

## Session 8.1

# Digital Validation at Eli Lilly

Jeff Denault | Eli Lilly



# **Kneat Gx for Analytical Instrument Qualification (AIQ)**

**Validate 2026, Dublin, Ireland**

**Jeff Denault, Ph.D.  
Eli Lilly and Company**

# Agenda

**01** Analytical Instrument Qualification (AIQ)

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**02** Kneat Deployment

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**03** Kneat Multi-Execute Test Documents

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**04** Kneat Folder Structure

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**05** Kneat Entities

# Eli Lilly and Company



## Founded 1876

Pharmaceutical chemist Eli Lilly; HQ Indianapolis, IN; offices in 18 countries, products sold in ~125 countries



## 50,000+ Employees

Global leader in diabetes, obesity, oncology, and immunology therapeutics



## World's Most Valuable Pharma

First healthcare company to reach \$1T market cap (Nov 2025). Ranked #4 by revenue among biomedical companies



## Expanding Pipeline

Growing oncology and immunology portfolios; oral GLP-1 orforglipron submitted in US and 40+ countries



## Manufacturing Investment

Expanding global capacity with new facility builds to meet growing demand across therapeutics



# Eli Lilly Manufacturing Sites - 2019

 Existing Sites



# Eli Lilly Manufacturing Sites - Today

■ New/Planned Sites   ■ Existing Sites



# **Analytical Instrument Qualification (AIQ)**

# Project Team

## Leadership



**Joseph  
Heyward**



**Jeff  
Denault**

## Quality & Compliance



**Theresa  
Nieto**



**Ashlee  
Brommer**

## IT & Systems



**Keith  
Parsons**



**Josh  
Ellis**

## Site Implementation



**Stephanie  
Ligoci**



**Surbhi  
Shelar**



**Heidi  
Studebaker**



**Chris  
Howe**



**Josh  
Ellis**



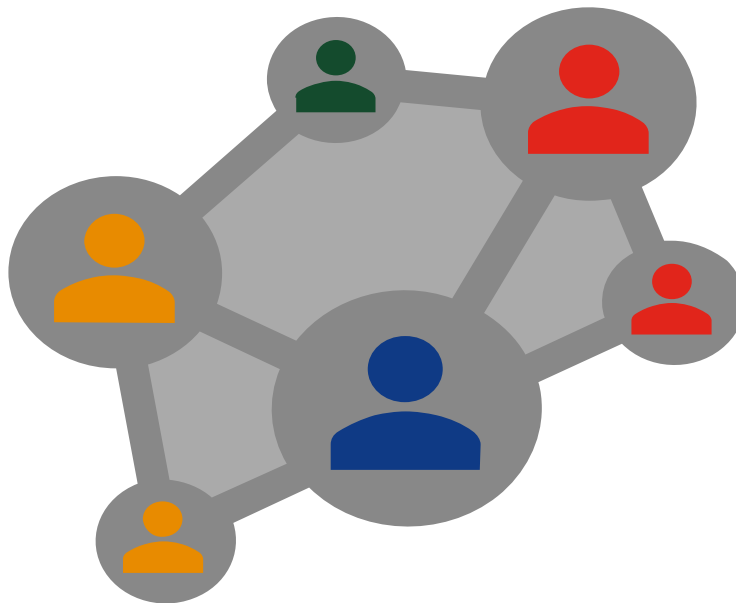
**Rob  
Walker**



**Rob  
Gleeson**



**Amanda  
Austerman**



# Analytical Instrument Qualification Standardization

## GOAL



Standardize QC lab instrument qualification using Kneat templates and electronic documentation

Qualification of the same instrument using the same qualification package

Global validation of instrument application software for replicate deployment

## HOW



Create a reusable deployment model to maximize efficiency at each site

Standardize key process points while leveraging naturally variable elements

Global Design Qualification, Vendor Evaluation, Qualification Plan, Multi-Execute Documents, CSV Requirements, Test Cases

