

Integrating OSIsoft PI System with synTQ for High Performance, Low Maintenance PAT Method Integration



Presented by: Mairtin Mc Namara (J&J)
Martin Gadsby (Optimal)



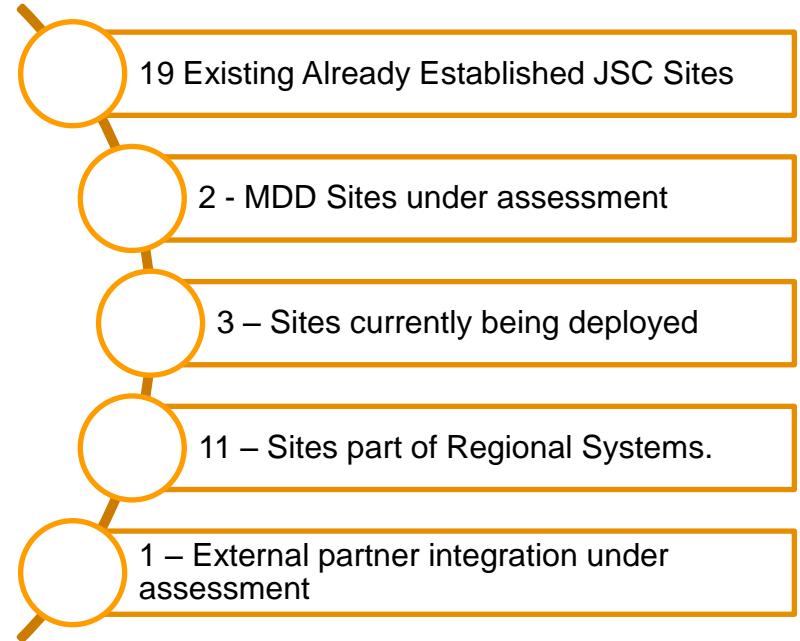
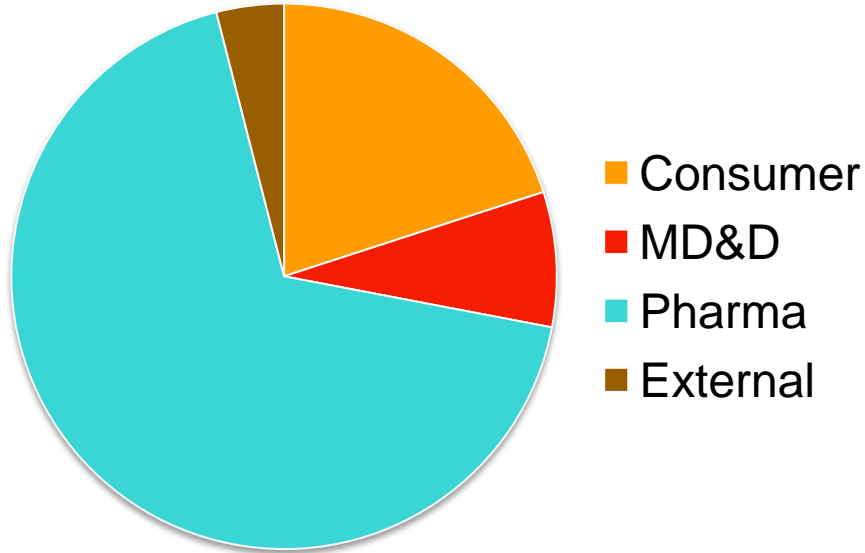
Overview

- Introduction *Johnson & Johnson, Mairtin Mc Namara PhD*
 - JnJ + PI
 - JnJ + PAT
 - PI + PAT = synTQ...?

- synTQ *Optimal, Martin Gadsby*
 - What is synTQ?
 - Case study
 - Evolving trends
 - Next steps
 - Benefits

