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

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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)

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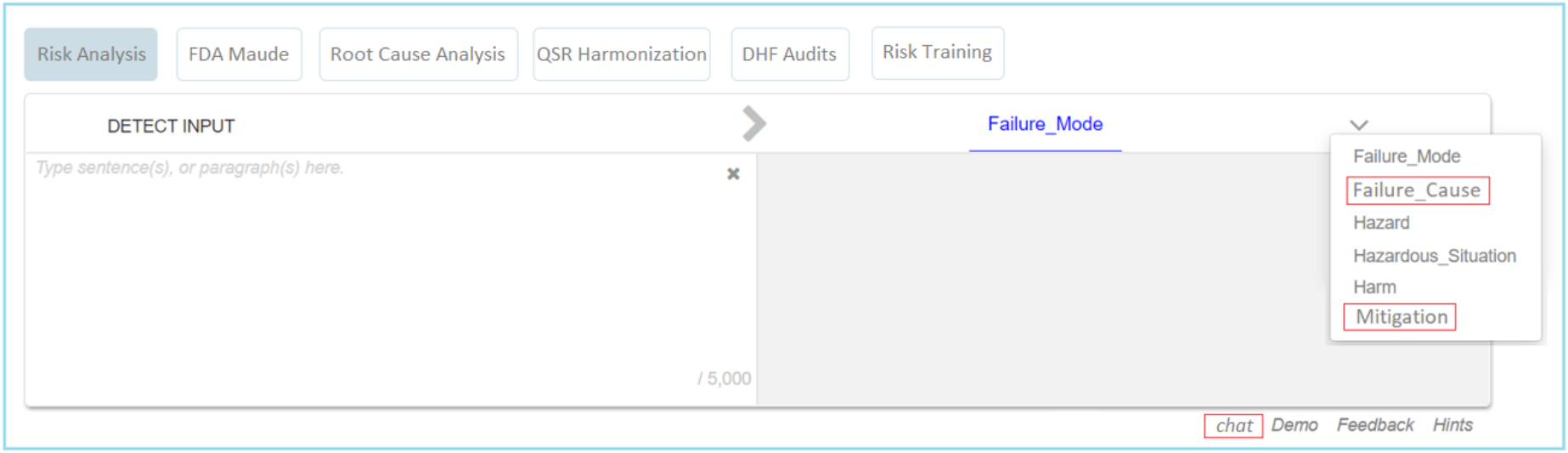
Webpage Layout

www.risk-risk.com



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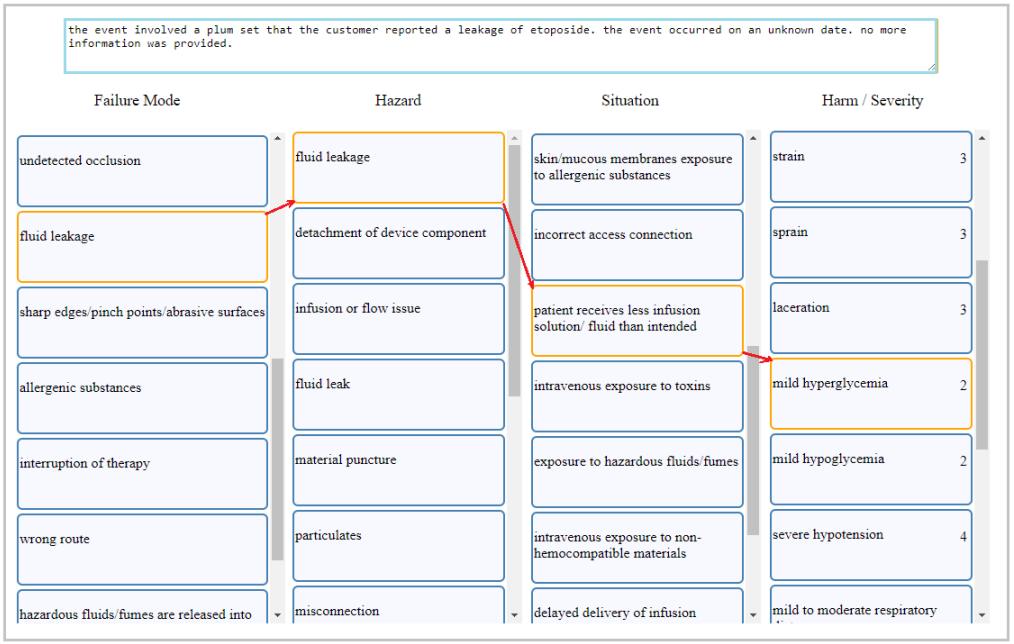
Section 1 Risk Analysis

