

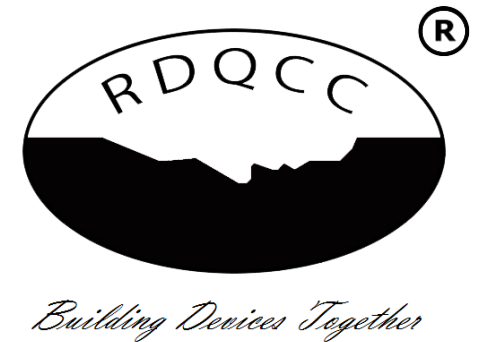
Reducing Product Safety Risks

(Build a customized risk management automation
for ICU Medical DAE Team)

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CQE, CQA, CSSBB, CRE

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icumedical

human connections

DAE Risk Management Webpage (Demo)

<https://www.icumed.com/risk-management>

Goals:

Develop a customized risk management system for ICU Medical to provide automation solutions in the fields of:

- **Risk predication:** *identify potential failure modes, hazards*
- **Complaint analysis:** *analyze FDA Maude data*
- **Root cause analysis:** *discern potential failure causes*
- **Risk mitigation:** *discovery potential mitigation actions*
- **Doc remediation:** *convert legacy docs to new template*
- **Risk training:** *randomly create question and score answers*
- **FMEA/PHA:** *electronical FMEA and Hazard Analysis worksheets*

Webpage Layout

<https://youwebpage.com/risk-management>

Risk PredictionComplaint AnalysisRoot Cause AnalysisRisk MitigationDoc RemediationRisk TrainingFMEA/HA

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

DemoFeedbackHints

Section 1: Risk Predication

- Use scenario: when working on FMEA worksheets, users need to predict potential failure modes, hazards, hazardous situations, harms, and severity levels.
- Operation: user only need to copy a requirement/function from FMEA/HA, paste to the left below, and pick up potential results.

Risk PredictionComplaint AnalysisRoot Cause AnalysisRisk MitigationDoc RemediationRisk TrainingFMEA/HA

STATEMENTS

Failure_ModeHazardHazardous_SituationHarm_Severity

it was reported that, on an unspecified date, the tubing involved in the event was noticed to have unknown impurities in the fluid path of the patient. there was unknown patient involvement reported. no additional information is known at this time.

particulate presented

exposure to toxins (e.g. pyrogens cytokines endotoxins)

drug with altered activity

biological contaminants

sharp edge

249 / 1,000

particulates

failure to deliver

device difficult to setup or prepare

occlusion within device

medication error

infusing particulates outside of the vessel

embolization into the vascular system

air infused into the body while connected to pump

patient receives less infusion solution/fluid than intended

patient blood loss due to backflow of blood into set/device

pulmonary embolism 4

stroke 4

myocardial infarction 4

thrombophlebitis 5

death 5

DemoFeedbackHints

Section 2: Complaint Analysis

- Use scenario: when working on periodic risk file review, users need to predict potential failure modes, hazards, hazardous situations, harms from FDA Maude database.
- Operation: users collect event statements in a excel file and upload to system, and final results shall be popup to screen and able to save to desktop.

The screenshot displays the 'Complaint Analysis' module of a risk management software. At the top, a navigation bar contains several tabs: 'Risk Prediction', 'Complaint Analysis' (which is highlighted), 'Root Cause Analysis', 'Risk Mitigation', 'Doc Remediation', 'Risk Training', and 'FMEA/HA'. Below this, the 'DETECT INPUT' section is active, showing a workflow from 'From_CSV' to 'Failure_Mode'. The 'From_CSV' step includes a 'Report Title' dropdown menu set to 'From_CSV' and a 'Choose File' button next to the filename 'FDA Maude ...moLock.csv'. A green progress bar is visible below the file selection area. A 'Parse' button is located at the bottom right of the input section. At the bottom of the interface, there is a preview window titled 'Predicting failure modes and hazards by ML' which displays a table of data extracted from the FDA Maude database. The table has columns for 'Failure mode', 'Hazard', and 'Event Description'. The 'Event Description' column contains a detailed medical incident report. The 'Failure mode' column lists 'after usage', 'leak', and 'Leak'. The 'Hazard' column lists 'leak', 'leak', and 'Leak'. Below the table, there are links for 'Demo', 'Feedback', and 'Hints'.

Failure mode	Hazard	Event Description
after usage	leak	Event Description: THE EVENT INVOLVED A PRIMARY FLUX SET THAT WAS NOTED AT 2:15 PM TO HAVE LEAKED DOORING 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 NURSE. OF A STAIN THE INFUSION WAS STOPPED, REMOVED, AND SENT TO THE PHARMACY. THE PATIENT AND RELATIVE WERE INSTRUCTED TO TAKE A BATH AND CHANGE THEIR CLOTHES. THE SINGLE CONTAMINATED LINEN WAS DISPOSED OF IN A CHENIO WASTE BIN. THE PATIENT WAS TRANSFERRED TO A DIFFERENT ROOM. THREE SMALL GROUPS OF DOORING WERE NOTED
leak	leak	
Leak	Leak	

Section 3: Root Cause Analysis

- Use scenario: when working on product failure analysis, users need to dig out potential failure causes on specific customer complaints.
- Operation: users copy complaint statement on the left table, system direct users to predict potent failure causes along the path of harm->hazardous situation->failure mode.

