Reducing Product Safety Risks
(Introduction of Product Risk Management system)

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DETAILS AND REGISTRATION

Monthly Dinner Forum July 17, 2019,

"Reducing Product Safety Risks"

Jinxing(Jerry) Xiao has worked with many medical device companies, such as Medtronic, Johnson & Johnson, Philips Healthcare, Becton Dickinson, Zimmer Biomet, Abbott, and small to medium sized companies, like Syncardia, Verb Surgical (Google+JnJ), and Intouch Health. His product risk management experiences cover from critical medical devices such as Total Artificial Heart, Pacemaker, Implantable Cardioverter Defibrillators (ICD), Robotic Surgical, Pumps (Insulin, Infusion), Ventilator, and Orthopedics Product, to simple disposables.

He obtained his MS in Quality System Engineering and holds the CQE (Certified Quality Engineer), CQA (Certified Quality Auditor), CSSBB (Certified Six Sigma Black Belt), and CRE (Certified Reliability Engineer) from ASQ (America Society for Quality).

Upcoming Events

American Society of Quality Dinner Forum
Wednesday, July 17, 2019 from 5:00 PM to 9:00 PM PDT

View all events

https://www.asq-silicon-valley.org

Agenda

- ❑ Overview
- ❑ Product risk Management System (methodology, approaches, state-of-art technology, real time manner)
- ❑ Case study (product risk analysis, deliverables)
- ❑ Risk Management System Automation
- ❑ References & QAs

Who are We?

- RdQCC LLC
- Founded in San Diego, California
- Company began in 2013
- Dedicatedly develop product risk management ERP system for medical devices & complex systems
- Launched RdPDM V1.0(2015), V2.0(2016), V3.0(2018)
- Company website: www.rdqcc.us
- You change the world, we secure it

Section 1: Overview
(scopes, failure rates, potential causes)

Risk for Medical Devices (Scope)

- **Product Safety Risk** is related to a hazard leading to user/patient harm. It is guided by ISO 14971.
- **Compliance Risk** is related to business safety if violating regulation requirements. It is guided by such as FDA audits, observations, warning letters.
- **Security Risk** is related to threat and vulnerability. It is guided by ISO 27001 and the others.

Medical Device Product Failures

- In the past decade, nearly two million injuries and more than 80,000 deaths have been linked to faulty medical devices (New York Times, 2019)

  https://www.nytimes.com/2019/05/04/opinion/sunday/medical-devices.html

- Over 90% of medical electrical devices have failed on the first submission over the last two years (Intertek, 2010)

  "why 90% of medical devices fail product certification testing in the first time certification testing the first time" Intertek ETL SEMKO

- Design failure ranked as No.1 root cause at 31% on 10980 model recalls between 2003 and 2009

  "Understanding barriers to medical device quality, FDA.gov, U.S. Department of Health & Human Devices"

- Thirty-one percent of organization have at some point have encountered cyber-attacks on their operation technology.

  https://www.uscybersecurity.net/risks-2019/

Medical Devices are Becoming Complex

- Software intense (real time, network, wireless)
- Challenged environment (implantable, MRI, radiation, battery, life cycle)
- High power consumption (e.g. energy, speed, size)
- Multiple levels of product structures (system integration)

Robotic Surgical

CRM

Copyright St Jude Medical

Proton Therapy

Copyright: Varian Medical System

Product Failures: Domino Effects

- Complex product structure architecture (e.g. software architecture, hardware architecture, Integration, OTS, SOUPs)

  One device can have 100+ software modules, 500+ hardware components, multiple layers, HW & SW integration;

  80% to 95% of modern apps consist of assembled components – Veracode

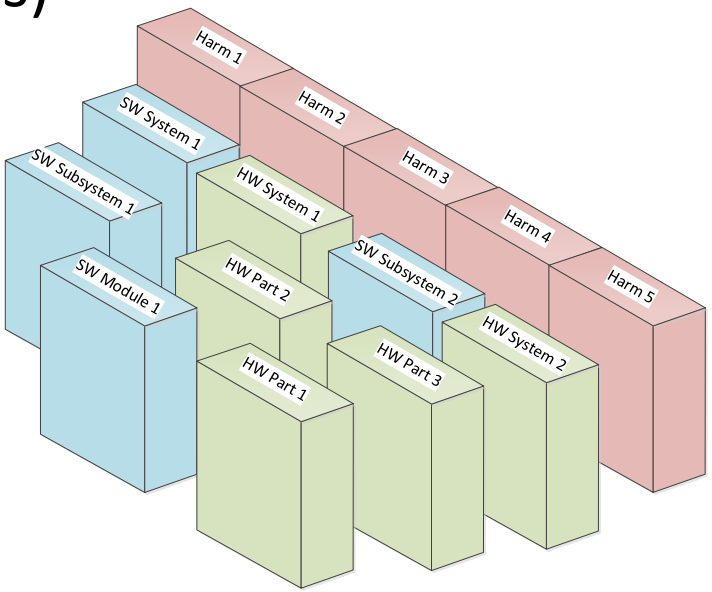
- High degree of novel technology (e.g. large risk analysis deliverables and vast failure modes)

  One device can be easily to have 50+ FMEA files, 50,000+ failure mode rows

- Dependency or interaction relationship among elements (Domino Effects)

  Top-down approach: trace down from patient harm to module/component failures (root cause analysis);

  Bottom-up approach: chain reaction from a module/component failures results to system failure or patient harm (FMEAs)