## WHY

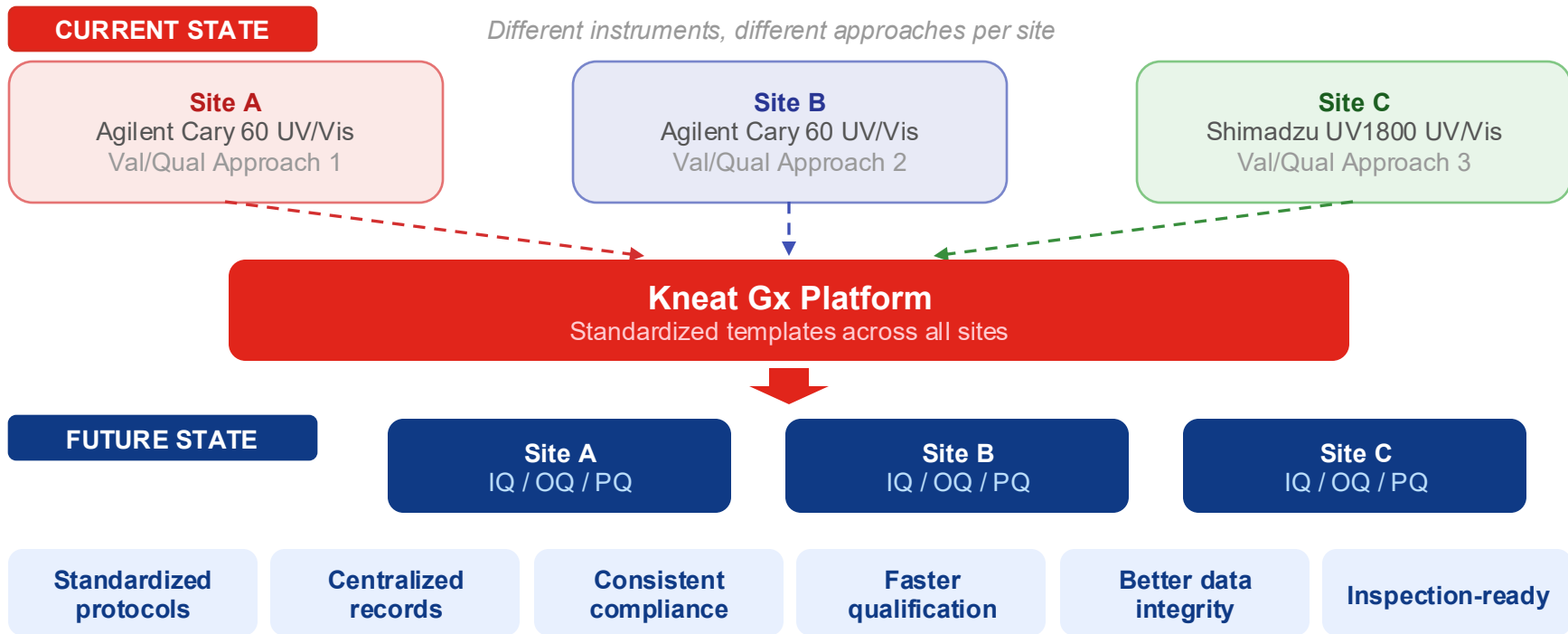


Advance operational excellence to support seamless, scalable network expansion

14+ new manufacturing sites (2020 forward)

New Lab Execution System

# One Platform, One Standard: Global AIQ Through Kneat



# Standardization and Electronic Documentation

## Standardized Protocols

Harmonize Qualification Plans and test documents, IQ, OQ, and PQ, across all sites for consistent global execution

## Centralized Records

Consolidate all qualification documentation into a single digital platform, eliminating paper-based records and scattered file systems

## Consistent Compliance

Enforce uniform compliance standards across all sites through standardized templates and automated validation controls

## Faster Qualification

Standardized documentation and workflow eliminate design rework. Pre-approved test documents minimize review and approval cycles.

## Better Data Integrity

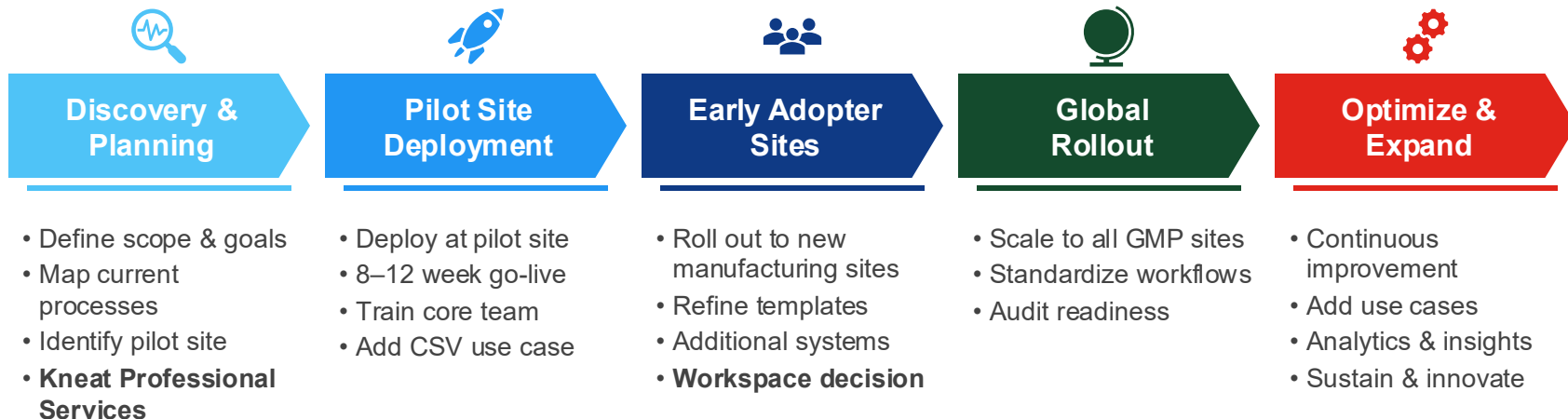
Enforced data entry controls ensure ALCOA+ compliance across activities

