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

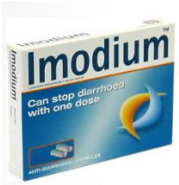
About Janssen

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

janssen
PHARMACEUTICAL COMPANIES
OF Johnson & Johnson

Risperdal TRADEMARK
RISPERIDONE

Remicade
INFLIXIMAB

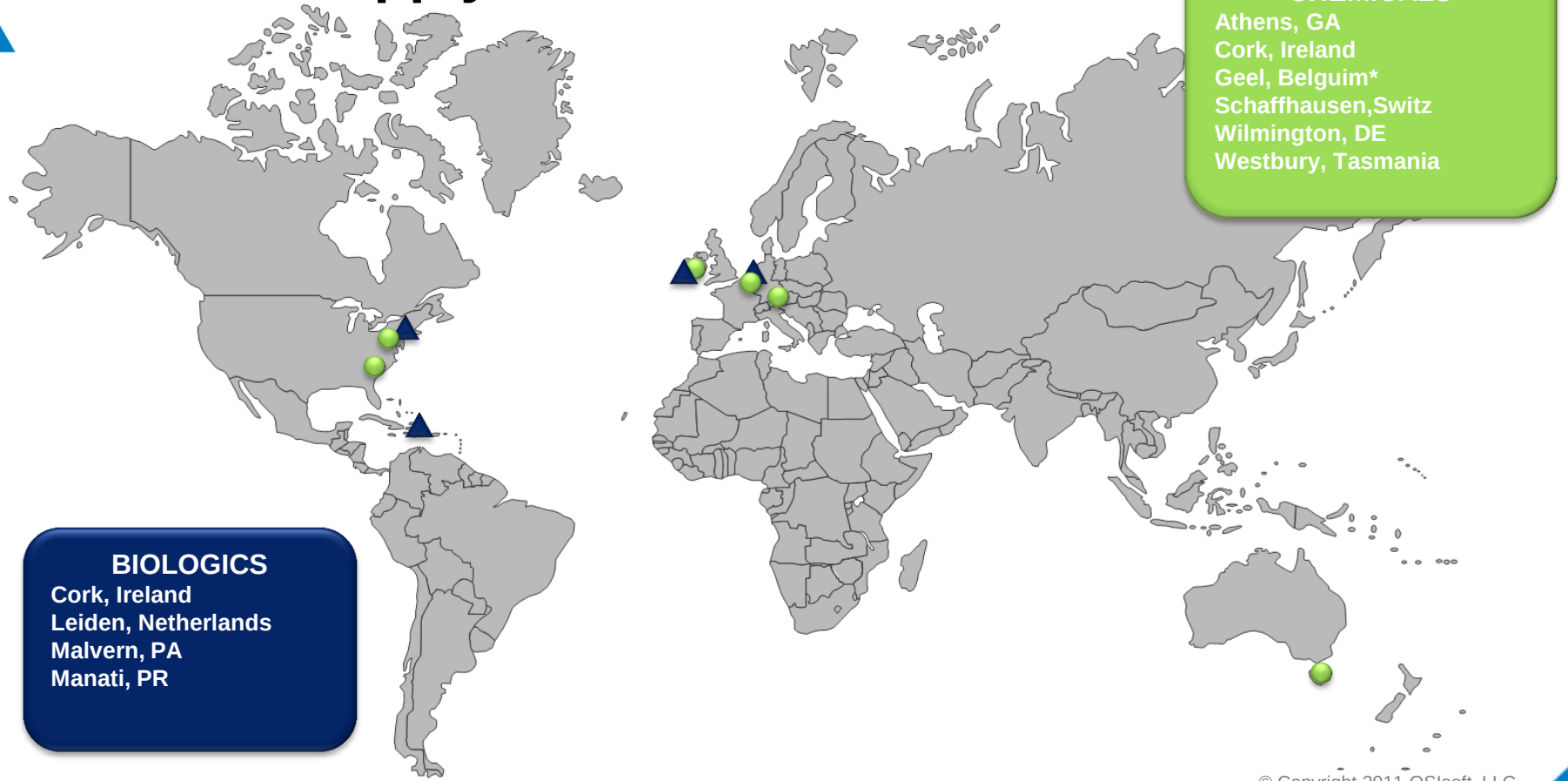


Stelara
ustekinumab

INVEGA
PALIPERIDONE
Extended-Release Tablets

Johnson & Johnson

JSC API Supply Chain



CHEMICALS
Athens, GA
Cork, Ireland
Geel, Belguim*
Schaffhausen,Switz
Wilmington, DE
Westbury, Tasmania

BIOLOGICS
Cork, Ireland
Leiden, Netherlands
Malvern, PA
Manati, PR

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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.

