



OSIsoft®

UC2010

Real Time Information — Currency of the New Decade

Hilton San Francisco Union Square | San Francisco, CA

April 26-28, 2010

Enterprise PI as an Enabler for Integrated Manufacturing & Development

Joel Hanson

Global Head, Strategic Operations

Johnson & Johnson

AGENDA

- Introduction
- Enterprise PI as an enabler for API Manufacturing
 - J&J Pharma, OSIsoft and the EA
 - Integrated Manufacturing Design
- Enterprise PI as an enabler for Product Development
 - Integrated Product Development & How PI Fits In

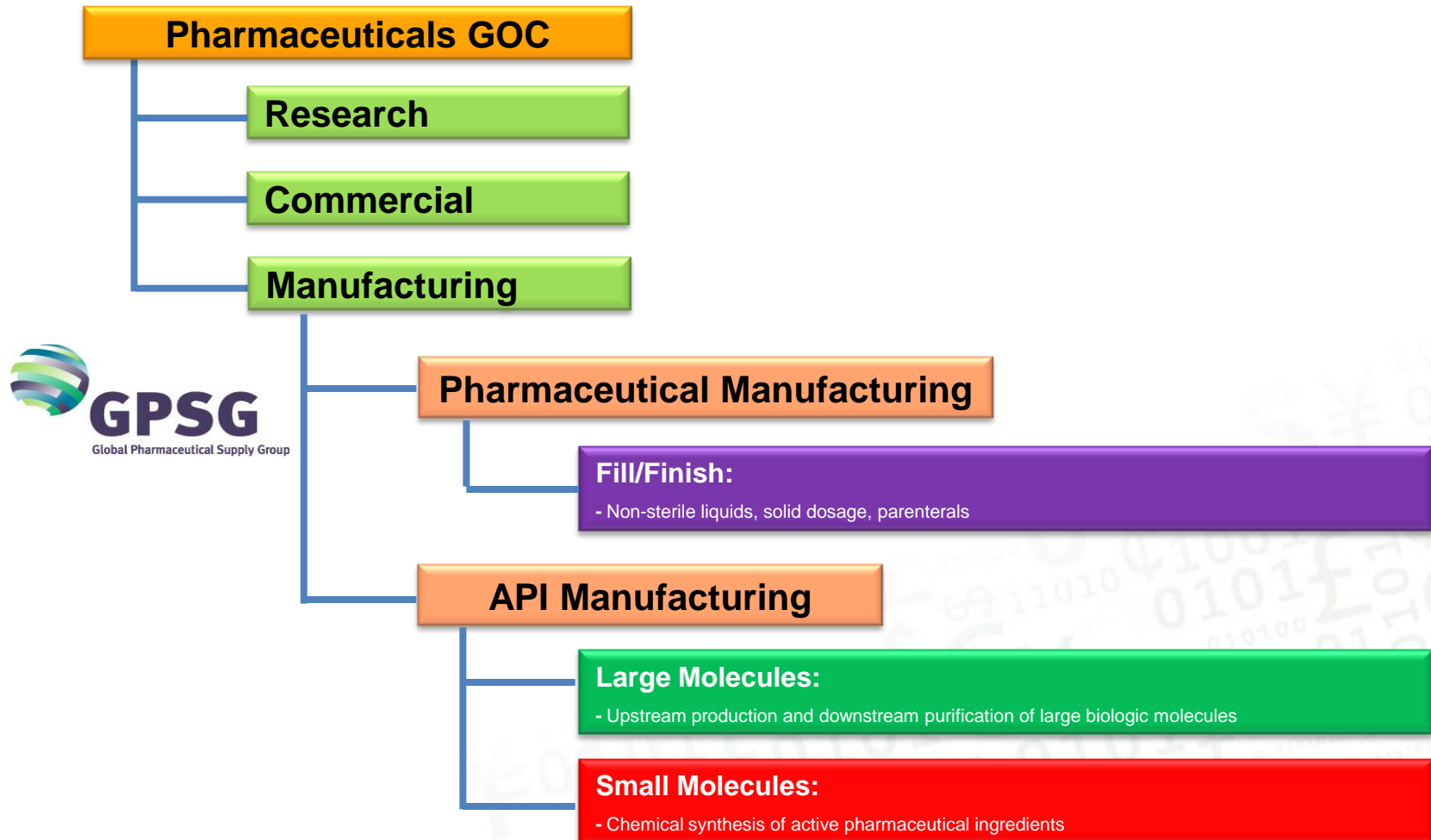
Johnson & Johnson

3 Business sectors:

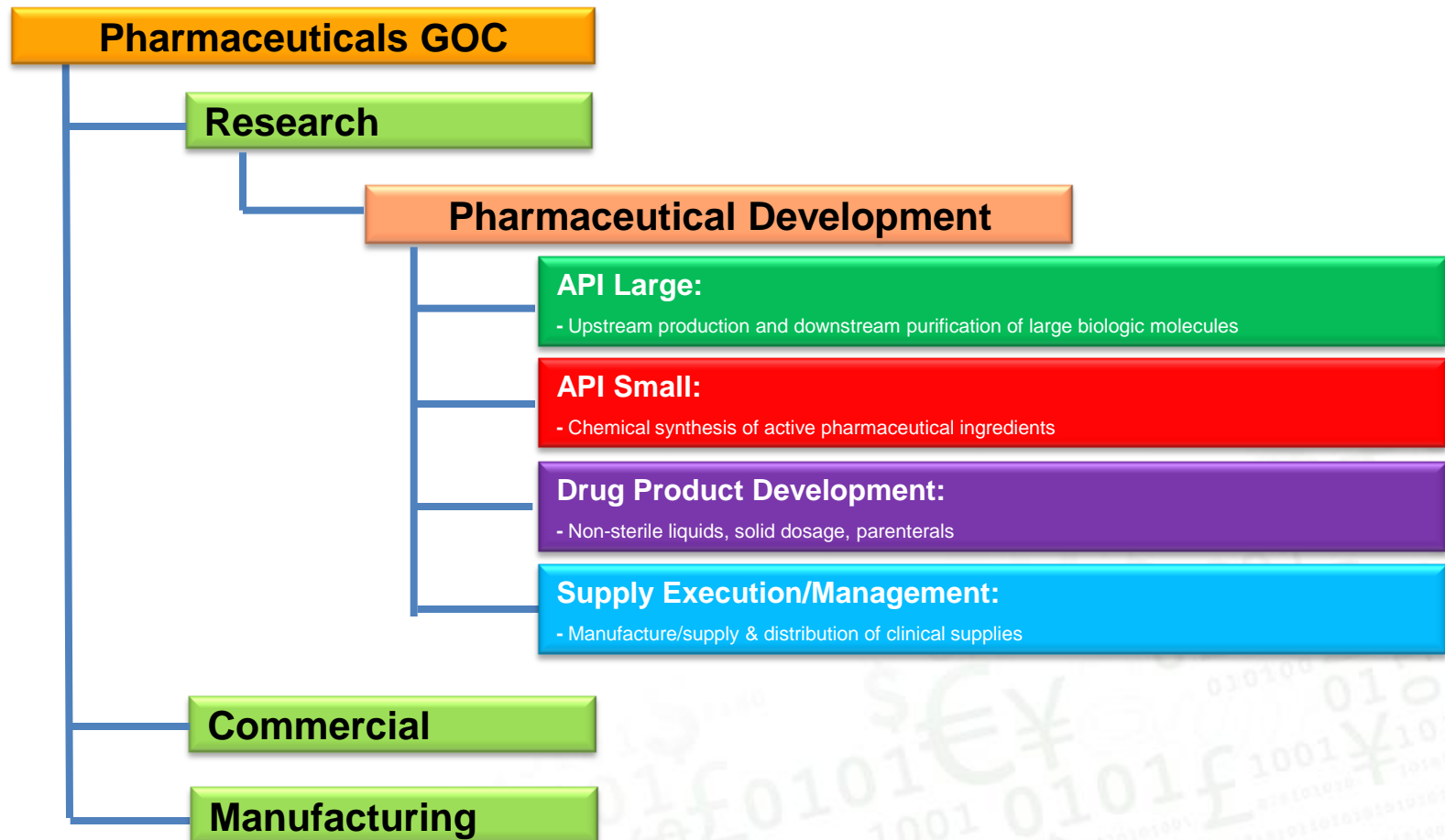
- Consumer (26%)
- Medical devices & diagnostics (38%)
- **Pharmaceuticals (36%)**



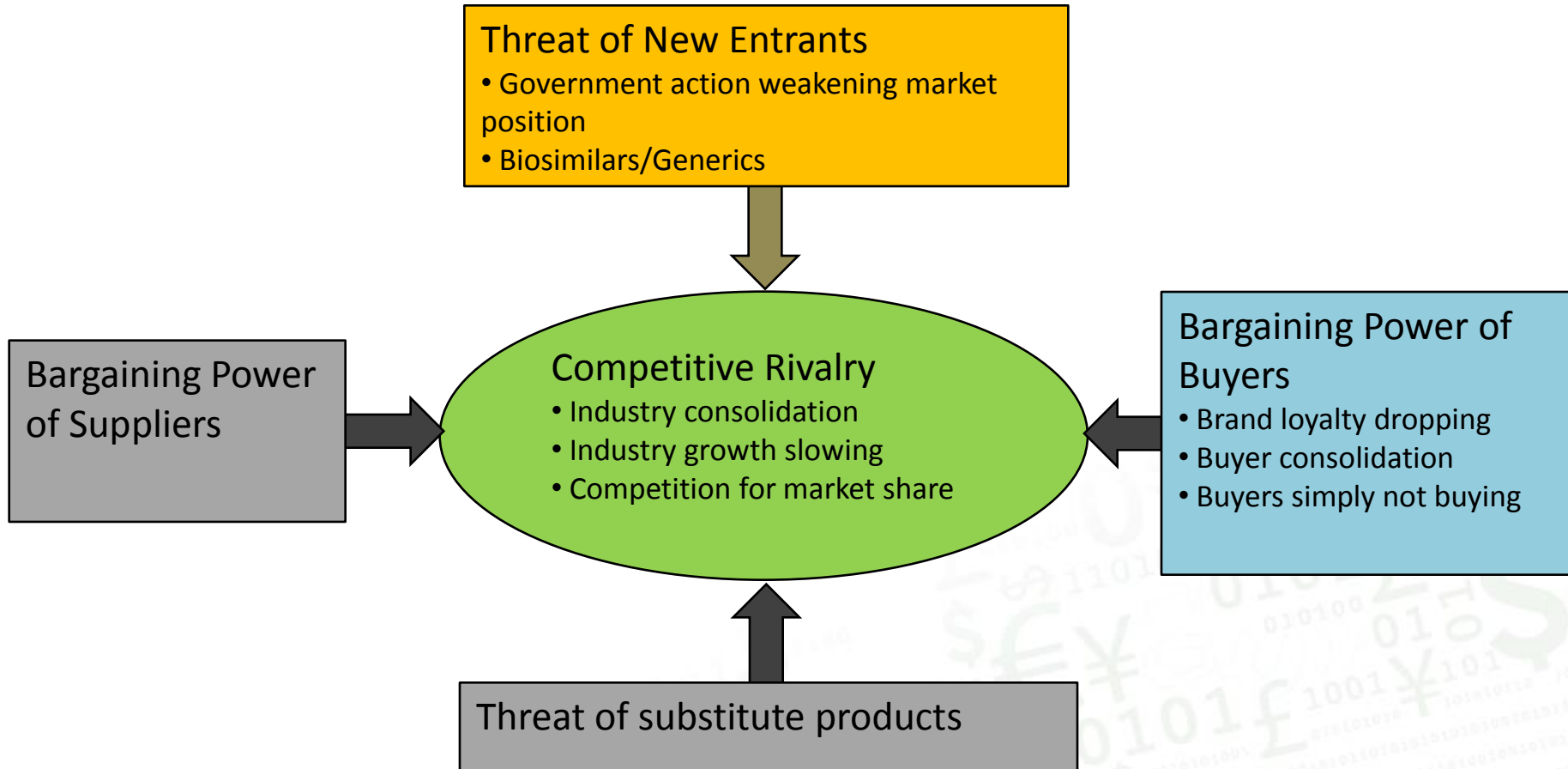
J&J Pharma Sector



J&J Pharma Sector



Business Realities



Agenda

- Introduction
- Enterprise PI as an enabler for API Manufacturing
 - J&J Pharma, OSIsoft and the EA
 - Integrated Manufacturing Design
- Enterprise PI as an enabler for Product Development
 - Integrated Product Development & How PI Fits In

