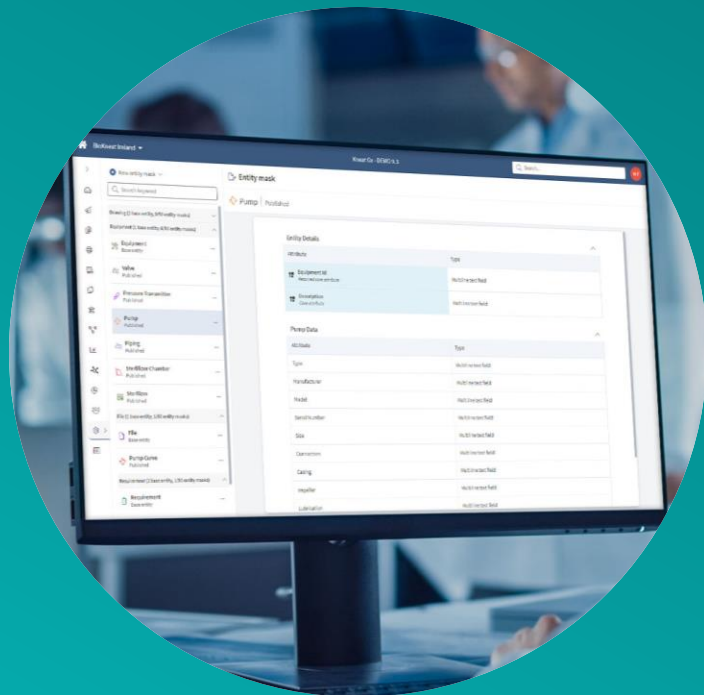


Kneat Integrations



Speakers



Joe Azzarella

Senior CSE,

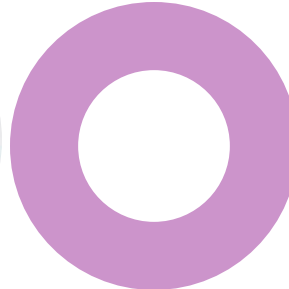
Kneat



Denis Bartley

Senior Integration Engineer

Kneat



Fintan Coady

CQV Specialist ORP Lead,

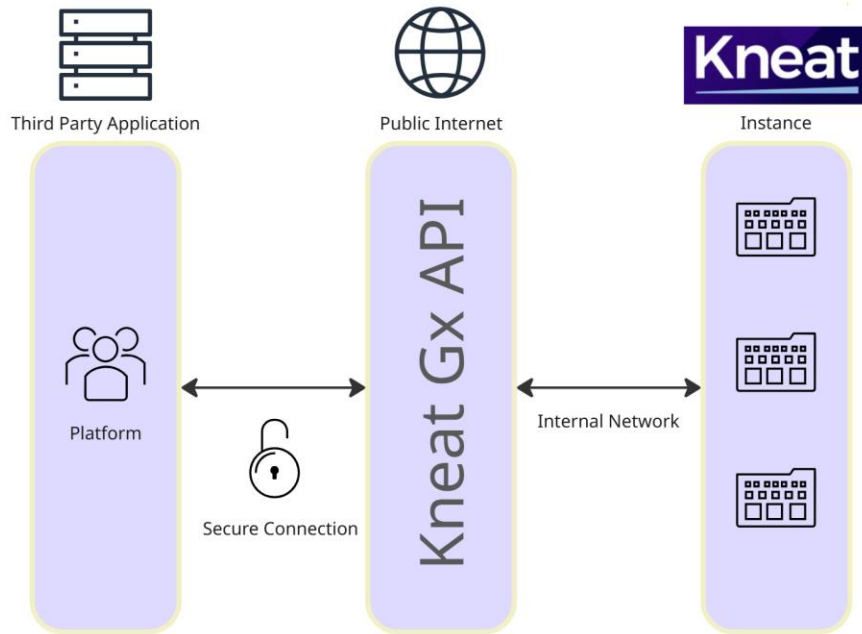
PM
GROUP

Kneat Open APIs

Connecting Kneat to Your World

- Your validation data lives in Kneat. Your business runs on data from across your ecosystem. Today we show you how they connect.
- Kneat's APIs are designed to fit your workflows, not define them.
- Kneat's APIs put automation and integration in your hands to connect your validation data to the workflows and tools that drive your business.

What is an API – Application Programming Interface



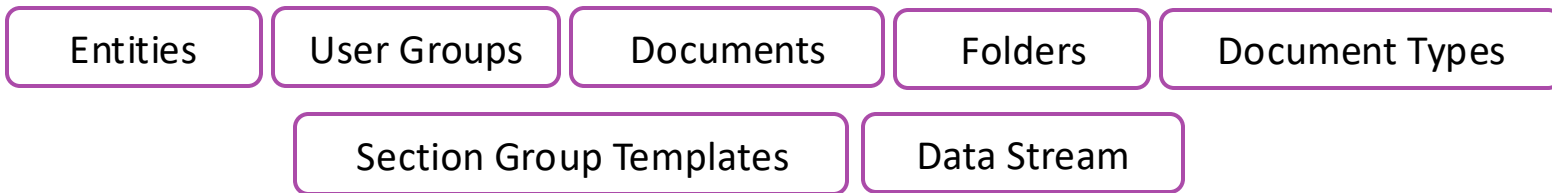
Kneat Gx API provides a standardised set of rules and requests that allows systems to communicate and exchange data efficiently and securely.

