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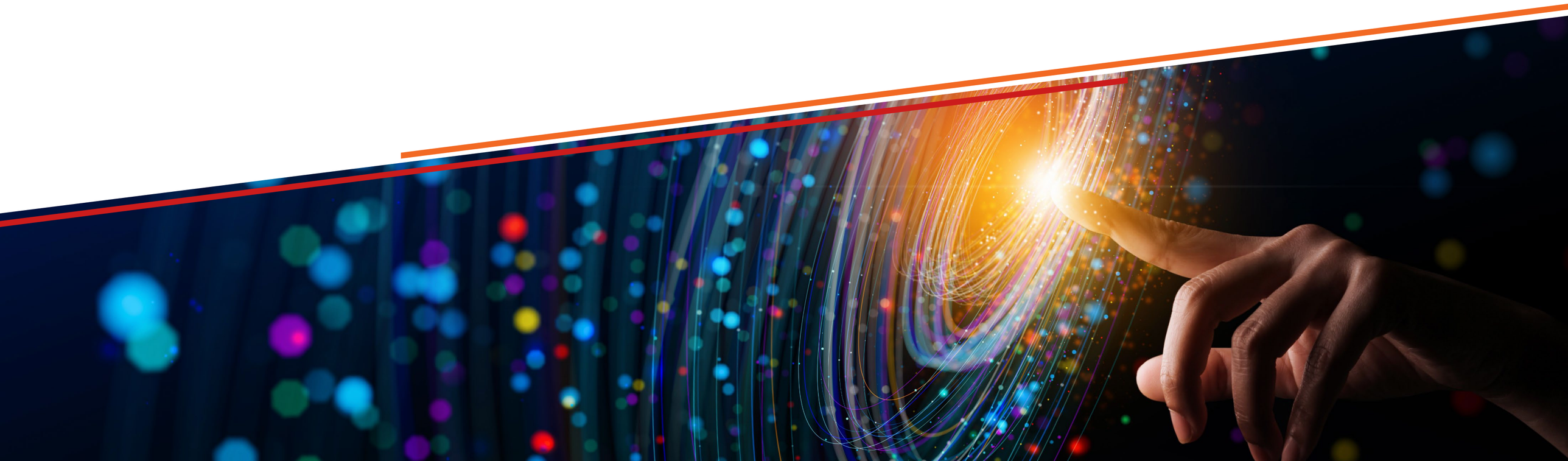
REIMAGINE YOUR POSSIBILITIES

PLM for Medical Device

Slavko Jovanovic

May 2023



Agenda

1. Why PLM for Medical Device
2. How are Medical Devices Companies Using PLM
3. Life without/pre Medical Device PLM
4. Medical Device with Aras PLM

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Why PLM Medical Device

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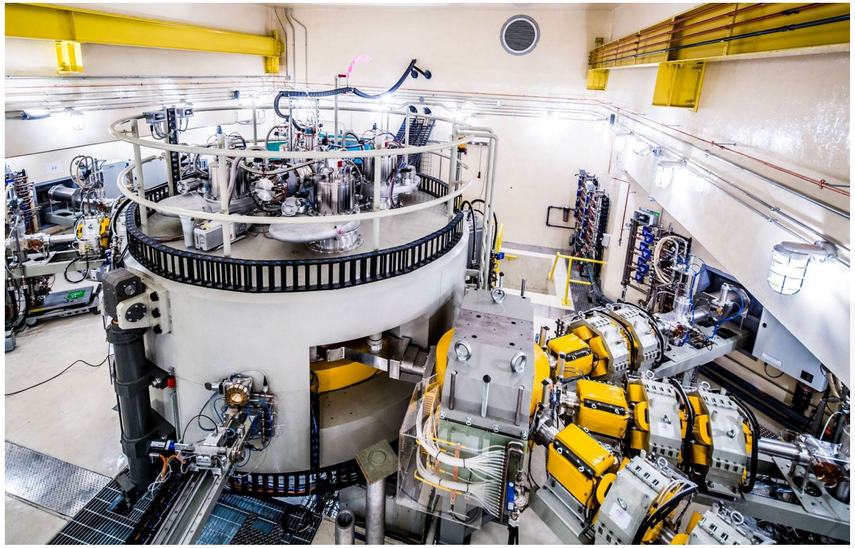
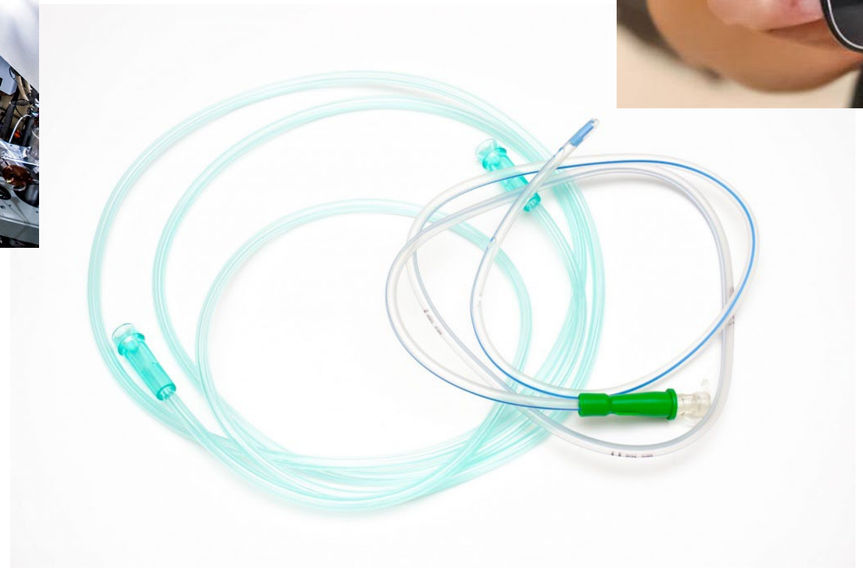
Medical Device Complexity and Diversity

- Diversity
  - Not a function of size.
  - Electromechanically devices with software.





Medical Device Regulatory Compliance

Design Control
- DHF
- Phase Gate & Design Review

CAPA Process
- Problem Reports
- Quality Service Request (root cause analysis)
- Change Orders