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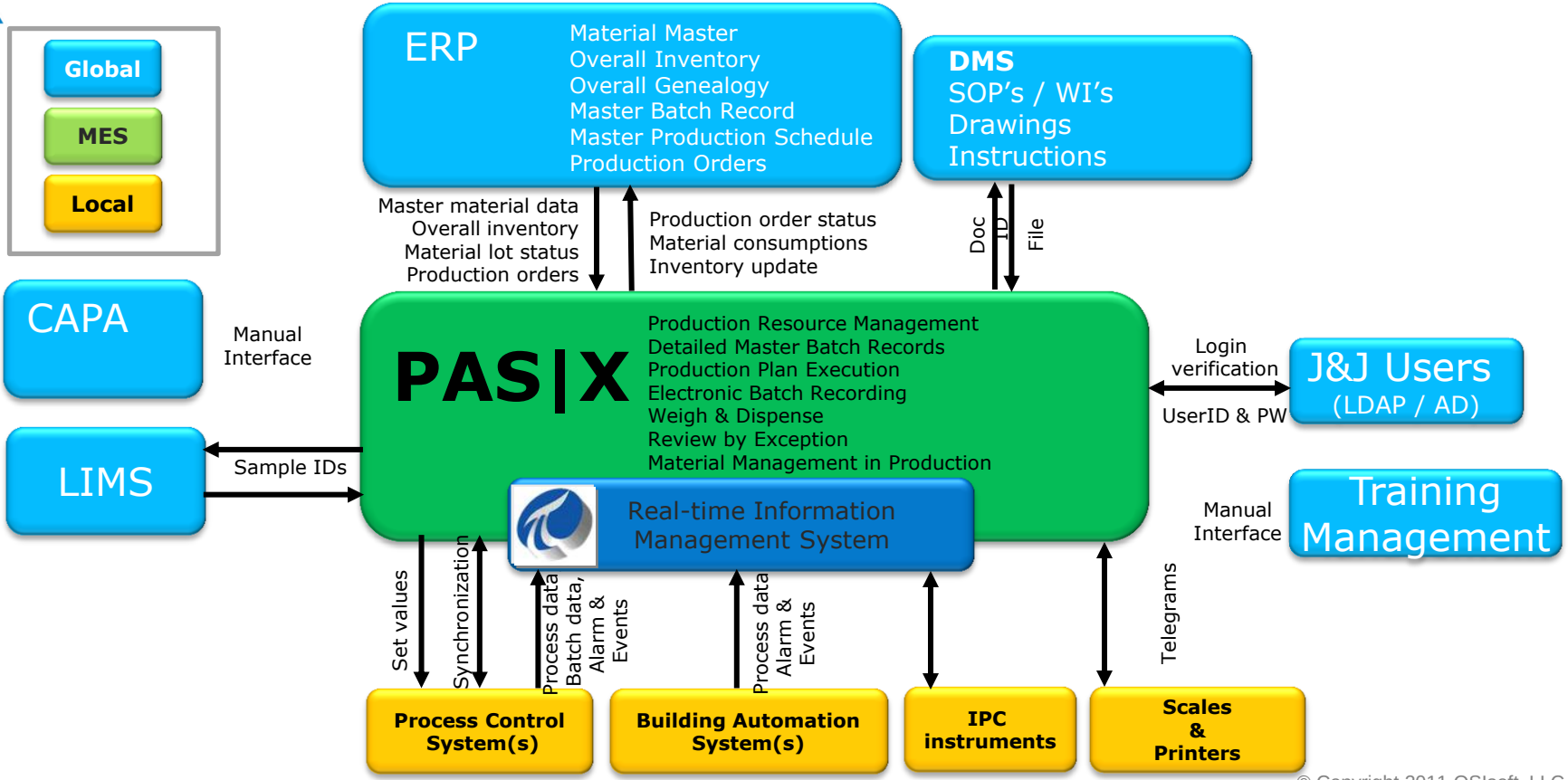
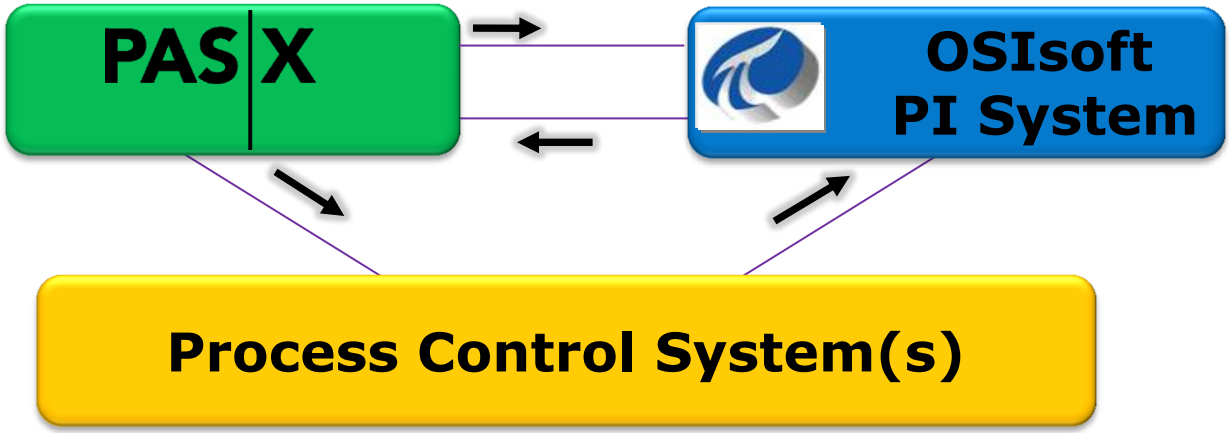
System Overview