Failures during the Course of Product Life Cycles

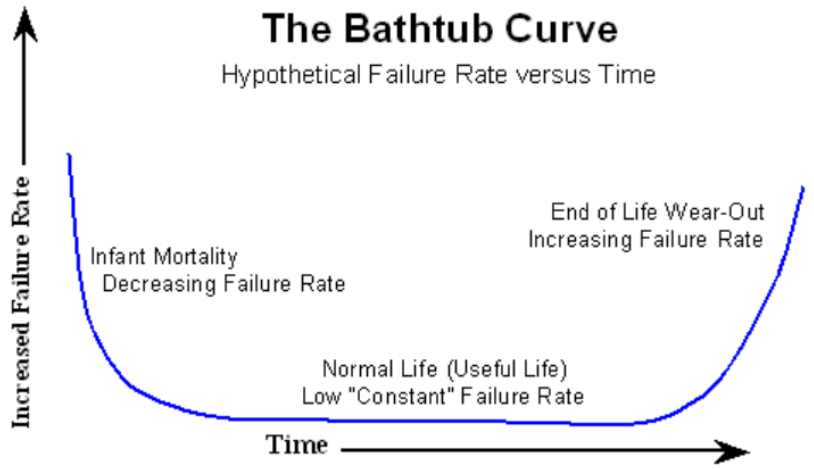
- ISO 14971 section 3.1 risk management process

The manufacturer shall establish, document and maintain throughout the life-cycle an ongoing process for identifying hazard…

- Product may be experienced changes in the course of life cycle from software upgrades, component degrades, environment changes, material … etc.

One design change may lead to new risks and/or update chains of risk management documents

- Product Failure Rate Curve



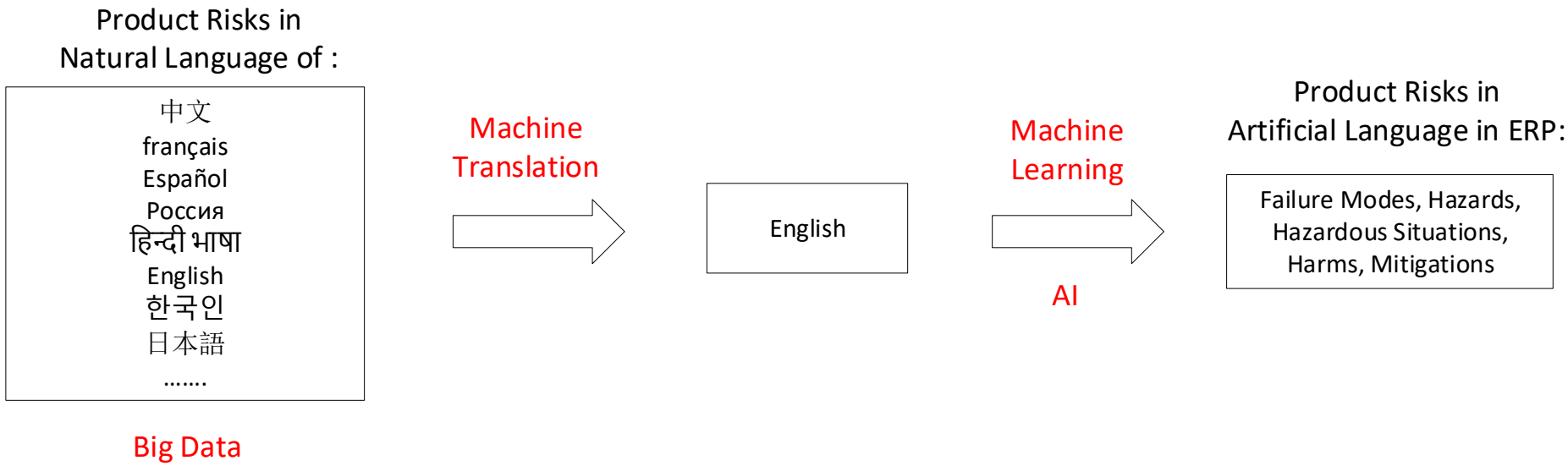
Section 2: Product Risk Management System (method, approaches, big data, AI, real time)

What is the Product Risk Management System?

- **Knowledge creation**: extract product risk knowledge from articles, clinical studies, competitors, FDA database, standards, regulations, design documents, post market complaints, etc.
- **Real time product risk management**: create, maintain, update product risks (failure modes, hazards, harms, risk regions, mitigations, residual risks, risk benefits).
- **Cross functional team involvements/benefits**: support product design & developments, regulatory submission, design changes, customer complaints, nonconforming materials, CAPA, FDA recalls.

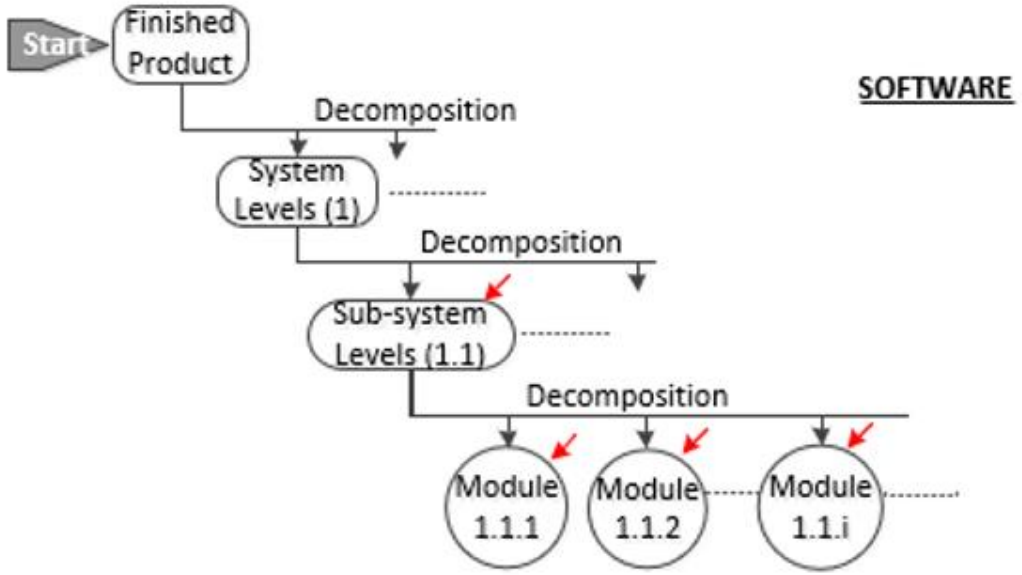
Product Risk Data in NL into the System

- Python is a simple yet powerful programming language with excellent functionality for processing linguistic data.



