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# Data vs Documentation:

## Balancing Compliance With Efficiency in a Digital Transformation

**Presented by:**

**Kneat Solutions | 11 March 2025**

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For Discussion Purposes Only

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# Agenda

- ALCOA+
- Thought Exercise
- What Data do we have?
- How do we manage Data?
- How to we present Data?

# Speaker

**Jamie O'Donnell**

Sr. Manager,
Customer Success Engineering,
Kneat

# ALCOA +


**C** - Context

# Thought Exercise

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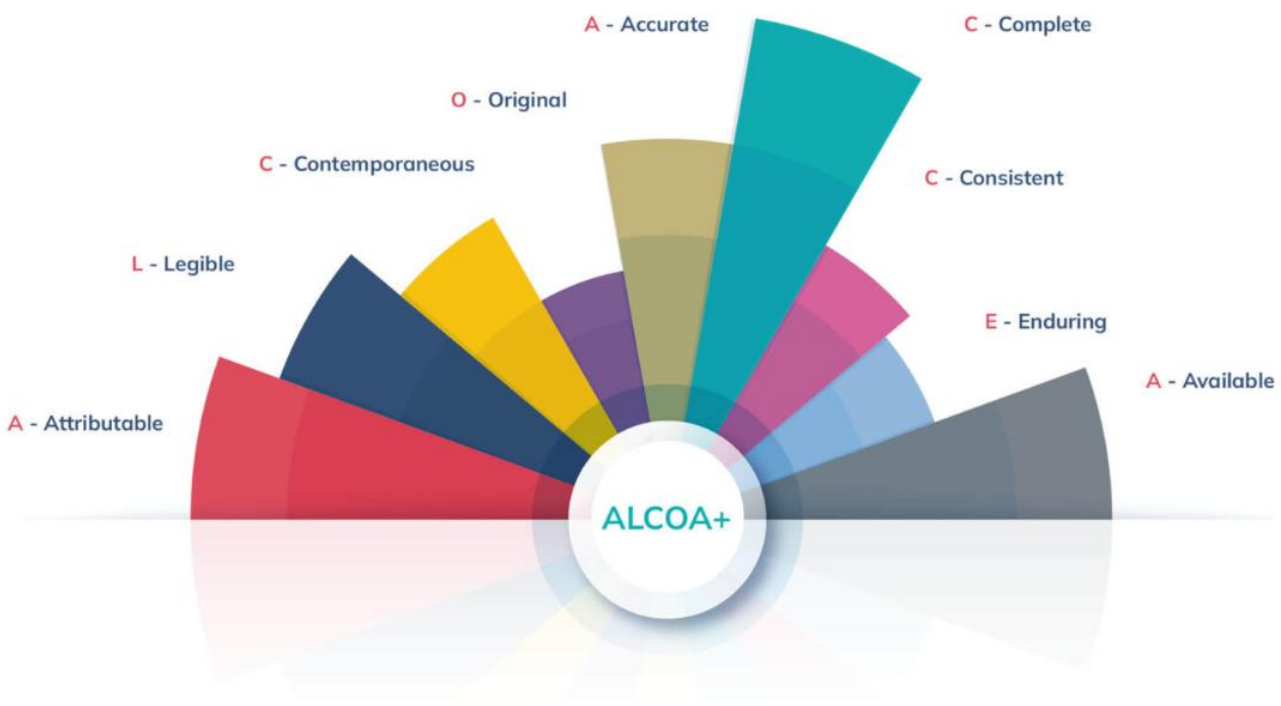
# What is Data

**Data** refers to facts, figures, or information collected for analysis and used to make decisions. It can be in various forms, such as numbers, text, images, or even sounds. Data is often processed and analyzed to extract meaningful insights or to support decision-making processes.

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# Poll Question 1

**Data** refers to facts, figures, or information collected for analysis and used to make decisions. It can be in various forms, such as numbers, text, images, or even sounds. Data is often processed and analyzed to extract meaningful insights or to support decision-making processes.


Does the above definition align to ALCOA?

- Yes
- No

# What is Data

**Data** refers to facts, figures, or information collected for analysis and used to make decisions. It can be in various forms, such as numbers, text, images, or sounds. Data is often processed and analyzed to extract meaningful insights or to support decision-making processes (Smith, 2020).

**Reference:** Smith, J. (2020). *Understanding Data*. London: Academic Press.


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# Poll Question 2

**Data** refers to facts, figures, or information collected for analysis and used to make decisions. It can be in various forms, such as numbers, text, images, or sounds. Data is often processed and analyzed to extract meaningful insights or to support decision-making processes (Smith, 2020).

**Reference:** Smith, J. (2020). *Understanding Data*. London: Academic Press.


With the updated reference does the above definition align to ALCOA?

- Yes
- No

# Data

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# What Data do we have?

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# Data

**Data** refers to facts, figures, or information collected for analysis and used to make decisions. It can be in various forms, such as numbers, text, images, or sounds. Data is often processed and analyzed to extract meaningful insights or to support decision-making processes (Smith, 2020).

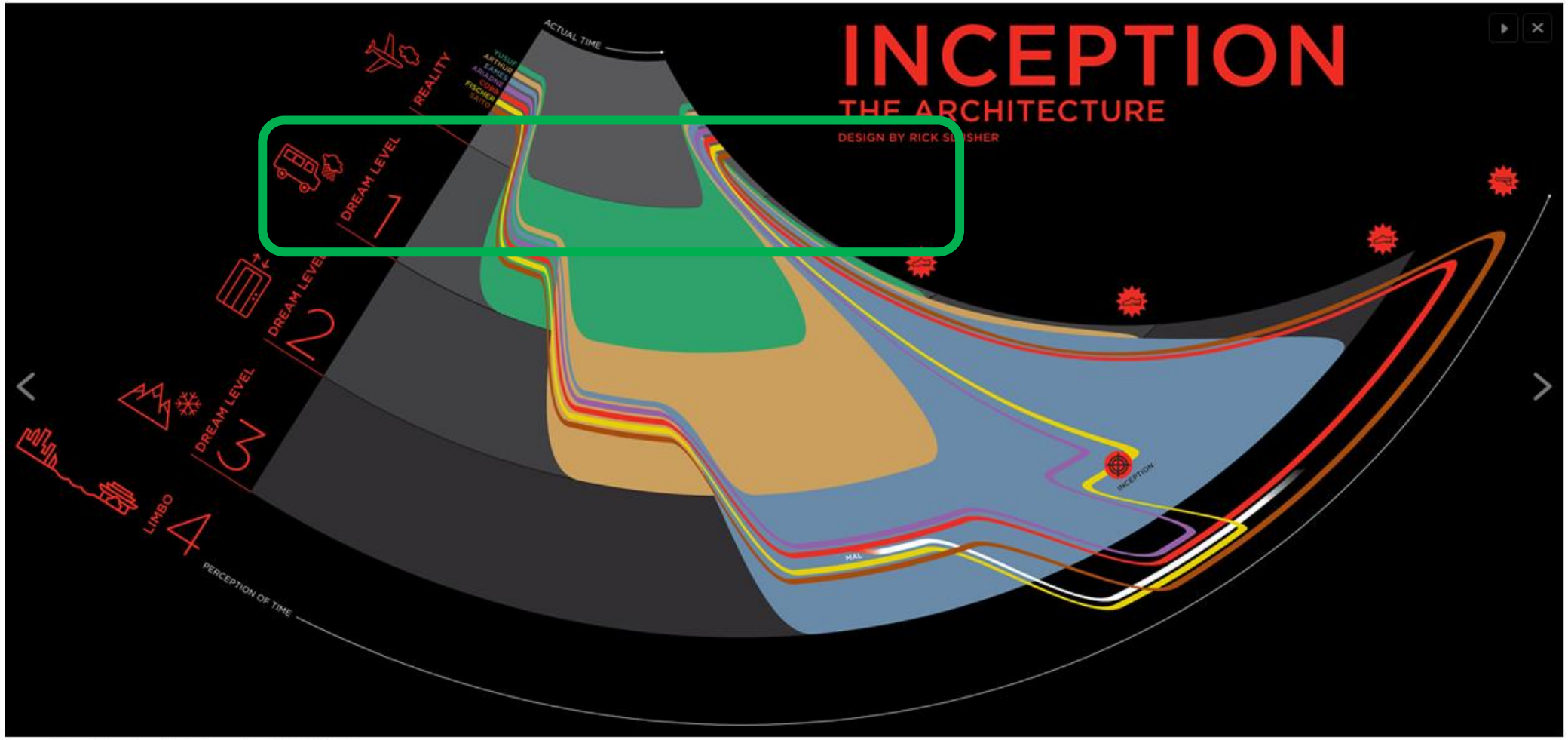
**Reference:** Smith, J. (2020). *Understanding Data*. London: Academic Press.