Risk PredictionComplaint AnalysisRoot Cause AnalysisRisk MitigationDoc RemediationRisk TrainingFMEA/HA

STATEMENTS	Harm_Severity	Hazardous_Situation	Failure_Mode	Failure_Cause
the event involved a connector that had a leak of an unspecified chemotherapy where a 0.5ml to 1ml droplet was found on a <u>chux</u> pad that resulted in hazardous drug exposure. the device was connected to a syringe for iv push administration. the set was primed according to instructions and there was no hole, cut, tears or any defect noted on the connector. a small bubble was noted outside the usual fluid path within the device which leaked out through the small opening. 472 / 1,000	death 5	air infused into the body while connected to pump	hazardous fluids/fumes released into environment	Material defect
	congestive 3	air infused into the body	allergenic substances	connector broken
	thrombophlebitis 5	air infused into the body in gravity mode	open fluid path	shipping damaged
	moderate toxic effects such as seizures abdominal pain	exposure to physical injury at infusion site	caustic substances	user error
	organ injury 4	exposure to hazardous fluids/fumes	air in line	air in line due to broken, loose, unsealed fluid path

DemoFeedbackHints

Section 4: Risk Mitigation

- Use scenario: when working on FMEA worksheet, users need to define different levels of risk mitigations for those unacceptable risk items.
- Operation: users input any statement (require./spec./complaint), system provides potential lists of 'safety by design', 'protective measures', 'info for safety' at one time.

The screenshot displays a web application interface for Risk Mitigation. At the top, there is a navigation bar with seven tabs: Risk Prediction, Complaint Analysis, Root Cause Analysis, Risk Mitigation (which is highlighted), Doc Remediation, Risk Training, and FMEA/HA. Below the navigation bar, the main content area is divided into four columns. The first column, titled 'STATEMENTS', contains a text input field with a sample complaint: 'the event involved a connector that had a leak of an unspecified chemotherapy where a 0.5ml to 1ml droplet was found on a chux pad that resulted in hazardous drug exposure. the device was connected to a syringe for iv push administration. the set was primed according to instructions and there was no hole, cut, tears or any defect noted on the connector. a small bubble was noted outside the usual fluid path within the device which leaked out through the small opening.' Below the text is a counter '472 / 1,000'. The second column, titled 'Safety_by_Design', lists five mitigations: material selection, leaking test, verification test, environmental test, and aging test. The third column, titled 'Protective_Measures', lists five mitigations: production inspection, material certificate, sampling test, connection loose inspection, and shipping report. The fourth column, titled 'Information_for_Safety', lists five mitigations: label: warning, IFU: precaution, IFU: inspect leak before use, User training, and IFU: tight connection. Each mitigation item has a progress bar below it. At the bottom right of the interface, there are links for 'Demo', 'Feedback', and 'Hints'.

STATEMENTS	Safety_by_Design	Protective_Measures	Information_for_Safety
the event involved a connector that had a leak of an unspecified chemotherapy where a 0.5ml to 1ml droplet was found on a <u>chux</u> pad that resulted in hazardous drug exposure. the device was connected to a syringe for iv push administration. the set was primed according to instructions and there was no hole, cut, tears or any defect noted on the connector. a small bubble was noted outside the usual fluid path within the device which leaked out through the small opening.	material selection	production inspection	label: warning
	leaking test	material certificate	IFU: precaution
	verification test	sampling test	IFU: inspect leak before use
	environmental test	connection loose inspection	User training
	aging test	shipping report	IFU: tight connection

Section 5: Document Remediation

- Use scenario: when working on FMEA remediation, users need to convert legacy risk files into new templates due to standard new revision, EU MDR, audit action.
- Operation: users upload the legacy risk files (e.g. Excel, word) to system, data will be dumped accordingly.

DFMEA Worksheet

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						

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 Training

- Use scenario: by using the system, users are able to update their risk assessment skills routinely.
- Operation: system randomly generates questions, interacts with users to predict risks, scores the results, and demos the correct answers.

Risk PredictionComplaint AnalysisRoot Cause AnalysisRisk MitigationDoc RemediationRisk TrainingFMEA/HA

STATEMENT	FAILURE MODE	HAZARD	HAZARD SITUATION	HARM / SEVERITY
sterile barrier system shall be designed to keep the product sterile and contamination free	open fluid path	particulates	infusing particulates outside of the vessel	pulmonary embolism 4
	exposure to toxins (e.g. pyrogens cytokines endotoxins)	device difficult to setup or prepare	embolization into the vascular system	death 5
	drug with altered activity	failure to deliver	incorrect setup of parenteral therapy	death 5
	biological contaminants	occlusion within device	air infused into the body while connected to pump	stroke 4
	particulate presented	medication error	patient blood loss due to backflow of blood into set/device	myocardial infarction 4

91 / 1,000

new sampleanswers25%

Section 7: FMEA and Hazard Analysis

- Operation: by integrating electrical FMEA worksheet with risk search engine, users are able to run entire risk analysis on one page and save risk results to database.

[Close X]

Review

WIFI Software FMEA Worksheet

Document: 1030

Revision: A

Market Status: Pre Market

Add a New Row

Upload from Child

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	Comment		
Risk ID	Description	Model Affected	Failure Mode	Failure Cause	Hazard	Hazardous Situations	Harm to Patients	S	P1	P2	P	Risk Ranking	Current Controls	Recommend Mitigation	Types of Controls	Verification & Effective Check	S	P1	P2	P	Risk Ranking	Risk Benefit Analysis	or New Failure Modes	Comment
6								4			3	C			D		4			1	A			
7								2			3	B			D		2			2	A			
8								2			2	A			D		2			1	A			

[Total: 3] [Current Page: 1 of 1]

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To Report To Excel Exit

*Your challenges inspire our solutions,
please let us know how we can help...*