## Inspection-Ready

Real-time access to centralized qualification history ensures immediate compliance evidence during inspections

# Kneat Deployment

# Kneat Implementation Roadmap



# One Workspace

## Consistent Standards Across Every QC Lab



### Kneat Features Availability

- Cross-reference across documents (updated)
- Execution forms shared globally
- Computer system validation visibility
- Full entity utilization across the function (can use but cannot modify entities across workspaces)



### Streamlined Access & Governance

- AIQ team: single access vs. 20+ workspaces
- Managed training and role-based access
- Template approval and user groups harmonized



### Consistency & Standards

- Consistent folder structure across sites
- Standardized naming conventions
- Harmonized workflows and templates



### Shared Learning & Collaboration

- Sites can view other sites' documents
- Best practices shared across network
- Accelerated onboarding for new sites

# Risks & Mitigation Strategies

## Site-to-Site Culture Differences

Varying digital maturity and resistance to change across global sites

## Rapid New Site Onboarding

Onboarding new facilities while standardizing AIQ processes in parallel

## QA & IT Alignment

Coordinating cross-functional alignment between QA and IT teams

## System Capabilities

Not "paper under glass" — must learn the Kneat limitations and requirements

## Champion Network

Appoint site-level champions to drive adoption and tailor change management to local maturity levels

## Deployment Playbook

Deployment playbook to define roles and responsibilities and expectations for Global rollout

## Joint Governance

Cross-functional steering committee with shared KPIs and a unified decision-making framework

## System Capabilities

Leverage Kneat platform features — entities, electronic signatures, and dynamic cross-references — to eliminate design gaps

# Design Challenges: Murphy's Law

If something can go wrong in document design, it will. Issues that have been encountered:

- **Choice Lists with No Choices** — Drop-down fields deployed empty or with incomplete options (mitigated by Kneat)
- **Witness Column with No Signature Column** — Witness column cannot be executed unless accompanying Signature column is included in the test document
- **Outdated Cross-References** — Document links pointing to superseded versions (flags)
- **No Comment Space / Columns** — Missing fields for explanation, deviations, or contextual observations
- **Locked Sections** — Protected template areas that cannot be updated when requirements change, requiring full document revision cycles

# **Kneat Execution Records**

# Kneat Multi-Execute Test Documents



## Global Qualification Packages

Create Global Qualification Packages using Execution Records.

Keep multi-execute test document in pre-approved status for version control and traceability.



## Consistent Execution

Drive consistency in documentation and execution with standardized templates. Ensure uniform quality outcomes across every site.



## Parent Design Caution

Leverage Kneat library properties and parameterized design constructs. Structure test cells so site-specific details are isolated and configurable.



## Rapid Startup

Fewer document designs and approvals needed. Enable consistent, repeatable qualification deployments that scale with network growth.



## Folder Structure Navigation

Organize folder structures for rapid execution record creation. Mitigate navigation challenges with scattered multi-execute test documents across sites.

# Test Document Design (Pre-Approved Test)

## Insert Object Value

The scope of this Installation Qualification includes the installation of the **<Enter Instrument Name Here>** with the COTS system software, configured per the applicable System Overview and Configuration (SOC) document, and connected for data collection and management.

## Insert Document Value

The scope of this Installation Qualification includes the installation of the **<Enter Instrument Name Here>** with the COTS system software, configured per the applicable System Overview and Configuration (SOC) document, and connected for data collection and management.

For the folder design structure, with all multi-execute test documents in one location, the use of the library property field requires the use of “Insert Document Value” NOT “Insert Object Value”

Use of the “Insert Document Value” will enable use of the Document Properties Report for the execution records.

# **Kneat AIQ Folder Structure**

AIQ

Kneat Gx - Production

Search...

JD

Workspace

Recents

AIQ

Global Computer System Validation

Instrument Qualification

AIQ Global Protocols

#Functional Requirements

AIQ Balance

AIQ Total Organic Carbon

AIQ UV-VIS Spectrophotometry

#Master Executable Protocols

AIQ IQ Test Case Entity

AIQ Agilent Cary 60 UV-VIS

AIQ Agilent Cary 3500 UV-VIS

AIQ Mettler Toledo XPR Balances

AIQ Pipettes

AIQ Veolia Sievers M9

Site 1

Site 2

Site 3

AIQ > Instrument Qualification

+ New Manage access Update document types

Group by Filter (0) Navigation mode

| Unique identifier ↑   | Description                            | Type                                |
|-----------------------|----------------------------------------|-------------------------------------|
| Folder (6)            |                                        |                                     |
| #AIQ Global Protocols | Global documents                       | Analytical Instrument Qualification |
| Site 1                | Site qualification execution documents | Analytical Instrument Qualification |
| Site 2                |                                        | Analytical Instrument Qualification |
| Site 3                |                                        | Analytical Instrument Qualification |
| Site 4                |                                        | Analytical Instrument Qualification |
| Site 5                |                                        | Analytical Instrument Qualification |

All local site qualification folders are in the same workspace with folder naming to facilitate easy navigation to global documents

Home

AIQ

Kneat Gx - Production

Search...