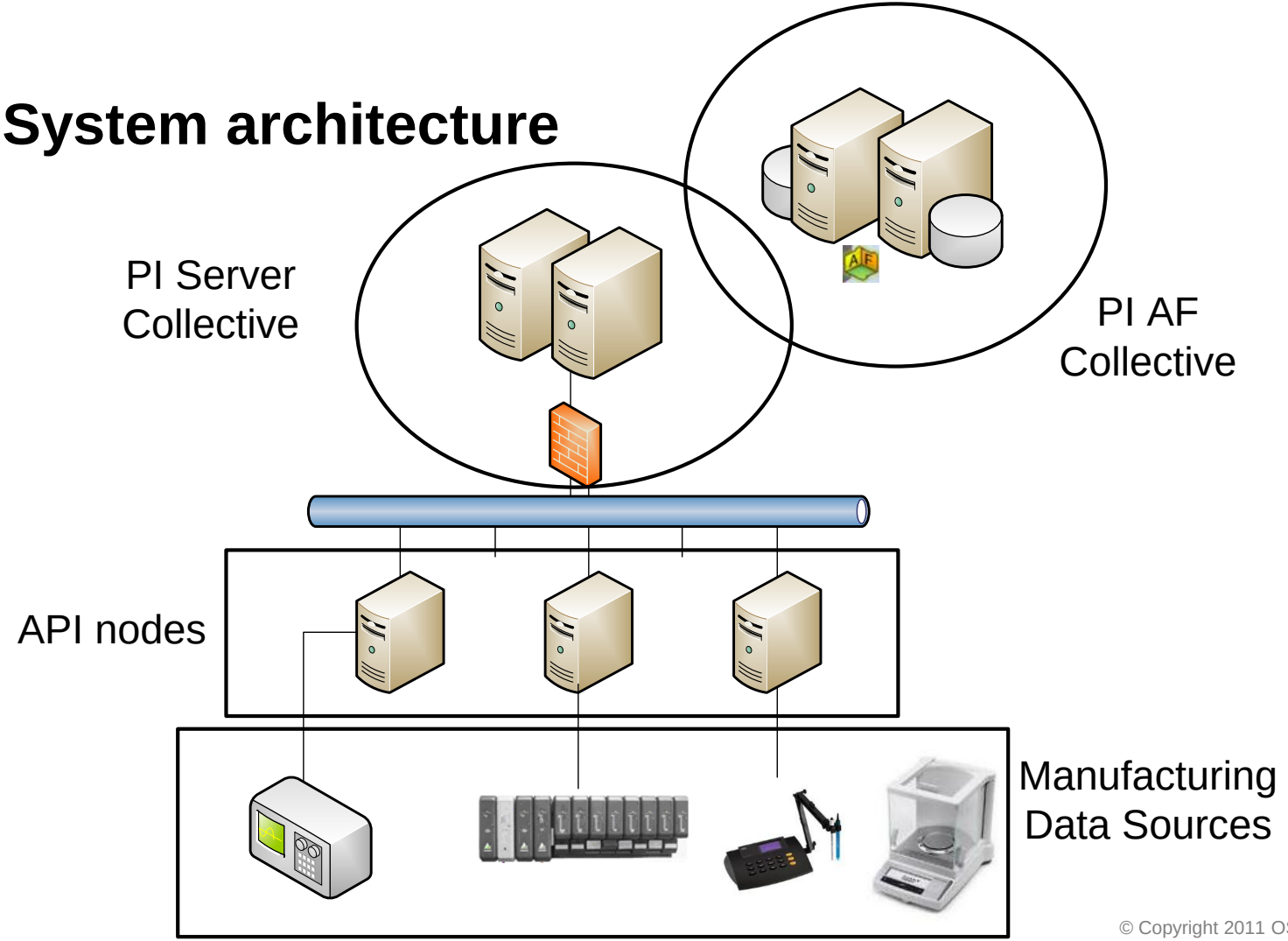


The New Trinity

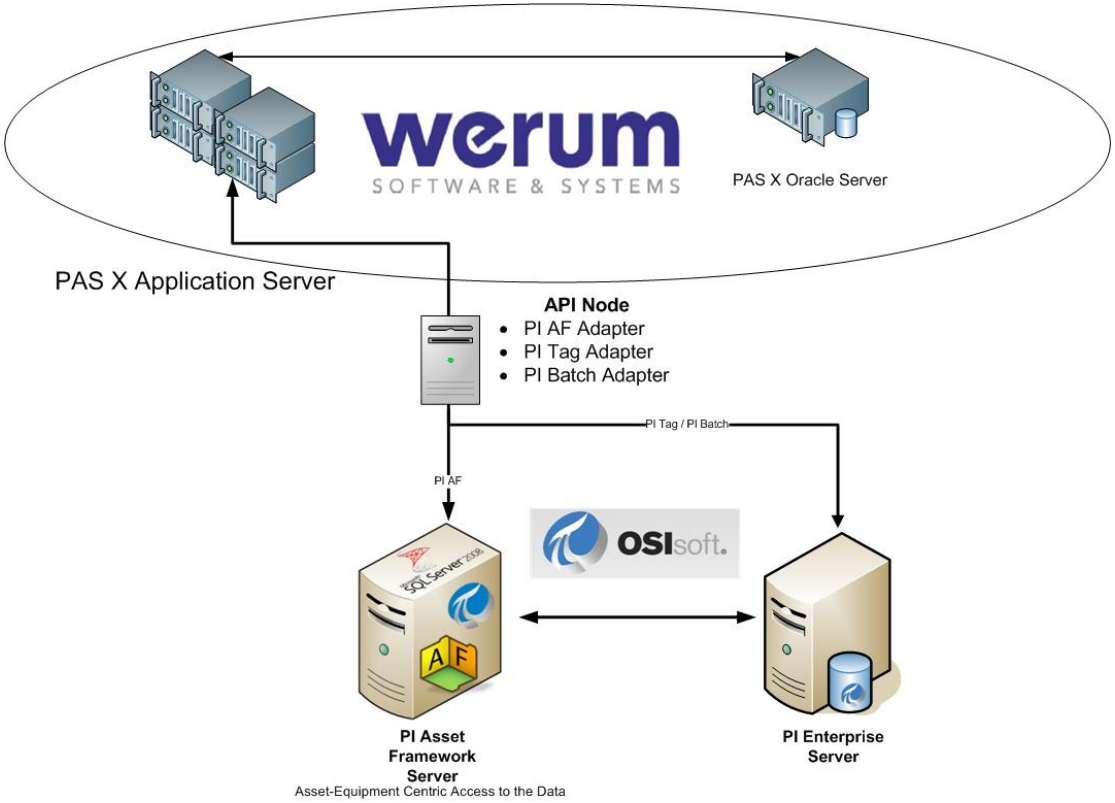
- PAS|X Commands & setpoints to Process Control System
- Process Data collected in the PI System
- The PI System data referenced in the PAS|X EBR
- PAS|X EBR batch execution data referenced in the PI System.



