Towards a Recipe Driven Organization

Presented by **Jim Kenyon, Pharmaceutical Development and Manufacturing Sciences, Janssen Research and Development, LLC**

Overview

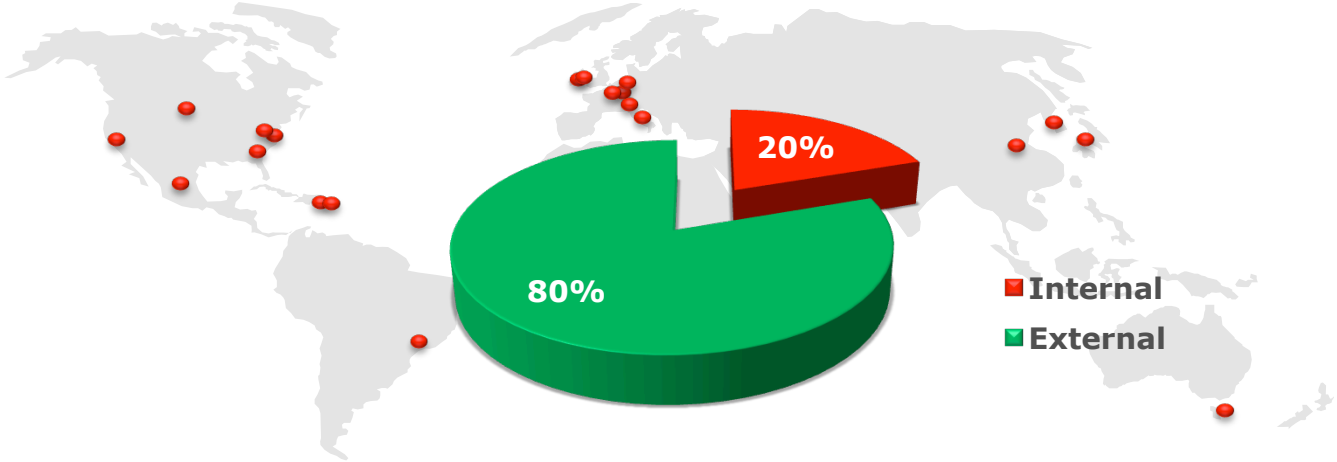
- Introduction to Janssen and our challenges
- Defining the recipe based knowledge management strategy
- How the OSI PI system enables that strategy
- Closing remarks

Janssen

Johnson & Johnson

janssen | PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Cardiovascular & Metabolism | Immunology | Infectious Diseases & Vaccines | Neuroscience | Oncology



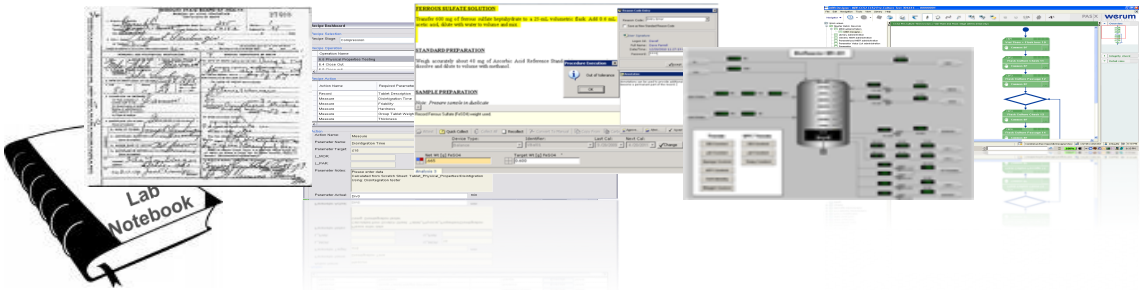
Current State

REACTIVE ANALYSIS

- More time spent on aggregation than analysis
- Lack of knowledge management strategy

- Mix of paper/electronic
- Unstructured data
- Few standards
- Little built-in context
- Efforts mainly focused internally

