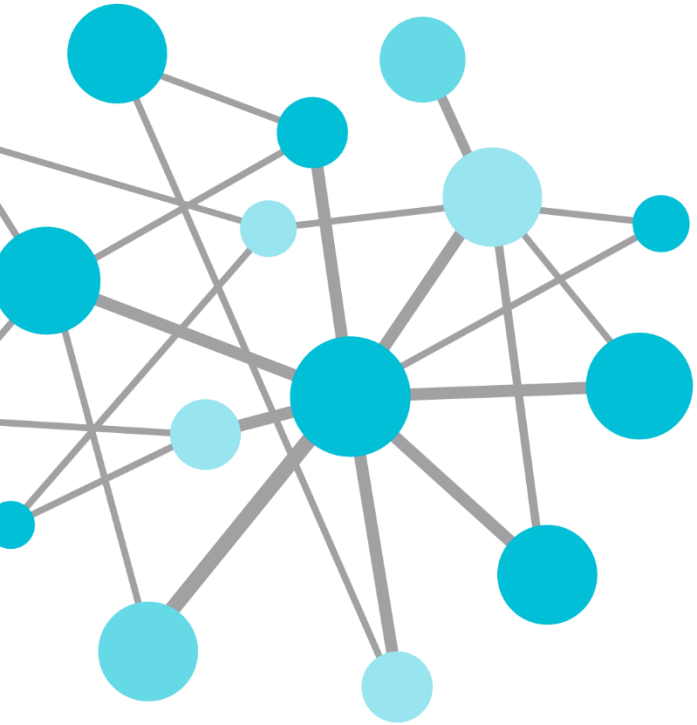


Recipe driven, data visualization from lab to commercial

Presented by **Barry Higgins and Koen Paeshuyse**

janssen
PHARMACEUTICAL COMPANIES
OF Johnson&Johnson

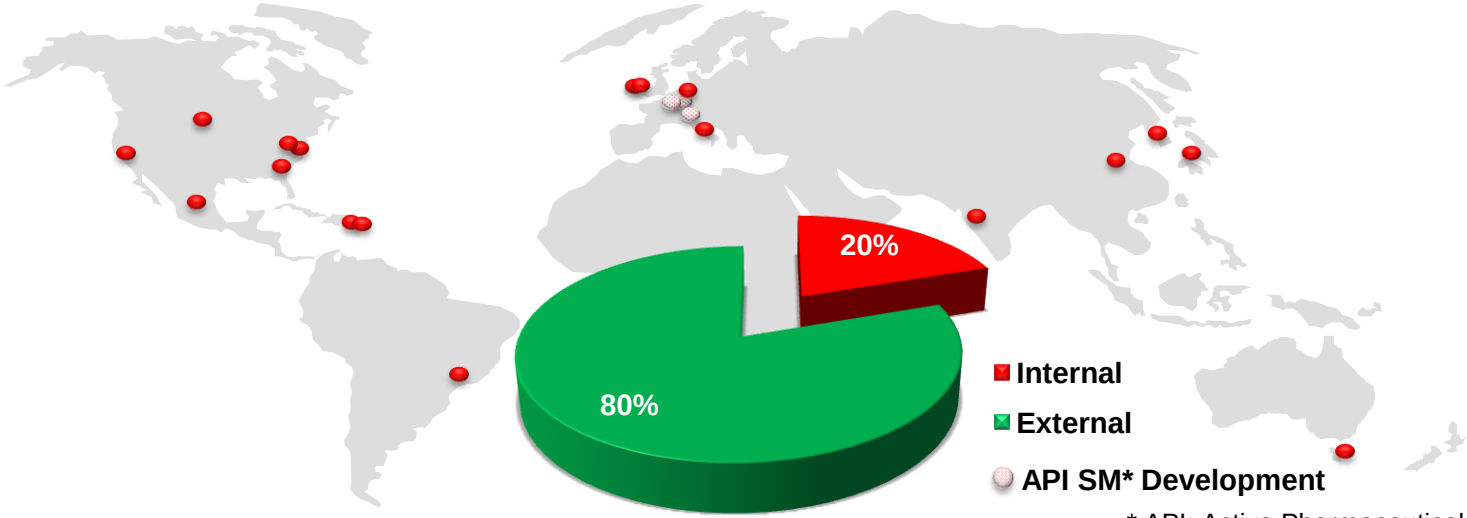
Agenda

- Introduction
- Goal and Challenges
- S88 recipe strategy
- Recipe integration into systems
- OSIsoft PI AF/EF setup
- Data visualization
- Conclusions

Introduction

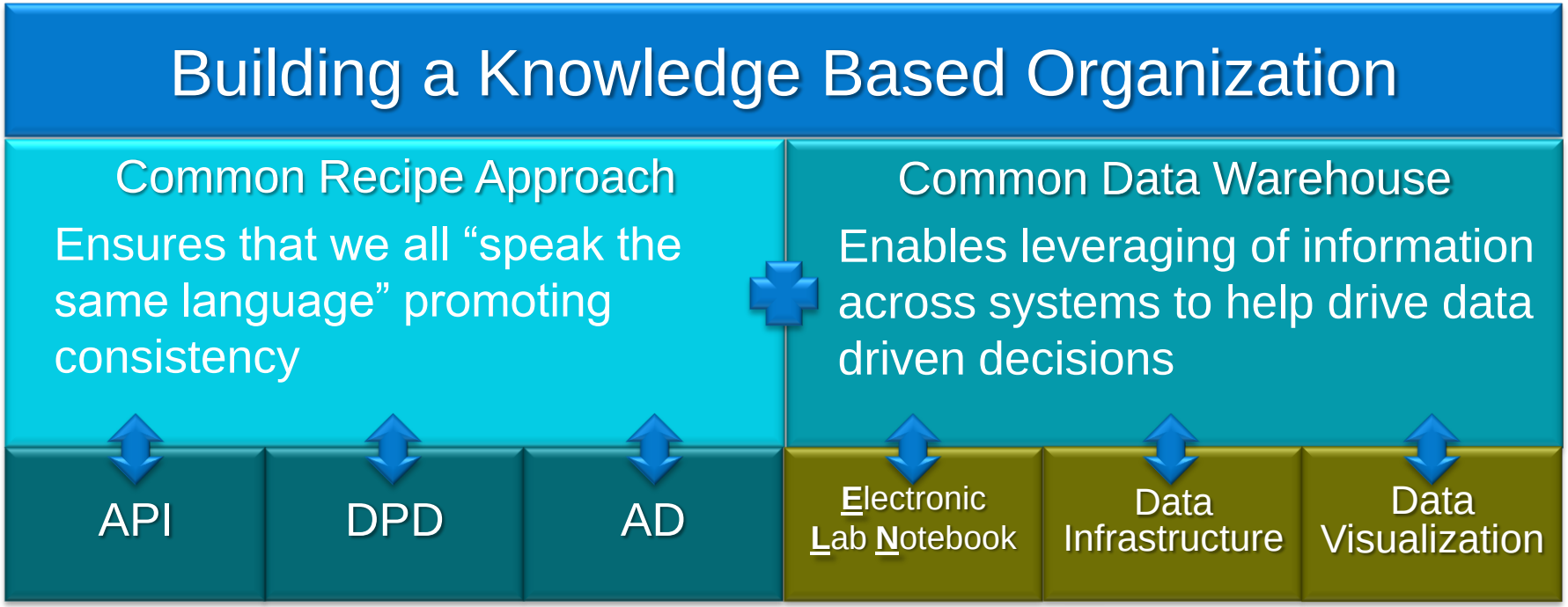
Janssen
PHARMACEUTICAL COMPANIES
OF Johnson & Johnson

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



* API: Active Pharmaceutical Ingredient
SM: Small Molecules

Goal and Challenges



S88 – What is it?

