

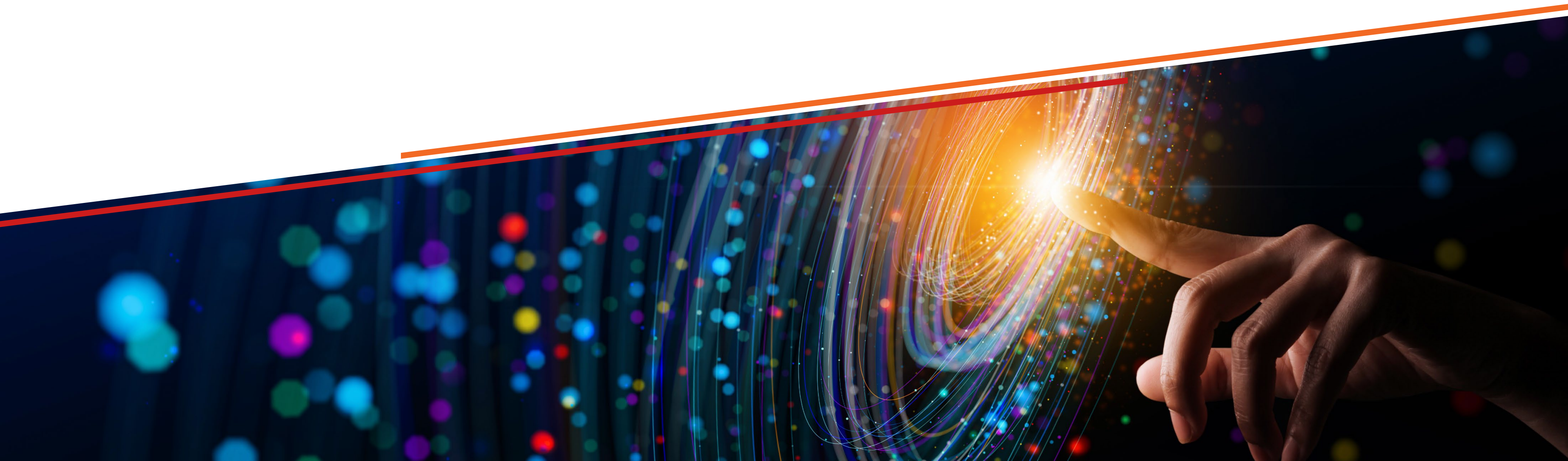
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REIMAGINE YOUR POSSIBILITIES