Lab/Clinical/Commercial



Future State

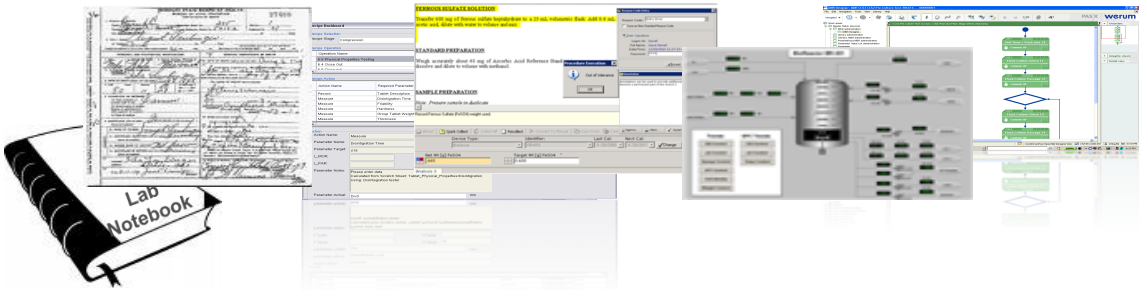
PROACTIVE ANALYSIS

- Automated data aggregation
- More time spent on analysis than aggregation
- Common knowledge management strategy

- Electronic data capture
- Structured data
- Common standards
- Internal/external focus