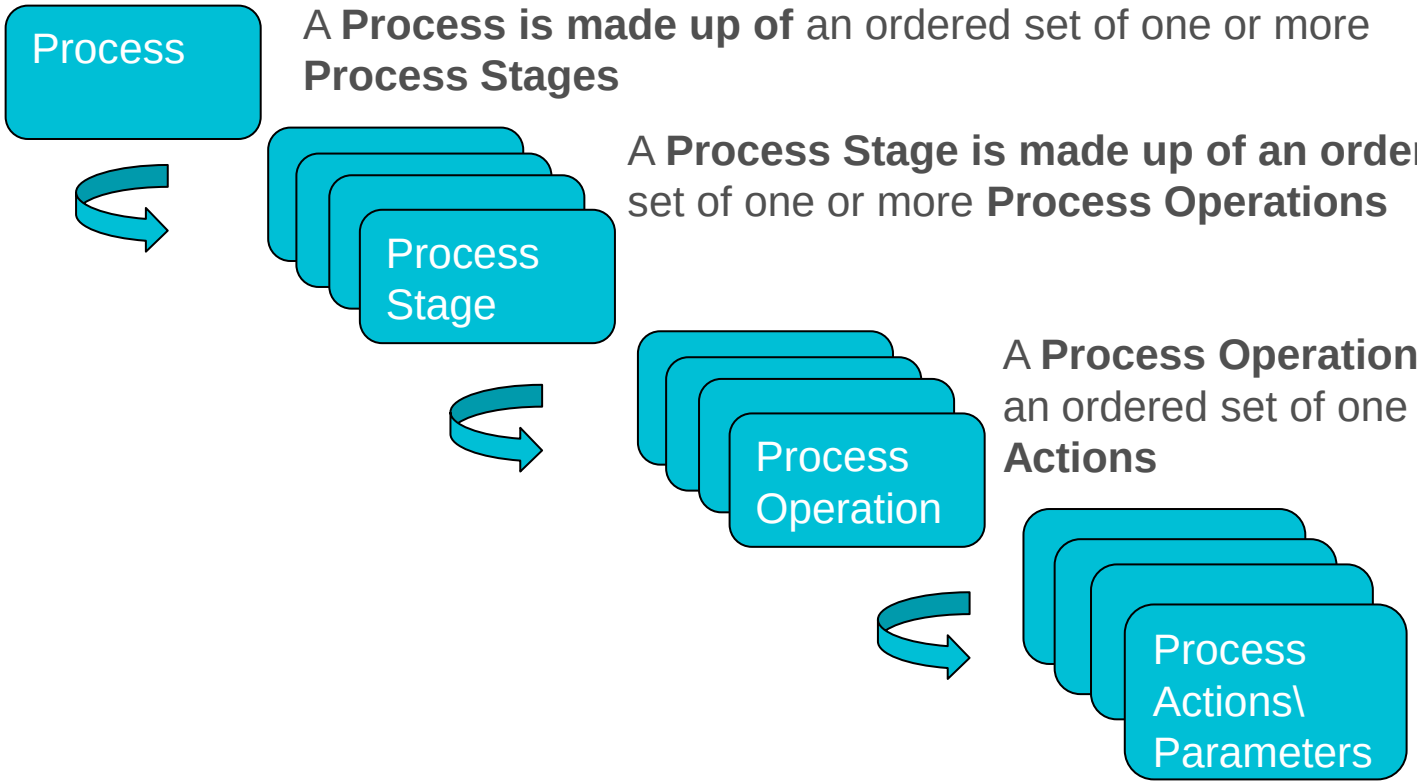
Short for ANSI/ISA-88

- ANSI is American National Standards Institute
- ISA is Instrumentation, Systems, and Automation Society

An industry standard addressing batch process control

S88 provides a consistent set of standards and terminology for batch control

S88 – Process Model



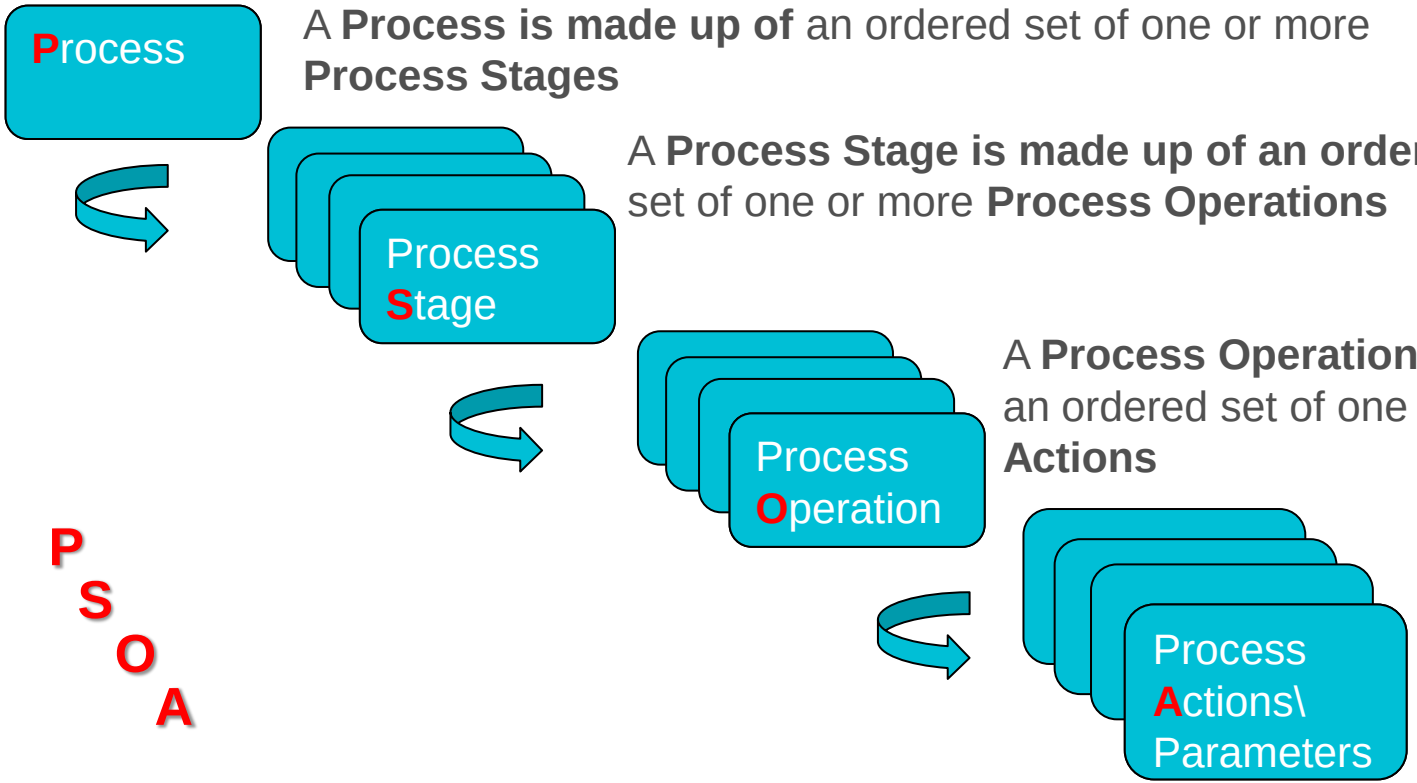
A **Process is made up of** an ordered set of one or more **Process Stages**

A **Process Stage is made up of an ordered** set of one or more **Process Operations**

A **Process Operation is made** up of an ordered set of one or more **Process Actions**