PLM for Medical Device

Slavko Jovanovic

May 2023



Agenda

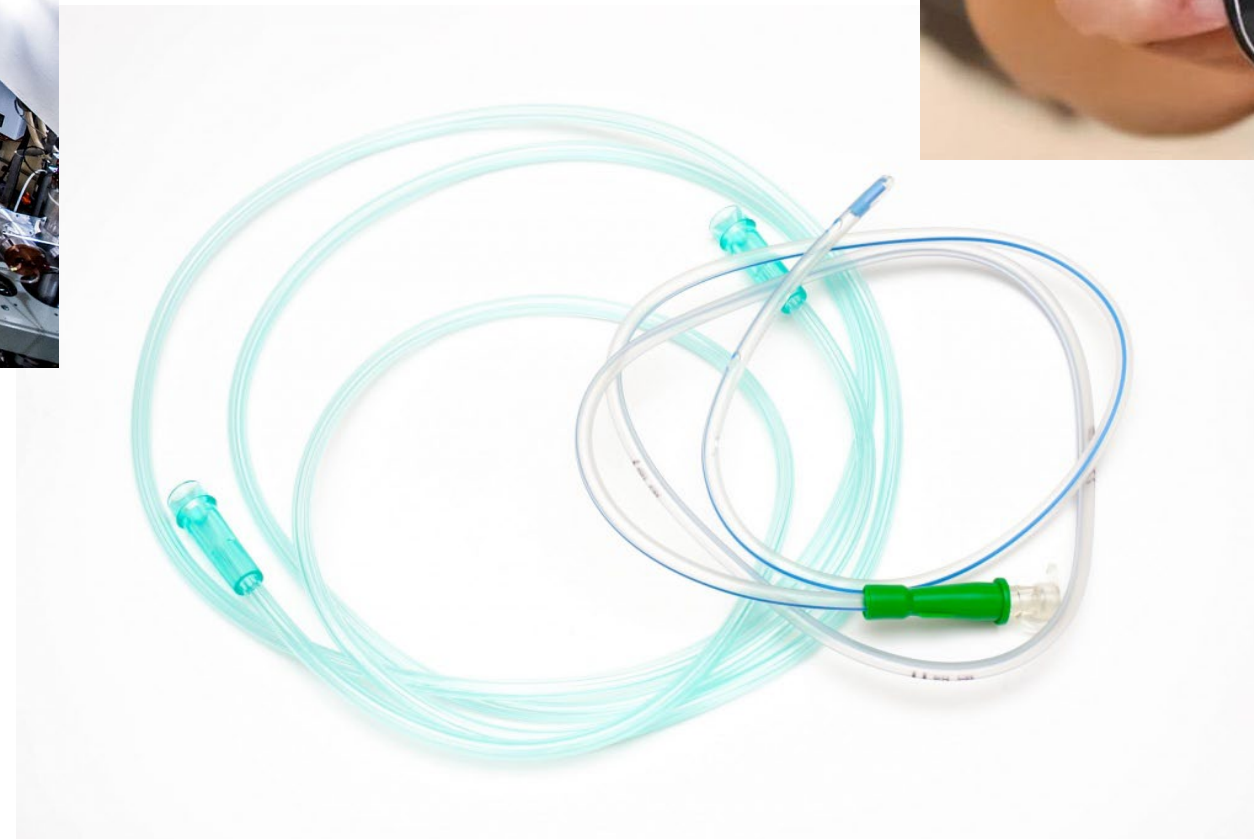
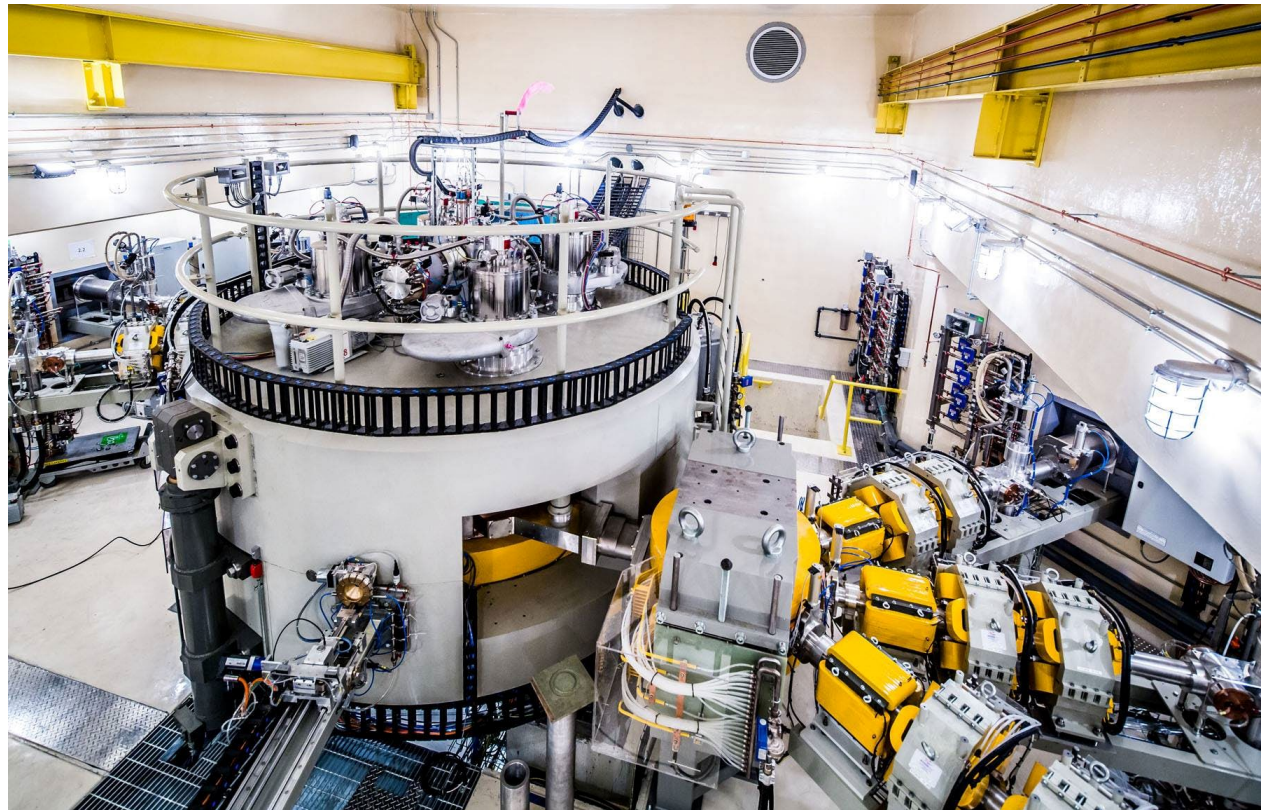
1. Why PLM for Medical Device
2. How are Medical Devices Companies Using PLM
3. Life without/pre Medical Device PLM
4. Medical Device with Aras PLM



