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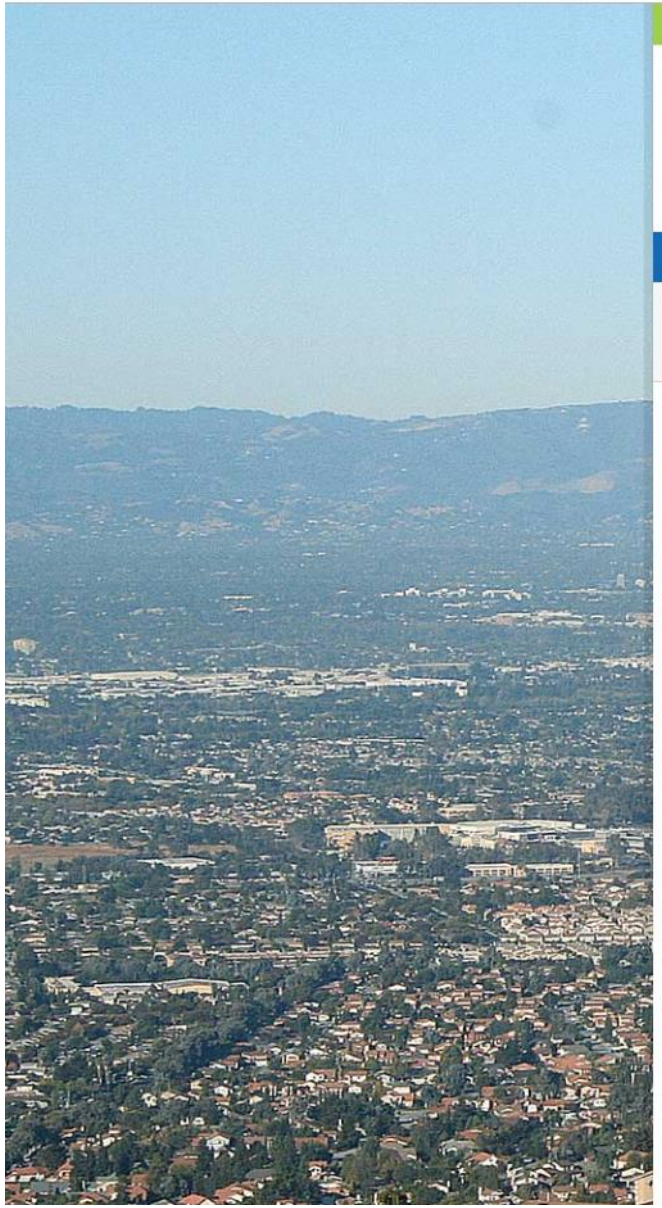

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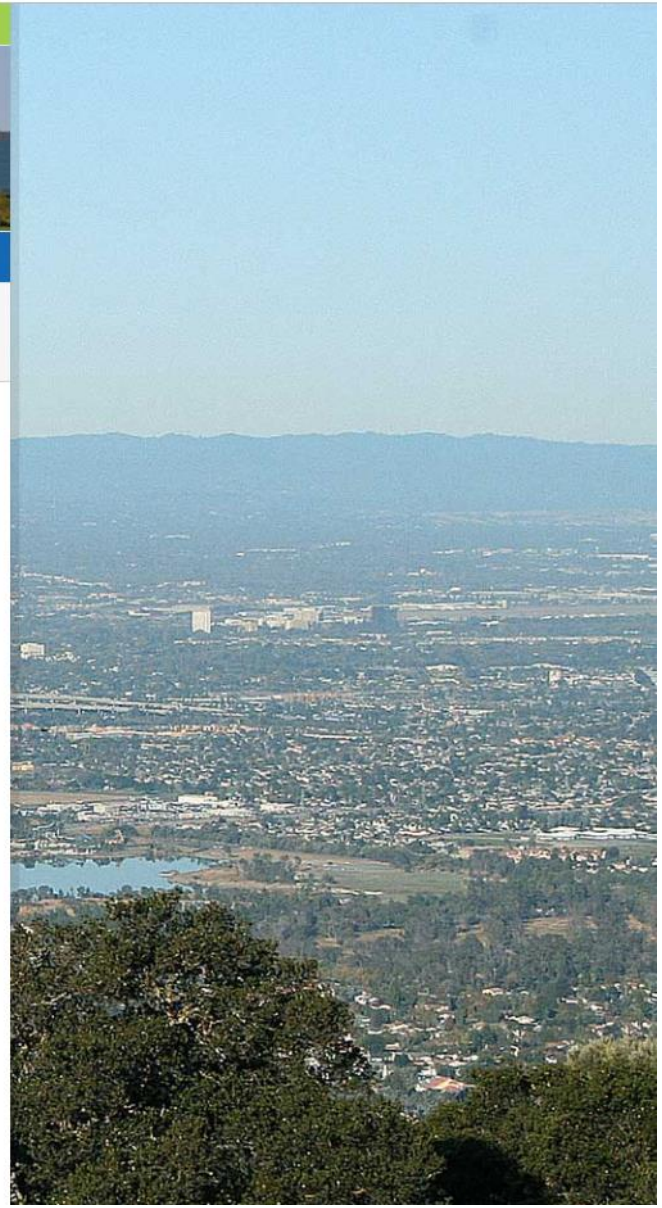


