



The Case for TEVA Pharmaceutical

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Agenda

- About TEVA
- Challenges
- Meeting with PI System
- Solution and Application examples
 - PI DataLink (Excel Add-Ins)
 - PI Batch Generator (PIBaGen)
 - PI ProcessBook
- Benefit
- Future Opportunities
- Conclusion

TEVA – TAPI Worldwide: 20 Sites



TEVA Hungary



Debrecen

Area: 230 000 m²

Main activities: solid dosage form & API production, R&D activities



Sajóbáony

Area: 35 000 m²

Main activity: API production



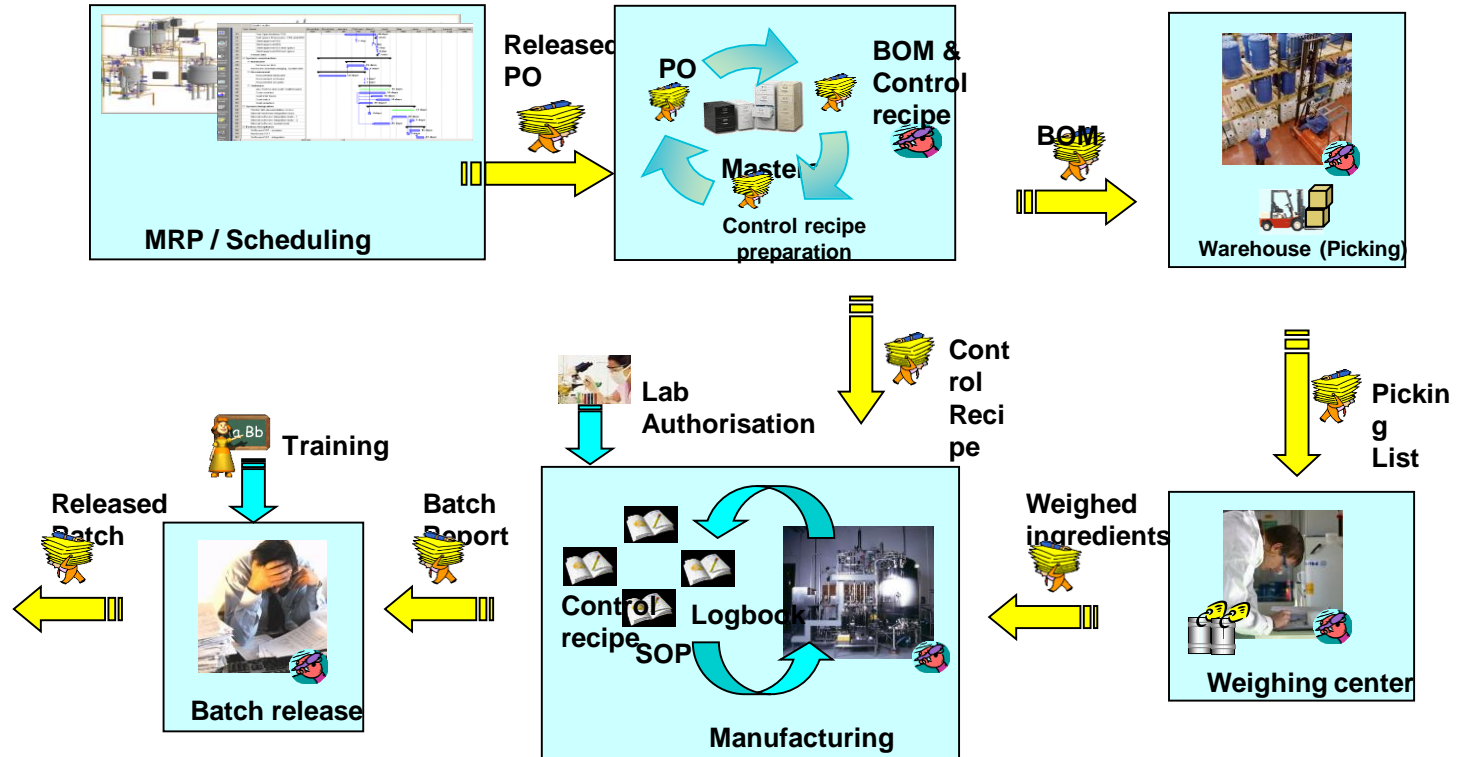
Gödöllő

Area: 207 000 m²

Main activities: sterile production, R&D activities



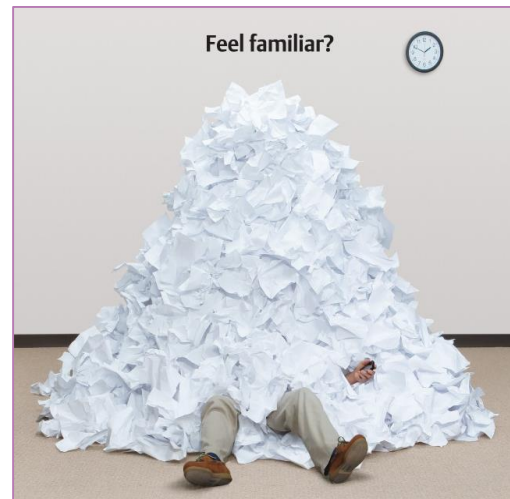
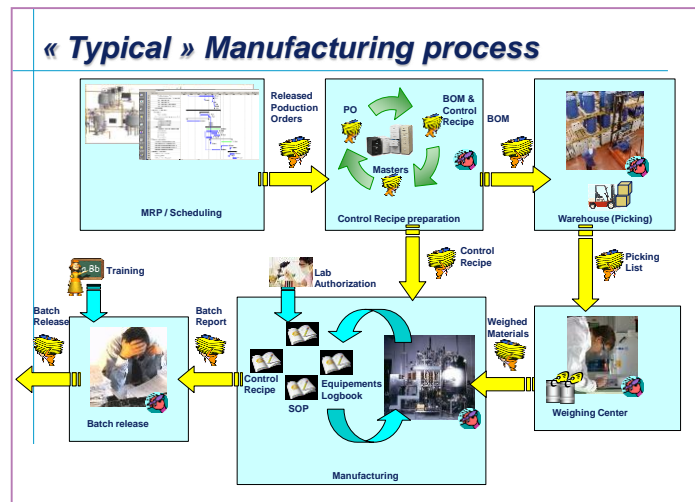
Challenges – Regulated Industry