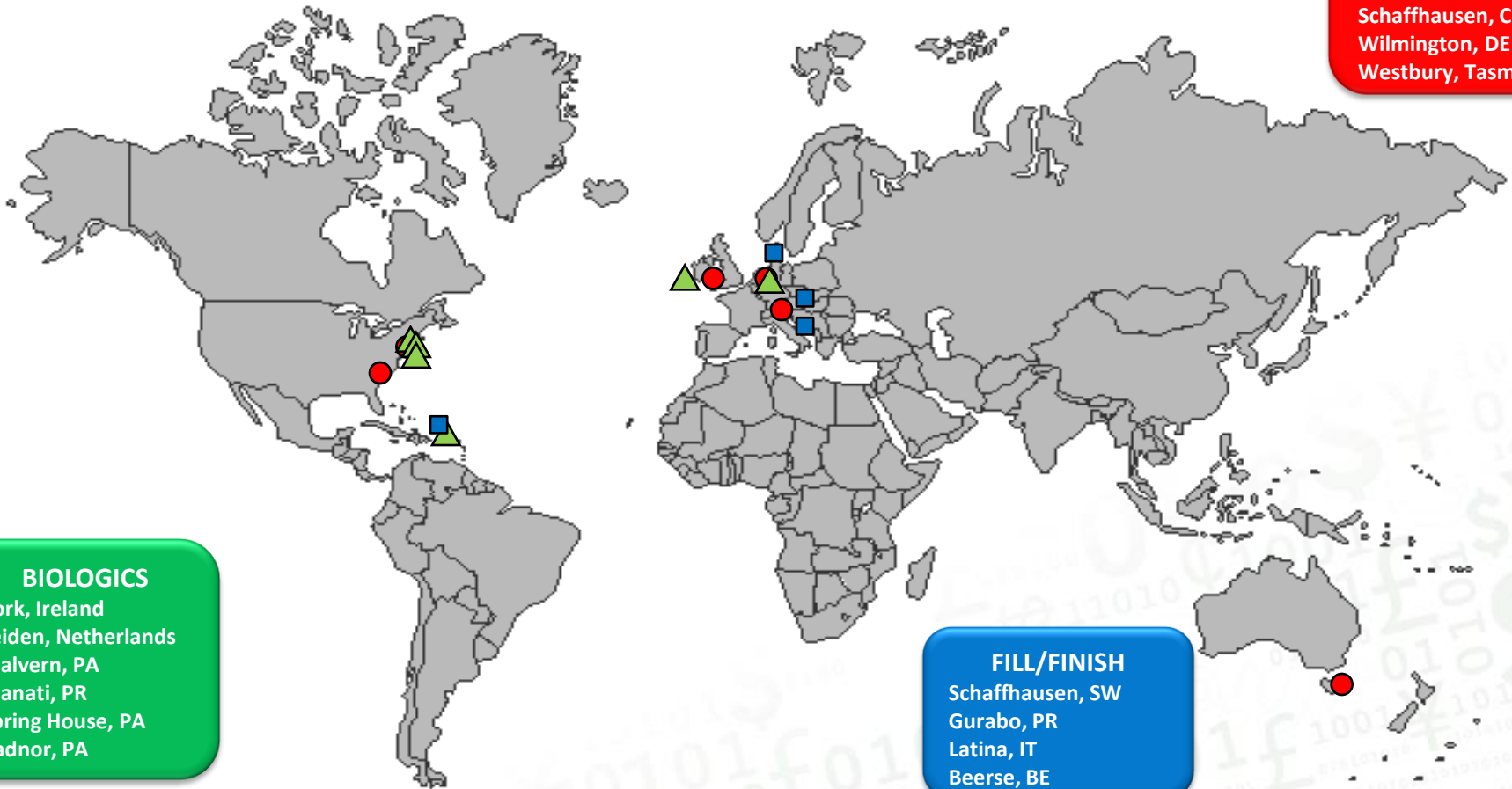
Enterprise Agreement

- Dec '08, Signed a J&J wide Enterprise Agreement (EA) with OSIsoft for the provision of their PI Infrastructure in a cost effective manner.
- Currently 3 agreed EA categories negotiated, namely
 - API manufacturing (Biologics or Chemical)
 - Development (Biologics or Chemical)
 - Fill Finish / Packaging

J&J Pharma

CHEMICALS

Athens, GA
Cork, Ireland
Geel, Belgium
Schaffhausen, CH
Wilmington, DE
Westbury, Tasmania



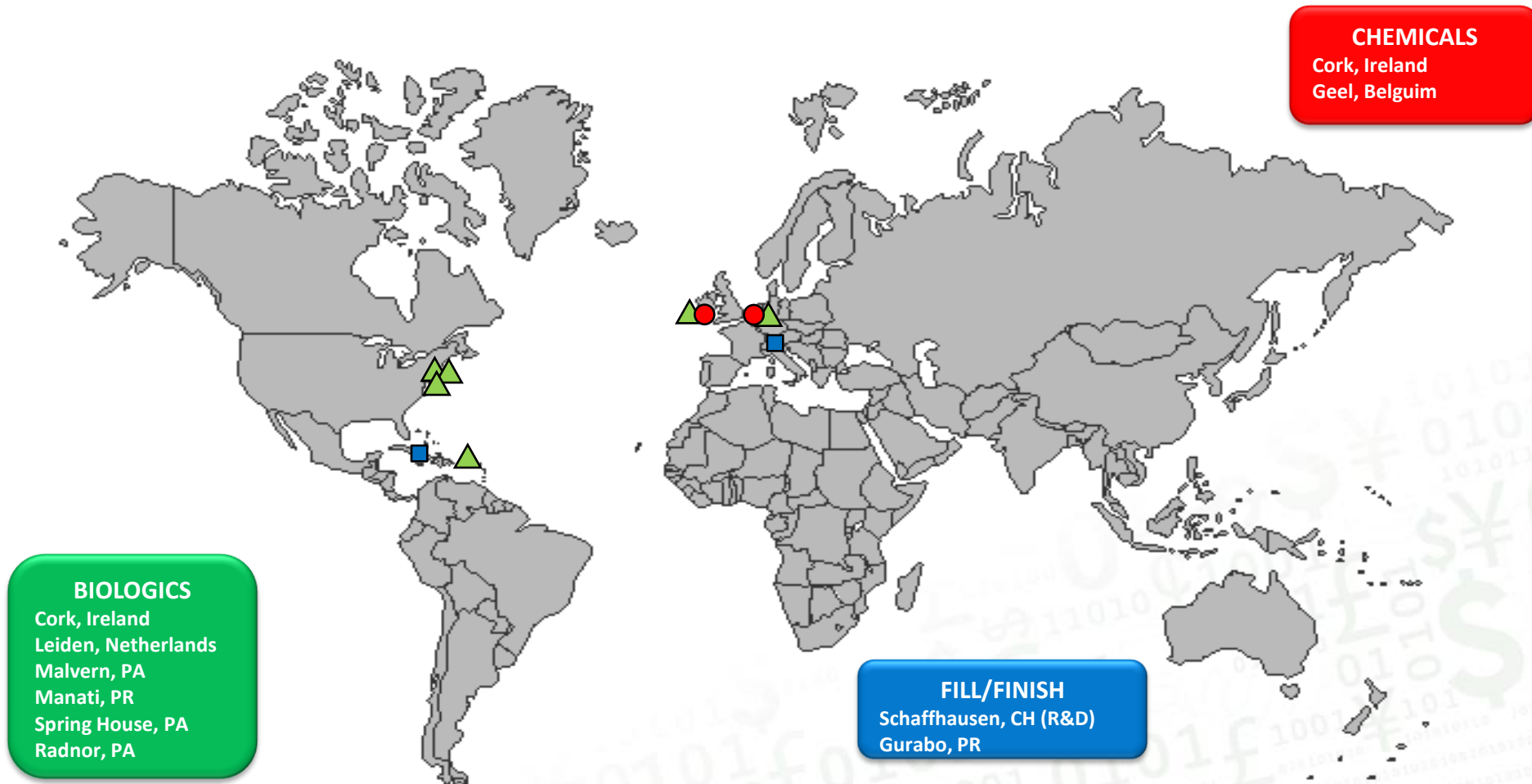
BIOLOGICS

Cork, Ireland
Leiden, Netherlands
Malvern, PA
Manati, PR
Spring House, PA
Radnor, PA