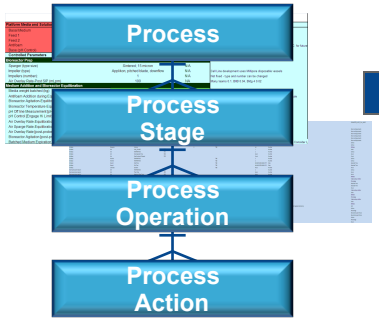
Recipe Based Knowledge Management

Lab/Clinical/Commercial

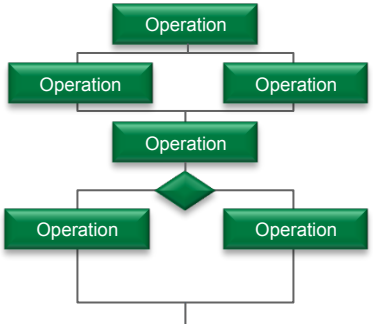


S88 Recipe Based Knowledge Management Strategy

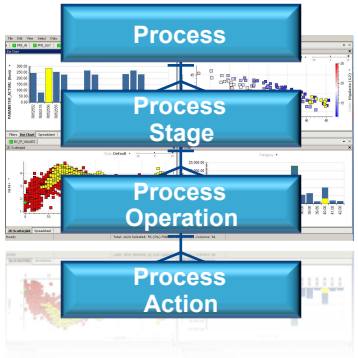
Content
Recipe Model



Execution
Recipe Based Workflow

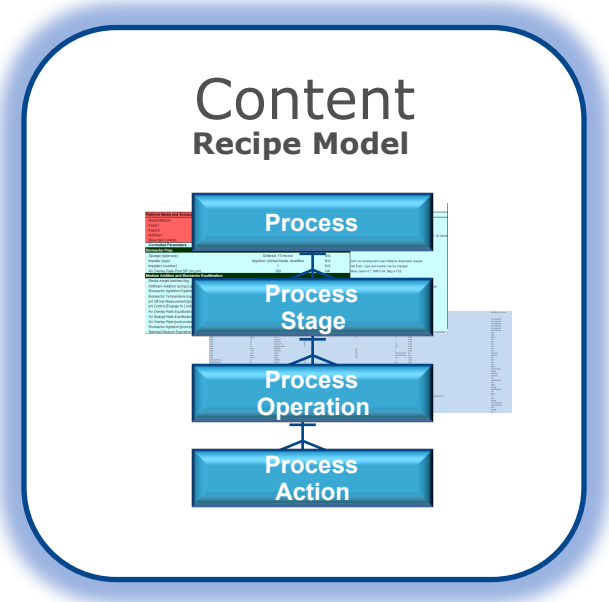


Visualization



Consistent S88 Structure

S88 Recipe KM Strategy: Content



PLATFORM OPERATING CONDITIONS: 3L Bioreactor Process

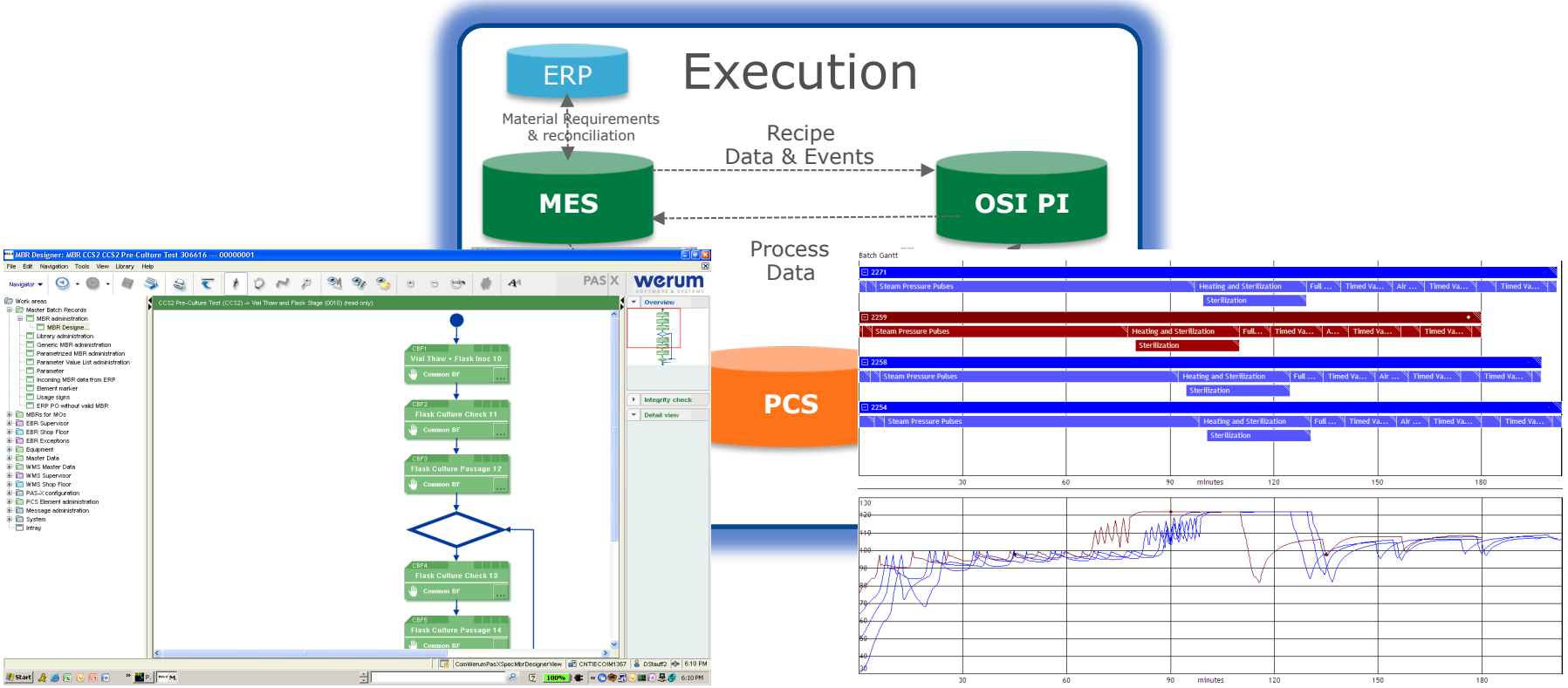
Platform Media and Solutions		CBL #	Comments
Basal Medium	MACH-1 + 8 g/L F8	CBL-024	Platform Basal Medium
Feed 1	BRX	CFL-001	Platform Feed 1
Feed 2	G8 (preferred) or G12	CFL-016/CFL-024	Platform Feed 2
Antifoam	Antifoam C (10,000 ppm stock)	N/A	Platform Anti Foam C - Explore Hyclone's Gam diated AFC for future
Base (pH Control)	2M Sodium Carbonate	N/A	Formula correct True 2M
Controlled Parameters	**Target**	**Range**	
Bioreactor Prep			
Sparger (type size)	Sintered, 15 micron	N/A	
Impeller (type)	Applikon, pitched blad	N/A	Ca nt uses M re Sta ress
Impellers (number)		N/A	Nat d - type ber ca chan