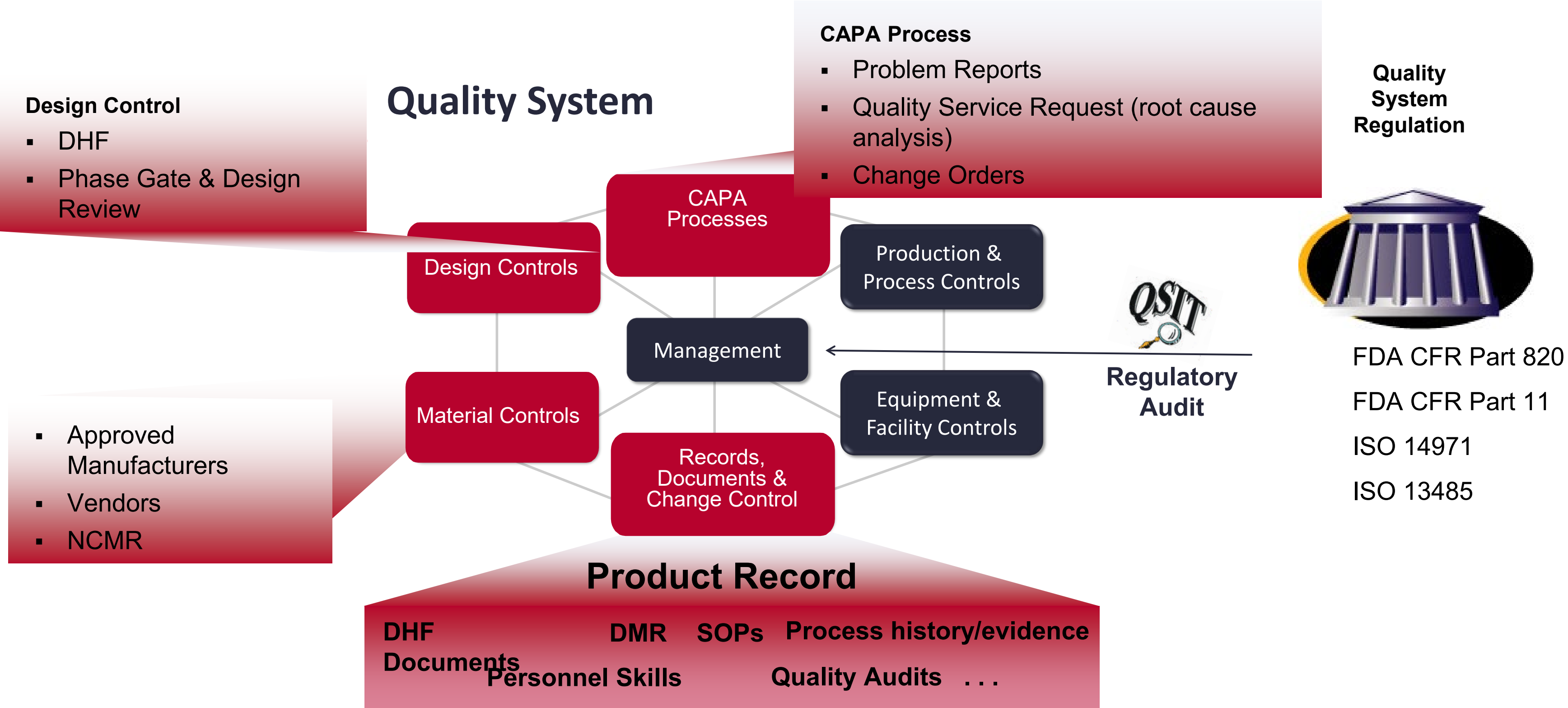
Why PLM Medical Device

Medical Device Complexity and Diversity

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



Medical Device Regulatory Compliance








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				
<u>Announcement</u>	<u>Minerva Announcement</u>	<u>Announcement</u>	<u>Announcement</u>	<u>Fujifilm Selects Aras</u>

Additional Medical Device Customers



Carestream



FUJIFILM
MEDICAL SYSTEMS



auditdata
Your Partner in Audiology Solutions



Vispero™



Carestream
DENTAL



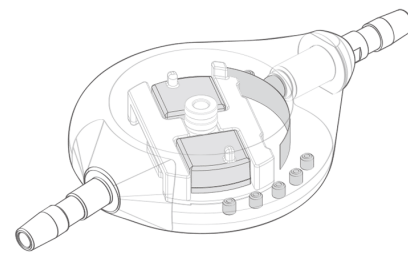
WEIBEL CDS AG
safer, easier and faster drug delivery