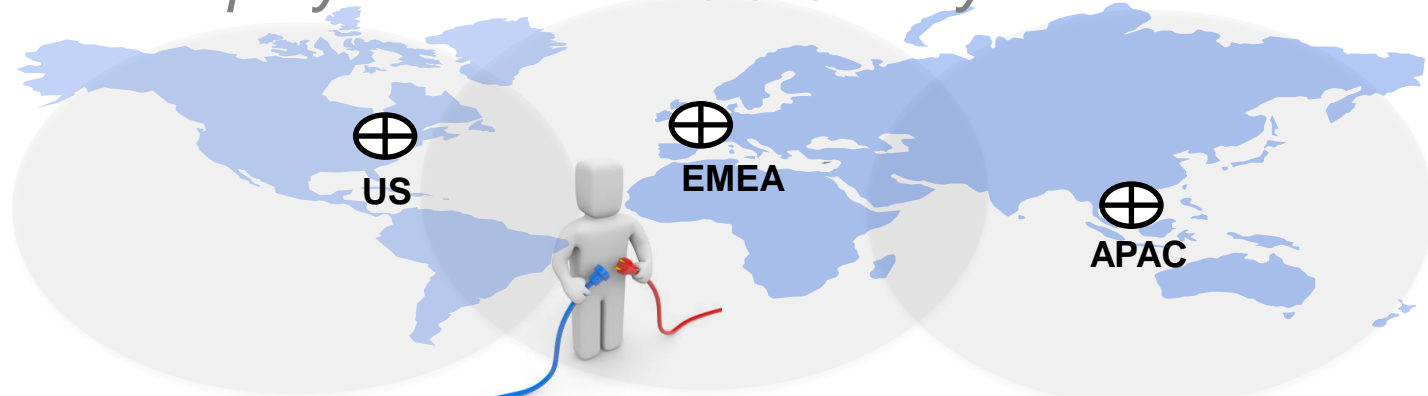
Current PI Landscape in J&J

- 26 Sites



Ready to Connect – Existing Infrastructure

- *Fully supported application infrastructure with 24/7 Health Monitoring.*
- *Sites connect to local API nodes which then connect to regional servers.*
- *Faster deployment of the OSISoft systems*



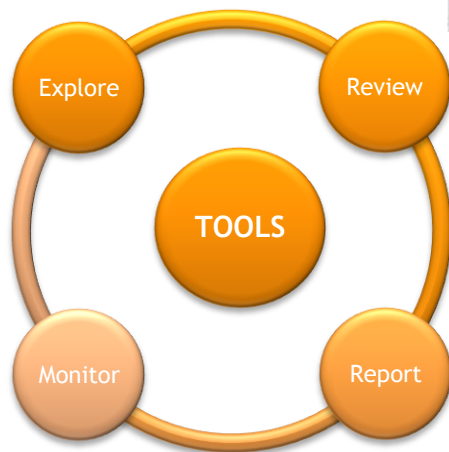
What Tools are J&J Using?



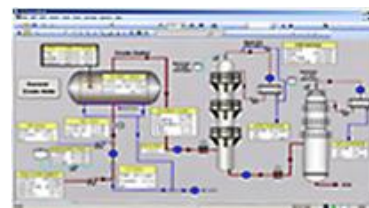
PI Coresight:
Ad Hoc Analysis &
Collaboration



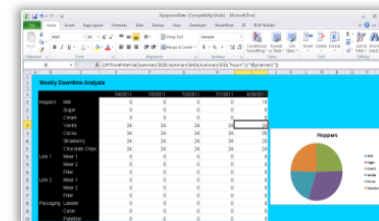
Livepoint:
Real time & Batch/ Batch Analytics
Cycle Time Retrieval
Energy & Utility Monitoring
Alarm & Event Visualization



- The OSIsoft PI platform is a key enabler to Process Data Collection for BI initiatives like CPV and Advanced Analytics



PI ProcessBook:
Display authoring and
Process monitoring



PI DataLink:
Reporting using
Microsoft Excel



RtReports
Automated Batch/ Program Report
Generation
Utility Systems Time Based Reporting

What is PAT?

- What isn't PAT?
 - “Traditional” measurements: Temperature, pressure, level meter, cake thickness, ...
- PAT more sophisticated eye on the process & answers:
 - Input concentration during my reaction step?
 - Much variation on my reaction end-point?
 - Particle size during my crystallization?
 - ...
- Measuring and ultimately controlling product quality is a key differentiator to ‘traditional’ plant operation

What is PAT?

- PAT realtime monitoring of process properties that can be used to optimize:
 - Product Quality
 - Cost of process development and manufacturing
 - Speed of development and manufacture
- This in turn enables:
 - The reduction of rework and waste
 - The reduction of Work In Progress (WIP)
 - The use of lower cost raw materials

As we always say, PAT is:

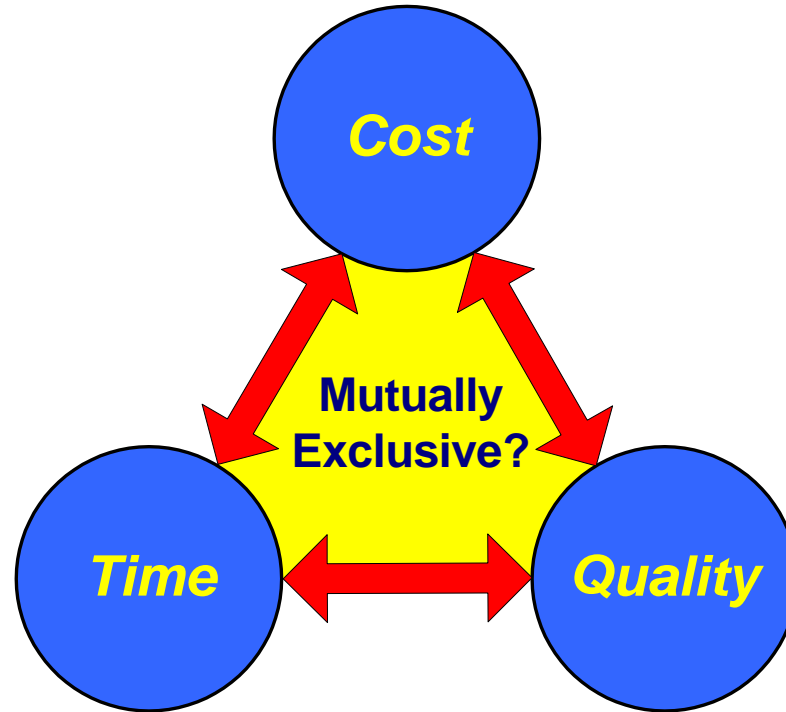
Measure

Understand

Control

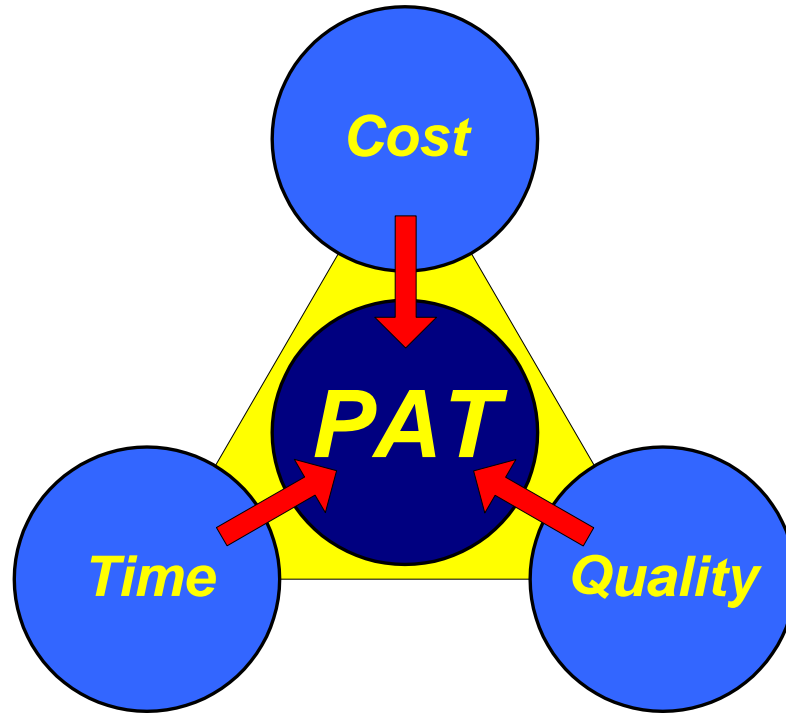
Production Drivers

The key drivers of production
(and development) are
traditionally mutually exclusive



The Role of PAT

PAT is one of the few technologies that enables you to optimize all 3 drivers



Why Use PAT in Manufacturing - Summary

- PAT enabled processes:
 - Measure your product quality in real time
 - Control actions based on product quality
 - Raw material variability catered for
 - Less rework and wastage
 - Reduced Work in Progress (WIP)
 - Shortened development and manufacturing times
 - Increased productivity, product quality and profitability



Where are Janssen Using PAT ?

- A number of PAT related projects ongoing across Janssen

Site	Area	PAT Instruments	Uses
Small Molecule	Solids Development – Continuous Manufacturing	Near Infra Red	LOD, Blend Uniformity, Content Uniformity.
Small Molecule	API Development	Fixed Beam Reflectance Measurement (FBRM) Mass Spectrometer Mid infrared refractive index	Crystallization profiling Endpoint detection of drying. Reaction chemometrics and profiling Solvent swaps, crystallization, phase splits profiling
Small Molecule	Laboratory - Commercial	Near Infra Red	Content Uniformity
Small Molecule	Solids Commercial – Continuous Manufacturing	Near Infra Red	Blend Uniformity, Content Uniformity
Large Molecule	API Development	Raman Spectroscopy	Closed loop feedback control on bioreactor. MVA model execution.
Large Molecule	Drug Product Development – Liquid Filling	Mass Spectrometer Slope Spectrometer	End Point detection of drying Online monitoring of protein concentration

Something is missing...

Data consolidation!