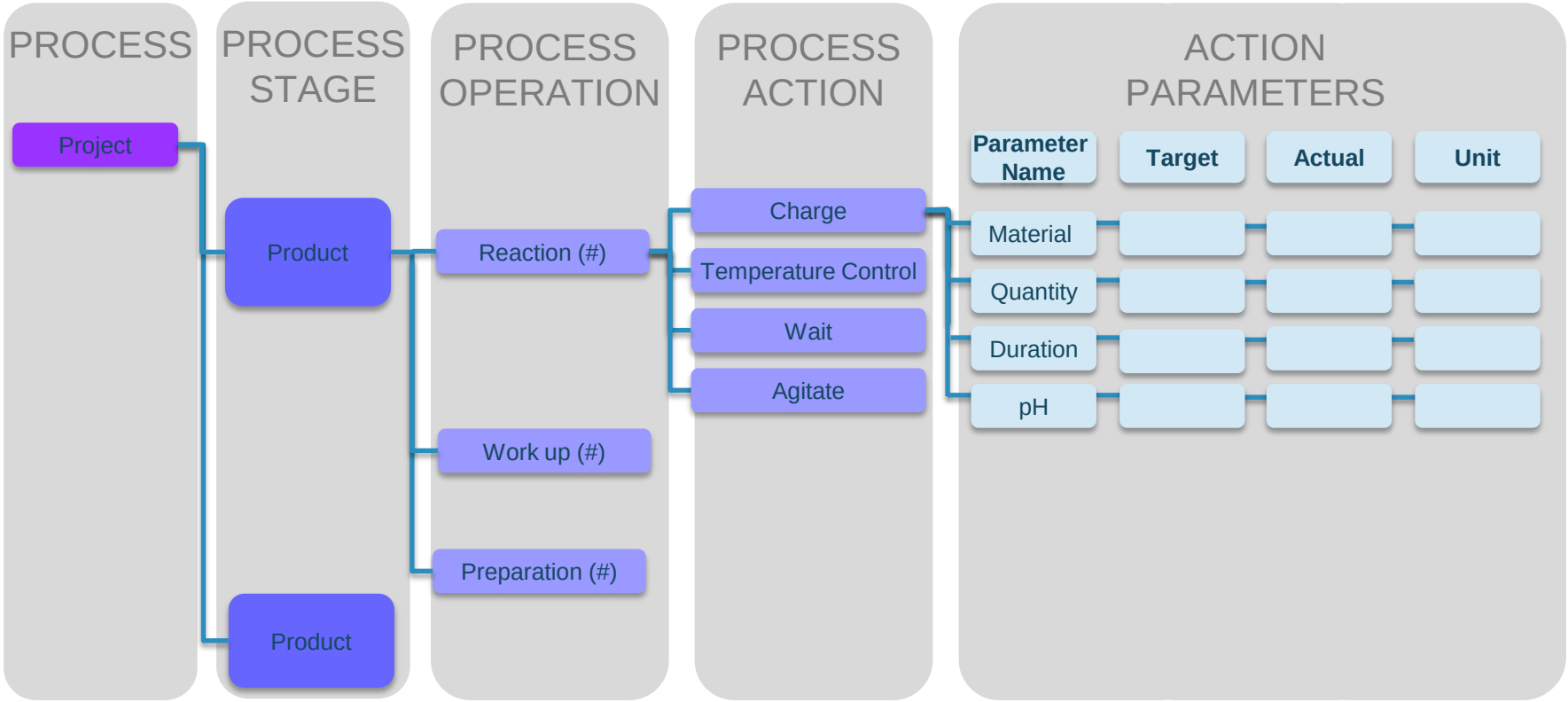
ANSI/ISA-88.00.03-2003
Part 3 Figure 6

S88 – Process Model

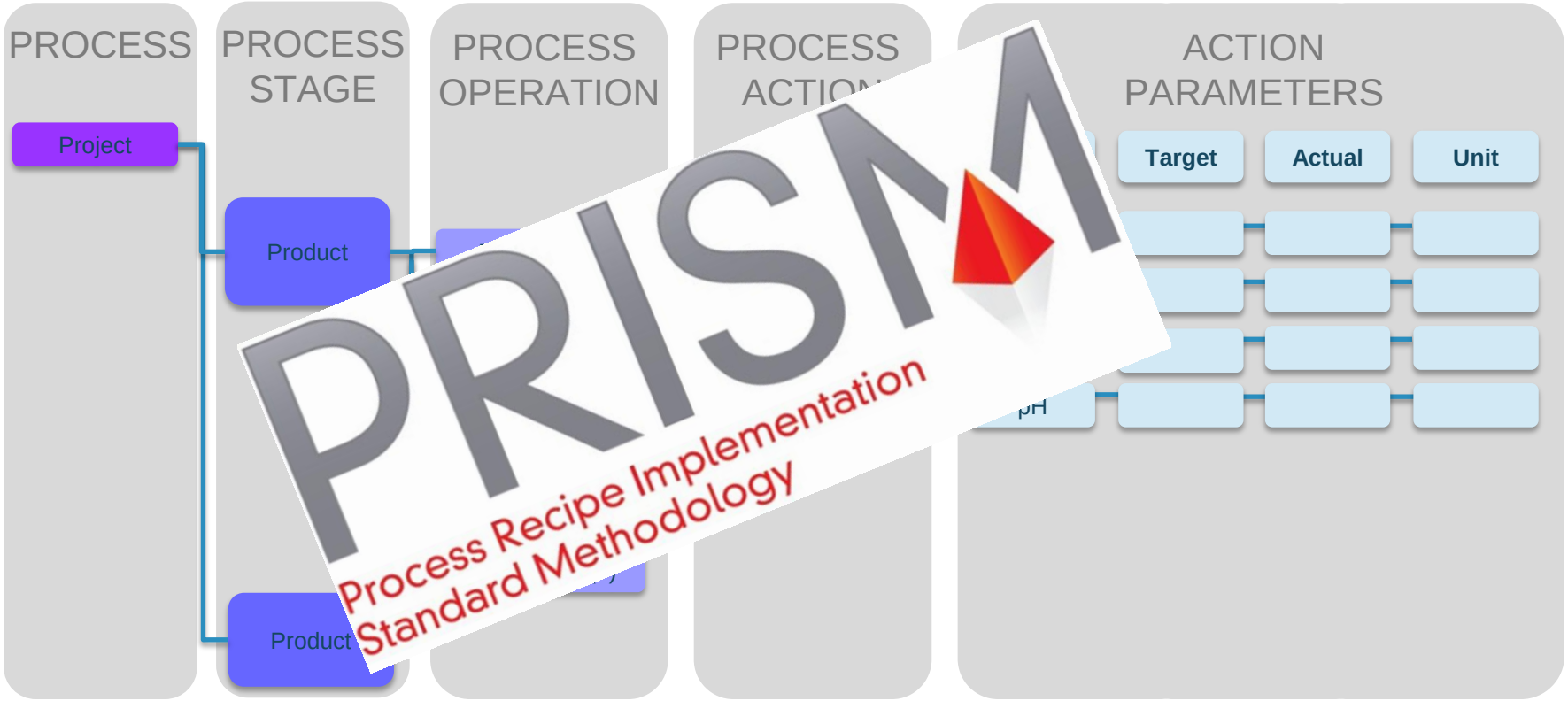


ANSI/ISA-88.00.03-2003
Part 3 Figure 6

S88 recipe model for API SM Dev



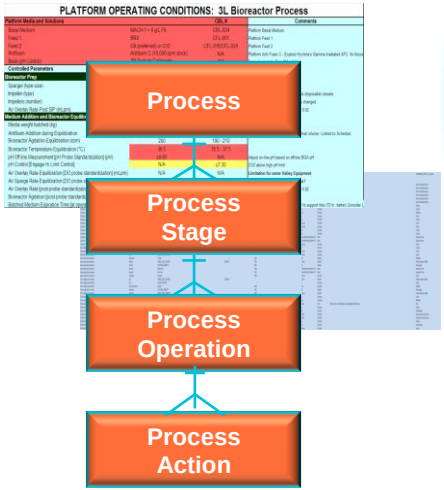
S88 recipe model for API SM Dev

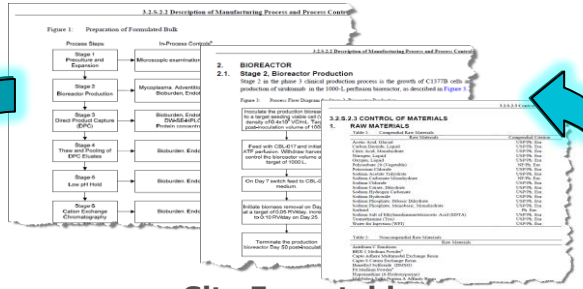


S88 Recipe KM* Strategy

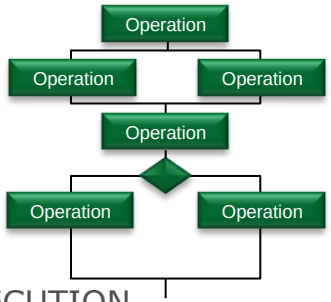
