C&Q Roadmap

VALIDATE 2026

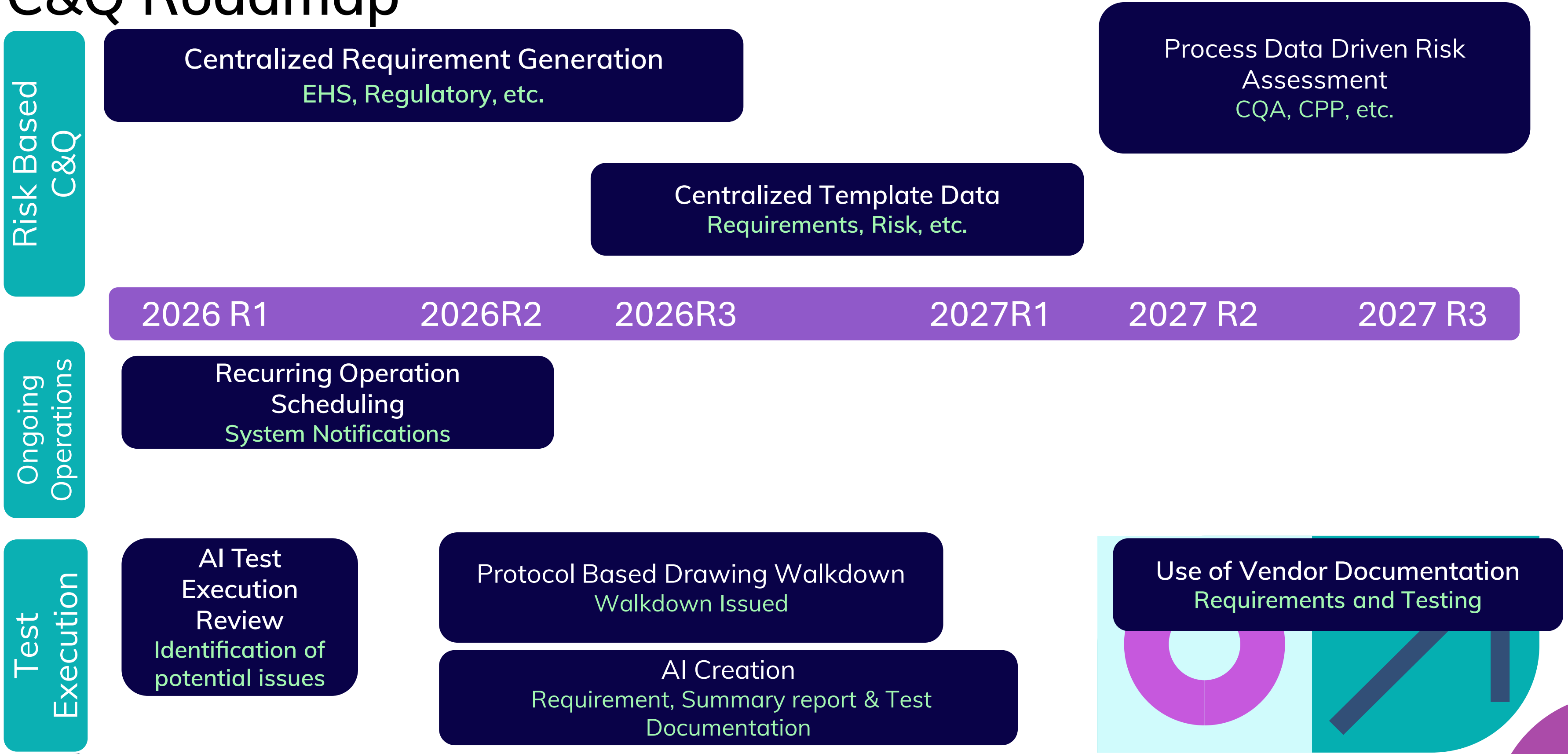
Speaker

Jamie O'Donnell
Senior Product Manager

Kneat

Kneat

C&Q Roadmap



Risk Based C&Q

Centralized Requirement Generation
EHS, Regulatory, etc.

Process Data Driven Risk Assessment
CQA, CPP, etc.

Centralized Template Data
Requirements, Risk, etc.

2026 R1 | 2026R2 | 2026R3 | 2027R1 | 2027 R2 | 2027 R3

Ongoing Operations

Recurring Operation Scheduling
System Notifications

Test Execution

AI Test Execution Review
Identification of potential issues

Protocol Based Drawing Walkdown
Walkdown Issued

AI Creation
Requirement, Summary report & Test Documentation

Use of Vendor Documentation
Requirements and Testing

Product Session

Cleaning Validation

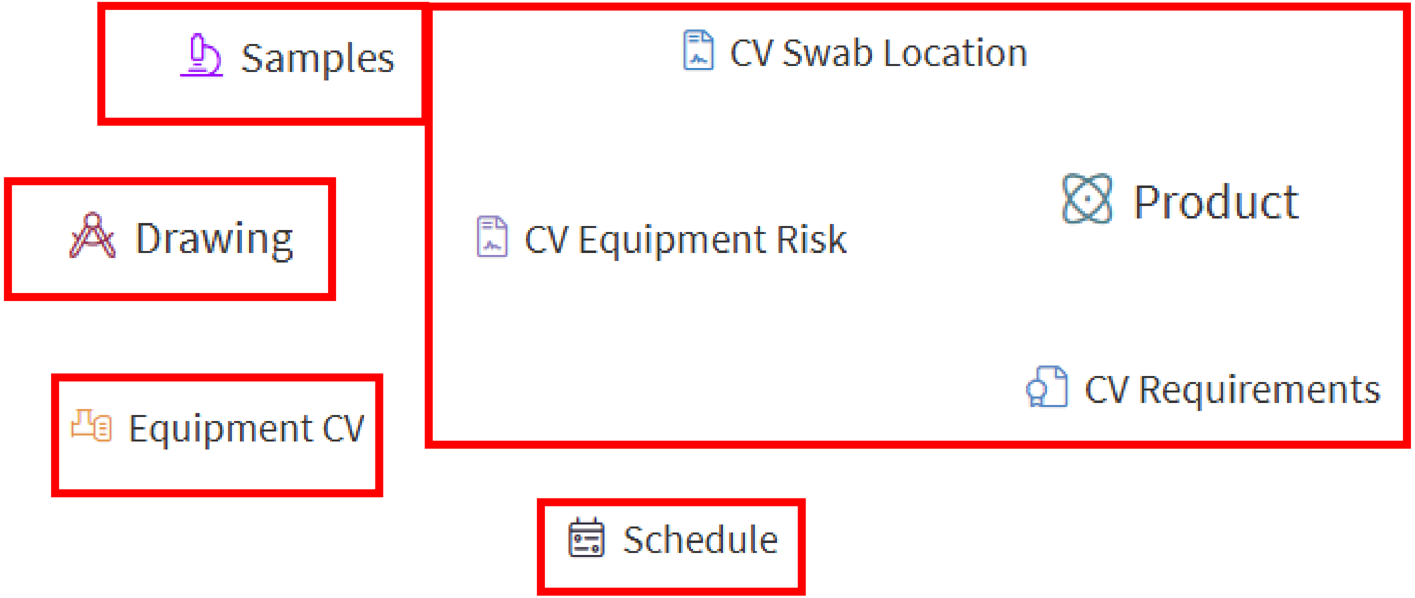
Kneat

Agenda

- The Data
- The Use
- The Roadmap

The Data

Cleaning Validation Data



Samples

CV Swab Location

Drawing

CV Equipment Risk

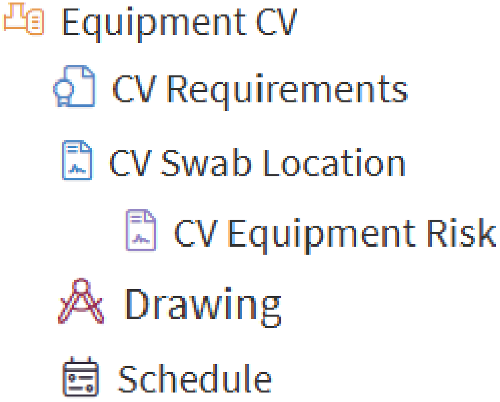
Product

Equipment CV

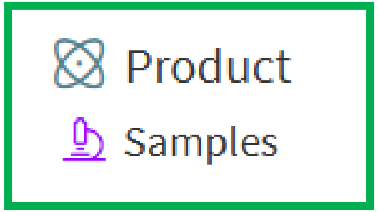
CV Requirements

Schedule

Cleaning Validation Data

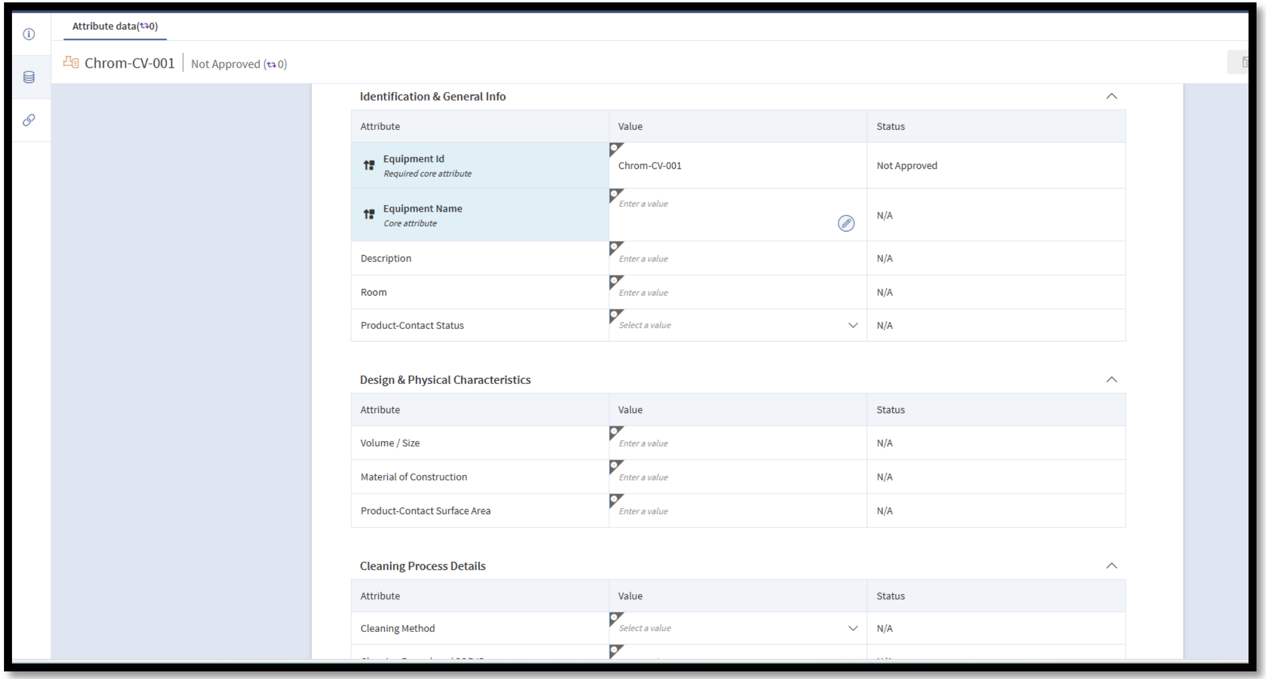


- Equipment CV
  - CV Requirements
  - CV Swab Location
    - CV Equipment Risk
  - Drawing
  - Schedule



- Product
- Samples

Putting Structure on Data



Attribute data(⇄0)

Chrom-CV-001 | Not Approved (⇄0)