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



Manual Process

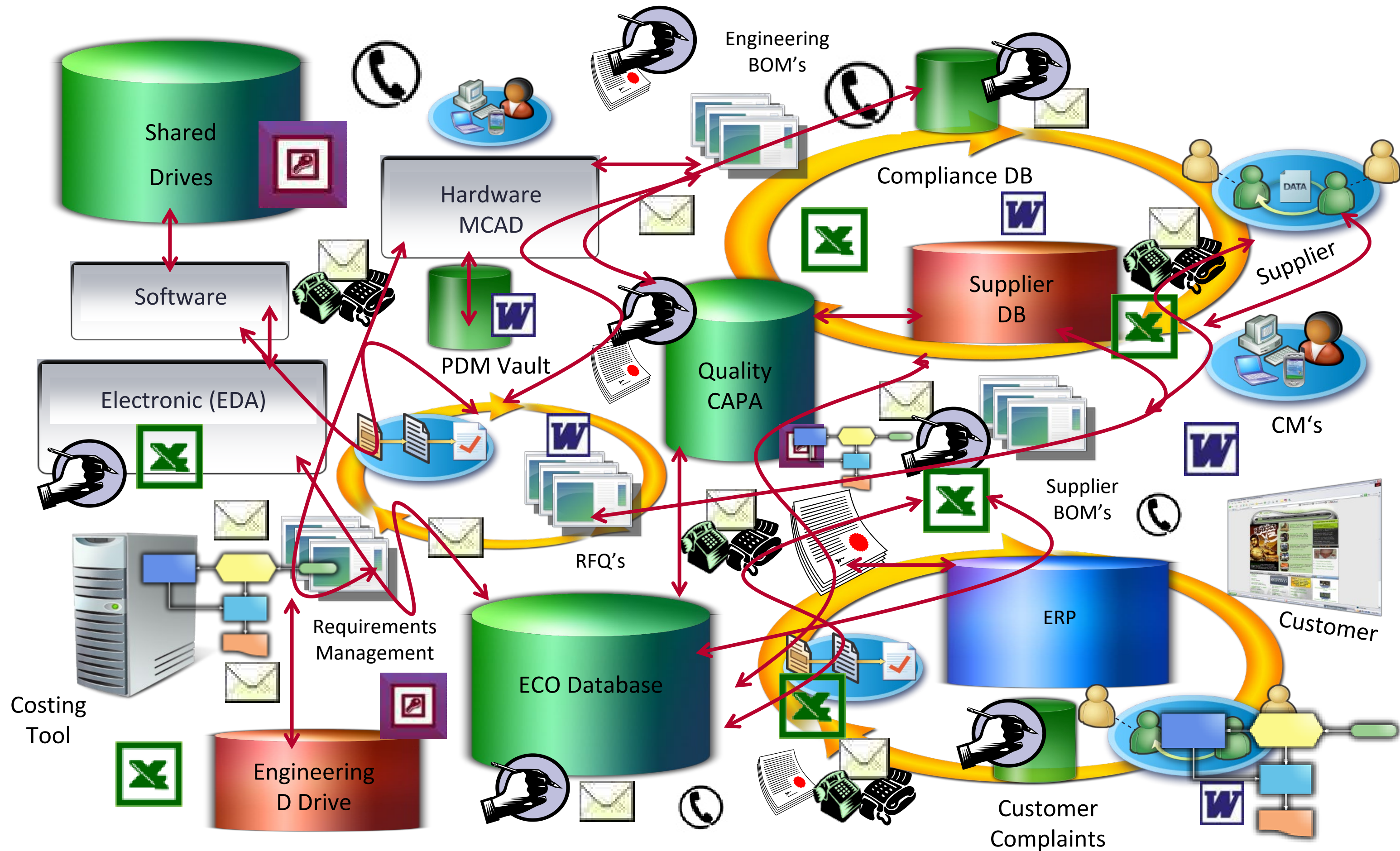


Risk Control

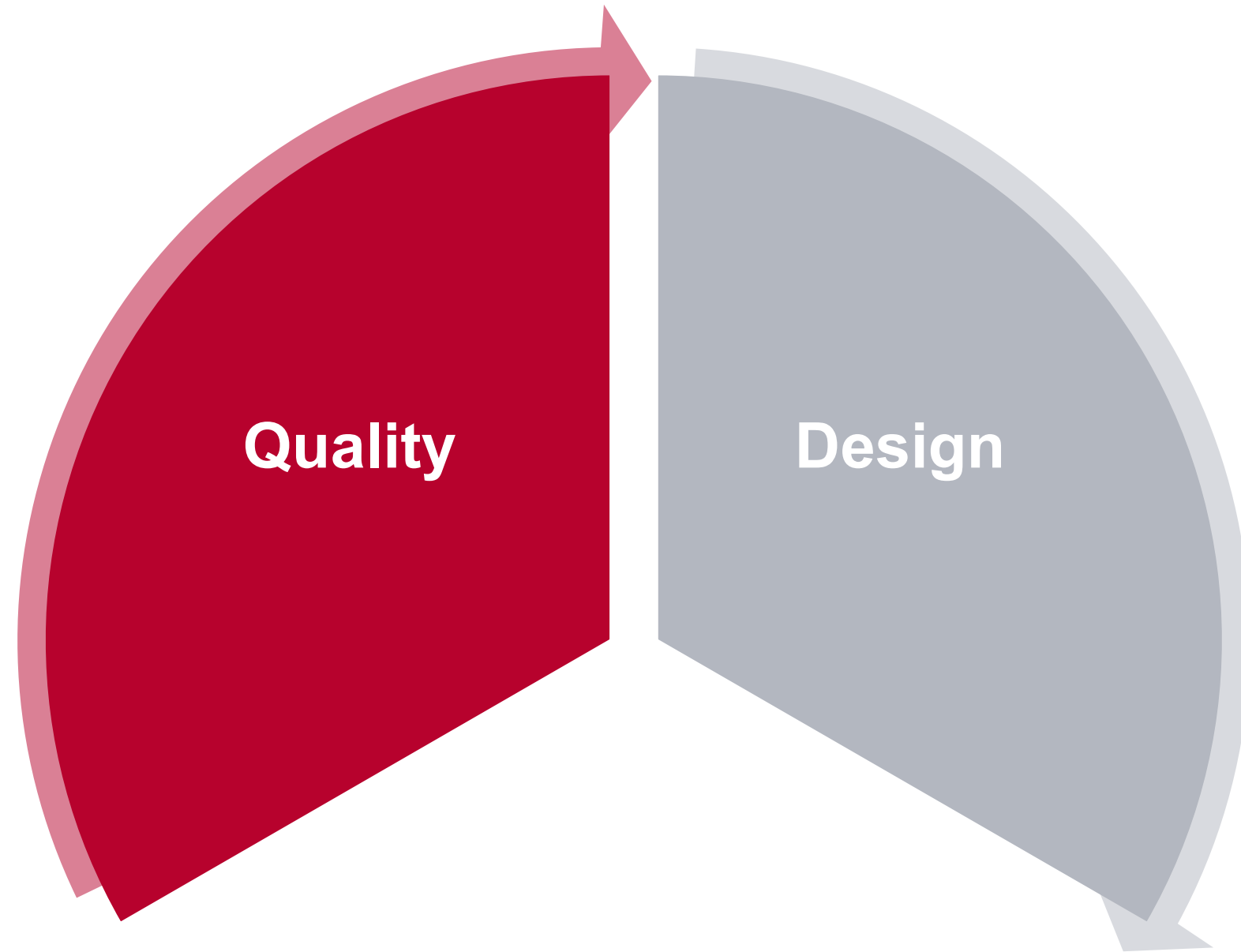


