA Performance



Reference: Jinxing Xiao

Challenges from ISO 14971



A generic process for risk management according to ISO 14971 compared with the steps in Failure Mode Effects Analysis.

- Add “Hazard”, “Hazardous situation”, “harm”, “risk benefit analysis”
- Replace the “RPN” by “Risk Region”.
- Replace the probability of effect P by conditional probability P1 and P2.
- Use FDA hazard codes (option)

Courtesy: Gantus

Challenges from Cross Functional Teams

Cross functional team involved:

- Medical science expert (clinical) provides consequence of hazard → hazardous situations → harm, and risk benefit analysis.
- Post market provides probability of harms (P) based on field data.
- Quality engineer (or risk management engineer) provides consequence of failure mode → hazard.
- Engineers take ownership. Process engineer (Process FMEA), Software engineer (Software FMEA), system engineer (system FMEA), packaging engineer (package FMEA), human factor engineer (user/application FMEA), and supplier quality engineer (supplier FMEA).

ISO 14971: Medical devices – Application of risk management to medical devices

Challenges from Post-Market Surveillance

FMEAs shall be updated in real time from:

- MAUDE: FDA Manufacturer and User Facility Device Experience. Each year, the FDA receives several hundred thousand medical reports (MDRs) of suspected device-associated deaths, serious injuries and malfunctions. The MAUDE database MDRs comprise one of the FDA's several important postmarket surveillance data sources.
- Medical Device Recalls: FDA database issues from a firm or FDA.
- Customer complaints: Company builds own website to collect complaints.
- NCMR: Nonconforming materials from company production lines.
- CAPA: Corrective Action and Preventative Action from auditors

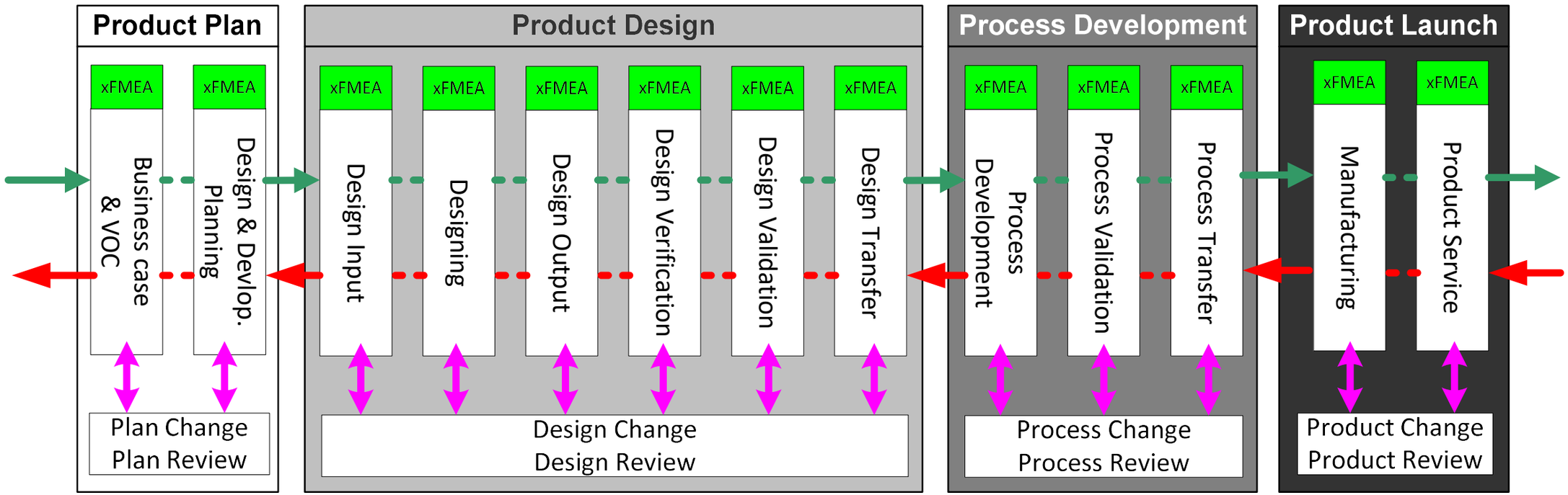
ISO 14971: Medical devices – Application of risk management to medical devices

Risk driven Quality Consulting Company (RdQCC)

- Founded in 2013 at San Diego, California
- Launched RdPDM V1.0 in 2015
- Launched RdPDM V2.0 in 2016
- Launched RdPDM V3.0 in 2018
- Company website: www.rdqcc.us

