

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

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 +



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.



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.



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



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?

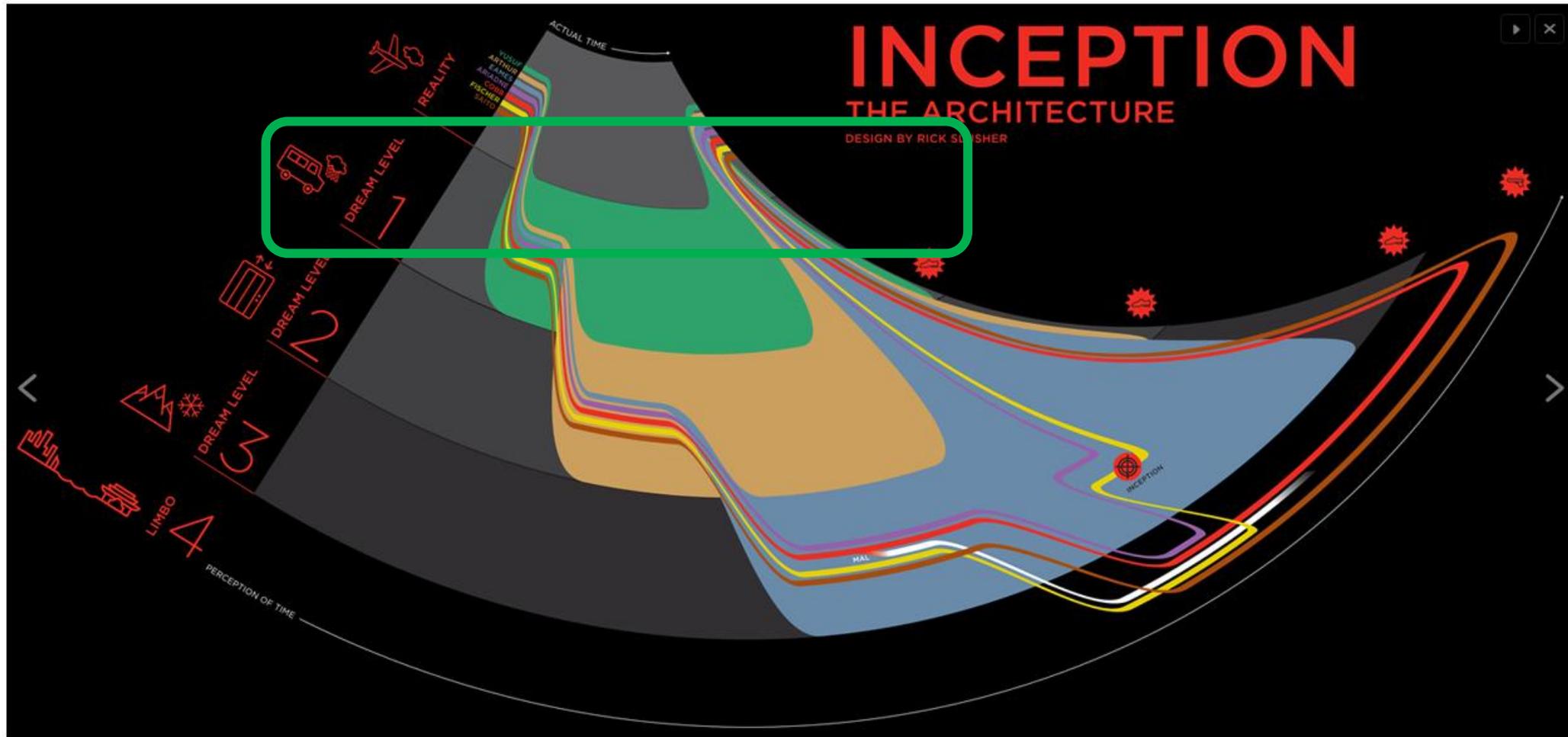
- Equipment Data

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

- System Data

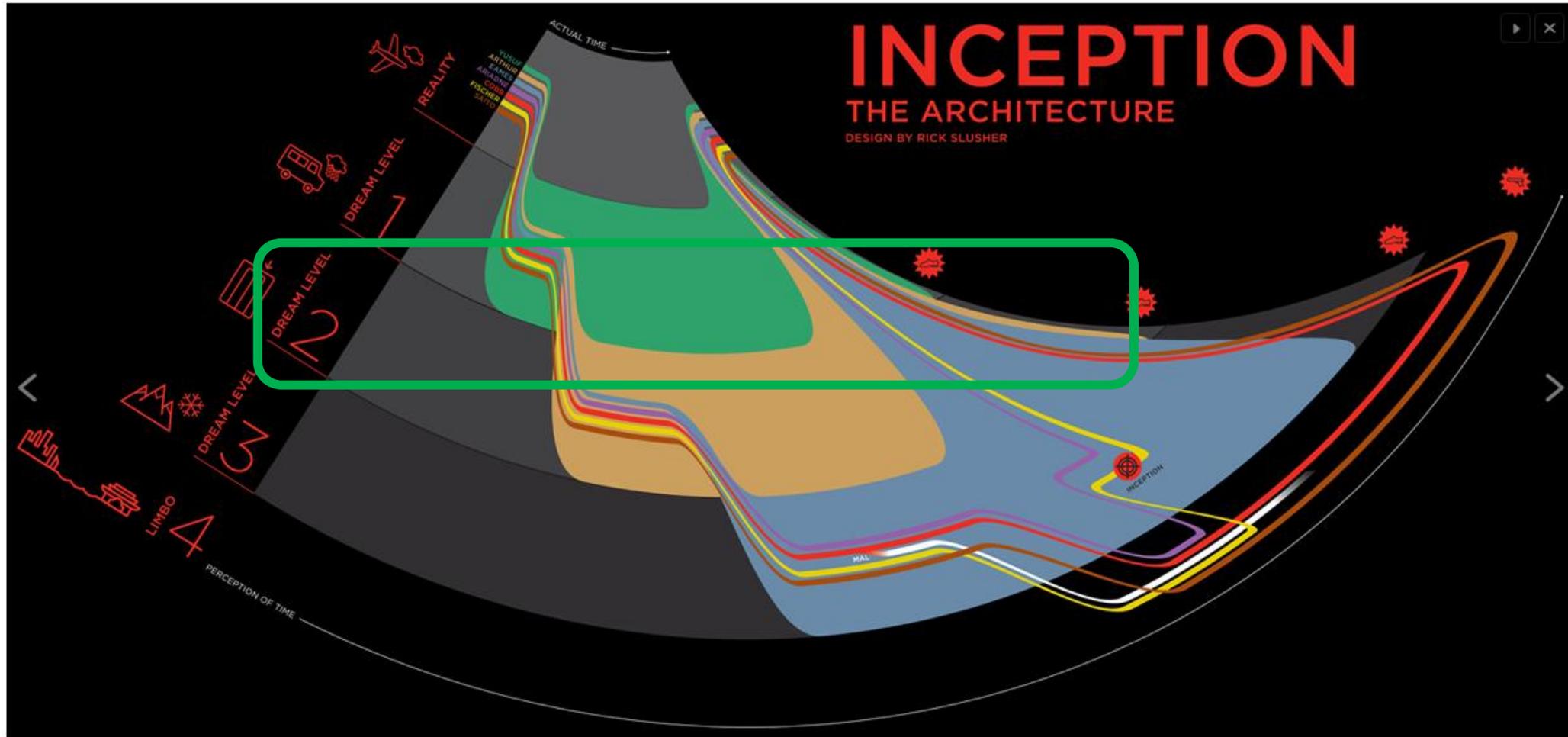
- System ID
- System Description
- System owner
- Qualification Status

How Deep can we go into data



Inception: The Architecture by Rick Slusher

How deep can we go?

