VALIDATE 2026

Session 2.2

Kneat Product Session: Entities & CSV

Lorna Whelan & Dan Tobin

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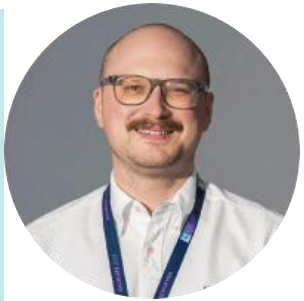
Speakers

Lorna Whelan
Senior Product Manager
Kneat



Dan Tobin
Senior Product Owner
Kneat

Agenda

- CSV/CSA Data
- Kneat Entity Data Model
- Demo
- Next Steps

CSV/CSA Data

CSV Deliverables

Plan	**Plan**: System Impact Assessment; Validation Plan; Supplier Assessment
Design	**Design**: Requirements; Drawings; Risk Assessment; Traceability Matrix; Programming Guides
Build & Test	**Build & Test:** Manuals; Test Protocols; Traceability Matrix; Reports; Risk Assessment
Op & Maint	**Operate & Maintain:** SOPs & Outputs (e.g. Validation Master Plan; Security; Periodic Review; Disaster Recovery; Config Mgt; Incident Mgt; Alarms Mgt; Change Control Mgt; Risk Mgt)
Decom	**Decommission:** Retirement Plan/Report; Data Migration Plan/Report; Risk Assessment

*Mgt= management

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Risk part of all Phases

Plan: System Impact Assessment; Validation Plan; Supplier Assessment

Design: Requirements; Drawings; Risk Assessment; Traceability Matrix; Programming Guides

Build & Test: Manuals; Test Protocols; Traceability Matrix; Reports; Risk Assessment

Operate & Maintain: SOPs & Outputs (e.g. Validation Master Plan; Security; Periodic Review; Disaster Recovery; Config Mgt; Incident Mgt; Alarms Mgt; Change Control Mgt; Risk Mgt)

Decommission: Retirement Plan/Report; Data Migration Plan/Report; Risk Assessment

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CSA Risk-based Approach

Computer Software Assurance Guidance

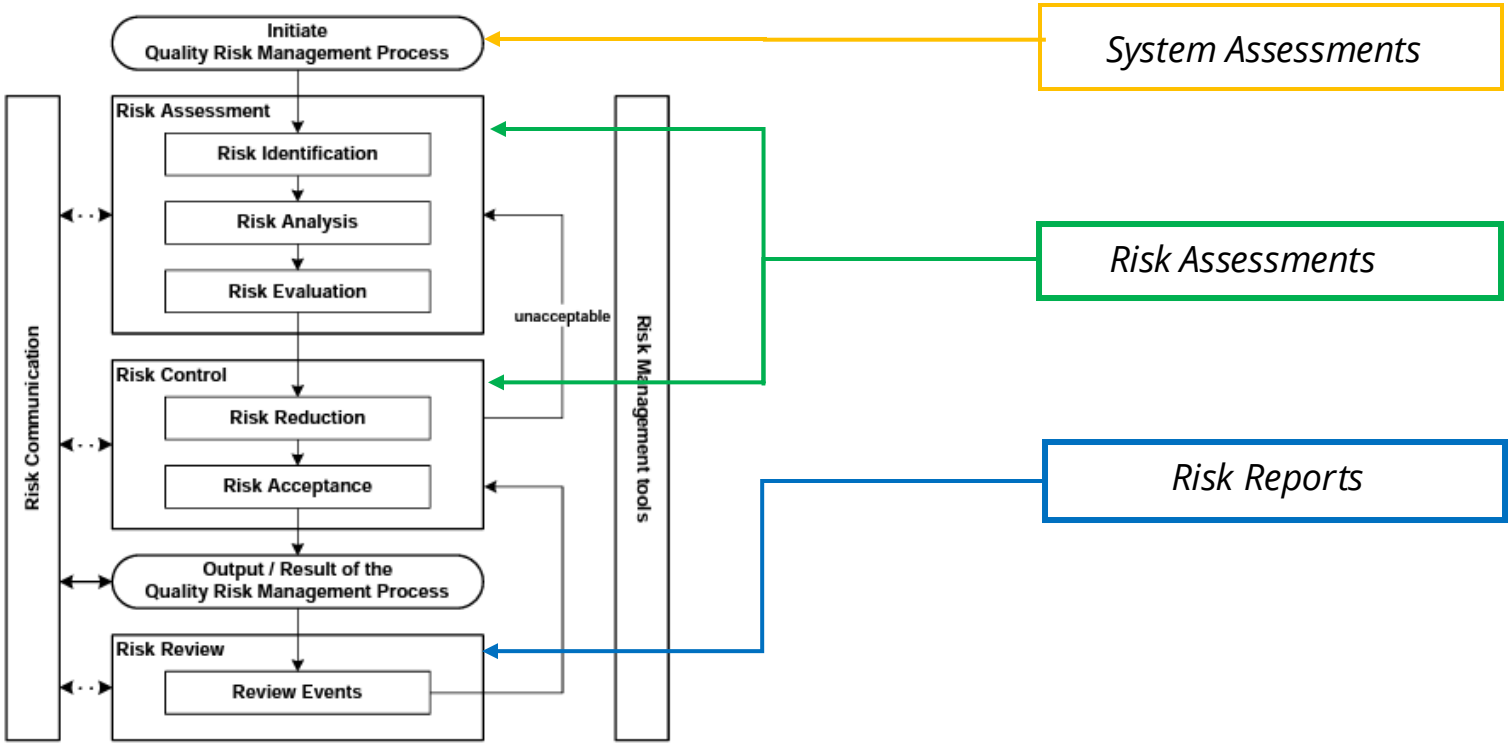
Why issued?