PI System architecture



PI System – PAS|X architecture



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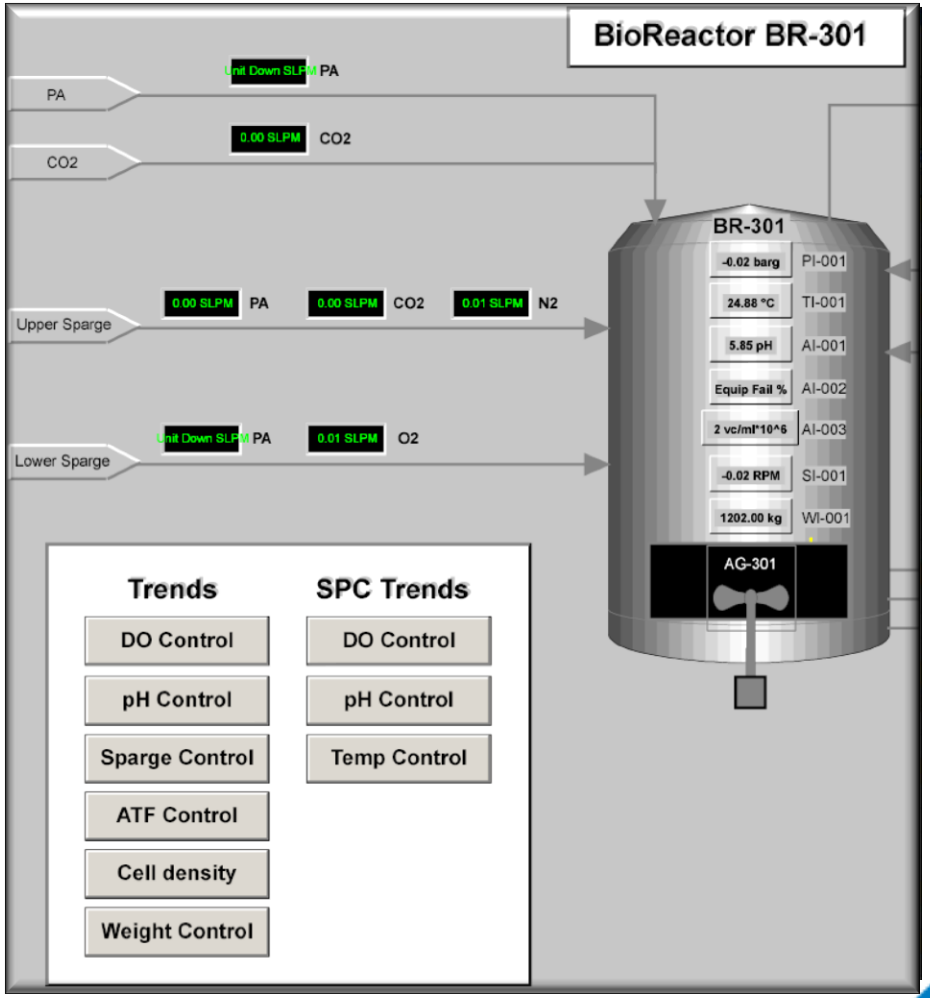
PI Asset Framework

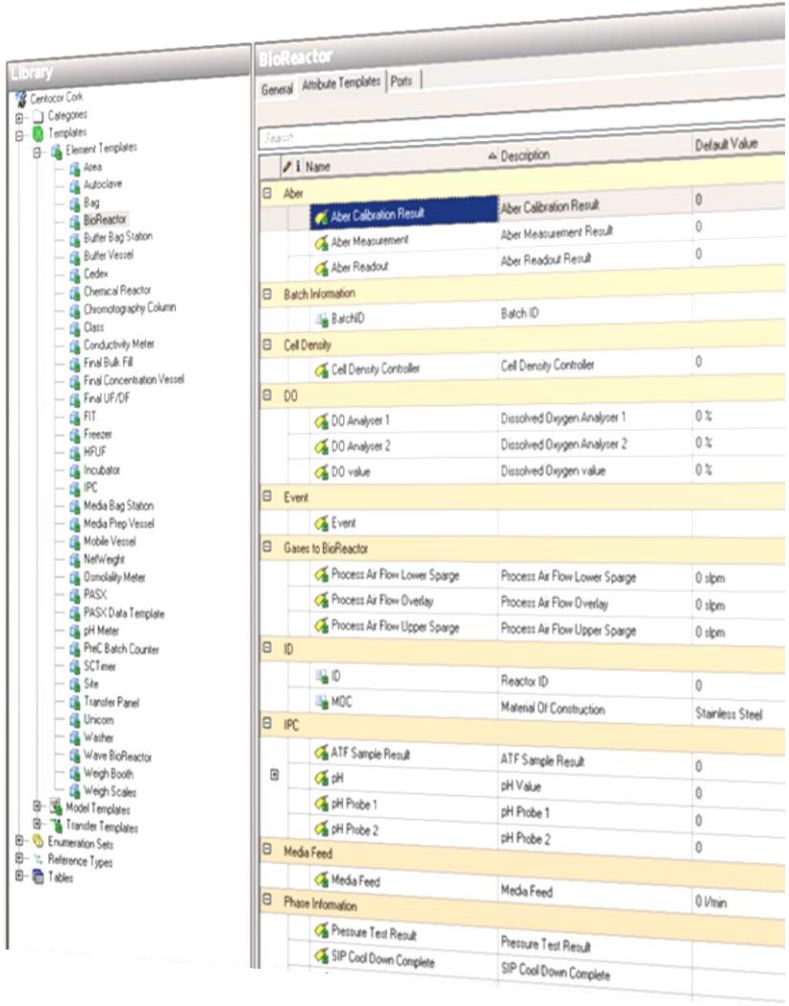
- What is PI Asset Framework ?
  - A database of user configured “Process Object Models” called elements which represent the logical components in your process.
  - Allows data from multiple PI Servers to be combined in one common view.
  - Allows the user access to non PI System data sources, e.g. external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