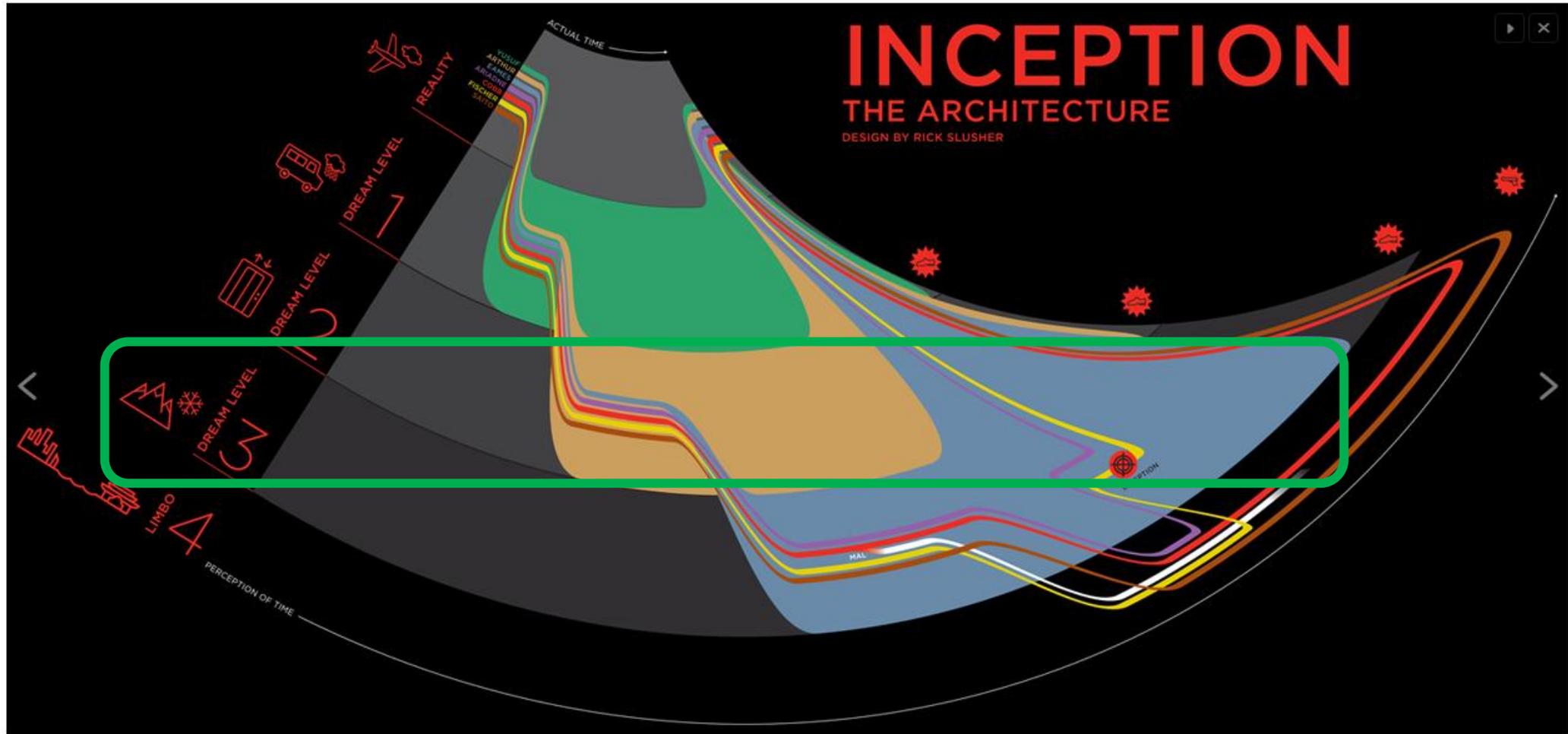


Inception: The Architecture by Rick Slusher