Challenges

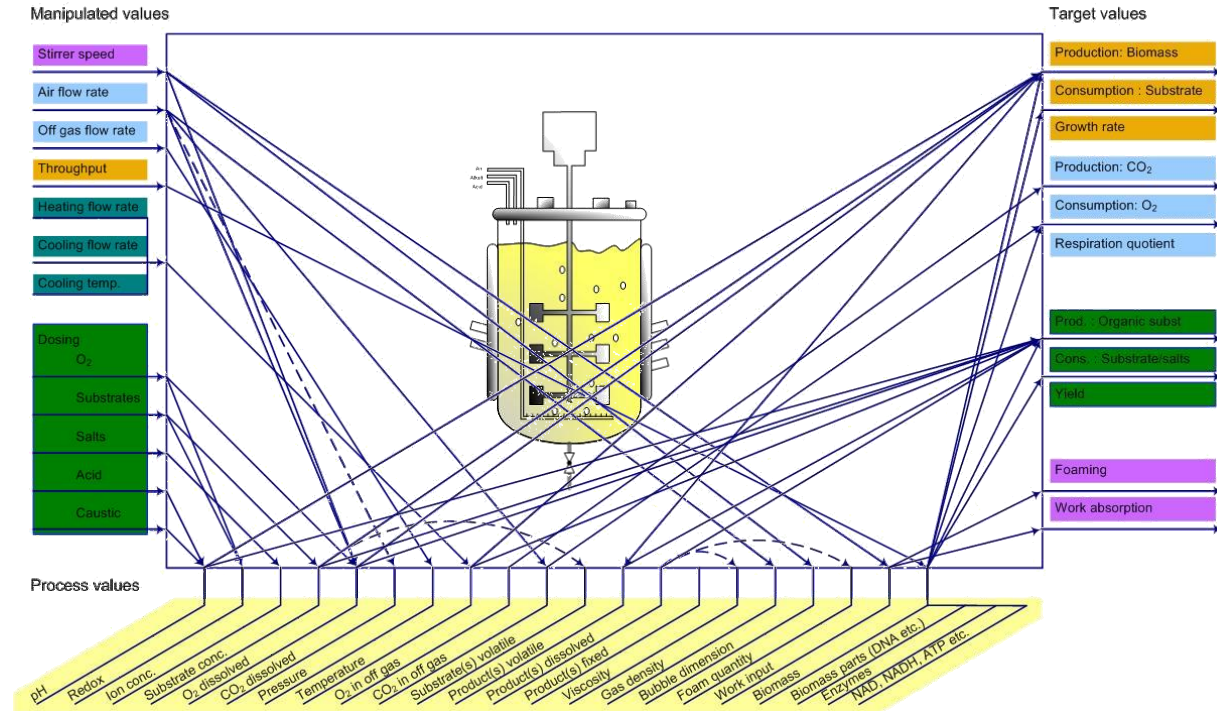
- Very strong validation requirements
→ **Stability even lack of flexibility**
- Today, subject to high economic pressures
→ **Improve industrial performance**