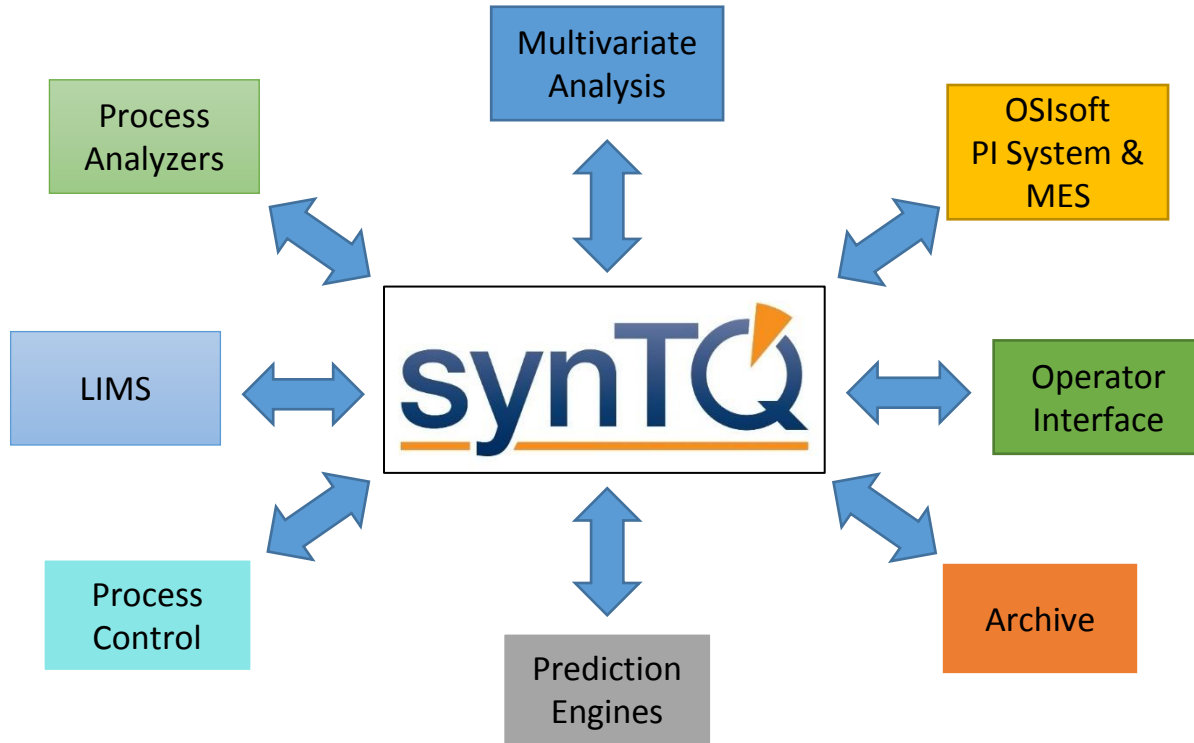
The Role of OSIsoft Products and synTQ

- OSIsoft products and synTQ are used together to great effect by many manufacturers.
- Typically OSIsoft PI System takes responsibility for all univariate and batch data
- synTQ is responsible for all PAT Methods (Orchestrations) and spectral data.
- Such systems are being used in R&D, Pilot Plants and full scale GMP Manufacturing, leveraging the advantages of both products.

What is synTQ?

- Put simply, synTQ is a Data/Knowledge Manager to enable the implementation of Process Analytical Technology (PAT)
- It interfaces to multiple systems such as:
 - Spectral\Multiarray data sources and instruments
 - MVA packages
 - Univariate data producers and consumers
- It permits the building of PAT Methods (Orchestrations) without the need for software
- It is used extensively in batch and continuous processes

What is synTQ?



Put simply, synTQ is the central co-ordinator that allows:

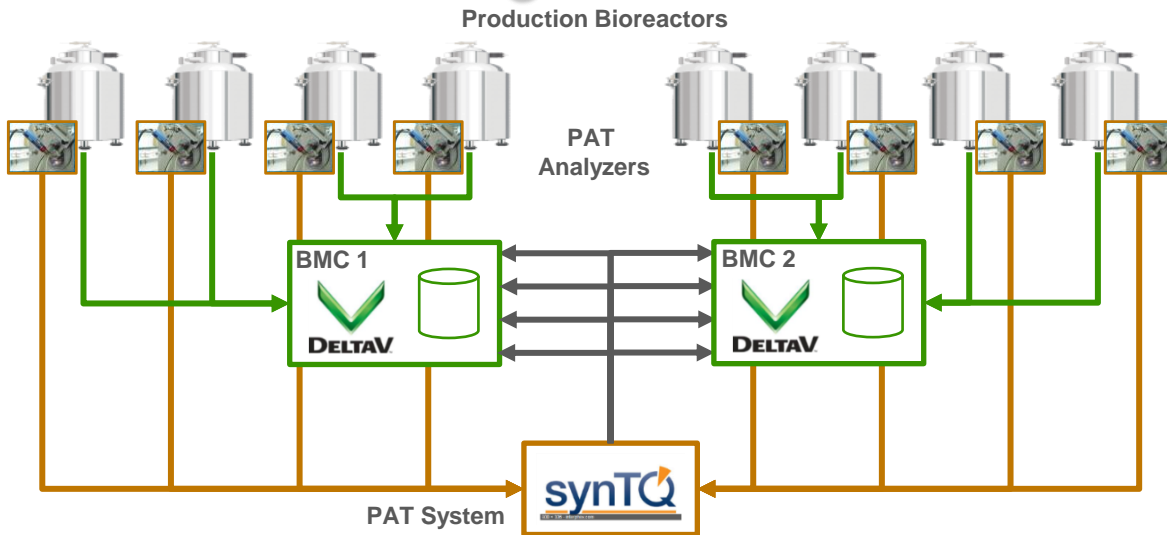
- Disparate system interfacing & collaboration
- Easy PAT Method (Orchestration) creation
- Real time quality predictions
- PAT based real time control
- Effective SME functioning
- Regulatory compliance

An OSIssoft and synTQ example use case:

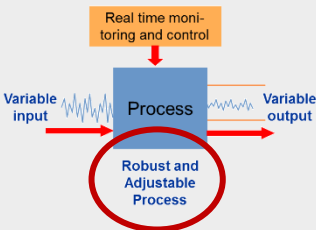
Using PAT to Reduce Variability in a High-Throughput Biologics Manufacturing Plant

Biogen's Next-Generation Facility

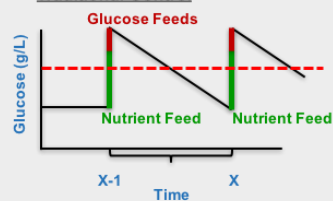
- Under construction in Solothurn, Switzerland
- Start production in 2019
- Bio-Manufacturing Cells (BMC)
 - Initial: 2 BMCs, ~10 Metric Tons
 - Expandable to 35 Metric Tons
- 3X platform – up to 15 g/L CC titer
- 55,000 m² in Phase 1
- Advanced Model-Based Control



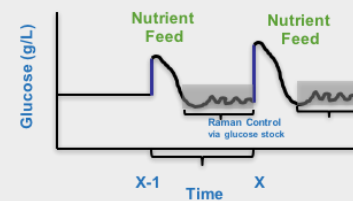
PAT Systems, models, and In-Line Analyzers to improve control to drive process efficiency and reduce variability



Traditional Control



Raman based Control



The Market Trend

- PAT is now being rolled out company wide for many customers
- There is a growing trend where PAT is being applied to multiple, identical unit operations
 - Laboratory
 - Pilot Plant
 - Manufacturing
- The need to simplify their PAT and OSIsoft PI System implementation methods is essential