- 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



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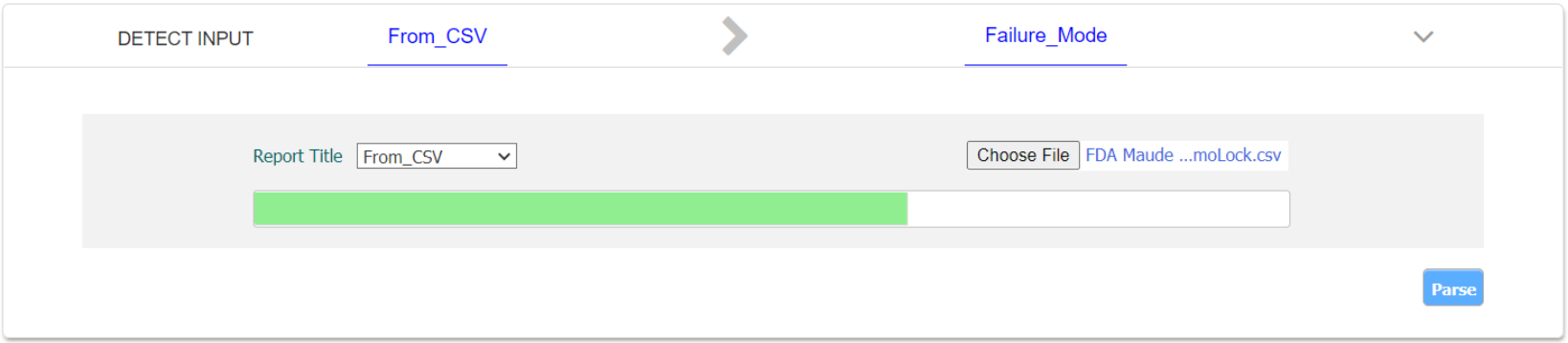
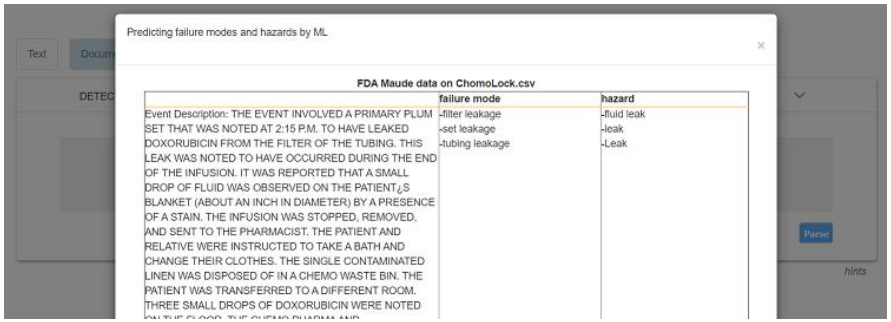
Section 2 FDA Maude Data Analysis

- 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.





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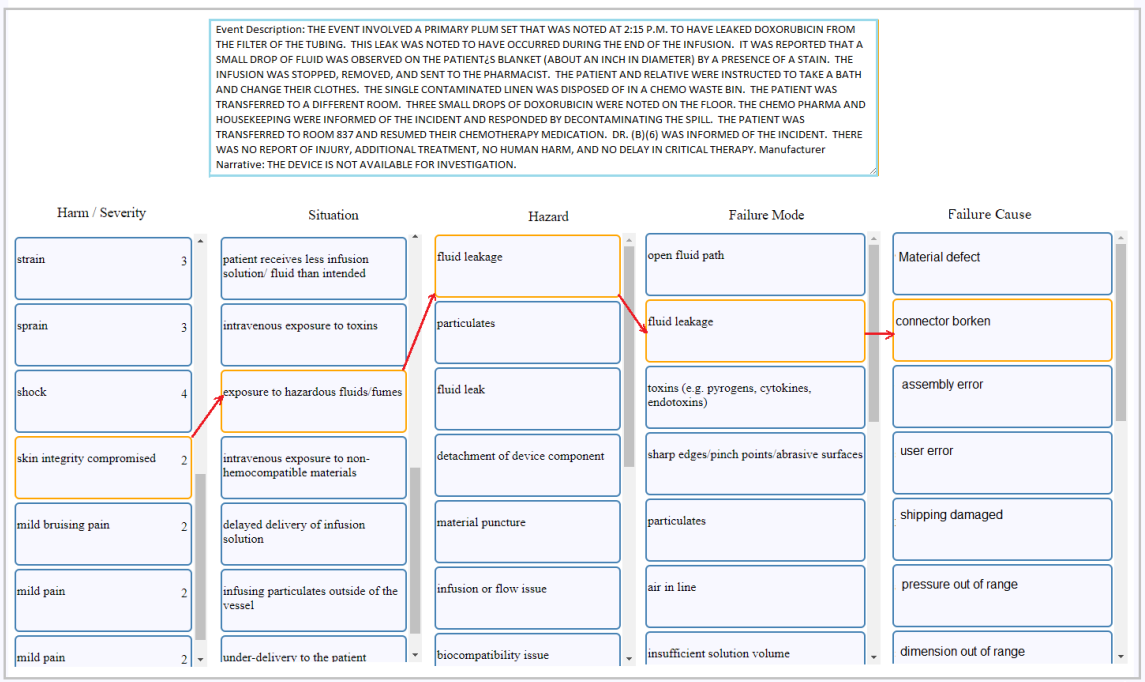
Section 3 Root Cause Analysis