JD

Workspace

Recents

AIQ

- Global Computer System Validation
- Instrument Qualification
  - #AIQ Global Protocols
    - #Functional Requirements
      - AIQ Balance
      - AIQ Total Organic Carbon
      - AIQ UV-VIS Spectrophotometry
    - #Master Executable Protocols
      - AIQ IQ Test Case Entity
      - AIQ Agilent Cary 60 UV-VIS
      - AIQ Agilent Cary 3500 UV-VIS
      - AIQ Mettler Toledo XPR Balances
      - AIQ Pipettes
      - AIQ Veolia Sievers M9
    - Site 1
    - Site 2
    - Site 3

AIQ > Instrument Qualification > #AIQ Global Protocols

+ New

Manage access

Update document types

Group by

Filter (0)

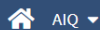
Navigation mode

| Unique identifier ↑             | Description | Type                                |
|---------------------------------|-------------|-------------------------------------|
| Folder (7)                      |             |                                     |
| #Functional Requirements        |             | Analytical Instrument Qualification |
| #Master Executable Protocols    |             | Analytical Instrument Qualification |
| AIQ Agilent Cary 60 UV-VIS      |             | Analytical Instrument Qualification |
| AIQ Agilent Cary 3500 UV-VIS    |             | Analytical Instrument Qualification |
| AIQ Mettler Toledo XPR Balances |             | Analytical Instrument Qualification |
| AIQ Pipettes                    |             | Analytical Instrument Qualification |
| AIQ Veolia Sievers M9           |             | Analytical Instrument Qualification |

Functional User Requirements

Multi-execute test documents

Vendor Protocols and Global Qualification Plans



AIQ ▾

Kneat Gx - Production

JD

## Workspace

🕒 Recents

🌐 AIQ

➤ 📁 Global Computer System Validation

▼ 🌐 Instrument Qualification

▼ 📁 #AIQ Global Protocols

▼ 📁 #Functional Requirements

➤ 📁 AIQ Balance

➤ 📁 AIQ Total Organic Carbon

➤ 📁 AIQ UV-VIS Spectrophotometry

▼ 📁 #Master Executable Protocols

📊 AIQ IQ Test Case Entity

➤ 📁 AIQ Agilent Cary 60 UV-VIS

📁 AIQ Agilent Cary 3500 UV-VIS

📁 AIQ Mettler Toledo XPR Balances

📁 AIQ Pipettes

📁 AIQ Veolia Sievers M9

➤ 📁 Site 1

➤ 📁 Site 2

➤ 📁 Site 3

AIQ &gt; Instrument Qualification &gt; #AIQ Global Protocols &gt; #Master Executable Protocols

+ New ▾

Manage access

Update document types



Group by ▾

🔍 Filter (0)

Navigation mode ▾

| Unique identifier ↑                                       | Description | Type      |
|-----------------------------------------------------------|-------------|-----------|
| ▼ Document (3)<br><i>Sorted by process document order</i> |             |           |
| ○  IQOQPQ-Agilent Cary 60 UV-VIS                          |             | IQOQPQ    |
| IQOQPQ-Agilent Infinity III HPLC                          |             | IQOQPQ    |
| IQOQPQ-Veolia M9 TOC                                      |             | IQOQPQ    |
| ▼ Test Case (1)                                           |             |           |
| AIQ IQ Test Case Entity                                   |             | Test Case |

Multi-execute test documents

Test case entities





AIQ ▾

Kneat Gx - Production

Search...