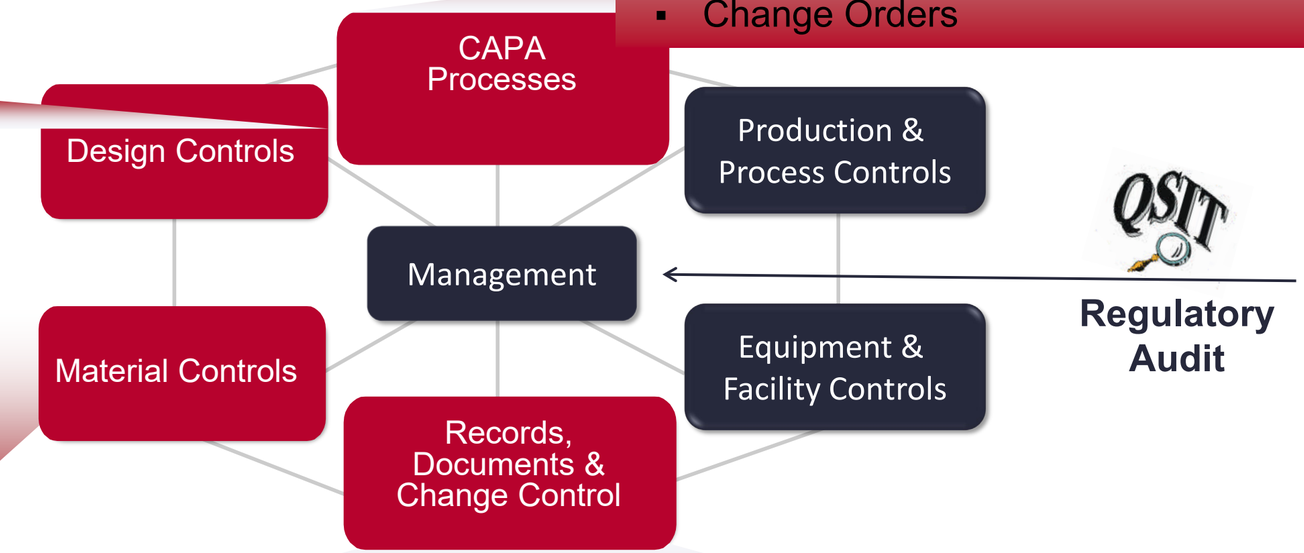
Quality System Regulation

FDA CFR Part 820

FDA CFR Part 11

ISO 14971

ISO 13485



Regulatory Audit

- Approved Manufacturers
- Vendors
- NCMR

Product Record

DHF Documents **DMR** **SOPs** **Process history/evidence** **Personnel Skills** **Quality Audits** **. . .**

How are companies using PLM for Medical Devices

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Use by Medical Device Customers

Carestream	Dräger	Edwards	Biotronik	Fujifilm
				
$2.4b	€2.1b	$3.4b	€487m	¥2.600
Medical and Dental Imaging	Hospital Portfolio	Structural Heart Disease (Class III)	Cardiovascular & Endovascular Solutions (Class III)	Diagnostic Imaging
DHF/DMR/UDI Global Change Control	DFH/DMR Global Change Control	UDI,EUDAMED, Jurisdiction Control	DFH/DMR Global Change Control	Global Product Development
Global New Product Development				
Announcement	Minerva Announcement	Announcement	Announcement	Fujifilm Selects Aras

Additional Medical Device Customers

Carestream

FUJIFILM MEDICAL SYSTEMS

auditdata
Your Partner in Audiology Solutions

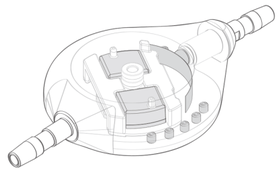
Vispero™

Carestream DENTAL

WEIBEL CDS AG
safer, easier and faster drug delivery

Dräger

BAUSCH + LOMB
See better. Live better.



SOPHYSA

TELEDYNE DALSA
A Teledyne Technologies Company

HASELMEIER
Drug Delivery. Tailormade.

NDI

Life without Medical Device PLM

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Stories from the Battlefield

How's that going to affect our financial quarter?

What are our highest paid engineers doing?

