

Reducing Product Safety Risks

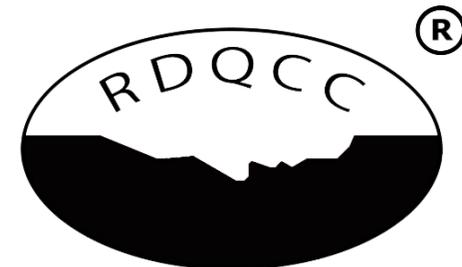
(Build a customized risk management automation
based on the RdPDM™ platform)

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Building Devices Together

Goals:

Develop a customized risk management system based on the RdPDM™ platform 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 Prediction	Complaint Analysis	Root Cause Analysis	Risk Mitigation	Doc Remediation	Risk Training	FMEA/HA
STATEMENTS	Failure_Mode	Hazard	Hazardous_Situation	Harm_Severity		
<p>Type sentence(s) here.</p> <p>/ 1,000</p>						
Demo Feedback Hints						

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.

The screenshot displays a software interface for risk prediction. At the top, there are navigation tabs: Risk Prediction (selected), Complaint Analysis, Root Cause Analysis, Risk Mitigation, Doc Remediation, Risk Training, and FMEA/HA. Below the tabs, a workflow is shown with five columns: STATEMENTS, Failure_Mode, Hazard, Hazardous_Situation, and Harm_Severity. The STATEMENTS column contains a text box with a scenario: "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." Below the text is a counter "249 / 1,000". The Failure_Mode column lists "particulate presented", "exposure to toxins (e.g. pyrogens cytokines endotoxins)", "drug with altered activity", "biological contaminants", and "sharp edge". The Hazard column lists "particulates", "failure to deliver", "device difficult to setup or prepare", "occlusion within device", and "medication error". The Hazardous_Situation column lists "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", and "patient blood loss due to backflow of blood into set/device". The Harm_Severity column lists "pulmonary embolism" (severity 4), "stroke" (severity 4), "myocardial infarction" (severity 4), "thrombophlebitis" (severity 5), and "death" (severity 5). At the bottom right, there are links for "Demo", "Feedback", and "Hints".

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 software interface. At the top, there are navigation tabs: 'Risk Prediction', 'Complaint Analysis' (active), 'Root Cause Analysis', 'Risk Mitigation', 'Doc Remediation', 'Risk Training', and 'FMEA/HA'. Below these is a 'DETECT INPUT' section with a 'From_CSV' dropdown menu and a 'Choose File' button. The file 'FDA Maude ...moLock.csv' is selected. 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, a preview window titled 'Predicting failure modes and hazards by ML' shows a table with columns for 'Event Description', 'Failure Mode', and 'Hazard'. The table contains one row of data with detailed text in the 'Event Description' column and 'After usage' in the 'Failure Mode' column. Navigation links 'Demo', 'Feedback', and 'Hints' are located at the bottom right of the interface.

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.

The screenshot displays a software interface for Root Cause Analysis. At the top, there are navigation tabs: Risk Prediction, Complaint Analysis, Root Cause Analysis (selected), Risk Mitigation, Doc Remediation, Risk Training, and FMEA/HA. Below the tabs, the interface is divided into several sections:

- STATEMENTS:** A text area containing a 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." A close button (x) is visible in the top right of this section. At the bottom right of this section, it says "472 / 1,000".
- Harm_Severity:** A list of predicted harms with associated severity scores and progress bars:
 - death (5)
 - congestive (3)
 - thrombophlebitis (5)
 - moderate toxic effects such as seizures abdominal pain
 - organ injury (4)
- Hazardous_Situation:** A list of predicted hazardous situations with progress bars:
 - air infused into the body while connected to pump
 - air infused into the body
 - air infused into the body in gravity mode
 - exposure to physical injury at infusion site
 - exposure to hazardous fluids/fumes
- Failure_Mode:** A list of predicted failure modes with progress bars:
 - hazardous fluids/fumes released into environment
 - allergenic substances
 - open fluid path
 - caustic substances
 - air in line
- Failure_Cause:** A list of predicted failure causes with progress bars:
 - Material defect
 - connector broken
 - shipping damaged
 - user error
 - air in line due to broken, loose, unsealed fluid path

At the bottom right of the interface, there are links for "Demo", "Feedback", and "Hints".

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 software interface for Risk Mitigation. At the top, there are seven tabs: Risk Prediction, Complaint Analysis, Root Cause Analysis, Risk Mitigation (selected), Doc Remediation, Risk Training, and FMEA/HA. Below the tabs, the interface is divided into three main sections: STATEMENTS, Safety_by_Design, Protective_Measures, and Information_for_Safety. The STATEMENTS section contains a text input field with a sample statement: "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 Safety_by_Design section lists five mitigations: material selection, leaking test, verification test, environmental test, and aging test. The Protective_Measures section lists five mitigations: production inspection, material certificate, sampling test, connection loose inspection, and shipping report. The Information_for_Safety section lists five mitigations: label: warning, IFU: precaution, IFU: inspect leak before use, User training, and IFU: tight connection. At the bottom right, there are links for Demo, Feedback, and Hints.

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 Covered 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.

The screenshot displays a software interface for risk training. At the top, there are navigation buttons: Risk Prediction, Complaint Analysis, Root Cause Analysis, Risk Mitigation, Doc Remediation, Risk Training (highlighted), and FMEA/HA. Below these is a table with five columns: STATEMENT, FAILURE MODE, HAZARD, HAZARD SITUATION, and HARM / SEVERITY. The first row of the table contains the following data:

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

At the bottom left of the interface, there is a progress indicator showing '91 / 1,000' and a 'new sample' button. At the bottom center, there is an 'answers' button and a '25%' progress indicator.

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.

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] < < Go to 1 > >

To Report To Excel Exit

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