FILL/FINISH

Schaffhausen, SW
Gurabo, PR
Latina, IT
Beerse, BE

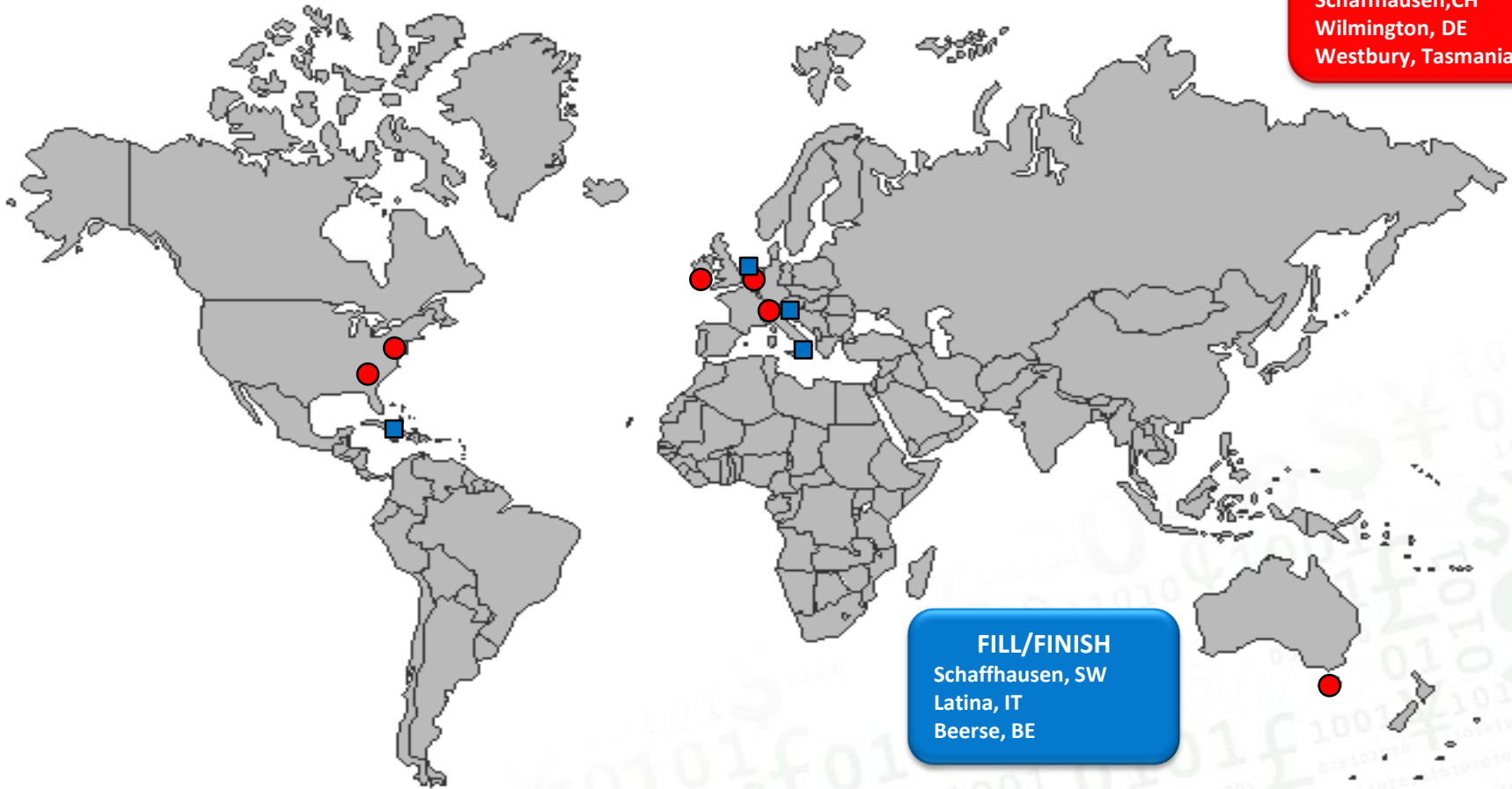
Active J&J Pharma sites



J&J Pharma potential

CHEMICALS

Athens, GA
Schaffhausen, CH
Wilmington, DE
Westbury, Tasmania



FILL/FINISH

Schaffhausen, SW
Latina, IT
Beerse, BE

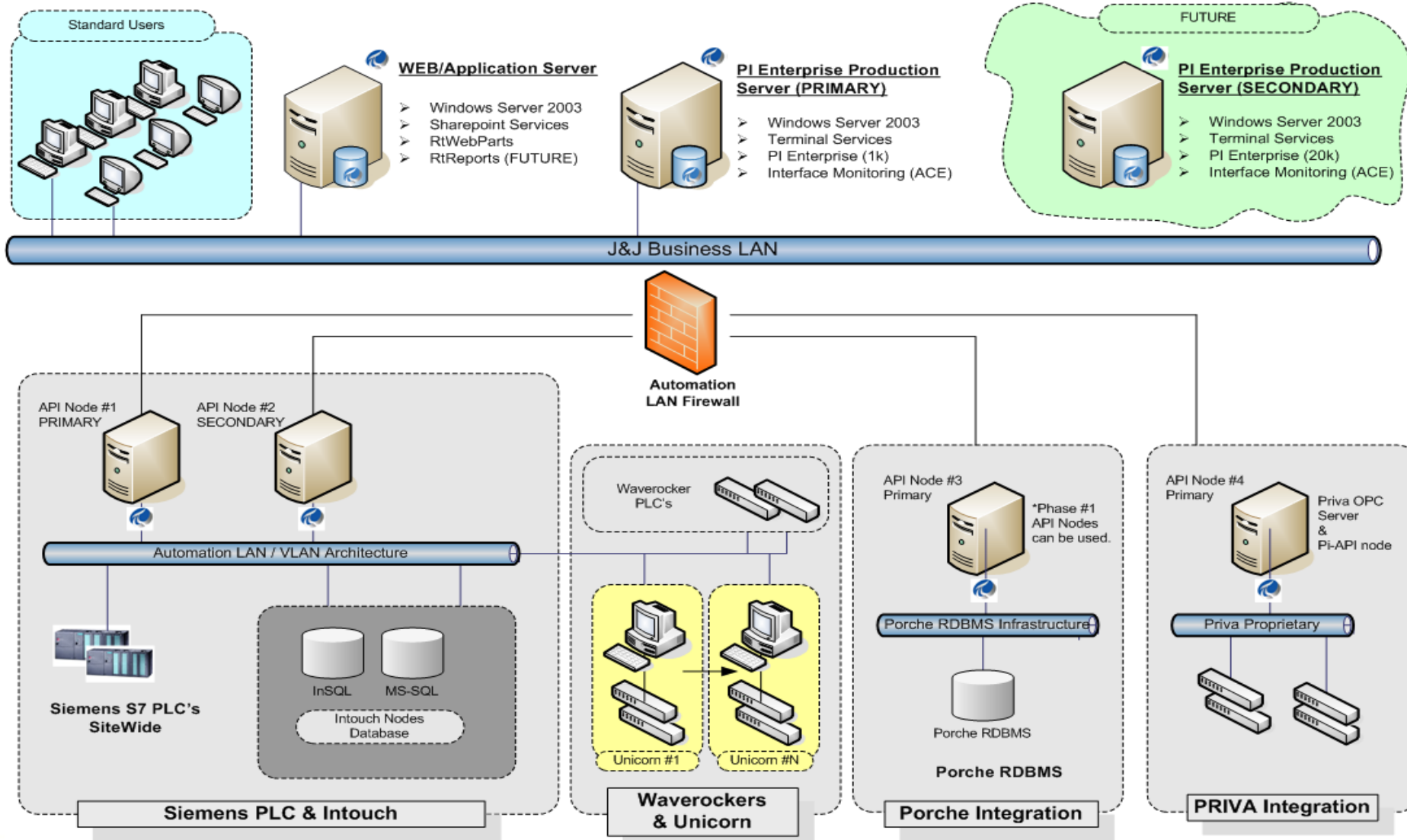
Justification of OSIsoft PI Investment (EA)

- Effort reduction
 - Elimination of manual data transcription and associated manual cross-checking
 - Consolidated alarm reporting for building management, process, laboratory, warehouse and utility systems
 - Minimization of data gathering time required to perform investigations
 - Consolidation of data visualization for improved process monitoring and historical batch analysis
- Enabling step for integrated manufacturing design

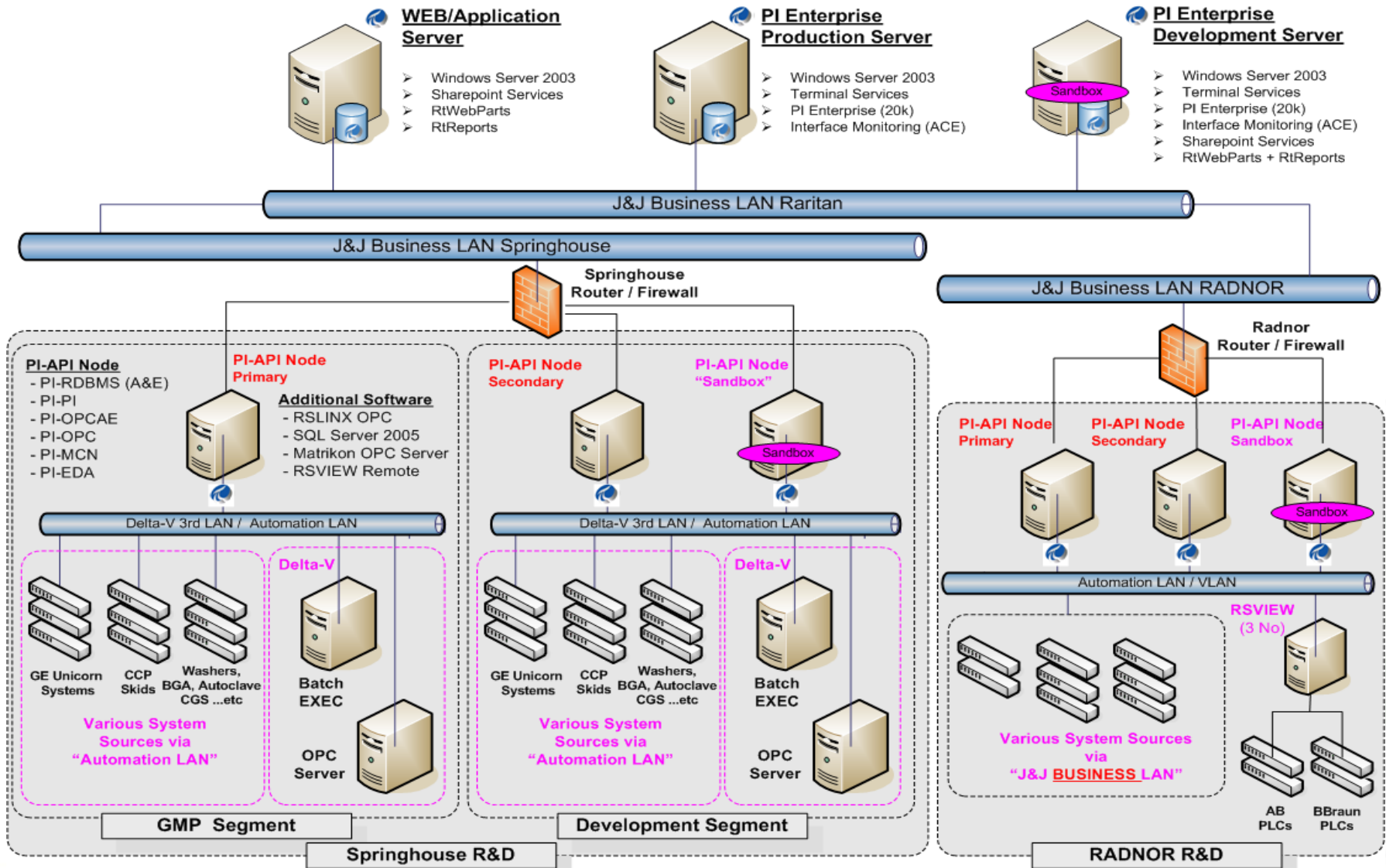
Other Benefits of the Enterprise Agreement

- Licensing flexibility allows for better engineering decisions
- Cost certainty leads to easier project justification **Free UC vouchers!!!**
- Partnership with the OSIsoft CoE and TQS creates:
 - Standard approach to system design
 - Creation of standard validation protocols

Architecture Design #1 – Local J&J Server



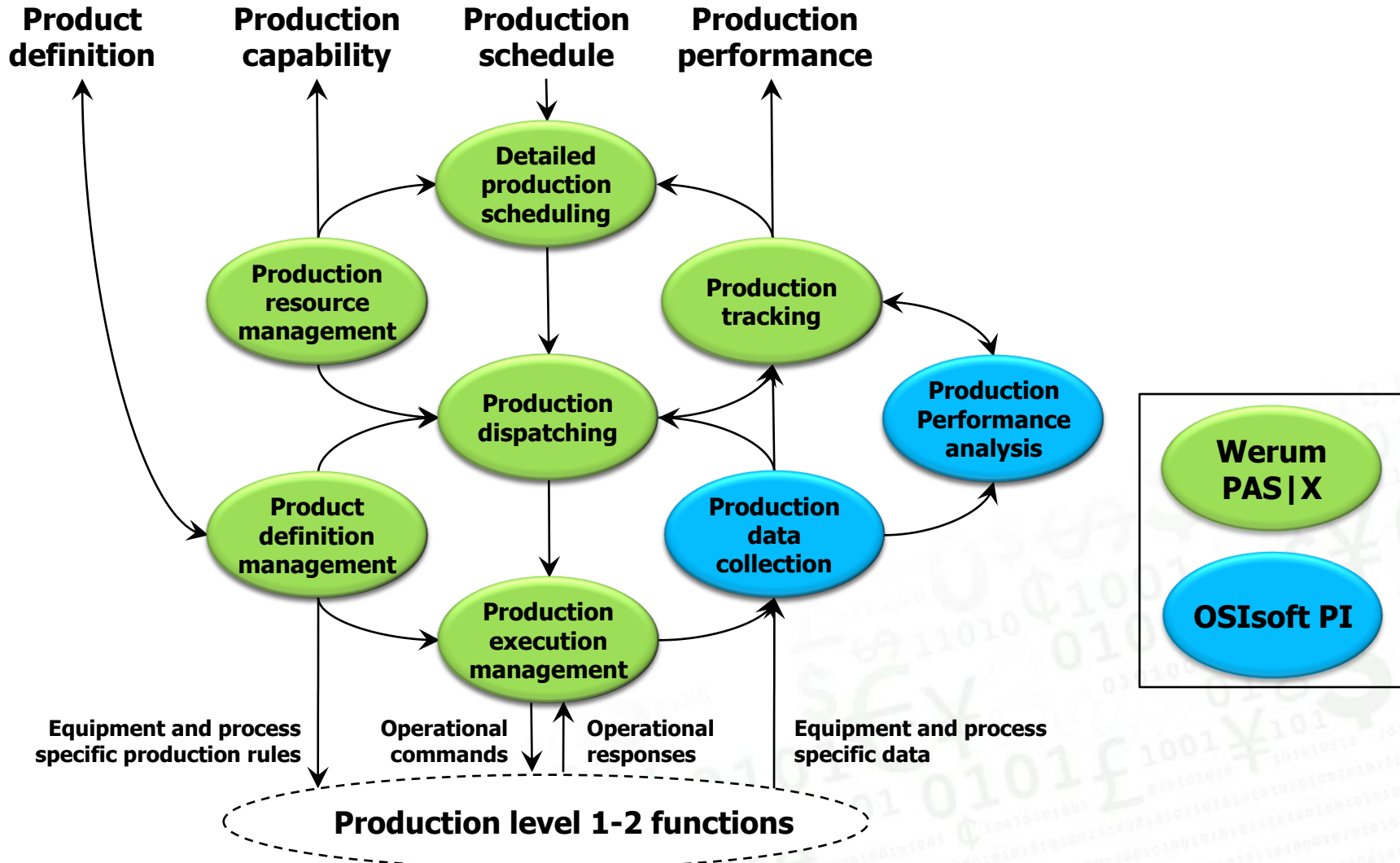
Architecture Design #2 – Remote J&J Server



Agenda

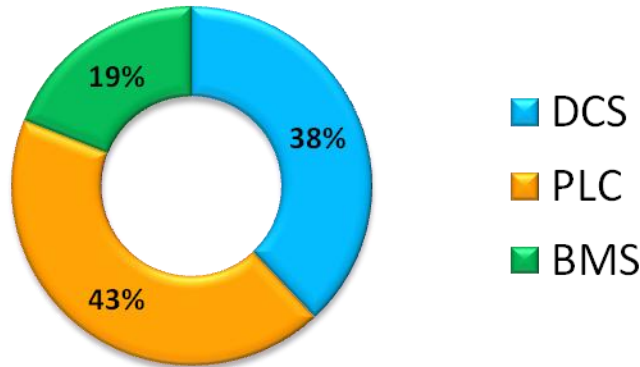
- Introduction
- **Enterprise PI as an enabler for API Manufacturing**
 - J&J Pharma, OSIsoft and the EA
 - Integrated Manufacturing Design
- Enterprise PI as an enabler for Product Development
 - Integrated Product Development & How PI Fits In