RdQCC LLC
RdQCC IS PIONEERING A PRODUCT RISK MANAGEMENT SYSTEM
* Electronic FMEA Worksheets
* Risk Database Is Created from Internal & External Sources (Requirements, NCMRs, FDA Maude) by Machine Learning
* Risk Diagram Is Initiated from Product Architecture for Top-Down Approach(FTA) & Bottom-Up Approach(FMEA)
* Intelligent Search Engine on Risk Items (Failure Modes, Failure Causes, Hazards, Hazardous Situation, Harms)
* Life Cycle Times Product Risk Management
* Support Cross Functional Team in Real Time
https://www.rdqcc.us
Los Altos, CA
San Diego, CA


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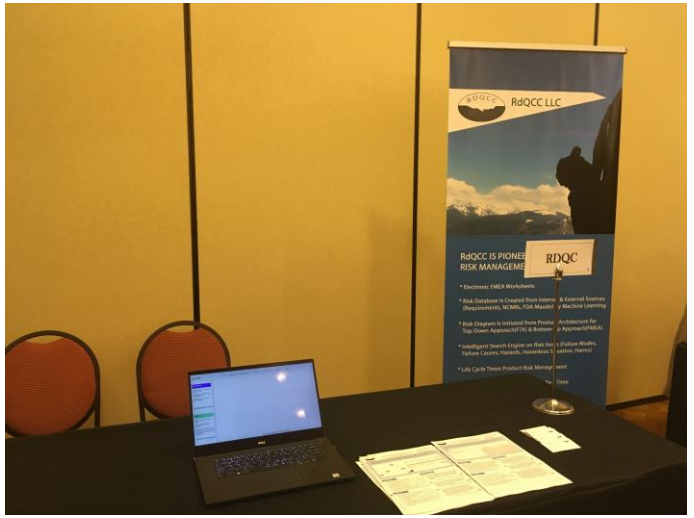
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DQM Big Picture
DQM has three Concurrent Processes*
*ISO 8000-61:2016
Data Quality Management Reference Model

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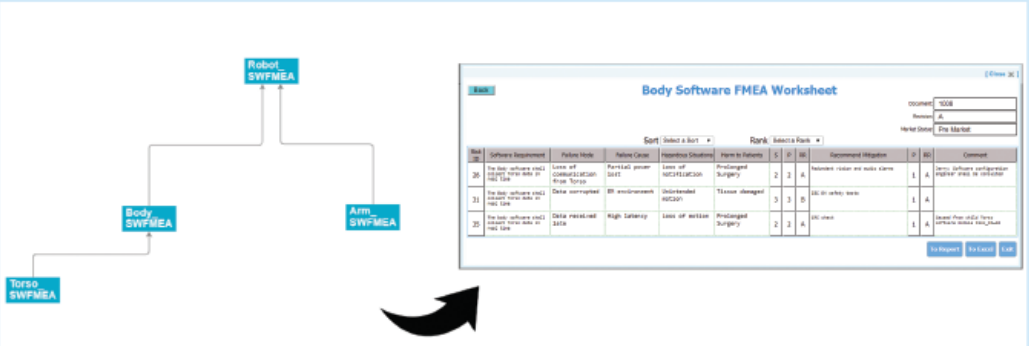
RdPDM Product Risk Management System

Product Risk Diagram Module

RdPDM is pioneering a product risk management system that leverages AI to collect, assess, and reduce risks & uncertainties in real time, traversing product architecture and life cycles.