FDA wants industry to use automation, but industry was reluctant due to the perceived high **level of validation effort & thus high $**

What is it?

CSA is a **framework,** with worked examples, on how to use Quality Risk Management (QRM) to focus CSV effort.

QRM Framework (ICH Q9)



ICH = The International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation (ICH)

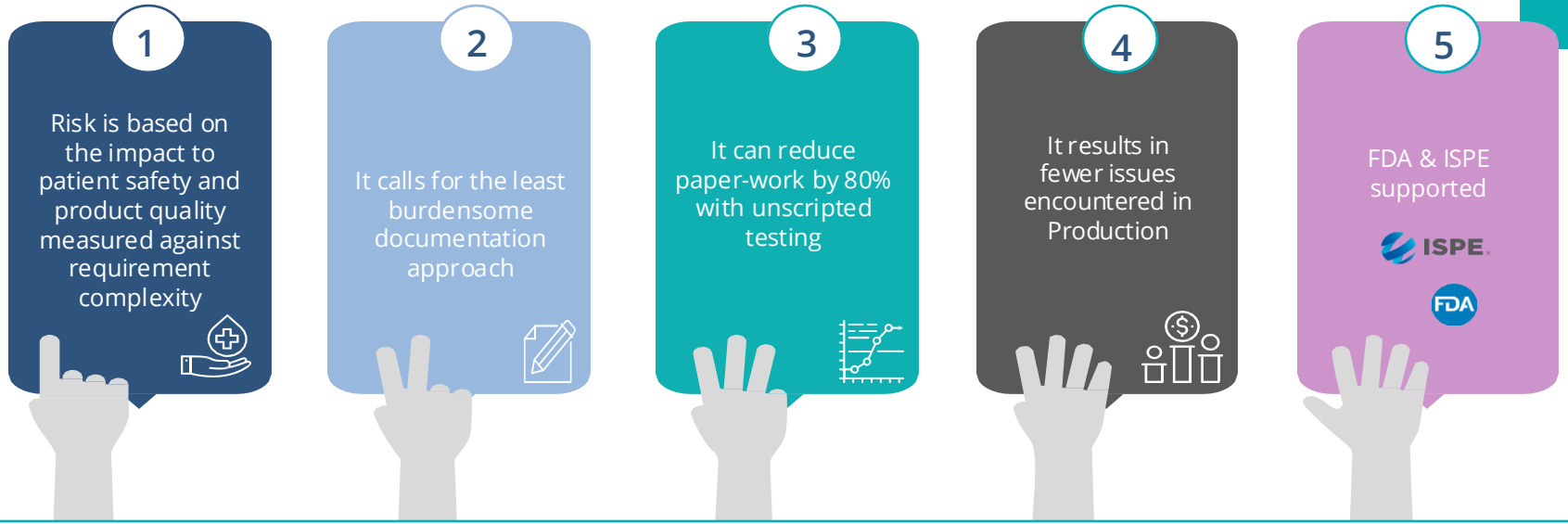
Example of Risk Level driving Testing Approach

Functional Risk Assessment on GxP URS Reqs

Risk Level		Testing Approaches
High Risk	High Risk	(Robust) Scripted testing Detailed test steps & expected results (**higher $** to develop/execute)
Not High-Risk	Medium Risk	(Limited) Scripted testing Limited detail & expected results (**lower $** to develop/execute)
	Low Risk	Unscripted testing (e.g. Ad hoc) High level objective; no expected results; summary filled in by tester (**lowest $** to develop/execute)

Appropriate records should incl the intended use; Risk assessment; test results; issues; conclusion, who/when; R/A

CSA - Five Things You Need To Know



- ✓ Improved Quality and Efficiency
- ✓ Validation Effort Reduced by 30%
- ✓ Spending More Time Challenging System