Integrations provide:

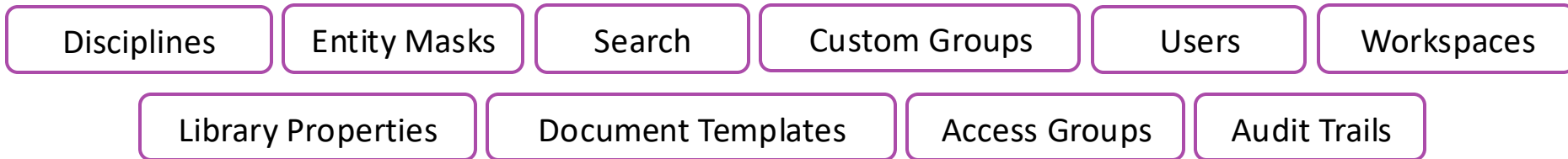
- Reduce Manual Effort
- Enable automated workflows
- Embed Kneat into your ecosystems
- Time-To-Value

Current API Feature Support

New API Additions and Enhancements



Foundation APIs



Integrations Built With Kneat API



The Industry Problem – Drowning in Data

The Concept of DRIP

- As we transition to a Pharma 4.0 world, we are drowning in data (values in databases, PDF files with extensive information, values from instrumentation, etc.). This allows us to be **Data Rich**.
- This data is not easily identifiable or transferred to our systems of choice. Being able to answer a simple question should not require using the correct system with the right query if that option is available at all. This leaves us **Information Poor** in situations where we need immediate answers.
- This combination leaves us **Data Rich and Information Poor (DRIP)**.

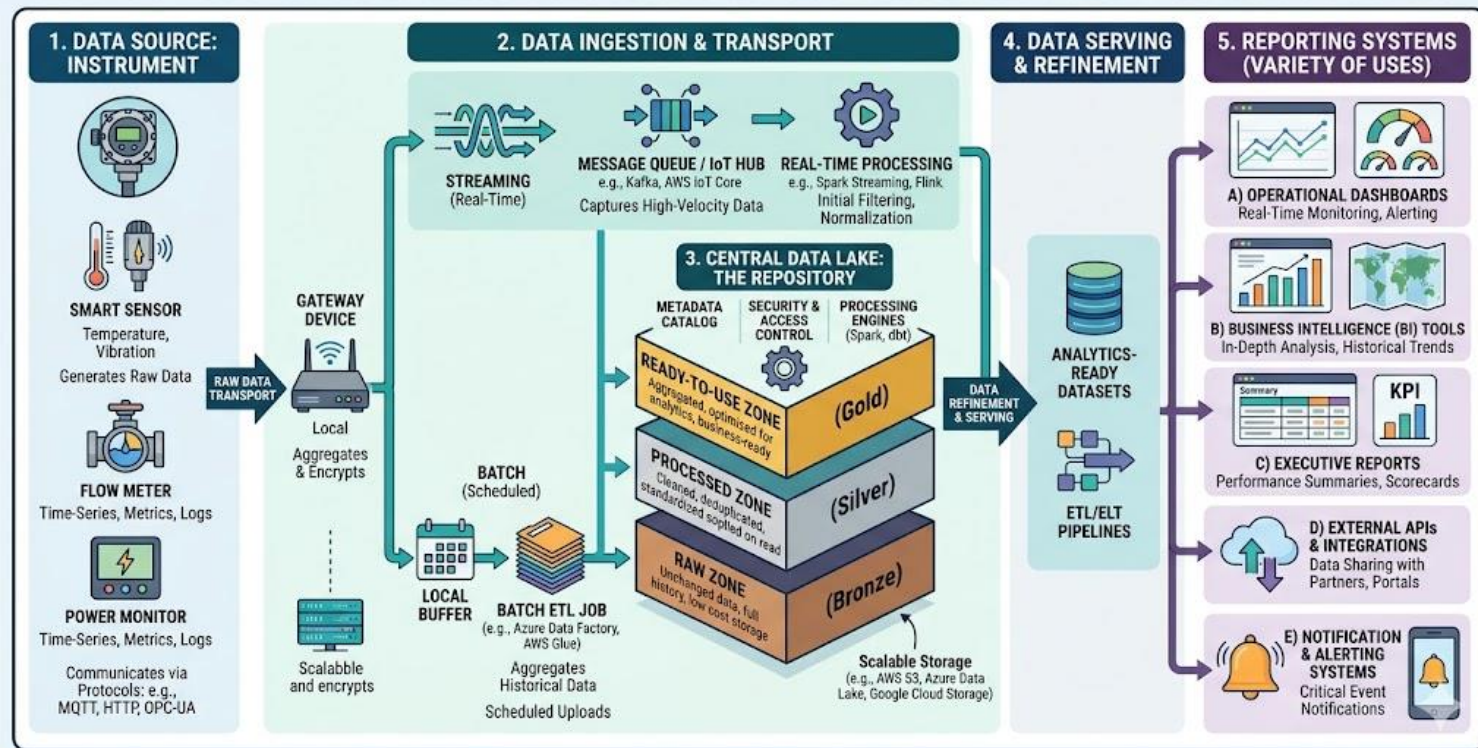


The Industry Problem – Drowning in Data

DRIP Challenges

1. Data Ingestion & Transport Chaos
2. Governance & Security Nightmare
3. Multiple Versions of the Truth
4. Hidden Costs & Wasted Resources
5. Sluggish & Unreliable Reporting

END-TO-END DATA PIPELINE: INSTRUMENT TO DATA LAKE TO REPORTING SYSTEMS





*A 20-minute query is a report.
A 10-second query is a conversation.*



Kneat's Solution to DRIP – Data Stream

What is Data Stream?