# What Data do we have?

- Equipment Data
  - Tag number
  - Description
  - Status
  - Location
  - Calibration Range
  - Model
  - Serial Number

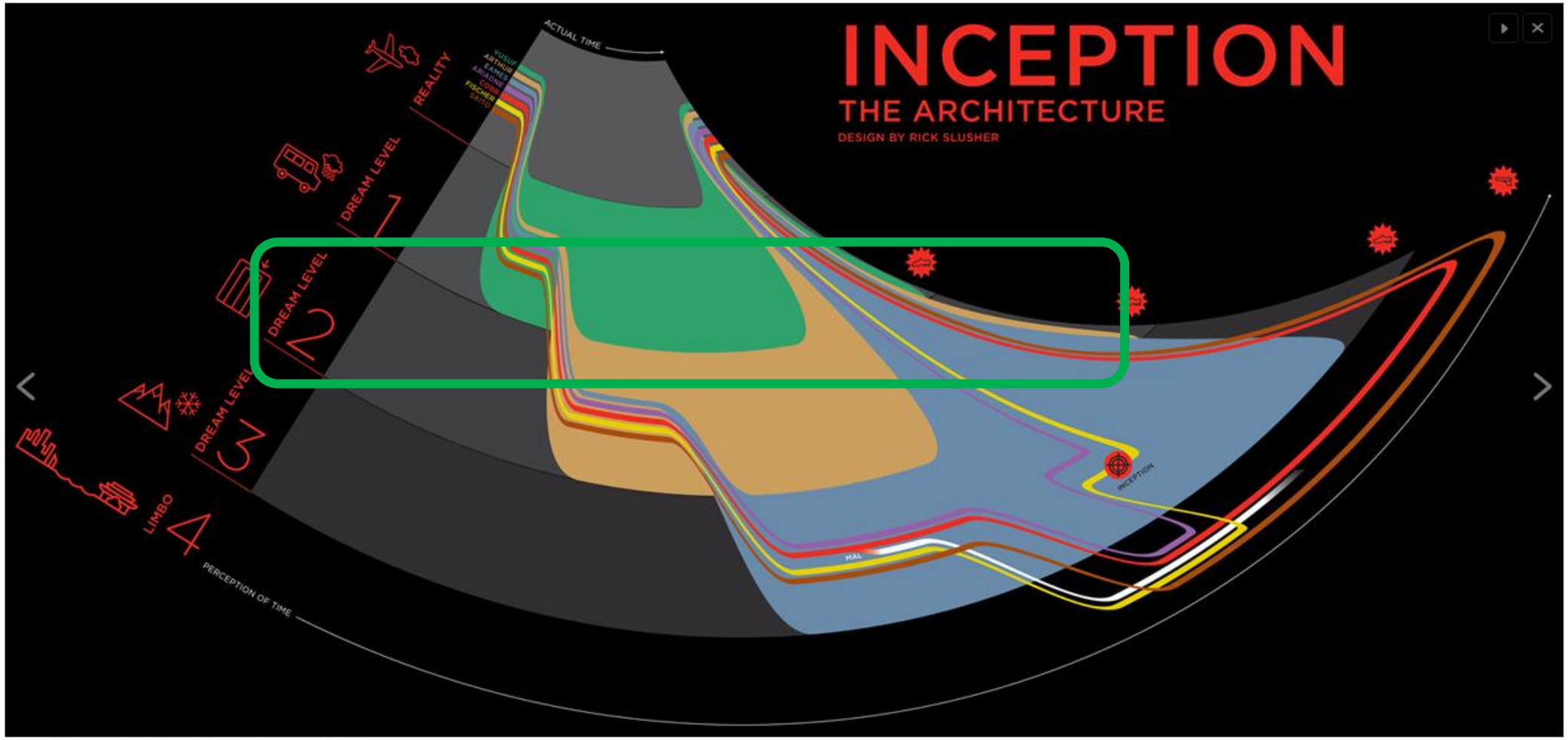
- System Data
  - System ID
  - System Description
  - System owner
  - Qualification Status

