

# icumedical

human connections

## DAE Risk Management Webpage (Demo)

<https://www.risk-seek.com>

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# Goals:

Develop a platform based on RdPDM™ Machine Learning Technology to provide solutions for ICU Medical needs 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
- Provide supports for Audits
- Others

# Webpage Layout

<https://www.risk-seek.com>

Risk AnalysisRoot Cause AnalysisDoc RemediationRisk AuditRisk Training

STATEMENTS	Failure_Mode	Hazard	Hazardous_Situation	Harm_Severity
<div>Type sentence(s) here.</div> <div>✕</div> <div>/ 1,000</div>				

DemoFeedbackHints

# Section 1 Risk Analysis

- Use scenario: when working on FMEA worksheet, DAE needs to predict failure modes, failure causes, hazards, hazardous situations, harms, severity level, mitigation actions.
- How to use this tool: user only need to copy a requirement/function from FMEA/HA, paste to the left below, and pick up potential results.

Risk AnalysisRoot Cause AnalysisDoc RemediationRisk AuditRisk Training

STATEMENTS	Failure_Mode	Hazard	Hazardous_Situation	Harm_Severity
the seal shall be continuous without any skips or breaks in the pattern sufficient to cause a discontinuity in the seal following worst case sterilization, shipping and handling simulation, and environmental preconditioning	biological contaminants setup delayed particulate presented exposure to toxins (e.g. pyrogens cytokines endotoxins) biologic - bacteria virus other agent	device contamination with biological material fumes or vapors contamination during use retraction problem misconnection	skin/mucous membranes exposure to biological contaminants exposure to biological contaminants infused via a parenteral route into the skin / mucous membrane exposure to infectious agent exposure to biological contaminants infused via parenteral route into the exposure to patient blood caused by fluid leaks	localized skin swelling 2 redness 4 temporary discomfort 1 death 5 cardiopulmonary arrest 5

223 / 1,000

DemoFeedbackHints

# Section 2 Risk Knowledge Training

- Use scenario: DAE may need to update their risk management skills and knowledge routinely.
- How to use this tool: the tool shall randomly generate questions, provide lists of selections on each step (e.g. failure modes, hazards, hazardous situations, harms, severity levels), score, and demo the corrections.

Risk Analysis

Root Cause Analysis

Doc Remediation

Risk Audit

Risk Training

STATEMENTS	Failure_Mode	Hazard	Hazardous_Situation	Harm_Severity
when contrast was injected via automatic injector, the clave would not allow forward flow. so, contrast leaked out all over the table instead of going into the patient. when tech didn't see contrast on images, she discovered it had leaked. when she attempted to flush with saline, it would not flow and leaked out from the clave connector instead.	<div>setup delayed</div> <div>therapy interrupted</div> <div>biological contaminants</div> <div>drug with altered activity</div> <div>sharp edge</div>	<div>device difficult to setup or prepare</div> <div>short fill</div> <div>failure to deliver</div> <div>misconnection</div> <div>inadequate user interface</div>	<div>delayed delivery of infusion solution</div> <div>delayed delivery of infusion of blood products (blood product does not need to be</div> <div>blood/blood product rendered unusable during setup</div> <div>infusing particulates outside of the vessel</div> <div>patient access device is pulled out</div>	<div>temporary discomfort/ user discomfort 1</div> <div>seizure 4</div> <div>temporary discomfort/ user discomfort 1</div> <div>mild to moderate hypotension3</div> <div>mild to moderate hypotension3</div>

new sample

answers

75%

# Section 3 FDA Maude Data Analysis

## (under construction)

- Use scenario: when working on periodic risk file review, DAE needs to predict failure modes and hazards on individual complaint from FDA Maude database (this is a time consuming process due to big data).
- How to use this tool: user only need to upload the complaint raw data as one file, and automatically obtain an output file with all failure modes and hazards in short period times.