RdPDM V3.0 Animation

Embedded FMEA into New Product Development and Post market Surveillance

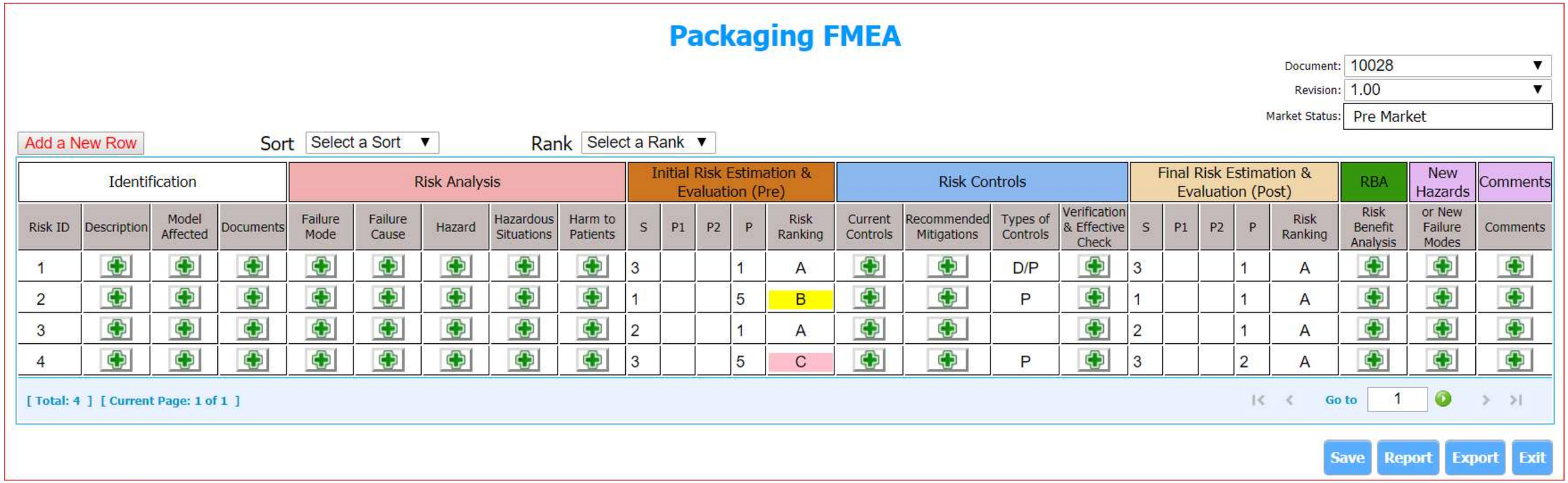


FMEA Automation

- One FMEA Worksheet for All (etc. Design, Process, Application, Software, System)

Align to EN ISO 14971: 2012 version; sort/filter tables; statistical analysis; user error prevention, export to excel file, and create PFMEA report.

- One FMEA Worksheet uses for both Pre-market and post market



Packaging FMEA

Document: 10028 ▼
Revision: 1.00 ▼
Market Status: Pre Market

Add a New Row Sort: Select a Sort ▼ Rank: Select a Rank ▼

Identification				Risk Analysis					Initial Risk Estimation & Evaluation (Pre)					Risk Controls				Final Risk Estimation & Evaluation (Post)					RBA	New Hazards	Comments
Risk ID	Description	Model Affected	Documents	Failure Mode	Failure Cause	Hazard	Hazardous Situations	Harm to Patients	S	P1	P2	P	Risk Ranking	Current Controls	Recommended Mitigations	Types of Controls	Verification & Effective Check	S	P1	P2	P	Risk Ranking	Risk Benefit Analysis	or New Failure Modes	Comments
1									3			1	A			D/P		3			1	A			
2									1			5	B			P		1			1	A			
3									2			1	A					2			1	A			
4									3			5	C			P		3			2	A			

[Total: 4] [Current Page: 1 of 1] Go to 1

Save Report Export Exit

Risk Management Animation Demo

References and Q&A

- Carl S. Carlson. Effective FMEAs Achieving safe, reliable, and economical products and process using failure mode and effects analysis. Wiley, a John Wiley & Sons Inc.
- DFR Fundamentals: An Introduction to Design for Reliability. 2007. ReliaSoft Corporation.
- Jinxing Xiao. Research Proposal, Identifying and Evaluating Potential Product Hazards By Correctly Analyzing Product Requirements