# How Deep can we go into data




Inception: The Architecture by Rick Slusher

# How deep can we go?

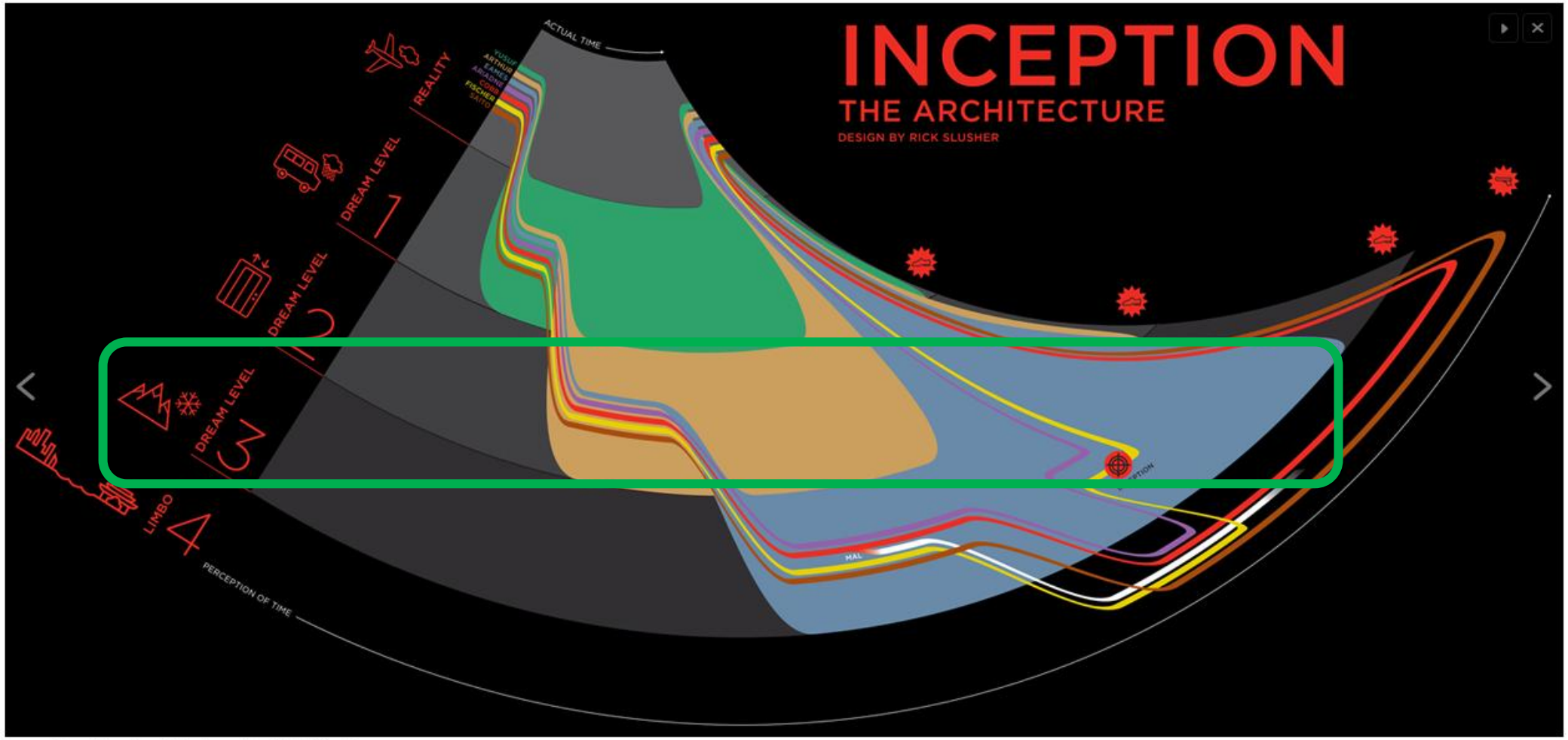



Inception: The Architecture by Rick Slusher

# What is a system?

- System Data
  - Computer System
    - SAP
    - Delta V
    - Etc
  - Equipment System
    - Bioreactor
    - Chrom Skid
      - Instrumentation
      - Flow meters
      - Pressure transmitter
      - Level Switches
      - Pumps

# How deep can we go?




Inception: The Architecture by Rick Slusher

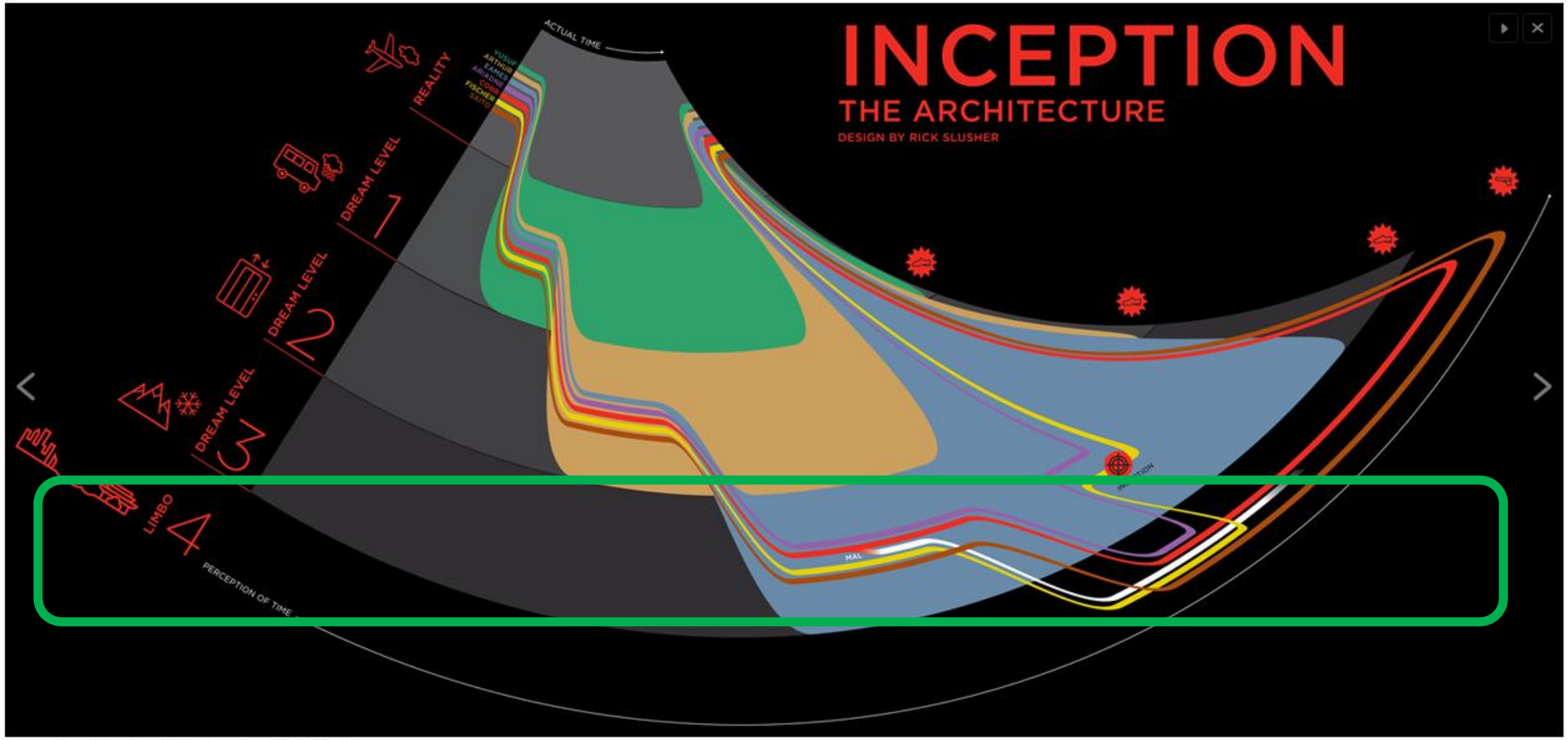
# New Data (That we always had)

- Requirements
  - URS
  - FS
  - DS
  - CS
  - Requirement ID
  - Acceptance Criteria
  - Traceability
- Testing
  - Results
  - Pass/Fail rates
  - Conclusions
  - Deviations
  - Traceability

# New Data (That we always had)

- Risks
  - Risk ID
  - Risk rating
  - Occurrence
  - Detection
  - Residual risk levels

# How deep can we go?




Inception: The Architecture by Rick Slusher

# Data of the Data

- Approval of data
  - When was the data approved
  - Who approved the data
  - Where was the data approved
- Review and Approval of files, drawings, documents.
  - Who Reviewed
  - How long was it reviewed
  - Who approved
  - How long did the approval take
  - True copy
- Impact
  - Live State of data
  - Where is the data being used
  - How is the data being used

# How do we manage Data?

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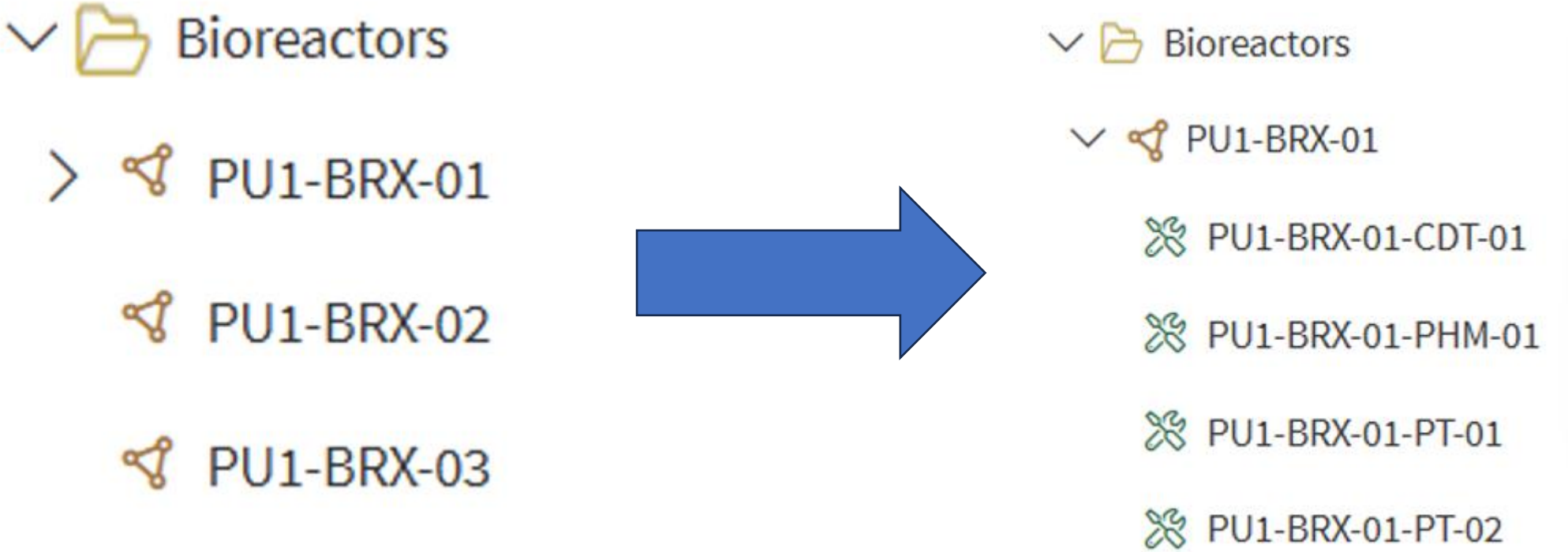
# ALCOA +


