

A decorative graphic on the left side of the slide, consisting of a large, irregular shape made of many small blue triangles. The triangles are arranged in a way that creates a sense of depth and movement, with some triangles pointing towards the center and others pointing away from it. The overall effect is a complex, geometric pattern that adds visual interest to the presentation.

MES Integration with OSIsoft's PI System

Presented by
Barry Higgins



Agenda

- Introduction
- Why MES in API?
- Where does the PI System fit in?
- PI System integration with MES
- Benefits and Next Steps

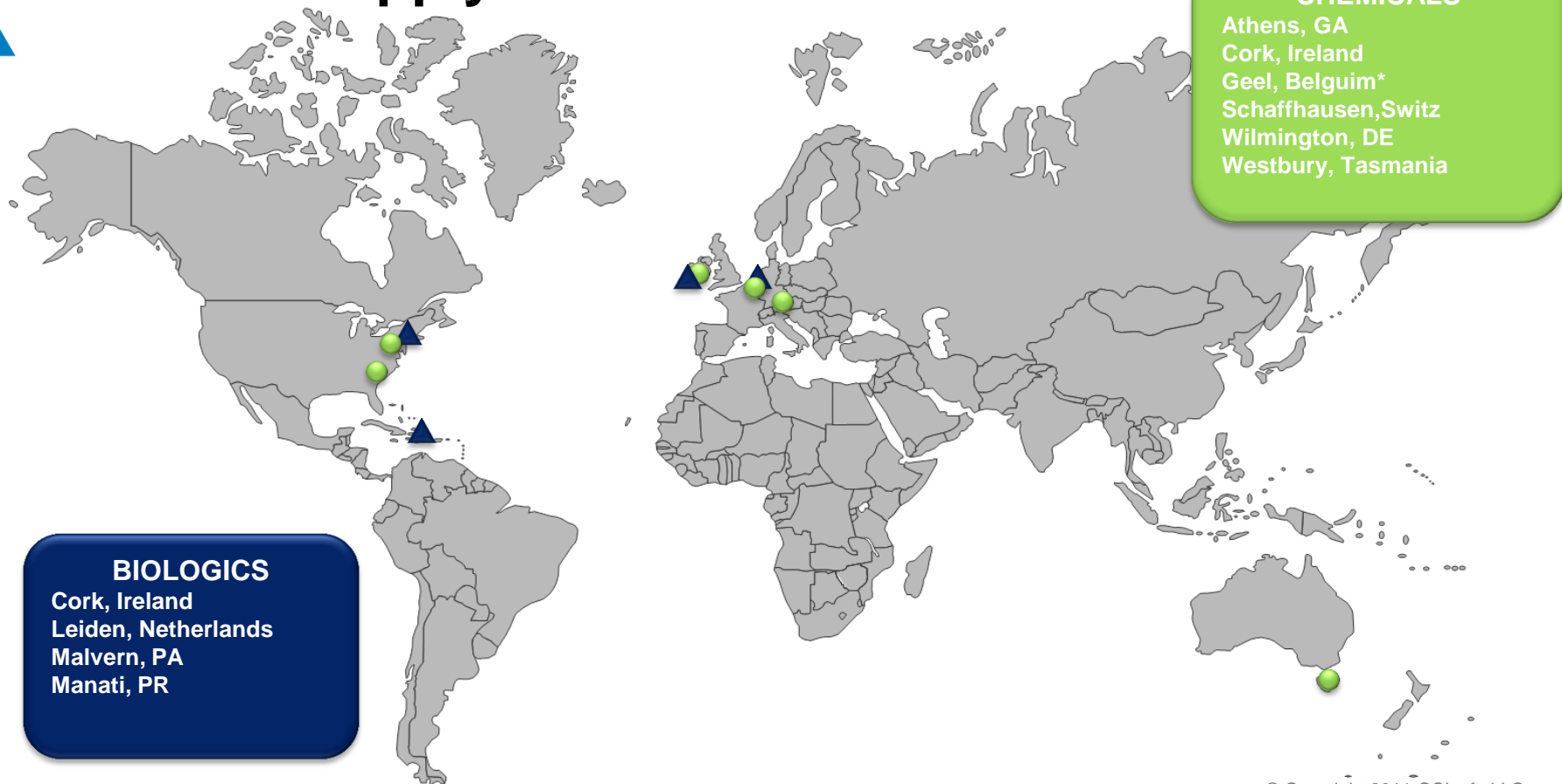
About Janssen

- 3 Main areas:
 - Consumer
 - Medical devices & diagnostics
 - Prescription Products
- JSC API Supply Chain.
 - Chemicals – 6 sites
 - Biologics – 5 sites



Johnson & Johnson

JSC API Supply Chain





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Why MES in API ?