- Retrieve your KPI data through the Kneat API
- Data is updated every 24 hours
- Supports automated retrieval of data
- Contact your CSM/CSE for more information on how to access Data Stream in the future

Kneat Gx Data Stream

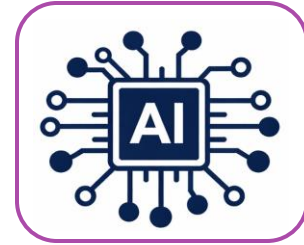
How the data can be used!



Data Warehouse / Data Lake



Reports



Artificial Intelligence

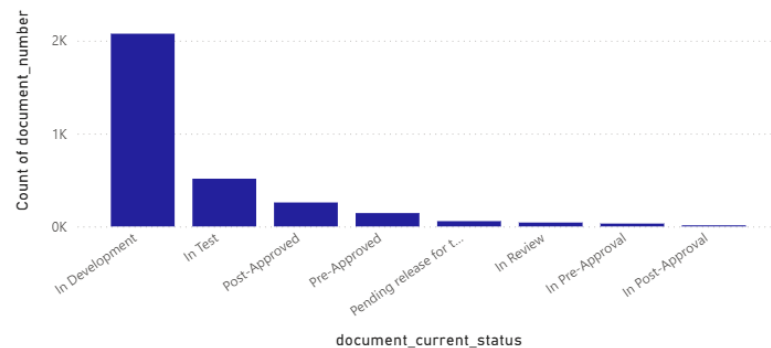
Kneat Gx Data Stream

Document Time Estimate Overview

Issue Count	Average Issue Resolution Time (days)
570	38.34
Protocol Count	Average Protocol Execution Time (days)
3130	47.34

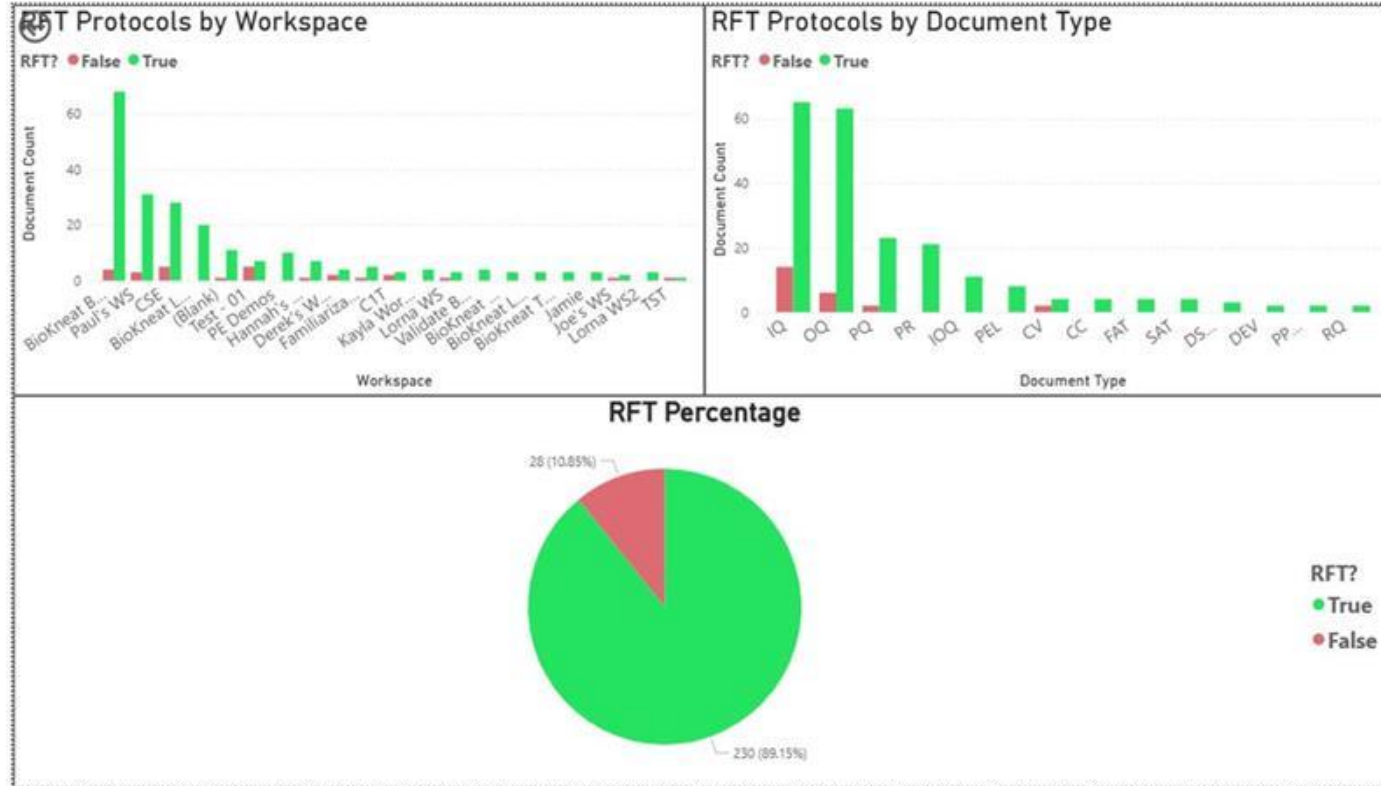
Count of Protocol Docs by Status

Issue? ● False



Kneat Gx Data Stream

Protocol Count per Document Status



“Your Validation, Your Way”