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Kneat Entity Data Model

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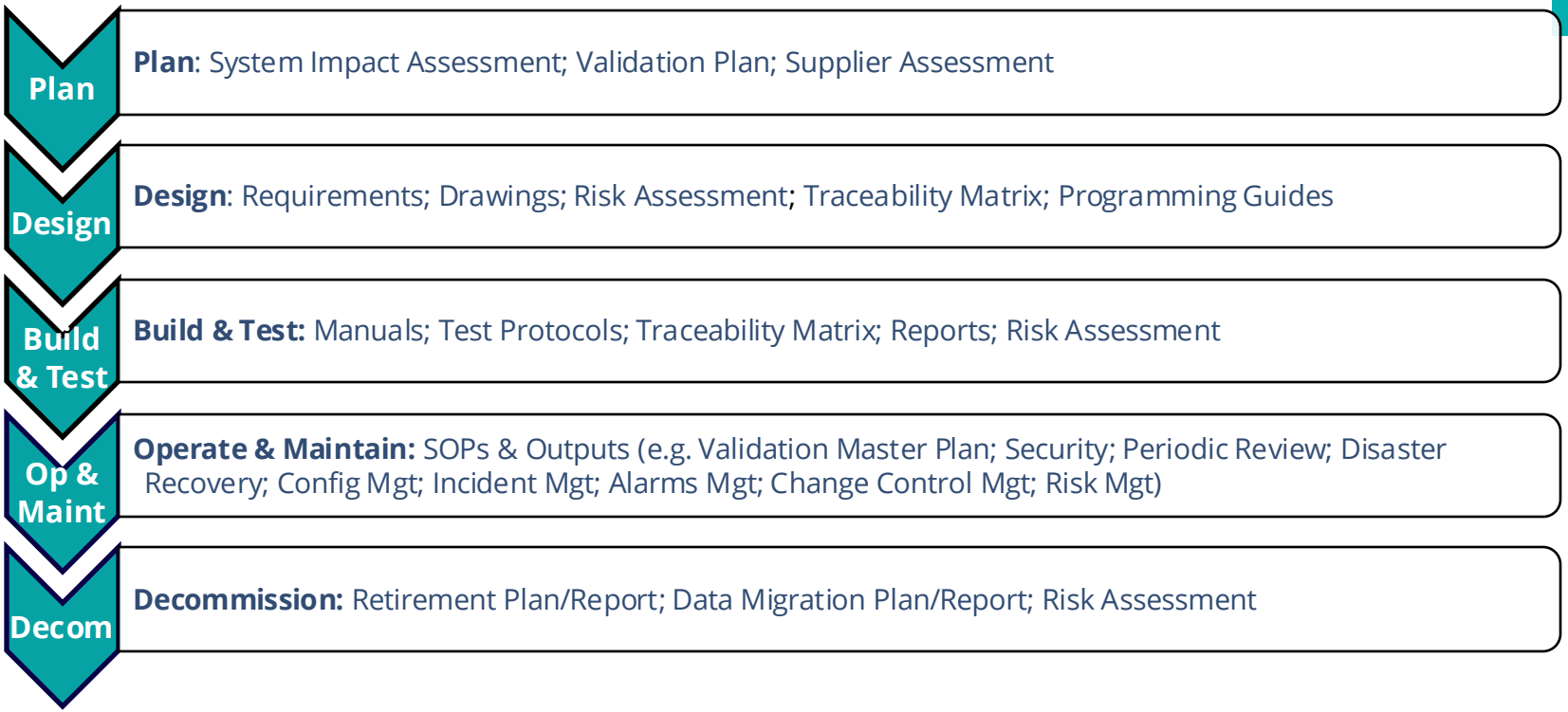
CSV Deliverables



*Mgt= management

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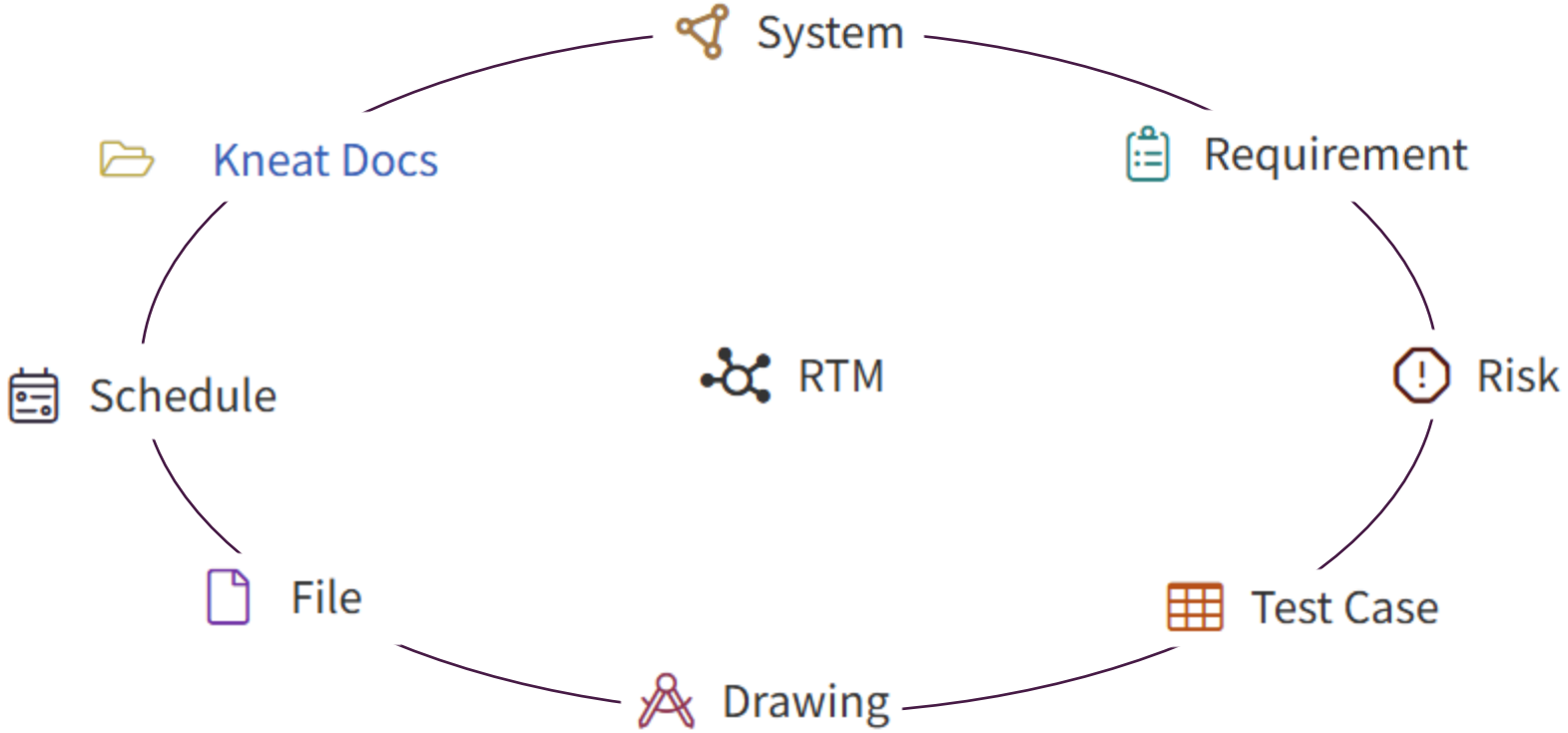
CSV Data – from Deliverables