- **Benefits envisaged.**
 - Automate the manufacturing workflow.
 - Streamline the release process.
 - Replace existing bespoke legacy systems with a single standardised manufacturing system.
 - Eliminate the 'hidden-factory' related to the current paper based process, e.g. effort to generate, maintain, correct, distribute batch records, logbooks, etc.



Why MES in API ?

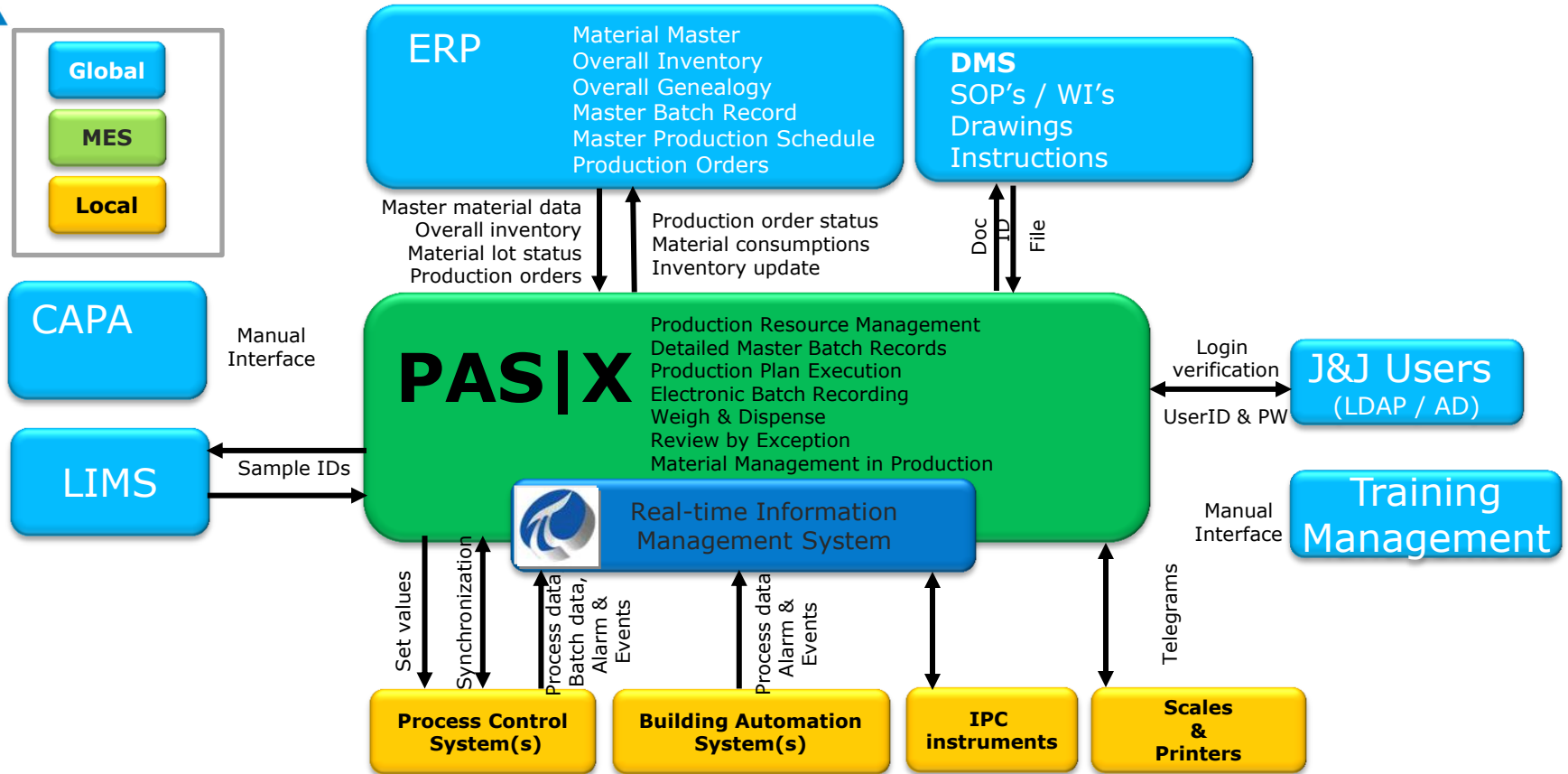
- **Compliance**
 - Eliminating Good Documentation Practice errors.
 - Enforced workflow.
- **Productivity**
 - Interface with plant systems eliminates manual data entry steps.
 - Process Data historian, LIMS, Balances etc. interfaced
 - Interface with LIMS eliminates manual steps.
 - System checks greatly reduce the number of operator verification steps (system acts as witness).
- **Continuous Improvement**
 - Real-time data in batch context facilitates process improvement efforts.
 - Real-time material transactions highlight scrap reduction opportunities.