PI AF and Janssen

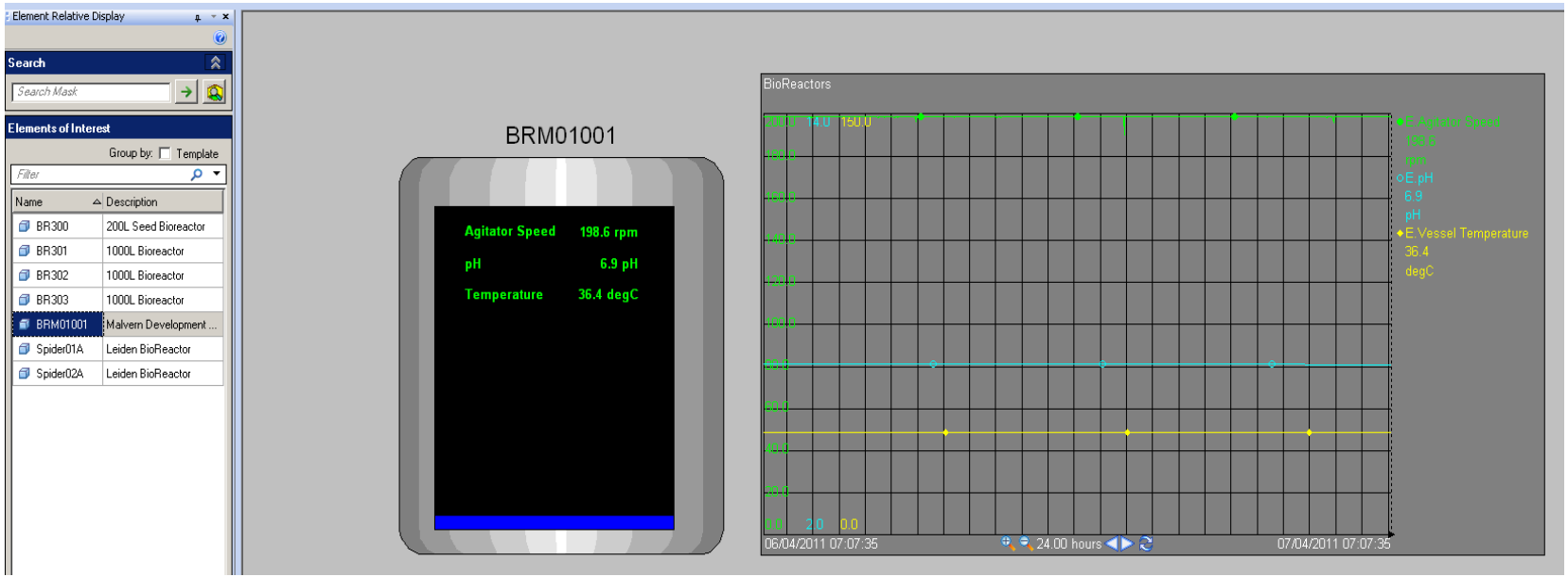
- Super Class concept.
  - Class based templates – built in conjunction with process and subject matter experts.
  - Only process critical information grouped together in a logical model.
  - Ensures that the entire organisation have a common taxonomy.

- PAS|X \ PI AF
  - Using Unit based templates allows us to build unit based MBR elements that can be applied on other sites.

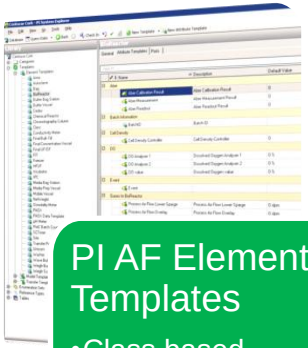


PI AF – All talking the same language.