Goal: S95 Production Operations Activity Model



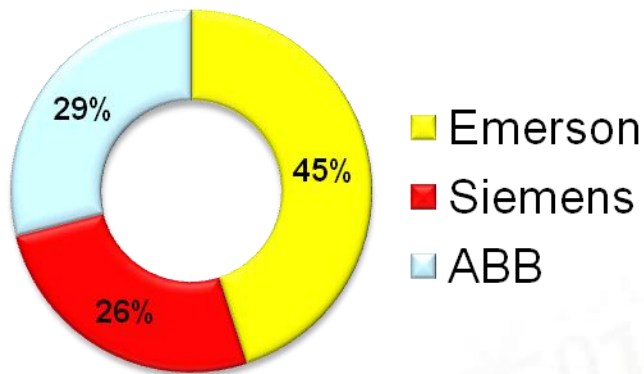
Challenge #1 – Process Control Systems

GPSG API - PCS Landscape

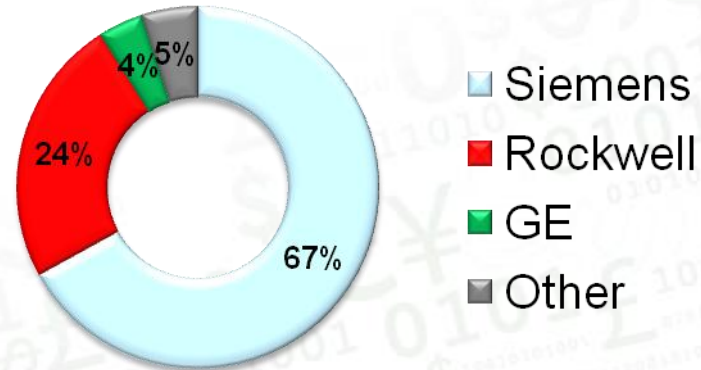


Process Control System(s)

GPSG API - DCS Vendors



GPSG API – PLC Vendors



Challenge #2 – Inconsistent terminology across organization

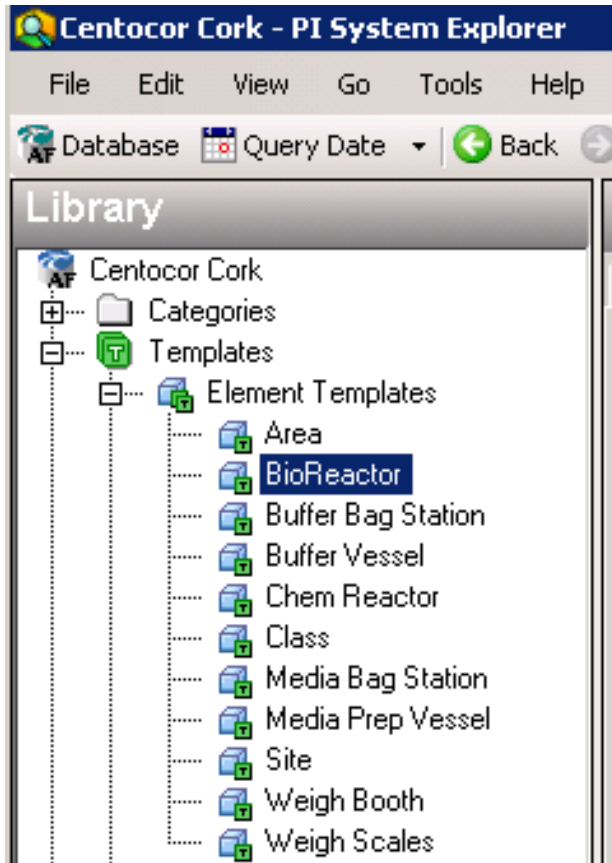
Flow Through Chromatography (Development)

Eluate Filtration
Eluate Storage
Equilibrate
Load
Rinse1
Rinse2
Rinse3
Sanitization
Storage
Strip
Wash1

Flow Through Chromatography (Commercial)

Filtration
Storage
Equilibrate
Load
Rinse
Sanitization
Storage
Strip
Wash

Solution: PI AF and MES



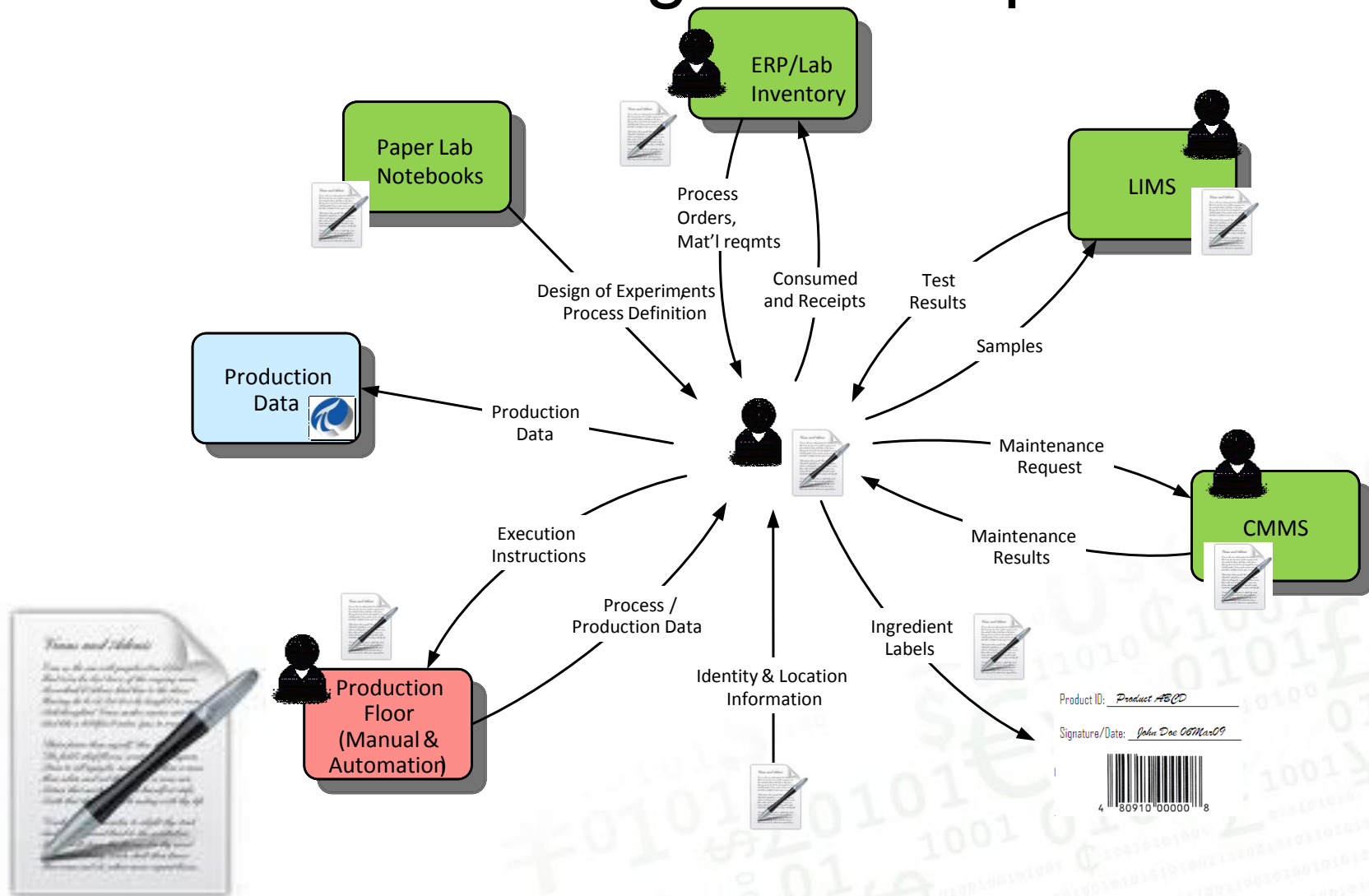
- Library element templates – Elements represent either physical or logical entities.
- AF element template library used to generate ‘Super Class’ of equipment for use across all of GPSG.

Solution: PI AF and MES

- Each Element template is made up Attribute templates (Aliases).
- Attributes can be linked to read/write data from/to PI or other data source.
- PAS|X will query the AF database, based on the Unit Class\Attribute name.

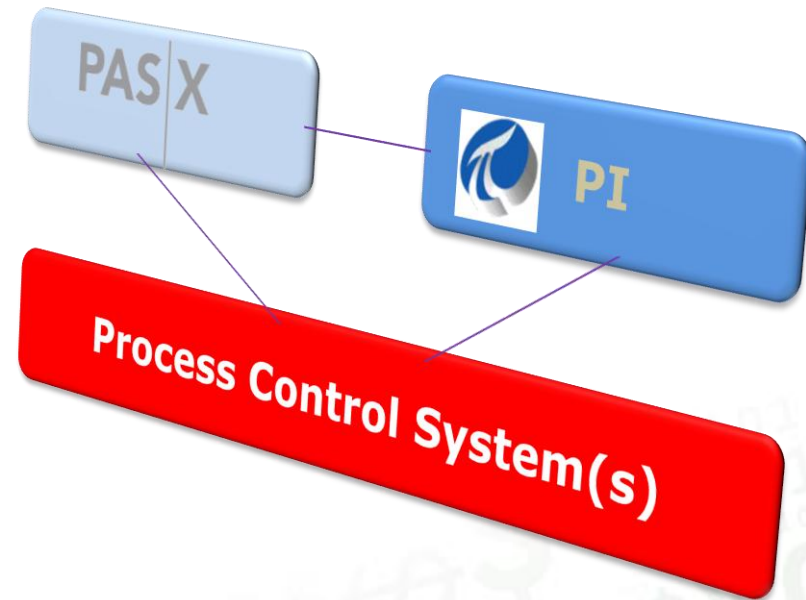
[-] Air Flow			
	Air Flow Rate	Overlay Air Flow Rate	0 slpm
[-] Batch Information			
	BatchID	Batch ID	
[-] Cell Density			
	Cell Density Controller	Cell Density Controller	0
[-] DO			
	DO value	Dissolved Oxygen value	0 %
	DO Analyser 1	Dissolved Oxygen Analy...	0 %
	DO Analyser 2	Dissolved Oxygen Analy...	0 %
[-] Event			
	Event		
[-] Gases to BioReactor			
	Process Air Flow	Process Air Flow	0 slpm
[-] ID			
	ID	Reactor ID	0
	MOC	Material Of Construction	Stainless Steel
[-] IPC			
	pH	pH Value	0
	pH Probe 1	pH Probe 1	0
	pH Probe 2	pH Probe 2	0
[-] Media Feed			
	Media Feed	Media Feed	0 l/min
[-] Pressure			
	Vessel Head Pressure	Vessel Head Pressure	0 barg
[-] Temperature			
	Vessel Temperature	Vessel Temperature	0 °C
[-] Weight			
	Vessel Weight	Vessel Weight	0 kg