Agenda

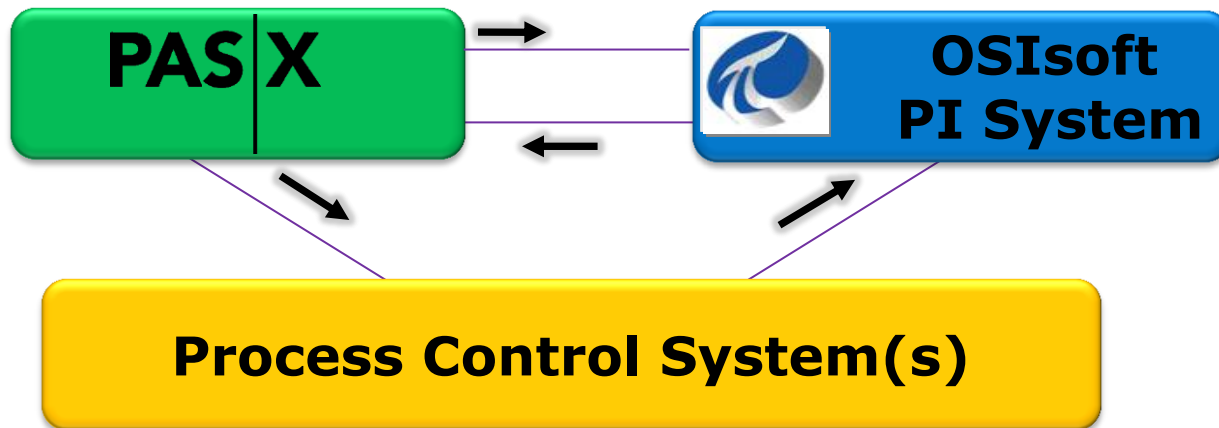
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System Overview