**C** - Context

# Equipment and Systems

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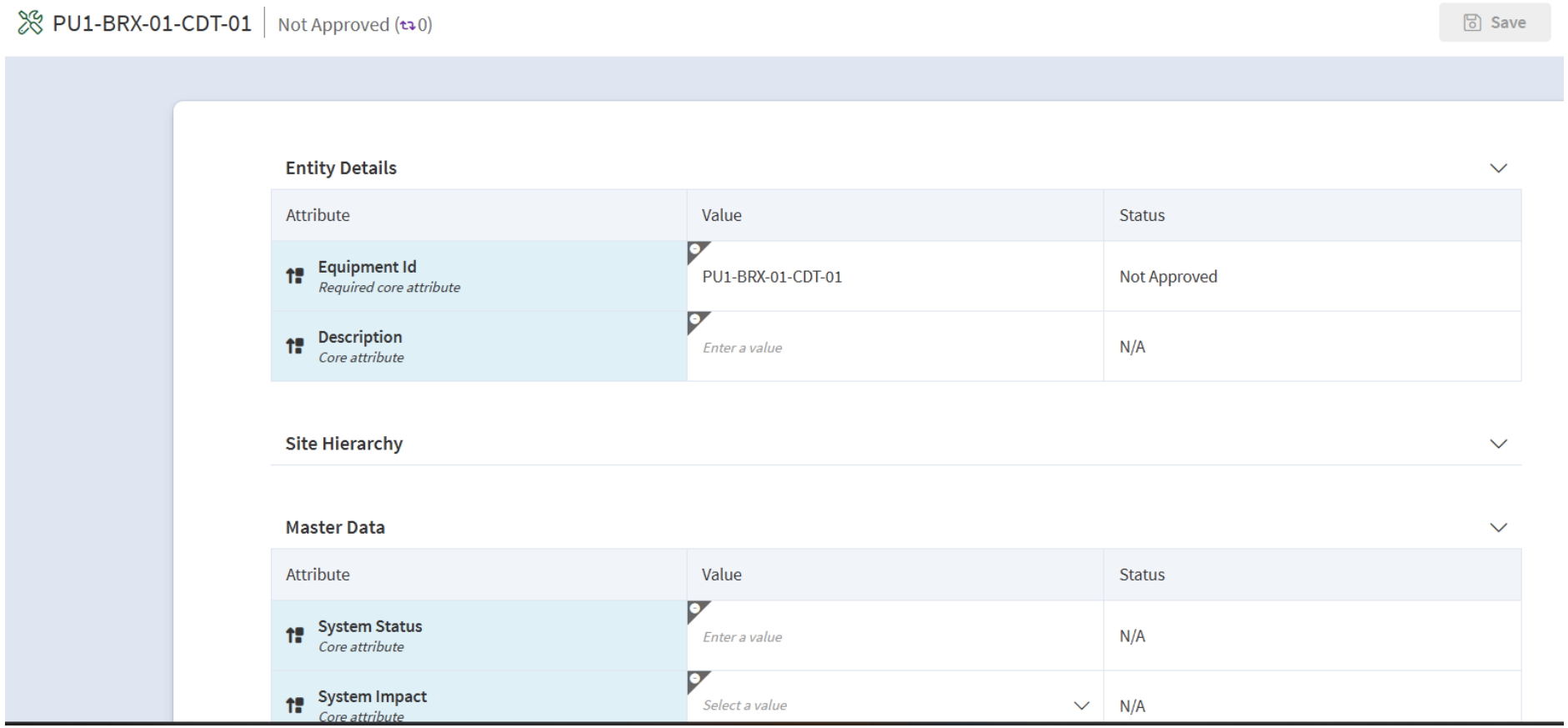
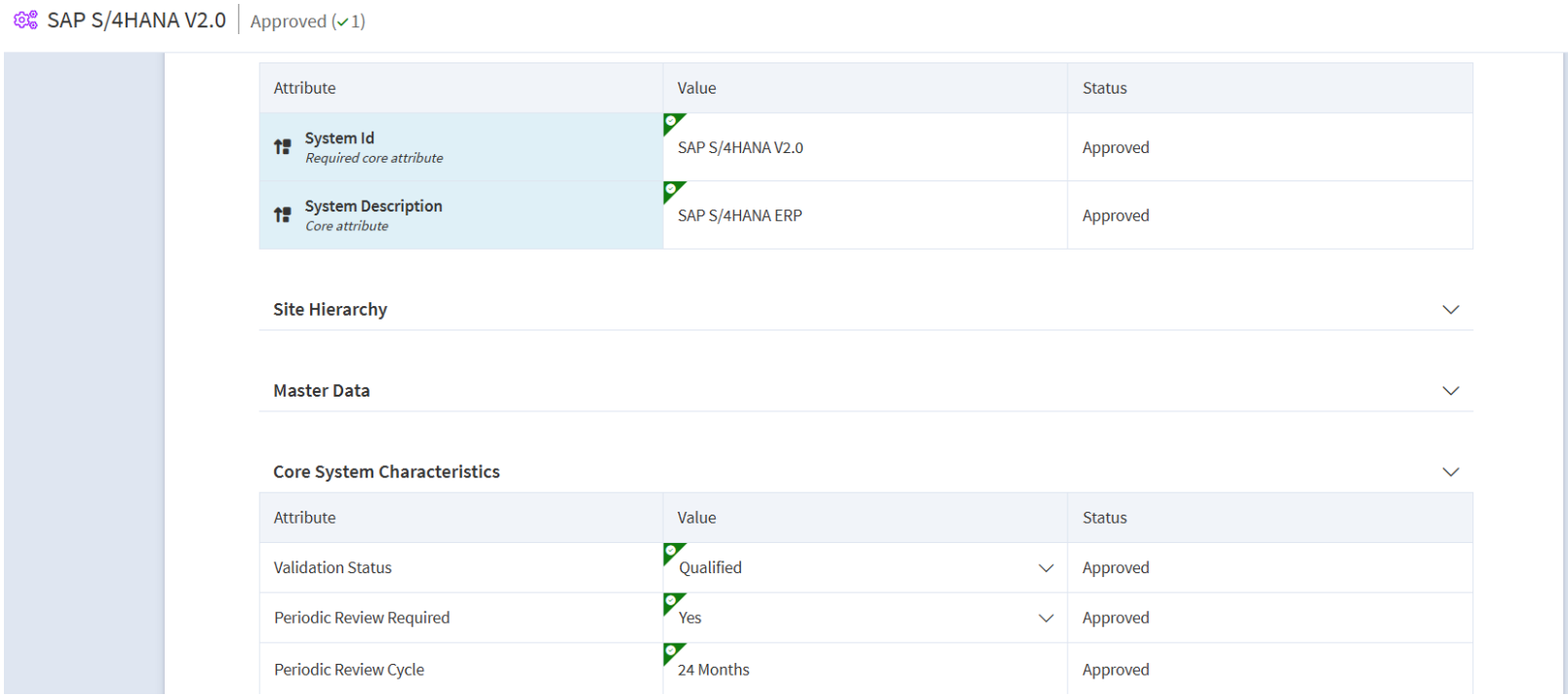
# Equipment and Systems