Identification & General Info

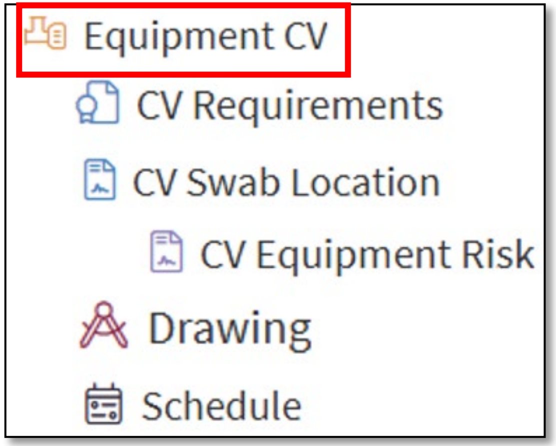
Attribute	Value	Status
Equipment Id *Required core attribute*	Chrom-CV-001	Not Approved
Equipment Name *Core attribute*	*Enter a value*	N/A
Description	*Enter a value*	N/A
Room	*Enter a value*	N/A
Product-Contact Status	*Select a value*	N/A

Design & Physical Characteristics

Attribute	Value	Status
Volume / Size	*Enter a value*	N/A
Material of Construction	*Enter a value*	N/A
Product-Contact Surface Area	*Enter a value*	N/A

Cleaning Process Details

Attribute	Value	Status
Cleaning Method	*Select a value*	N/A



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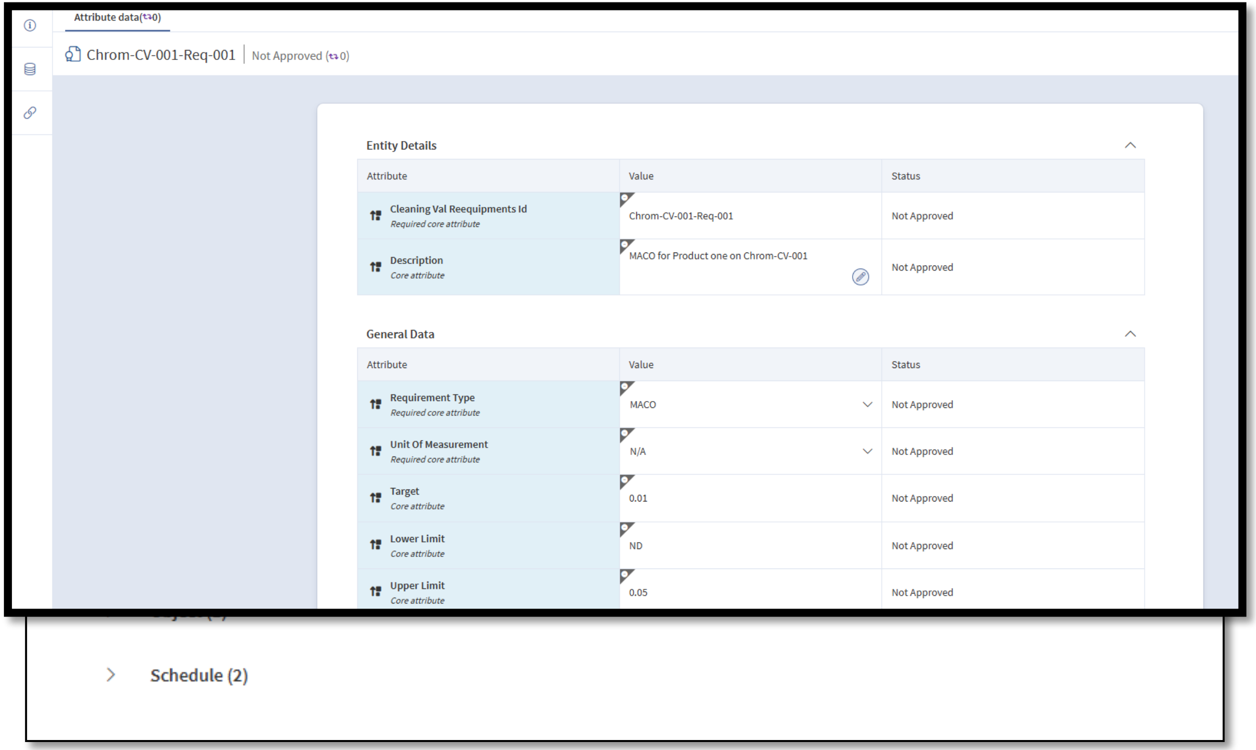


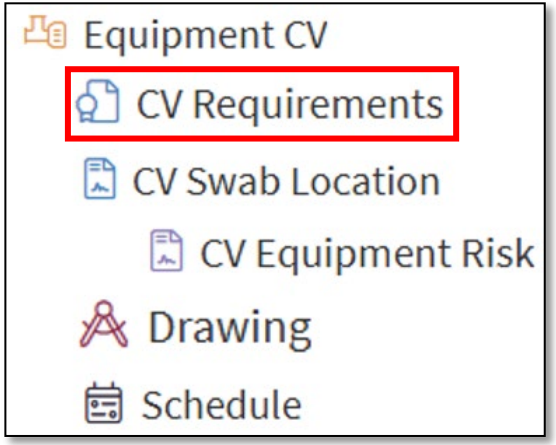
Chrom-CV-001-Req-001 | Not Approved (⇆0)

Entity Details

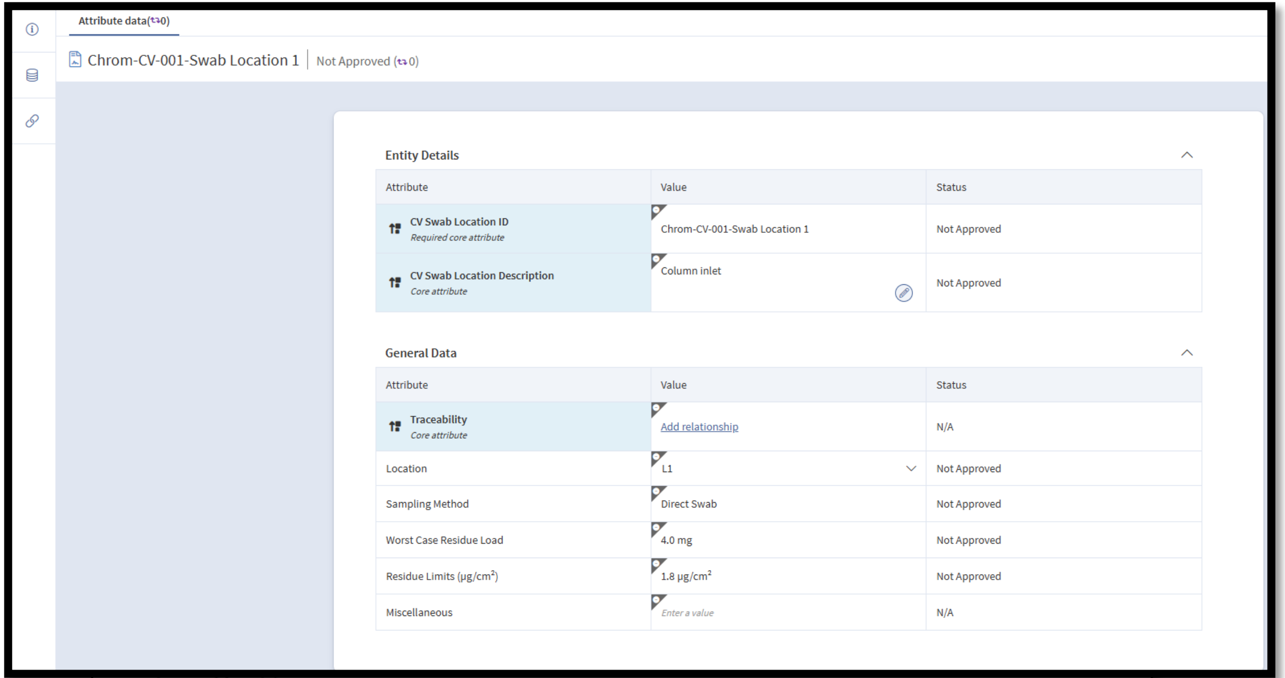
Attribute	Value	Status
Cleaning Val Reequipments Id *Required core attribute*	Chrom-CV-001-Req-001	Not Approved
Description *Core attribute*	MACO for Product one on Chrom-CV-001	Not Approved

General Data

Attribute	Value	Status
Requirement Type *Required core attribute*	MACO	Not Approved
Unit Of Measurement *Required core attribute*	N/A	Not Approved
Target *Core attribute*	0.01	Not Approved
Lower Limit *Core attribute*	ND	Not Approved
Upper Limit *Core attribute*	0.05	Not Approved



Putting Structure on Data



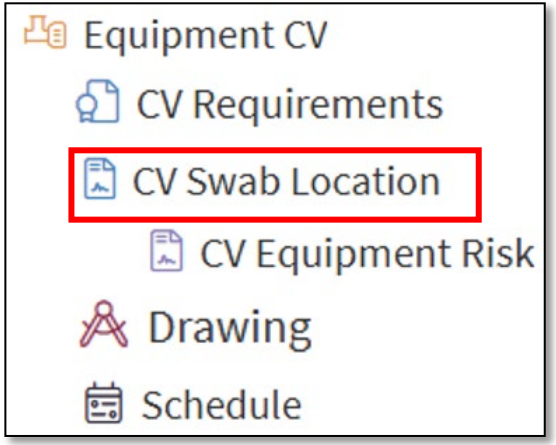
Chrom-CV-001-Swab Location 1 | Not Approved (⇆0)

Entity Details

Attribute	Value	Status
CV Swab Location ID *Required core attribute*	Chrom-CV-001-Swab Location 1	Not Approved
CV Swab Location Description *Core attribute*	Column inlet	Not Approved

General Data

Attribute	Value	Status
Traceability *Core attribute*	Add relationship	N/A
Location	L1	Not Approved
Sampling Method	Direct Swab	Not Approved
Worst Case Residue Load	4.0 mg	Not Approved
Residue Limits (µg/cm²)	1.8 µg/cm²	Not Approved
Miscellaneous	*Enter a value*	N/A