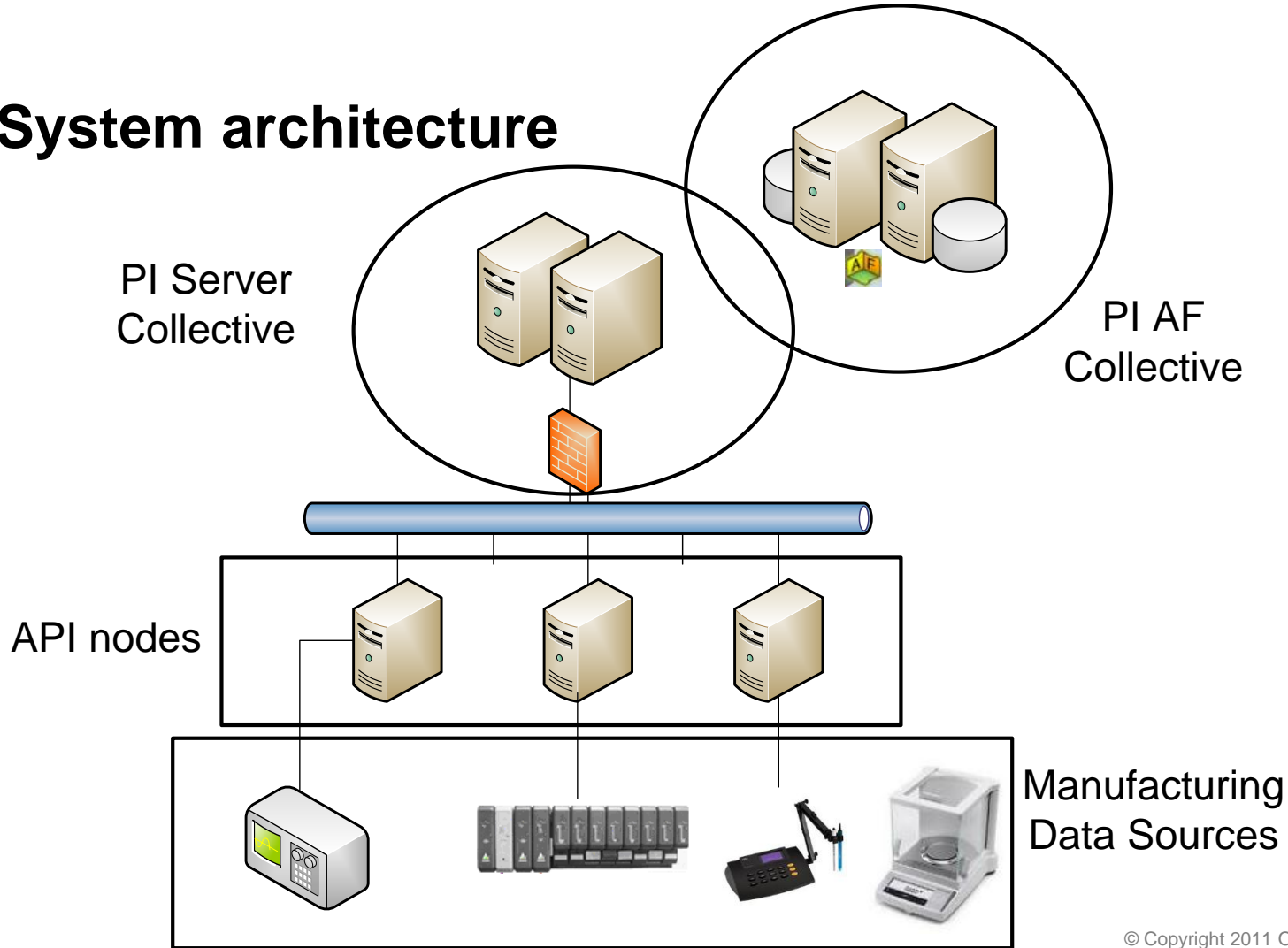


The New Trinity

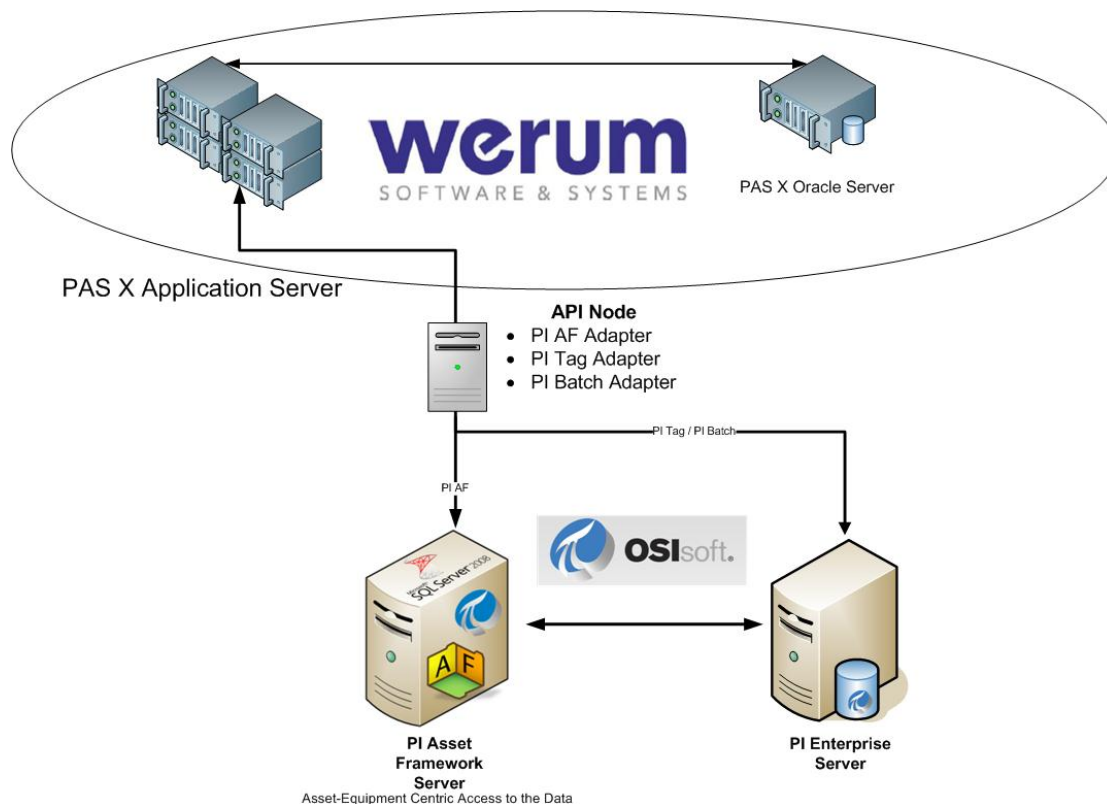
- PAS|X Commands & setpoints to Process Control System
- Process Data collected in the PI System
- The PI System data referenced in the PAS|X EBR
- PAS|X EBR batch execution data referenced in the PI System.