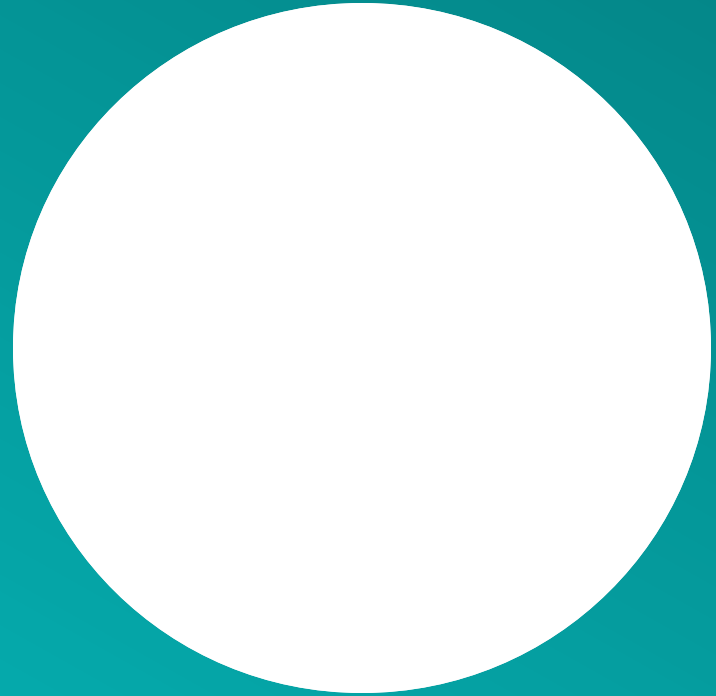


“Connectivity, Your Way”

Kneat Integrations

Panio's Digital Dashboards

Fintan Coady | PM Group



Panios Digital Platform & Unified Watchtower

Electronic Validation

Digital validation management, protocol execution, and real-time readiness tracking across all CQV activities.

Automation Project Tracking

Automation change monitoring and tracking, with oversight of automation change requests including MES integration, supported by operator dashboards and seamless data exchange for end-to-end operational visibility.

Document Management System

Controlled documents, SOPs, training materials, and regulatory compliance in a single validated system.

Change Control/ Deviation EQMS

Deviation, CAPA, and change control management with closure tracking post-handover for sustained compliance.

Unified Dashboard "Watchtower"



Risk register & action tracker: •
Training readiness status
• Tech transfer visibility
• Cross-stream KPIs in real time

01.

Foundation

Governance and digital platform establishment

02.

Population

Workshops, SIPOCs, comprehensive risk register

03.

Integration

System linkage, dashboard cadence

04.

Optimisation

Continuous improvement post Day One

We deliver a facility not just built, but truly ready to run from Day One.

[Back to report](#)

CQV MILESTONE SCHEDULE ACTIVITIES GROUPED BY MODULE AND CATEGORY

Activity	Start Date	End Date	Category
Clean Utilities - Commissioning Execution			
741-XU001 - Process Air (LP) Distribution - OQ Execution	May 2025	Jun 2025	OQ Execution
741-XU081 - Clean Steam (DR3/DR2) Distribution - OQ Execution	Sep 2025	Nov 2025	OQ Execution
Module X - Commissioning Execution			
741-XS182 - Biosealer (x3) - IQO Execution (incl. Shakedown & EMR Calibration)	May 2025	Oct 2025	OQ Execution
741-XS176 - Air Sampler - IQO Execution (incl. Shakedown & EMR Calibration)	Jun 2025	Jul 2025	OQ Execution
741-XS179 - Airborn Germ Collector - IQO Execution (incl. Shakedown & EMR Calibration)	Jun 2025	Aug 2025	OQ Execution
741-XS153 - pH-Meter and conductivity - IQO Execution (incl. Shakedown & EMR Calibration)	Jul 2025	Jul 2025	OQ Execution
741-XS040 - Refrigerator 2 °C to 8 °C - IQO Execution (1 Unit)	Aug 2025	Oct 2025	OQ Execution
741-XS160 - FIT-Station - IQO Execution	Sep 2025	Dec 2025	OQ Execution
741-XS164 - Particle counter (x2) - IQO Execution (incl. Shakedown & EMR Calibration)	Sep 2025	Nov 2025	OQ Execution
741-XP660 - Filtration and Filling - OQ Execution	Sep 2025	Nov 2025	OQ Execution
741-XS370 - Floor Scale (x2) - IQO Execution	Sep 2025	Oct 2025	OQ Execution
741-XP050 - Buffer Hold Tank - OQ Execution	Sep 2025	Sep 2025	OQ Execution
741-XS371 - Bench Scale - IQO Execution	Sep 2025	Oct 2025	OQ Execution
741-XP610 - Pool Vessel - OQ Execution	Sep 2025	Sep 2025	OQ Execution
741-XP630 - Pool Vessel - OQ Execution	Sep 2025	Sep 2025	OQ Execution
741-XP640 - Ultrafiltration/Diafiltration - OQ Execution	Sep 2025	Nov 2025	OQ Execution
741-XP615 - Carbon Filtration - OQ Execution	Oct 2025	Oct 2025	OQ Execution
741-XS670 - CIP acid DSP - OQ Execution	Oct 2025	Nov 2025	OQ Execution
741-XS672 - CIP Loop - OQ Execution	Oct 2025	Nov 2025	OQ Execution
741-XS300 - WFI PoU WFI Break Bag - Chromatography - OQ Execution	Oct 2025	Nov 2025	OQ Execution
741-XS301 - WFI PoU WFI Break Bag - Final Dilution - OQ Execution	Oct 2025	Nov 2025	OQ Execution
741-XS302 - WFI PoU Cleaning Room ES506 - OQ Execution	Oct 2025	Nov 2025	OQ Execution
741-XP625 - Chromatography - OQ Execution	Oct 2025	Nov 2025	OQ Execution
741-XP655 - SU Mixing Bag Container 1'000 L - IQO Execution	Oct 2025	Oct 2025	OQ Execution
741-XP620 - Pool Vessel - OQ Execution	Oct 2025	Oct 2025	OQ Execution
741-XP656 - SU Mixing Bag Container 200 L - IQO Execution	Oct 2025	Oct 2025	OQ Execution
741-XP657 - SU Mixing Bag Container 50 L - IQO Execution	Oct 2025	Oct 2025	OQ Execution
741-XP600 - SU Mixing Bag Container 1'500 L - IQO Execution	Oct 2025	Oct 2025	OQ Execution
741-XP601 - SU Mixing Container Filling Station - IQO Execution	Oct 2025	Oct 2025	OQ Execution