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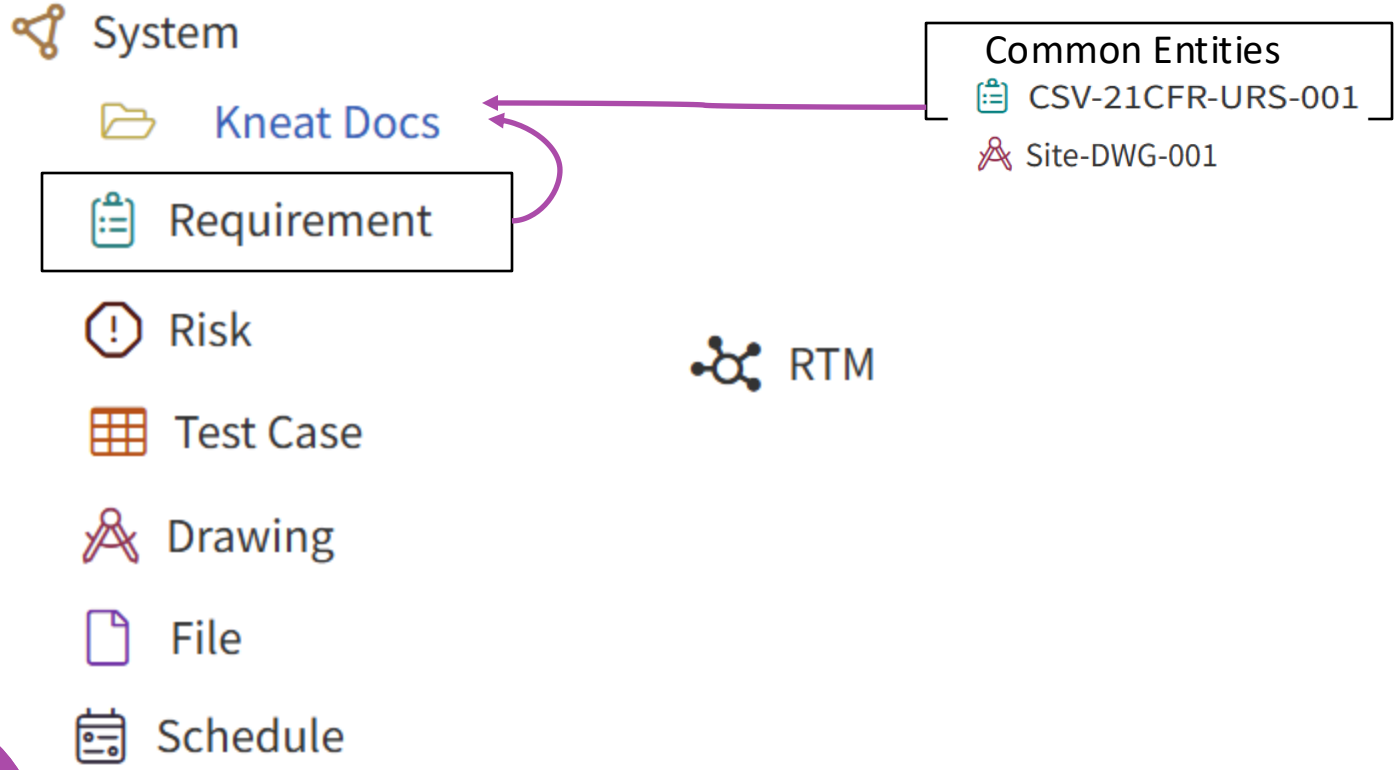
CSV Data – from Deliverables



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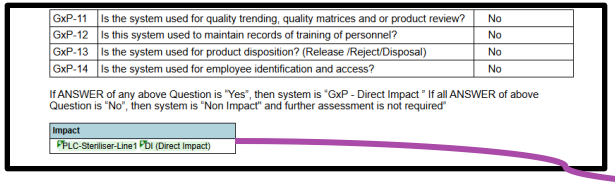
Plan Phase - System Impact Assessment

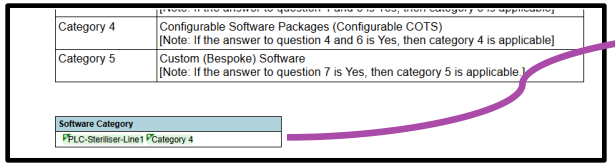
System Impact Assessment Document



GxP-11	Is the system used for quality trending, quality matrices and or product review?	No
GxP-12	Is this system used to maintain records of training of personnel?	No
GxP-13	Is the system used for product disposition? (Release /Reject/Disposal)	No
GxP-14	Is the system used for employee identification and access?	No

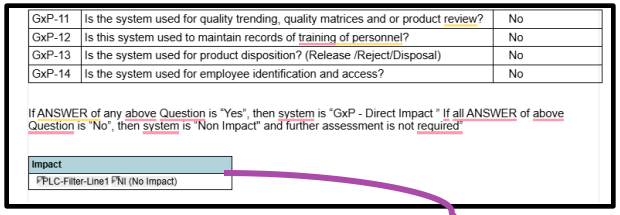
If ANSWER of any above Question is "Yes", then system is "GxP - Direct Impact " If all ANSWER of above Question is "No", then system is "Non Impact" and further assessment is not required"