PI System architecture



PI System – PAS|X architecture



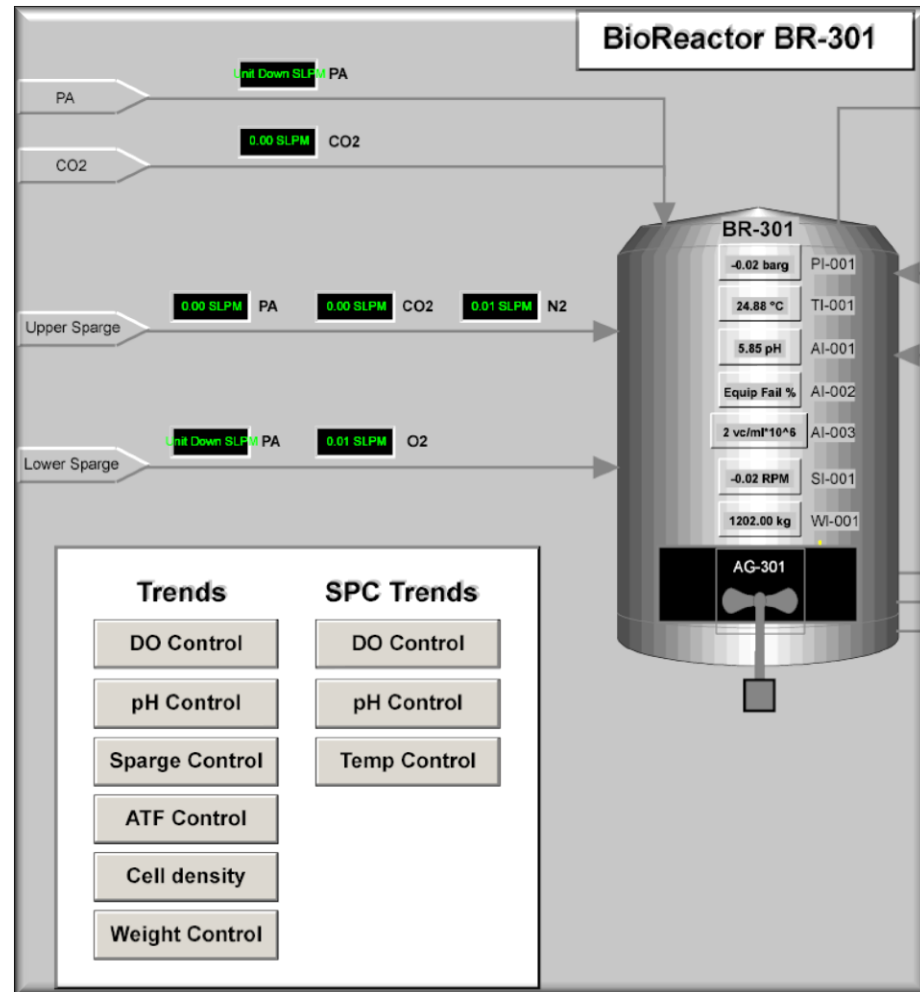


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PI Asset Framework

- What is PI Asset Framework ?
 - A database of user configured “Process Object Models” called elements which represent the logical components in your process.
 - Allows data from multiple PI Servers to be combined in one common view.
 - Allows the user access to non PI System data sources, e.g. external databases.
 - Allows process specialists to build process relative models without the need for extensive PI System knowledge.



PI AF and Janssen

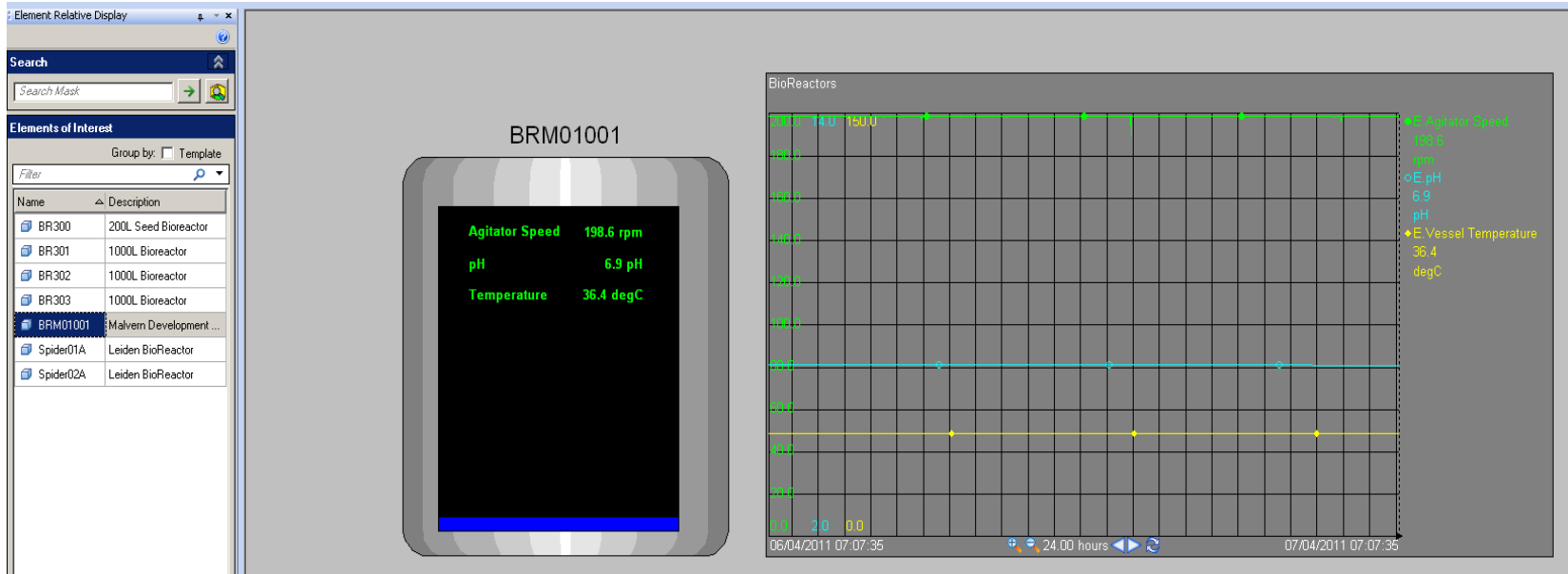
- Super Class concept.
 - Class based templates – built in conjunction with process and subject matter experts.
 - Only process critical information grouped together in a logical model.
 - Ensures that the entire organisation have a common taxonomy.
- PAS|X \ PI AF
 - Using Unit based templates allows us to build unit based MBR elements that can be applied on other sites.