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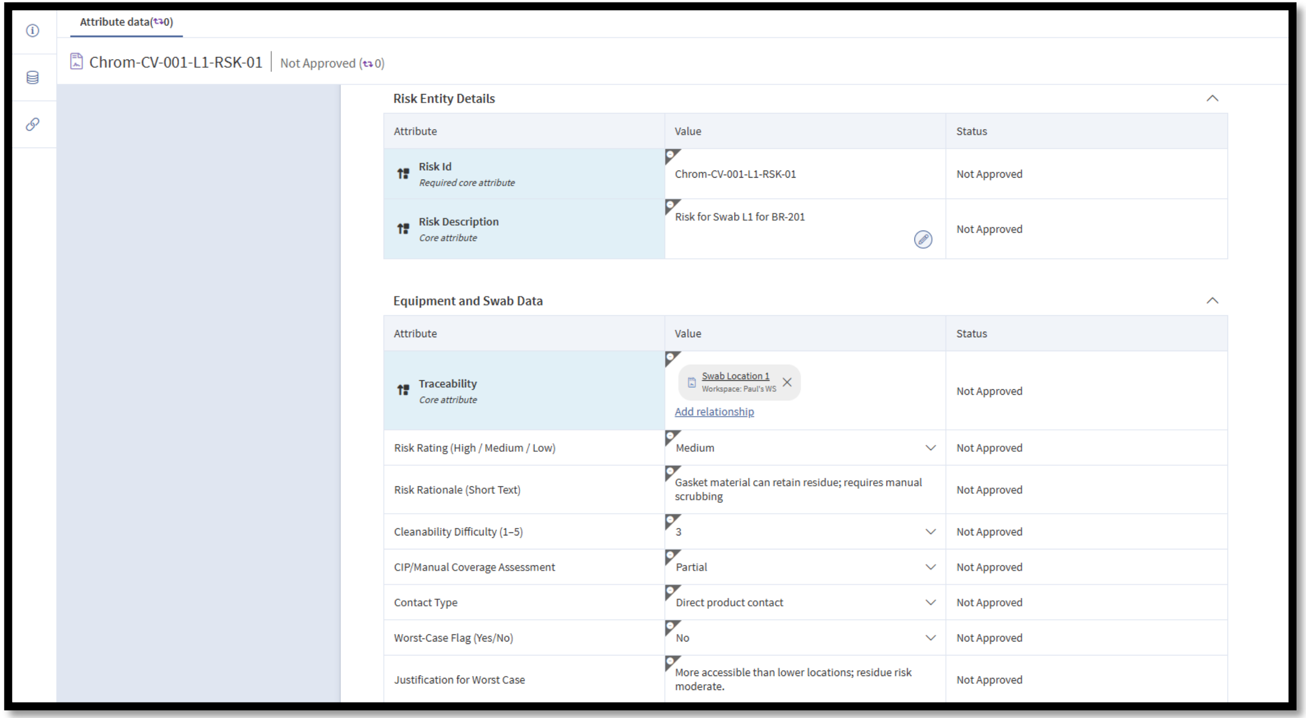
Putting Structure on Data



Attribute data(⇆0)

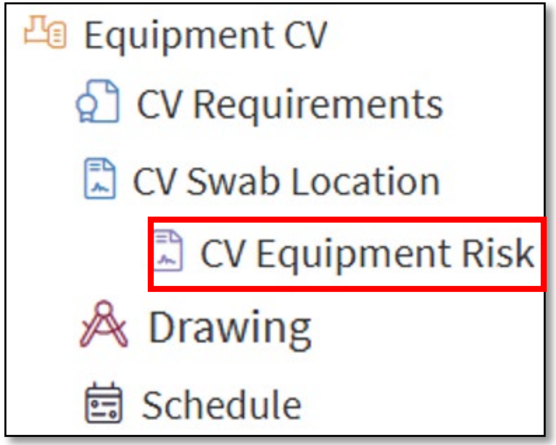
Chrom-CV-001-L1-RSK-01 | Not Approved (⇆0)

Risk Entity Details

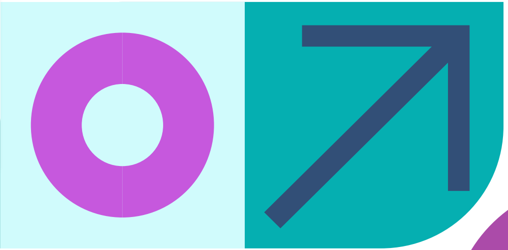
Attribute	Value	Status
Risk Id *Required core attribute*	Chrom-CV-001-L1-RSK-01	Not Approved
Risk Description *Core attribute*	Risk for Swab L1 for BR-201	Not Approved

Equipment and Swab Data

Attribute	Value	Status
Traceability *Core attribute*	Swab Location 1 Workspace: Paul's WS Add relationship	Not Approved
Risk Rating (High / Medium / Low)	Medium	Not Approved
Risk Rationale (Short Text)	Gasket material can retain residue; requires manual scrubbing	Not Approved
Cleanability Difficulty (1–5)	3	Not Approved
CIP/Manual Coverage Assessment	Partial	Not Approved
Contact Type	Direct product contact	Not Approved
Worst-Case Flag (Yes/No)	No	Not Approved
Justification for Worst Case	More accessible than lower locations; residue risk moderate.	Not Approved



- Equipment CV
  - CV Requirements
  - CV Swab Location
    - CV Equipment Risk
  - Drawing
  - Schedule



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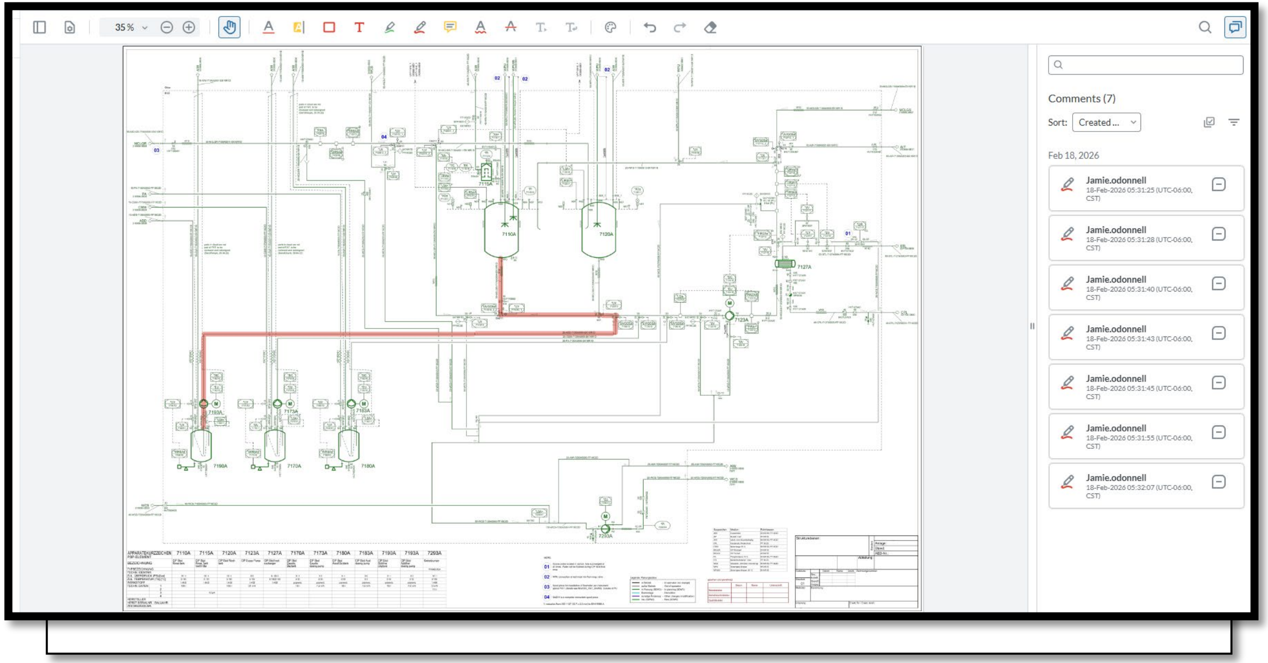

Comments (7)

Sort: Created ...

Feb 18, 2026

- Jamie.odonnell 18-Feb-2026 05:31:25 (UTC-06:00, CST)
- Jamie.odonnell 18-Feb-2026 05:31:28 (UTC-06:00, CST)
- Jamie.odonnell 18-Feb-2026 05:31:40 (UTC-06:00, CST)
- Jamie.odonnell 18-Feb-2026 05:31:43 (UTC-06:00, CST)
- Jamie.odonnell 18-Feb-2026 05:31:45 (UTC-06:00, CST)
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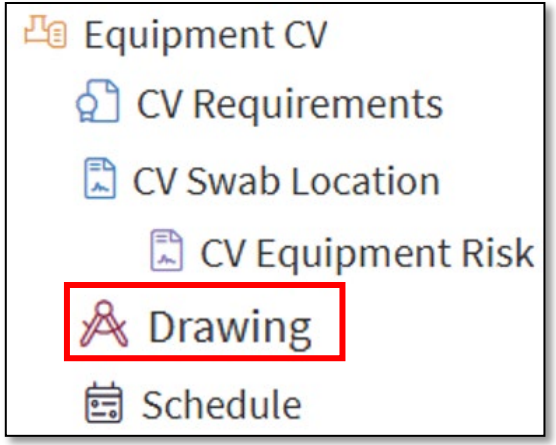

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  - CV Swab Location
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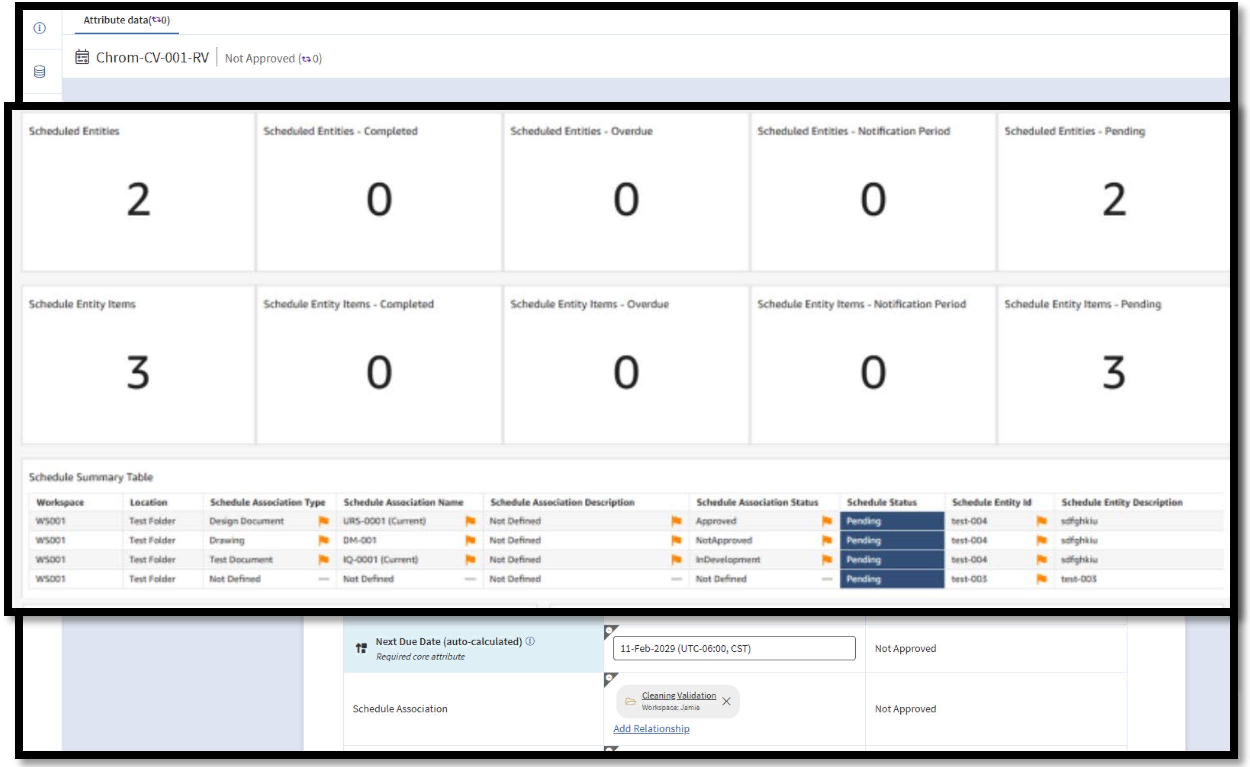
  - Schedule

Putting Structure on Data



Chrom-CV-001-RV | Not Approved (⇆0)