Challenge #3: Paper

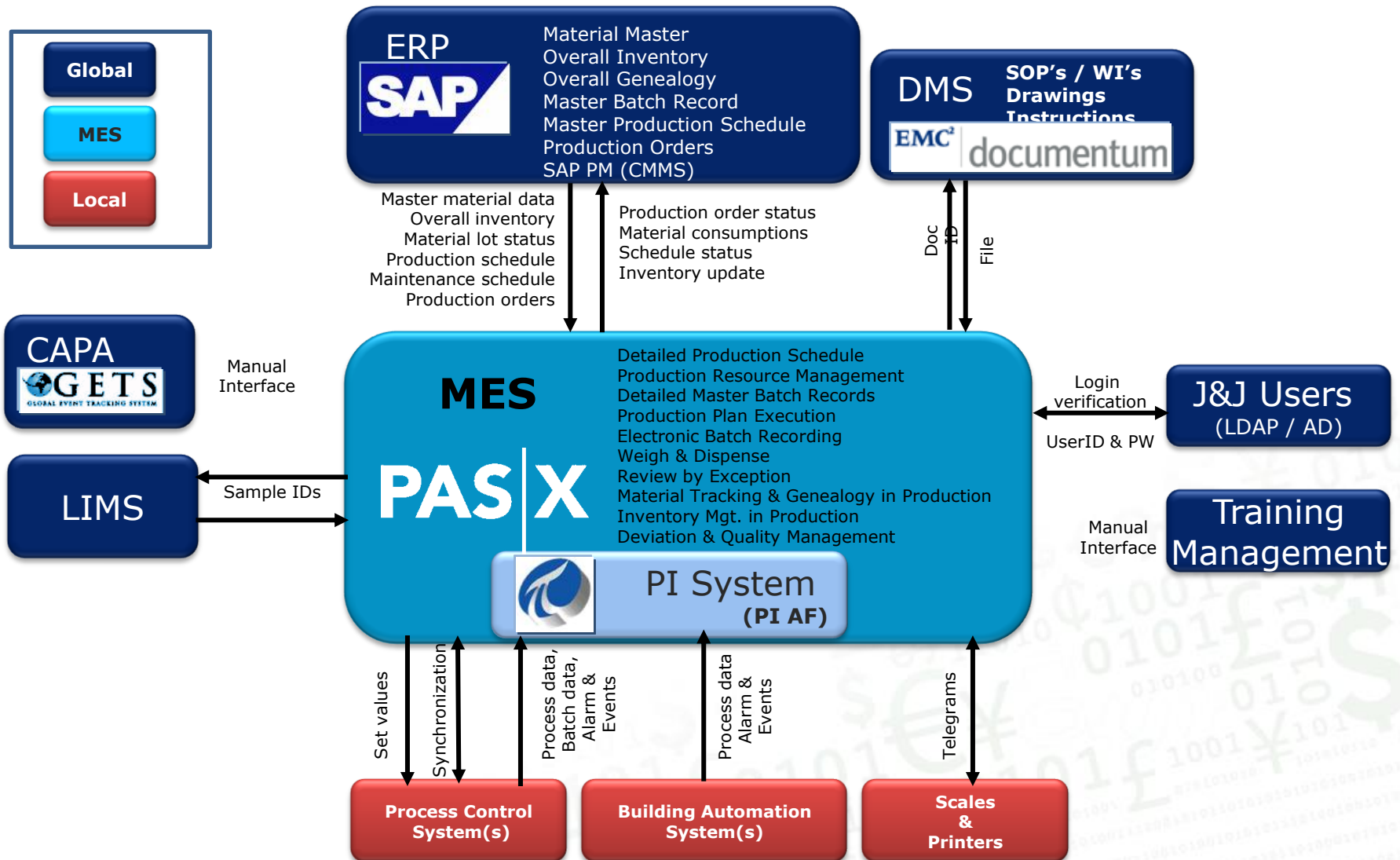


Solution: Production Analysis using PAS-X EBR Framing

- OSIsoft and Werum are collaborating to develop a batch event interface which will become a standard OSIsoft PI product.
- This will enable us to perform batch analysis at the EBR level from a BO or BF perspective.
- The capability to store basic function activities as batch events will be provided similar to current DCS batch engines.



Integrated Manufacturing Systems



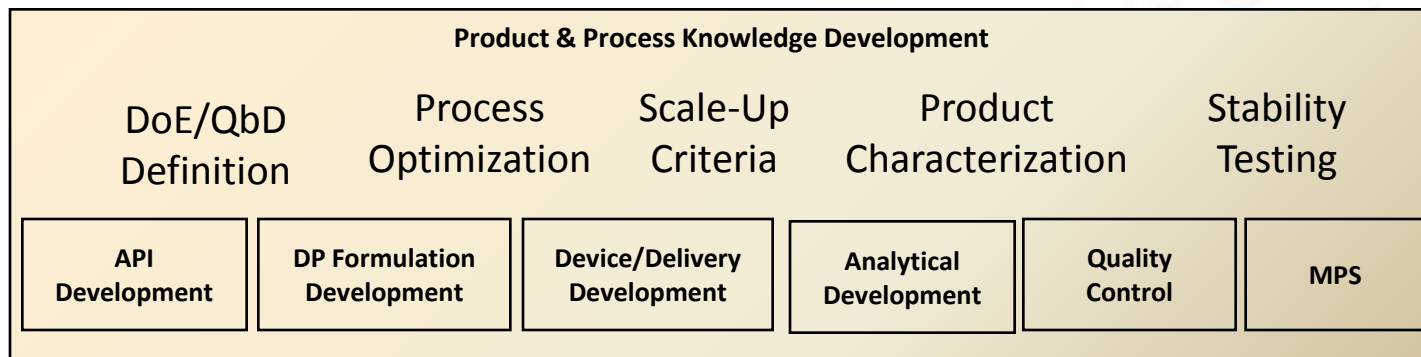
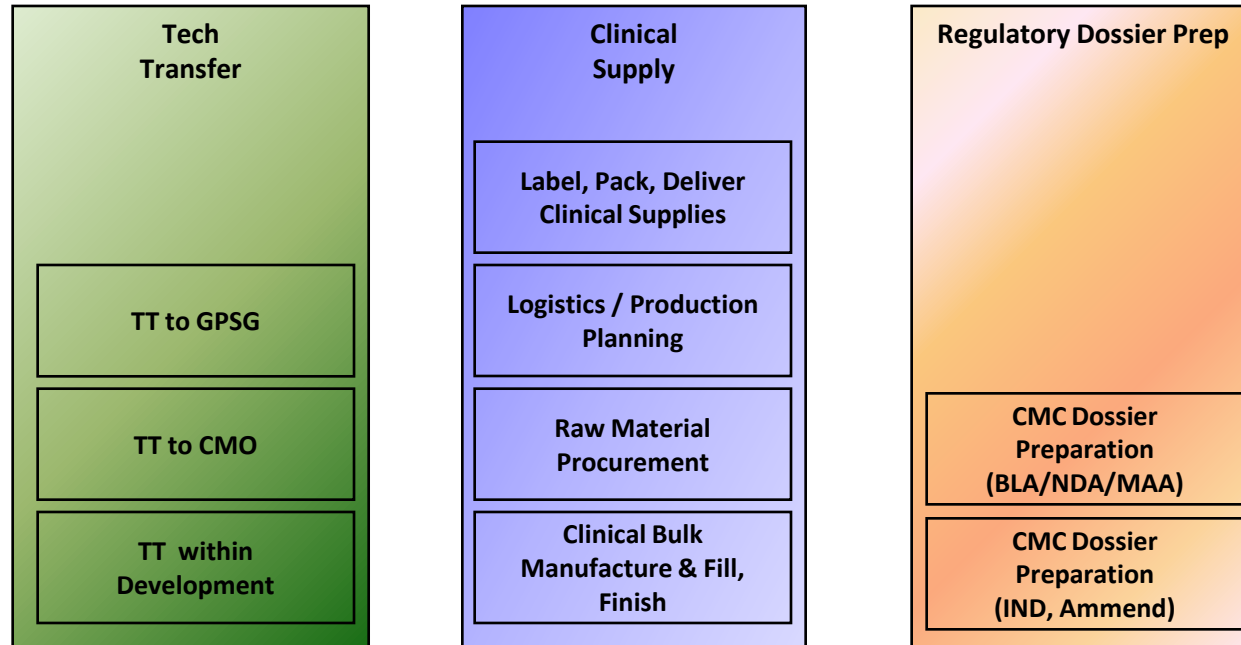
Summary

- J&J Pharma has committed to significant reduction in its COGS over a 5 yr period
- OSIsoft PI is a key element of an integrated system that delivers:
 - Improve Efficiency of Production Administration
 - Operational Efficiency Improvement
 - Yield Improvement
 - Reduced Cost of Investigations
 - Decrease TCO of Legacy Systems
 - Cost Avoidance, investment in legacy systems
- Bottom line result: Demonstrated a strong positive NPV (not including other intangible benefits)

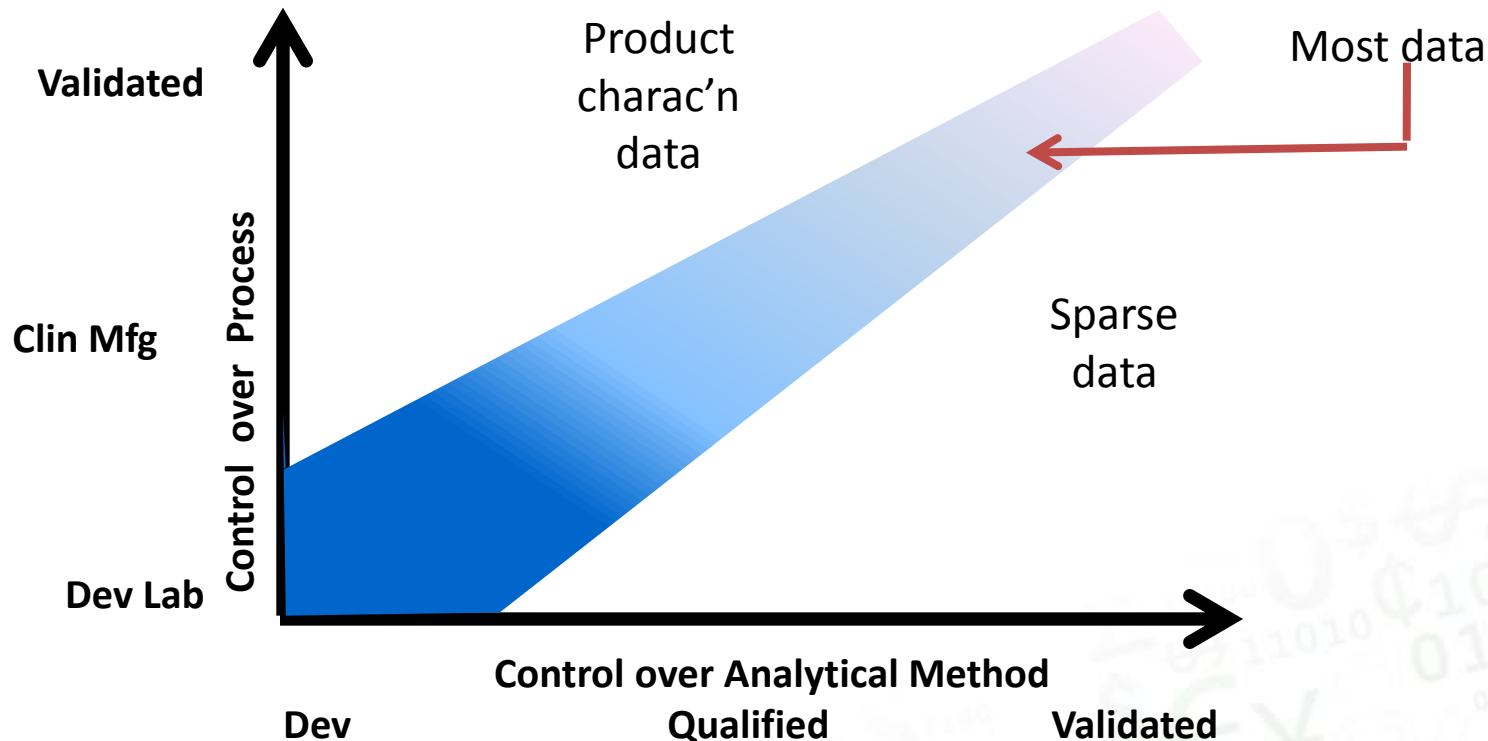
Agenda

- Introduction
- Enterprise PI as an enabler for API Manufacturing
 - J&J Pharma, OSIsoft and the EA
 - Integrated Manufacturing Design
- **Enterprise PI as an enabler for Product Development**
 - Integrated Product Development & How PI Fits In

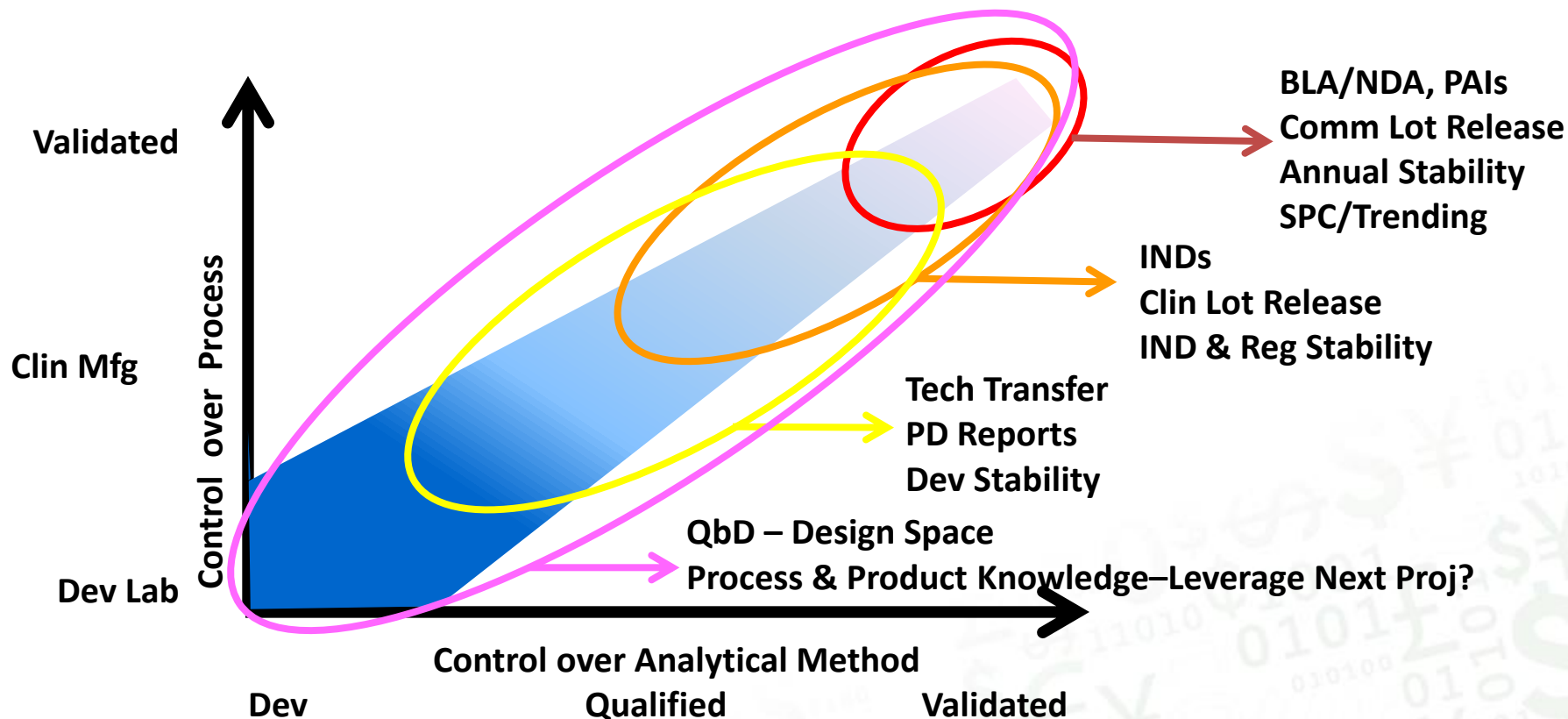
Goal: Integrated, lean product development