The screenshot displays the BioReactor software interface. On the left is a 'Library' pane with a tree view of templates categorized by function (e.g., Area, Autoclave, Bag, BioReactor, Buffer Bag Station, Buffer Vessel, Caden, Chemical Reactor, Chromatography Column, Class, Conductivity Meter, Final Bulk Fill, Final Concentration Vessel, Final UF/DF, FIT, Freezer, HPLC, Incubator, IPC, Media Bag Station, Media Prep Vessel, Mobile Vessel, Net/Weight, Osmolality Meter, PASX, PASX Data Template, pH Meter, Plet Batch Counter, SCTimer, Site, Transfer Panel, Uncorn, Washer, Wave BioReactor, Weigh Booth, Weigh Scales). On the right is a table titled 'BioReactor' with tabs for 'General', 'Attribute Templates', and 'Ports'. The 'Attribute Templates' tab is active, showing a table with columns 'Name', 'Description', and 'Default Value'. The table lists various attributes grouped by sections like 'Aber', 'Batch Information', 'Cell Density', 'DO', 'Event', 'Gases to BioReactor', 'ID', 'IPC', 'Media Feed', and 'Phase Information'.

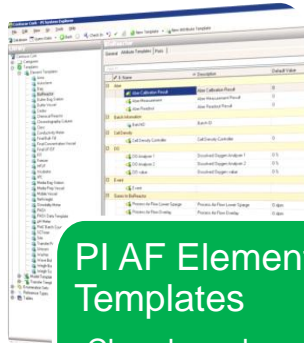
Name	Description	Default Value
Aber		
Aber Calibration Result	Aber Calibration Result	0
Aber Measurement	Aber Measurement Result	0
Aber Readout	Aber Readout Result	0
Batch Information		
BatchID	Batch ID	
Cell Density		
Cell Density Controller	Cell Density Controller	0
DO		
DO Analyser 1	Dissolved Oxygen Analyser 1	0 %
DO Analyser 2	Dissolved Oxygen Analyser 2	0 %
DO value	Dissolved Oxygen value	0 %
Event		
Event		
Gases to BioReactor		
Process Air Flow Lower Sparge	Process Air Flow Lower Sparge	0 slpm
Process Air Flow Overlay	Process Air Flow Overlay	0 slpm
Process Air Flow Upper Sparge	Process Air Flow Upper Sparge	0 slpm
ID		
ID	Reactor ID	0
MOC	Material Of Construction	Stainless Steel
IPC		
ATF Sample Result	ATF Sample Result	0
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
Phase Information		
Pressure Test Result	Pressure Test Result	
SIP Cool Down Complete	SIP Cool Down Complete	

PI AF – All talking the same language.

- A BioReactor is a BioReactor no matter where you are.

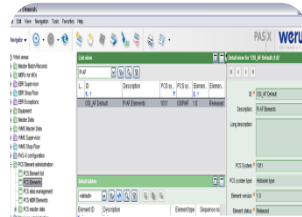


From PI AF to EBR



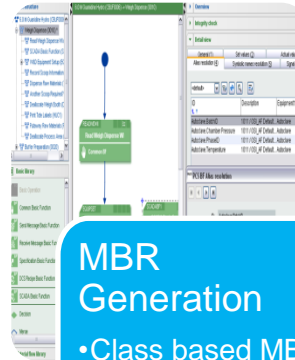
PI AF Element Templates

- Class based template.
- Unit Elements created from template.