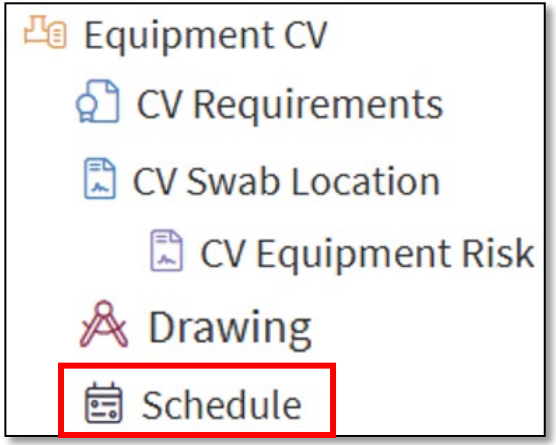
Scheduled Entities	Scheduled Entities - Completed	Scheduled Entities - Overdue	Scheduled Entities - Notification Period	Scheduled Entities - Pending
2	0	0	0	2

Schedule Entity Items	Schedule Entity Items - Completed	Schedule Entity Items - Overdue	Schedule Entity Items - Notification Period	Schedule Entity Items - Pending
3	0	0	0	3

Schedule Summary Table

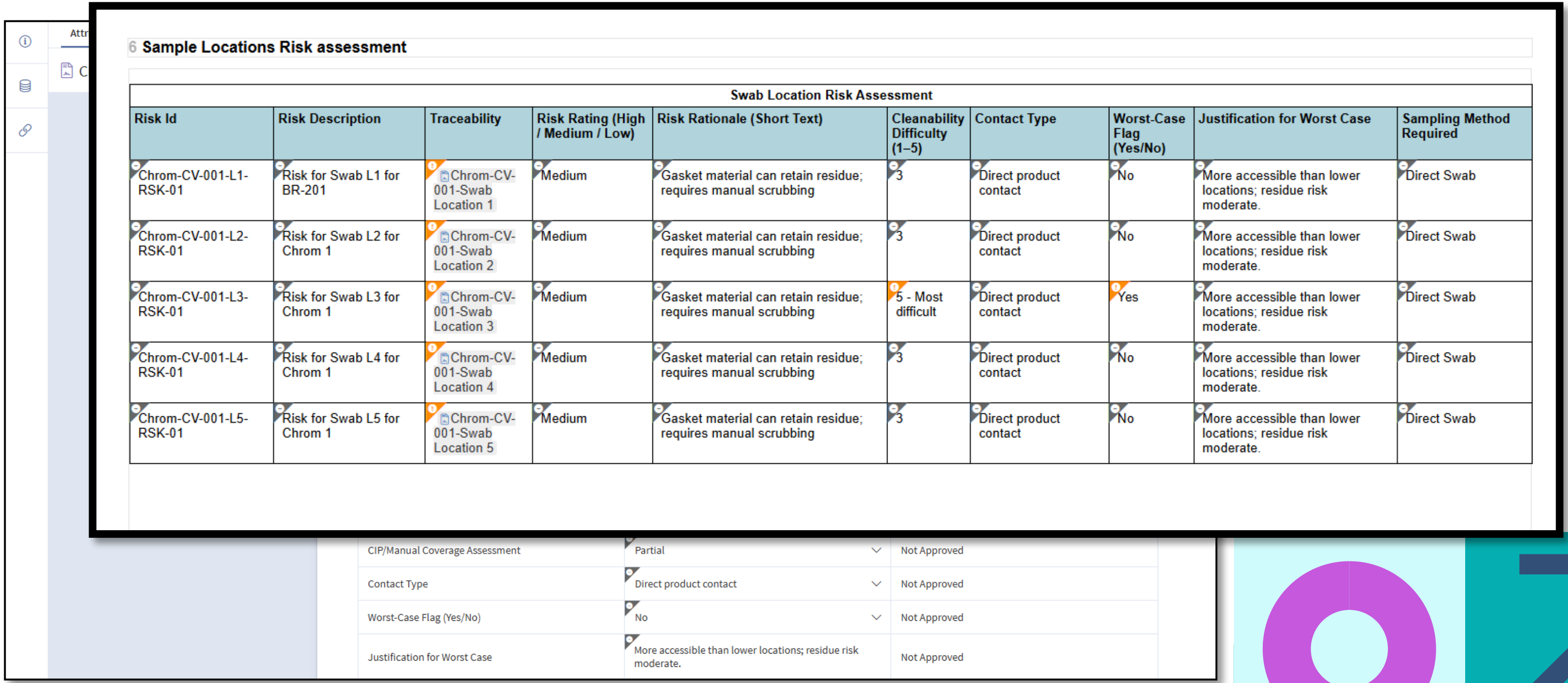
Workspace	Location	Schedule Association Type	Schedule Association Name	Schedule Association Description	Schedule Association Status	Schedule Status	Schedule Entity Id	Schedule Entity Description
WS001	Test Folder	Design Document	URS-0001 (Current)	Not Defined	Approved	Pending	test-004	sdfghkiu
WS001	Test Folder	Drawing	DM-001	Not Defined	NotApproved	Pending	test-004	sdfghkiu
WS001	Test Folder	Test Document	IQ-0001 (Current)	Not Defined	InDevelopment	Pending	test-004	sdfghkiu
WS001	Test Folder	Not Defined	Not Defined	Not Defined	Not Defined	Pending	test-003	test-003

Next Due Date (auto-calculated) ⓘ *Required core attribute*	11-Feb-2029 (UTC-06:00, CST)	Not Approved
Schedule Association	Cleaning Validation Workspace: Jamie Add Relationship	Not Approved


- Equipment CV
  - CV Requirements
  - CV Swab Location
    - CV Equipment Risk
  - Drawing
  - Schedule

The Use

Assessing Risk



6 **Sample Locations Risk assessment**

Swab Location Risk Assessment									
Risk Id	**Risk Description**	**Traceability**	**Risk Rating (High / Medium / Low)**	**Risk Rationale (Short Text)**	**Cleanability Difficulty (1–5)**	**Contact Type**	**Worst-Case Flag (Yes/No)**	**Justification for Worst Case**	**Sampling Method Required**
Chrom-CV-001-L1-RSK-01	Risk for Swab L1 for BR-201	Chrom-CV-001-Swab Location 1	Medium	Gasket material can retain residue; requires manual scrubbing	3	Direct product contact	No	More accessible than lower locations; residue risk moderate.	Direct Swab
Chrom-CV-001-L2-RSK-01	Risk for Swab L2 for Chrom 1	Chrom-CV-001-Swab Location 2	Medium	Gasket material can retain residue; requires manual scrubbing	3	Direct product contact	No	More accessible than lower locations; residue risk moderate.	Direct Swab
Chrom-CV-001-L3-RSK-01	Risk for Swab L3 for Chrom 1	Chrom-CV-001-Swab Location 3	Medium	Gasket material can retain residue; requires manual scrubbing	5 - Most difficult	Direct product contact	Yes	More accessible than lower locations; residue risk moderate.	Direct Swab
Chrom-CV-001-L4-RSK-01	Risk for Swab L4 for Chrom 1	Chrom-CV-001-Swab Location 4	Medium	Gasket material can retain residue; requires manual scrubbing	3	Direct product contact	No	More accessible than lower locations; residue risk moderate.	Direct Swab
Chrom-CV-001-L5-RSK-01	Risk for Swab L5 for Chrom 1	Chrom-CV-001-Swab Location 5	Medium	Gasket material can retain residue; requires manual scrubbing	3	Direct product contact	No	More accessible than lower locations; residue risk moderate.	Direct Swab

CIP/Manual Coverage Assessment	Partial	Not Approved
Contact Type	Direct product contact	Not Approved
Worst-Case Flag (Yes/No)	No	Not Approved
Justification for Worst Case	More accessible than lower locations; residue risk moderate.	Not Approved

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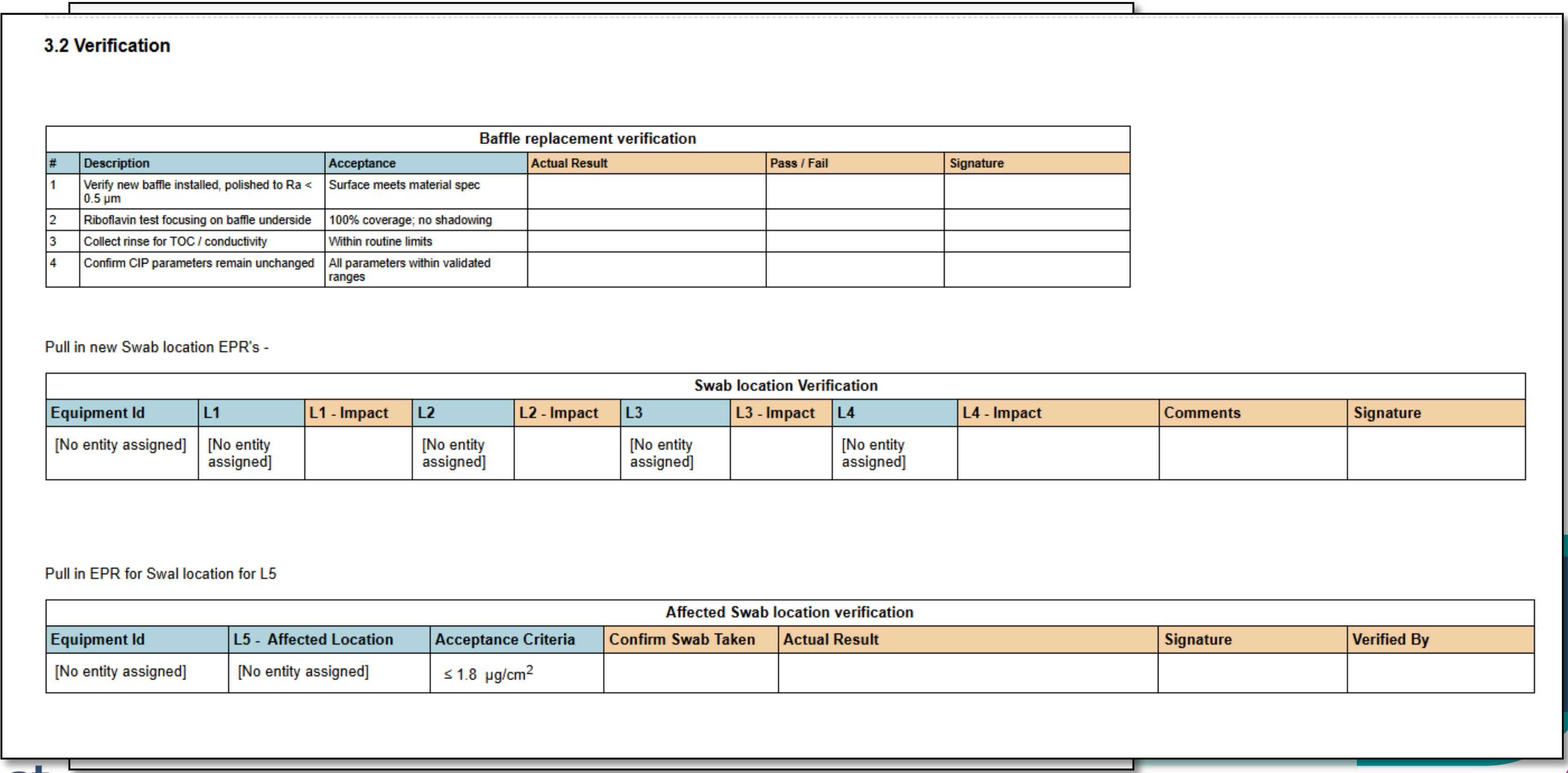
Managing Change



3.2 Verification

Baffle replacement verification

#	Description	Acceptance	Actual Result	Pass / Fail	Signature
1	Verify new baffle installed, polished to Ra < 0.5 µm	Surface meets material spec			
2	Riboflavin test focusing on baffle underside	100% coverage; no shadowing			
3	Collect rinse for TOC / conductivity	Within routine limits			
4	Confirm CIP parameters remain unchanged	All parameters within validated ranges			