JD

## Workspace

Recents

AIQ

Global Computer System Validation

Instrument Qualification

#AIQ Global Protocols

#Functional Requirements

#Master Executable Protocols

AIQ Agilent Cary 60 UV-VIS

AIQ Agilent Cary 3500 UV-VIS

AIQ Mettler Toledo XPR Balances

AIQ Pipettes

AIQ Veolia Sievers M9

Site 1

Site 2

Site 3

Site 4

Site 5

AIQ &gt; Instrument Qualification &gt; #AIQ Global Protocols &gt; AIQ Veolia Sievers M9

+ New ▾

Manage access

Update document types



Group by ▾

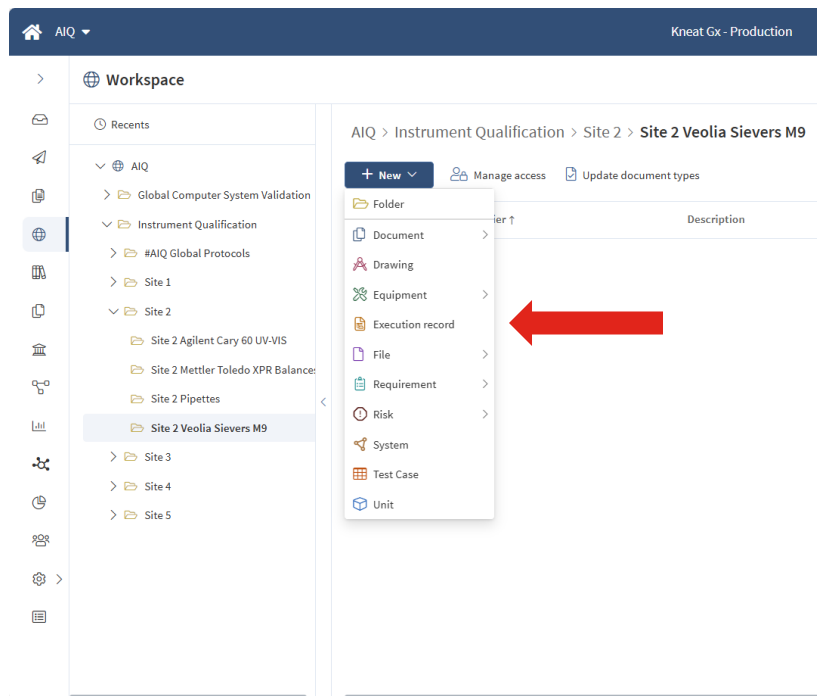
Filter (0)

Navigation mode ▾

| Unique identifier ↑                              | Description                                 | Type                              | Status         |
|--------------------------------------------------|---------------------------------------------|-----------------------------------|----------------|
| AIQ Vendor Qualification Protocol (1)            |                                             |                                   |                |
| Veolia M9 ver 001                                | Vendor Qualification Protocol (File entity) | AIQ Vendor Qualification Protocol | Approved (✓ 2) |
| Document (2)<br>Sorted by process document order |                                             |                                   |                |
| AIQ-VQP-Veolia Sievers M9                        | Vendor Qualification Protocol evaluation    | AIQ-VQP                           | Approved (1.0) |
| AIQ-QP-Veolia Sievers M9                         | Global Qualification Plan                   | AIQ-QP                            | Approved (1.0) |



# Creation of an Execution Record



# Finding the Multi-execute Test Document

AIQ

Kneat Gx - Production

Search...

JD

### Select approved content

Create Cancel

Select approved content to apply to the execution record. Previous execution data will not be included in the new record.

... > Site 2 > Site 2 Veolia Sievers M9

Filter by identifier Type

| Unique identifier   | Description |
|---------------------|-------------|
| No Items to display |             |

☐ ☒ ☐

Please select an approved test document.

# Navigate to Multi-execute Test Document “Repository”

The screenshot displays the Kneat Gx - Production interface. At the top, there is a dark blue header bar with a home icon, 'AIQ' dropdown, 'Kneat Gx - Production' text, a search bar, and a user profile icon 'JD'. Below the header, a modal dialog titled 'Select approved content' is open. The dialog has 'Create' and 'Cancel' buttons in the top right. Inside the dialog, there is a message: 'Select approved content to apply to the execution record. Previous execution data will not be included in the new record.' Below this, a breadcrumb path shows 'Site 2 > Site 2 Veolia Sievers M9'. A dropdown menu is open, showing 'AIQ' and 'Instrument Qualification'. A large red arrow points to 'Instrument Qualification'. Below the dropdown, there is a table with columns 'Unique identifier' and 'Description'. The table is empty, showing 'No Items to display'. To the right of the table, there are three document selection cards. The middle card is selected, indicated by a blue border and a checkmark icon. Below the cards, the text 'Please select an approved test document.' is displayed. The left sidebar of the application contains various icons for navigation.

# Navigate to Multi-execute Test Document “Repository”

The screenshot displays the Kneat Gx - Production interface. At the top, there is a dark blue header bar with a home icon, 'AIQ' dropdown, 'Kneat Gx - Production' text, a search bar, and a user profile icon 'JD'. Below the header, a modal dialog titled 'Select approved content' is open. The dialog has 'Create' and 'Cancel' buttons in the top right. Inside the dialog, there is a sub-header 'AIQ > Instrument Qualification'. Below this, there is a filter section with 'Filter by identifier' and a 'Type' dropdown. A table follows with two columns: 'Unique identifier' and 'Description'. The table contains six entries: '#AIQ Global Proto...', 'Site 1', 'Site 2', 'Site 3', 'Site 4', and 'Site 5'. A red arrow points to the '#AIQ Global Proto...' entry. To the right of the table, there is a large light blue area with three horizontal bars representing progress or status. The middle bar is highlighted with a blue checkmark icon. Below this area, the text 'Please select an approved test document.' is displayed. The bottom of the interface shows a dark blue footer bar with a small icon on the right.