Idiot Savant

Stop the ~~presses~~ production we have an audit

Death by a thousand spreadsheets

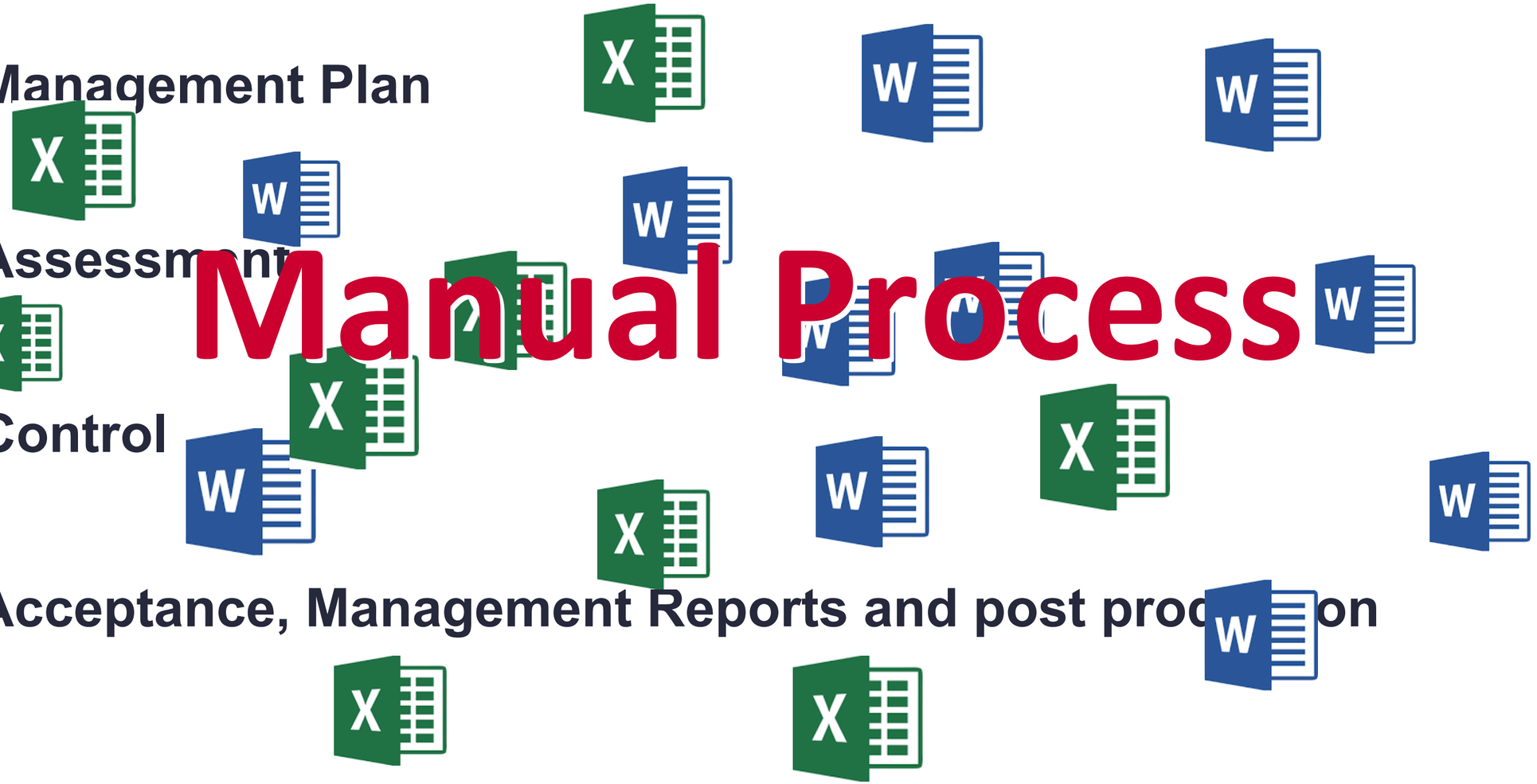
Typical Industry Practice

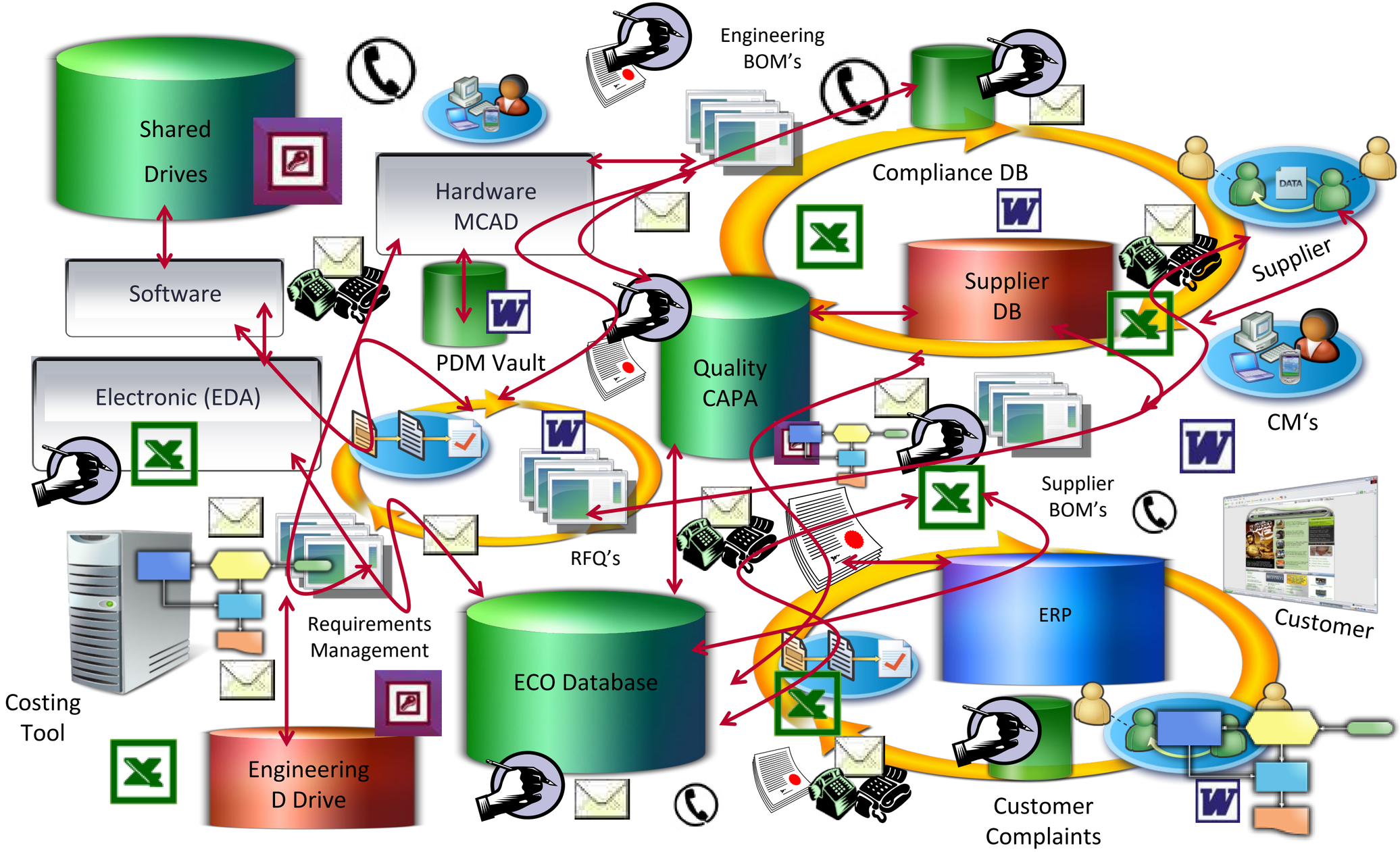
Risk Management Plan

Risk Assessment

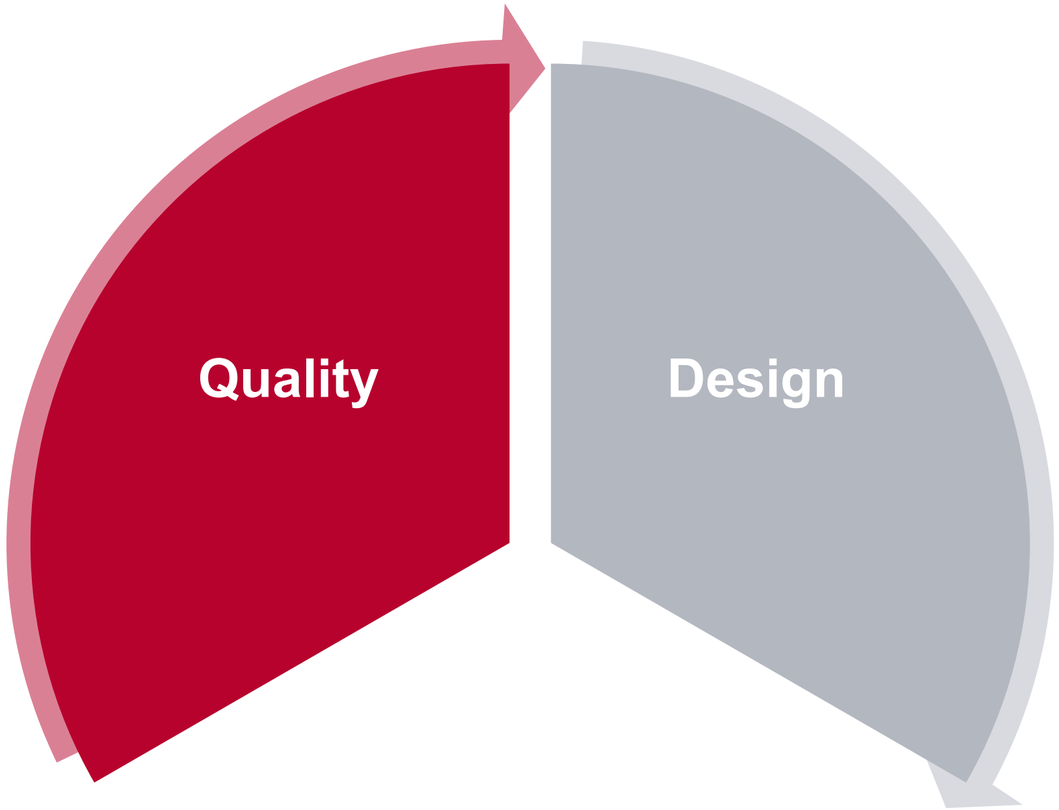
Risk Control

Risk Acceptance, Management Reports and post production



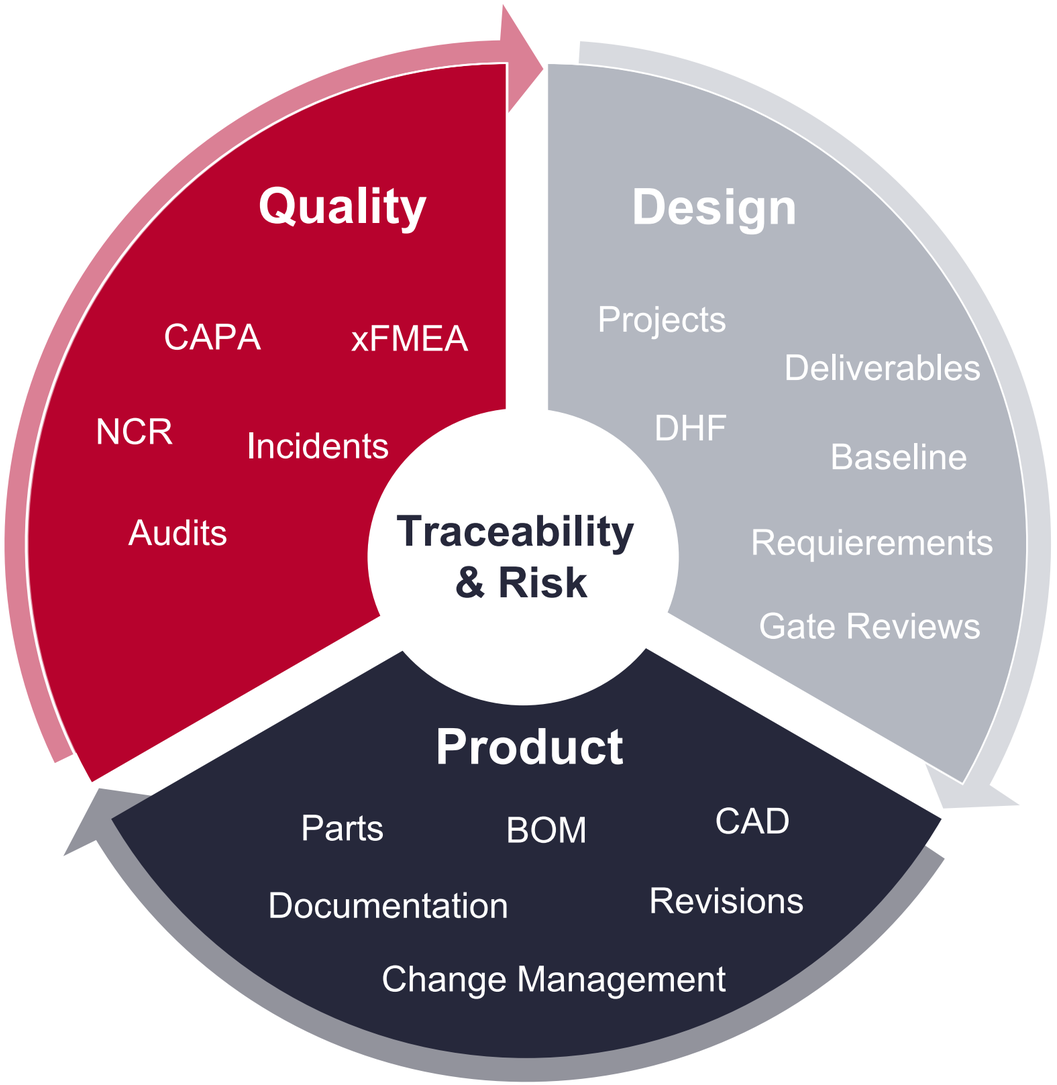

Engineering
BOM's
Shared
Drives
Hardware
MCAD
Compliance DB
Supplier
DB
Supplier