Pull in new Swab location EPR's -

Swab location Verification

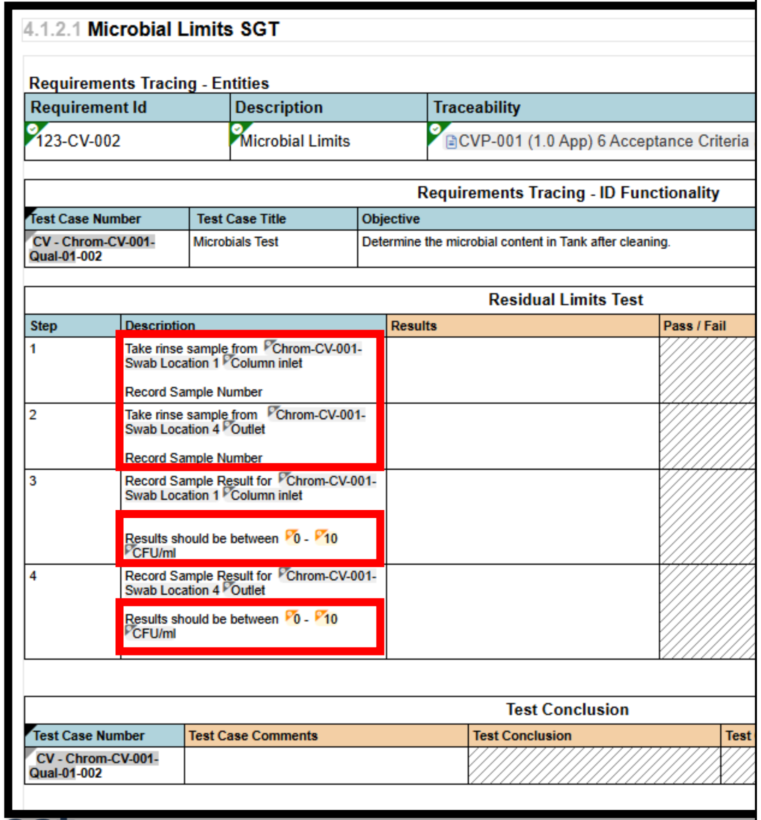
Equipment Id	L1	L1 - Impact	L2	L2 - Impact	L3	L3 - Impact	L4	L4 - Impact	Comments	Signature
[No entity assigned]	[No entity assigned]		[No entity assigned]		[No entity assigned]		[No entity assigned]			

Pull in EPR for Swal location for L5

Affected Swab location verification

Equipment Id	L5 - Affected Location	Acceptance Criteria	Confirm Swab Taken	Actual Result	Signature	Verified By
[No entity assigned]	[No entity assigned]	$\leq 1.8\ \mu g/cm^2$				

Using Your data



4.1.2.1 **Microbial Limits SGT**

Requirements Tracing - Entities

Requirement Id	Description	Traceability
123-CV-002	Microbial Limits	CVP-001 (1.0 App) 6 Acceptance Criteria

Requirements Tracing - ID Functionality

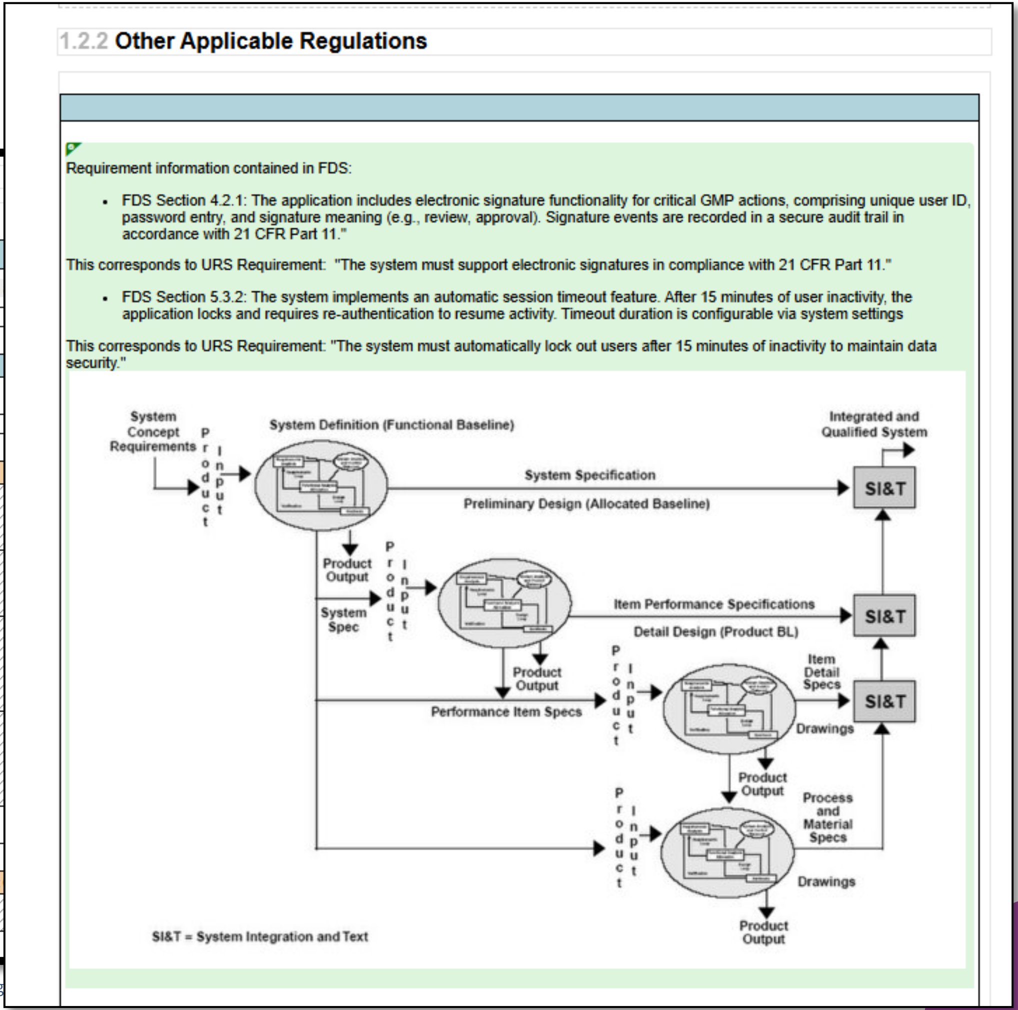
Test Case Number	Test Case Title	Objective
CV - Chrom-CV-001-Qual-01-002	Microbials Test	Determine the microbial content in Tank after cleaning.

Residual Limits Test

Step	Description	Results	Pass / Fail
1	Take rinse sample from Chrom-CV-001-Swab Location 1 Column inlet Record Sample Number		
2	Take rinse sample from Chrom-CV-001-Swab Location 4 Outlet Record Sample Number		
3	Record Sample Result for Chrom-CV-001-Swab Location 1 Column inlet Results should be between 0 - 10 CFU/ml		
4	Record Sample Result for Chrom-CV-001-Swab Location 4 Outlet Results should be between 0 - 10 CFU/ml		

Test Conclusion

Test Case Number	Test Case Comments	Test Conclusion	Test
CV - Chrom-CV-001-Qual-01-002			



1.2.2 **Other Applicable Regulations**

Requirement information contained in FDS:

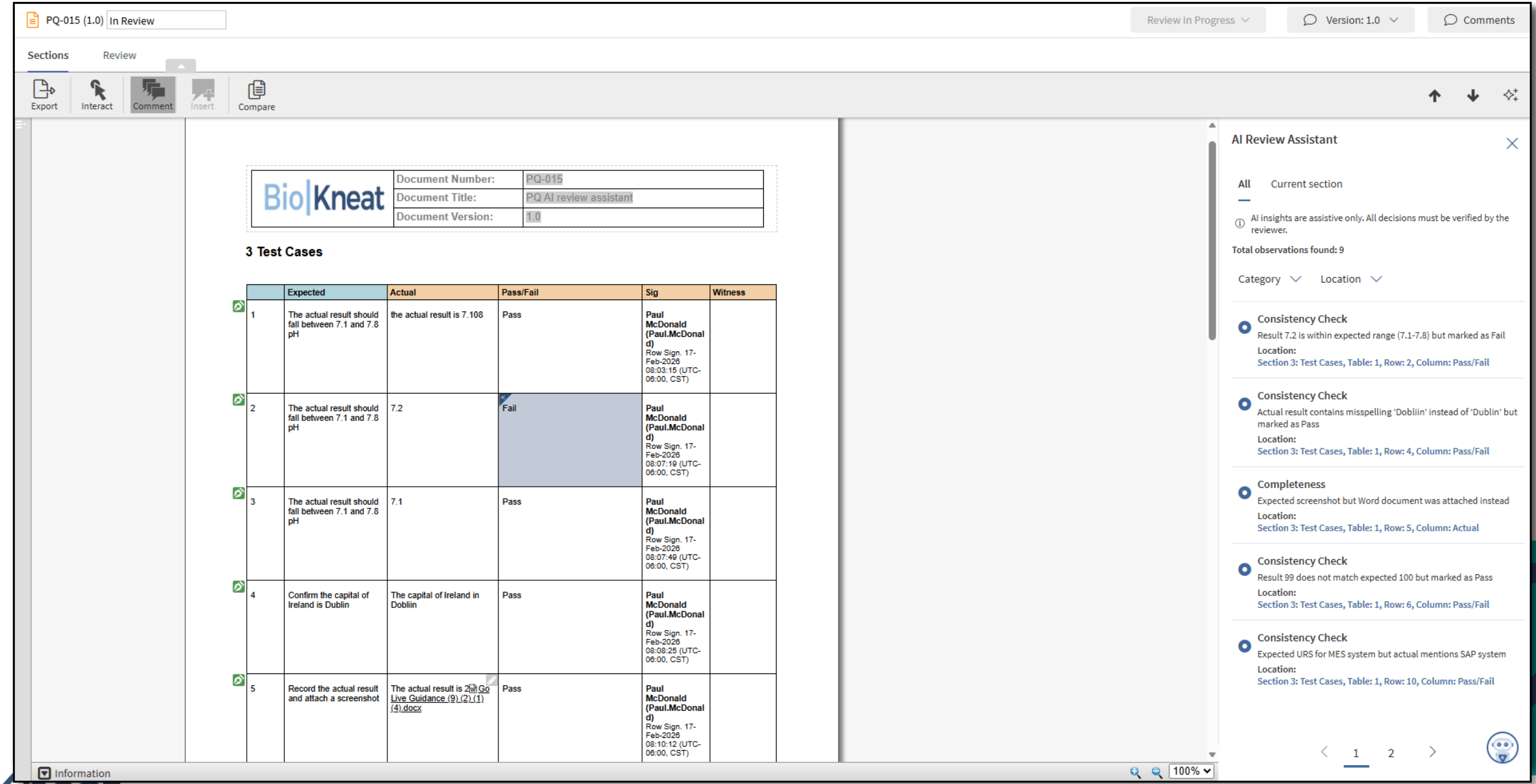
- FDS Section 4.2.1: The application includes electronic signature functionality for critical GMP actions, comprising unique user ID, password entry, and signature meaning (e.g., review, approval). Signature events are recorded in a secure audit trail in accordance with 21 CFR Part 11."

This corresponds to URS Requirement: "The system must support electronic signatures in compliance with 21 CFR Part 11."

- FDS Section 5.3.2: The system implements an automatic session timeout feature. After 15 minutes of user inactivity, the application locks and requires re-authentication to resume activity. Timeout duration is configurable via system settings

This corresponds to URS Requirement: "The system must automatically lock out users after 15 minutes of inactivity to maintain data security."

