

Paperless Manufacturing **Solutions With MES PAS-X** and **OSIsoft's** PI System For Bio Manufacturing

Presented by Barry Higgins, Janssen Biologics
Robert Welter, Werum Software & Systems



Barry Higgins

bhiggin2@its.jnj.com
Manufacturing Systems Engineer
Janssen Biologics, Ireland

Robert Welter

robert.welter@werum.com

Head of Department PAS-X Product Management Werum Software & Systems AG

About Janssen



- Consumer
- Medical Devices & PREZISTA (darunavir) 300 mg (darunavir) 1 tablets **Diagnostics**
- **Prescription Products**
- JSC API Supply Chain
 - Chemicals 6 sites
 - Biologics 5 sites









Remicade

INTELENCE"









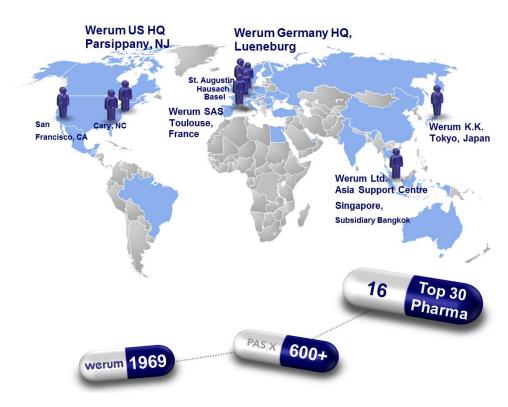




Who we are

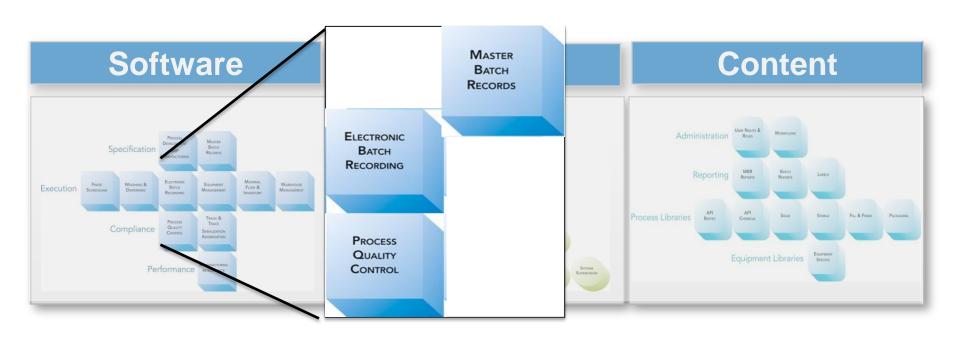






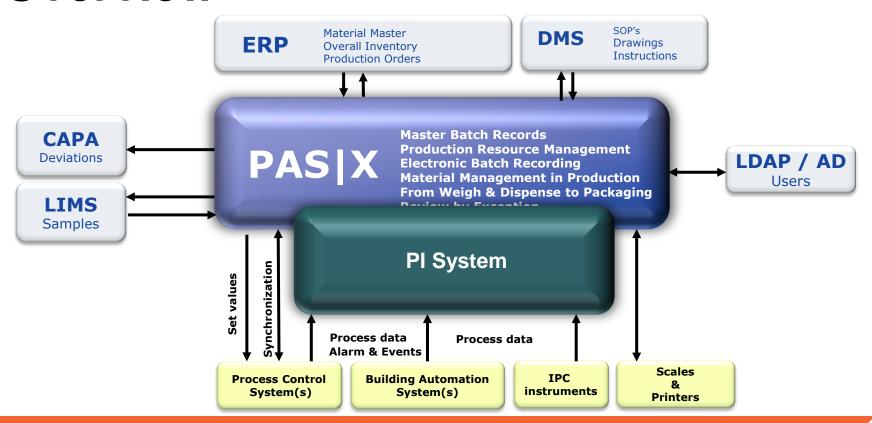
What we do





Overview





Electronic Batch Recording with PAS|X

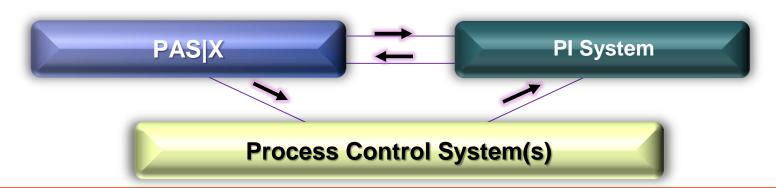




Integrated Approach

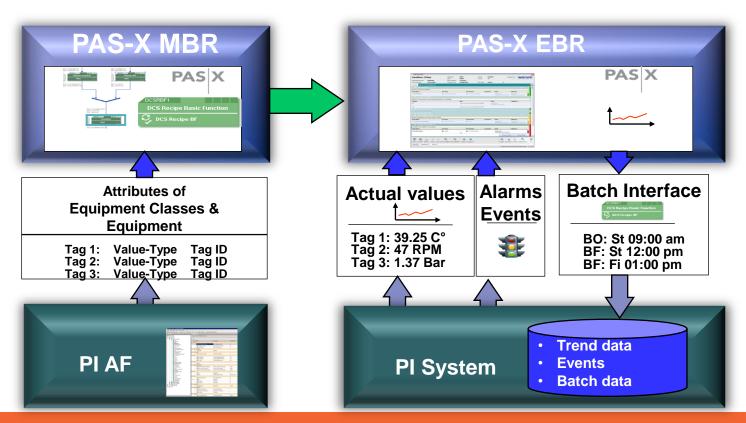


- PAS|X Commands & Set Points to Process Control System
- Process Data, Alarm & Events collected in the OSIsoft PI System
- OSIsoft PI System data referenced in the PAS|X EBR
- PAS|X EBR batch execution data referenced in the PI System