Risk Acceptance, Management Reports and post production



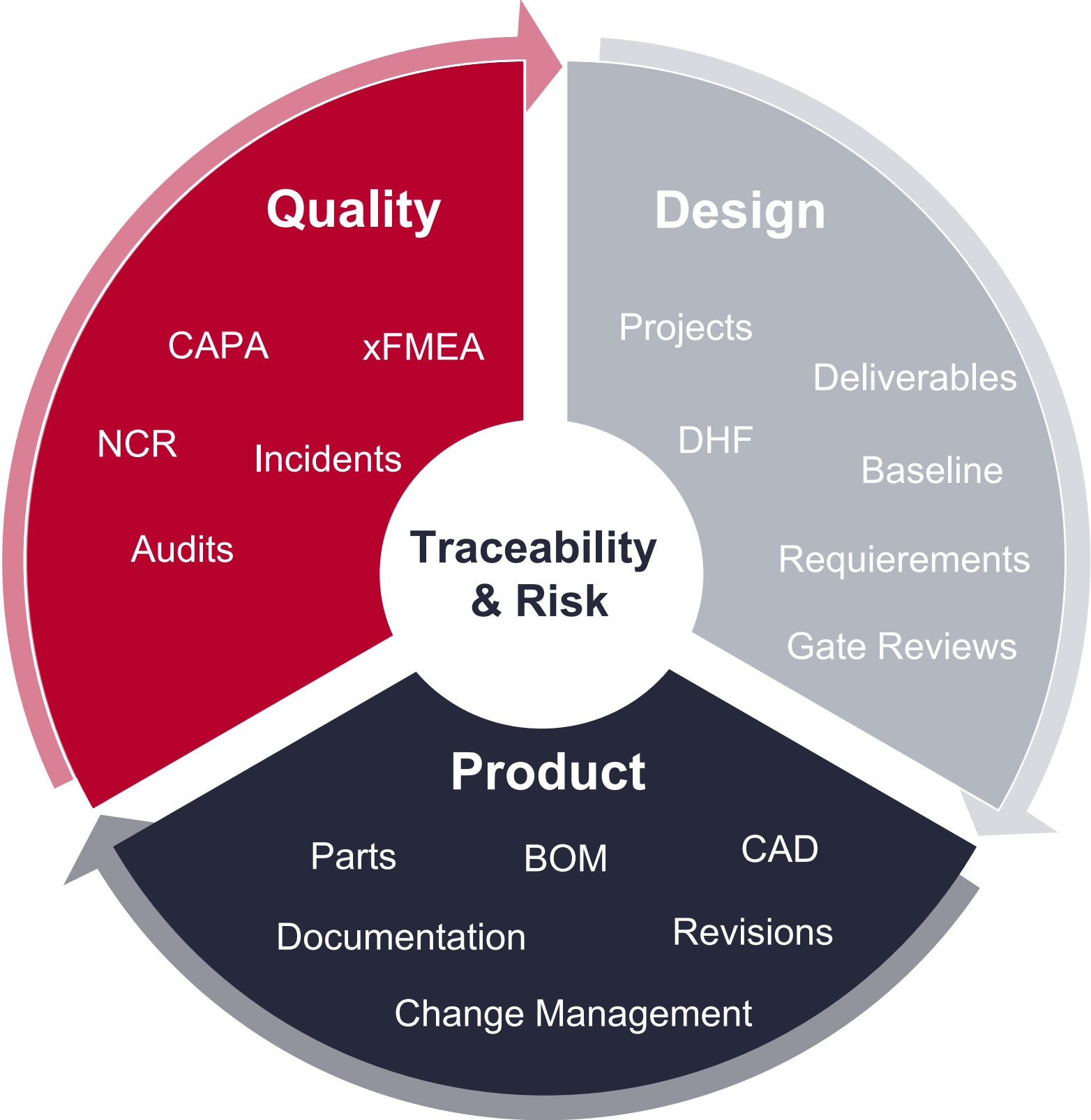


But I have a QMS System



Where is the product??