Speeding up Release



Document Number:	PQ-015
Document Title:	PQ AI review assistant
Document Version:	1.0

3 Test Cases

	Expected	Actual	Pass/Fail	Sig	Witness
1	The actual result should fall between 7.1 and 7.8 pH	the actual result is 7.108	Pass	**Paul McDonald (Paul.McDonald)** Row Sign. 17-Feb-2026 08:03:15 (UTC-06:00, CST)	
2	The actual result should fall between 7.1 and 7.8 pH	7.2	Fail	**Paul McDonald (Paul.McDonald)** Row Sign. 17-Feb-2026 08:07:19 (UTC-06:00, CST)	
3	The actual result should fall between 7.1 and 7.8 pH	7.1	Pass	**Paul McDonald (Paul.McDonald)** Row Sign. 17-Feb-2026 08:07:49 (UTC-06:00, CST)	
4	Confirm the capital of Ireland is Dublin	The capital of Ireland in Dobliin	Pass	**Paul McDonald (Paul.McDonald)** Row Sign. 17-Feb-2026 08:08:25 (UTC-06:00, CST)	
5	Record the actual result and attach a screenshot	The actual result is 2 Go Live Guidance (9) (2) (1) (4).docx	Pass	**Paul McDonald (Paul.McDonald)** Row Sign. 17-Feb-2026 08:10:12 (UTC-06:00, CST)	

AI Review Assistant

All   Current section

ⓘ AI insights are assistive only. All decisions must be verified by the reviewer.

Total observations found: 9

Category   Location

Consistency Check
Result 7.2 is within expected range (7.1-7.8) but marked as Fail
Location:
Section 3: Test Cases, Table: 1, Row: 2, Column: Pass/Fail

Consistency Check
Actual result contains misspelling 'Dobliin' instead of 'Dublin' but marked as Pass
Location:
Section 3: Test Cases, Table: 1, Row: 4, Column: Pass/Fail

Completeness
Expected screenshot but Word document was attached instead
Location:
Section 3: Test Cases, Table: 1, Row: 5, Column: Actual

Consistency Check
Result 99 does not match expected 100 but marked as Pass
Location:
Section 3: Test Cases, Table: 1, Row: 6, Column: Pass/Fail

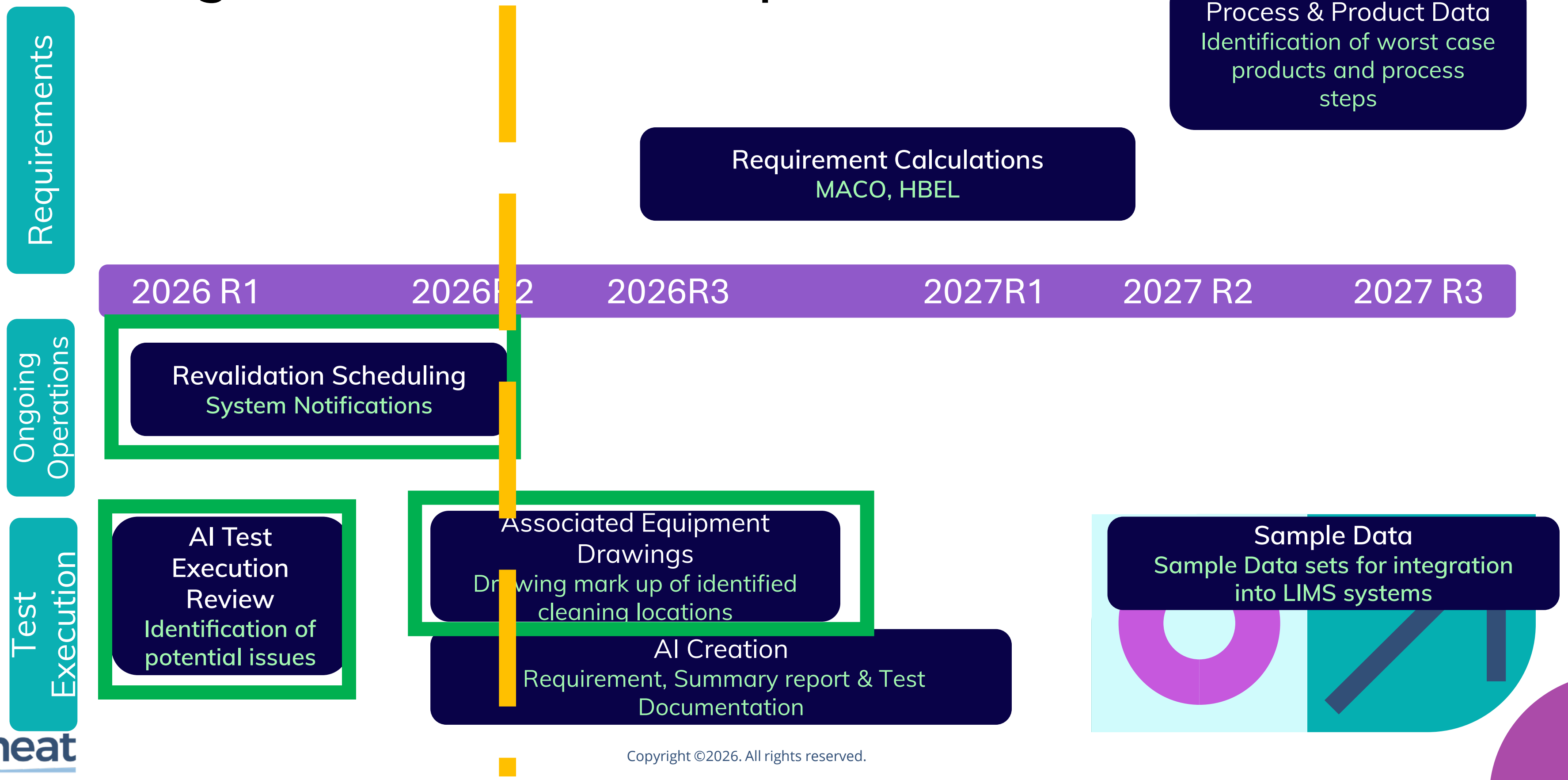
Consistency Check
Expected URS for MES system but actual mentions SAP system
Location:
Section 3: Test Cases, Table: 1, Row: 10, Column: Pass/Fail

< 1 2 >

The Roadmap

Kneat

Cleaning Validation Roadmap



Requirements

Process & Product Data
Identification of worst case products and process steps

Requirement Calculations
MACO, HBEL

2026 R1 | 2026R2 | 2026R3 | 2027R1 | 2027 R2 | 2027 R3

Ongoing Operations

Revalidation Scheduling
System Notifications

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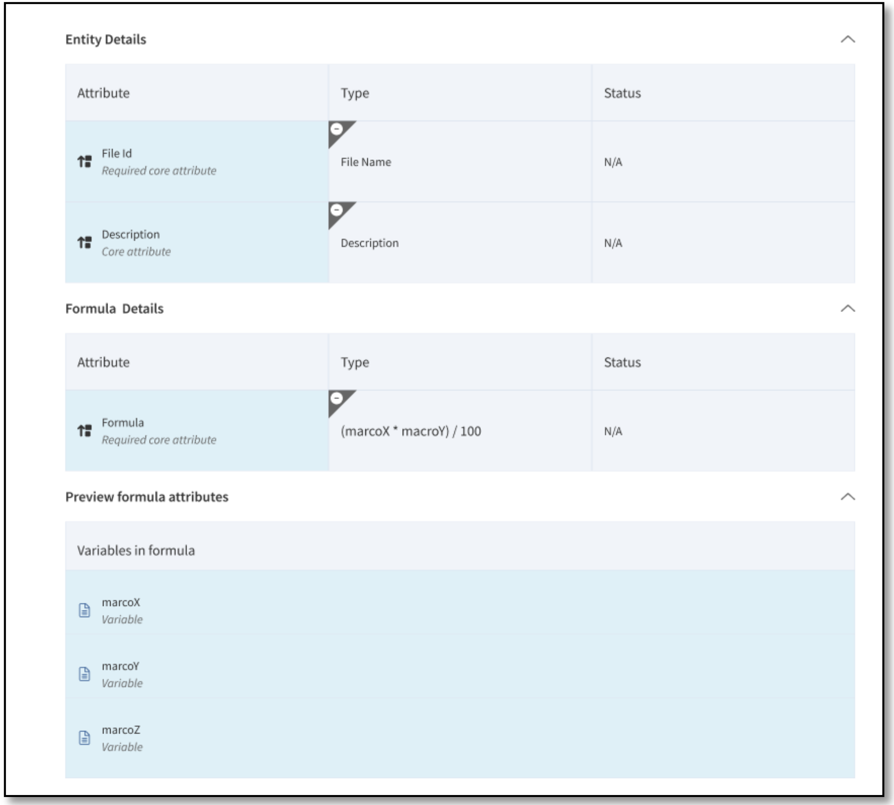
AI Test Execution Review
Identification of potential issues

Associated Equipment Drawings
Drawing mark up of identified cleaning locations

AI Creation
Requirement, Summary report & Test Documentation

Sample Data
Sample Data sets for integration into LIMS systems

Calculations



Entity Details

Attribute	Type	Status
File Id *Required core attribute*	File Name	N/A
Description *Core attribute*	Description	N/A

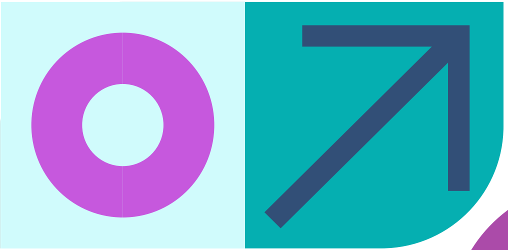
Formula Details

Attribute	Type	Status
Formula *Required core attribute*	(marcoX * macroY) / 100	N/A