Software
PDM Vault
Quality
CAPA
Electronic (EDA)
CM's
Supplier
BOM's
RFQ's
Requirements
Management
ERP
Customer
Costing
Tool
ECO Database
Engineering
D Drive
Customer
Complaints

But I have a QMS System



Where is the product??

But I have a QMS System



Medical Device with PLM (Design Control)

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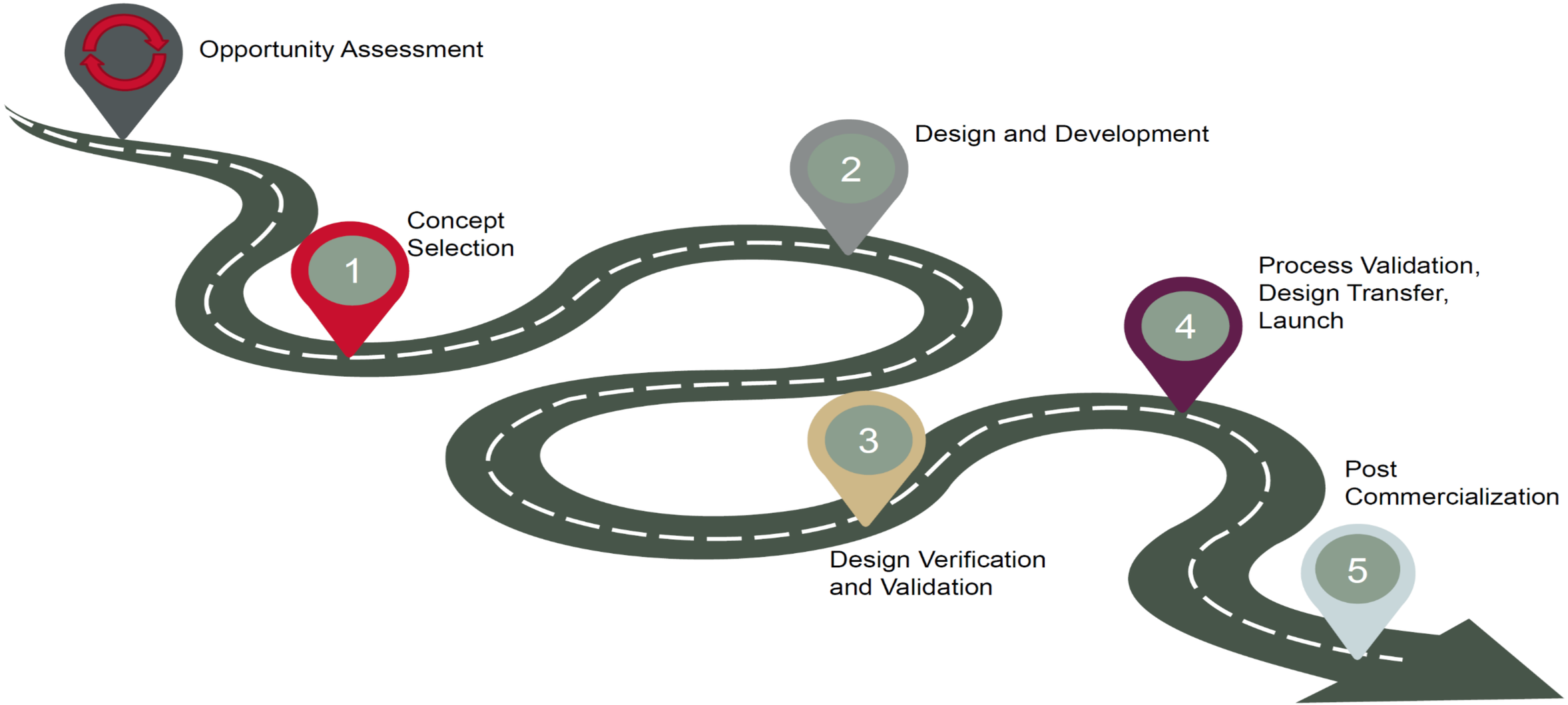
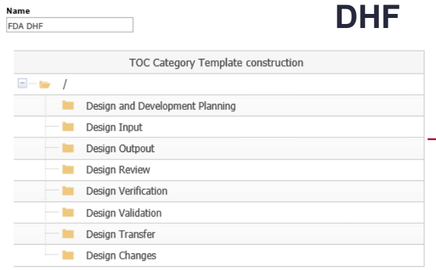
Medical Device Product Development Process (PDP)