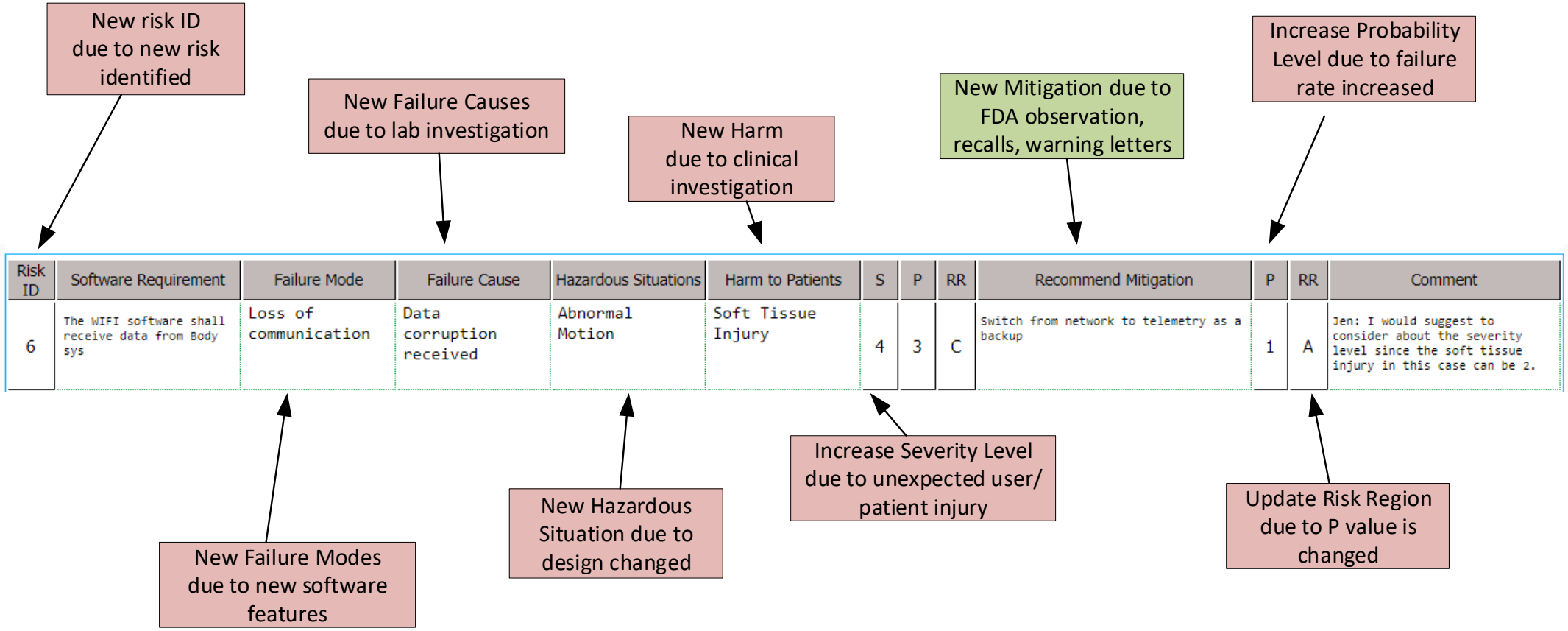
Methods & Approaches

- **Create Product Architecture**: Use the "Palette" to drag & drop elements and connect them by links (uni-arrow, bi-arrows) for hardware, or software.
- **Map Product Risk Structure:** Each element represents its risk analysis deliverable (Arm FMEAs), each link represents its relationship of failure cause and failure consequence.
- **Top-down Analysis**: if a product has a malfunction in the field, trace down potential failure cause at module level.
- **Bottom-up Analysis**: if a failure occurs at module level, trace up to a product failure at system level.