✓ **Paper** is the major challenge for better performance

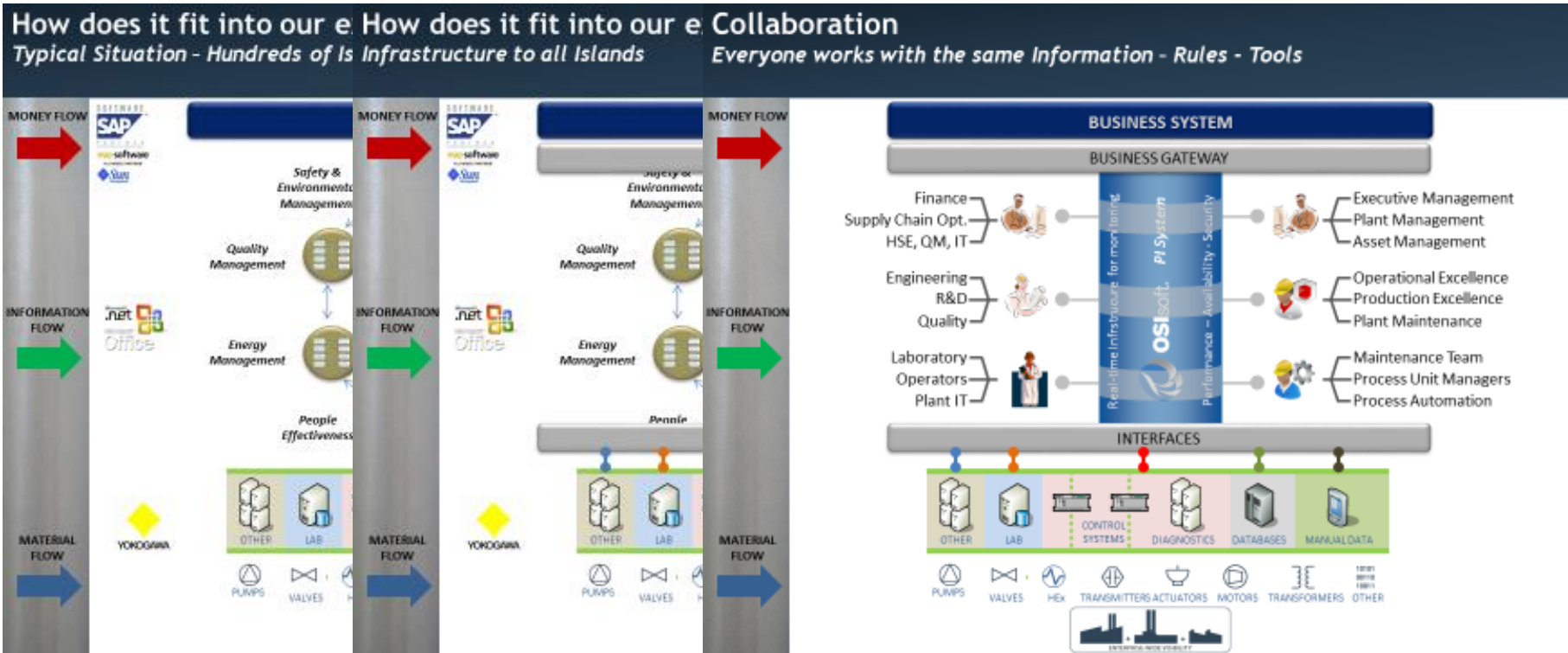


Challenges

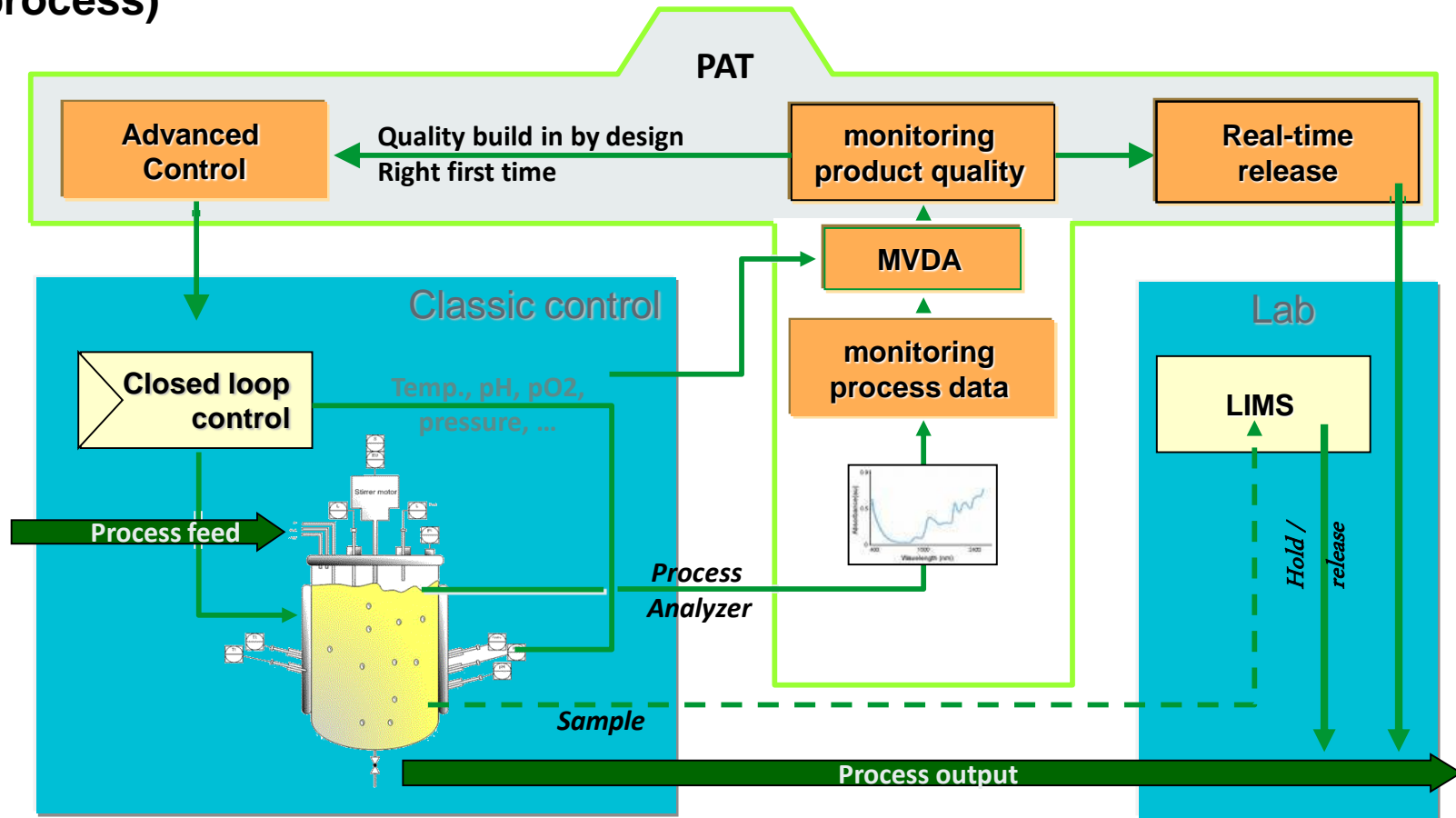
- The fermentation cycle takes a few weeks, we have to make a judgment according to the process values with a goal of ensuring final product quality.
- DATA – > It's better to have it and not need it, than need it and not have it.