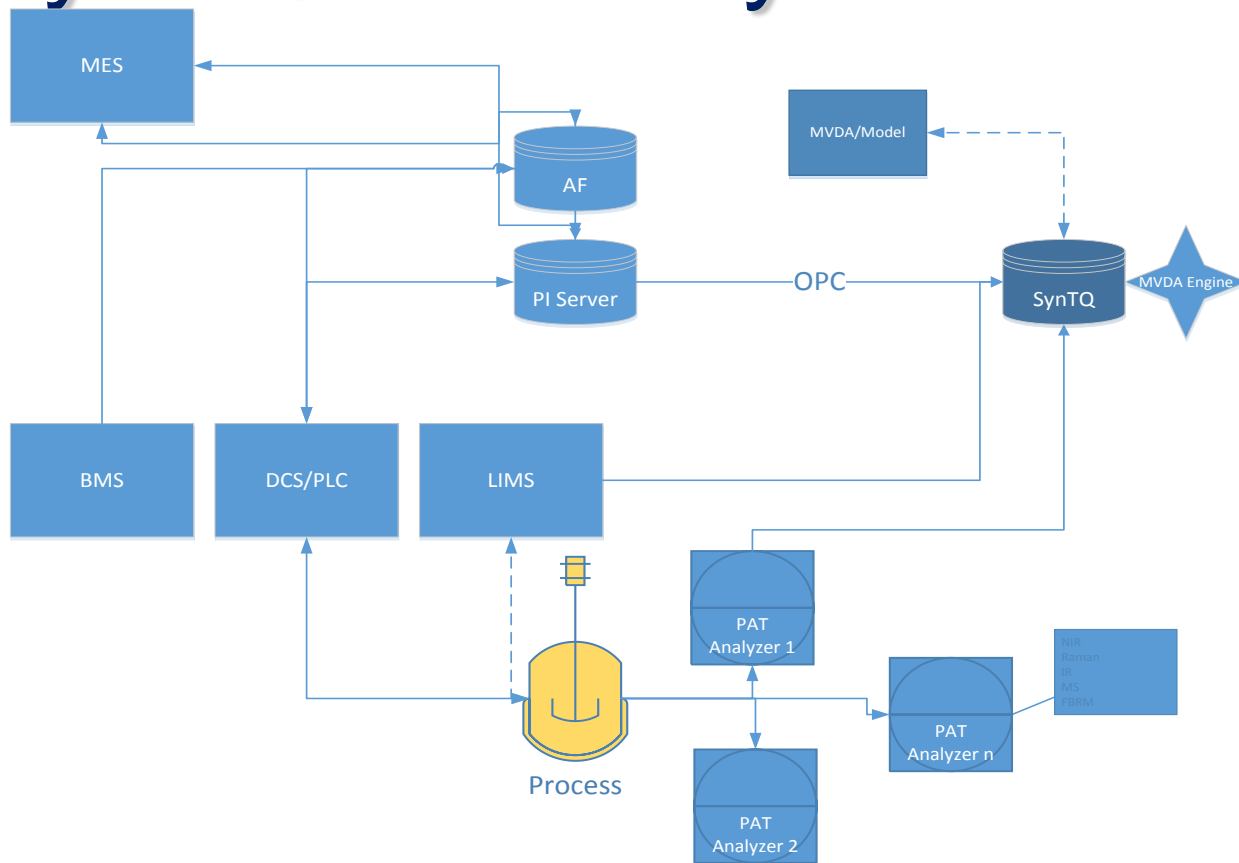
The Tighter Integration Need

- Many very effective synTQ to PI interfaces exist, but these use OPC DA
 - The disadvantages of using OPC DA are:
 - New OPC tags need to be created for every unit operation
 - A new Orchestration needs to be created for every process unit
 - DCOM can also pose integration problems on some sites
 - OPC DA also provides increasing challenges in relation to Cyber Security
 - OPC DA can pose Data Integrity questions
 - As a result, system setup and maintenance are time consuming

The Tighter Integration Need

- On a GMP site every Orchestration would need to be qualified, and this is not an insignificant task!
- There is no way of leveraging the fact that the OSIsoft PI Asset Framework is being used
 - Using OPC DA means that each process 'unit' needs to be treated as a standalone item even if they are created from the same element template within the PI AF

The synTQ and PI System Using OPC



The Requirements

- Optimal and OSIsoft hosted a TC with synTQ and OSIsoft Users from a range of companies to discuss general requirements of the tighter synTQ to OSI PI interface



The Requirements

- The priorities were ordered as:
 - Phase 1 – Integration with PI Asset Framework (PI AF)
 - Phase 2 – Develop Orchestration Templates within synTQ that can further leverage PI AF

Phase 1 of the OSIsoft PI System Integration has therefore focused on the PI Asset Framework integration

Phase 1 Administration Setup

- For the development work, the PI AF SDK has been used
 - This provides direct integration from the synTQ FM Server to the OSIsoft PI AF server without using any intermediary steps, i.e. OPC & ODBC are no longer required
- Each OSIsoft PI AF Server can be accessed from synTQ using a simple method that a synTQ Administrator can use, and includes details such as:
 - OSIsoft PI AF Server Name
 - Connection Username
 - Connection Password
 - Connection Domain

Orchestration Configuration Steps

- By using 5 simple steps you can select:
 - OSI AF server to use
 - Database to use
 - Template to use
 - Tags to use and whether each is read or write
 - Select the method of association between the Orchestration and the Unit ID. This can be:
 - Fixed at time of configuration
 - Selected by an operator on start-up
 - Configured by a PLC/DCS/SCADA system on start-up

The screenshot displays two panels from a configuration interface. The left panel, titled 'Instrument Settings', contains several dropdown menus: 'Connect' (button), 'Select Database' (MP-TestDB), 'Selected Template' (Bioreactor), and 'Select Input Type' (Input). A 'Write to Selected Attributes' checkbox is checked. Below this is a 'Template Attributes' table with columns for attribute name and value. The right panel, titled 'Template', includes a 'Location Config' dropdown (AF Location), buttons for 'Create new location configuration' and 'Add Model', a 'Templated Config' dropdown, and buttons for 'Apply Template' and 'Save as Template'.

