

icu medical

human connections

DAE Risk Management Webpage (www.risk-seek.com)

Presenter: Jerry Xiao

18-April-2021



Goals:

Develop a platform based on RdPDM™ Machine Learning Technology to increase efficiency and accuracy for DAE team in the fields of:

- Risk analysis (e.g., DFMEA, PFMEA, UFMEA, Hazard Analysis)
- Complaint data risk analysis (e.g., FDA Maude)
- Root cause analysis
- Periodic risk file review
- Remediation on the legacy risk files (QSR Harmonization plan)
- Risk knowledge training
- DHF Audits (e.g., DDP, TAR)
- Others (request team needs)

Webpage Layout

www.risk-risk.com

Risk AnalysisFDA MaudeRoot Cause AnalysisQSR HarmonizationDHF AuditsRisk Training

DETECT INPUT

Type sentence(s), or paragraph(s) here.

x

/ 5,000

Failure_Mode

Failure_Mode

Failure_Cause

Hazard

Hazardous_Situation

Harm

Mitigation

chat

Demo

Feedback

Hints

Section 1 Risk Analysis

- Use scenario: when working on FMEA worksheet, DAE shall develop failure modes, failure causes, hazards, hazardous situations, harms, severity level, mitigation actions manually.
- Webpage operation: user copies the input sentence and picks up the best of predicting options through entire which are provided by ML

the event involved a plum set that the customer reported a leakage of etoposide. the event occurred on an unknown date. no more information was provided.

Failure Mode	Hazard	Situation	Harm / Severity
undetected occlusion	fluid leakage	skin/mucous membranes exposure to allergenic substances	strain 3
fluid leakage	detachment of device component	incorrect access connection	sprain 3
sharp edges/pinch points/abrasive surfaces	infusion or flow issue	patient receives less infusion solution/ fluid than intended	laceration 3
allergenic substances	fluid leak	intravenous exposure to toxins	mild hyperglycemia 2
interruption of therapy	material puncture	exposure to hazardous fluids/fumes	mild hypoglycemia 2
wrong route	particulates	intravenous exposure to non-hemocompatible materials	severe hypotension 4
hazardous fluids/fumes are released into	misconnection	delayed delivery of infusion	mild to moderate respiratory

Section 2 FDA Maude Data Analysis

- Use scenario: when working on periodic risk file review, DAE needs to download complaints from Maude on specific product during the periods, then determine failure modes on each complaint based on 'event text' and 'device problem'.
- Webpage operation: user uploads the complaint raw data at webpage and obtain failure modes and hazards automatically.