System in Real Time

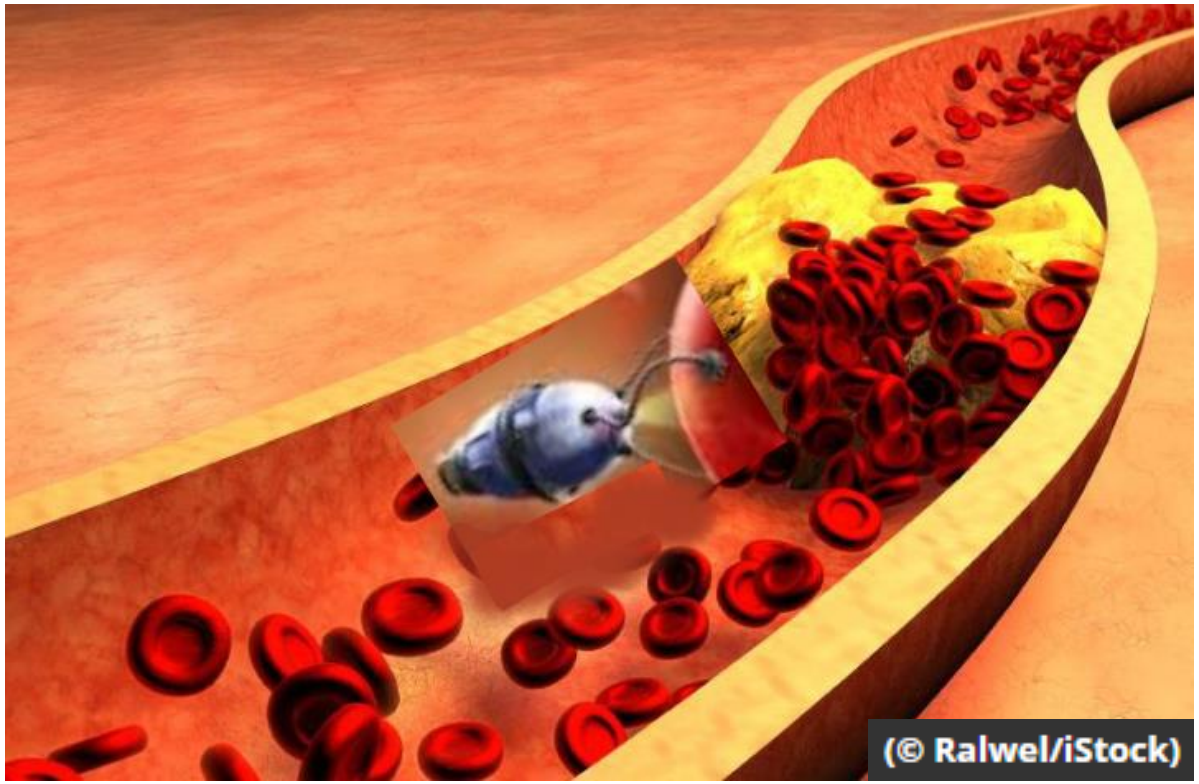
- FDA expects Risk Management Files shall be maintained in real time



Risk ID	Software Requirement	Failure Mode	Failure Cause	Hazardous Situations	Harm to Patients	S	P	RR	Recommend Mitigation	P	RR	Comment
6	The WIFI software shall receive data from Body sys	Loss of communication	Data corruption received	Abnormal Motion	Soft Tissue Injury	4	3	C	Switch from network to telemetry as a backup	1	A	Jen: I would suggest to consider about the severity level since the soft tissue injury in this case can be 2.

Section 3:
Product Risk Analysis Case Study

Case Study:
Micro Robot for Cleaning Clogged Arteries

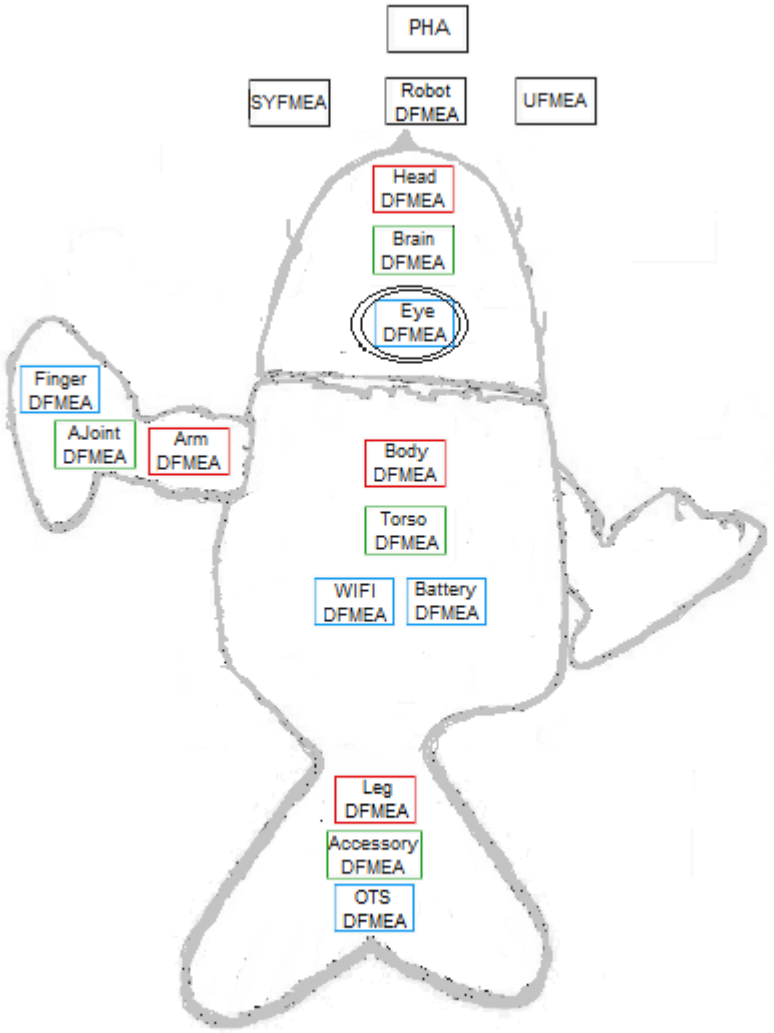


- Micro-swimmers that loosen arterial plaque and release drugs into the bloodstream

https://www.smithsonianmag.com/innovation/tiny-robots-can-clear-clogged-arteries-180955774/

- Body (WIFI, Battery, Torso)
- Arm (Arms, Joints, Elbows, Fingers)
- Head (Eyes, Ears, Nose, Brain)
- Accessories (OTS, Cyber, Medicine)