But I have a QMS System

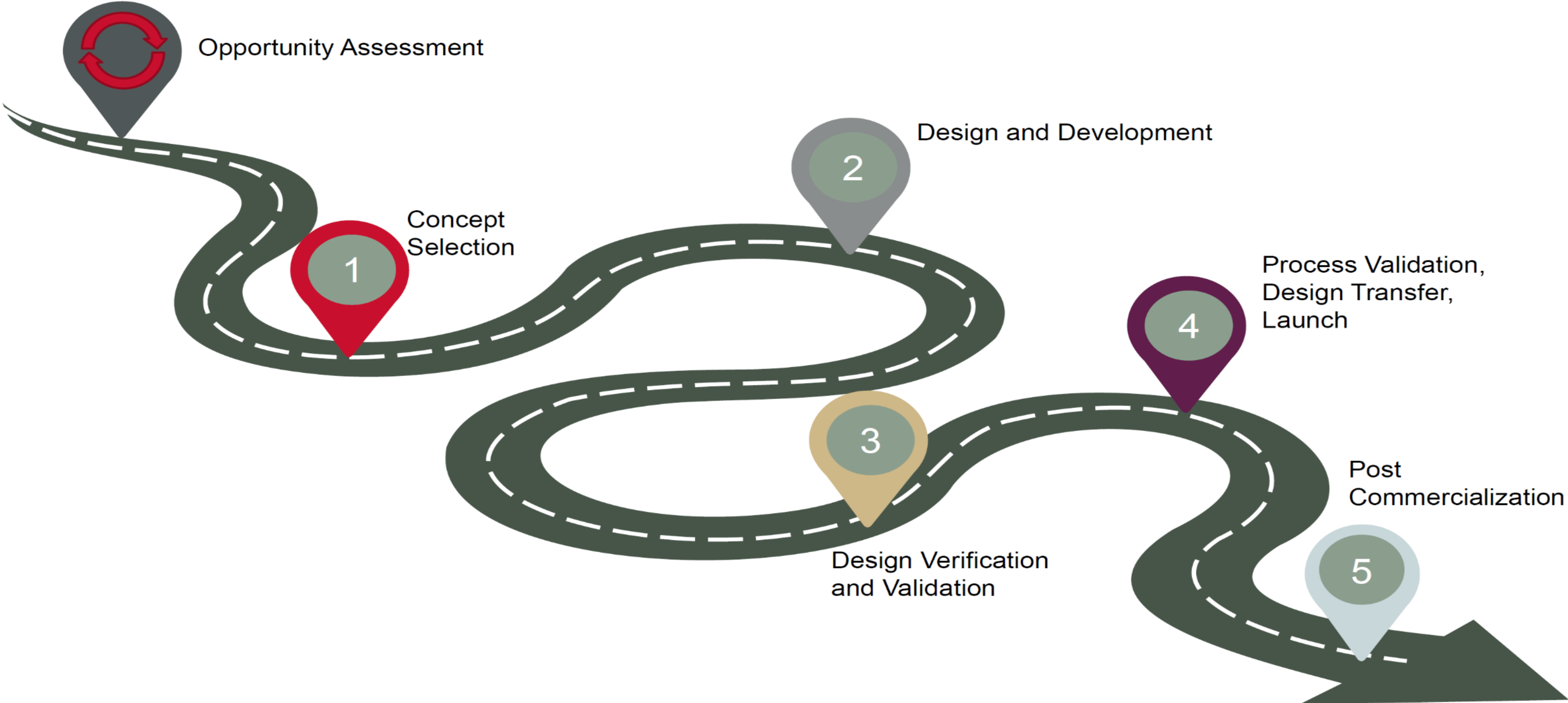


Medical Device with PLM (Design Control)

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Medical Device Product Development Process (PDP)



Medical Device PLM

Templates

Instances

Product

Name
FDA DHF

DHF

TOC Category Template construction

- Design and Development Planning
- Design Input
- Design Output
- Design Review
- Design Verification
- Design Validation
- Design Transfer
- Design Changes

Name
FDA DMR

DMR

TOC Category Template construction

- Device Specifications
 - Functional Specifications
 - Technical Specifications
- Production Process Specifications
- Quality Assurance Procedures
- Packaging and Labelling Specifications
- Installation
- Maintenance
- Servicing

Project Record

Number: 99-00000941
State: Start
Created By: mdi
Date Created: 09/12/2015 16:15:08
Description: Training Project Description
Project Start Date: 09/12/2015
Project Finish Date: 09/12/2015

Project

Order	Name	State	Phase Start Date [...]	Phase Finish Date [...]	DMR [...]	Deliverable Matrix [...]
10	Phase 1	Pending	09/12/2015			
20	Phase 2	Pending				
30	Phase 3	Pending		30/12/2015		

Deliverable Matrix

Deliverable	Rev	Phase	State	Project Manager	Action Phase
Design Input	1	Phase 1	Approved
Design Output	1	Phase 2	Approved
Design Verification	1	Phase 3	Approved
Design Validation	1	Phase 4	Approved
Design Transfer	1	Phase 5	Approved
Design Changes	1	Phase 6	Approved

Part

Part Number: 000001
Name: Design Input
Type: Design Input
Sub Class: Design Input

DHF Categories / Deliverables	Lock	Rev	Name	Type	Status
Design Input	---	---	Design Requirements	Specification	Preliminary
Copy of D1001	A	A	Functional Requirements	Project	Preliminary
Copy of D1006	A	A	Intended Use	Product	Preliminary
Design and Development Planning	---	---	---
Design Output	---	---	---
Design Verification	---	---	---
Design Validation	---	---	---
Design Transfer	---	---	---
Design Changes	---	---	---

Deliverable Matrix

Deliverable	Rev	Phase	State	Project Manager	Action Phase
Design Input	1	Phase 1	Approved
Design Output	1	Phase 2	Approved
Design Verification	1	Phase 3	Approved
Design Validation	1	Phase 4	Approved
Design Transfer	1	Phase 5	Approved
Design Changes	1	Phase 6	Approved

DHF

Design History File

Number: 000-0001
Created On: 07/07/2016 10:40:13
Description: ...

Project Records	DHF View
Design Input	---
Copy of D1001	A
Copy of D1006	A
Design and Development Planning	---
Copy of D1001	A
Copy of D1006	A
Design Output	---
Copy of D1001	A
Copy of D1006	A
Design Verification	---
Copy of D1001	A
Copy of D1006	A
Design Validation	---
Copy of D1001	A
Copy of D1006	A
Design Transfer	---
Copy of D1001	A
Copy of D1006	A
Design Changes	---
Copy of D1001	A
Copy of D1006	A

DMR

Device Master Record

Number: 000-0001
Created On: 07/07/2016 10:40:13
Description: ...