Module:

21.05.2025 > Week 21

Breakdown

Select to filter results

All

Status

Filter

In progress

Critical

Critical path



Document List

Data acquired from KNEAT application

number	title	version	modifiedDate	status	link
CLIA - MP016-01	Component Level Impact Assessment for LOG-0002-01	0.3	5/1/2025 4:04:22 PM	InDevelopment	link
CUCTP-MP016-02	Clean Utility Commissioning Test Protocol for MP016-LOG-001-02	0.1	4/4/2025 9:44:18 AM	InDevelopment	link
CUIOQ - MP016-LOG-001-03	Clean Utility Installation Operational Qualification Test Protocol for MP016-LOG-001-03	0.1	3/14/2025 12:32:11 PM	InDevelopment	link
DQ-MP016-01	Design Qualification for LOG-	0.3	5/13/2025 1:29:30 PM	InDevelopment	link

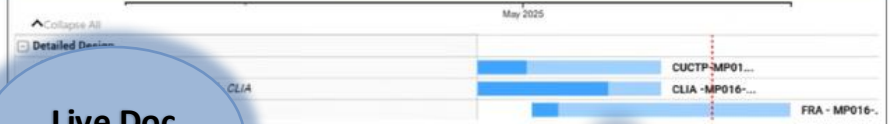
Document History

Data acquired from KNEAT application

number	issuedDate	status	version	link
CLIA - MP016-01	4/8/2025 3:07:31 PM	Review Closed	0.1	link
DQ-MP016-01	4/9/2025 1:35:57 PM	Review Closed	0.1	link
FRA - MP016-02	4/15/2025 3:52:32 PM	Review Closed	0.1	link
FRA - MP016-02	4/16/2025 12:25:38 PM	Review Closed	0.2	link
FRA - MP016-02	4/16/2025 12:32:07 PM	Review Closed	0.3	link
FRA - MP016-02	4/21/2025 10:35:23 AM	Review Closed	0.4	link
FRA - MP016-02	4/23/2025 8:45:44 PM	Review Closed	0.5	link
URS - MP016-01	4/28/2025 10:30:12 AM	Approved	1.0	link
BTM - MP016-01	4/28/2025 10:45:40 AM	Approved	1.0	link

Schedule

Activities grouped by module and category



Live Doc Updates

Color Coded Status

Direct Document Links

Project Timeline



Handover Risks and Progress Tracking


 Module: **Risk Register** 16.04.2026 > Week 16
 Last data update: 30 Mar 2026 

S Date filter

S Status

Closed
Issue (PCN)
Open

R Risk Matrix - Risks

Ri Risk count - by probability and impact

Li	Likelihood	Header	1 Low	2 Medium	3 High	4 Very High	5 Extreme
1 Rare	0	0	1	0	1	6	
2 Unlikely	3	3	2	1	6	1	
3 Possible	7	2	10	8	7	7	
4 Likely	0	0	4	1	2	2	
5 Almost Certain	1	0	1	0	2	2	
Total	11	5	18	10	18		

Punch List Status

approved 704
open 458
closed 32
Assigned OK ZK

Count by worksheet

Risk or Opportunity Risk

Worksheet	Count
7 - Quality System & Op...	18
13 - MSAT	10
14 - Tech Transfer	10
5b - Supply Chain	6
8 - QC Labor & L...	5
0 - Cust... Relati...	4
11 - Produ... Meth...	3
15 - Analy... Meth...	3
(Blank)	1
1 - Facility Install...	1
10 - Facility Utiliti...	1
16 - Regul... and Prepa...	1
5a - Procu... Dossier Process	1
Other	1