DETECT INPUT

From_CSV

Failure_Mode

Report Title From_CSV

Choose File FDA Maude ...moLock.csv

Parse

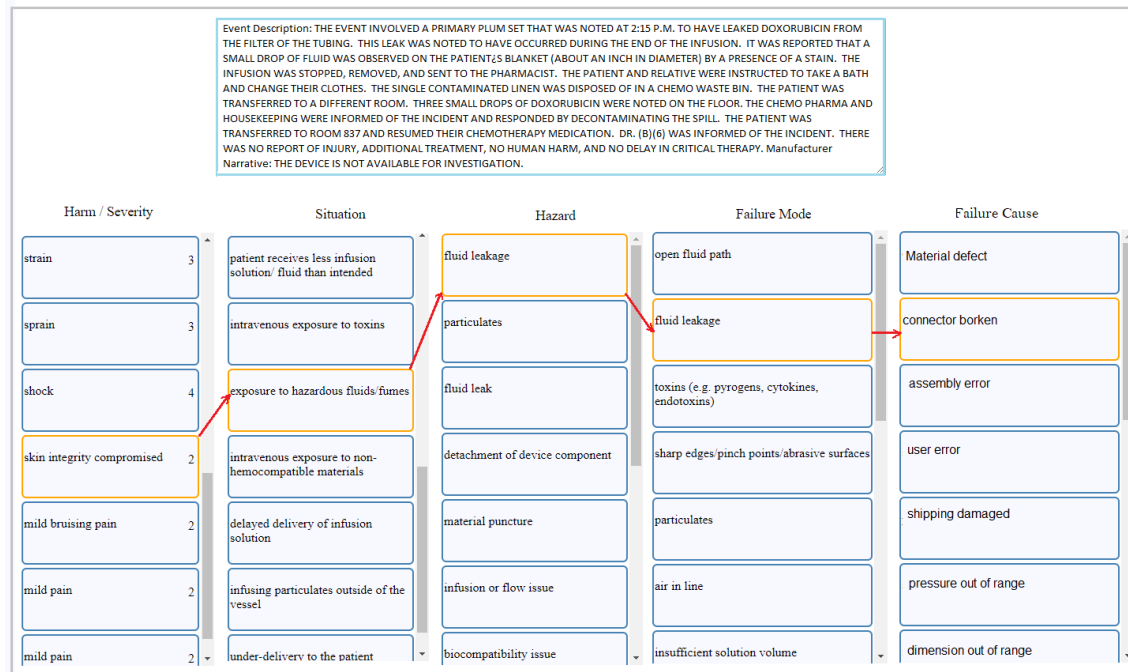
Predicting failure modes and hazards by ML

FDA Maude data on ChomoLock.csv

	failure mode	hazard
Event Description: THE EVENT INVOLVED A PRIMARY PLUM SET THAT WAS NOTED AT 2:15 P.M. TO HAVE LEAKED DOXORUBICIN FROM THE FILTER OF THE TUBING. THIS LEAK WAS NOTED TO HAVE OCCURRED DURING THE END OF THE INFUSION. IT WAS REPORTED THAT A SMALL DROP OF FLUID WAS OBSERVED ON THE PATIENT'S BLANKET (ABOUT AN INCH IN DIAMETER) BY A PRESENCE OF A STAIN. THE INFUSION WAS STOPPED, REMOVED, AND SENT TO THE PHARMACIST. THE PATIENT AND RELATIVE WERE INSTRUCTED TO TAKE A BATH AND CHANGE THEIR CLOTHES. THE SINGLE CONTAMINATED LINEN WAS DISPOSED OF IN A CHEMO WASTE BIN. THE PATIENT WAS TRANSFERRED TO A DIFFERENT ROOM. THREE SMALL DROPS OF DOXORUBICIN WERE NOTED ON THE FLOOR. THE SUBSEQUENT...	-filter leakage	-fluid leak
	-set leakage	-leak
	-tubing leakage	-Leak

Section 3 Root Cause Analysis

- Use scenario: when working on complaint data, DAE needs to trace back fail cause along the path harm → hazardous situation → hazard → failure mode → failure causes.
- Webpage operation: user copies the complaint statement and picks up the best of predicting options through entire which are provided by ML



Section 4 Periodic Risk File Review

- Use scenario: users need to update risk files periodically for addressing new failure modes, hazards, or P1 increasing from complaint data in a period of times per ISO 14971.
- Webpage operation: users may upload complaint data (e.g. FDA Maude) and target risk files (e.g. FMEA); the webpage shall provide lists of new failure modes and lists of increased P1 value

A Failure_Modes from the FDA Complaints	B Chemolock_connector (UFMEA/DFMEA/PFMEA) RSK00-00205
1	
2 balloon detached ✓	UFMEA
3 cap detached ✓	Doesn't connect
4 chamber leakage	No fluid flow
5 closed male luer leakage	No click when connectors pushed together
6 closed system transfer device leakage	Units don't come apart when required
7 connection leakage	Unable to connect device to a luer
8 connector adaptor leakage	Chemo Lock accidentally disconnects at the ISO luer
9 connector detached	Leak at connection point
10 connector falling apart ✓	Fluid residue at connection point
11 connector housing leakage	DFMEA
12 connector leakage	Leaks
13 connector port leakage	Stick-down, silicone fails to return after activation
14 foreign material inside	Difficult to activate
15 loose connection	Fails to latch on to the poppet body
16 medication sprayed	Fails to unlatch from the poppet body
17 particles in the fluid path	Fails to latch on to the poppet body
18 Port blocked ✓	Fails to unlatch from the poppet body
19 port leakage	Post fails to seal on Silicone or Main Seal
20	Post fails to seal on Poppet