Regulatory Filing = General Recipe

CONTENT
Critical Parameters and Steps
Structured in S88 Format

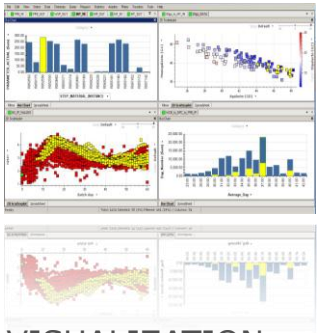




Site Executable Recipe



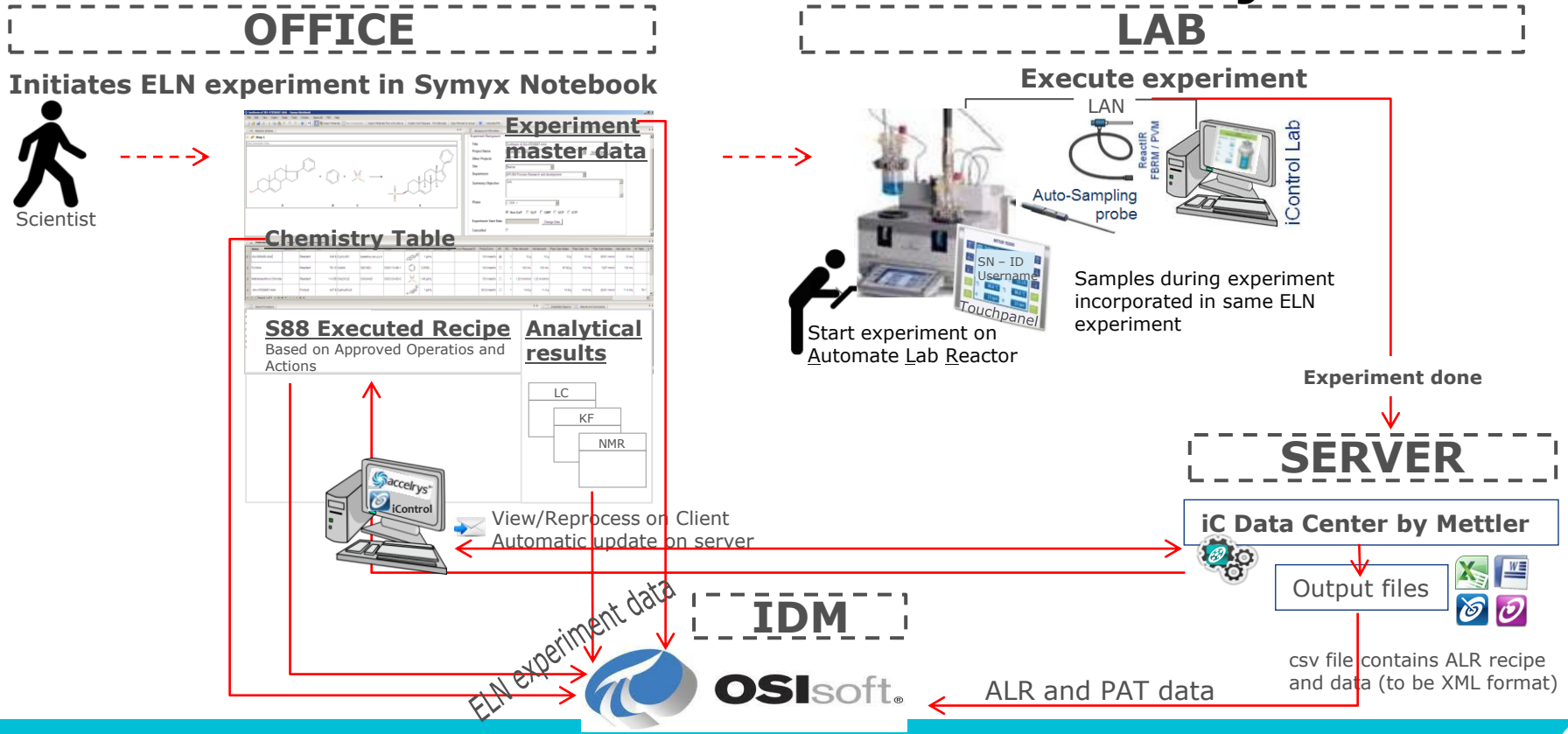
EXECUTION
Data generated in S88 Format
Contains additional site details



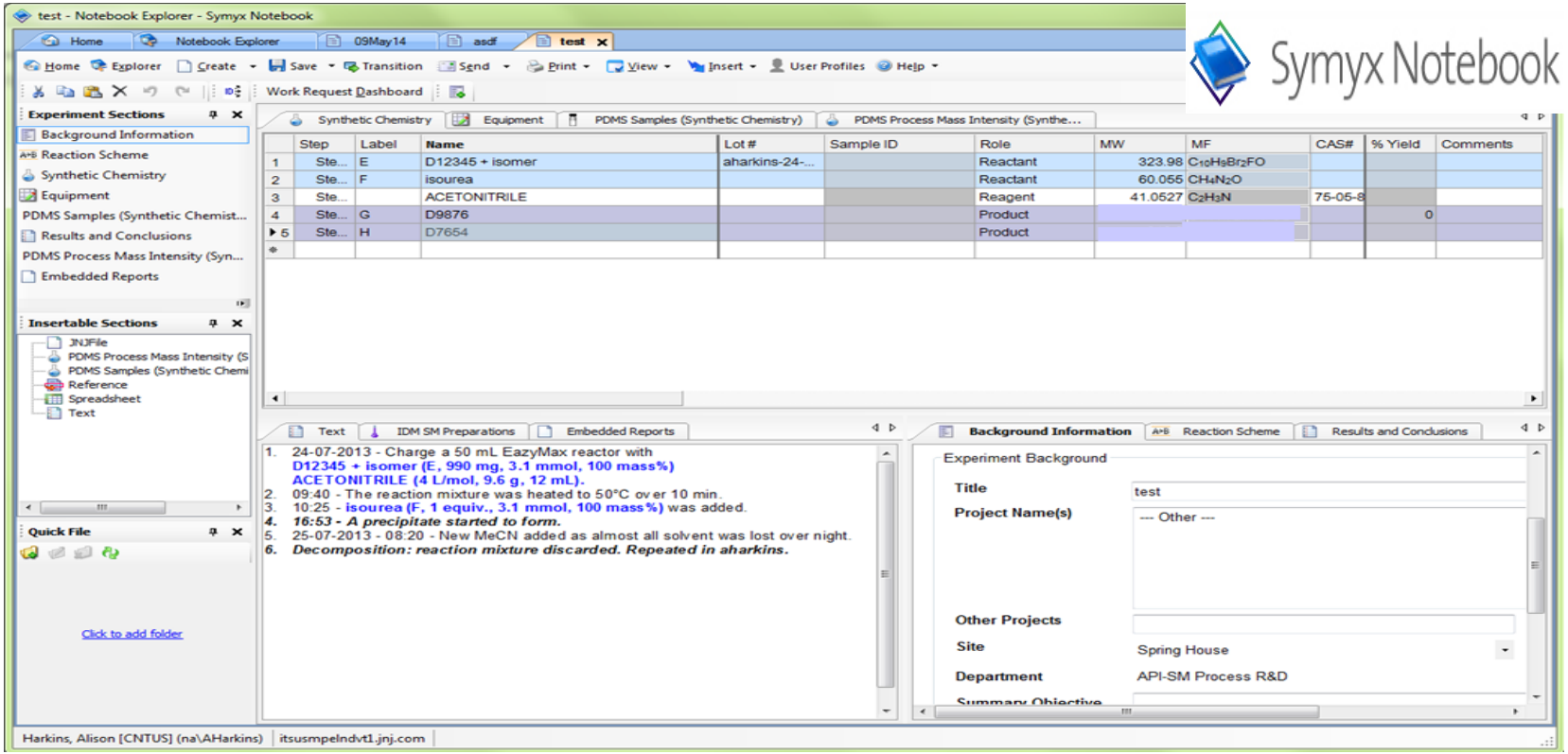
VISUALIZATION
Critical Parameters and Steps
Context rich data