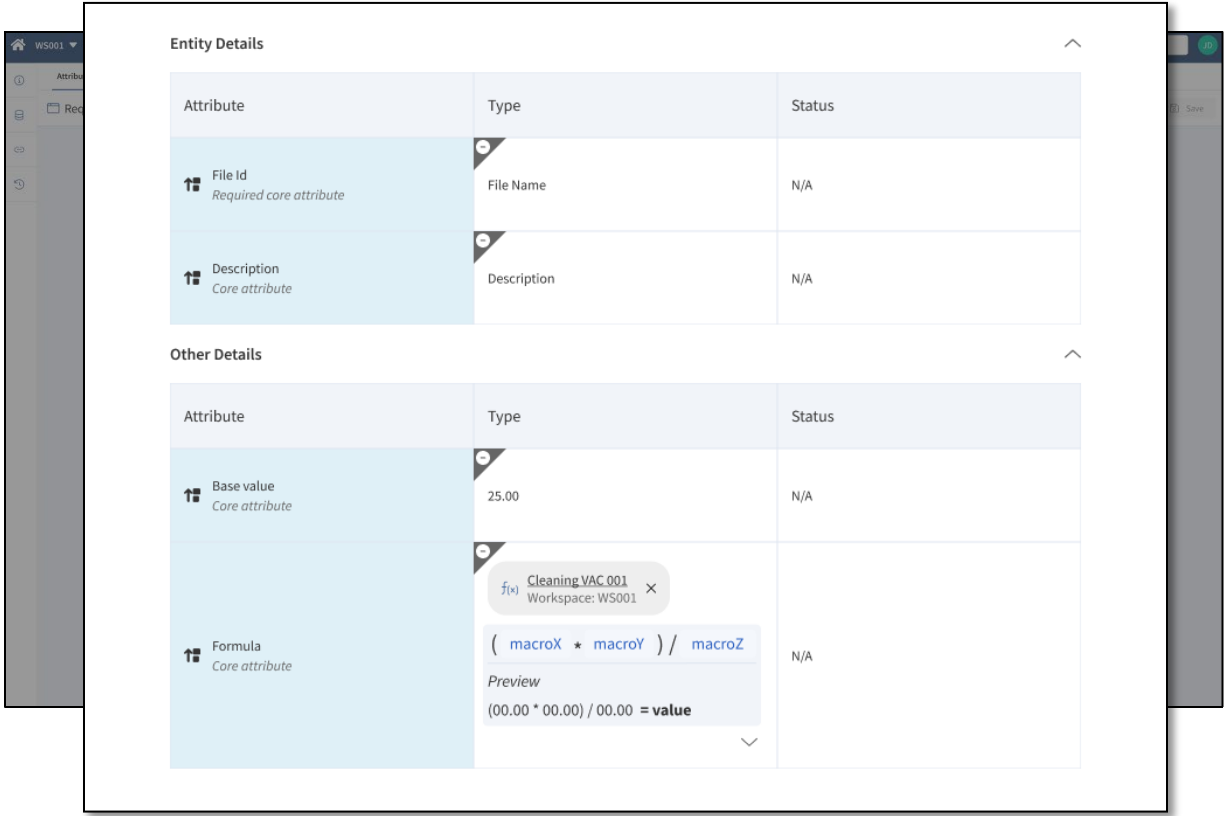
Preview formula attributes

Variables in formula
marcoX *Variable*
marcoY *Variable*
marcoZ *Variable*

- Formula Creator
  - Building you formula
  - Approve your formula



Calculations



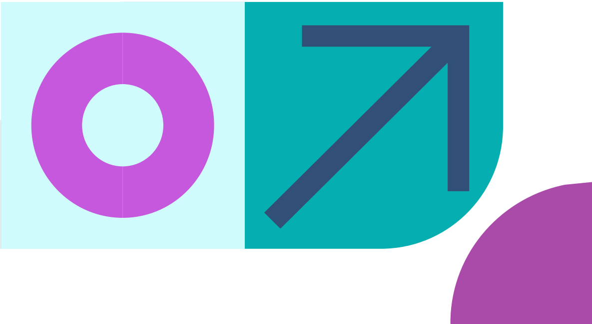
Entity Details

Attribute	Type	Status
File Id *Required core attribute*	File Name	N/A
Description *Core attribute*	Description	N/A

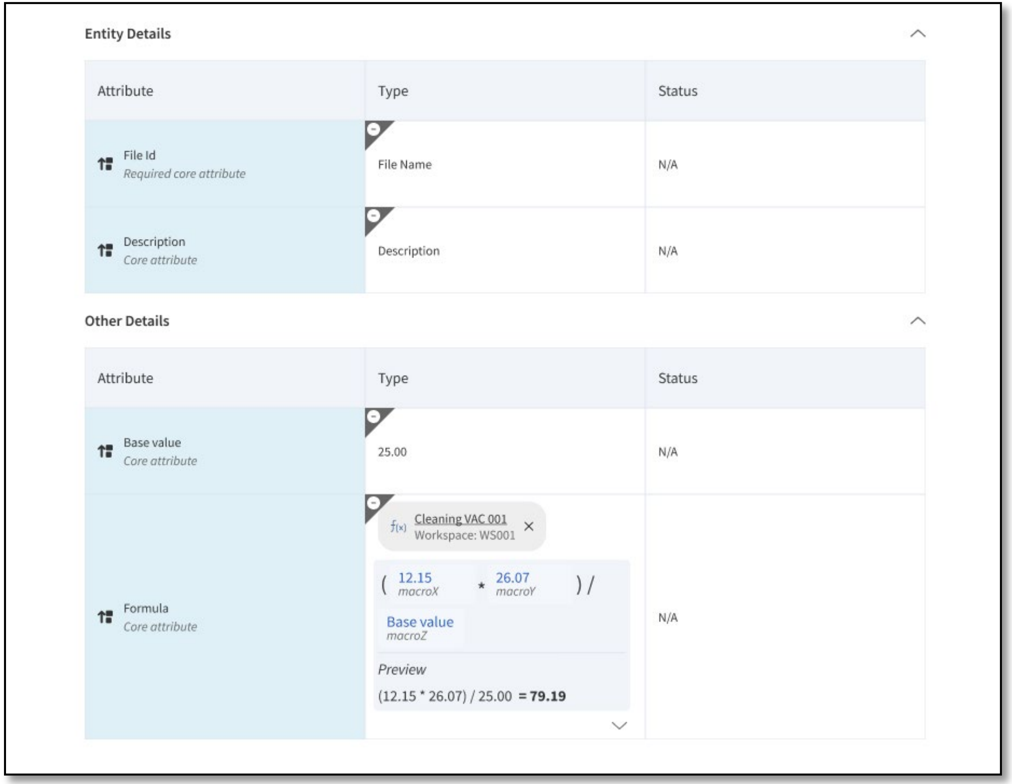
Other Details

Attribute	Type	Status
Base value *Core attribute*	25.00	N/A
Formula *Core attribute*	Cleaning VAC 001 Workspace: WS001 (macroX * macroY) / macroZ *Preview* (00.00 * 00.00) / 00.00 = **value**	N/A

- Add a Formula



Calculations



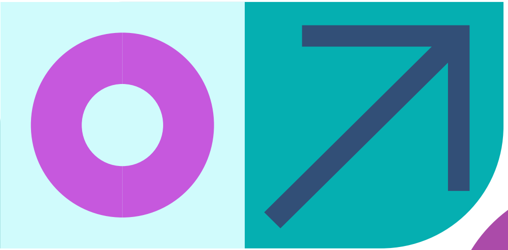
Entity Details

Attribute	Type	Status
File Id *Required core attribute*	File Name	N/A
Description *Core attribute*	Description	N/A

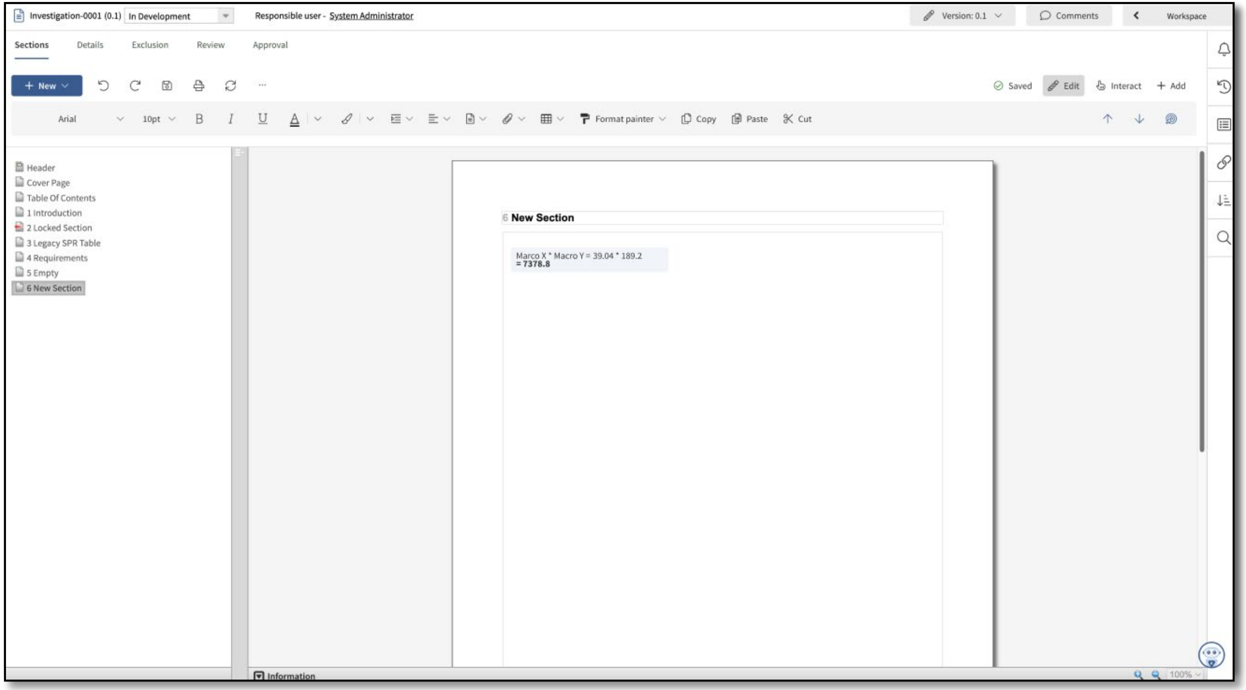
Other Details

Attribute	Type	Status
Base value *Core attribute*	25.00	N/A
Formula *Core attribute*	Cleaning VAC 001 Workspace: WS001 (12.15 *macroX* * 26.07 *macroY*) / Base value *macroZ* *Preview* (12.15 * 26.07) / 25.00 = **79.19**	N/A

- Calculating (Data View)



Calculations



Investigation-0001 (0.1) In Development

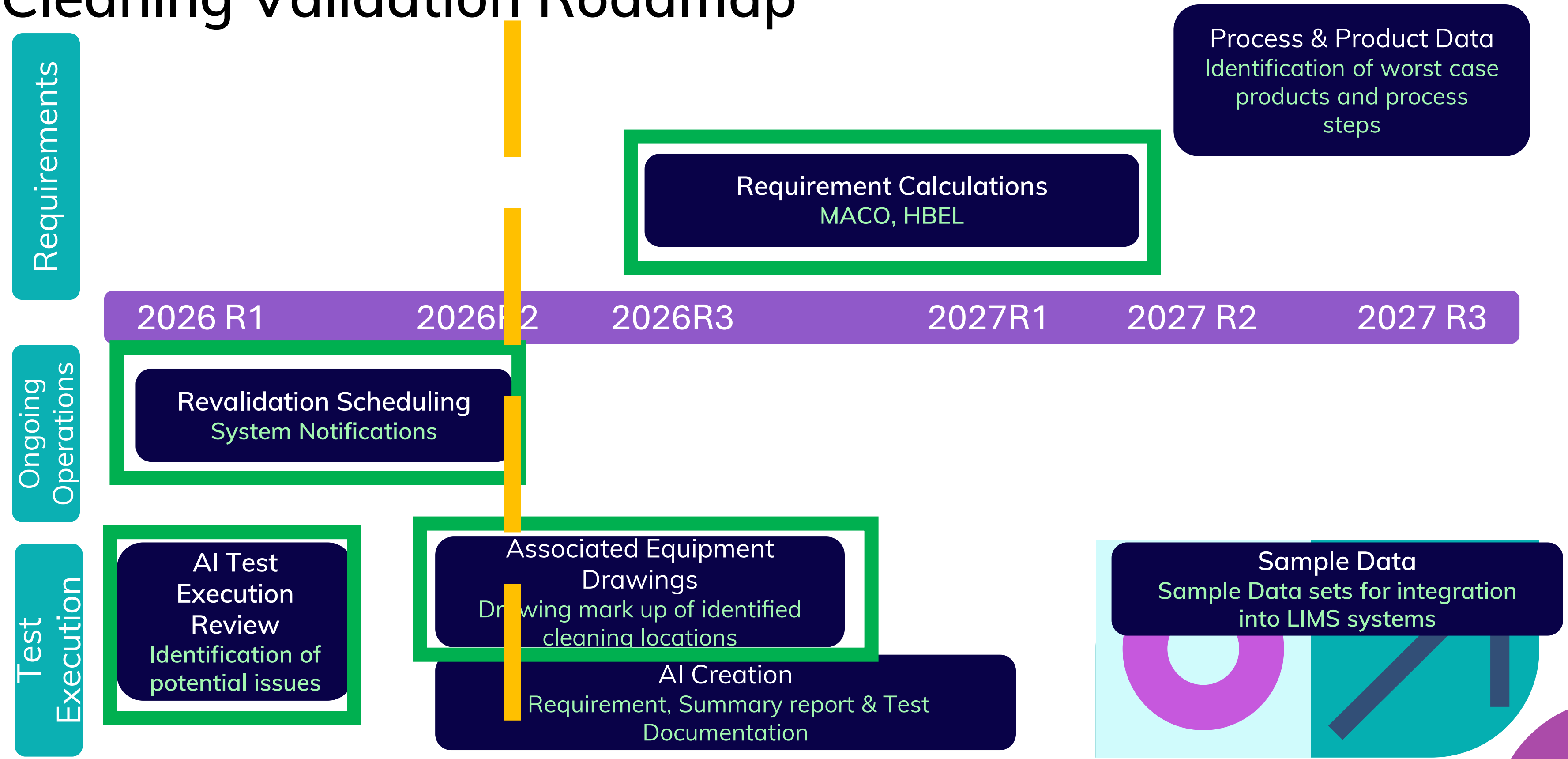
Responsible user - System Administrator

6 New Section

Marco X * Macro Y = 39.04 * 189.2
= 7378.8

- Calculating (Document View)