AIQ

Kneat Gx - Production

Search...

JD

Select approved content

Create Cancel

Select approved content to apply to the execution record. Previous execution data will not be included in the new record.

AIQ > Instrument Qualification

Filter by identifier Type

| Unique identifier    | Description |
|----------------------|-------------|
| #AIQ Global Proto... |             |
| Site 1               |             |
| Site 2               |             |
| Site 3               |             |
| Site 4               |             |
| Site 5               |             |

Please select an approved test document.

# Multi-execute Test Documents

The screenshot shows the Kneat Gx - Production interface. At the top, there is a search bar and a user profile icon. The main area is titled 'Select approved content' and contains a table of test documents. A red arrow points to the third row of the table, which is highlighted. The table has two columns: 'Unique identifier' and 'Description'. The third row is 'IQQPQ-Veolia M...'. To the right of the table, there is a section with three radio buttons and a checkmark icon. The middle radio button is selected, and the text 'Please select an approved test document.' is displayed below it.

AIQ

Kneat Gx - Production

Search...

JD

Create Cancel

Select approved content

Select approved content to apply to the execution record. Previous execution data will not be included in the new record.

... > #Master Executable Protocols

Filter by identifier Type

| Unique identifier     | Description |
|-----------------------|-------------|
| AIQ IQ Test Case E... |             |
| IQQPQ-Agilent C...    |             |
| IQQPQ-Veolia M...     |             |

✓

Please select an approved test document.

# Execution Record Creation

AIQ

Kneat Gx - Production

Search...

JD

Select approved content

CreateCancel

Select approved content to apply to the execution record. Previous execution data will not be included in the new record.

... > #Master Executable Protocols

Filter by identifier

Type

Unique identifier

Description

AIQ IQ Test Case E...

IQOQPQ-Agilent C...

IQOQPQ-Veolia M...

Document Number

IQOQPQ-Site 2 Veolia M9 TOC(1.0)-001

Edited

Title (optional)

Source document number & version: IQOQPQ-Veolia M9 TOC(1.0)

Approval

Approval

Approval

IQOQPQ-Veolia M9 TOC

Document TitleValue

Workspace : AIQ

Document No : IQOQPQ-Veolia M9 TOC

Document Title : Document TitleValue

Version : 1.0

This is a representation of an electronic record that was signed electronically and this page is a manifestation of the electronic signature. The electronic signatures for this document are maintained in the Kneat system.

Pre-Approval

| Signed By        | Signatory Capacity | User Group | Date Approved              |
|------------------|--------------------|------------|----------------------------|
| Denault, Jeffrey | Approver           | Approver   | 02-Apr-2026 03:28:56 (UTC) |

Post-Approval

# Execution Record Created

Home

AIQ

Kneat Gx - Production

Search...

JD

>

Workspace

Recents

AIQ

Global Computer System Validation

Instrument Qualification

#AIQ Global Protocols

Site 1

Site 2

Site 2 Agilent Cary 60 UV-VIS

Site 2 Mettler Toledo XPR Balance

Site 2 Pipettes

Site 2 Veolia Sievers M9

Site 3

Site 4

Site 5

AIQ > Instrument Qualification > Site 2 > Site 2 Veolia Sievers M9

+ New

Manage access

Update document types

Group by

Filter (0)

Navigation mode

| Unique identifier ↑                  | Description | Type   | Status              |
|--------------------------------------|-------------|--------|---------------------|
| Execution record (1)                 |             |        |                     |
| IQOQPQ-Site 2 Veolia M9 TOC(1.0)-001 |             | IQOQPQ | Pending release for |

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External Public - 3b not remove

# Kneat Entities

# Kneat Entities



## Structured Data Objects

- Requirements, file, risks, test cases as entities
- Replace static documents with live data
- Enable traceability and cross-referencing



## Reusability Across Processes

- Link entities across validation types
- URS entities reused in CSV and Qualification processes



## Impact Analysis

- Change one entity, see all affected items
- Automated downstream impact assessment
- Reduces change control cycle time



## Analytics-Ready Data

- Structured data enables real-time dashboards
- Track validation KPIs across the network
- Data-driven continuous improvement

# Kneat Entity Types and Masks



## Requirements Entities

Functional and CSV requirements traced through the full validation lifecycle

CSV requirements mask based on regulations and Lilly procedures

Functional requirements mask based on compendia and Lilly procedures



## File Entities

Attachments, SOPs, screenshots, and evidence files linked directly to qualification records