# Equipment and Systems

SAP S/4HANA V2.0



# Equipment and Systems (Initial SRA)

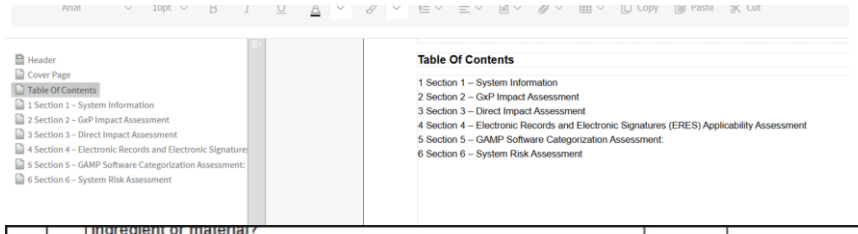


Table Of Contents

1 Section 1 – System Information
2 Section 2 – GxP Impact Assessment
3 Section 3 – Direct Impact Assessment
4 Section 4 – Electronic Records and Electronic Signatures (ERES) Applicability Assessment
5 Section 5 – GAMP Software Categorization Assessment:
6 Section 6 – System Risk Assessment

| | | | |
|---|---|---|---|
| | Ingredient or material? (e.g., Buffer and Media Preparation Equipment) | | |
| 4 | Will the system be used for process control of GXP manufacturing operations? | No | |
| 5 | Will the system be used for Quality Control operations that are intended to determine the Critical Quality Attributes of the product such as release and stability? | No | |
| 6 | Will the system be used to store formulated bulk or finished product in a temperature-controlled environment? | **No** | |

**GxP Impact**

- IF all answers in Section 2 are "NO"? THEN Note system impact s " No Impact".
- IF one or more answers in Section 2 are "YES" & If all answers in Section 3 are "No" THEN Note system impact as "Non-Direct Impact (NDI)
- IF one or more answers in Section 2 are "YES" &If one or more answers in Section 3 are "YES" THEN Note system impact as "Direct Impact (DI)

DI

| Attribute | Value | Status |
|---|---|---|
| Software Category *Core attribute* | GAMP Category 4 | Approved |
| Electronic Record *Core attribute* | Yes | Approved |
| Electronic Signature *Core attribute* | Yes | Approved |
| System Impact *Core attribute* | DI | Approved |
| Risk Level *Core attribute* | Medium | Approved |

| CONCLUSION TABLE 1: | |
|---|---|
| **The System is: Closed/Open** | **The System type is Electronic Record: Yes/No** |
| Closed | Electronic Record: Yes |

| CONCLUSION TABLE 2: | |
|---|---|
| **The System is Electronic Signature: Yes/No** | **Biometrics? No/ Retina scan/ Fingerprints** |
| Electronic Signature: Yes | No |

**NOTE: For each of the items checked above, include appropriate 21 Part 11 requirements in the system URS.**

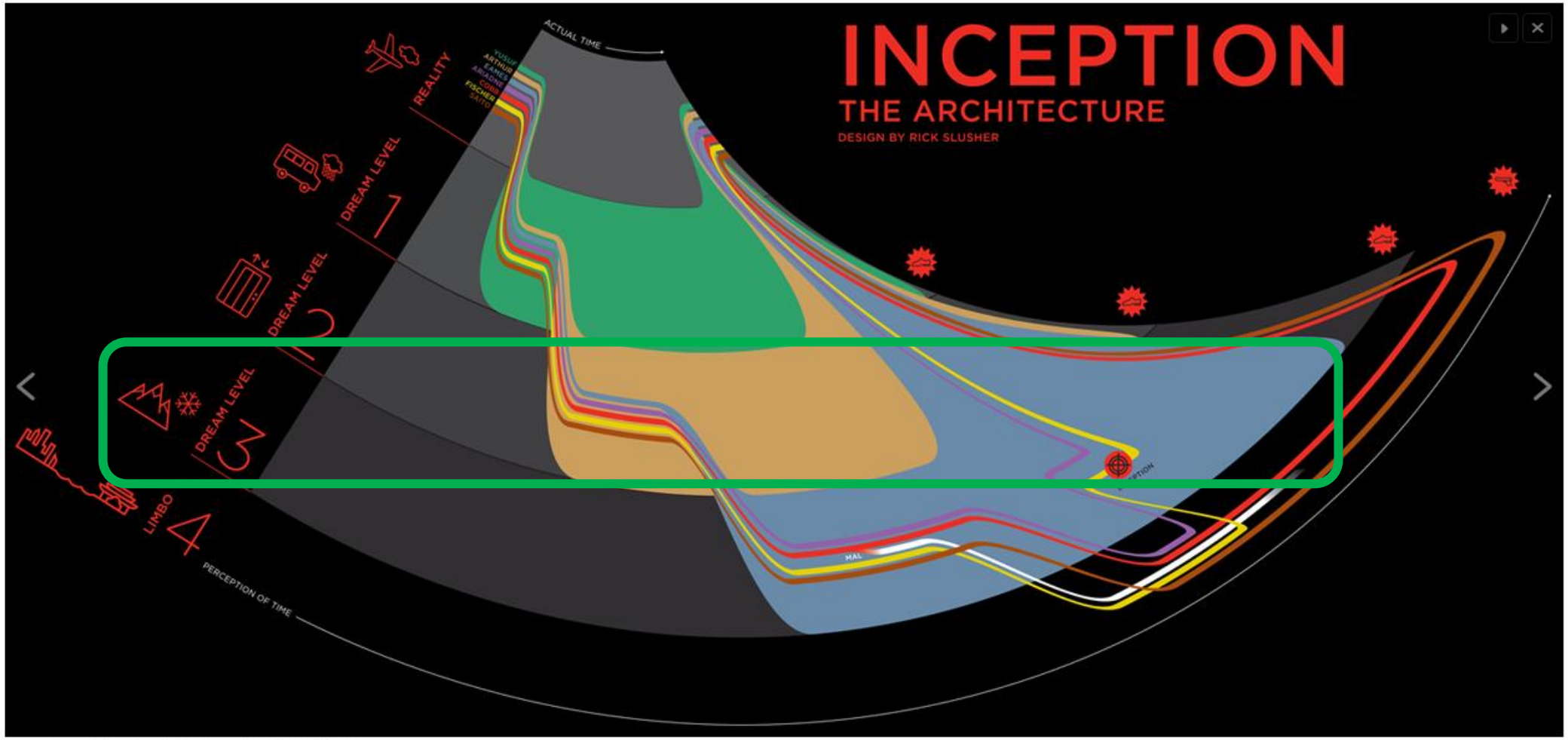
**GAMP 5 Category**
**(1 if Q1 is Yes; 3 if Q2 is Yes; 4 if Q3 is Yes; 5 if Q4 is Yes)**

Software Category: GAMP Category 4

| | | | | | |
|---|---|---|---|---|---|
| | Complexity | | | | |
| Data Impact | CPP/CQA Impact | 12 | Does the data generate considered to be CPPs or CQAs? | No | 3 |
| Data Impact | Clinical Trial Impact | 13 | Does the system generate or store patient data that has direct impact on clinical trials? | No | 3 |
| Data Impact | Patient Impact | 14 | Does the system generate or store data that would pose a direct risk to patients' health if compromised? | Yes | 6 |

| Total Risk Score (Ri) (Total figures from above table ) | System Risk Level (Low <=42; Medium > 42 & <=63; High > 63) |
|---|---|
| 60 | Risk Level: Medium |