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

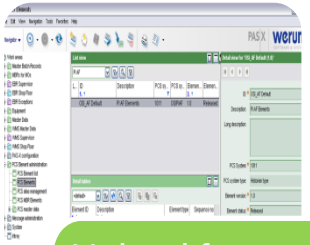


From PI AF to EBR



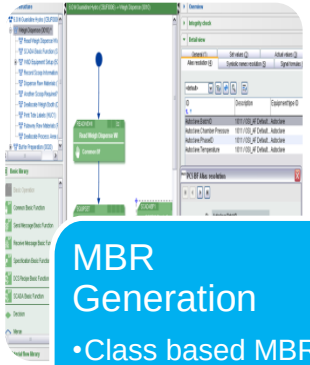
PI AF Element Templates

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



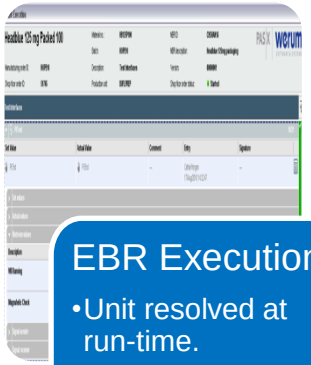
Upload from PI AF

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



MBR Generation

- Class based MBR



EBR Execution

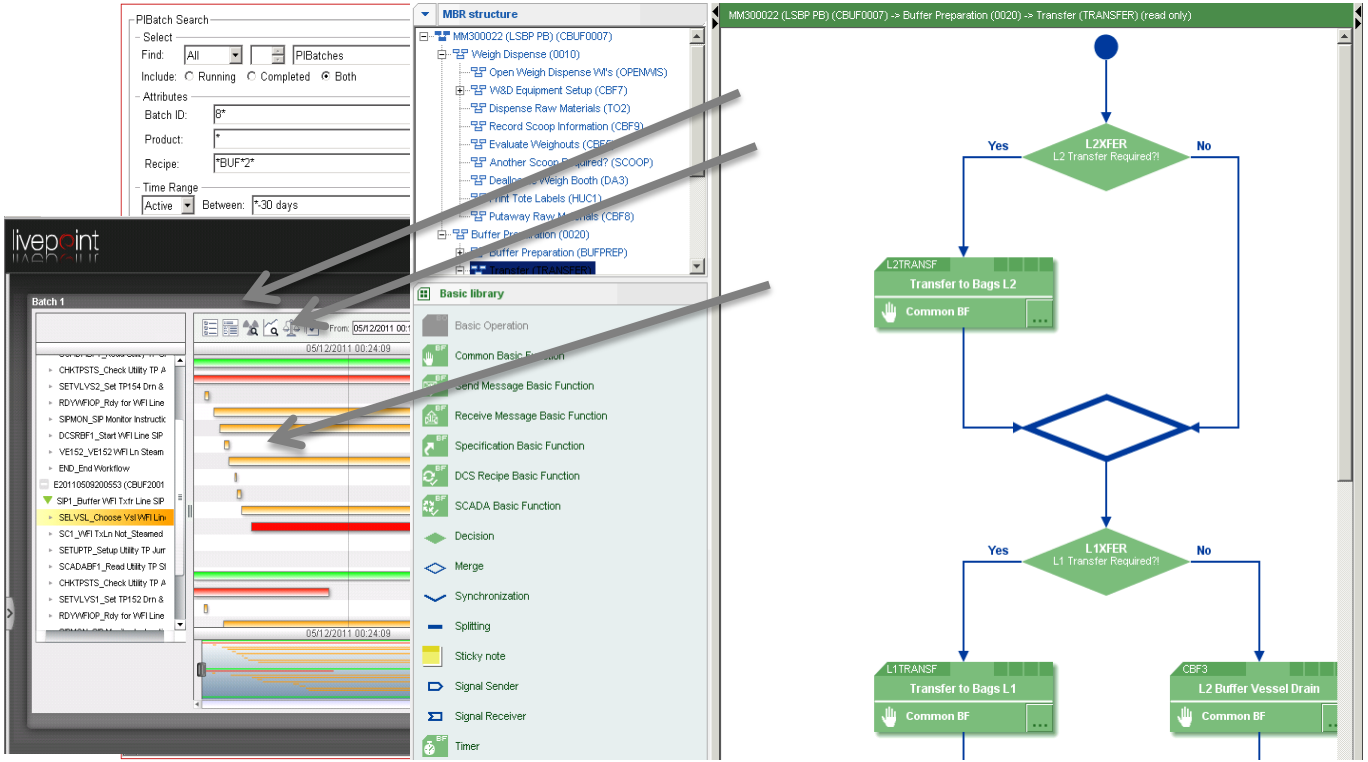
- Unit resolved at run-time.
- Data retrieved from PI AF Unit Element

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.