Impact
PLC-Steriliser-Line1 DI (Direct Impact)



Category 4	Configurable Software Packages (Configurable COTS) [Note: If the answer to question 4 and 6 is Yes, then category 4 is applicable]
Category 5	Custom (Bespoke) Software [Note: If the answer to question 7 is Yes, then category 5 is applicable]

Software Category
PLC-Steriliser-Line1 Category 4



GxP-11	Is the system used for quality trending, quality matrices and or product review?	No
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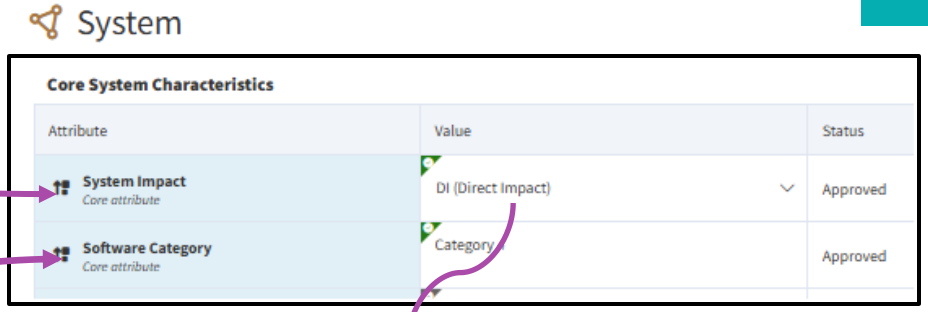
If ANSWER of any above Question is "Yes", then system is "GxP - Direct Impact " If all ANSWER of above Question is "No", then system is "Non Impact" and further assessment is not required"

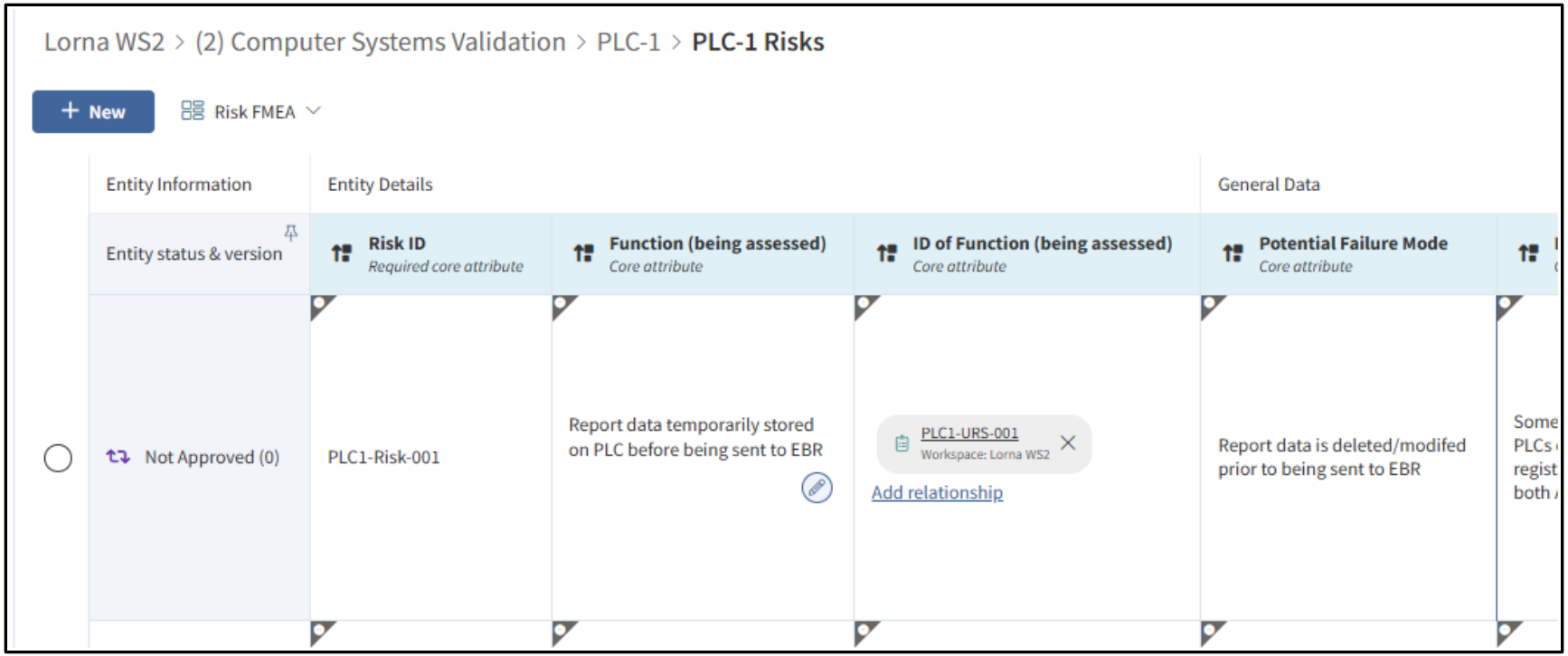
Impact
PLC-Filter-Line1 NI (No Impact)