DHF Categories / Deliverables	Lock	Rev	Name	Type	Status
Design Input	---	---	Design Requirements	Specification	Preliminary
Copy of D1001	A	A	Functional Requirements	Project	Preliminary
Copy of D1006	A	A	Intended Use	Product	Preliminary
Design and Development Planning	---	---	---
Design Output	---	---	---
Design Verification	---	---	---
Design Validation	---	---	---
Design Transfer	---	---	---
Design Changes	---	---	---

Medical Device with PLM (Risk Management)

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Risk Management



Risk Management File

Part - MP2954 (read only) - Internet Explorer

File Edit Views Search Actions Reports Tools Help

Part

Part Number: MP2954 Revision: B State: Preliminary

Name: Extruder

Type: Assembly Unit: EA Make / Buy: Make Cost (Calculated): 692.9600

Long Description:

Assigned Creator:

Designated User:

Effective Date:

Created By: Mike Miller
 Created On: 3/8/2016
 Modified By: Innovator Admin
 Modified On: 11/6/2016
 Locked By:
 Major Rev: B
 Release Date:
 Effective Date:
 Generation: 8
 State: Preliminary

AML Documents CAD Documents Goals Changes Risk Management Part Submission Warrants Require

Item Type	Name	Status	Revision	Team [...]
Document	Risk Management Plan	Preliminary	A	
Document	Risk Evaluation	Preliminary	A	
Document	Risk Control	Preliminary	A	
Document	Evaluation of Risk Acceptability	Preliminary	A	
Document	Risk Management Report	Preliminary	A	
Document	Production and Post Production Risk	Preliminary	A	
Risk Assessment	RA-8 MakerBot 3D Printer Risk Assessment	Preliminary	A	Product Team
Traceability Matrix	TM-1 Traceability Matrix for Extruder MP2954	Preliminary	A	Product Team

Ready Items 1-8 of 8. Page 1 of 1 Aras Innovator

- 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)

DQD-0021A ☆

Edit ↻ 🔍 📄 📊 🗑️ 📄 📄 🗑️

Search for

Item	Function	Failure Mode	Effects/Causes			Controls				Recommendations						
			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									
					Worn shaft bearing	1	Ensure proper torque specified on Molded Drive Block bolts									
		Excessive heat buildup in Extruder Assembly	9			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	6	Print operation efficiency compromised	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						
			Excessive heat in extruder nozzle	8	No power to fan motor											

Risk Assessment (top down)

RSK-0000002 Product 4 RMO M1 A ☆

Edit [Refresh] [Share] [More]

Risk Evaluation Matrices

Risk Evaluation Matrix

Likely	1	1	1
Possible	1	1	2
Unlikely	1	1	1
	Minor	Moderate	Major

Probabilities (y-axis), Severities (x-axis)

Residual Risk Evaluation Matrix

Likely	2		
Possible	2	2	
Unlikely	1	1	2
	Minor	Moderate	Major

Probabilities (y-axis), Severities (x-axis)

Risks

Risk ID	Acceptance	Life Cycle Sta...	Hazard [...]	Hazardous Si...	Harm [...]	Probability [...]	Severity [...]
RSKITEM-00000001	Accepted		Air can get int...	One risk.	Operator catc...	Unlikely	Minor
RSKITEM-00000002	Accepted		Air inflation to...	One risk.	Inflation syste...	Unlikely	Moderate
RSKITEM-00000003	Accepted		Fuel line deta...	One risk.	Operator catc...	Unlikely	Major
RSKITEM-00000004	Accepted		Heating elem...	Several risks.	Patient is elec...	Possible	Minor
RSKITEM-00000005	Accepted		Uncovered Wi...	Several risks.	Patient suffer ...	Possible	Moderate
RSKITEM-00000006	Need Mitigati...		Valves improp...	Several risks.	User burns ha...	Possible	Major

Controls

Stat...	Control ID	Status	Control Meth...	Name	Description [...]	Co
	CTL-00000001	In Work		RC01		
	CTL-00000002	In Work		RC02		
⊗	CTL-00000003	In Work		RC03		
	CTL-00000004	In Work		RC04		
	CTL-00000005	In Work		RC05		
	CTL-00000006	In Work		RC06		

Medical Device with PLM (Training Records & LMS)

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Training Records and LMS

The image displays two overlapping software interfaces. The background interface is Minerva.LMS, showing a sidebar with 'My trainings' (To do, Available, Passed, List all, History) and a main content area with a search bar and a document titled 'Standard Operating Procedure'. The foreground interface is aras INNOVATOR, showing a 'Contents' sidebar with categories like 'Changes', 'MD Templates', 'Risk Management', 'Test Management', and 'Training Records'. The main area of aras INNOVATOR displays a 'Training Record...' table with filters for 'Mandatory', 'All training', and 'Direct Employees'. A table of records is shown with columns for Manager, ISO certification, Medical Exam, and seq610 Training. A right-hand panel provides details for a specific record, including 'seq970 Training ... Failed', 'Test B user 1', 'Failed on: 3/21/2022', and 'Attempts: 1'.

Manager	ISO certification	Medical Exam	seq610 Training
x			
md admin			
md manager	Passed Updated on: 3/19/2022	Passed End of validity: 3/21/2023	Mandatory
md manager			
md manager	Planned session on: 3/27/2022		Mandatory
md manager			
md manager	Failed Failed on: 3/19/2022 - Planned	Failed Failed on: 3/21/2022	
md manager			
md manager	Planned session on: 3/27/2022		
md manager			
md manager			
md 1			

Medical Device with PLM (Verification and Validation)

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Verification and Validation

The screenshot displays the Aras MedDev PLM interface, divided into several key sections:

- Test Specification:** Shows details for item TS-0052, titled "MedDev 11.5 Test Cases". It includes prerequisites, a scenario name "MedDev: Creating a Project Record", a purpose, and expected results.
- Scenarios Table:** A list of scenarios with columns for sequence number, name, and expected results.