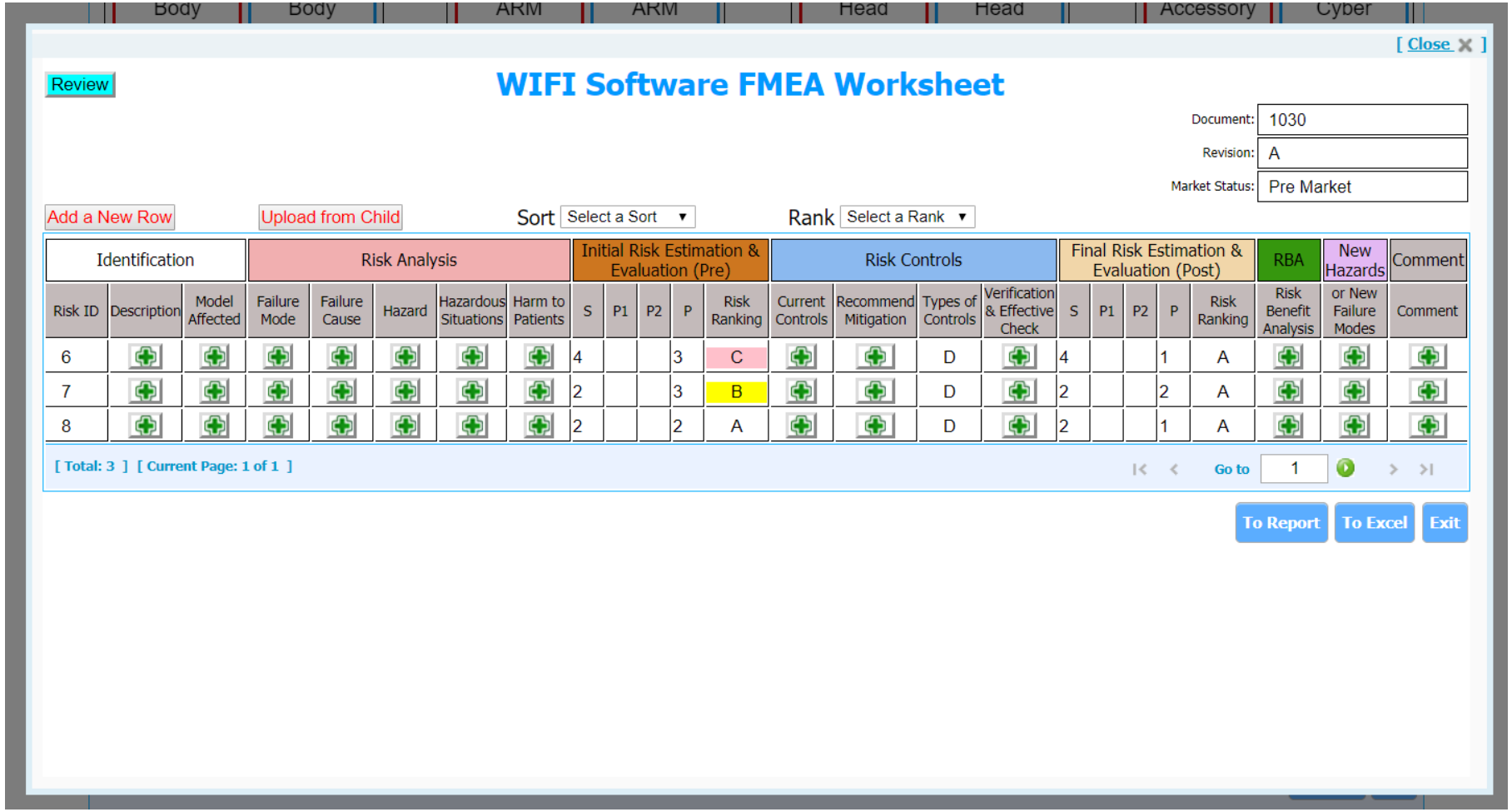
Layout of Product Risk Deliverables



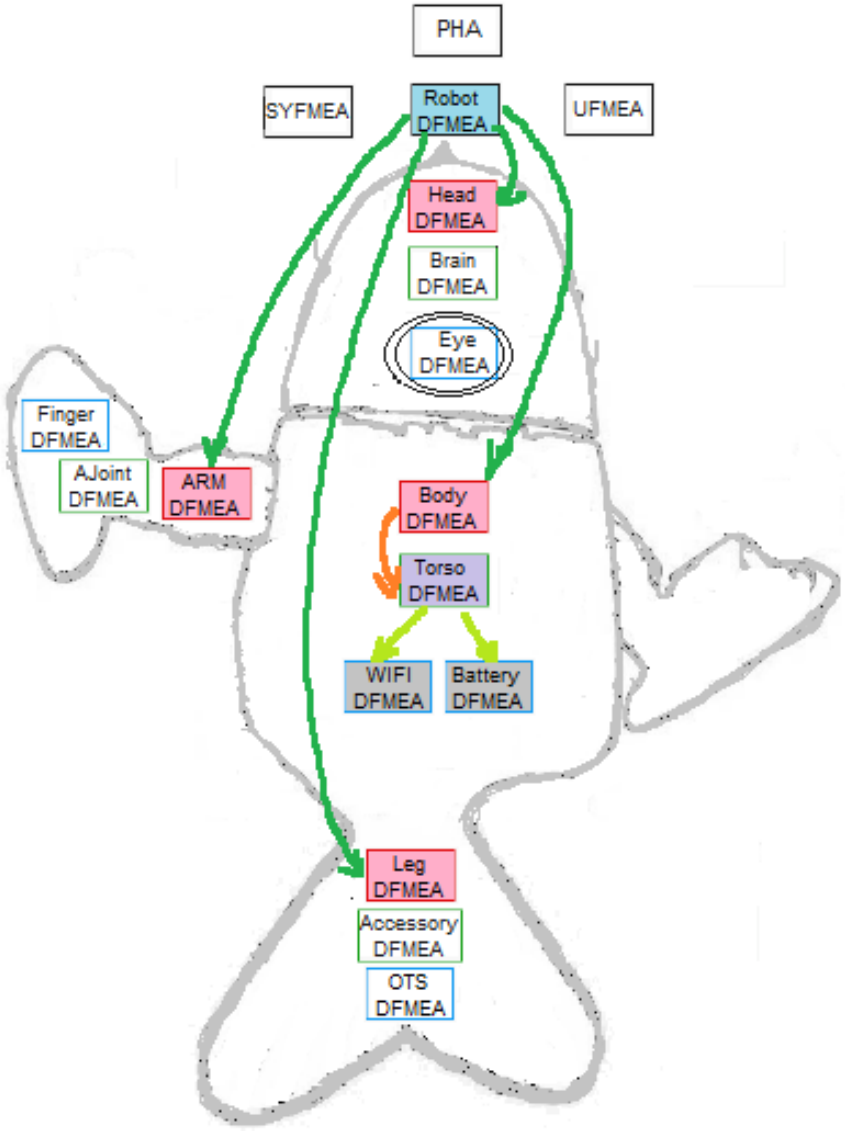
Based on regulatory submission requirement and product architecture, the DFMEA deliverables are visualized:

- Top level deliverables:
  PHA, UFMEA, SYFMEA, Robot DFMEA
- System level deliverables:
  (Head, Body, Arm, Leg) DFMEA
- Sub-system level deliverables:
  (Brain, Torso, ArmJoint, Accessories) DFMEA
- Component-level deliverables:
  (Eye, Finger, WIFI, Battery, OTS) DFMEA

FMEA Worksheet



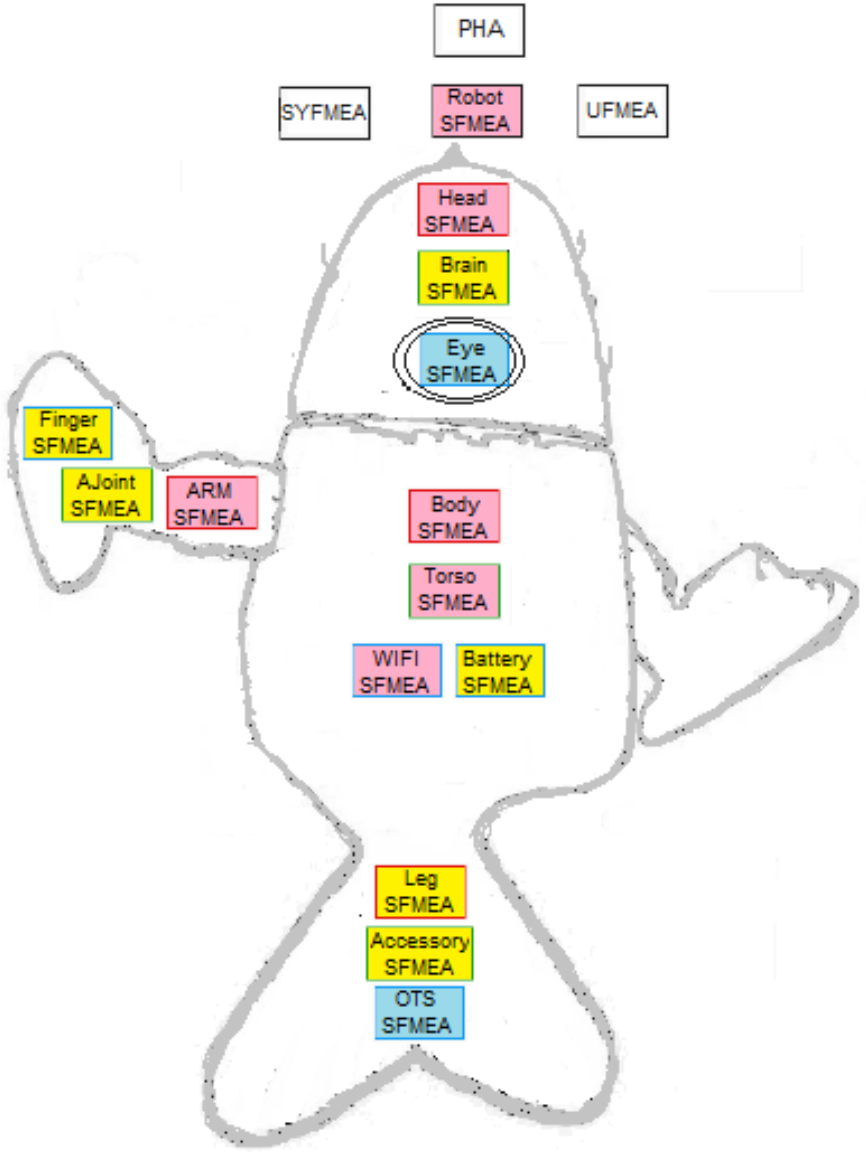
Top-Down Product Dependancy Approach



Top-down dependency between product risk deliverables:

- Click on any deliverable, show its children levels immediately
- Able to trace the dependency relationship from top to bottom levels