Attribute Name	Value
SITE_NAME	Bioreactor
PI SERVER NAME	Bioreactor
Day_Count_Transmitter	Bioreactor
BatchID	Bioreactor
Agitator.PV	Bioreactor
Cell Density.PV	Bioreactor
Dissolved Oxygen.PV	Bioreactor
Pressure.PV	Bioreactor

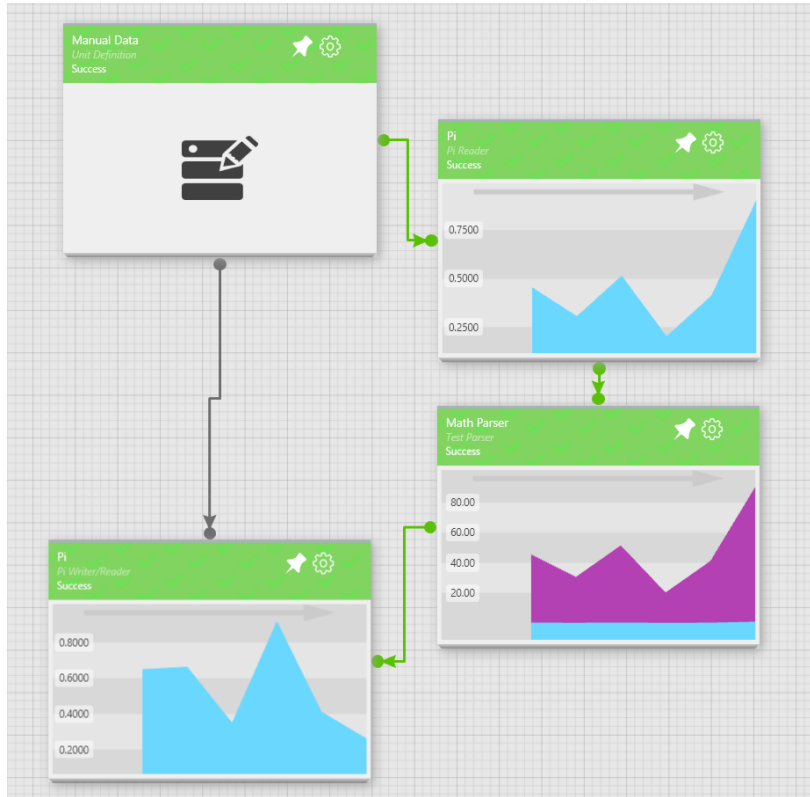
Example Setup

- Operation: Bio Reactor
- PI AF Template: BioreactElement
- Tags in Template:
 - AgitatorSpeed: [Read]
 - Temperature: [Read]
 - pH [Read]
 - GlucoseLevel: [Write]
 - Viability: [Write]
- Possible Bioreactor Unit IDs: BR1, BR2, BR3 BRn

Example Orchestration

- At runtime the tags to be read from or written to would be determined by combining the Unit ID entered as a runtime variable and the tag name.
- E.g.:
 - \BR1\BioreactElement\AgitatorSpeed
 - \BR1\BioreactElement\Temperature
 - \BR1\BioreactElement\pH
 - \BR1\BioreactElement\GlucoseLevel
 - \BR1\BioreactElement\Viability