Section 5 Remediation on Legacy Risk Files

- Use scenario: users need to convert legacy risk files into new templates due to requirements from ISO 14971 new version, Eu MDR, audit remediation actions, or company QMS integration.
- Webpage operation: users need to upload the legacy risk files to webpage and all history data will be dumped into new template efficiently and accurately. Furthermore, more data can be filled as needs (e.g. ID, S, RR)

DFMEA Worksheet for TEGO 2
 Component: 1. TEGO Connector
 Item: 1. Over-molded Body

Failure Modes	Causes	Failure Effects	Current Conditions				Current Controls	Recommended Actions	Actions Taken	Action Results			
			S	O	D	R P N				S	O	D	R P N
1. Silicone separates from polycarbonate	1. Molding process error	1. Fluid leak	7	2	2	28	1. Mold qualification						
		2. Occluded pathway	5	2	2	20	2. Molding process limit sheets						
							3. Design verification						
	2. Incorrect material	1. Fluid leak	7	2	2	28	1. Design verification						
		2. Occluded pathway	5	2	2	20	2. Material and material vendor selection						
	3. Contaminated polycarbonate housing	1. Fluid leak	7	2	2	28	1. Design verification						

RSK65-00195

ID	Function	Failure Mode	Effects of Failure Mode	Cause of Failure Mode	Trace from Effect of Failure to Next Higher Level	Impact	Control Mechanism	Method of Control	Failure Modes or Effects Caused by Control	Method of Control Requirements	Frequency of Occurrence

Section 6 Risk Knowledge Training

- Use scenario: entry level engineers shall have training to familiar with how to define failure modes, failure causes, hazards, hazardous situations, harms, severity level, mitigation levels per job requirements.
- Webpage operation: the system provides random training material, scores the results, and indicates the correction visually.

the event involved a tego connector that after a blood test with a sterile vacutainer performed on the arterial branch of the patients right tunnel catheter, air was noted in the line. the patient was not connected to a dialysis session at the time. valve installation date: (b)(6) 2020.

[play](#) [refresh](#) [view answers](#) 50%

Failure Mode	Hazard	Situation	Harm / Severity
air in line	infusion or flow issue	incorrect access connection	temporary discomfort
open fluid path	fluid leak	user ingests removable component	stroke 4
particulates	fluid leakage	intravenous exposure to toxins	pulmonary embolus 3
air leakage	material puncture	incorrect access connection	death 5
air in line	detachment of device component	embolization into the vascular system	temporary discomfort 2
abrasive surfaces	infusion or flow issue	air infused into the body	cardiopulmonary arrest 4
removable component	insufficient flow or underinfusion	slips/falls	inconvenience 1

Section 7 DHF Audits

- Use scenario: in order to preparing audits for design control and risk management, DAE needs to review DHF including DDP, TAR, and V&V protocols/reports to ensure they have no violation manually.
- Webpage operation: the system generates lists of audit findings and associated correction lists on the reviewed documentations.

ID	Audit Findings and Description	Corrections
1	DDP uses obsoleted template	use the new 0302-001-R01 DDP template
2	refer to obsolete Rev 01 of VVQ0007534	refer to the new Rev 02
3	improper check on 2.2.2.5 for software development plan	remove the check mark
4	improper check on 2.2.2.1 design for reliability	remove the check mark
5	Missing approvers at Agile including Jose Alfredo Reyes (operation), evelyn foss (labeling), tracie kirtz (marketing)	require missing signatures
6		
7		
8		
9		
10		

> ≡ BSI DDP0000202 - Bag Clips