Air Overlay Rate-Post SIP (mLpm)	100	NA	Many teams 0.1, Bl 0.04, Bldg 4 0.02
Medium Addition and Bioreactor Equilibration			
Media weight batched (kg)	TBDE	RDE	Adjust based on N-1 cell count
Antifoam Add	19 ppm ed on final ume		Adjust based on predicted reactor final volume / Linked to Schedule
Bioreactor Ag on-Equilibr m (rp	200	190 - 210	
Bioreactor Tem rature-Equ ation (°C)	36.5	35.5 - 37.5	
pH Off line Meas Probe S dardization] (p	±0.05	N/A	Adjust on-line pH based on off-line BGA pH
pH Control [Engag Hi Limit Control]	N/A	≤7.30	CO2 above high pH limit
Air Overlay Rate- ibration [DO pro dardization] (mLpm)	N/A	N/A	**Limitation for some Valley Equipment**
Air Sparge Rate-E ibration [DO probe standardization] (mLpm)	100	N/A	**Does this need data confirmation?**
Air Overlay Rate [post-probe standardization] (mLpm)	100	NA	Many teams 0.1, BIIB 0.04, Bldg 4 0.02
Bioreactor Agitation [post-probe standardization] (rpm)	200	190 - 210	ttHt
Batched Medium Expiration Time [at operating Temp] (hrs)	≤48	≤48	Need to compile data with MACH-1 to support this (72 hr better) Consider L