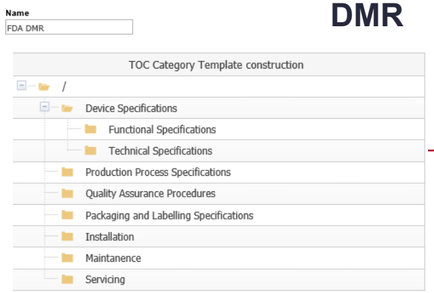
Medical Device PLM

Templates

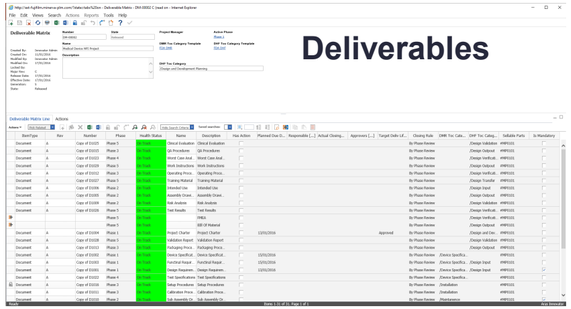
DHF



DMR

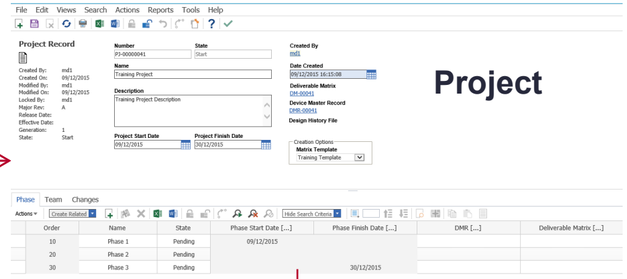


Deliverables

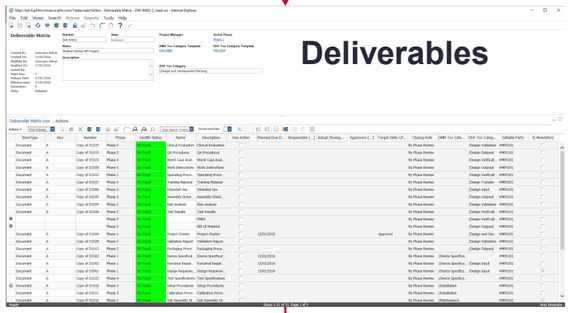


Instances

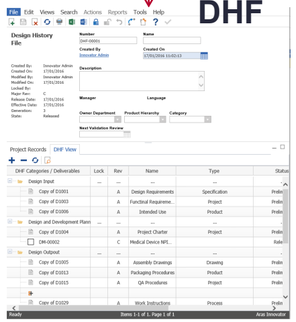
Project



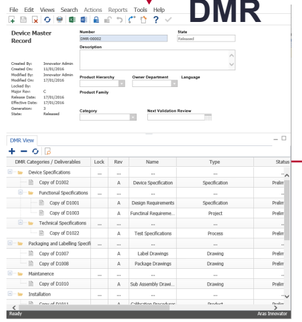
Deliverables



DHF

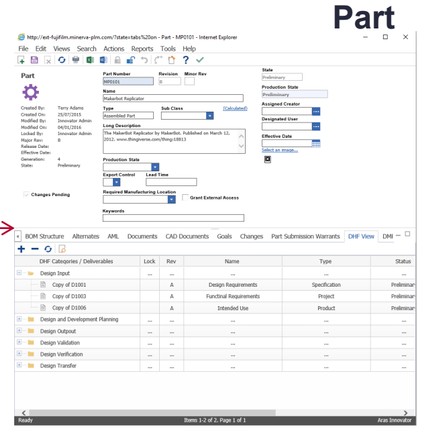


DMR



Product

Part



Medical Device with PLM (Risk Management)