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

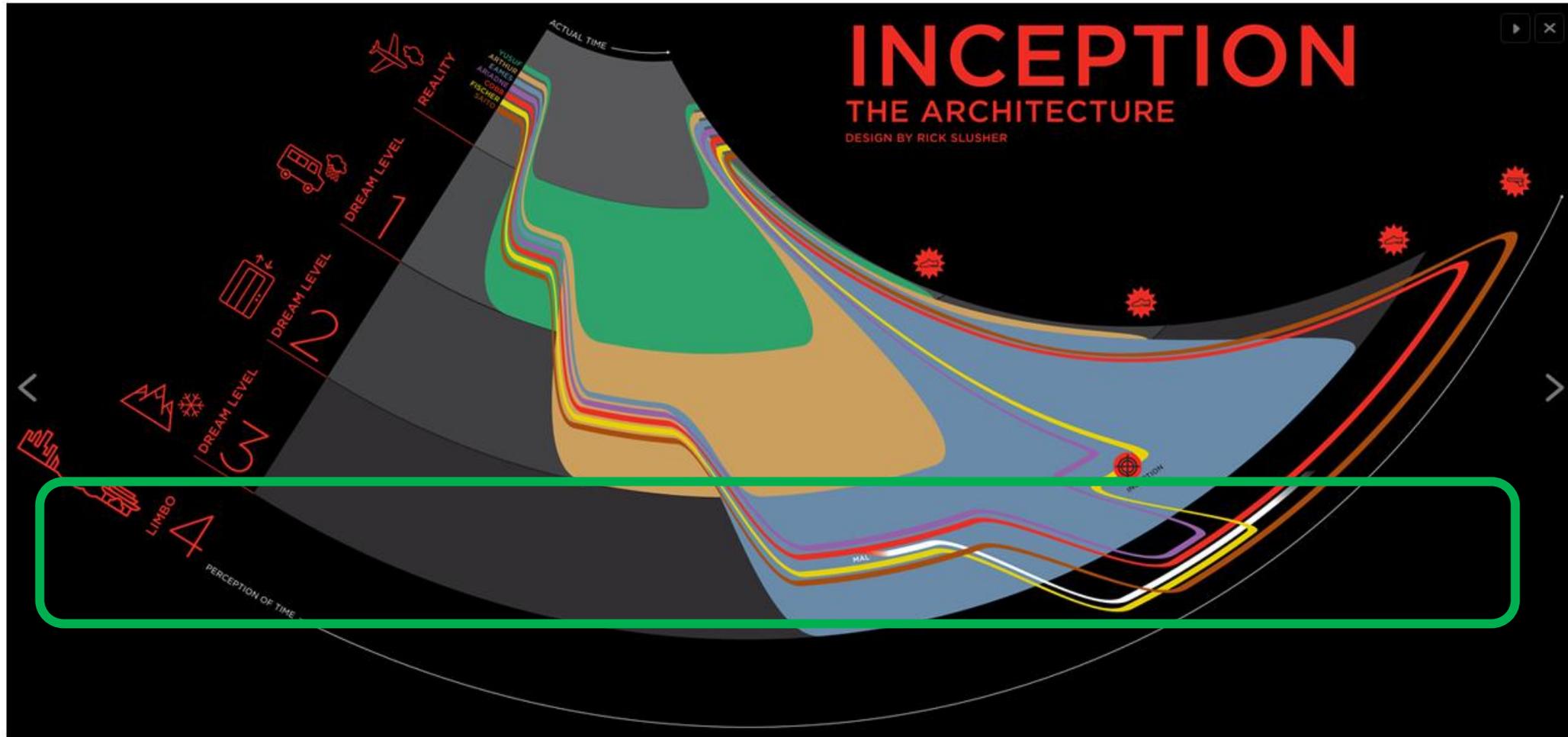
New Data (That we always had)