Table View

Module

I

M Suite1

X

Mechanical Complet

0 100.0% 264 264

Lookahead

Maximum Lead

100

0

Aggr

Qr

Handover I

Module

I

M Suite1

X

KNEAT Status

Equipment ID

727-U197

735-MS700

IVs

Document Status

Module 1

100.00%

IQFRs

Document Status

Module 1

100.00%

Description

VH207 & VH208 vent line installed c

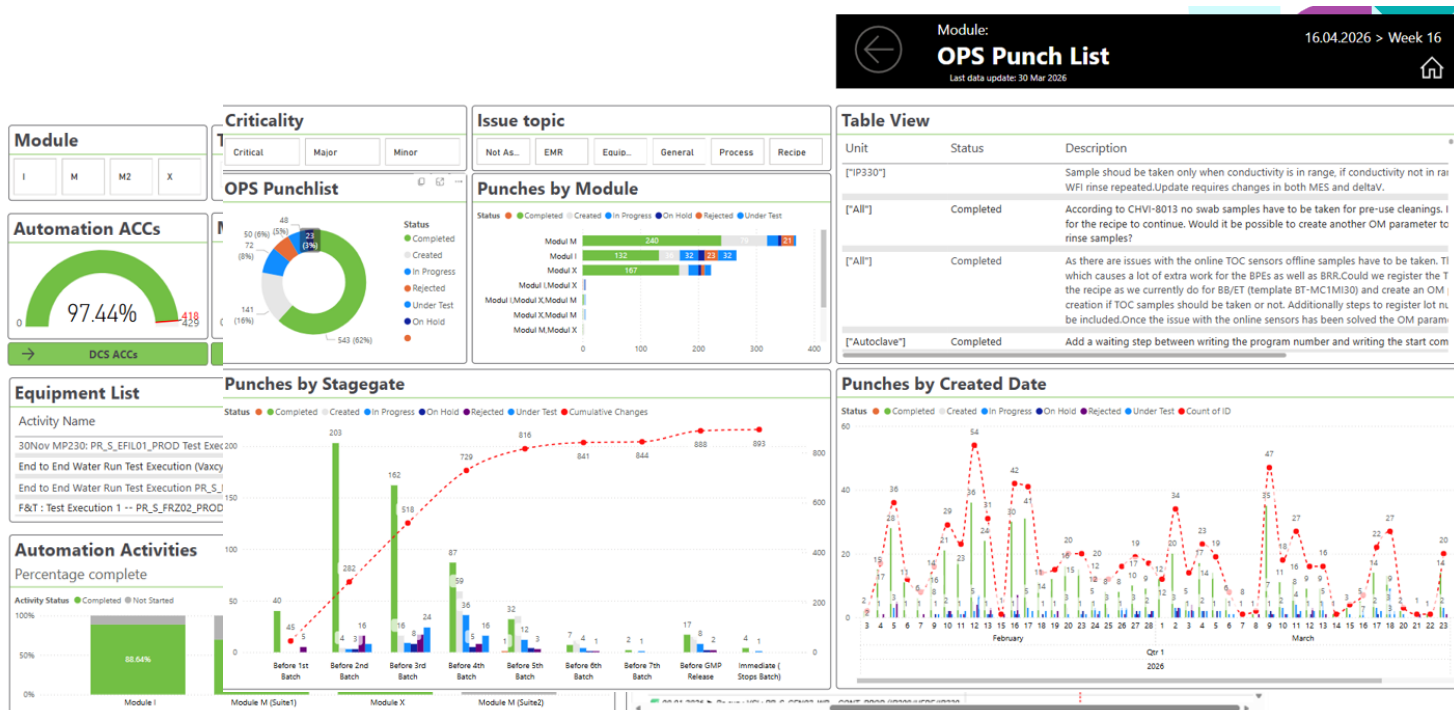
"Rust" staining was observed on the

(General punch) Insulation that has l

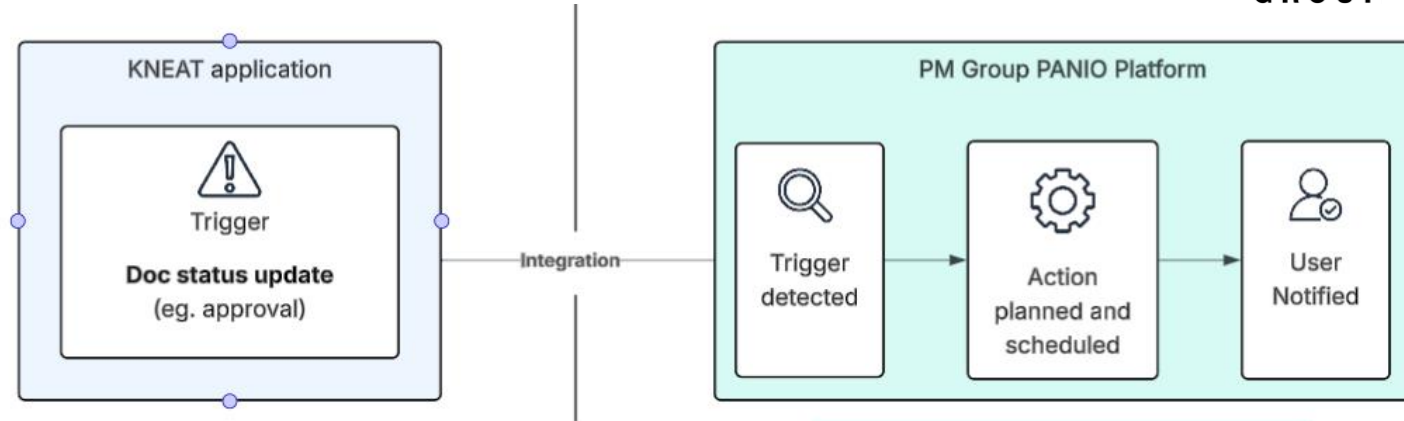
1 metal tag required at these locatio

Table of Contents		14 - Tech Transfer Process			
1	Overview	Workstream			
2	Introduction	Process / MSAT Lead			
3	Process	Discipline			
4	Process Readiness	Category			
5	Process Readiness	(Blank)			
6	Process Readiness	Peters			
7	Process Readiness	Risk lead Monza			
8	Process Readiness	Risk lead Vaxcyte			
9	Process Readiness	Risk lead Vaxcyte			
10	Process Readiness	Risk lead Vaxcyte			
11	Process Readiness	Risk lead Vaxcyte			
12	Process Readiness	Risk lead Vaxcyte			
13	Process Readiness	Risk lead Vaxcyte			
14	Process Readiness	Risk lead Vaxcyte			
15	Process Readiness	Risk lead Vaxcyte			
16	Process Readiness	Risk lead Vaxcyte			
17	Process Readiness	Risk lead Vaxcyte			
18	Process Readiness	Risk lead Vaxcyte			
19	Process Readiness	Risk lead Vaxcyte			
20	Process Readiness	Risk lead Vaxcyte			
21	Process Readiness	Risk lead Vaxcyte			
22	Process Readiness	Risk lead Vaxcyte			
23	Process Readiness	Risk lead Vaxcyte			
24	Process Readiness	Risk lead Vaxcyte			
25	Process Readiness	Risk lead Vaxcyte			
26	Process Readiness	Risk lead Vaxcyte			
27	Process Readiness	Risk lead Vaxcyte			
28	Process Readiness	Risk lead Vaxcyte			
29	Process Readiness	Risk lead Vaxcyte			
30	Process Readiness	Risk lead Vaxcyte			
31	Process Readiness	Risk lead Vaxcyte			
32	Process Readiness	Risk lead Vaxcyte			
33	Process Readiness	Risk lead Vaxcyte			
34	Process Readiness	Risk lead Vaxcyte			
35	Process Readiness	Risk lead Vaxcyte			
36	Process Readiness	Risk lead Vaxcyte			
37	Process Readiness	Risk lead Vaxcyte			
38	Process Readiness	Risk lead Vaxcyte			
39	Process Readiness	Risk lead Vaxcyte			
40	Process Readiness	Risk lead Vaxcyte			
41	Process Readiness	Risk lead Vaxcyte			