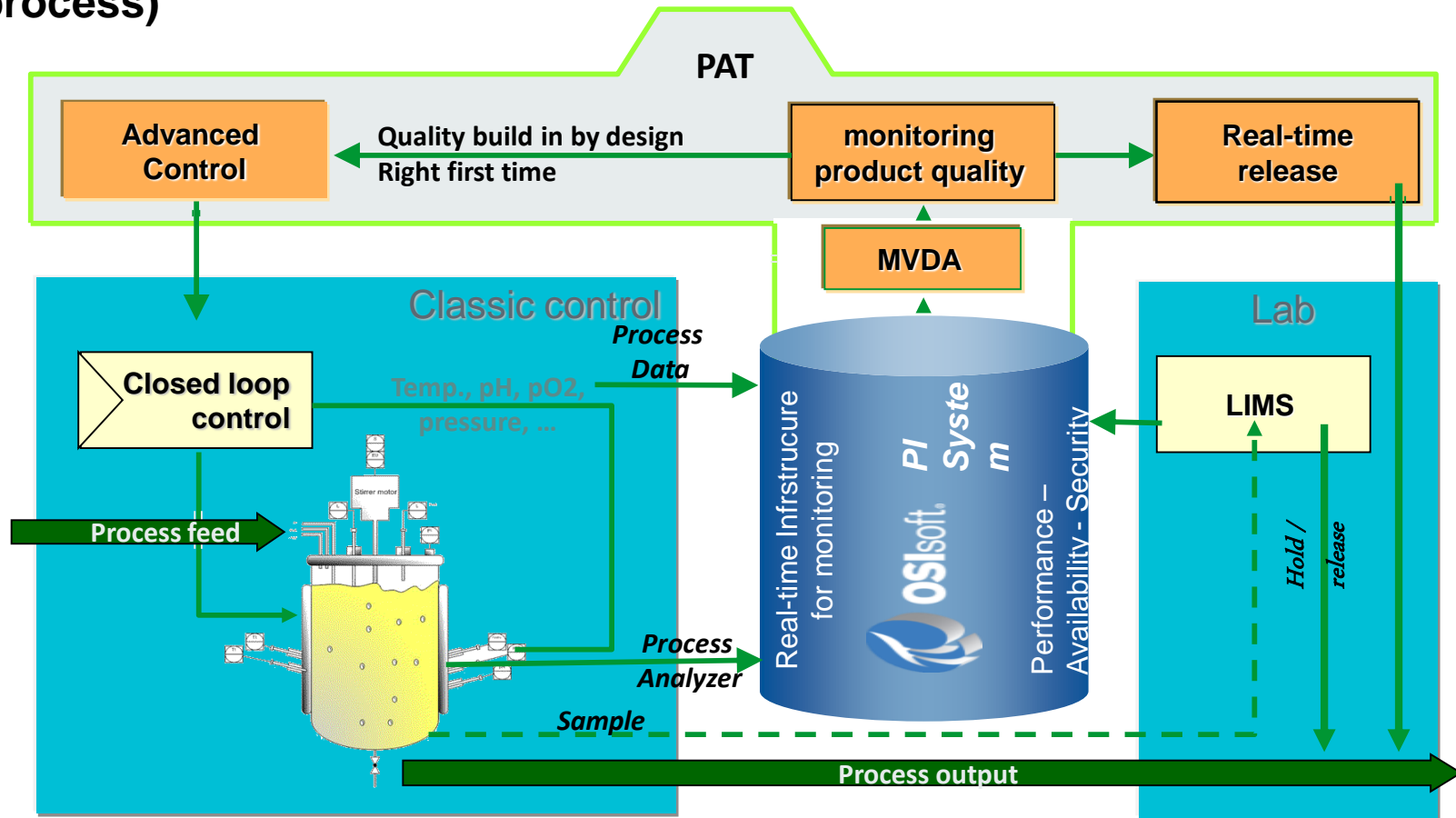
Meeting with PI System



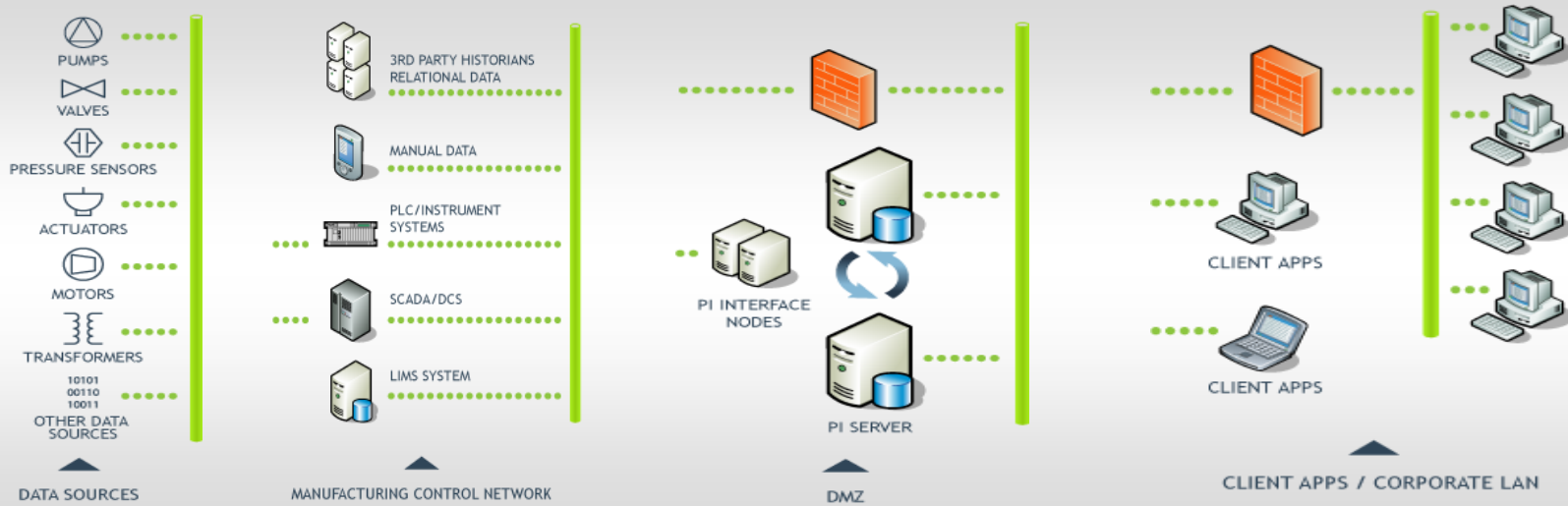
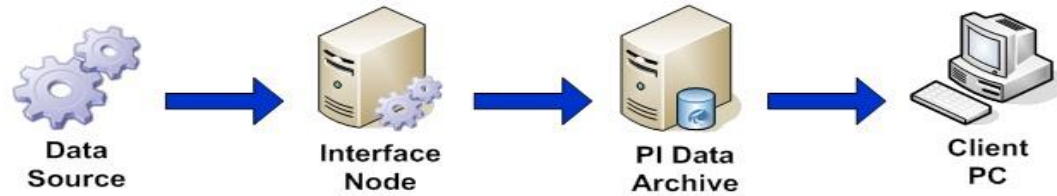
Application: PI and PAT(= Understanding + controlling the manufacturing process)