Seque...	Name	Expe
56	MedDev: Create Test Users	5 Users are cr
128	MedDev: Create DHF TOC Category Templates	TOC Category
512	MedDev: Create Deliverable Matrix Template(DMT)	A DMT is crea
640	MedDev: Promote Deliverable Matrix	The DM State
768	MedDev: Creating a Project Record	A Project Recc
896	MedDev: Make changes to the Project Record	
1024	MedDev: Add additional members to the team	Members are :
1152	MedDev: Configure DM Part 1	Deliverable Ma
1280	MedDev: Configure DM Part 2	If no Action is
1408	MedDev: Delete a Deliverable Matrix line	
1536	MedDev: change phase for deliverable with use of CU...	The Deliverab
- Test Run:** A detailed view of a specific test run, showing its status as "Pending", creation/modification dates, and a list of steps (e.g., "Scenario for test X", "Scenario for test Y").
- Scenario for test X:** A detailed view of a scenario, including its purpose, expected results, and a list of steps (e.g., "Step X1").

Medical Device with PLM (Traceability)

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Traceability Matrix

Design Input

Design Output

ity Matrix - TM-1 Traceability Matrix for Extruder MP2954 - Internet Explorer

File Edit Views Search Actions Reports Tools Help

- REQ-00000001
- REQ-00000003
- REQ-00000004
- REQ-00000039
- REQ-00000040
- REQ-00000047
- REQ-00000005
- MP2954
- MP1872
- MP2963
- MP2956
- TC-4
- Mike Miller
- Mike Miller
- REQ-00000006
- REQ-00000014
- REQ-00000015
- REQ-00000044
- REQ-00000045
- REQ-00000046
- TC-5
- REQ-00000048

User Needs		Design Inputs			Design Outputs				Verification Plan			
Title	Status	Number	Title	Status	Part Number	Rev	Part Title	Status				
Appearance	Draft	REQ-00000013	Visual Apperance	Draft								
		REQ-00000009	Environmental	Draft								
		REQ-00000041	Machine Size	Draft								
		REQ-00000003	Material Costs	Draft								
		REQ-00000004	Operating Cost	Draft								
		REQ-00000039	Price	Draft								
Cost	Draft	REQ-00000040	Annual Service	Draft								
		REQ-00000005	Fabrication Speed	Draft	MP2954	B	Extruder	Preliminary	TC-4	A	Fabrication S	
					MP1872	C	Stepper Motor NEMA17	Released				
Build Time	Draft				MP2963	A	Stepper Motor Assembly	Released				
					MP2956	A	Gantry	Released				
		REQ-00000006	Software	Draft								
		REQ-00000014	Technologies	Draft								
		REQ-00000015	Printing Technology	Draft								
		REQ-00000044	Accuracy	Draft								
		REQ-00000045	Resolution	Draft								
		REQ-00000046	Speed	Draft			MP2966	C	Wire-Filament Extruder Guide	Released		
		REQ-00000002	Construction Steps	Draft			MP0101	B	Makerbot Replicator	Preliminary		
		REQ-00000008	Software Use	Draft			MP2988	A	Makerbot MightyBoard Software	Preliminary		
REQ-00000013	Visual Apperance	Draft										

Verification Protocol

Verification Plan

Verification Report

Validation Protocol

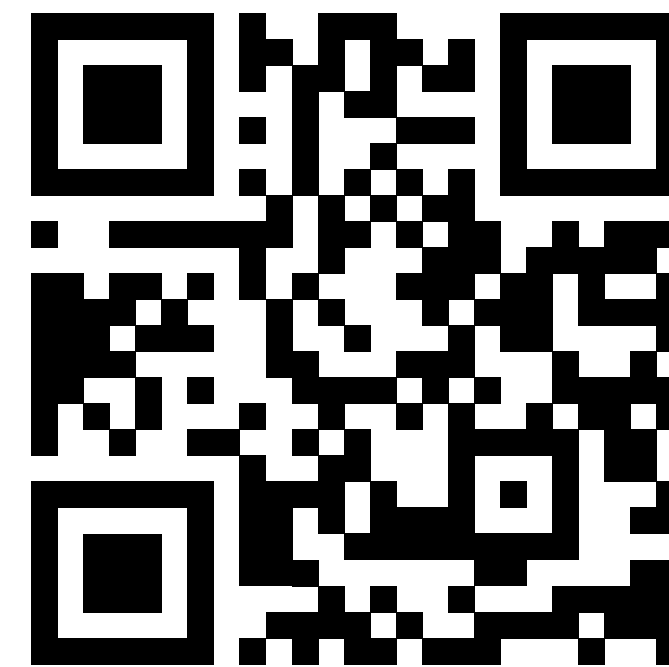
Validation Plan

Validation Report

We value your feedback – and so do your peers

As a longtime Aras customer, we'd love if you could share why you chose Aras Innovator and what you've enjoyed the most about your experience.

Please take a few minutes to leave Aras a five-star review on **Gartner Peer Insights**. Reviews are anonymous and you can leave one by scanning this QR code.



LEAVE A REVIEW!



Thank You!

Slavko Jovanovic
sjovanovic@aras.com