FUNCTIONS

The product risk diagram module consists of:

- Elements: represent risk analysis objects on parts, modules, sub-systems, or systems
- Links: represent communication/connection among elements which can be uni or bi-direction
- Product Risk Diagrams: supports bottom-up approach (FMEAs) and Top-down approach (FTAs)
- FMEAs: click on any elements from the diagram, pop up an electronic FMEA worksheet for risk analysis
- Traceability: demonstrate risk Domino effect within systems

FEATURES

- Map risk architecture to product architecture (e.g. system, sub-system, components, module level)
- Elements can be any types of FMEAs (e.g. Design, Application, Process, software, system)
- Links indicates data flow, risk transmission path, and module interaction
- One electronic FMEA worksheet satisfies for all types of FMEAs
- FMEA worksheet allows to manually add new rows, upload one file, or pull risks from its children levels
- FMEA worksheet allows to export to excel file, or generate word report

USER EXPERIENCE

> Top-down Approach allows our post market team to quickly act on customer complaints and trace down failure causes from system, sub-system, all the away down to module levels.
>
> -- feedback from a cardiac rhythm product company

> Bottom-up approach allows our design team to predict any new potential failures at the system level if one new feature is added at component/module levels.
>
> -- feedback from an infusion pump company

> During the early product design phase, this software not only allows us to quickly establish a product risk diagram mapped to the product architecture, but also rapidly catch up any design changes and refresh the product risk architecture at once.
>
> -- feedback from a robotic surgery product company

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RdPDM Product Risk Management System

Risk Intelligence Search Module

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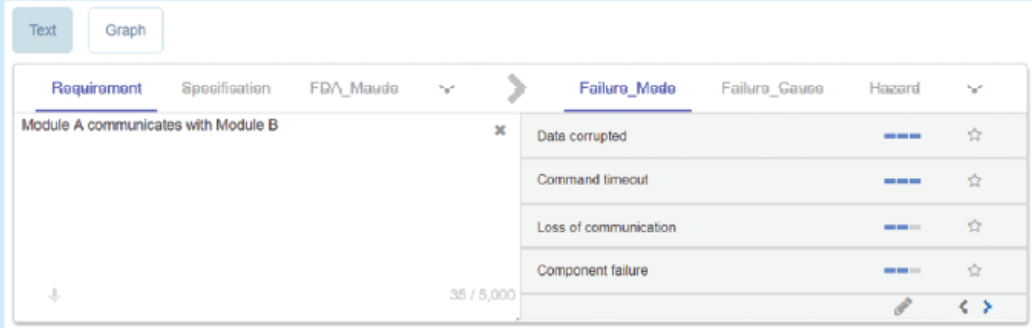

FUNCTIONS

This search engine provides functions as:

- Dynamically search for failure modes, failure causes, hazards, hazardous situations, severity levels, harms, mitigation actions
- Analyze words, sentences, paragraphs from technical reports to generate potential failure modes based on AI technology
- Broadly search and generate failure modes from internet (e.g. Product Performance Reports, FDA Maude, and recalls)
- Predict unknown failure modes and increase similarity scores based on Machine Learning technology
- Establish customized risk management database library

FEATURES

- Rank search results based on its frequency
- Collect feedback from users (click on "star" button)
- Add new risk items into database (use "pencil" button)
- Extract failure modes from internal technical documents (e.g. product requirements, specifications, CAPA, NCMR, complaints)
- Provide autocomplete search suggestions
- Provide similarity analysis for unknown failure modes
- Link with customer risk management SOPs, WIs and embed into risk analysis such as FMEA worksheet.

USER EXPERIENCE

> The search engine supports cross functional team on their deliverables (CAPA, failure analysis, complaint evaluation, design or process changes, NCMs). The more efforts we put the more benefits we get.
>
> -- feedback from a cardiac rhythm product company

> The search engine quickly provides answers, prioritize the suggestions, and self learning. It helps our risk analysis consistently and makes decisoin based on data.
>
> -- feedback from an infusion pump company

> During the early design stage, there are limited product risk knowledge. It is very helpful to learn product failures from the marketed products. The challenge is that this is a time consume process and data is expanded daily, it is hard to be handled by humans but very efficient for the tool.
>
> -- feedback from a robotic surgery product company