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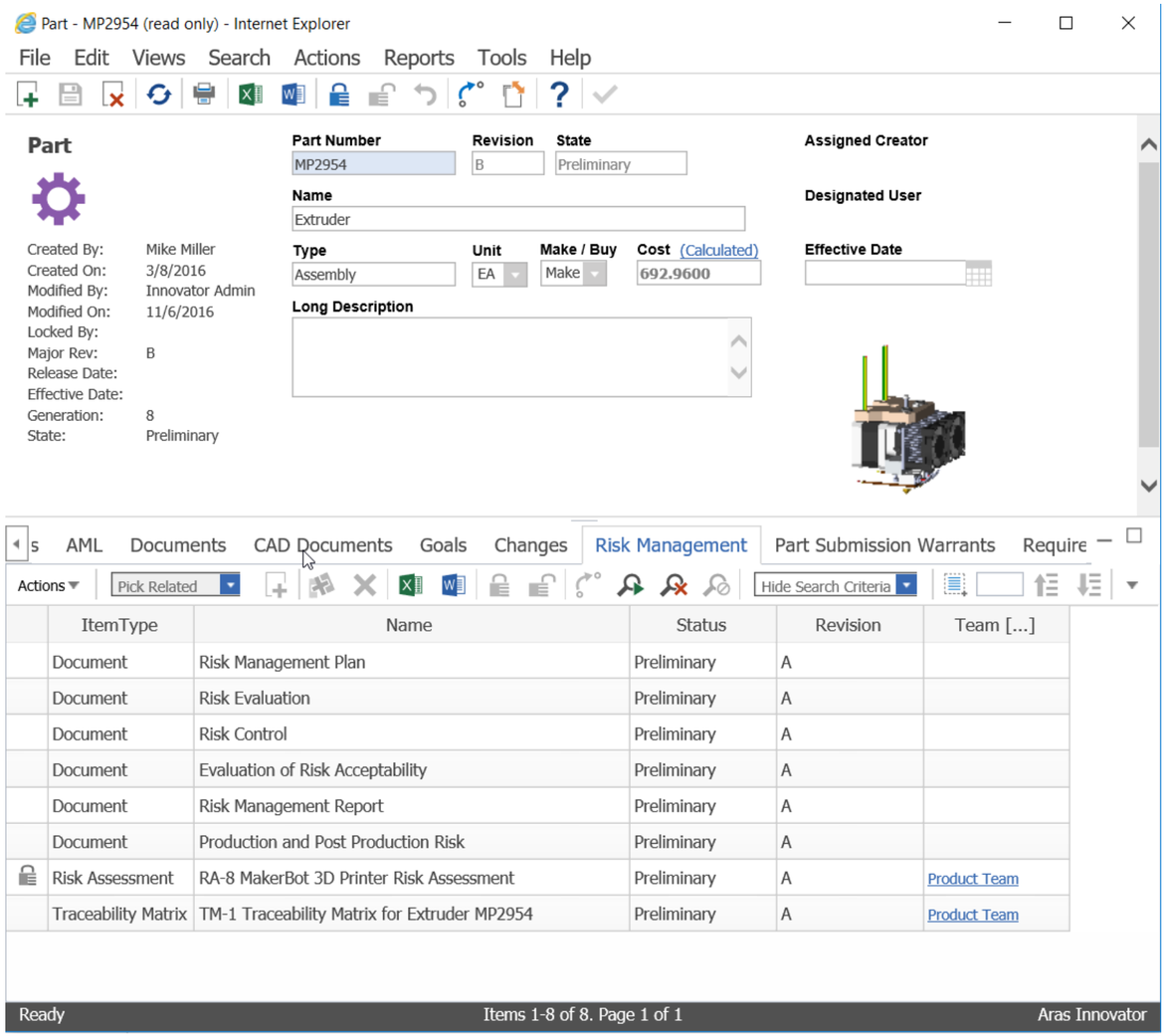
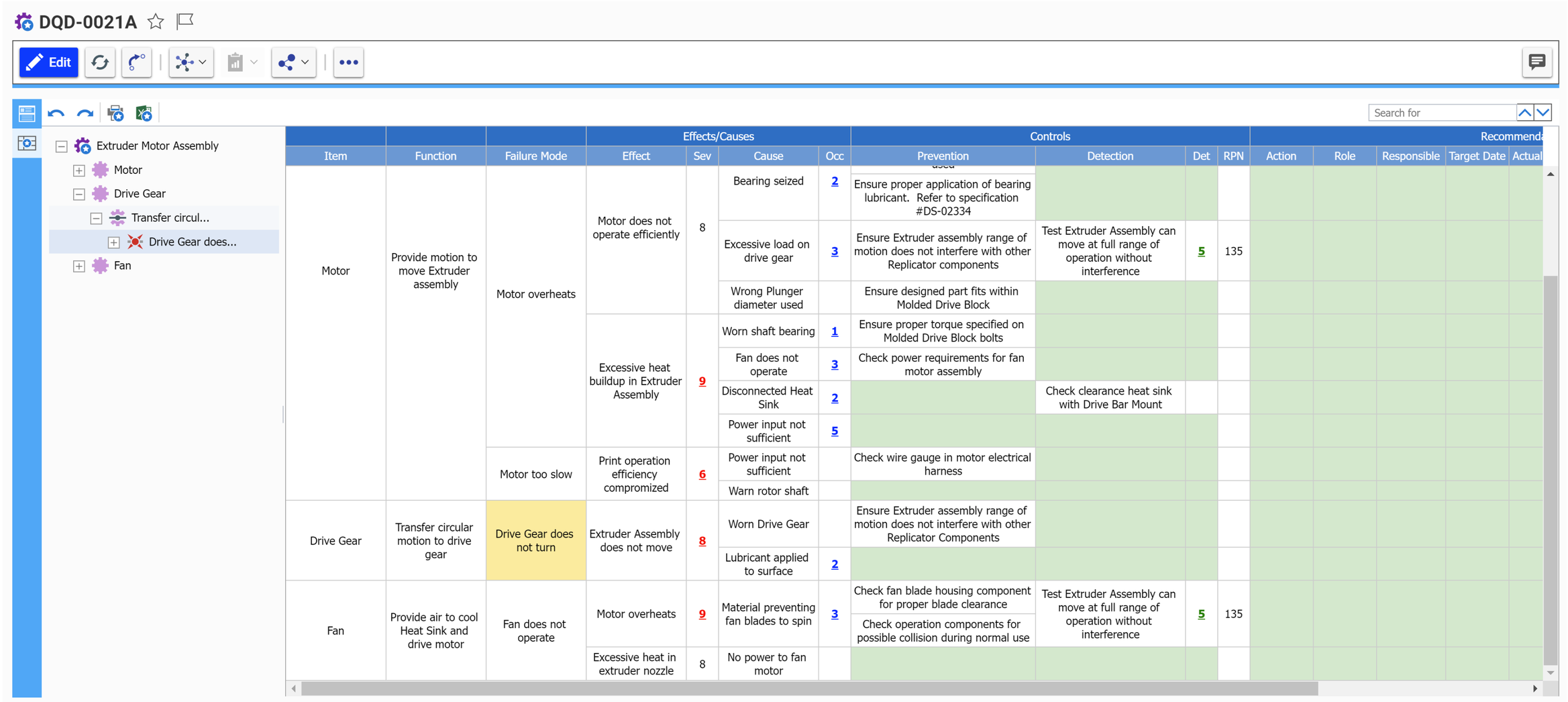
Risk Management

Risk Management File



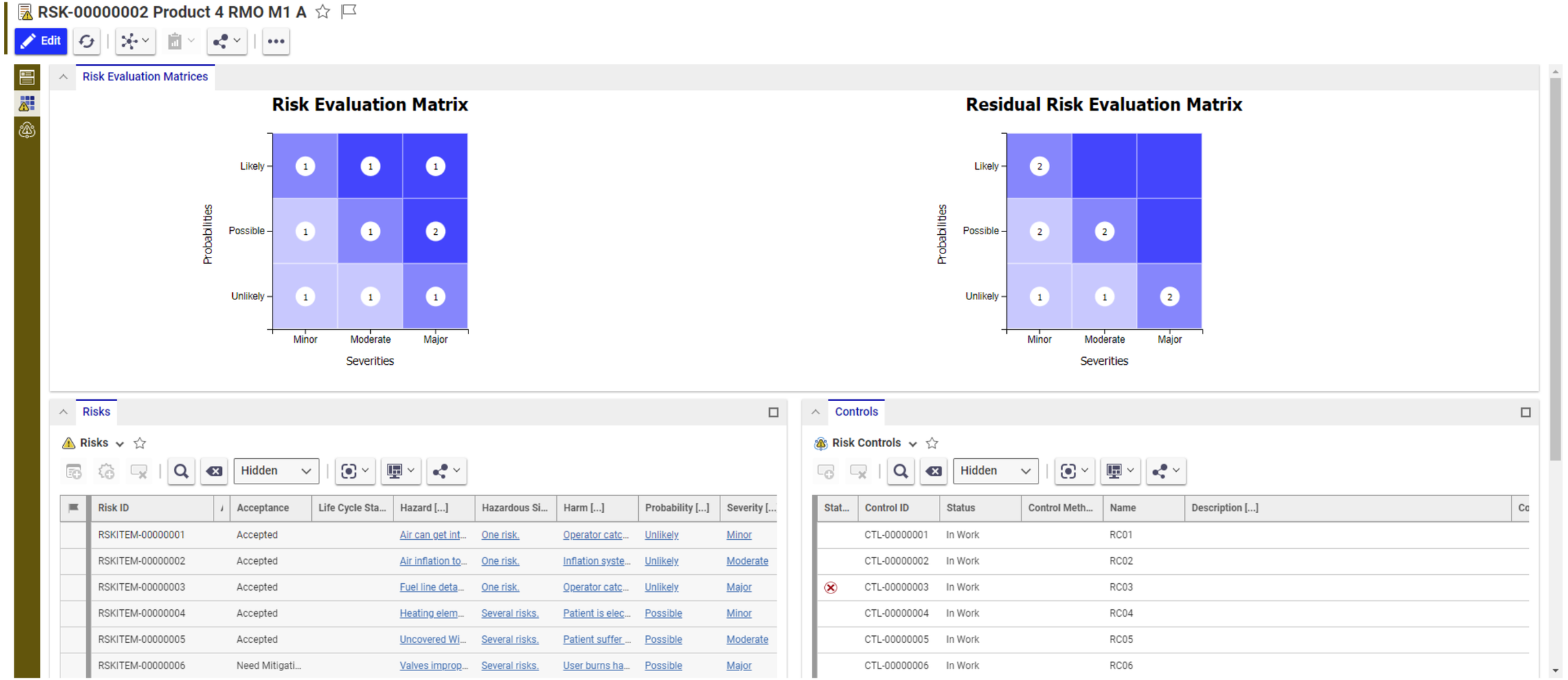
- Risk Management Plan
- Risk Analysis
- Risk Evaluation
- Risk Controls
- Evaluation of Overall Risk Acceptability
- Risk Management Report
- Production and Post-Production Risks