- 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 +



Equipment and Systems

- ▼  Bioreactors
 - >  PU1-BRX-01
 -  PU1-BRX-02
 -  PU1-BRX-03



- ▼  Bioreactors
 - ▼  PU1-BRX-01
 -  PU1-BRX-01-CDT-01
 -  PU1-BRX-01-PHM-01
 -  PU1-BRX-01-PT-01
 -  PU1-BRX-01-PT-02

Equipment and Systems

PU1-BRX-01-CDT-01 | Not Approved (0)

Save

Entity Details

Attribute	Value	Status
 Equipment Id <i>Required core attribute</i>	PU1-BRX-01-CDT-01	Not Approved
 Description <i>Core attribute</i>	<i>Enter a value</i>	N/A

Site Hierarchy

Master Data

Attribute	Value	Status
 System Status <i>Core attribute</i>	<i>Enter a value</i>	N/A
 System Impact <i>Core attribute</i>	<i>Select a value</i>	N/A

Equipment and Systems

 SAP S/4HANA V2.0

 SAP S/4HANA V2.0 | Approved (✓1)

Attribute	Value	Status
 System Id <i>Required core attribute</i>	 SAP S/4HANA V2.0	Approved
 System Description <i>Core attribute</i>	 SAP S/4HANA ERP	Approved
Site Hierarchy ∨		
Master Data ∨		
Core System Characteristics ∨		
Attribute	Value	Status
Validation Status	 Qualified	∨ Approved
Periodic Review Required	 Yes	∨ Approved
Periodic Review Cycle	 24 Months	Approved

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 <i>Core attribute</i>	GAMP Category 4	Approved
Electronic Record <i>Core attribute</i>	Yes	Approved
Electronic Signature <i>Core attribute</i>	Yes	Approved
System Impact <i>Core attribute</i>	DI	Approved
Risk Level <i>Core attribute</i>	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