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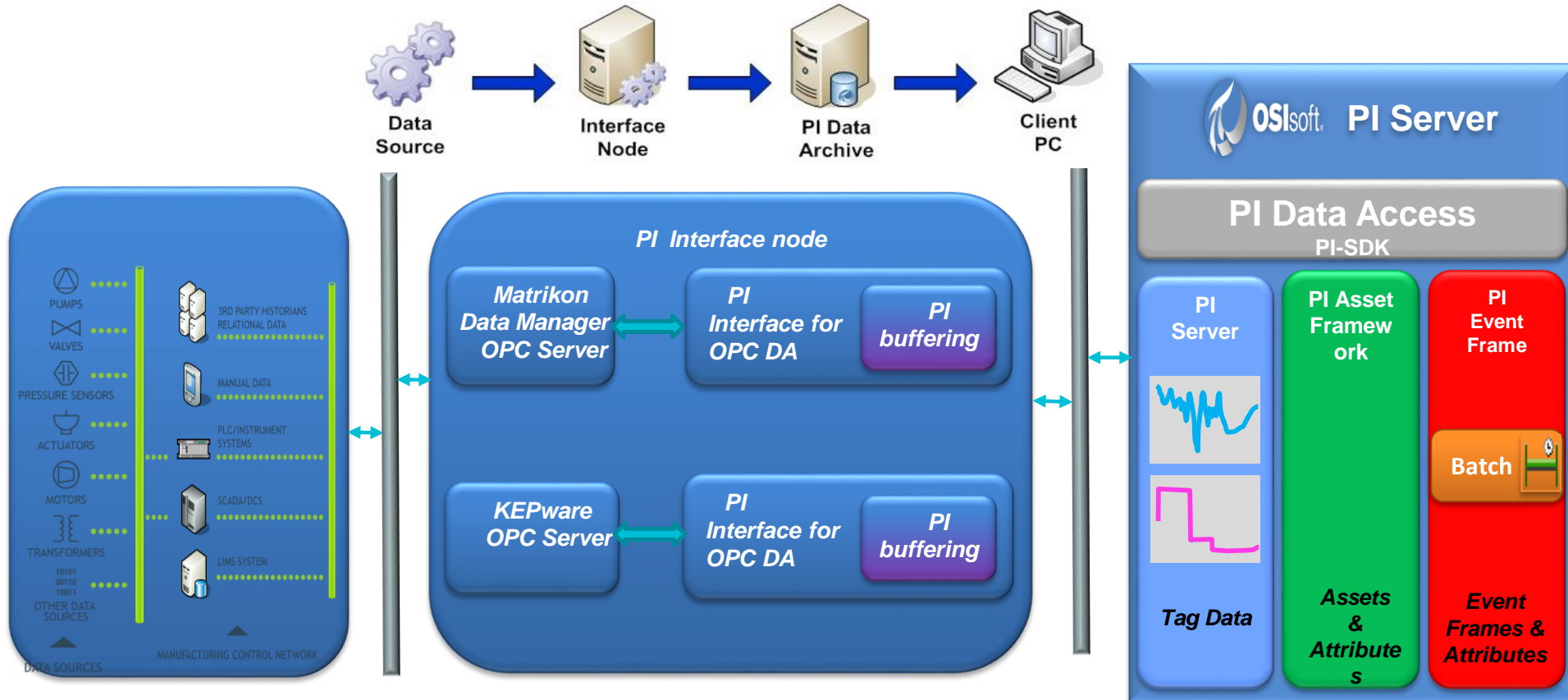


PI System Architecture



PI System Architecture

- 2000 tags
- OPC DA Interface (2 pcs)
- PI Batch Generator (PIBaGen)



The PI System in Virtual Environment

DEBAPITSM - vSphere Client

File Edit View Inventory Administration Plug-ins Help

Home Inventory VMs and Templates

DEBAPITSM

TEVA-27

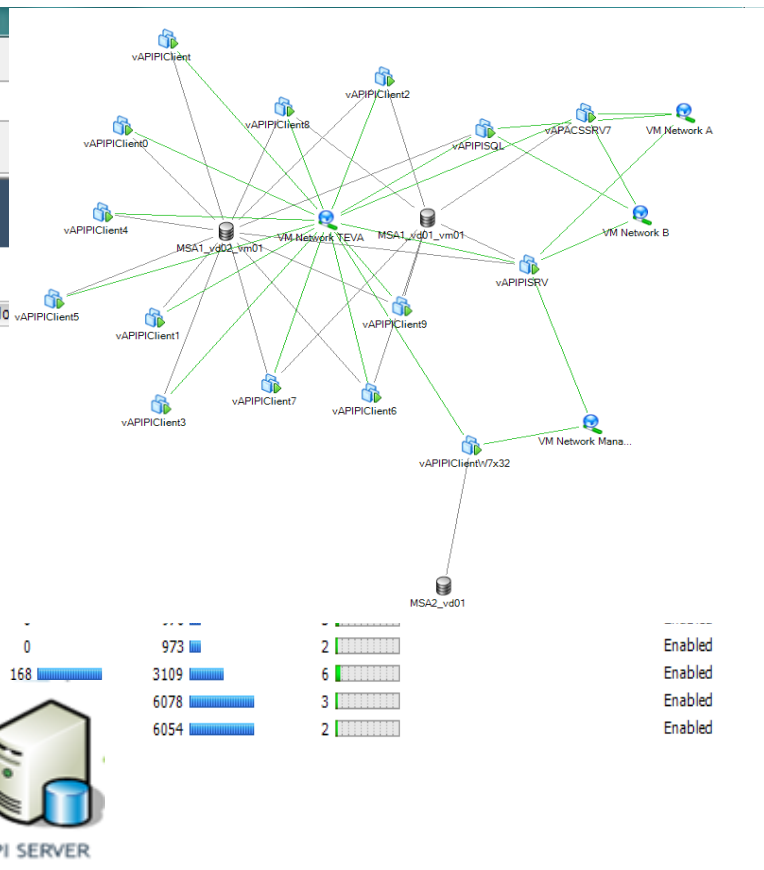
PI

Getting Started Virtual Machines Tasks & Events Alarms Permissions Maps Update Manager