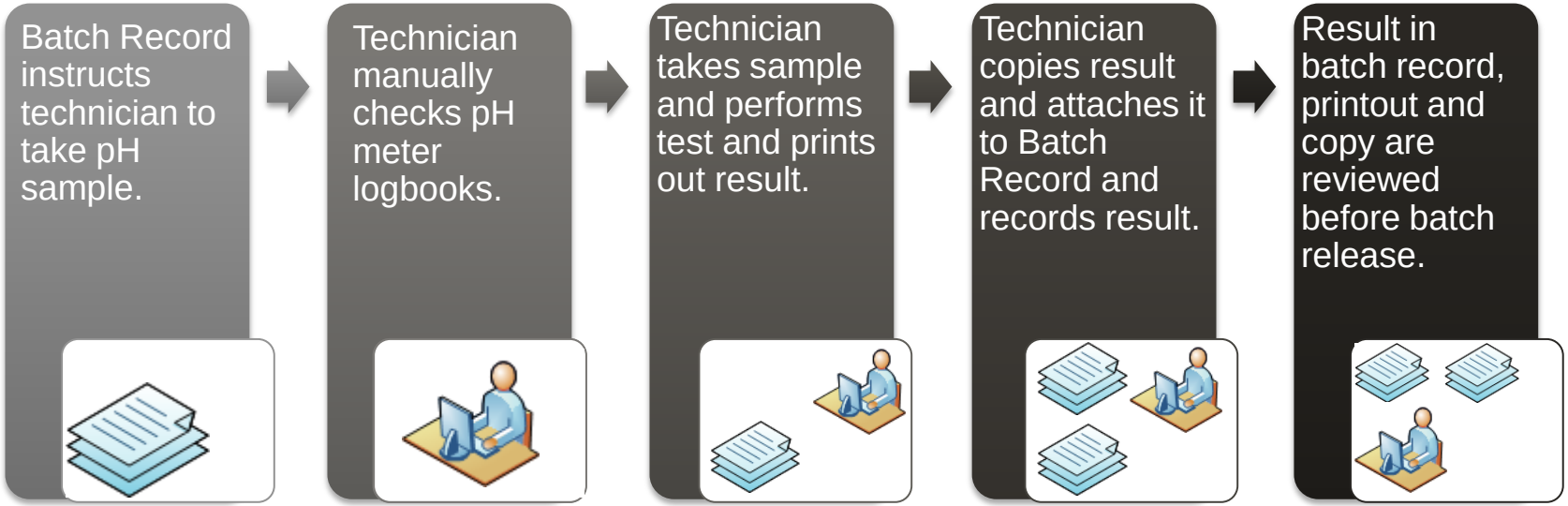
PAS|X to PI Batch

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



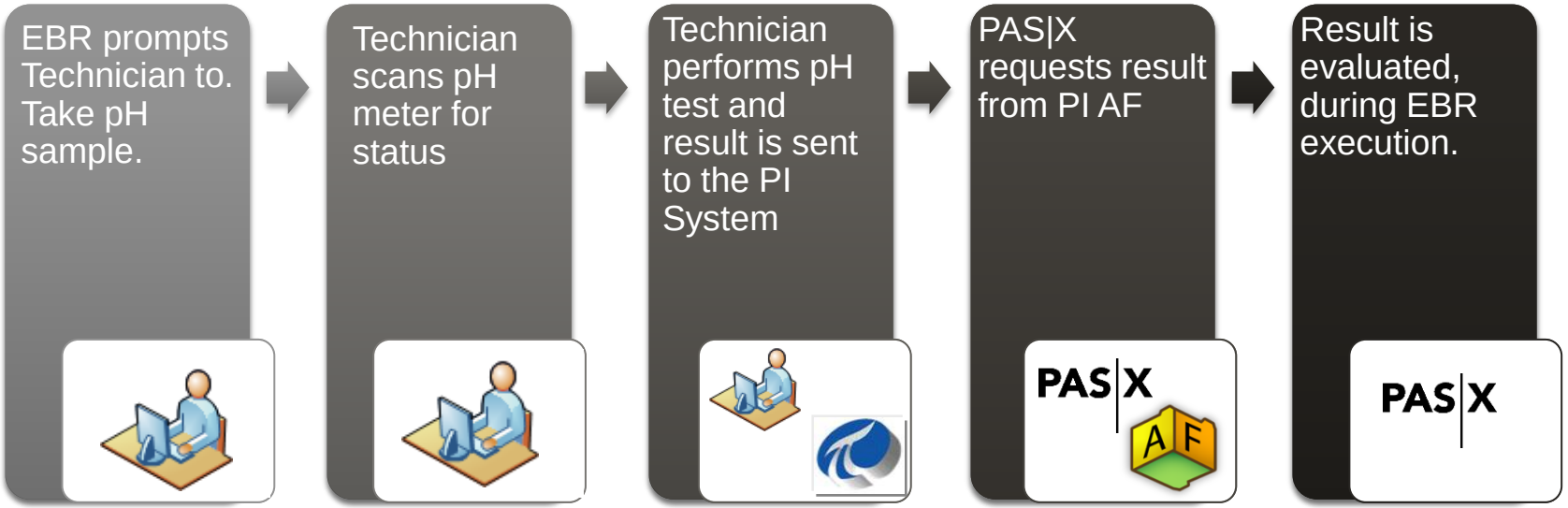
The PI System effect.

- 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

Barry Higgins

Email: bhiggin2@its.jnj.com

Thank you