# How deep can we go?

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# Requirements Data

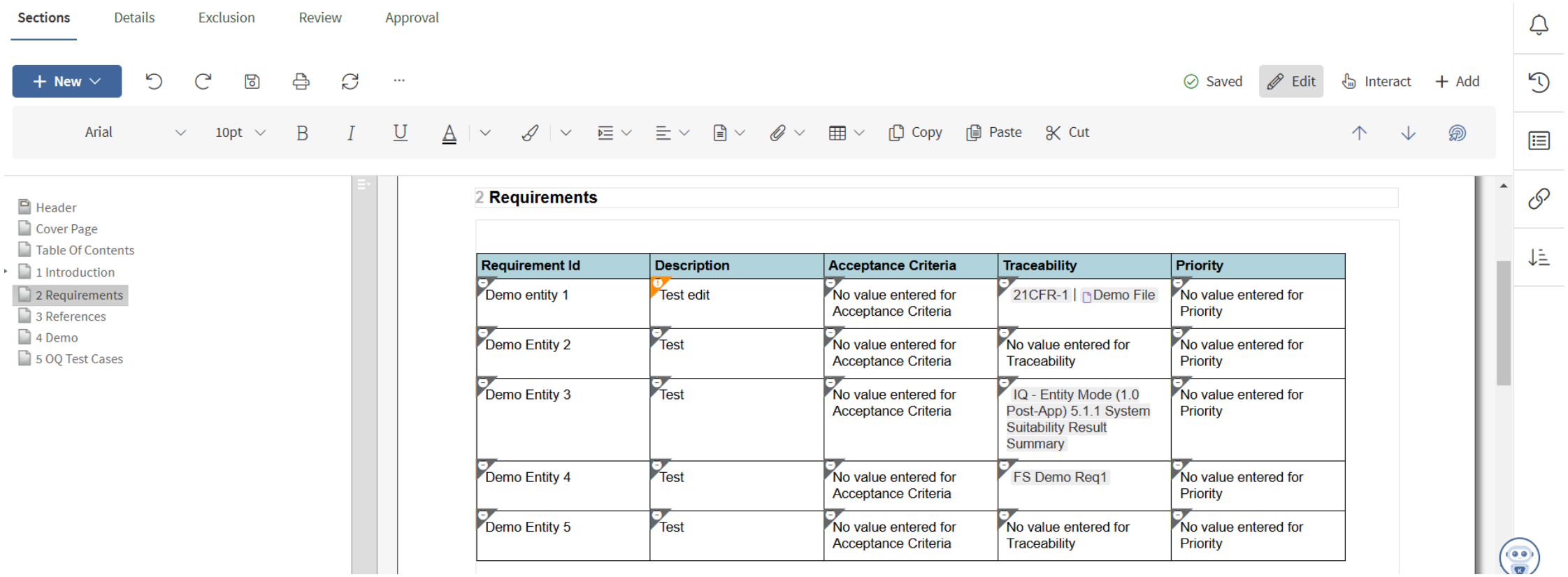
**Workspace**

Jamie > Entities > **URS**

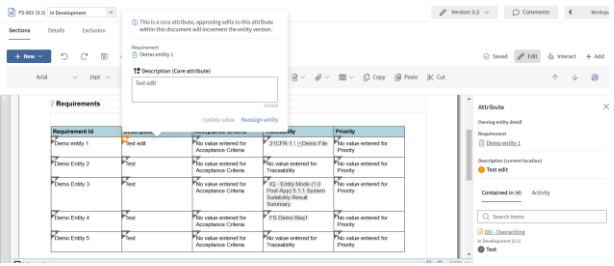
+ New | Requirement | Settings | Entity mode

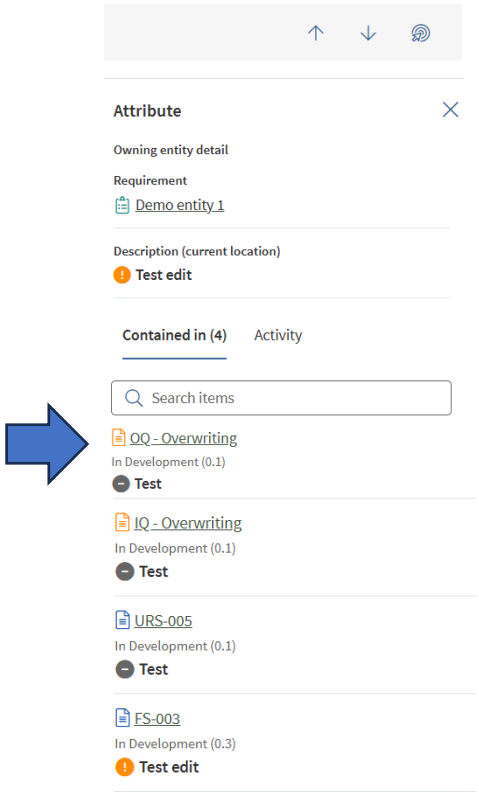
| | Entity status & version | Requirement Id *Required core attribute* | Description *Core attribute* | Acceptance Criteria *Core attribute* | Traceability *Core attribute* | Priority *Core attribute* |
|---|---|---|---|---|---|---|
| ○ | Not Approved (0) | Demo entity 1 | Test | *Enter a value* | 21CFR-1 ✕ Demo File ✕ Add Relationship | *Select a value* |
| ○ | Not Approved (0) | Demo Entity 2 | Test | *Enter a value* | Add Relationship | *Select a value* |
| ○ | Not Approved (0) | Demo Entity 3 | Test | *Enter a value* | IQ - Entity Mode (1.0 Post-App) 5.1.1 System Suitability Result Summary ✕ Add Relationship | *Select a value* |
| ○ | Not Approved (0) | Demo Entity 4 | Test | *Enter a value* | FS Demo Req1 ✕ Add Relationship | *Select a value* |
| ○ | Not Approved (0) | Demo Entity 5 | Test | *Enter a value* | Add Relationship | *Select a value* |