* KM: Knowledge Management

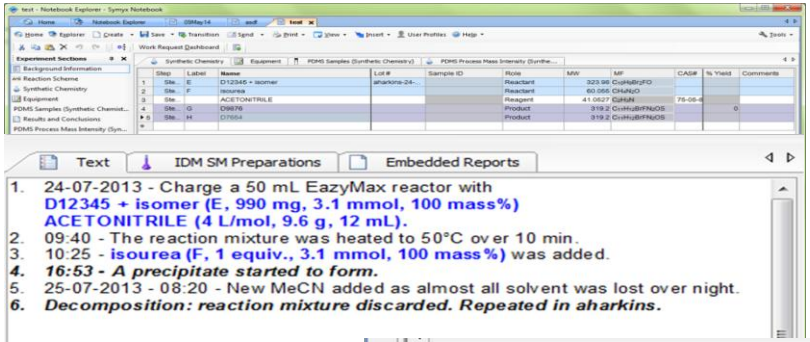
Dataflow in the Process Chemistry lab

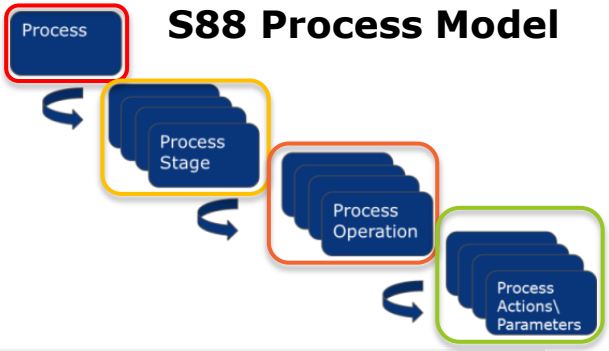


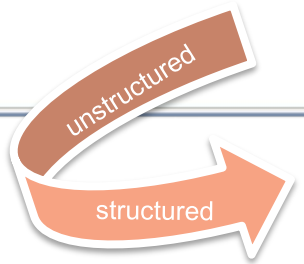
S88 integration in ELN

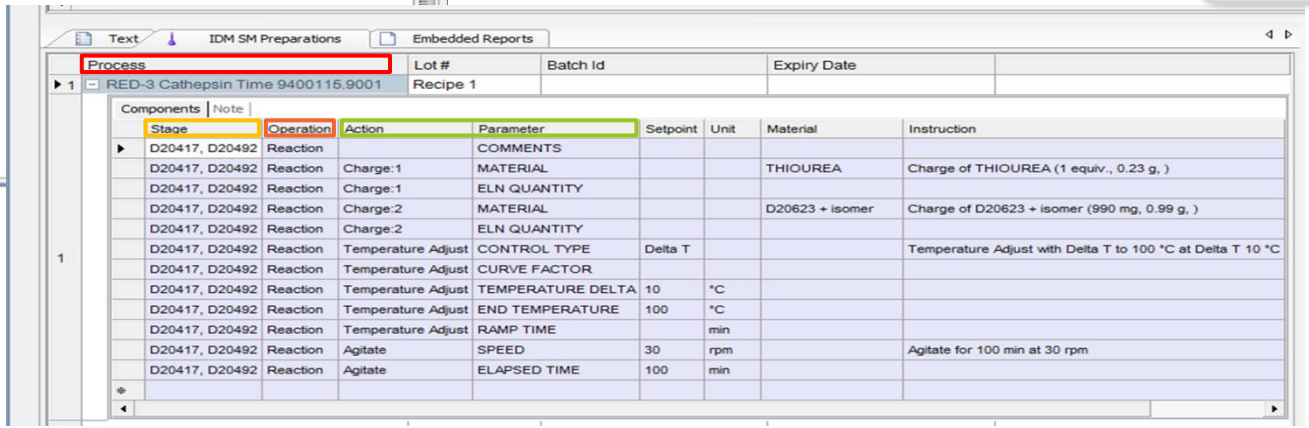


S88 integration in ELN









S88 integration in OSIsoft PI System

Text | IDM SM Preparations | Embedded Reports

	Process	Lot #	Batch Id	Expiry Date
1	RED-3 Cathepsin Time 9400115.9001	Recipe 1		

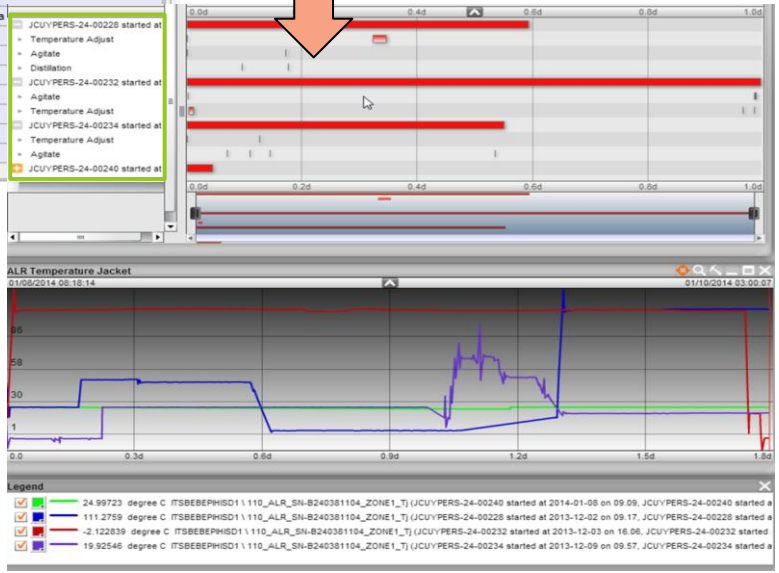
Components | Note

	Stage	Operation	Action	Parameter	Setpoint	Unit	Material	Instruction
▶	D20417, D20492	Reaction		COMMENTS				
	D20417, D20492	Reaction	Charge:1	MATERIAL			THIOUREA	Charge of THIOUREA (1 equiv., 0.23 g,)
	D20417, D20492	Reaction	Charge:1	ELN QUANTITY				
	D20417, D20492	Reaction	Charge:2	MATERIAL			D20623 + isomer	Charge of D20623 + isomer (990 mg, 0.99 g,)
	D20417, D20492	Reaction	Charge:2	ELN QUANTITY				
	D20417, D20492	Reaction	Temperature Adjust	CONTROL TYPE	Delta T			Temperature Adjust with Delta
	D20417, D20492	Reaction	Temperature Adjust	CURVE FACTOR				
	D20417, D20492	Reaction	Temperature Adjust	TEMPERATURE DELTA	10	°C		
	D20417, D20492	Reaction	Temperature Adjust	END TEMPERATURE	100	°C		
	D20417, D20492	Reaction	Temperature Adjust	RAMP TIME		min		
	D20417, D20492	Reaction	Agitate	SPEED	30	rpm		Agitate for 100 min at 30 rpm
	D20417, D20492	Reaction	Agitate	ELAPSED TIME	100	min		