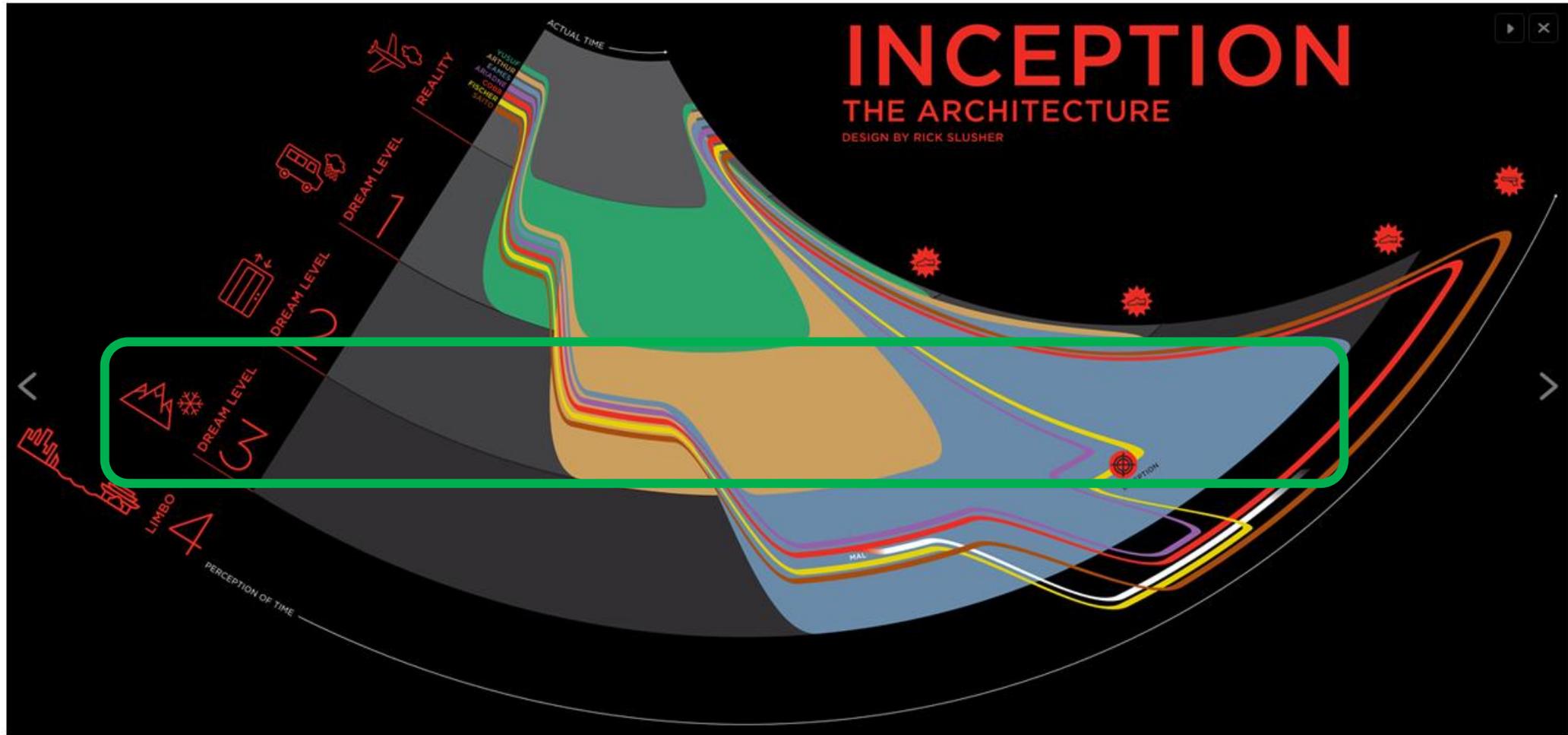
NOTE: For each of the items checked above, include appropriate 21 Part 11 requirements in the system URS.

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	Category	Complexity	(Note to the results from Section 2 for this answer)		
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?



Inception: The Architecture by Rick Slusher

Requirements Data

Workspace

Jamie > Entities > URS

+ New

Requirement

Settings

Entity mode

Entity status & version	Requirement Id <i>Required core attribute</i>	Description <i>Core attribute</i>	Acceptance Criteria <i>Core attribute</i>	Traceability <i>Core attribute</i>	Priority <i>Core attribute</i>
<input type="radio"/> ↻ Not Approved (0)	Demo entity 1	Test	Enter a value	<input type="text" value="21CFR-1"/> <input type="text" value="Demo File"/> Add Relationship	Select a value
<input type="radio"/> ↻ Not Approved (0)	Demo Entity 2	Test	Enter a value	Add Relationship	Select a value
<input type="radio"/> ↻ Not Approved (0)	Demo Entity 3	Test	Enter a value	<input type="text" value="IO - Entity Mode (1.0 Post-App) 5.1.1 System Suitability Result Summary"/> Add Relationship	Select a value
<input type="radio"/> ↻ Not Approved (0)	Demo Entity 4	Test	Enter a value	<input type="text" value="FS Demo Req1"/> Add Relationship	Select a value
<input type="radio"/> ↻ Not Approved (0)	Demo Entity 5	Test	Enter a value	Add Relationship	Select a value

Requirements Data

Sections Details Exclusion Review Approval

+ New



Saved

Edit

Interact

+ Add

Arial

10pt

B

I

U

A

Copy

Paste

Cut

- Header
- Cover Page
- Table Of Contents
- 1 Introduction
- 2 Requirements
- 3 References
- 4 Demo
- 5 OQ Test Cases