GxP System so **do** perform a Quality RA

Not GxP System so **do not** perform a Quality RA

Design Phase - Risk Entity



Design Phase – Risk Assessment in Kneat

2 Risk Assessment

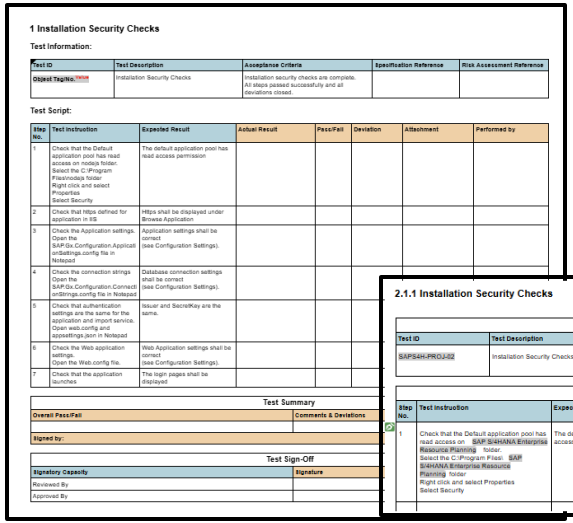
SYSTEM: PLC-1 PLC to control Steriliser
Product Affected: Product xxx
Leader: Jane Doe
Prepared By: John Smith
Team Members: John Doe; Jane Smith; Larry Smith

Risk ID	Function (being assessed)	ID of Function (being assessed)	Potential Failure Mode	Potential Effects of Failure	Current Controls	Severity	Occurrence	Detection	RPN	Overall Risk Level	Recommended Action Item	Occurrence (After mitigation)	Detection (After mitigation)	RPN (after mitigation)	Overall Risk Level (After mitigation)
PLC1 - Risk-001	Report data	PLC1-URS-001	Report data is deleted	Question on quality of product (as missing EBR data)	• Control 1 • + • Control 2 • + • Control 3	5	2	1	10	Medium	Action 1	1	1	5	Low
PLC1 - Risk-002	Report data	PLC1-URS-001	Report data is modifed	Question on quality of product (as incorrect EBR data)	Control 4	5	2	1	10	Medium	Action 2	1	1	5	Low
PLC1 - Risk-003	Control XXX	PLC1-URS-002	Temperature is not controlled	Product is not sterilised	• Control 5 • + • Control 6	5	1	1	5	Low	N/A	N/A	N/A	N/A	N/A

Build & Test Phase – Tests

- Develop Tests – level of detail based on Risk Level in RA

Test in SPR (SGT)



1 Installation Security Checks

Test Information:

Test ID	Test Description	Acceptance Criteria	Specification Reference	Risk Assessment Reference
Object Tag:No Value	Installation Security Checks	Installation security checks are complete. All steps passed successfully and all deviations closed.		

Test Script:

Step No.	Test Instruction	Expected Result	Actual Result	Pass/Fail	Deviation	Attachment	Performed by
1	Check that the Default application pool has read access on nodejs folder. Select the C:\Program Files\nodejs folder Right click and select Properties Select Security	The default application pool has read access permission					
2	Check that https defined for application in IIS	Https shall be displayed under Browse Application					
3	Check the Application settings. Open the SAP.Dx.Configuration.ApplicationSettings.config file in Notepad	Application settings shall be correct (see Configuration Settings).					
4	Check the connection strings Open the SAP.Dx.Configuration.ConnectionStrings.config file in Notepad	Database connection settings shall be correct (see Configuration Settings).					
5	Check that authentication settings are the same for the application and import service. Open web.config and appsettings.json in Notepad	Issuer and SecretKey are the same.					
6	Check the Web application settings. Open the Web.config file.	Web Application settings shall be correct (see Configuration Settings).					
7	Check that the application launches	The login pages shall be displayed					

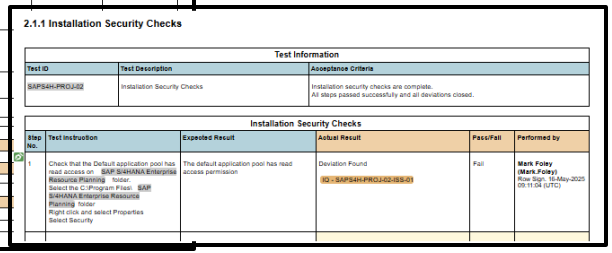
Test Summary

Overall Pass/Fail	Comments & Deviations
Signed by:	

Test Sign-Off

Signatory Capacity	Signature
Reviewed By	
Approved By	

Test in Execution



2.1.1 Installation Security Checks

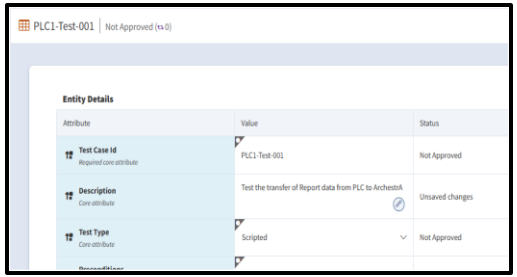
Test Information

Test ID	Test Description	Acceptance Criteria
SAPS4H-PROJ-02	Installation Security Checks	Installation security checks are complete. All steps passed successfully and all deviations closed.