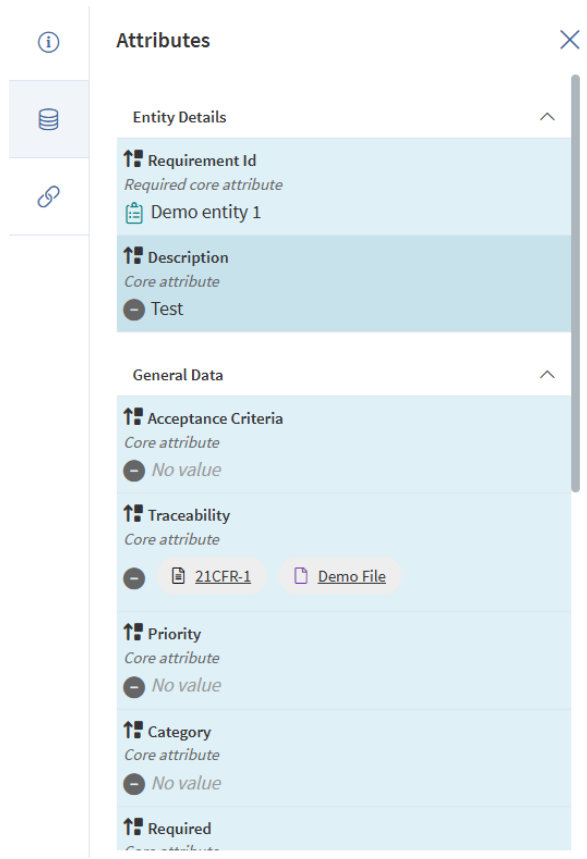
# Requirements Data

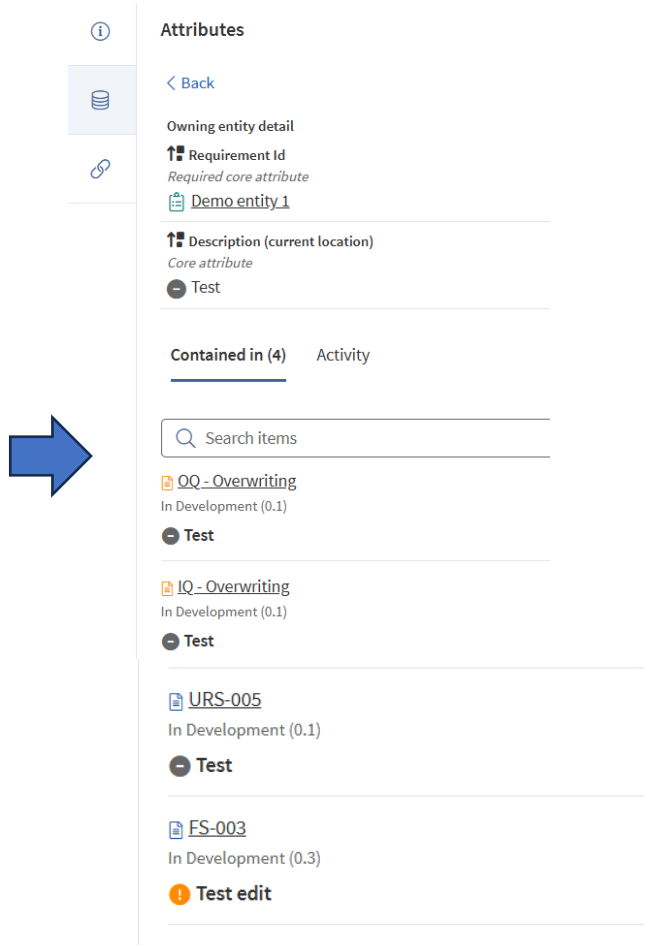


# Requirements Data





# How do we present Data?

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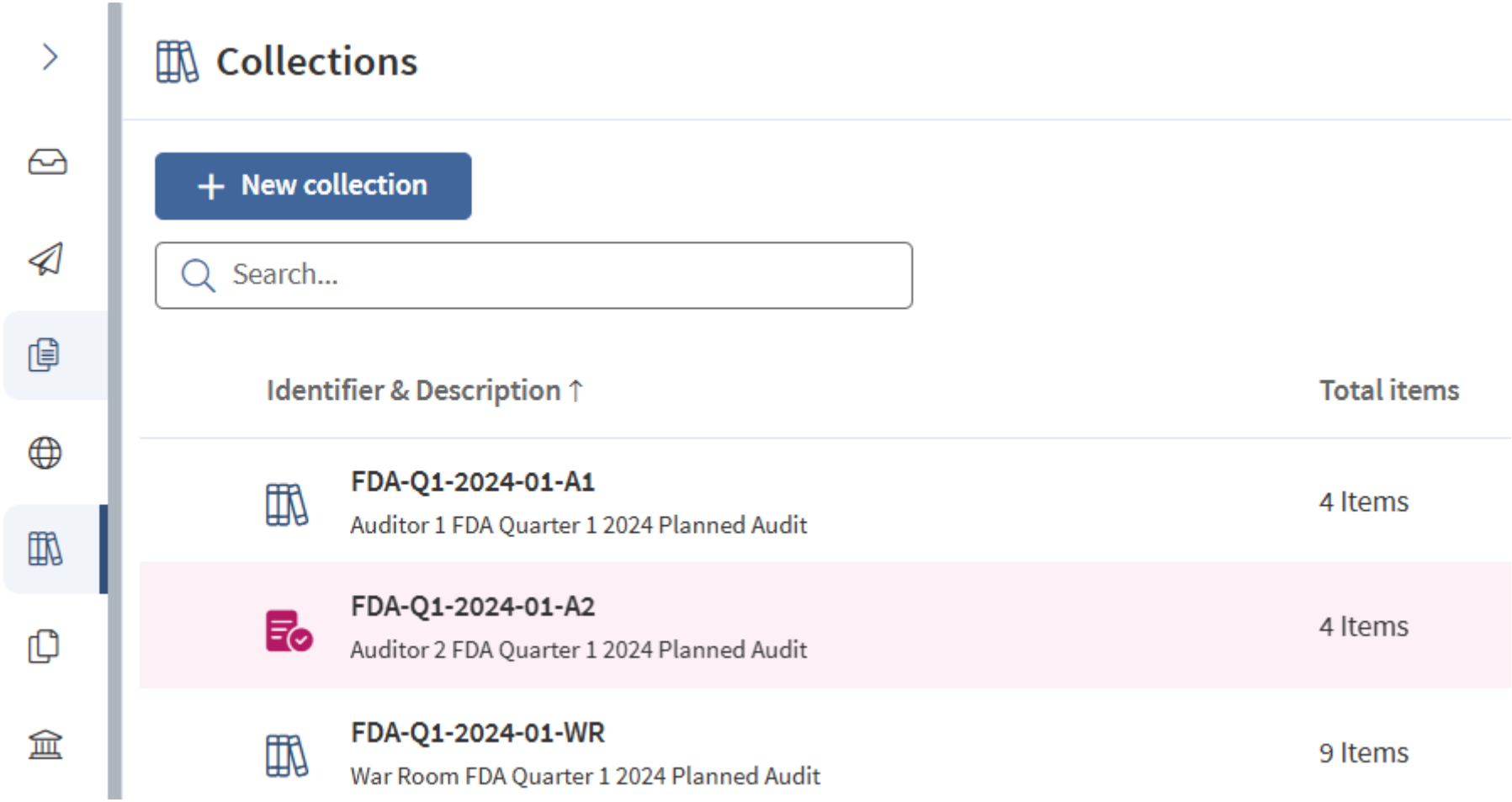
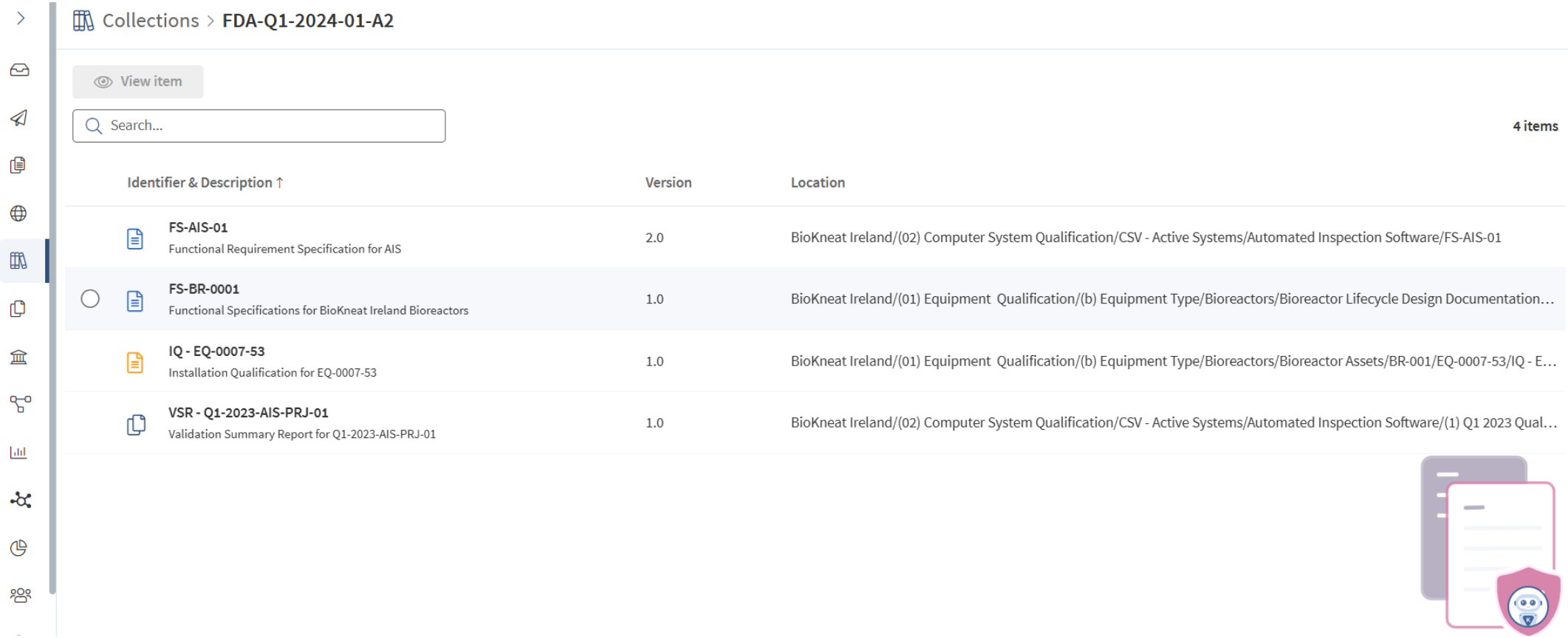
# Audits