2 Requirements

Requirement Id	Description	Acceptance Criteria	Traceability	Priority
Demo entity 1	Test edit	No value entered for Acceptance Criteria	21CFR-1 Demo File	No value entered for Priority
Demo Entity 2	Test	No value entered for Acceptance Criteria	No value entered for Traceability	No value entered for Priority
Demo Entity 3	Test	No value entered for Acceptance Criteria	IQ - Entity Mode (1.0 Post-App) 5.1.1 System Suitability Result Summary	No value entered for Priority
Demo Entity 4	Test	No value entered for Acceptance Criteria	FS Demo Req1	No value entered for Priority
Demo Entity 5	Test	No value entered for Acceptance Criteria	No value entered for Traceability	No value entered for Priority

Requirements Data

The screenshot shows a software application interface. On the left, there is a table with columns for Requirement ID, Test edit, Acceptance Criteria, and Priority. Below the table, there are several rows of data. On the right, there is a panel titled 'Attribute' showing details for 'Description (Core attribute)' with a 'Test edit' button.



↑ ↓ 🔄

Attribute

Owning entity detail

Requirement
📄 Demo entity_1

Description (current location)
⚠️ Test edit

Contained in (4) Activity

- 📄 **QQ - Overwriting**
 In Development (0.1)
⚠️ Test
- 📄 **IQ - Overwriting**
 In Development (0.1)
⚠️ Test
- 📄 **URS-005**
 In Development (0.1)
⚠️ Test
- 📄 **FS-003**
 In Development (0.3)
⚠️ Test edit



ⓘ ×

Attributes

Entity Details

- ↑ **Requirement Id**
Required core attribute
📄 Demo entity_1
- ↑ **Description**
Core attribute
⚠️ Test

General Data

- ↑ **Acceptance Criteria**
Core attribute
⚠️ No value
- ↑ **Traceability**
Core attribute
⚠️ 📄 21CFR-1 📄 Demo File
- ↑ **Priority**
Core attribute
⚠️ No value
- ↑ **Category**
Core attribute
⚠️ No value
- ↑ **Required**
Core attribute

ⓘ ×

Attributes

[← Back](#)

Owning entity detail

- ↑ **Requirement Id**
Required core attribute
📄 Demo entity_1
- ↑ **Description (current location)**
Core attribute
⚠️ Test

Contained in (4) Activity

- 📄 **QQ - Overwriting**
 In Development (0.1)
⚠️ Test
- 📄 **IQ - Overwriting**
 In Development (0.1)
⚠️ Test
- 📄 **URS-005**
 In Development (0.1)
⚠️ Test
- 📄 **FS-003**
 In Development (0.3)
⚠️ Test edit

How do we present Data?

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Audits

>  Collections

+ New collection

Identifier & Description ↑		Total items
	FDA-Q1-2024-01-A1 Auditor 1 FDA Quarter 1 2024 Planned Audit	4 Items
	FDA-Q1-2024-01-A2 Auditor 2 FDA Quarter 1 2024 Planned Audit	4 Items
	FDA-Q1-2024-01-WR War Room FDA Quarter 1 2024 Planned Audit	9 Items

Audits

> Collections > FDA-Q1-2024-01-A2

View item

Search...

4 items

Identifier & Description ↑	Version	Location
 FS-AIS-01 Functional Requirement Specification for AIS	2.0	BioKneat Ireland/(02) Computer System Qualification/CSV - Active Systems/Automated Inspection Software/FS-AIS-01
 FS-BR-0001 Functional Specifications for BioKneat Ireland Bioreactors	1.0	BioKneat Ireland/(01) Equipment Qualification/(b) Equipment Type/Bioreactors/Bioreactor Lifecycle Design Documentation...
 IQ - EQ-0007-53 Installation Qualification for EQ-0007-53	1.0	BioKneat Ireland/(01) Equipment Qualification/(b) Equipment Type/Bioreactors/Bioreactor Assets/BR-001/EQ-0007-53/IQ - E...
 VSR - Q1-2023-AIS-PRJ-01 Validation Summary Report for Q1-2023-AIS-PRJ-01	1.0	BioKneat Ireland/(02) Computer System Qualification/CSV - Active Systems/Automated Inspection Software/(1) Q1 2023 Qual...