Recipe Step Risks

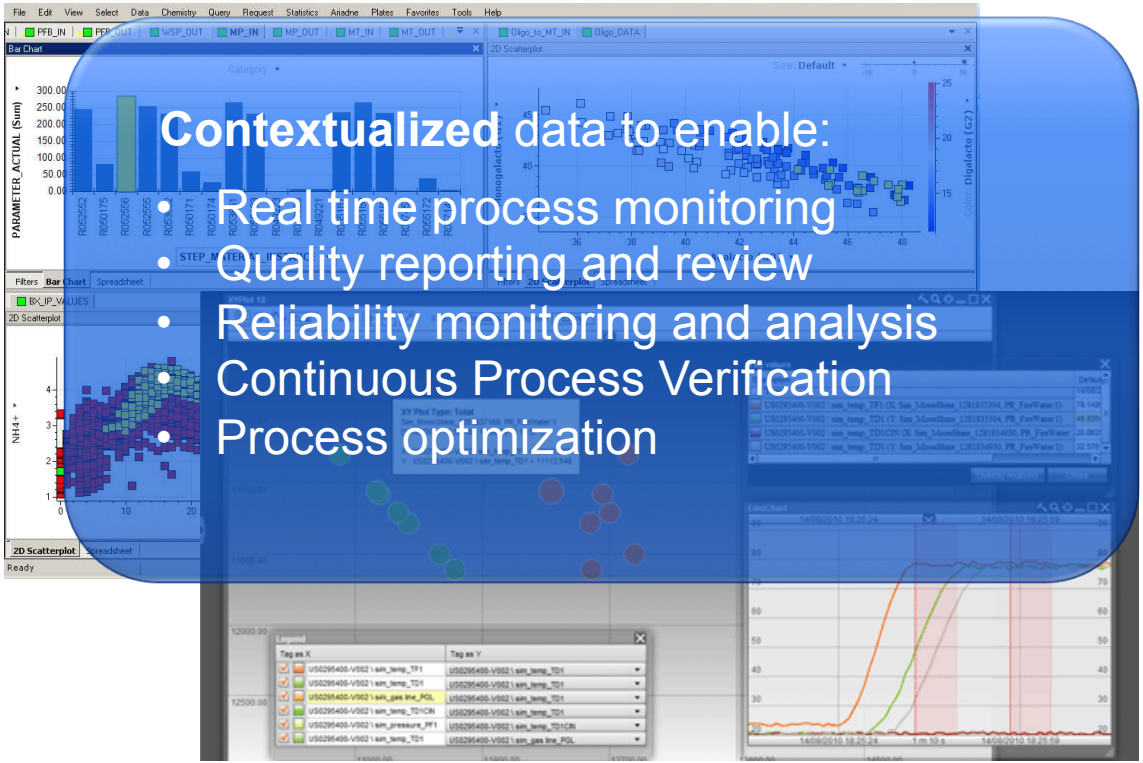
Step	Risk Asset	Severity	Occurren	Det	Criticality	RPN
Solution Preparation\Add Materials and Mix\Addition:10	Addition:10	5		7	15	105
Solution Preparation\Add Materials and Mix\Addition:11	Addition:11	8	2	5	16	80
Solution Preparation\Add Materials and Mix\Addition:12	Addition:12	3	1	1	3	3
Solution Preparation\Add Materials and Mix\Addition:13	Addition:13	1	4	5	4	20
Solution Preparation\Add Materials and Mix\Addition:14	Addition:14	4	1	1	4	4
Solution Preparation\Add Materials and Mix\Addition:2	Addition:2	3	1	5	15	15
Solution Preparation\Add Materials and Mix\Addition:3	Addition:3	2	4	1	8	8
Solution Preparation\Add Materials and Mix\Addition:4	Addition:4	4		1	4	4
Solution Preparation\Add Materials and Mix\Addition:5	Addition:5	4	1	5	4	20
Solution Preparation\Add Materials and Mix\Addition:6	Addition:6	3	1	1	3	3
Solution Preparation\Add Materials and Mix\Addition:7	Addition:7	1	10	1	10	10
Solution Preparation\Add Materials and Mix\Addition:8	Addition:8	1	4	5	4	20
Solution Preparation\Add Materials and Mix\Addition:9	Addition:9	1	1	1	1	1