Software Safety Classification



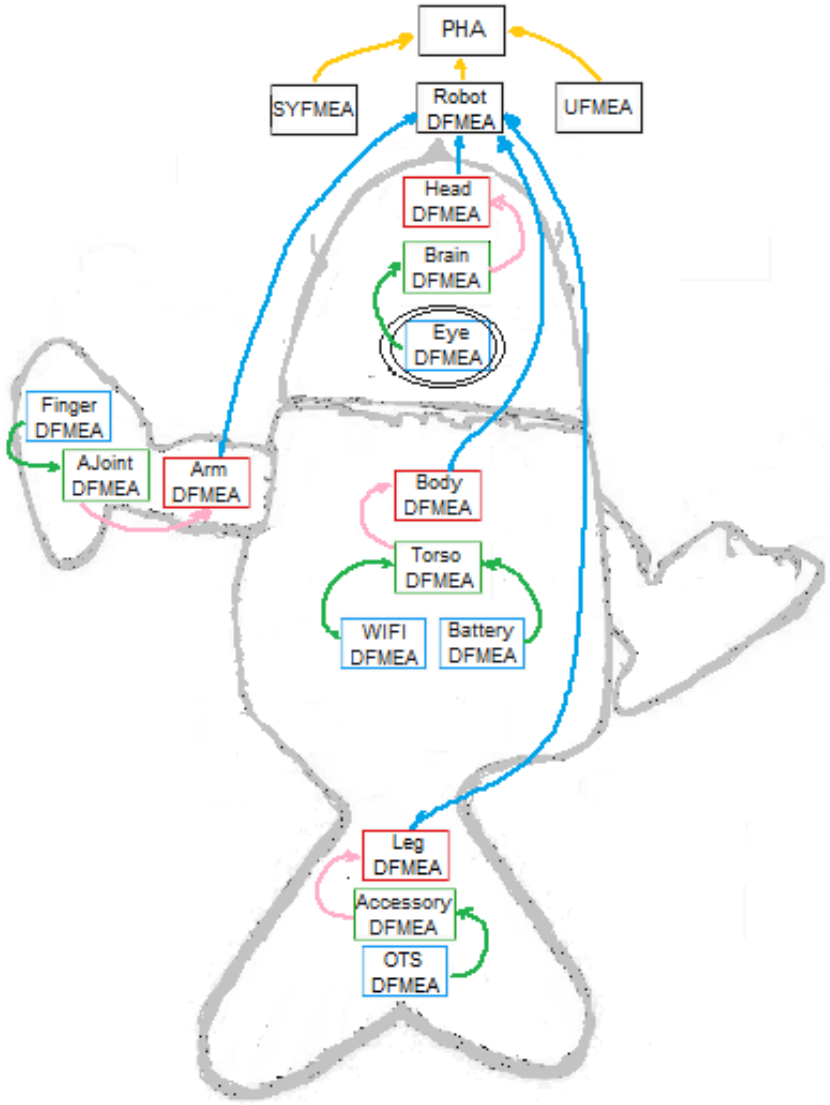
IEC 62304 software safety classification:

- Class C: pink background
- Class B: yellow background
- Class A: blue background

Classification validation check:
Use color to verify if the Parent safety classification higher than Children Levels

Overview technical, workload, and lead time focus on SWFMEAs

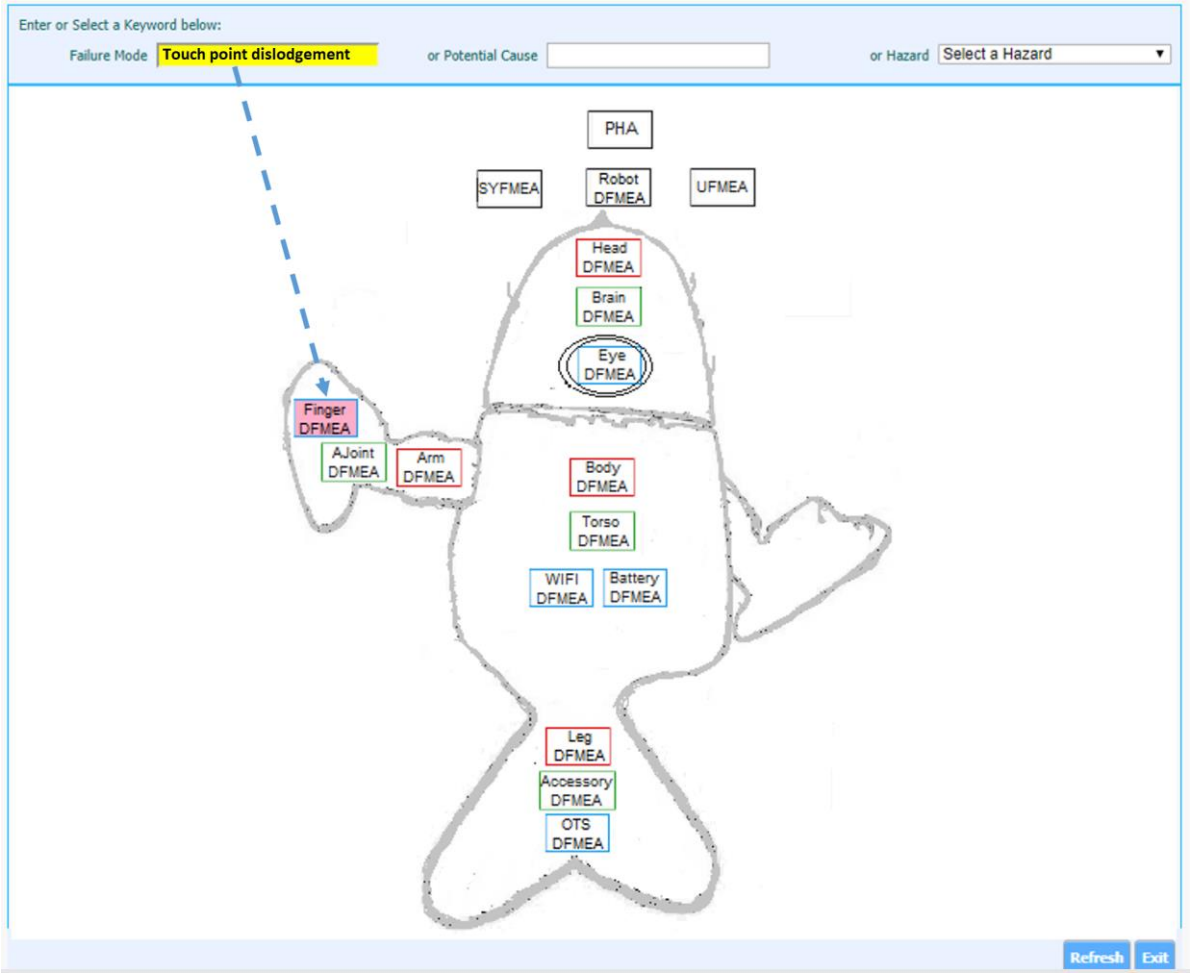
Bottom-Up Product Risk Analysis Approach



Bottom-up method allows to pull risks from children levels to parent level for creating new risks, visualize the risks transmission.