PI INTERFACE NODES

	State	Status	Provisioned Space	Used Space	HO
?IClient4	Powered On	✓ Normal	25.09 GB	25.09 GB	
?IClient3	Powered On	✓ Normal	25.09 GB	25.09 GB	
?IClient7	Powered On	✓ Normal	25.09 GB	25.09 GB	
?IClient1	Powered On	✓ Normal	25.09 GB	25.09 GB	
?IClientW7x32	Powered On	✓ Normal	50.11 GB	50.11 GB	
?IClient9	Powered On	✓ Normal	25.09 GB	25.09 GB	
vAPIPIClient5	Powered On	✓ Normal	25.09 GB	25.09 GB	
vAPIPIClient5	Powered On	✓ Normal	25.09 GB	25.09 GB	
vAPIPIClient2	Powered On	✓ Normal	25.09 GB	25.09 GB	
vAPIPIClient	Powered On	✓ Normal	26.14 GB	26.14 GB	
vAPIPIClient8	Powered On	✓ Normal	25.09 GB	25.09 GB	
vAPIPIClient0	Powered On	✓ Normal	25.09 GB	25.09 GB	
vAPACSSRV7	Powered On	✓ Normal	40.09 GB	40.09 GB	
vAPIPISRV	Powered On	✓ Normal	198.11 GB	198.11 GB	
vAPIPISQL	Powered On	✓ Normal	326.11 GB	326.11 GB	

PI SERVER



PI SMT (System Management Tool)

The screenshot displays the PI SMT (System Management Tool) interface. The left pane shows a tree view of the system structure, with 'PI System Management Tools' highlighted. The middle pane shows a list of servers and points, with 'CPR2401.FV' selected. The right pane shows a list of tools, with 'PI System Management Tools' selected. A red circle highlights the 'PI System Management Tools' section in the left pane.

PI System Management Tools

PI SMT consists of a container application, known as the host, and a library of plug-in tools designed for specific management tasks. Select a tool in the **System Management Tools** tree and the tool appears. In some cases the tool is disabled until you select one or more PI Servers.

Note: SMT tools are not standalone applications and cannot be placed in user-written programs, with the exception of the **Archive Editor** and **Module Database** tools, which are also available as part of **PI SDK** tools.

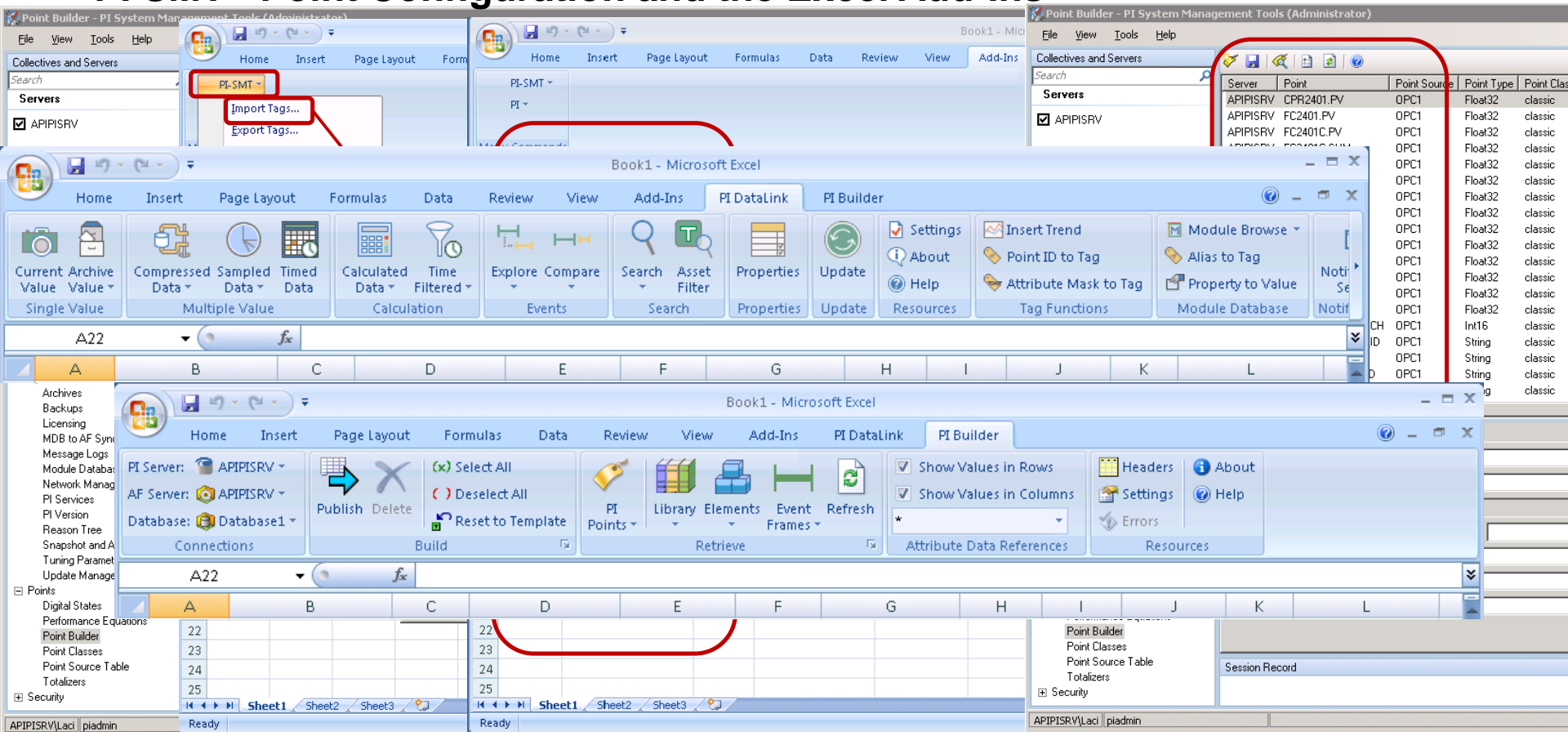
In This Section

- [Select a Server](#)
- [View the Session Record](#)
- [See How You Are Connected](#)
- [Set the Time Format](#)