- Vendor Qualification Protocol
- Data Flow Diagram
- Process Data Flow Map

Mask developed based on relevant metadata from vendor protocols



## Risk Entities

QRM entries linked to vulnerabilities and test cases for risk-based validation

Utilization of the Kneat default QRM mask



## Test Case Entities

Structured test scripts with defined steps, expected results, and pass/fail criteria

- Installation Qualification
- Operational Qualification
- Performance Qualification
- Computer System Validation

# Kneat Entities Utilization



## Entity per Row Table

Use Entity per Row for BOTH entity attribute entry and design data entry for a specific system



## Entity Creation

Creation of entities using Entity per Row tables



## Minimal Updates

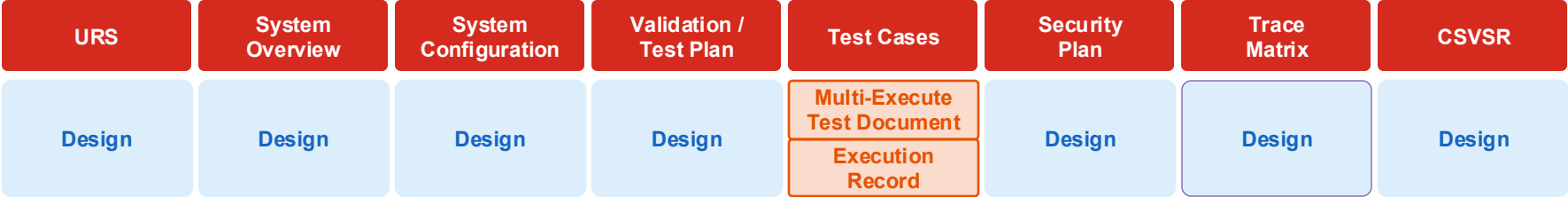
One entity per instrument type, not per instrument — minimizes required updates across the system