Risk Assessment (bottom up)



			Effects/Causes				Controls				Recommend				
Item	Function	Failure Mode	Effect	Sev	Cause	Occ	Prevention	Detection	Det	RPN	Action	Role	Responsible	Target Date	Actual
Motor	Provide motion to move Extruder assembly	Motor overheats	Motor does not operate efficiently	8	Bearing seized	2	Ensure proper application of bearing lubricant. Refer to specification #DS-02334								
					Excessive load on drive gear	3	Ensure Extruder assembly range of motion does not interfere with other Replicator components	Test Extruder Assembly can move at full range of operation without interference	5	135					
					Wrong Plunger diameter used		Ensure designed part fits within Molded Drive Block								
			Excessive heat buildup in Extruder Assembly	9	Worn shaft bearing	1	Ensure proper torque specified on Molded Drive Block bolts								
					Fan does not operate	3	Check power requirements for fan motor assembly								
					Disconnected Heat Sink	2		Check clearance heat sink with Drive Bar Mount							
					Power input not sufficient	5									
		Motor too slow	Print operation efficiency compromized	6	Power input not sufficient		Check wire gauge in motor electrical harness								
					Warn rotor shaft										
Drive Gear	Transfer circular motion to drive gear	Drive Gear does not turn	Extruder Assembly does not move	8	Worn Drive Gear		Ensure Extruder assembly range of motion does not interfere with other Replicator Components								
					Lubricant applied to surface	2									
Fan	Provide air to cool Heat Sink and drive motor	Fan does not operate	Motor overheats	9	Material preventing fan blades to spin	3	Check fan blade housing component for proper blade clearance	Test Extruder Assembly can move at full range of operation without interference	5	135					
							Check operation components for possible collision during normal use								
			Excessive heat in extruder nozzle	8	No power to fan motor										

Risk Assessment (top down)



Medical Device with PLM (Training Records & LMS)

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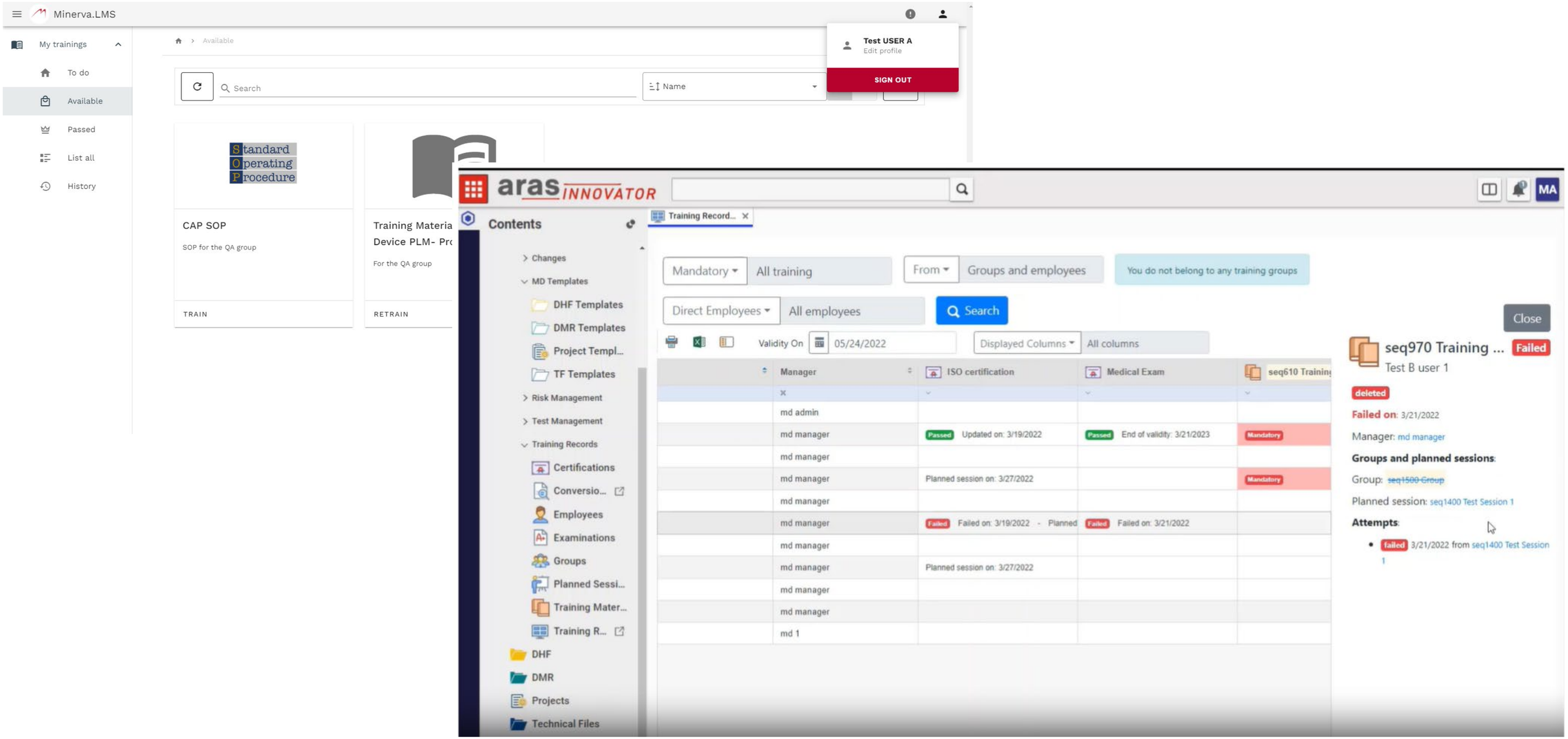
Training Records and LMS



Medical Device with PLM (Verification and Validation)