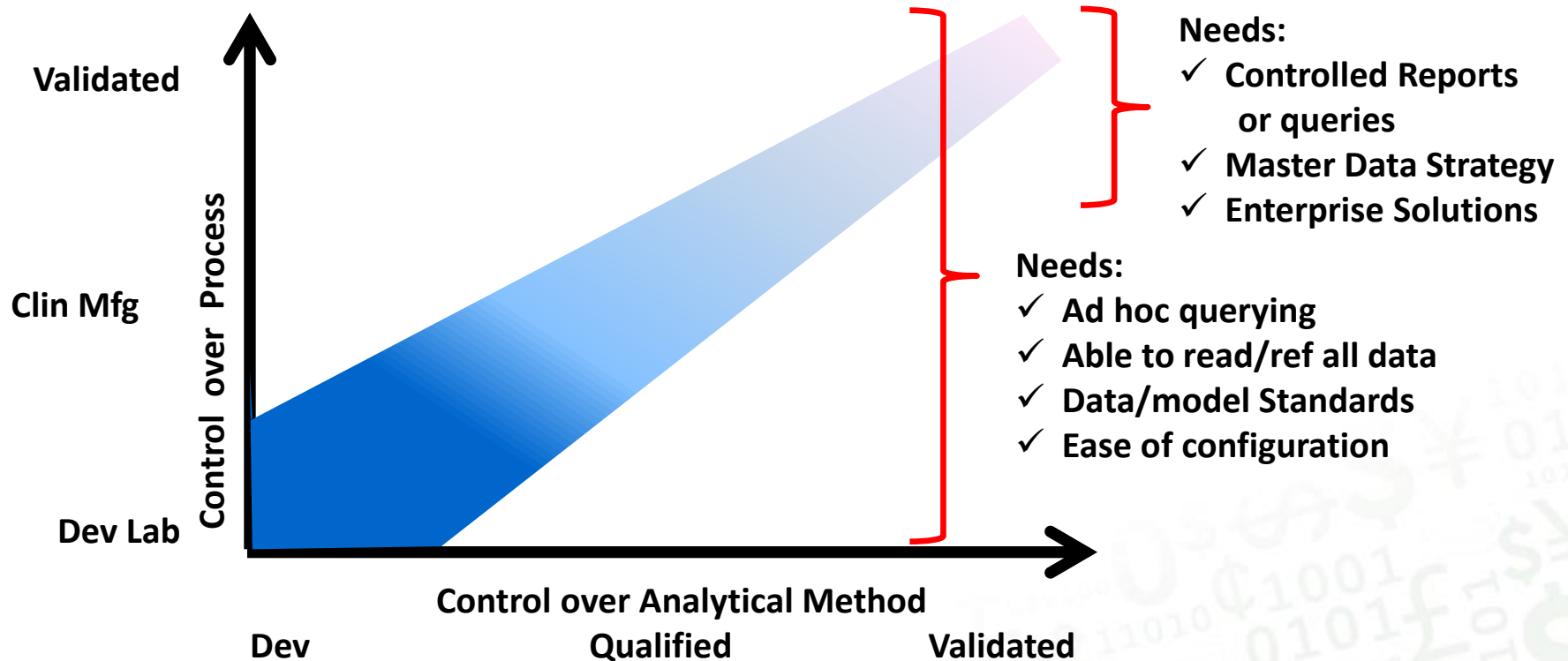
Challenge #1: Manage & control our data



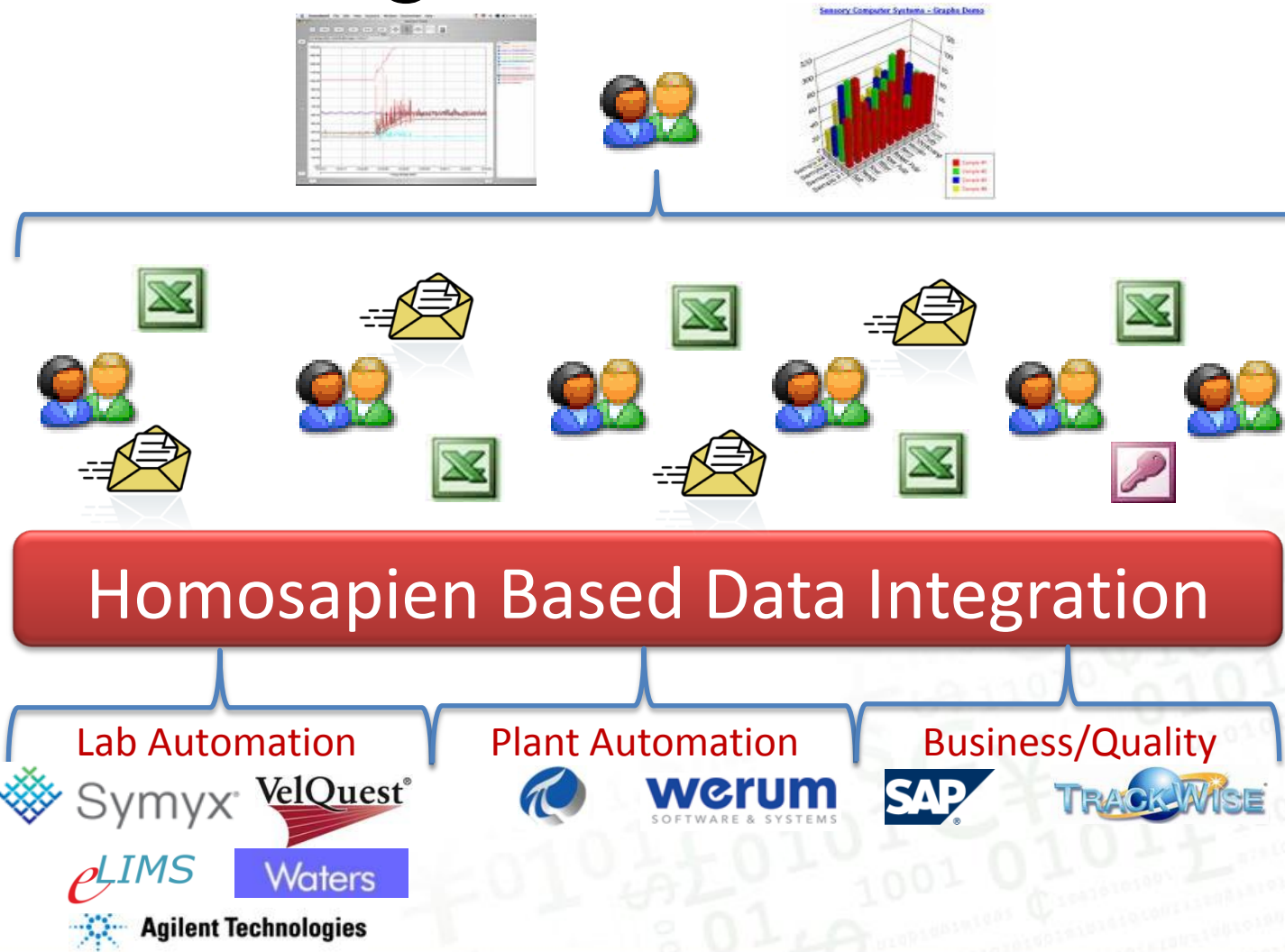
Challenge #1: Manage & control our data



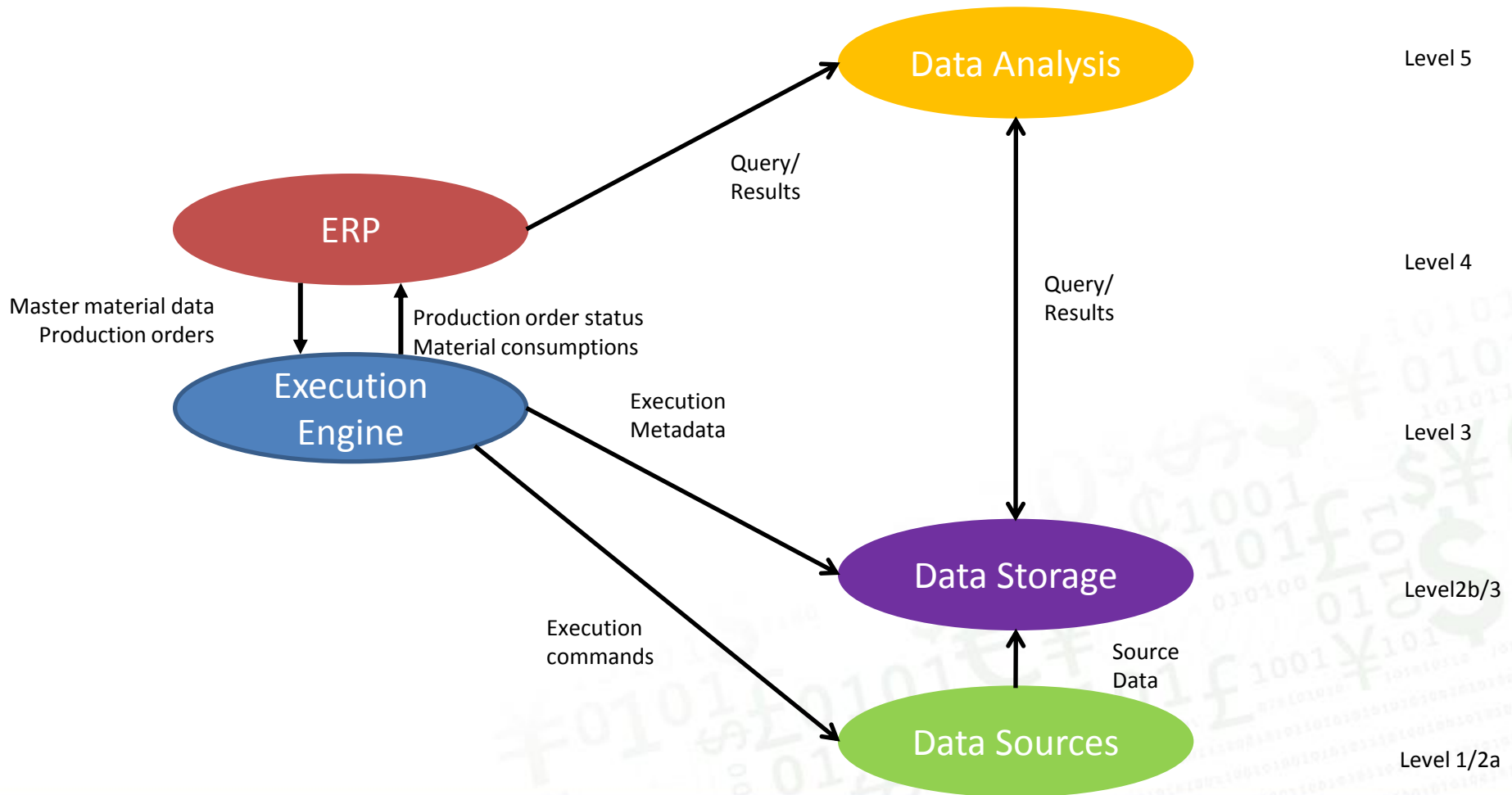
Challenge #1: Manage & control our data



Challenge #2: Current State

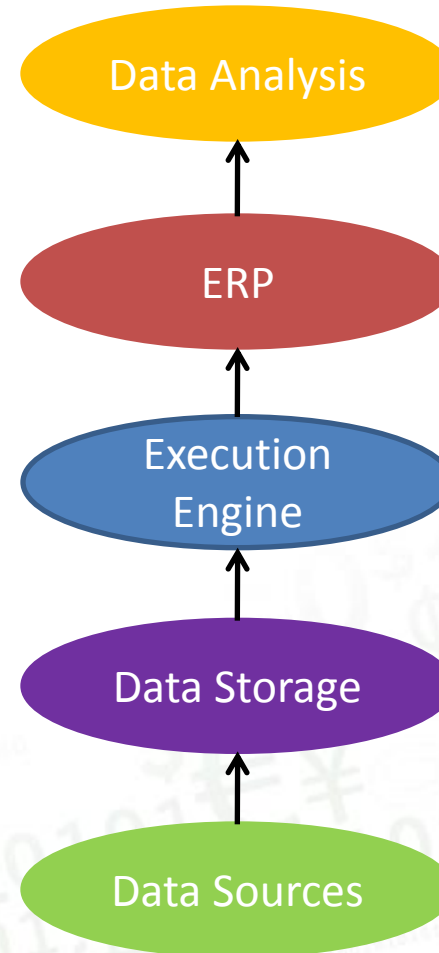


Solution: Business Intelligence through S95, Recipe, and Data Warehousing



Key Concept #1 – S95

- **Level 5: Business Intelligence**
- Level 4: Capability & Scheduling level (Months, Weeks & Days)
- Level 3: Workflow execution level (Days, Shifts, Hours, Minutes, Seconds)
- Level 2: Monitor/control level (Minutes, Seconds & sub-seconds)
- Level 1: Sensing level (Seconds & sub-seconds)



Key Concept #2 – Recipe based execution



Header:

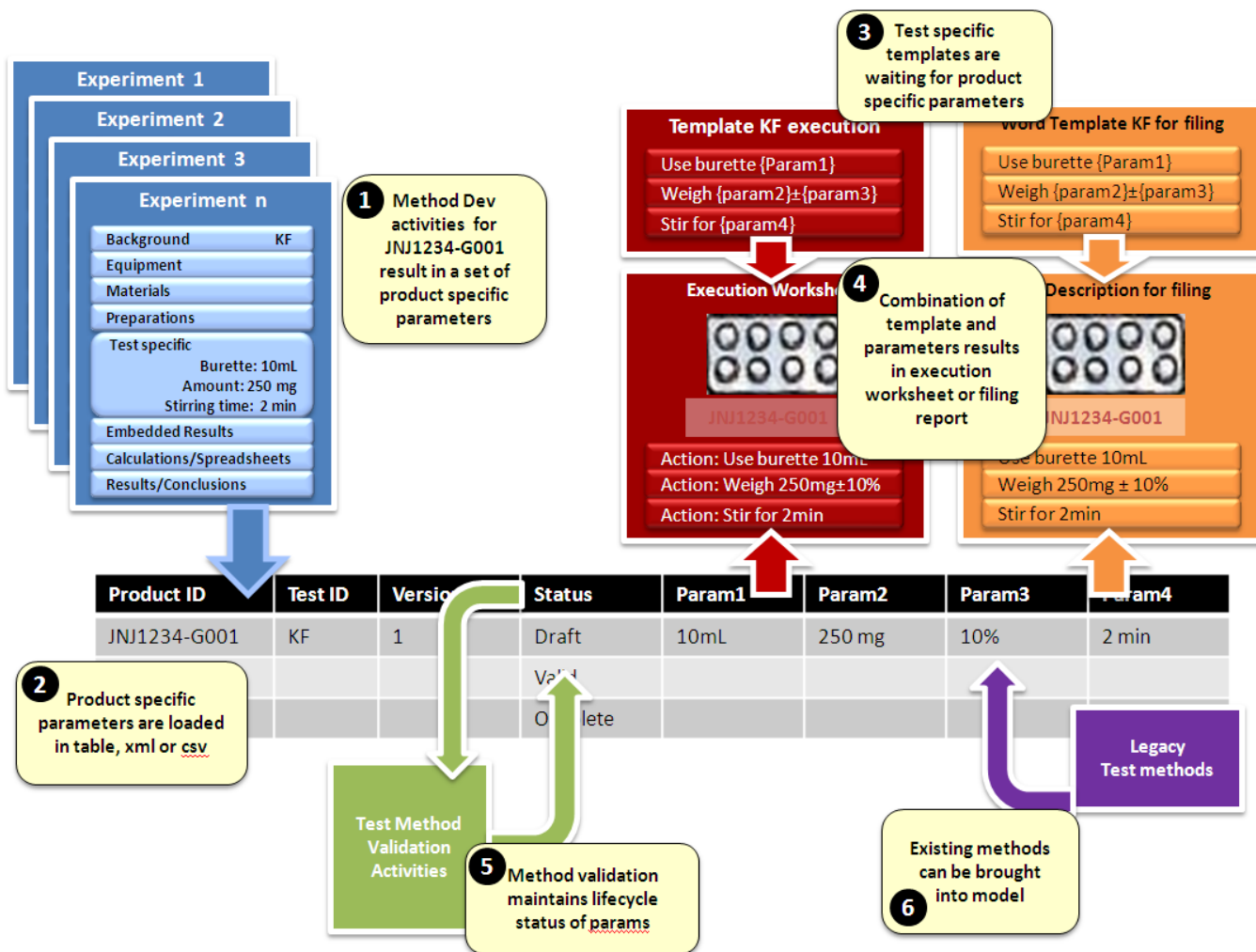
Dark Chocolate Cake

Author: Grandma, 1965

Formula

Raw Materials	Raw Material Quantities	Process Parameters	Recipe Procedure (Process Description)	Equipment Requirements
all-purpose flour	2 cups	350 degrees F	Preheat oven	Oven
white sugar	2 cups		Grease and flour a pan.	9x13 inch pan
unsweetened cocoa	3/4 cup		In a bowl, combine the flour, sugar, cocoa, baking soda, baking powder and salt.	Bowl, Spoon
baking soda	2 teaspoons		Make a well in the center	
baking powder	1 teaspoon		Pour in the eggs, coffee, milk, oil and vinegar.	
salt	1/2 teaspoon		Mix until smooth, batter will be thin.	
eggs	2	3 minutes	Pour into prepared pan.	
cold brewed coffee	1 cup		Bake in the preheated oven	
milk	1 cup	35 to 40 minutes	Allow to cool	Cooling Rack
vegetable oil	1/2 cup			
vinegar	2 teaspoons	72 F		