Installation Security Checks

Step No.	Test Instruction	Expected Result	Actual Result	Pass/Fail	Performed by
1	Check that the Default application pool has read access on SAP S/4HANA Enterprise Resource Planning folder. Select the C:\Program Files\ SAP S/4HANA Enterprise Resource Planning folder Right click and select Properties Select Security	The default application pool has read access permission	Deviation Found IQ - SAPS4H-PROJ-02-ISS-01	Fail	Mark Foley (Mark.Foley) Row Sign. 16-May-2025 05:11:04 (UTC)

Test Case Entity



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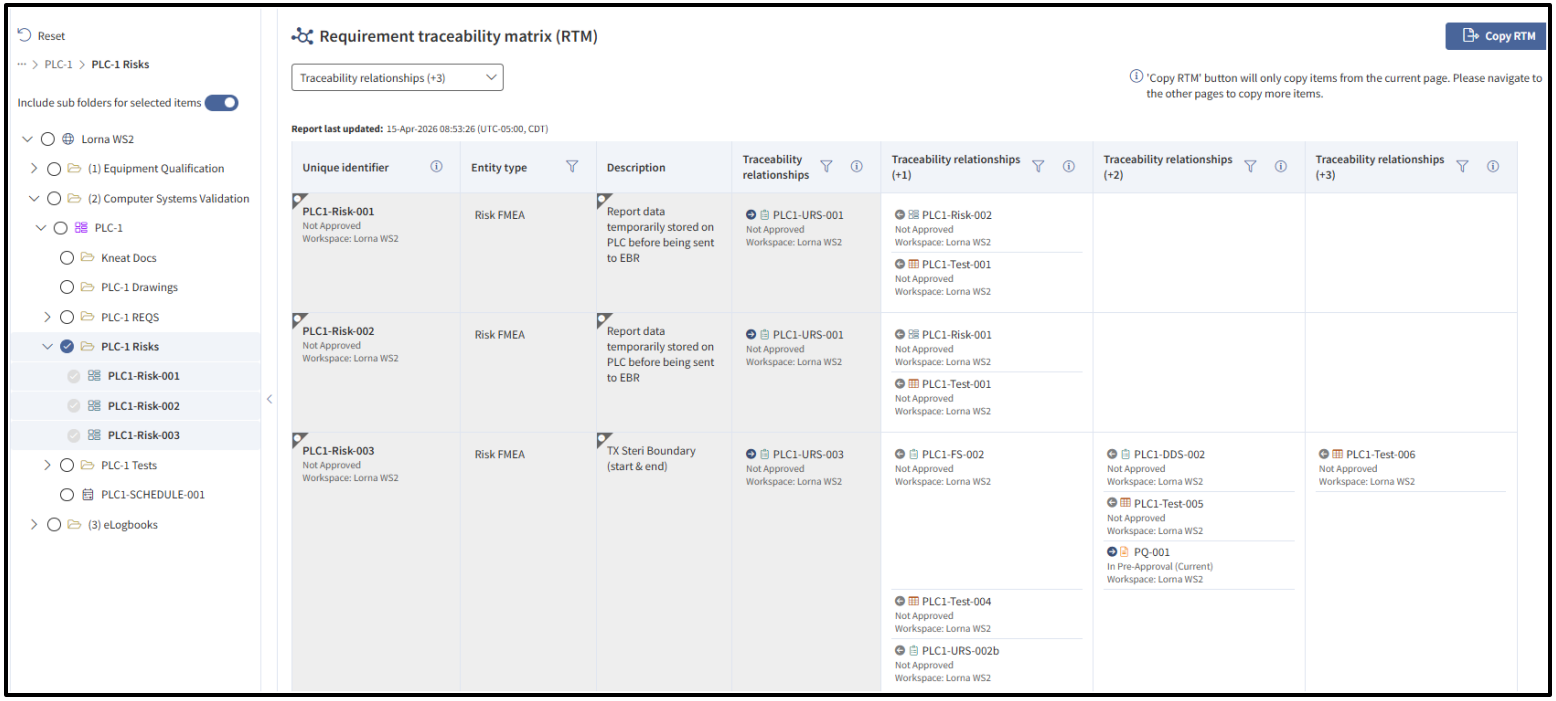
Build & Test Phase – Traceability Matrix



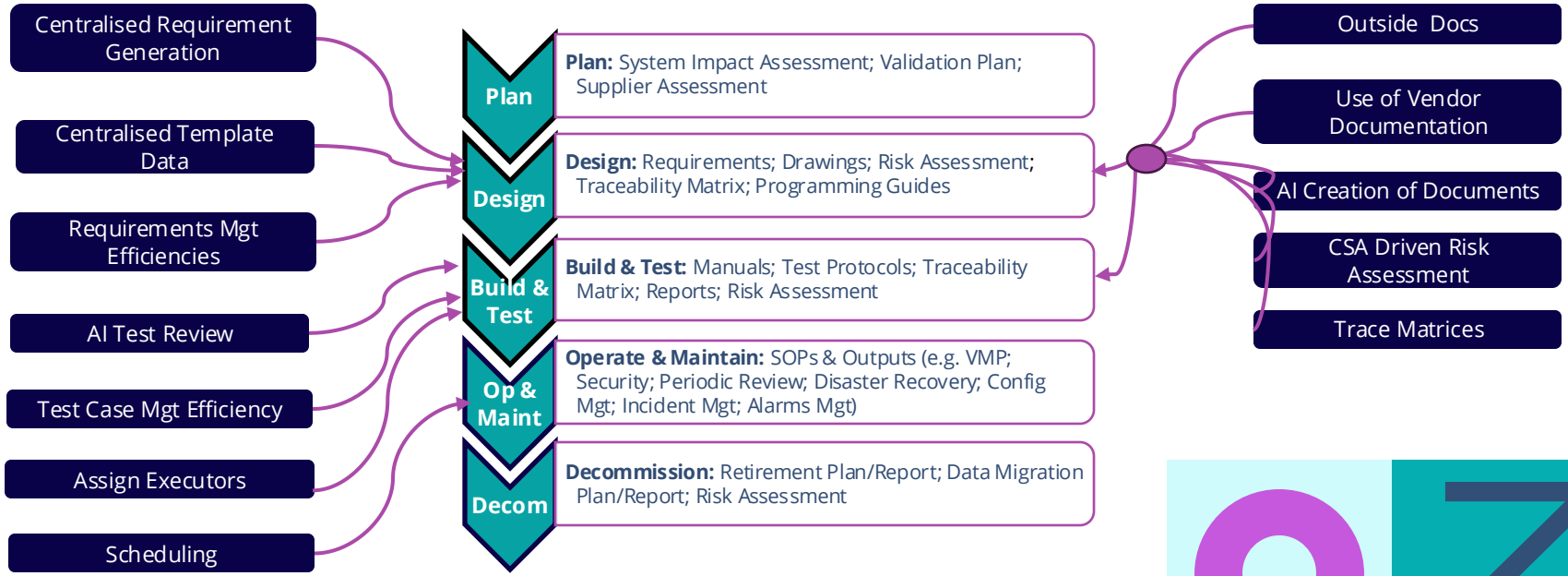
Benefits of Kneat Entity Data Model for CSV