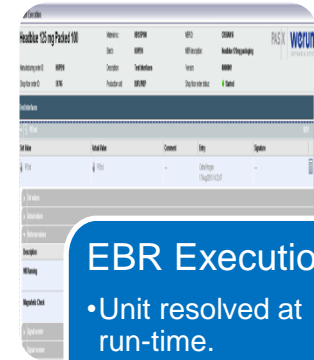
Upload from PI AF

- Class based PCS MBR elements
- Building blocks for MBR modellers



MBR Generation

- Class based MBR



EBR Execution

- Unit resolved at run-time.
- Data retrieved from PI AF Unit Element



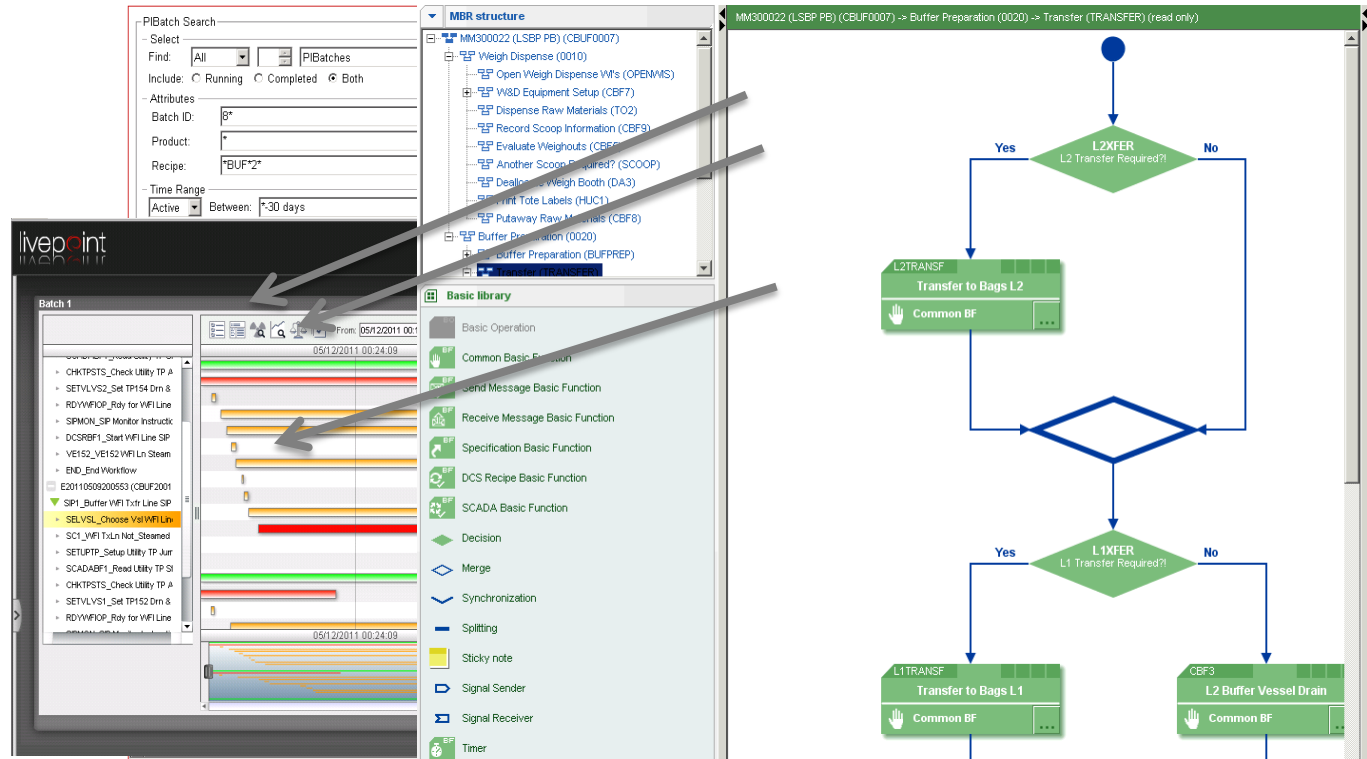


Production Analysis using PAS|X to PI Batch

- OSIsoft and Werum collaborated to develop a batch event interface which will become a standard OSIsoft PI product.
- This enables 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 is similar to current DCS batch events.