ELN

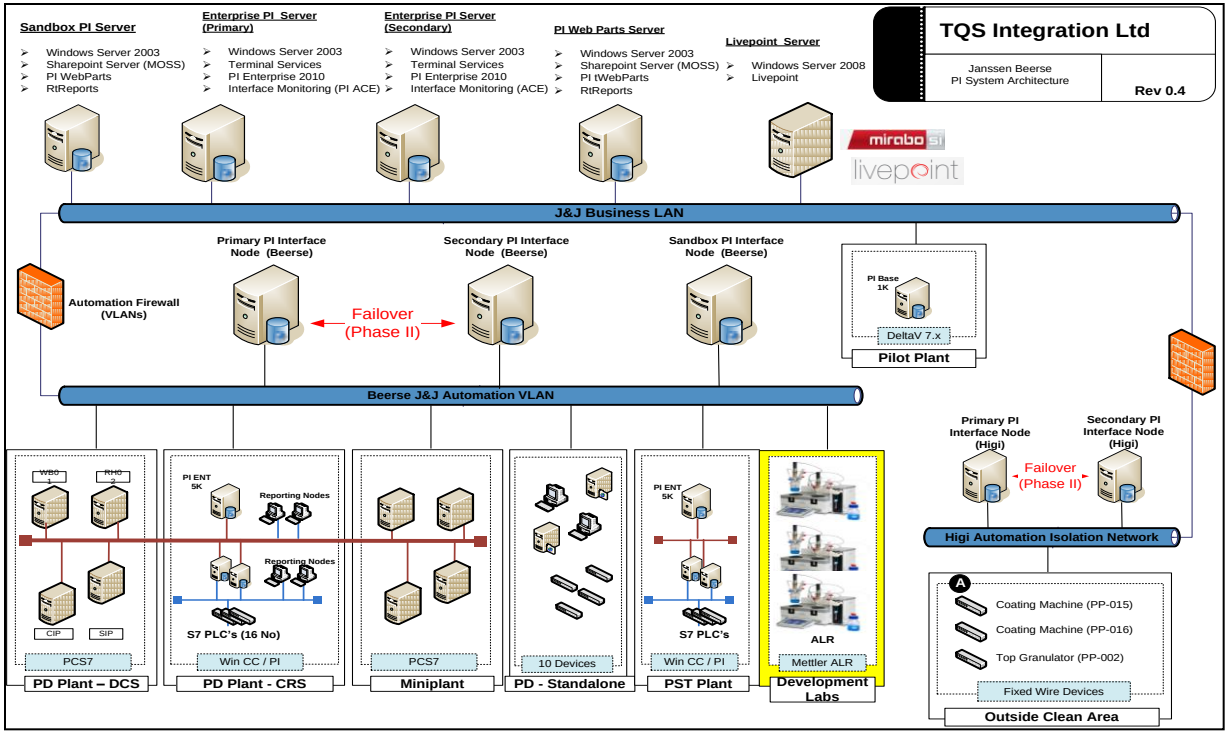
Automated **L**ab **R**eactor

Process **A**nalytical **T**echnology tools

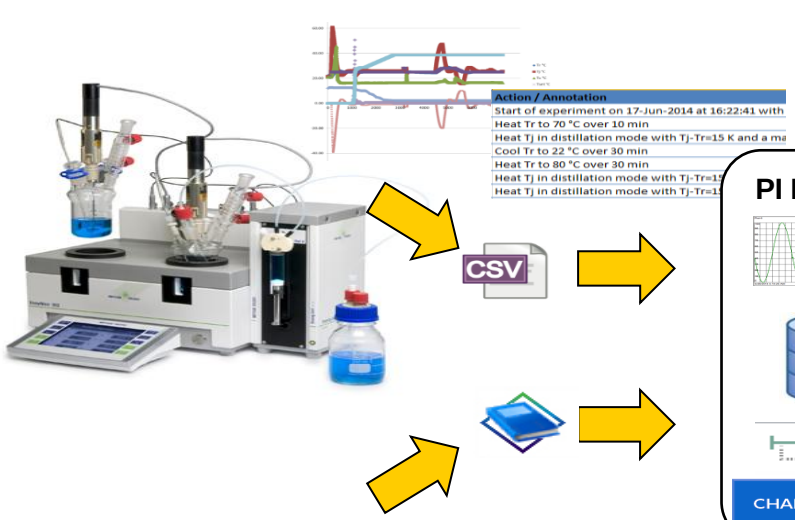


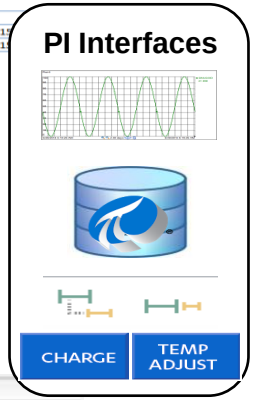
OSIsoft PI System Architecture

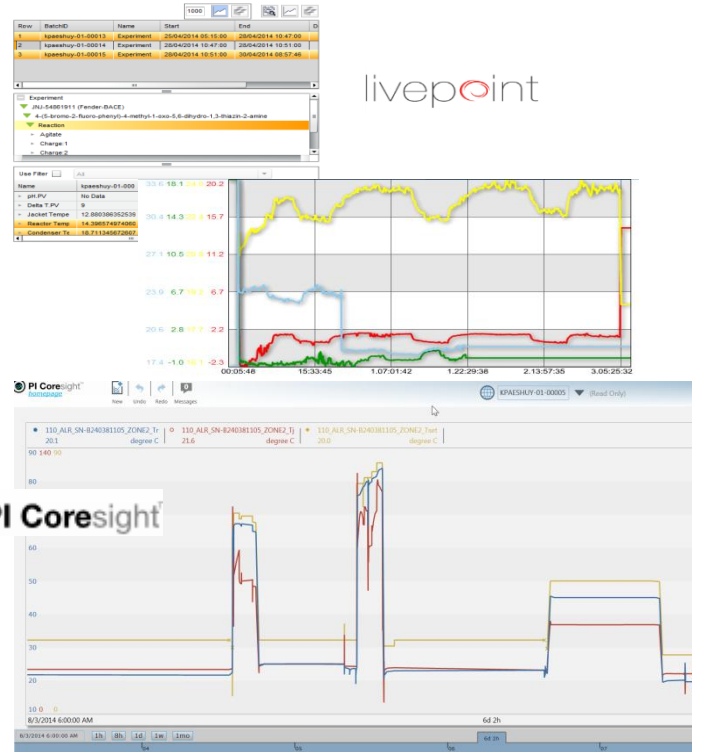
- Existing infrastructure utilized.
- Development and Production environments.
- 74 **A**utomated **L**ab **R**eactors (ALRs) across 20 of labs.