- Configurability – build entities to suit your Validation process
- Data Governance – build Standardised entities ensuring consistency, saving time
- In-app CSA –build & manage Risks within your validation system
- Save Time - reduce transcription errors; re-use of entities
- Efficient Design– agile editing outside docs; real-time Traceability Matrices
- Change Management – audit history per entity ; assess impact of change on systems
- Share data – integrations and data export

Demo

Next Steps

Features coming soon – as affecting CSV deliverables



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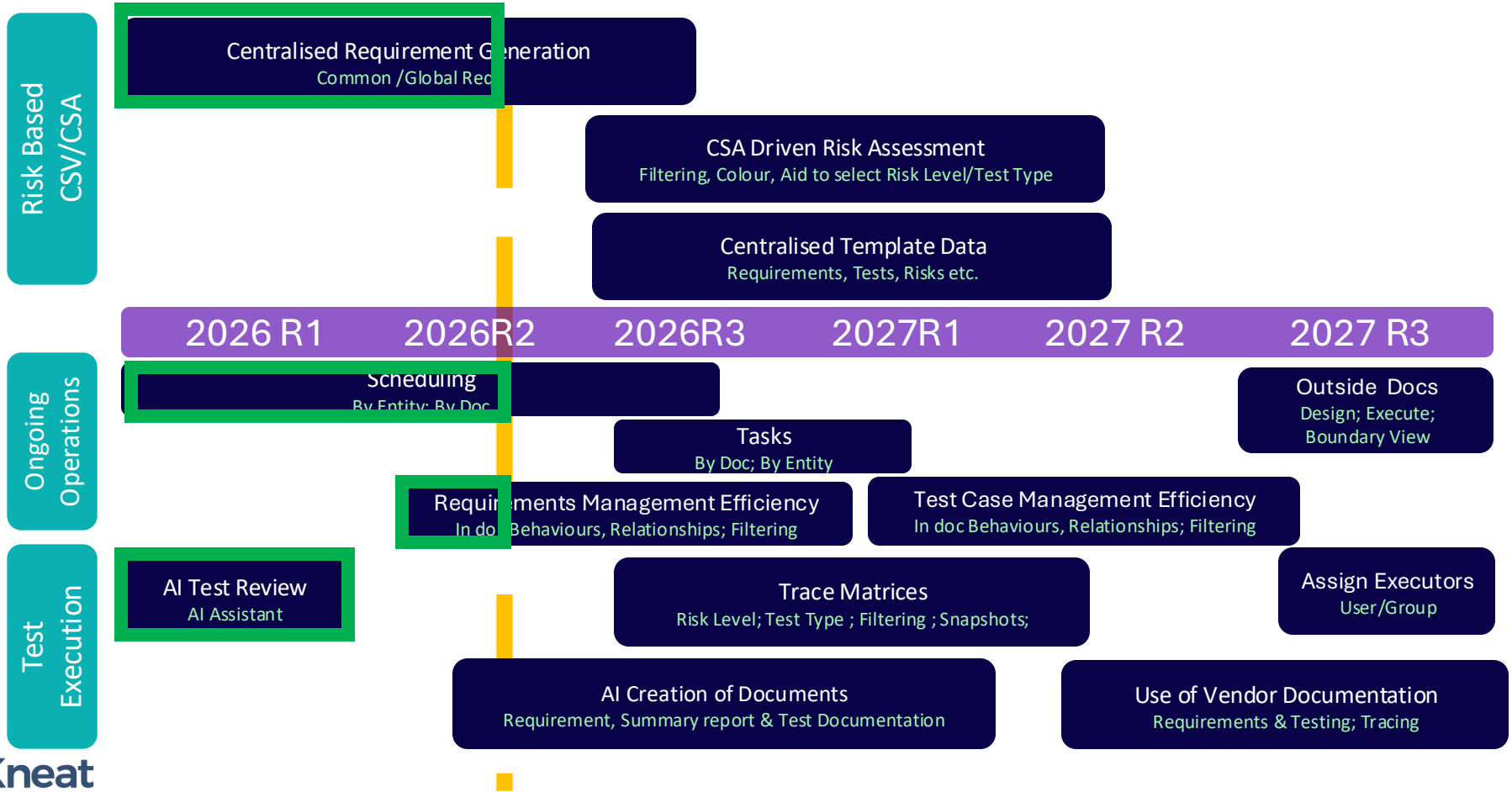
Kneat GX CSV/CSA Roadmap 2026/2027



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Q&A