42	Process Readiness	Risk lead Vaxcyte			
43	Process Readiness	Risk lead Vaxcyte			
44	Process Readiness	Risk lead Vaxcyte			
45	Process Readiness	Risk lead Vaxcyte			
46	Process Readiness	Risk lead Vaxcyte			
47	Process Readiness	Risk lead Vaxcyte			
48	Process Readiness	Risk lead Vaxcyte			
49	Process Readiness	Risk lead Vaxcyte			
50	Process Readiness	Risk lead Vaxcyte			
51	Process Readiness	Risk lead Vaxcyte			
52	Process Readiness	Risk lead Vaxcyte			
53	Process Readiness	Risk lead Vaxcyte			
54	Process Readiness	Risk lead Vaxcyte			
55	Process Readiness	Risk lead Vaxcyte			
56	Process Readiness	Risk lead Vaxcyte			
57	Process Readiness	Risk lead Vaxcyte			
58	Process Readiness	Risk lead Vaxcyte			
59	Process Readiness	Risk lead Vaxcyte			
60	Process Readiness	Risk lead Vaxcyte			
61	Process Readiness	Risk lead Vaxcyte			

Punches and Changes



Periodic Review and Approval triggers



Live Prompts for Periodic Tasks- Integrations with Kneat & Scheduling tools allows PM Group Dashboards to trigger alarms for user against emerging reviews, re-qualifications & re-approvals.

- **Detect** triggers from external apps (KNEAT API).
- **Validate** events
- **Plan** actions using custom logic (rules, prioritization, dependencies).
- **Persist** planned actions with state tracking.
- **Notify** users with context-rich messages (email, Teams)
- **Track** execution and feedback (status updates, re-planning, audit logs).

Digital Factory and APIs

Diğer

GRO

Serotype

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☐ DS

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☐ PS

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Batch

3221346001

3221370001

Serotype

19A

3

Breakdown

☐ (Blank)

⌵

☐ Conjugation / PS

☐ Microfluidizer

☐ Pool Vessel

☐ Ultrafiltration/Diafilter

⌵

☒ DSP

☐ Buffer Hold Tank

☐ Centrifuge

☐ Chromatography

☐ Filtration & Filling

☐ Pool Vessel

☐ SU Mixing Bag Contair

☐ Ultrafiltration/Diafilter

⌵

☐ USP

☐ Biological Safety Cabin

☐ Break Tank 200 L

☐ Buffer Hold Tank

☐ Centrifuge

☐ Feed Tank 1000 L

☐ Feed Tank 75 L

☐ Incubator

⌵

☐ Media Preparation 120 L

Planned C

Batch Type

(Blank)

DS

5

0

PS

5

0

2026

20

Febru...