The Details





Integrated Solution - Benefits

PAS|X

PI System

Seamless integration of process data into Master Batch Record definition and Electronic Batch Recording

Handling of Alarm & Events according regulatory requirements

Batch analysis at the EBR level

Long-term archiving of process data



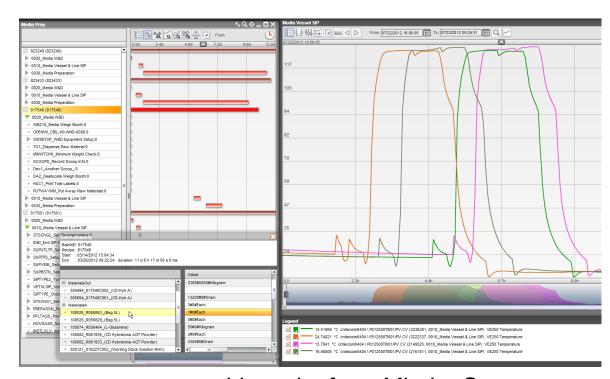
Using industry standard MES and Historian

Pro-active development of new features & functionality

Predefined, configured and reliable integration

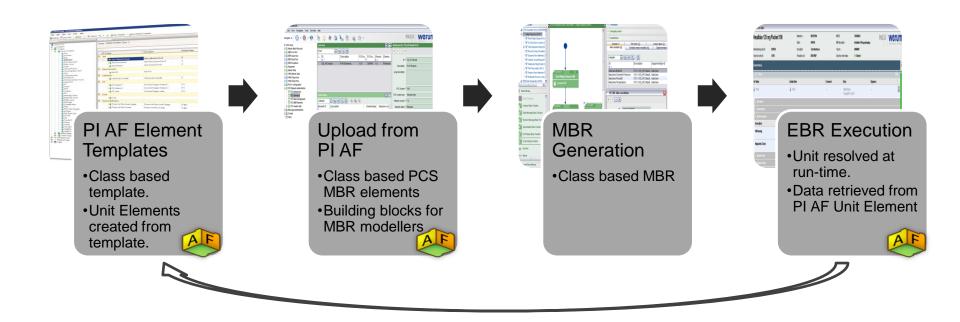
PAS|X to PI Event Frames

- OSIsoft and Werum collaborated to develop the Werum PAS-X Batch Interface which will become standard OSIsoft product.
- This enables us to perform batch analysis at the EBR level from a Basic Operation (BO) or Basic Function (BF) perspective.
- The capability to store basic function activities as batch events is similar to current DCS batch events.
- Material and equipment usage data can be captured.



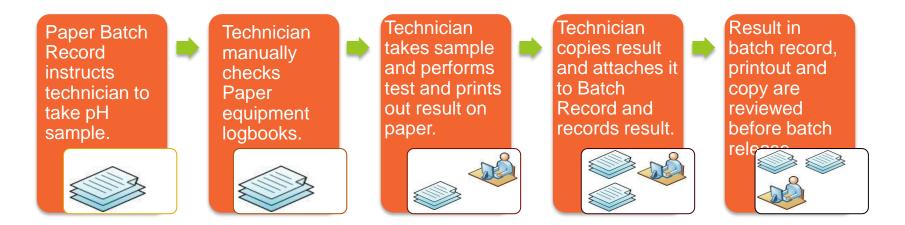
Livepoint from Mirabo Systems

PI Asset Framework – From PI AF to eBR



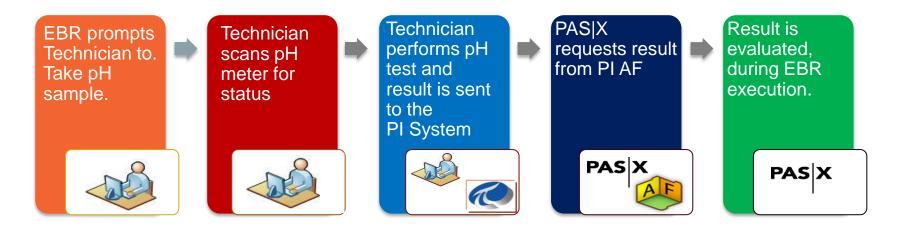
Removing Paper

pH testing before PAS|X & OSISoft PI:



Removing Paper

pH testing after PAS|X & OSIsoft PI System:



Benefits of PAS|X and PI AF

- One Screen, multiple sources of live data.
- Visual Equipment status



Benefits of PAS|X and PI AF

One location for multiple data sources:

- MES data
- SAP data
- OSIsoft PI System data
- QA information



Benefits

Removal of over 1000 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 Master Batch Record