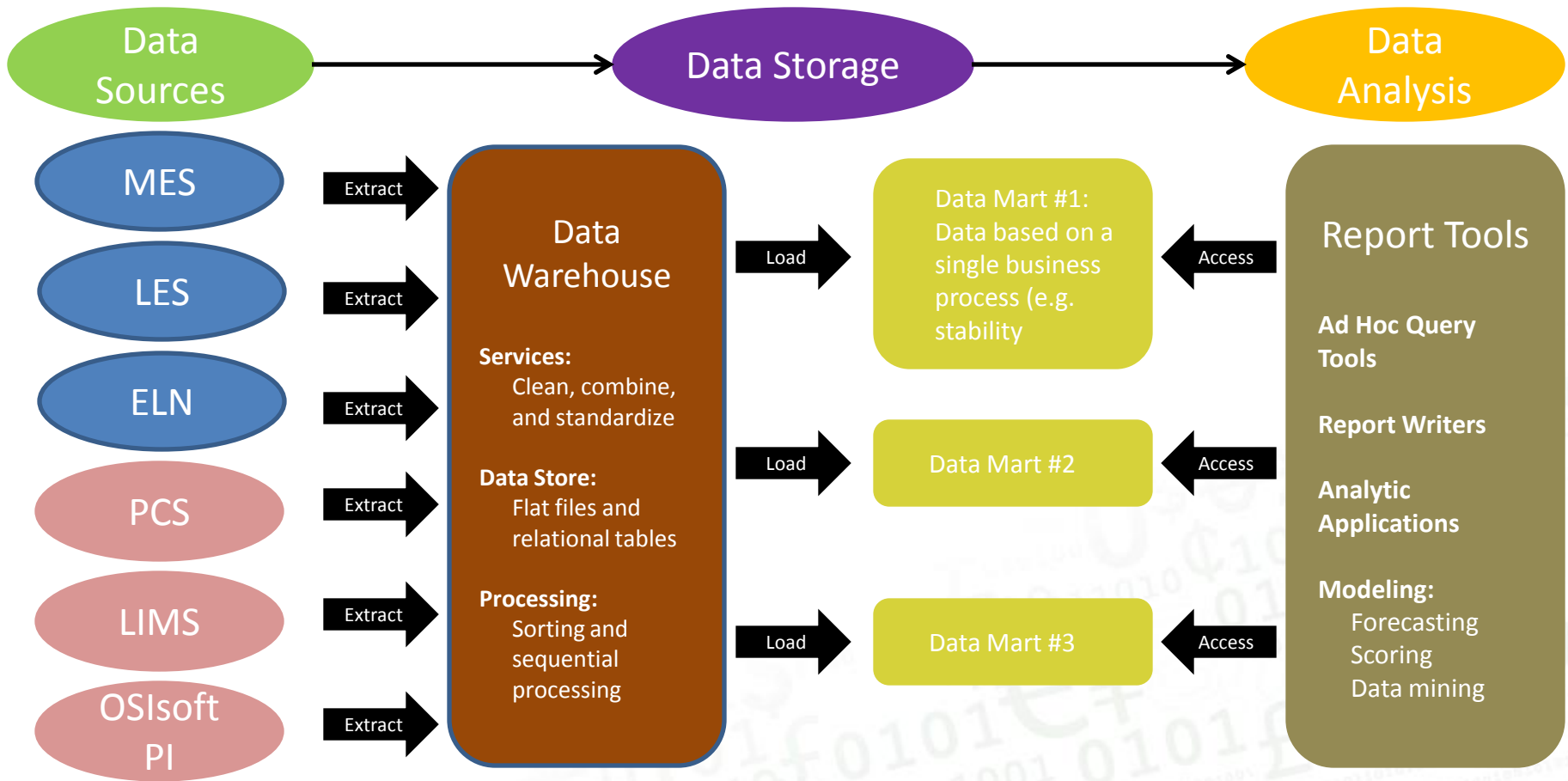
Key Concept #2 – Recipe based execution



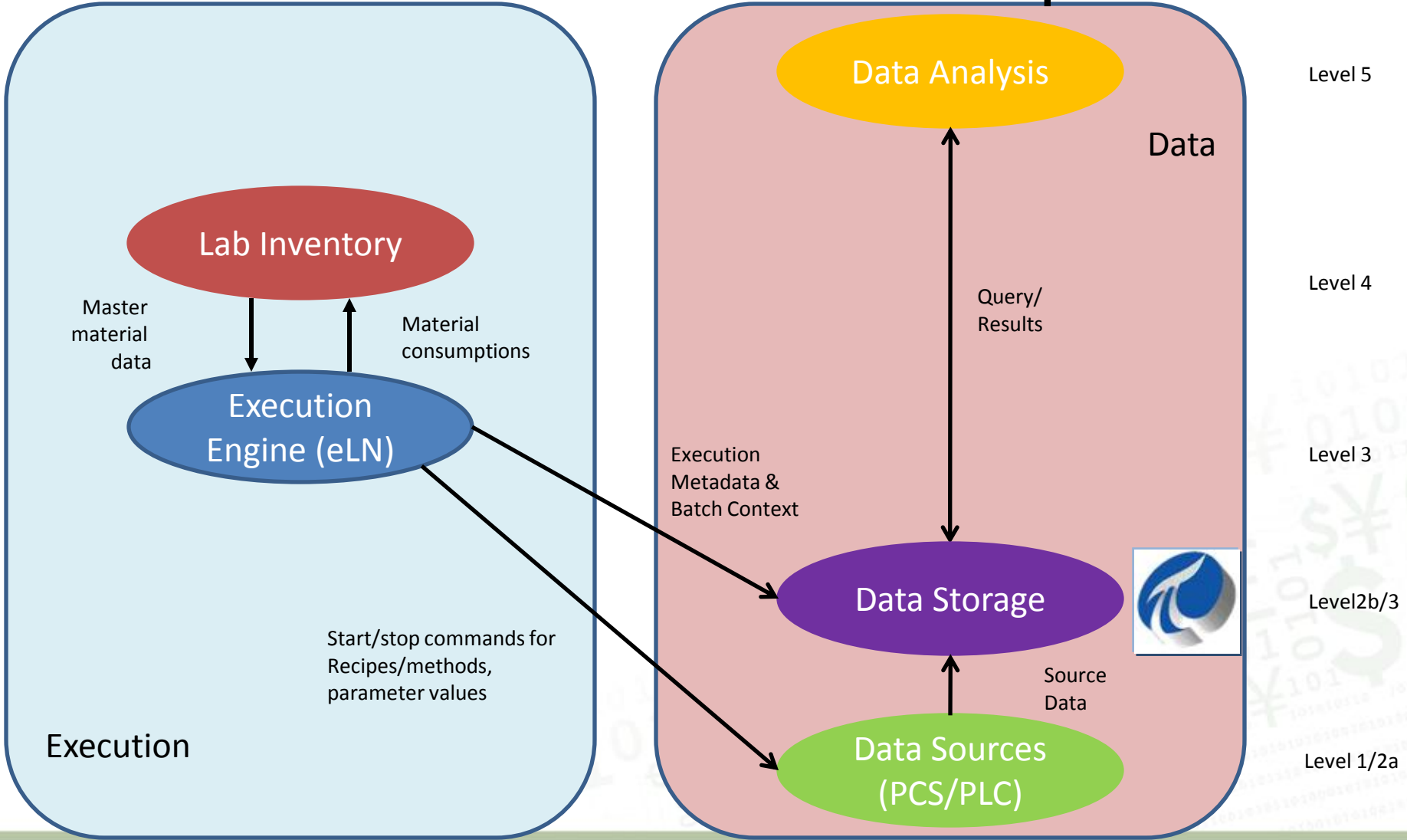
System independent recipe model

- Requirements:
 - a harmonized data model across systems
 - systems capability to configure re-usable libraries of standard unit operations.
 - exchange recipe structures between our eLN and MES/RES systems based on XML schemas underwritten by the recipe based approach (e.g. B2MML).
 - contextualization of our data regardless of the system it was generated in.
- Results
 - Inherent Quality by Design!

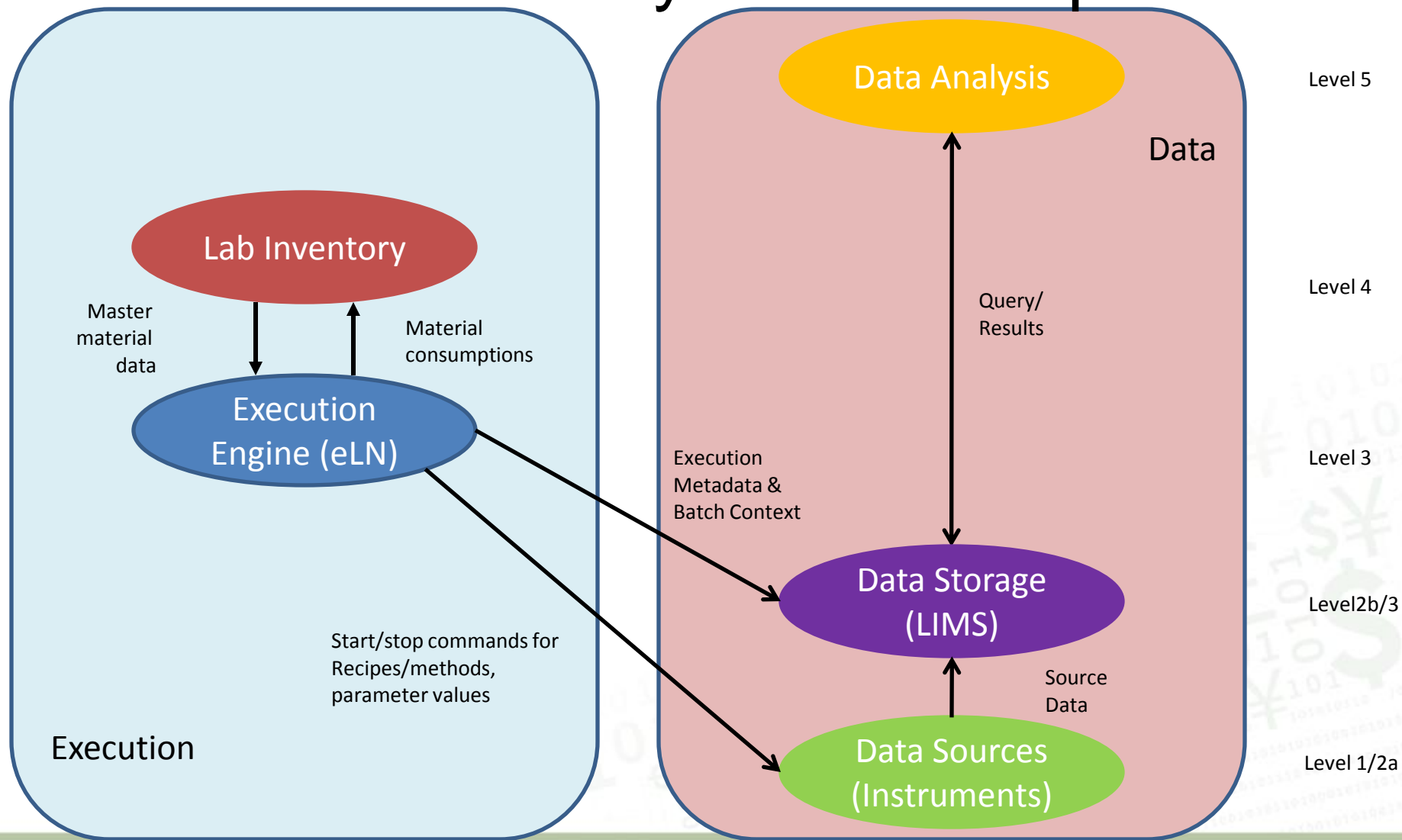
Key Concept #3 – Data Warehousing



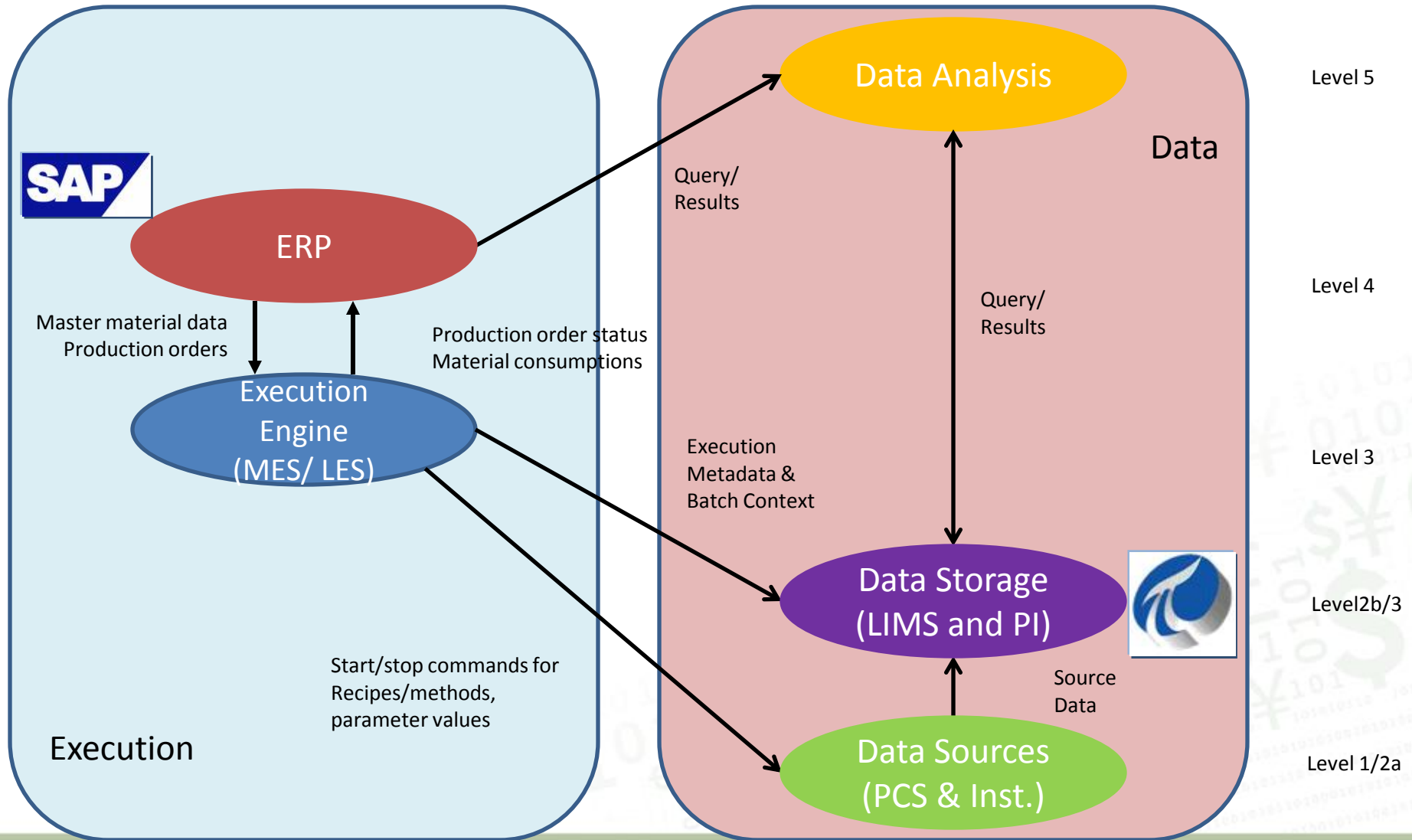
Put to Use: Process Development



Put to use: Analytical Development



Put to use: Clinical Production

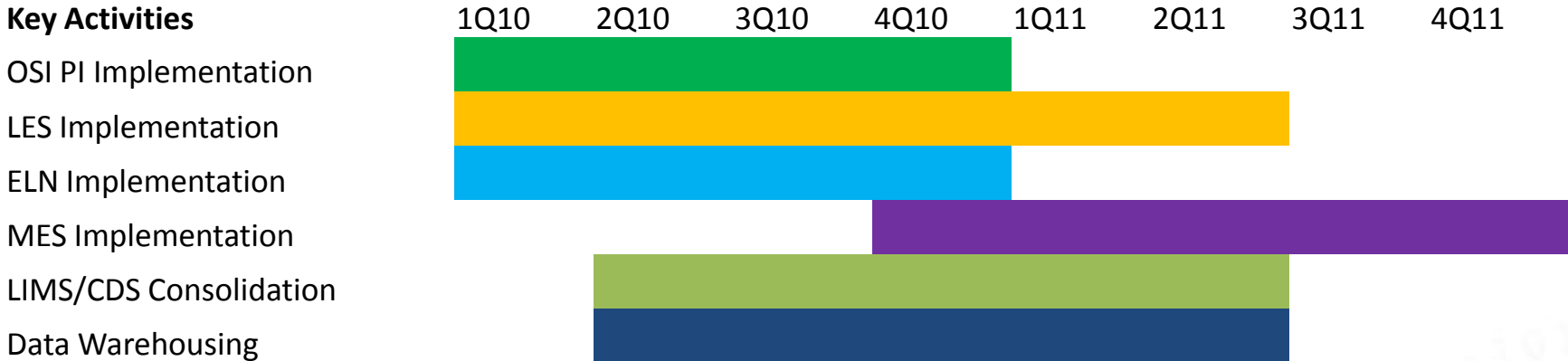


Business Impact (Expected)

- **Tech Transfer**
 - First time right electronic transfer of processes and analytical methods from eLN to MES/LES with rich data support from OSIsoft PI and LIMS
- **Clinical Production**
 - Paperless production & zero day product release enabled by MES/LES, LIMS, and OSIsoft PI
- **Regulatory Filings**
 - Standard data structure enabled by recipe-based approach and use of MES/LES/ELN eliminates non-value added time in dossier preparation
- **Knowledge Management**
 - Standard data structure promotes reuse of experiment design; easy access to knowledge improves future development and enables Quality by Design approach to product development

Timeline

Key Activities



Conclusion

- Pharma industry has to act now to better leverage what technology can do in the area of knowledge management in both the manufacturing & development spaces
- OSIsoft is a key partner because:
 - OSIsoft PI is a fundamental piece of the data management strategy for both the Pharma supply chain and drug development functions
 - OSIsoft has proven to be a strong collaboration partner with other key platform vendors
 - Enterprise Agreements (specifically through the CoE and TQS) enable standardization in system structure and flexibility in system implementation



OSIsoft®

UC2010

Real Time Information — Currency of the New Decade

Thank you

© Copyright 2010 OSIsoft, LLC., 777 Davis St., San Leandro, CA 94577