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PI SMT - Point Configuration and the Excel Add-Ins



PI Batch Generator example

PI System Management Tools (Administrator)

File View Tools Help

Collectives and Servers

Search

Servers

☒ APIISRVR

System Management Tools

Search

Alarms

Batch

Batch Custom Names

Batch Database

Batch Generator

Data

Interfaces

IT Points

Operation

Archives

Backups

Licensing

MDB to AF Synchronization

Message Logs

Module Database

Network Manager Statistics

PI Services

PI Version

Reason Tree

Snapshot and Archive Statistics

Tuning Parameters

Update Manager

APIISRVR

HeadingSets

Modules

%DSI

%DSI_MCN

API

DEB

SBB

UNF2401

Aliases

AirFlow

BATCHID

BSTS

CO2

CPR

Glucose

GlucoseSUM

Mixing

O2

OUR

pH

PO2

PROD_ID

SPHASE

Temperature

Weight

PIBaGen

UNF2402

Manipulated values

Stirrer speed

Air flow rate

Off gas flow rate

Throughput

Heating flow rate

Cooling flow rate

Cooling temp

Dosing

O₂

Substrate

Salts

Acid

Caustic

Process values

pH

Redox

Ion conc.

Substrate conc.

O₂ dissolved

CO₂ dissolved

Pressure

Temperature

O₂ in off gas

CO₂ in off gas

Substrate(s) volatile

Product(s) volatile

Product(s) dissolved

Product(s) fixed

Viscosity

Gas density

Bubble dimension

Foam quantity

Work input

Biomass

Biomass parts (DNA etc.)

Enzymes

IMD, TADH, ATP etc.

Target values

Production: Biomass

Consumption: Substrate

Growth rate

Production: CO₂

Consumption: O₂

Respiration quotient

Prod. - glucose (g/L)

Prod. - Substrate (g/L)

Yield

Foaming

Work absorption

Session Record

APIISRVR\Laci piadmin

PI Batch Generator example

The image displays two screenshots of the OSIsoft PI Batch Generator software interface, illustrating a process flow for a fermentation batch.

Left Screenshot (UNF2401 SFC):

- Process Flow:** A sequence of steps: 1 Start, 2 Fermentation, 3 End. A red box highlights the 'Start' step.
- Batch Generator:** A sidebar on the left lists various data sources and interfaces. A red box highlights the 'Fermentales' step in the 'Batch Generator' list.
- Process Diagram:** A central diagram shows a fermentation vessel with various inputs and outputs. A red arrow points from the 'Start' step to the 'Fermentales' step in the 'Batch Generator'.

Right Screenshot (UPR2401 SFC):

- Process Flow:** A sequence of steps: 1 Initialize, 2, 3 Alaphelyzet, 4 Reszenlet, 5 Szurot.steriliz, 6 Uresagos.steriliz, 7, 8 Tpt.Fogadas, 9 Tpt.steriliz, 10 Oltas, 11 Fermentales, 12, 13 Hidrolizis, 14 Reszleengedes, 15 Mozas, 16 Emergency, 17, 18. A red box highlights the 'Fermentales' step.
- Batch Generator:** A sidebar on the left lists various data sources and interfaces. A red box highlights the 'Fermentales' step in the 'Batch Generator' list.
- Process Diagram:** A central diagram shows a fermentation vessel with various inputs and outputs. A red arrow points from the 'Fermentales' step to the 'Fermentales' step in the 'Batch Generator'.

PI Batch Generator example

The screenshot displays the PI Batch Generator interface for a process named UNF2401. The main window shows a process flow diagram with various steps and operations. A red box highlights the 'Start' step (1) and the 'Fermentales' operation (11). A red arrow points from the 'Fermentales' operation to the configuration window on the right.

The configuration window, titled 'Configuration for', shows the following settings:

- Active Point: UNF2401.RUNS
- ActivePoint Behavior: ☒ Pulse, ☐ Step
- Include zeroth state (Continuous): ☐
- Strings indicating zeroth state (example: Inactive,Stop,Off): END
- Unit Batch ID Point: UNF2401.BATCH_ID
- Product Name Point: UNF2401.PROD_ID
- Procedure Name Point: UNF2401.SPHASE
- Evaluation Delay: 5 seconds
- Evaluate at the end of each UnitBatch: ☐
- Recovery Options: ☐ Do not recover anything, ☒ Recover all PI Batch Objects, ☐ Recover only PIBatches and PIUnitBatches
- Recovery time (in days): 4
- Merge Consecutive: ☒ Off, ☐ On
- PIUnit Debug messages: ☒ Off, ☐ On

PI BatchView with ProcessBook

PI ProcessBook - [Display1*]

File Edit View Insert Tools Draw Arrange Window Help

Batch Definition

Main Layout Settings

Search Parameters

Find: All PIUnitBatches APIISRV Search

Include: ☐ Running ☐ Completed ☒ Both

Batch ID * Product * Unit Name UNF240*

Time Range and Duration

Active Between: *-1 day and * Any Length

Batch ID	Start Time	End Time	Product	Unit Name	Proc
70120201114	5/17/2014 3:00:...	Still Running	701	UNF2406	
70120201014	5/14/2014 1:41:...	Still Running	701	UNF2404	
70120200914	5/12/2014 1:53:...	Still Running	701	UNF2403	
70120200814	5/10/2014 3:59:...	Still Running	701	UNF2402	
70120200714	5/7/2014 8:08:3	Still Running	701	UNF2401	

Available Aliases:

☒ Common ☐ All

Mixing O2 OUR PO2 PROD_ID

Add Alias -> Tag Search... Custom Placeholders

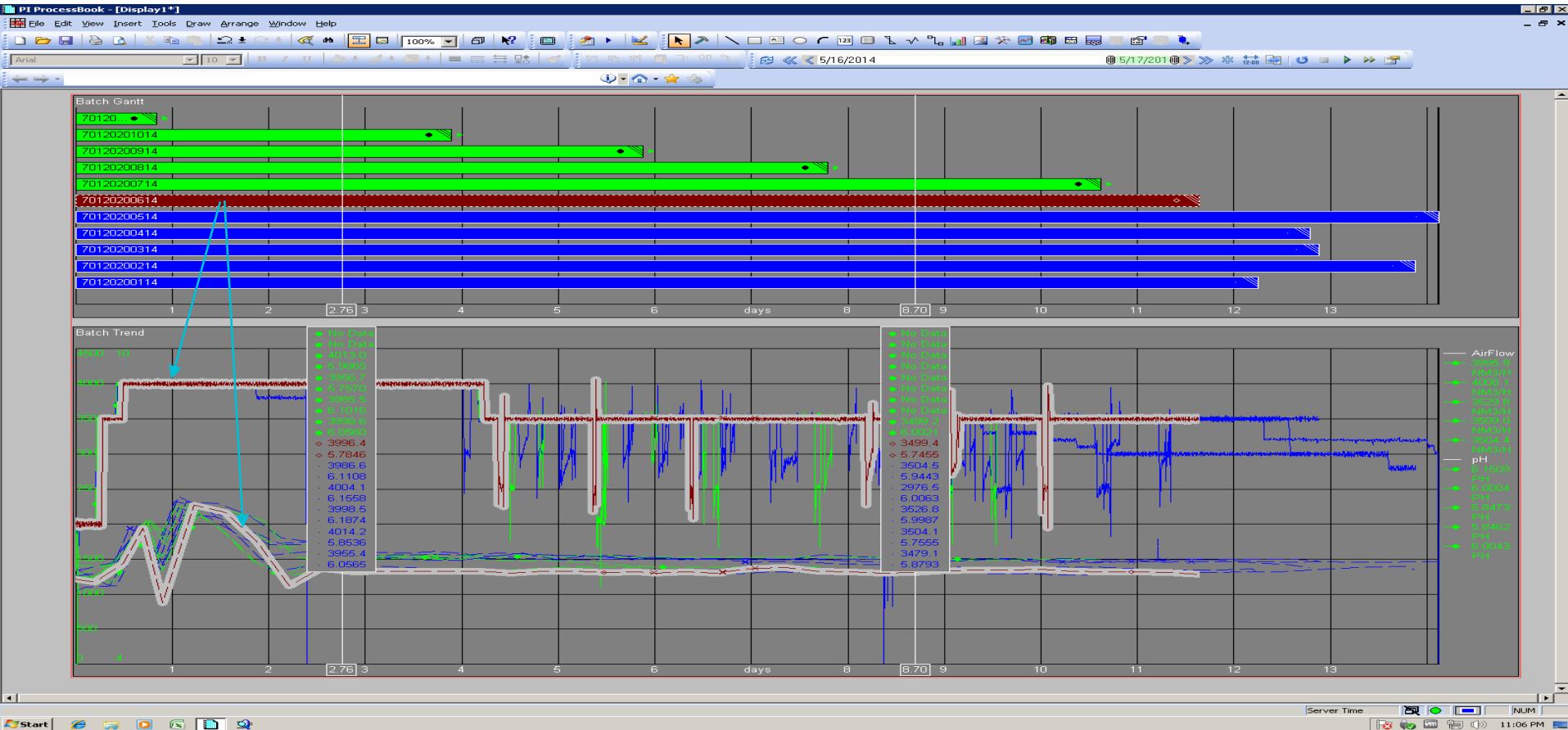
Tags/Aliases

AirFlow pH

OK Cancel Help

Ready Server Time NUM

PI BatchView with ProcessBook



Benefit

- Less paperwork
- Site-wide process visibility
- Batch tracking, investigations
- Users can get the data what they need

Future opportunities

- Batch Reporting based on RtReports
- More data source - PI Server extension
- More eyes on PI System – new clients
- MES integration
- Technology transfer from “Glass lab” to full scale manufacturing

Conclusion

Business Challenge

- Automate the manufacturing workflow
- Provide an easy tool for comparing and analyzing batches
- Provide a standard rapid and cost effective approach to capturing key process data

Solution

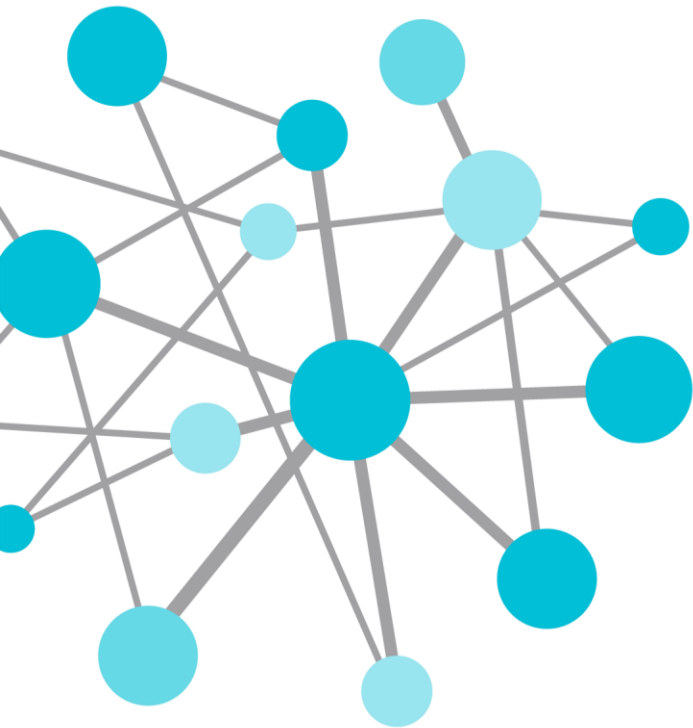
- PI System with Batch functionality

Results / Benefits

- Less paperwork
- More focus on process less time with data mining
- Optimized batch cycle time
- Better equipment utilization

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THANK
YOU

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