DETECT INPUT

From\_CSV

>

Failure\_Mode

▼

Report Title

From\_CSV ▼

Choose File

FDA Maude ...moLock.csv

Parse

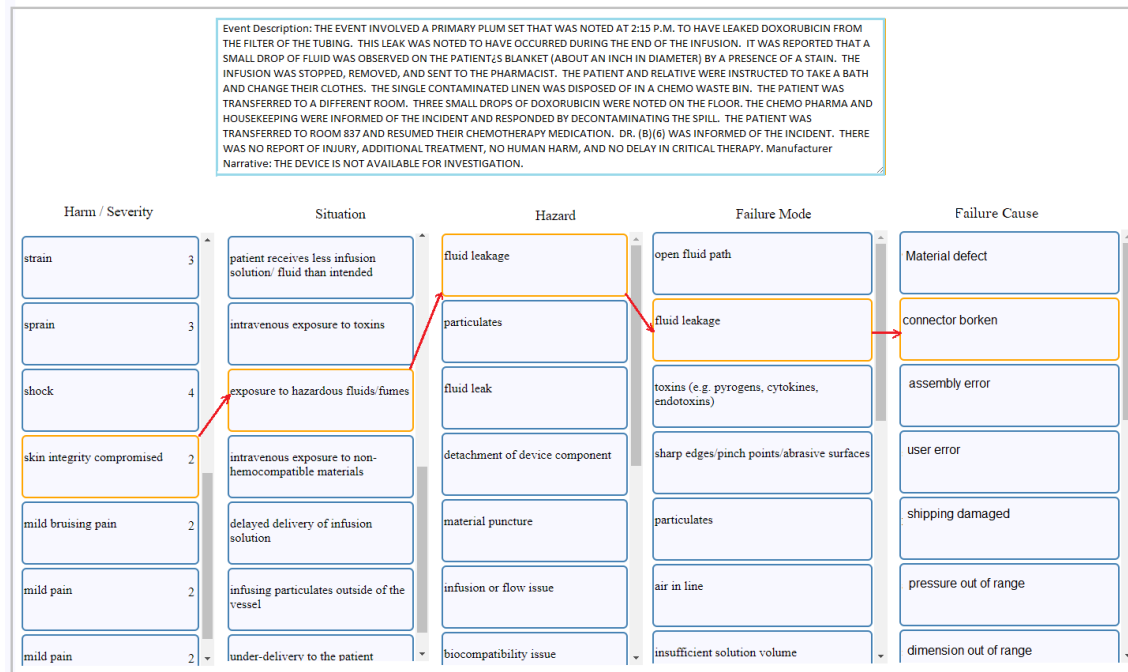
Predicting failure modes and hazards by ML

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 4 Root Cause Analysis

## (under construction)

- Use scenario: when working on complaint data, DAE may need to dig out potential failure causes on individual customer complaint.
- How to use this tool: user copies the complaint statement and picks up the best of predicting options through entire which are provided by ML



# Section 5 Periodic Risk File Review

## (under construction)

- 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 6 Remediation on Legacy Risk Files

## (under construction)

- 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 7 Support Risk Management Audit

## (under construction)

- Use scenario: auditor wants to quickly know how the failure mode 'material discolored' is managed (Auditor's question).
- Webpage operation: the system shall direct to associated engineering specifications, hazards, hazardous situations, harms, severity levels, mitigation actions, risk files (DFMEA, PFMEA, UFMEA, Hazard analysis), test reports, etc.

DETECT INPUT	<a href="#">Failure_Mode</a>		<a href="#">Specification</a>	<a href="#">Standards</a>
material discolored	x	material discoloration is acceptable for level II per WI-xxxx as shown below image		
		/ 5,000		

[Hazards](#)  
[Situations](#)  
[Harm](#)  
[Severity Level](#)  
[Mitigations](#)  
[DFMEA](#)  
[PFMEA](#)  
[UFMEA](#)  
[Hazard Analysis](#)  
[V&V Reports](#)

## Section 8: Others