# Audits



# Audits

FS-AIS-01

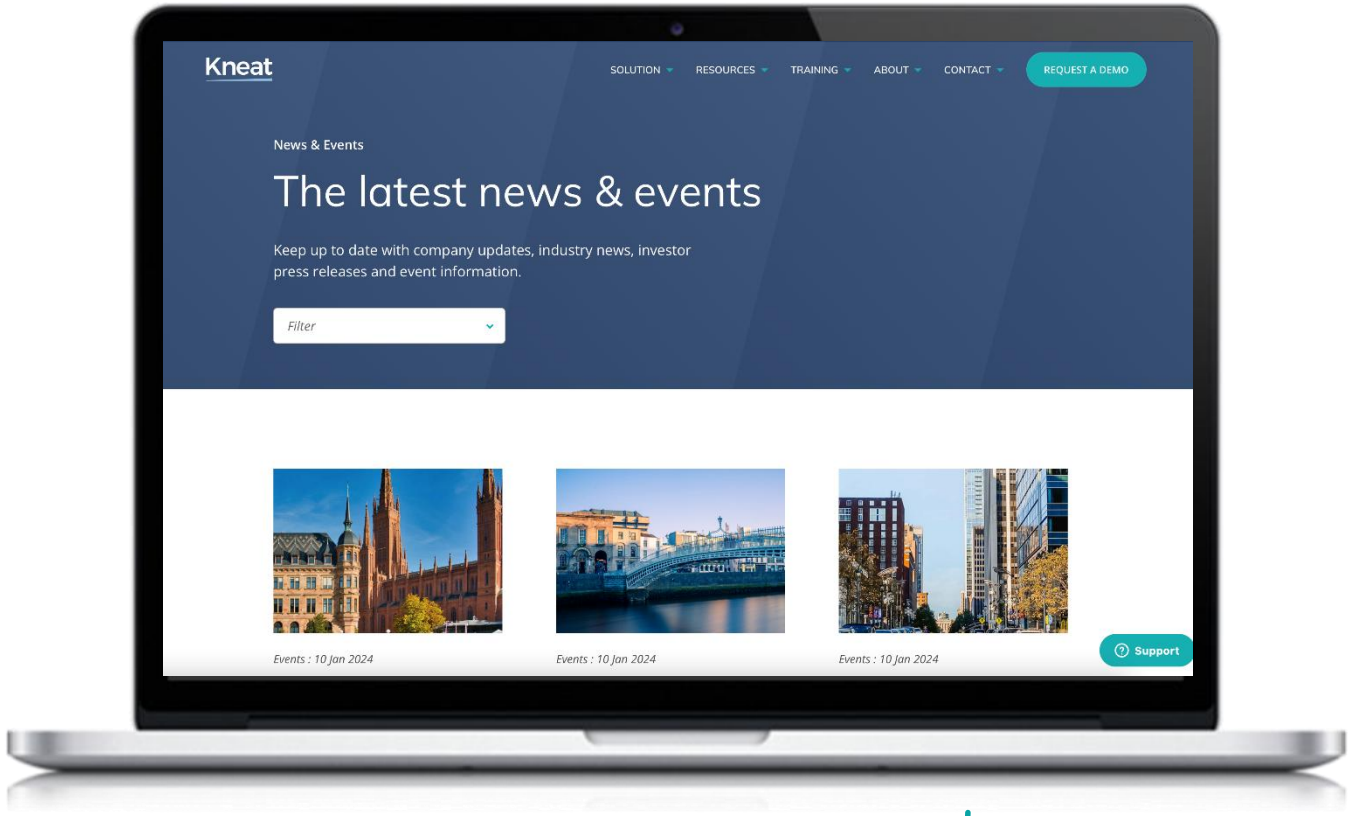
Back

160 %

## 5.1 Operational & Performance Requirements

| Functional Specification | | | | |
|---|---|---|---|---|
| # | FS ID | Description | Referenced URS | Comment |
| 1 | FS-AIS-01-001 | The system shall allow a user to import content from a Microsoft Word .doc file, into the following areas of the application:<br><br>1. AIS User Record Record groups content<br>2. AIS User Record Template Record groups content | URS-AIS-01 (2.0 App) 4.1 #URS-AIS-01-001 | None |
| 2 | FS-AIS-01-002 | The system shall prevent the user from importing more than one file at a time into a AIS User Record. | URS-AIS-01 (2.0 App) 4.1 #URS-AIS-01-002, #URS-AIS-01-006 | None |
| 3 | FS-AIS-01-003 | The system shall structure imported content into AIS User Record Record groups and sub Record groups accordingly, identifying Record groups using the Microsoft Word heading styles (Heading 1 through to Heading 9). | URS-AIS-01 (2.0 App) 4.1 #URS-AIS-01-010, #URS-AIS-01-007 | None |
| 4 | FS-AIS-01-004 | The system shall name imported Record groups and sub Record groups as per the source heading names. | URS-AIS-01 (2.0 App) 4.1 #URS-AIS-01-006, #URS-AIS-01-005 | None |
| 5 | FS-AIS-01-005 | The system shall number each Record groups and sub Record groups accordingly as per the user's placement of the file in the DCS System AIS User Record. * | URS-AIS-01 (2.0 App) 4.1 #URS-AIS-01-010, #URS-AIS-01-011 | None |
| 6 | FS-AIS-01-006 | When a user has imported a file into the application, the Record groups added to the AIS User Record shall be displayed in the AIS User Record of Contents as per their placement in the AIS User Record. | URS-AIS-01 (2.0 App) 4.1 #URS-AIS-01-011, #URS-AIS-01-012 | None |
| 7 | FS-AIS-01-007 | The system shall support the importing of portrait and landscape page orientations for content imported from MS Word. | URS-AIS-01 (2.0 App) 4.1 #URS-AIS-01-002, #URS-AIS-01-004 | None |
| 8 | FS-AIS-01-008 | The system shall support the importing of the supported page sizes for the content imported from MS Word. | URS-AIS-01 (2.0 App) 4.1 #URS-AIS-01-002, #URS-AIS-01-003, #URS-AIS-01-004, #URS-AIS- | None |

# Upcoming Events

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MARCH 25 // 11 AM ET

### Adapting to Evolving Regulations @ Life Sciences Connect

MARCH 26 // 2 PM ET

## Conferences

### ISPE San Francisco

MARCH 20 // San Francisco, CA

### GMP Pharma Congress

APRIL 8 & 9 // Wiesbaden, Germany

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