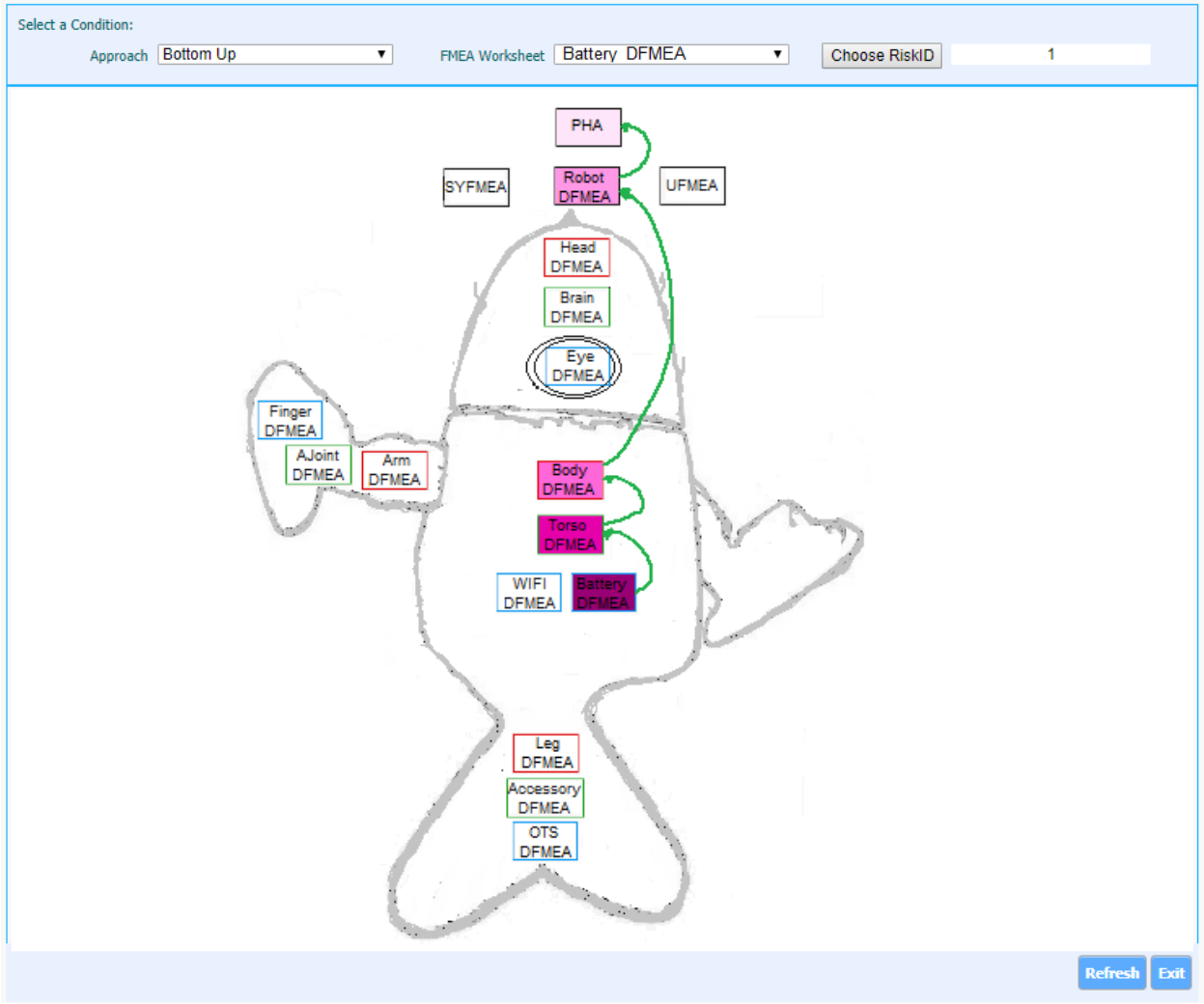
- Consider about module interaction
- Change impact analysis
- Team work together
- Root cause analysis
- Predication of failure chain reaction
- Estimation of software reliability

Search Risks within the System



- If you know any failure mode, potential cause, or hazard, the system will direct to FMEA files, even Risk IDs.
- Field failure analysis
- Quality annual reviews
- Support cross functional teams in real time

Trace Risk Cause & Effects in the Entire Systems (Domino Failure Effect)



- If you know any risk at component/module level, you can trace how it leads to new risks at sub-system, system levels.
- Vice versa. If any risk at system level (field report), you can trace back if it is original caused from component/module level.

Section 4:
Risk Management Automation & QA

Product Risk Management System Automation Demo

References and Q&A

- Carl S. Carlson. Effective FMEAs Achieving safe, reliable, and economical products and process using failure mode and effects analysis. Wiley, a John Wiley & Sons Inc.
- Adam Hoffman. Tiny Robots Can Clear Clogged Arteries, July 1, 2015

https://www.smithsonianmag.com/innovation/tiny-robots-can-clear-clogged-arteries-180955774/

- RdQCC LLC. Product Safety Risk Management ERP (RdPDM V3.0)