- 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



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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	B
1	Failure_Modes from the FDA Complaints	Chemolock_connector (UFMEA/DFMEA/PFMEA) RSK00-00205
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

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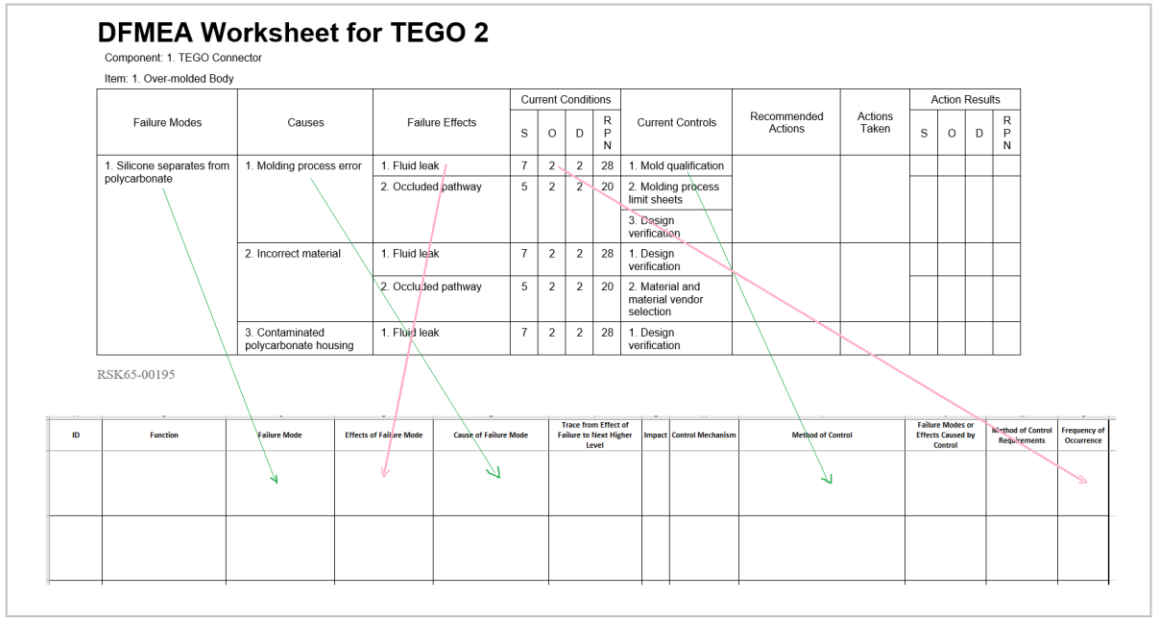
Section 5 Remediation on Legacy Risk Files

- 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 S	O	D	RPN	Current Controls	Recommended Actions	Actions Taken	Action Results S	O	D	RPN
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

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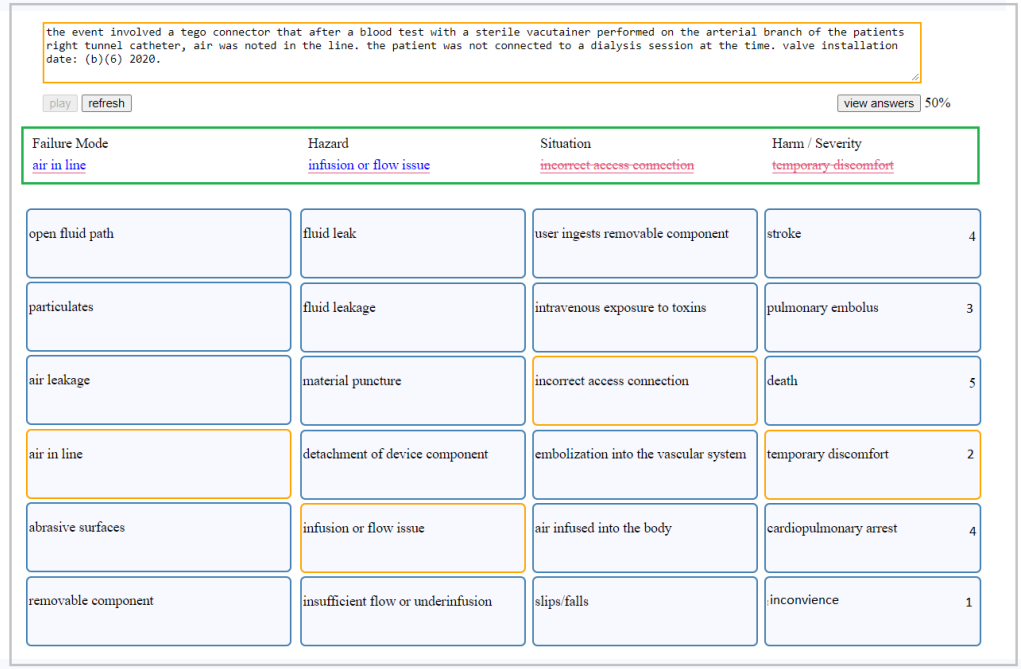
Section 6 Risk Knowledge Training

- 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.



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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