Example Orchestration



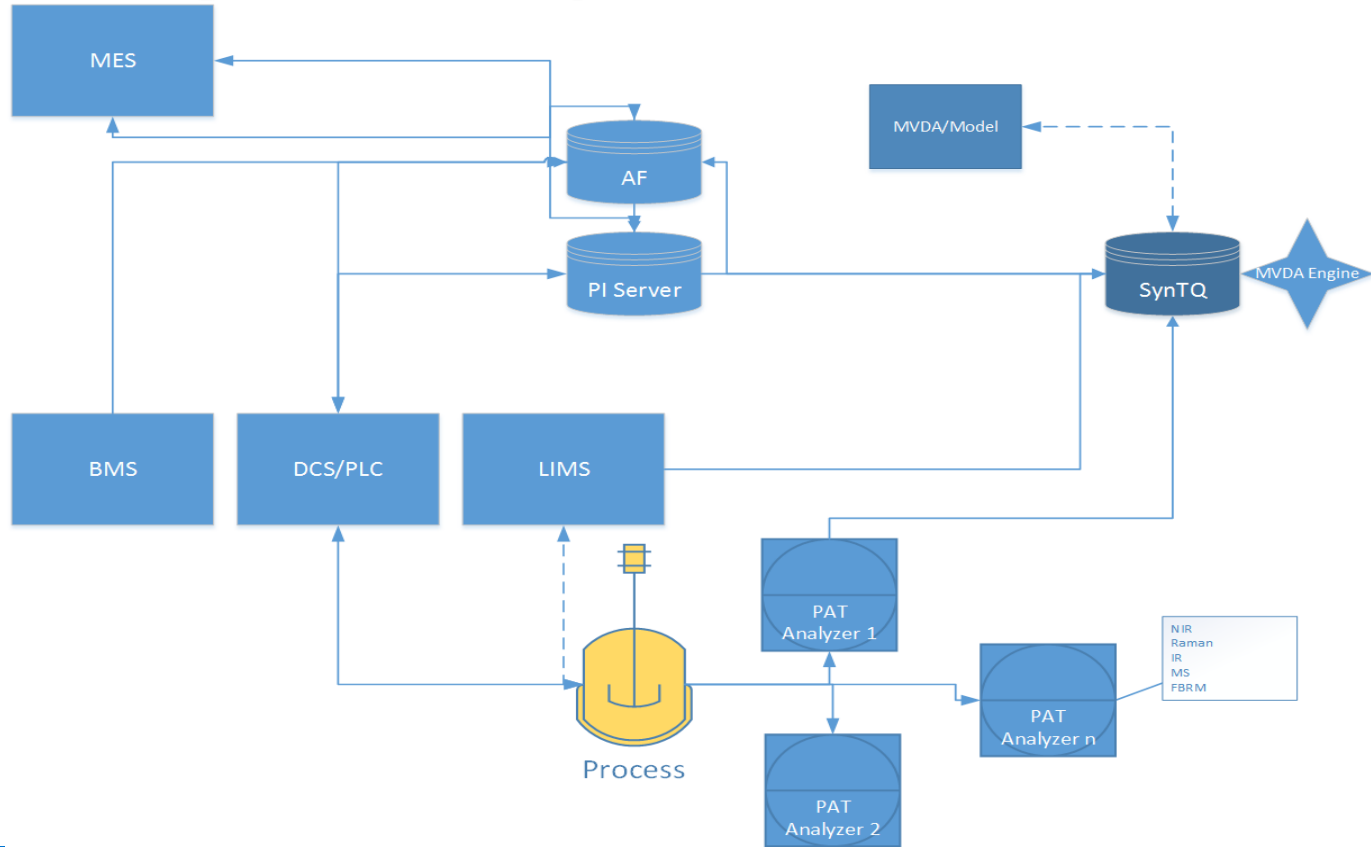
In this simple Orchestration the functions are:

- At the start, the operator is prompted to enter the required template
- synTQ then reads the target OSIsoft PI tags as determined by PI AF
- These are used in a workflow (which could include spectral data) where the quality predictions are made
- The output(s) can then be written back to OSIsoft PI System via the PI AF connection

Integration Details

- OSIssoft have provided us with the PI SDK development platform via the OSIssoft PI Developers Club
- This has enabled us to develop the Phase 1 adaptor, which is now under test
- Phase 2 will expand the system to include synTQ Templates
 - This means that only one synTQ template will be required, even if there are multiple identical unit operations
 - This will further enhance the flexibility and ease of use of the OSIssoft to synTQ interface
 - The target completion date is mid 2018

The Integrated synTQ and PI Interface



The Benefits

- With Phase 1 in place, the benefits to users are significant:
 - ✓ Create an Orchestration that has no fixed univariate address
 - ✓ Connect the Orchestration to plant equipment dynamically at runtime
 - ✓ Only create one Orchestration for many identical processes
 - ✓ Less Orchestration building, maintenance and validation

The Benefits

- Further advantages when Phase 2 is completed:
 - ✓ Concurrently run multiple instances of a single Orchestration template
 - ✓ Multiple processes can run concurrently, all using the same source PI AF template and same source synTQ template
 - ✓ Changes effecting all equipment now only made in 2 locations – the PI AF and synTQ templates
 - ✓ The advantages for system building, maintenance and validation are simply huge!

Mairtin Mc Namara

MMCNAMA3@ITS.JNJ.com

Speaker's Title: Procesingenieur
Tech Ops

Janssen Pharmaceutica N.V.



Martin Gadsby

mgadsby@optimal-ltd.co.uk

Speaker's Title: Director
Optimal Industrial Technologies



Questions

Please wait for the **microphone** before asking your questions

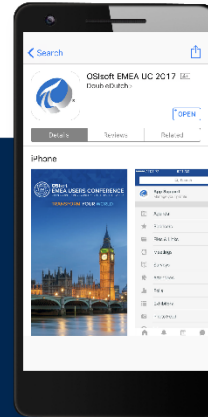


State your **name & company**

Please remember to...

Complete the Online Survey for this session

Download the Conference App



- View the latest agenda and create your own
- Meet and connect with other attendees

Search **OSISOFT** in the app store

Download on the

App Store

GET IT ON

Google Play

HTML

감사합니다

Danke

谢谢

Merci

Gracias

Thank You

ありがとう

Спасибо

Obrigado

Remember that the integrated OSIssoft/synTQ environment delivers the best results for optimized PAT Implementations!