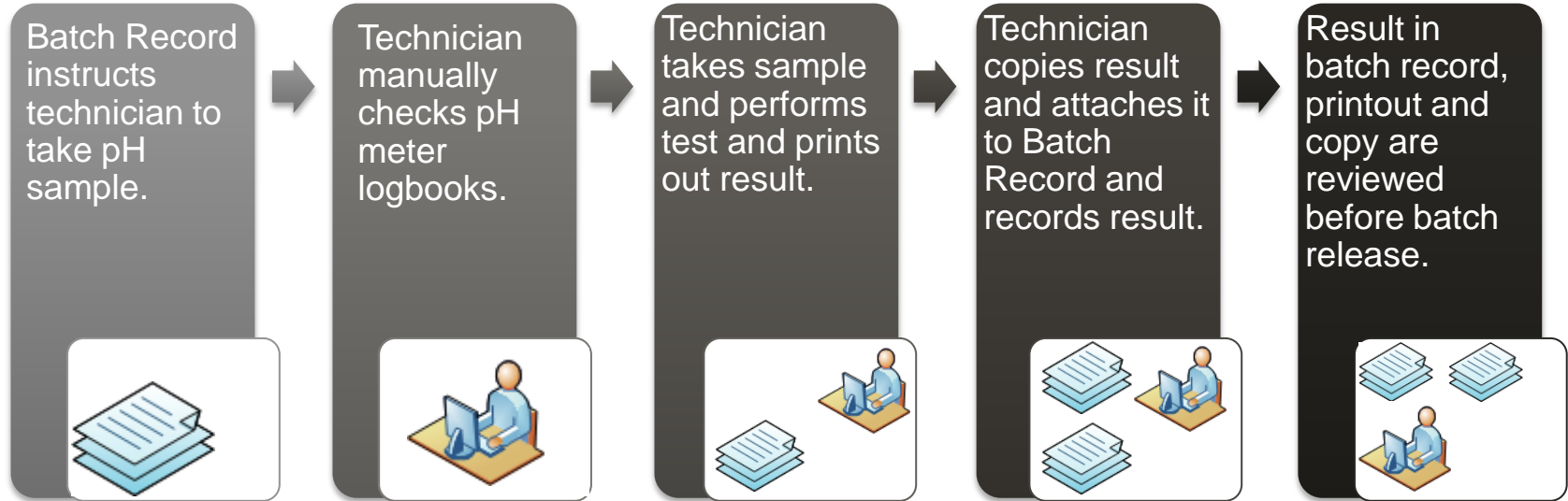
PAS|X to PI Batch

- Allows us to track, compare and analyse MES batches using standard tools.
- From Order creation in SAP to finished product delivered.



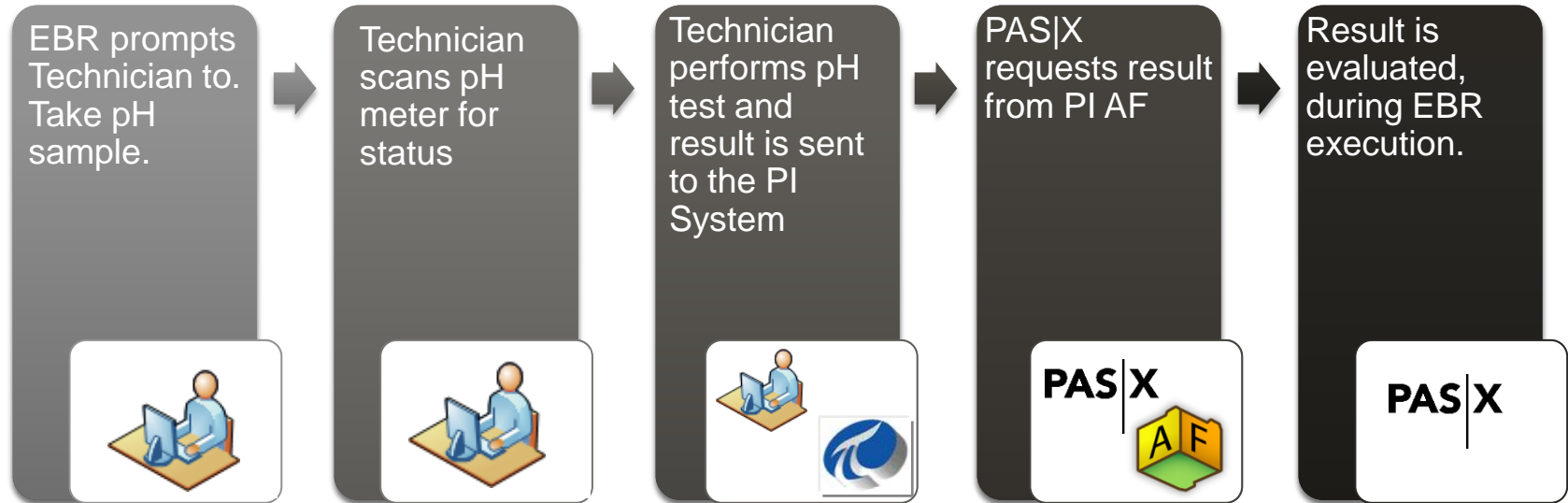
The PI System effect.

- pH testing before.



The PI System effect.

- pH testing after.





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Benefits Realised

- Removal of 580 paper documents (to date) from Manufacturing.
 - Interface of Scales to the PI System and PAS X eliminates manual entries.
 - Automated pH/Cond/Osmo/Filter integrity testing. Result retrieval directly from the instrument to the PI System.
- Greater visibility on status of Orders.
 - Process is tracked from Warehouse to Manufacturing to Warehouse.
- Exception Free manufacturing.
 - Mistake proofing in area of GDP errors and partially completed 'Paperwork' eliminated.
 - No more searching for Docs/ SOPs automatically linked to MBR.



Future Plans and Next Steps

- Complete roll out of PAS|X to remainder of site.
- Display process relevant data from PAS|X on shop floor using standard PI System tools, PI ProcessBook, PI DataLink
- Begin analysis of data gathered by the PI System from PAS|X to discover the next 'hidden-factory'.



OSIsoft Products and Services Employed

- Enterprise Agreement
- PI AF
- PI Interfaces
 - PI OPC
 - PI UFL
 - PI Batch
 - PI RDBMS



Questions

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Thank you