M

Material S

Component Descriptio

K2-HP04 HP EPBP

704732

141655263

141655264

141655205

141655206

141655267

141655268

141655269

141655270

141655271

141655272

141655273

141655274

141655275

141655276

Type	Stock																														
Available when required																															
	<table><tr><th>Component</th><th>Component Description</th><th>Stock</th></tr><tr><td>704583</td><td>Hy-Soy 11.34 KG</td><td>46,546.32</td></tr><tr><td>704585</td><td>CysL-HCl-H2O pH 1KG</td><td>3,971.59</td></tr><tr><td>704587</td><td>NaOH 5M 2.5L</td><td>5,412.15</td></tr><tr><td>704623</td><td>Deoxycholate-Na 1KG</td><td>4,101.89</td></tr><tr><td>704626</td><td>Fernstool, Manifold Parker, Typ E</td><td>702.00</td></tr><tr><td>704633</td><td>TUA-I-0.5"-1m-BB-TU</td><td>16,641.00</td></tr><tr><td>704635</td><td>TUA-III-0.375"-1m-GG-WS</td><td>3,230.00</td></tr><tr><td>704636</td><td>TUA-III-0.5"-1m-GG-WS</td><td>54,450.00</td></tr><tr><td>704637</td><td>TUA-III-0.5"-3m-GG-WS</td><td>17,064.00</td></tr></table>	Component	Component Description	Stock	704583	Hy-Soy 11.34 KG	46,546.32	704585	CysL-HCl-H2O pH 1KG	3,971.59	704587	NaOH 5M 2.5L	5,412.15	704623	Deoxycholate-Na 1KG	4,101.89	704626	Fernstool, Manifold Parker, Typ E	702.00	704633	TUA-I-0.5"-1m-BB-TU	16,641.00	704635	TUA-III-0.375"-1m-GG-WS	3,230.00	704636	TUA-III-0.5"-1m-GG-WS	54,450.00	704637	TUA-III-0.5"-3m-GG-WS	17,064.00
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704636	TUA-III-0.5"-1m-GG-WS	54,450.00																													
704637	TUA-III-0.5"-3m-GG-WS	17,064.00																													
Coverage with Stock																															
Release as planned																															
Reschedule to																															
Unplanned Coverage																															

Component Description	PO Placed	PO Confirmed	Quality Release Ready	Available Stock	First Category	VAX PO Number	Open Requirement
K2-HPO4 pH 7.0 BP SKG							
141655263		1		1		0 Pending quality release	POCH00131 0.03 KG
13.12.2025							
141655264		1		1		0 Pending quality release	POCH00131 0.03 KG
13.12.2025							
141655265		1		1		0 Pending quality release	POCH00131 0.03 KG
13.12.2025							
141655266		1		1		0 Pending quality release	POCH00131 0.03 KG
13.12.2025							
141655267		1		1		0 Pending quality release	POCH00131 0.03 KG
13.12.2025							
141655268		1		1		0 Pending quality release	POCH00131 0.03 KG
13.12.2025							
141655269		1		1		0 Pending quality release	POCH00131 0.03 KG
13.12.2025							



Module: **Material availability**

Last data update:

Available Stock

Availability Date	Initial Stock	UoM	Safety Stock	Component *
28.09.2025	10,738.03	KG	0	704740
31.10.2025	0.00	PC	0	705000
31.12.2025	0.00	KG	0	704732
04.01.2026	0.00	PC	0	705124
07.01.2026	0.00	PC	0	704782
07.01.2026	0.00	PC	0	705341
04.02.2026	1,538.21	KG	0	704623
09.02.2026	0.00	KG	0	704754
Total	7,577,315.32		0	



371K (21.84%)

13.42K (78.15%)

PO Overview					
Campaign	Product	Consumer	Requested Delivery Date	Vendor	Vendor Art. Description
ENG	PS	Module I	10.12.2025	Brunswick Chemie	SODIUM CARBONATE, 99.5%, ANHYDROUS, EXTRA PURE, CAS 497-19-8
GMP	PS	Module I	1.02.2026	Chemie Brunswick AG	Na-carbonat 25KG
GMP	PS	Module I	8.01.1900	Sartorius Stedim Biotech GmbH	FTU-III-0.2m-0.2um-PTFE-0
GMP	PS	Module I	8.01.1900	Sartorius Stedim Biotech GmbH	FTU-III-0.2m-0.2um-PTFE-0
GMP	PS	Module X8I	25.03.2026	Sartorius Stedim Biotech GmbH	FTU-III-0.2m-0.2um-PTFE-0
GMP	PS	Module X8I	25.03.2026	Sartorius Stedim Biotech GmbH	FTU-III-0.2m-0.2um-PTFE-0
GMP	PS	Module X8I	4.03.2028	Life Technologies BPD UK Ltd	TUA-III-0.5"-3m-GG-T8
GMP	PS	Module I	8.01.2026	Interlechnik Eize GmbH & Co. KG	TUA-XX-1-1.60-88-T8-CHV12
GMP	PS	Module I	8.01.2026	Interlechnik Eize GmbH & Co. KG	TUA-XX-1-1.60-88-T8-CHV12
Total					