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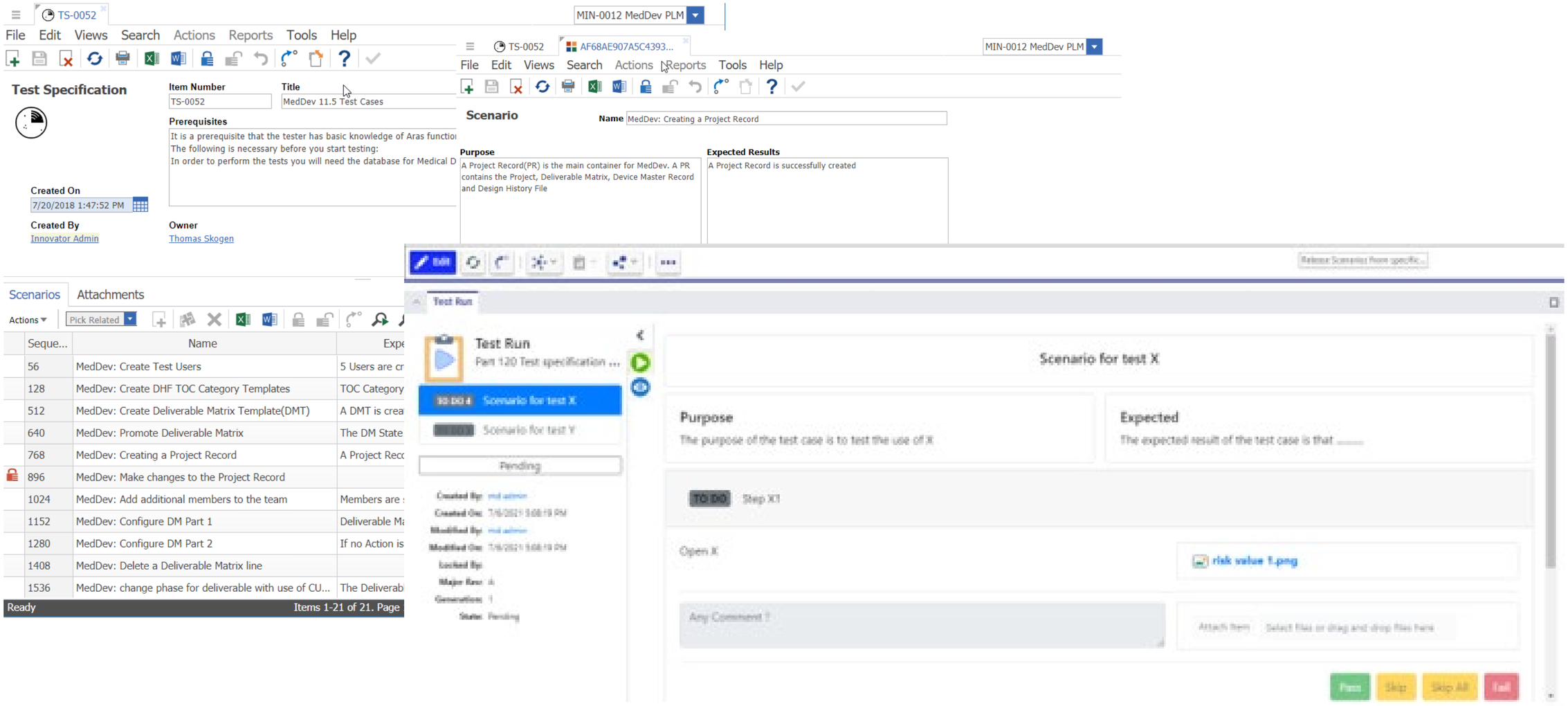
Verification and Validation



Medical Device with PLM (Traceability)

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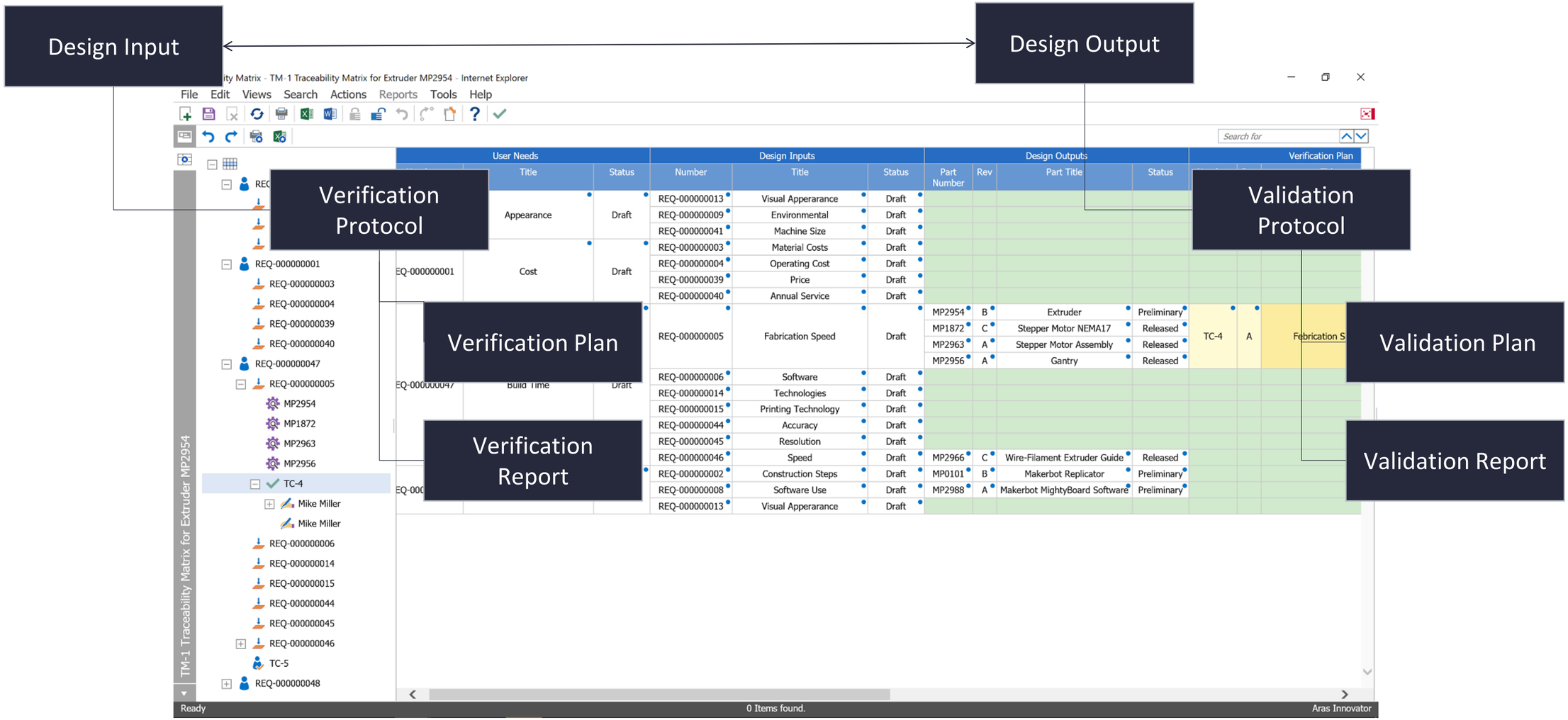
Traceability Matrix



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LEAVE A REVIEW!

Thank You!

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