PLATFORM CRITICALITY ASSESSMENT

S88 Recipe KM Strategy: Execution



S88 Recipe KM Strategy: Visualization



Contextualized data to enable:

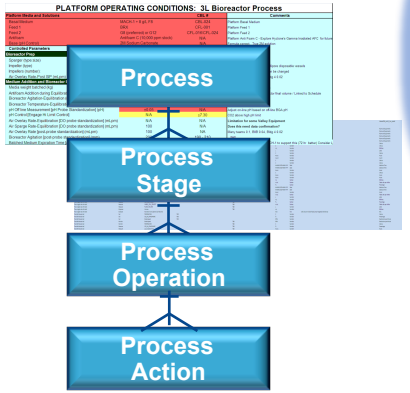
- Real time process monitoring
- Quality reporting and review
- Reliability monitoring and analysis
- Continuous Process Verification
- Process optimization

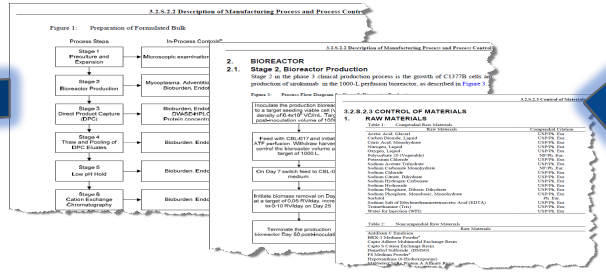
Visualization

S88 Recipe KM Strategy: Link to the Regulatory Filing

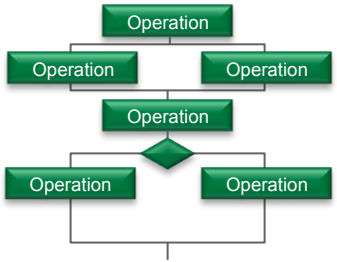
Regulatory Filing = General Recipe

CONTENT
Critical Parameters and Steps
Structured in S88 Format





Site Executable Recipe

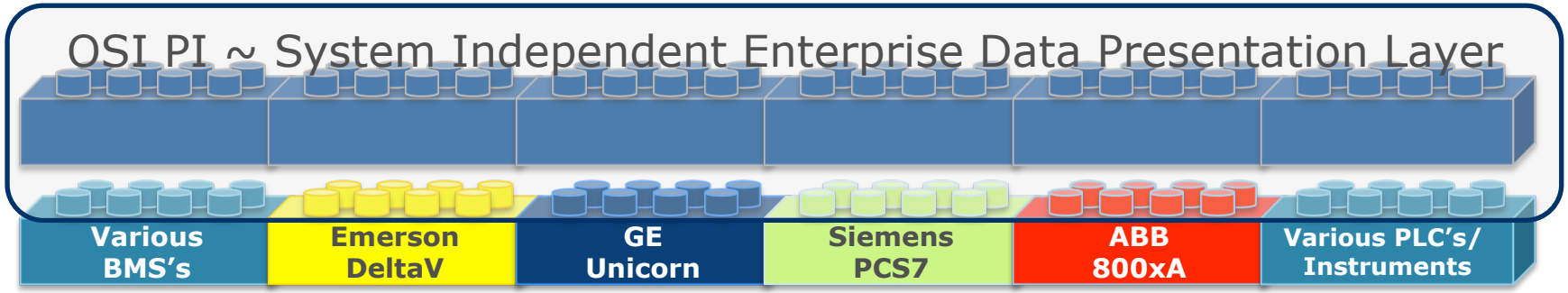


EXECUTION
Data generated in S88 Format
Contains additional site details

VISUALIZATION
Critical Parameters and Steps
Context rich data

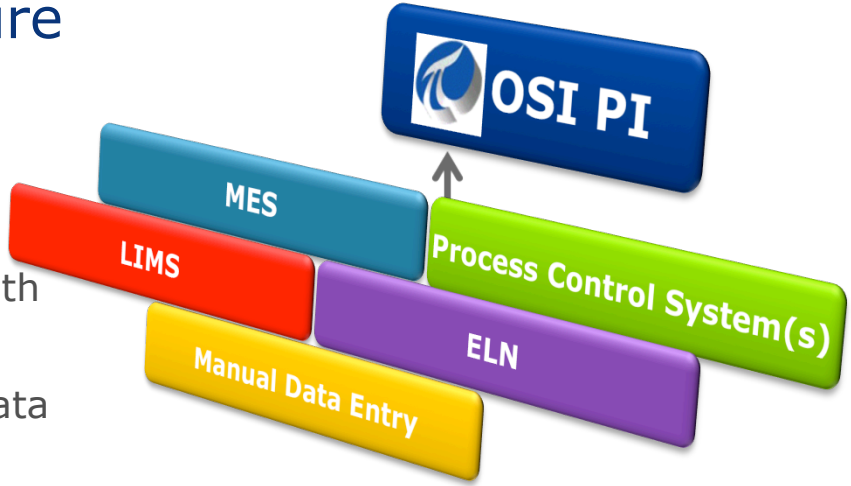
Value of the OSI PI System

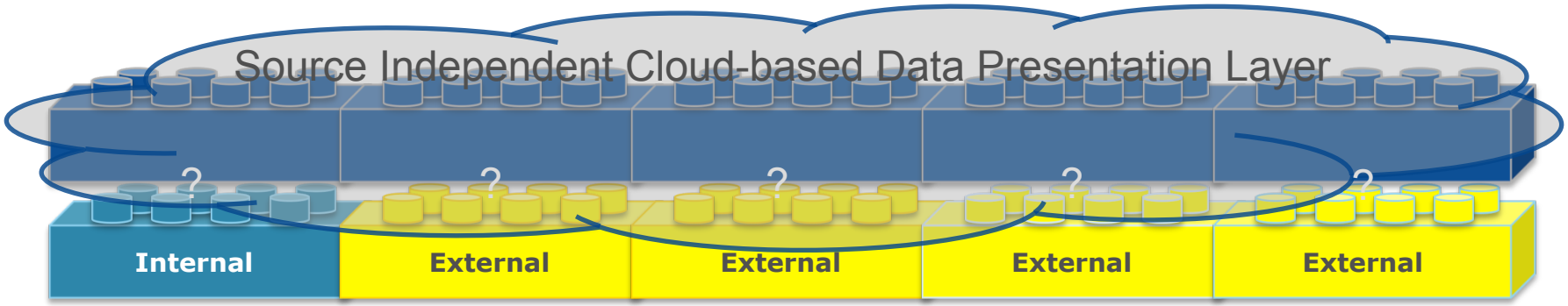
- Very disparate systems landscape
  - ranging from distributed process control systems with inherent historian capability to stand-alone instruments with paper printouts
- Require capability to capture and aggregate data for visualisation, reporting & analysis



Value of the OSI PI System: Future

- Very disparate systems landscape – now including MES, ELN, Manual Data Entry…
- Ability to share contextualized process data with external partners is critical
- Require capability to capture and aggregate data for visualisation, reporting & analysis





Conclusions

- Janssen is actively driving forward on S88 KM Strategy:
  - Content: Defining platform recipes
  - Execution: Aligning systems to S88 Platform definitions
  - Visualization: Building advanced analytical and modeling tools to help scientists and engineers gain advanced understanding of our processes
- A solution is required for a source independent data aggregation layer to include contextualized data from multiple enterprises.
- Collaboration with other companies would help drive this solution.

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