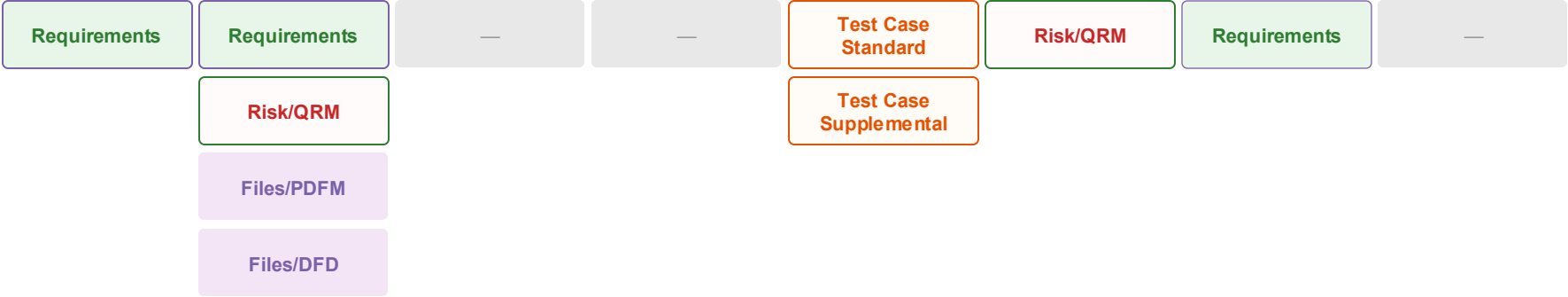
## RTM Limitation

RTM (Requirements Traceability Matrix) cannot be used with this entity approach

# Computer System Validation



## Kneat Entities Used



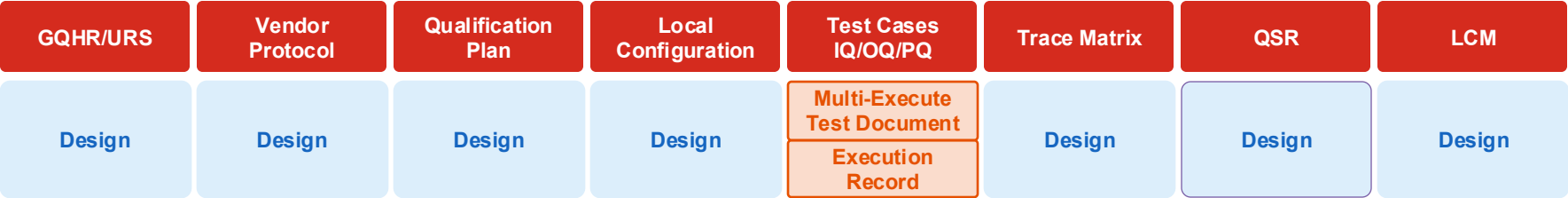
● Requirements

● Risk/QRM

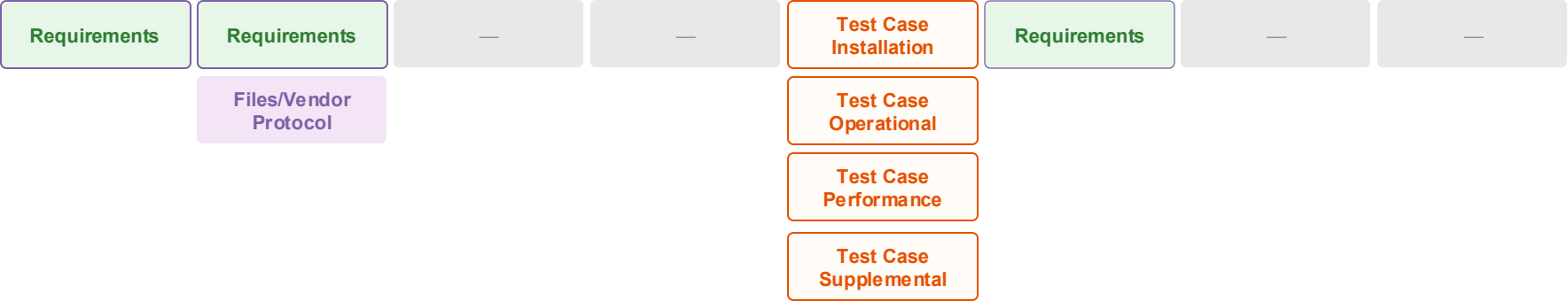
● Test Cases

● Files

# Functional Qualification



## Kneat Entities Used



● Requirements

● Risk/QRM

● Test Cases

● Files

# Entity per Row. Partial attributes and design

## 2 Vendor Qualification Protocol

Entity Per Row Table – All content contained in the Entity

Attribute

Design

| File Id             | Vendor   | Instrument Model | Version | Language  | True copy |
|---------------------|----------|------------------|---------|-----------|-----------|
| ✓ Veolia M9 ver 001 | ✓ Veolia | ✓ M9             | ✓ 001   | ✓ English | ✓ Yes     |

Entity Per Row Table – Table content contains partial attribute and partial design columns

| File Id             | State                   | Requirements Tested | Status   |
|---------------------|-------------------------|---------------------|----------|
| ✓ Veolia M9 ver 001 | ✓ Initial Qualification | All                 | All meet |

# Entity per Row. Partial attributes and design

## 2 Vendor Qualification Protocol

### Entity Per Row Table – All content contained in the Entity

Attribute Design

| File Id             | Vendor   | Instrument Model | Version | Language  | True copy |
|---------------------|----------|------------------|---------|-----------|-----------|
| ✓ Veolia M9 ver 001 | ✓ Veolia | ✓ M9             | ✓ 001   | ✓ English | ✓ Yes     |

### Entity Per Row Table – Table content contains partial attribute and partial design columns

| File Id             | State                   | Requirements Tested | Status   |
|---------------------|-------------------------|---------------------|----------|
| ✓ Veolia M9 ver 001 | ✓ Initial Qualification | All                 | All meet |

### Entity Per Row Table – Table content contains partial attribute and partial design columns

| User Requirements Specifications |                                                                                                 |                           |                   |
|----------------------------------|-------------------------------------------------------------------------------------------------|---------------------------|-------------------|
| Requirement Id                   | Description                                                                                     | Vendor Test               | Meets Requirement |
| ✓ TOC-F01                        | ✓ Must discriminate between organic and inorganic carbon.                                       | Operational test, page 22 | Yes               |
| ✓ TOC-F02                        | ✓ ≤ 0.050 mg/L of carbon                                                                        | Operational test, page 23 | Yes               |
| ✓ TOC-F03                        | ✓ The response efficiency (rE) of the system suitability solution must be NLT 85% and NMT 115%. | Operational test, page 30 | Yes               |
| ✓ TOC-F04                        | ✓ The precision of the TOC measurement must meet NMT 2.0% RSD.                                  | Operational test, page 31 | Yes               |

# Next Steps



## Expand to Additional Sites

- Deploy Kneat Gx to legacy QC laboratories
- Continue rollout to new QC labs globally
- Standardize AIQ processes across all sites



## Global Qualification Packages

- Create Global Qualification Plans
- Build multi-execute test documents
- Cover full suite of instruments in Lilly QC labs



## Increase System Utilization

- Develop software revision evaluation process and document revision assessments in Kneat
- Expand platform usage beyond core AIQ



## Measure and Demonstrate ROI

- Develop and track key performance indicators
- Collect user feedback across sites
- Optimize templates based on metrics

# Acknowledgements

## **Thao Phan & Jason Hasenour**

System Owners

## **Stephanie Ligoci & Colleen Tigani**

Execution Form & Entity process development

## **The AIQ Team**

Working through process changes