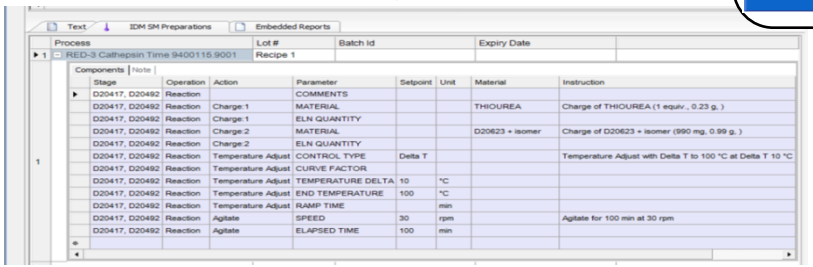


PI Event Frames Addition



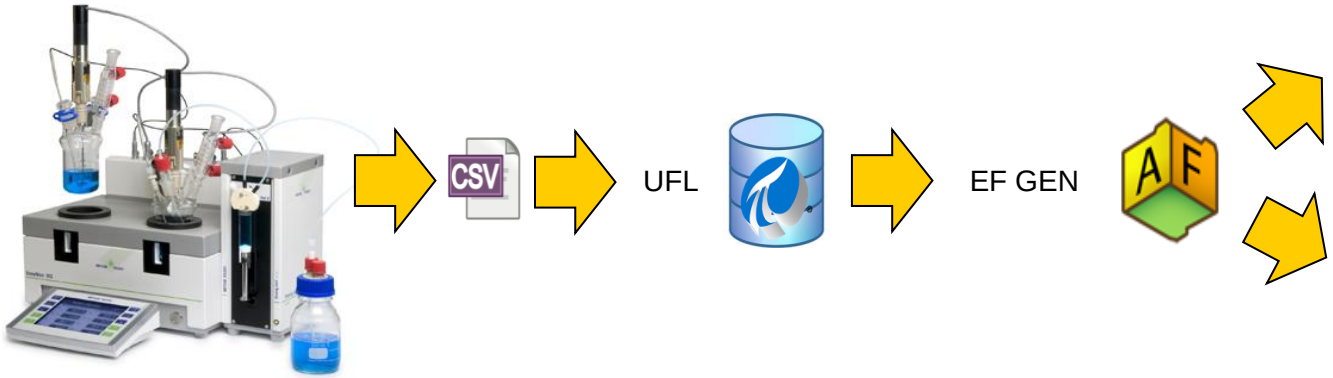


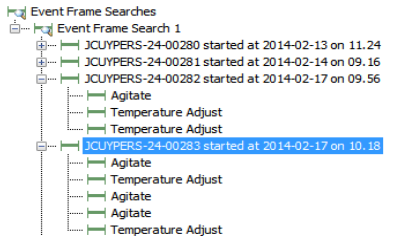




PI Event Frames 1 – ALR Data

- CSV generated from ALR, containing both continuous and event data.
- PI UFL Interface developed to write data to tags.
- PI System configured to generate PI Event Frames

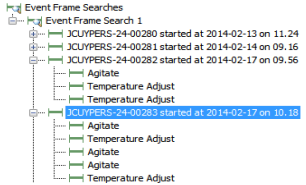




PI Event Frames 2 – ELN Data

- XML output from ELN exported every night.
- Stored Procedures run via PI RDBMS.

Symyx Notebook

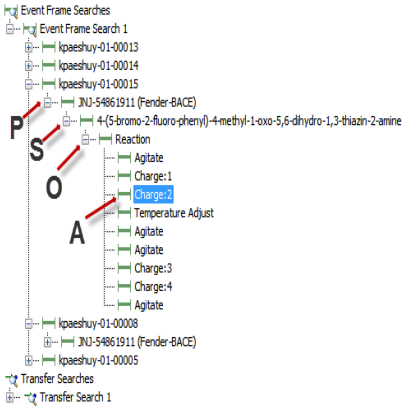


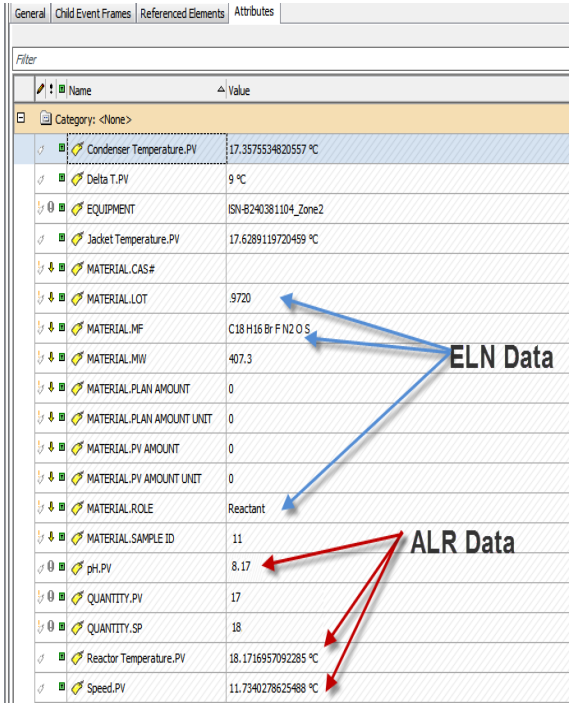
PI Event Frames 3 – ELN and ALR Data

- **Challenge** – ELN and ALR data are **not** time linked.
- **Goal** – Create a single event frame that contains and combines the ELN and ALR actions and all its data for analysis

PI Event Frames 3 – Bringing it all together

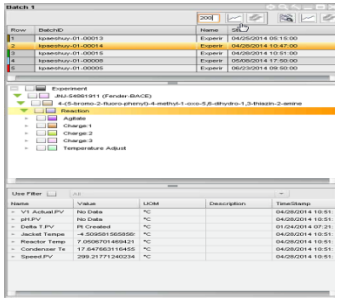
- Data and action timestamps.
- ELN Timestamps adjusted.
- Stored procedure call writes to PI System.
- Entire experiment is captured in one event.

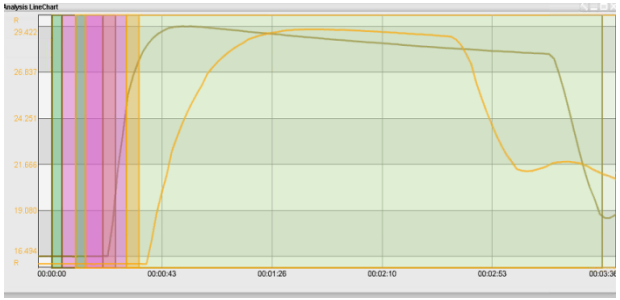


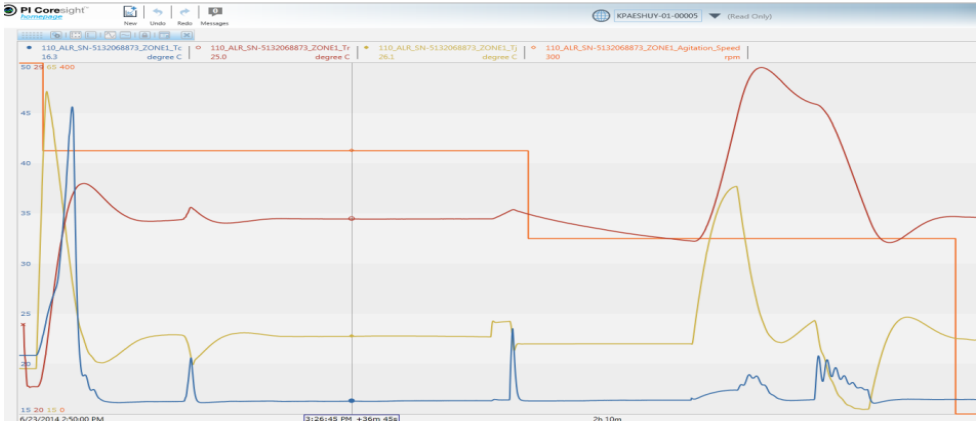


Visualizing the data

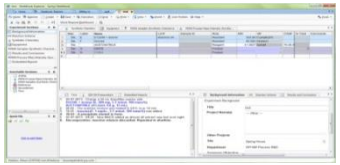
- Ability to view, analyze and share experiment data away from the lab.
- Web based tools preferred.
- PI Coresight live point.