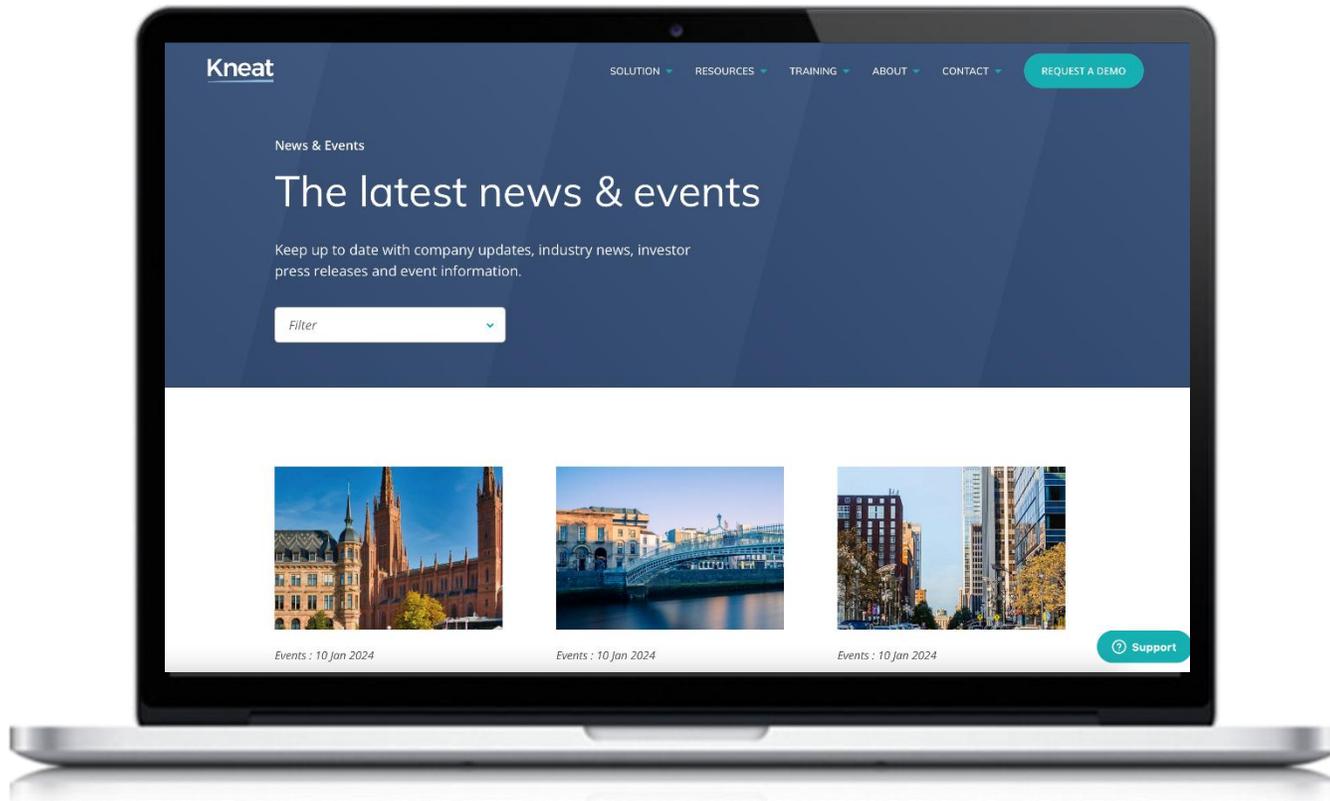
Audits

FS-AIS-01

Back

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: 1. AIS User Record Record groups content 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

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Monthly Software Demonstration
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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Thank You

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