Cleaning Validation Roadmap



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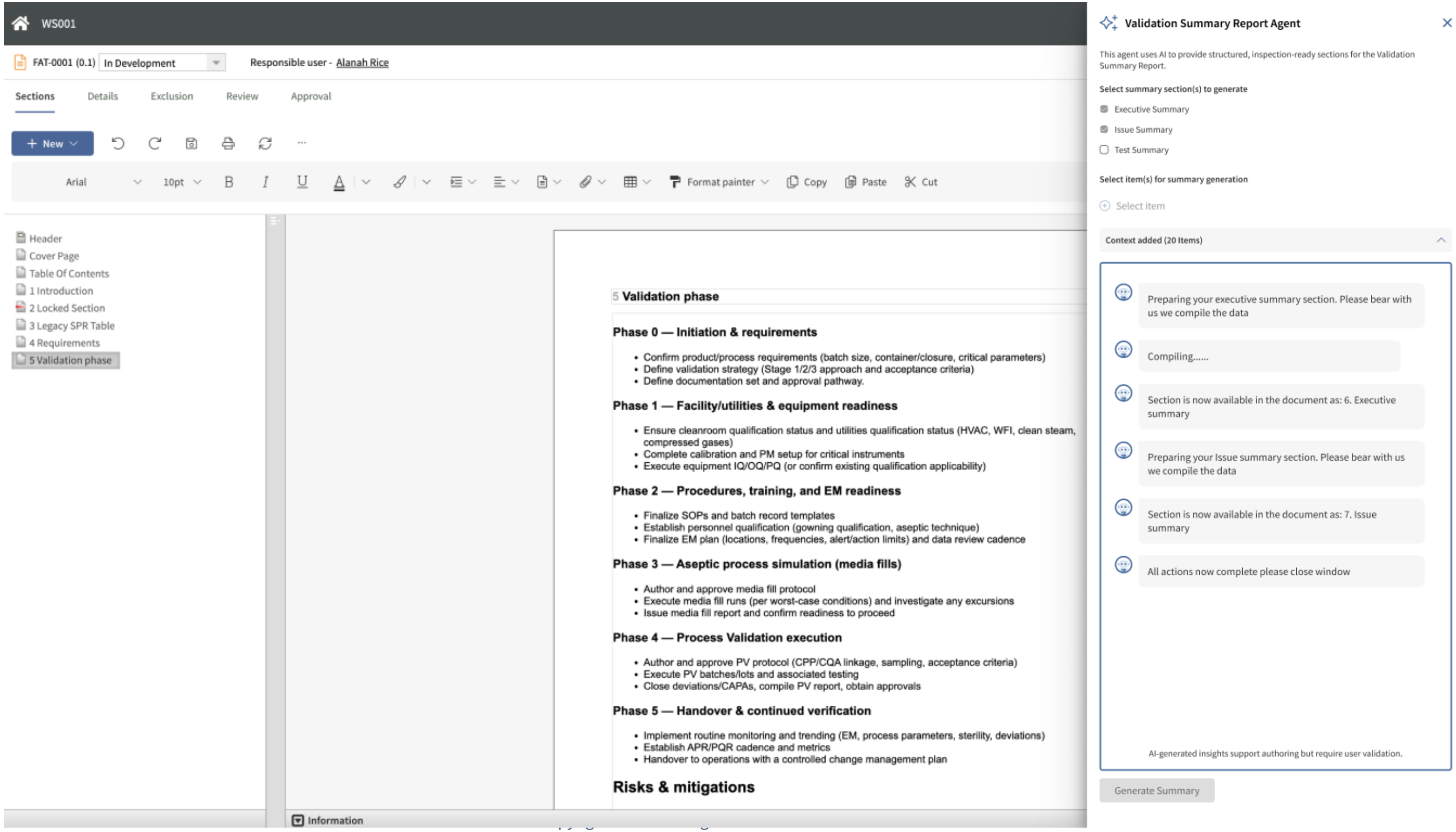


Responsible user - Alanah Rice

5 Validation phase

Phase 0 — Initiation & requirements

- Confirm product/process requirements (batch size, container/closure, critical parameters)
- Define validation strategy (Stage 1/2/3 approach and acceptance criteria)
- Define documentation set and approval pathway.

Phase 1 — Facility/utilities & equipment readiness

- Ensure cleanroom qualification status and utilities qualification status (HVAC, WFI, clean steam, compressed gases)
- Complete calibration and PM setup for critical instruments
- Execute equipment IQ/OQ/PQ (or confirm existing qualification applicability)

Phase 2 — Procedures, training, and EM readiness

- Finalize SOPs and batch record templates
- Establish personnel qualification (gowning qualification, aseptic technique)
- Finalize EM plan (locations, frequencies, alert/action limits) and data review cadence

Phase 3 — Aseptic process simulation (media fills)

- Author and approve media fill protocol
- Execute media fill runs (per worst-case conditions) and investigate any excursions
- Issue media fill report and confirm readiness to proceed

Phase 4 — Process Validation execution

- Author and approve PV protocol (CPP/CQA linkage, sampling, acceptance criteria)
- Execute PV batches/lots and associated testing
- Close deviations/CAPAs, compile PV report, obtain approvals

Phase 5 — Handover & continued verification

- Implement routine monitoring and trending (EM, process parameters, sterility, deviations)
- Establish APR/PQR cadence and metrics
- Handover to operations with a controlled change management plan

Risks & mitigations

Validation Summary Report Agent

This agent uses AI to provide structured, inspection-ready sections for the Validation Summary Report.

Select summary section(s) to generate

☑ Executive Summary
☑ Issue Summary
☐ Test Summary

Select item(s) for summary generation

Select item

Context added (20 Items)

Preparing your executive summary section. Please bear with us we compile the data

Compiling......

Section is now available in the document as: 6. Executive summary

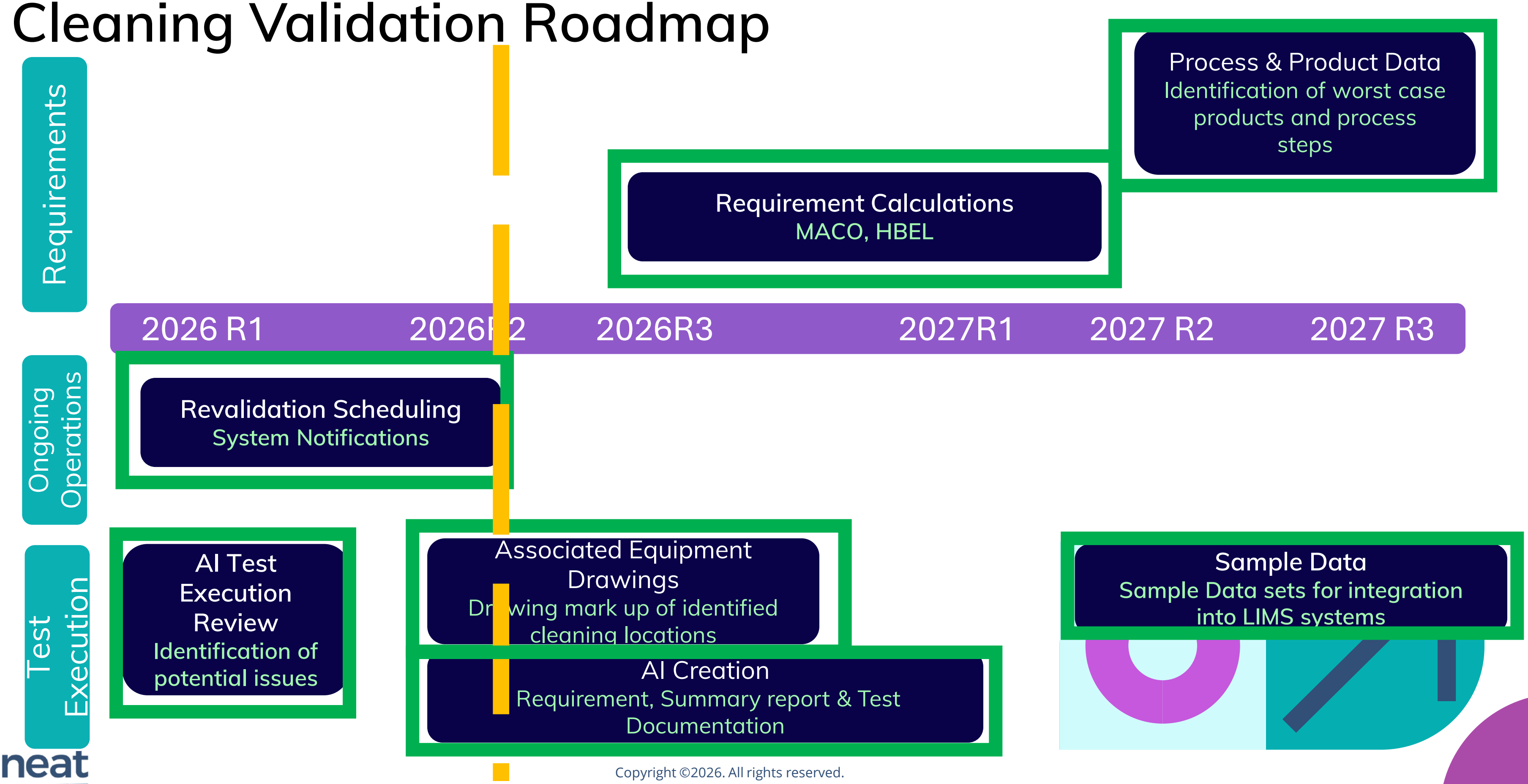
Preparing your Issue summary section. Please bear with us we compile the data

Section is now available in the document as: 7. Issue summary

All actions now complete please close window

AI-generated insights support authoring but require user validation.

Cleaning Validation Roadmap



Requirements

Requirement Calculations
MACO, HBEL

Process & Product Data
Identification of worst case products and process steps

2026 R1 | 2026R2 | 2026R3 | 2027R1 | 2027 R2 | 2027 R3

Ongoing Operations

Revalidation Scheduling
System Notifications

Test Execution

AI Test Execution Review
Identification of potential issues

Associated Equipment Drawings
Drawing mark up of identified cleaning locations

AI Creation
Requirement, Summary report & Test Documentation

Sample Data
Sample Data sets for integration into LIMS systems