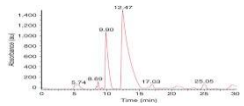






PI System lab data integration overview future





PAT

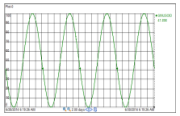
iControl, touch panel

ELN

Analytical Data

Pilot and Commercial Data

PI Interfaces

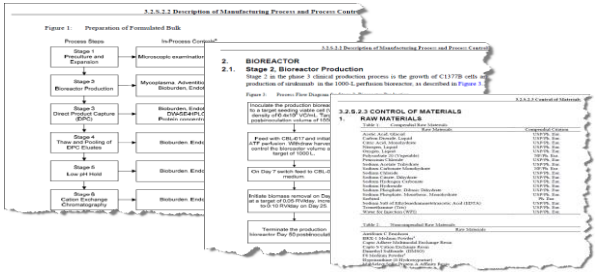


CHARGE

TEMP ADJUST

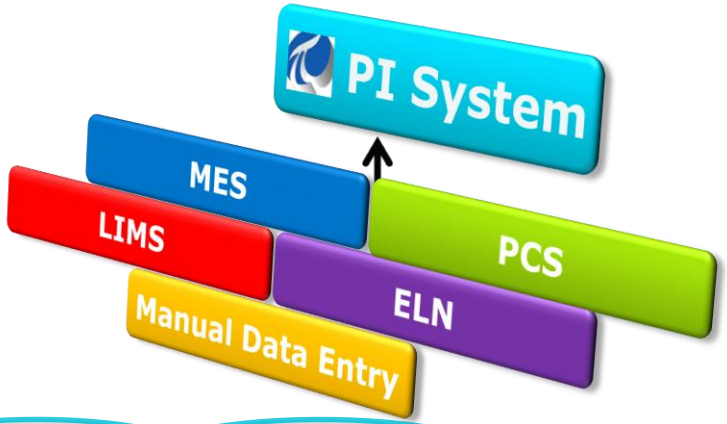
livepoint

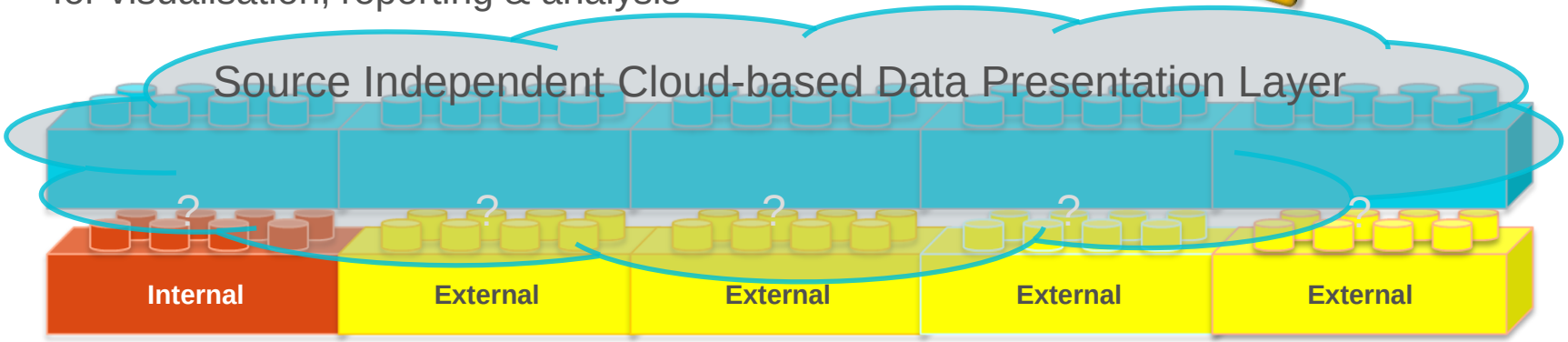
PI Coresight



Value of the OSIsoft PI System: Future

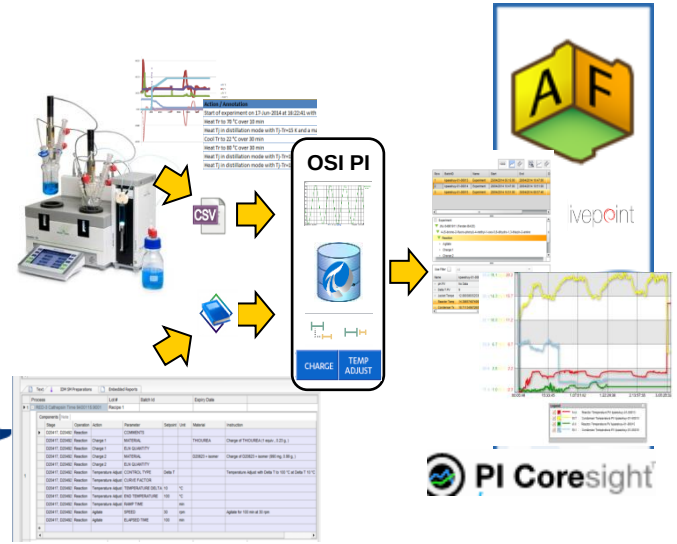
- Very disparate systems landscape – now including MES, ELN, Manual Data Entry…
- Ability to share contextualized process data with external partners is critical.
- Require capability to capture and aggregate data for visualisation, reporting & analysis





Recipe driven, data visualization from lab to commercial

- Enabling scientists to generate and capture consistent process data in a standard recipe context to generate information and knowledge from experiments.
- Enabling efficient transfer from the lab through our pilot plants, commercial operations and ultimately to our patients, capturing and building knowledge throughout.



janssen
PHARMACEUTICAL COMPANIES OF Johnson&Johnson

Business Challenge

- Streamline and implement the S88 recipe strategy in the different variety on lab systems we have in place
- Combining the data from multiple data sources

Solution

- OSIsoft PI System as our global Data Infrastructure is the key enabler towards this recipe concept.
- PI Asset Framework and PI Event Frames components to bring the data together

Results and Benefits

- Visualizing the data outside of the lab.
- By applying the S88 structure, lab to commercial comparisons are possible

Acknowledgments

Ryan Bass, Nick Dani, Adam Fermier, Alison Harkins, Jim Kenyon, Mike McGorry, Luc Moens, Terry Murphy, Chris Nichols, Gaby Wevers
…and many others

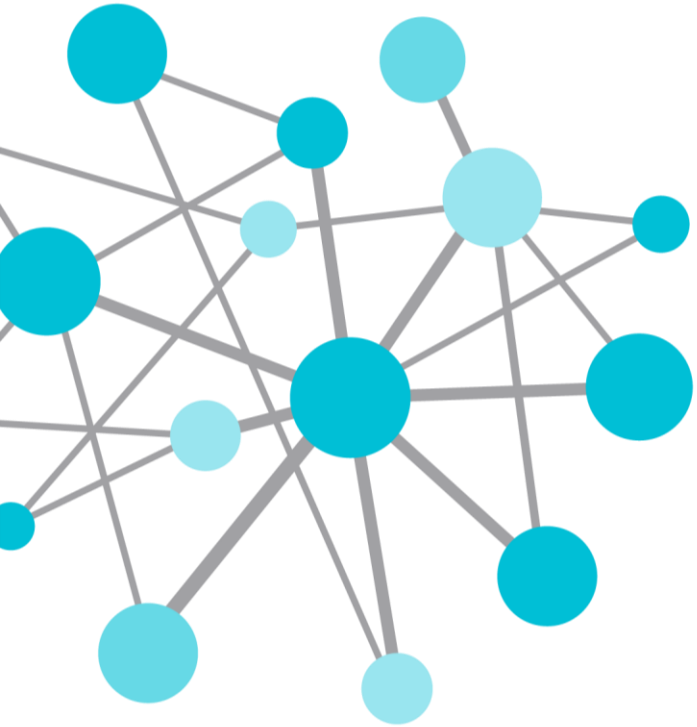
Thanks

- Barry Higgins – bhiggin2@its.jnj.com
- Koen Paeshuyse – kpaeshuy@its.jnj.com
- Janssen PDMS

Questions

Please wait for the **microphone** before asking your questions

State your **name & company**



THANK YOU

Brought to you by OSIsoft.

Please don’t forget to…

Complete the online survey for this session

eventmobi.com/emeauc14

Share with your friends

#UC2014