Transitioning to a Modern PI System in a Validated Environment

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Agenda

- About Abbott Nutrition
- Validation Strategy for PI System Infrastructure at Abbott, Granada Plant
- Collaboration Use Cases

About Abbott Nutrition

ABBOTT NUTRITION

- Global headquarters – Illinois, USA
- 16,000 people in Abbott Nutrition
  - Part of Abbott's overall network of 73,000 people worldwide
- 4 Business Functions
  - ANPD, ANI, ANSC, ANRD
- We make nutritional products
  - Used by ~19 million consumers daily
  - Products used across life span
  - Support healthy lives from infancy to adult
  - Drive improvement in healthcare treatment and recovery

ABBOTT'S BROAD AND BALANCED PORTFOLIO

SCIENCE-BASED NUTRITION FOR ALL AGES

PEDIATRIC	ADULT/MEDICAL	PERFORMANCE
• Infant formula • Growing-up milk/toddler • Supplemental mother	• Supplemental nutrition • Healthy snacks • Disease-specific (diabetes, cancer, kidney)	• Elite athlete • Sports and fitness enthusiast • Active and healthy

AMONG THE MOST TRUSTED NAMES IN NUTRITION WORLDWIDE

Abbott Nutrition – Granada Plant

Granada (Plant - R&D)

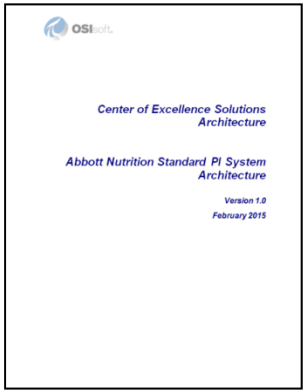
Nutritional Powders: Cans, Pouches and Sachets

Granada Team

Granada Manufacturing Process

Where is the PI System in Abbott Nutrition ?

- Abbott Nutrition Before the EA
- Abbott Enterprise Agreement signed in 2007
- BluePrint defined between Abbott and OSIsoft CoE in 2014.
- PI System reference architecture in order to lead the PI System integration across 14 Abbott Nutrition sites in a regulated environment.


OSIsoft.

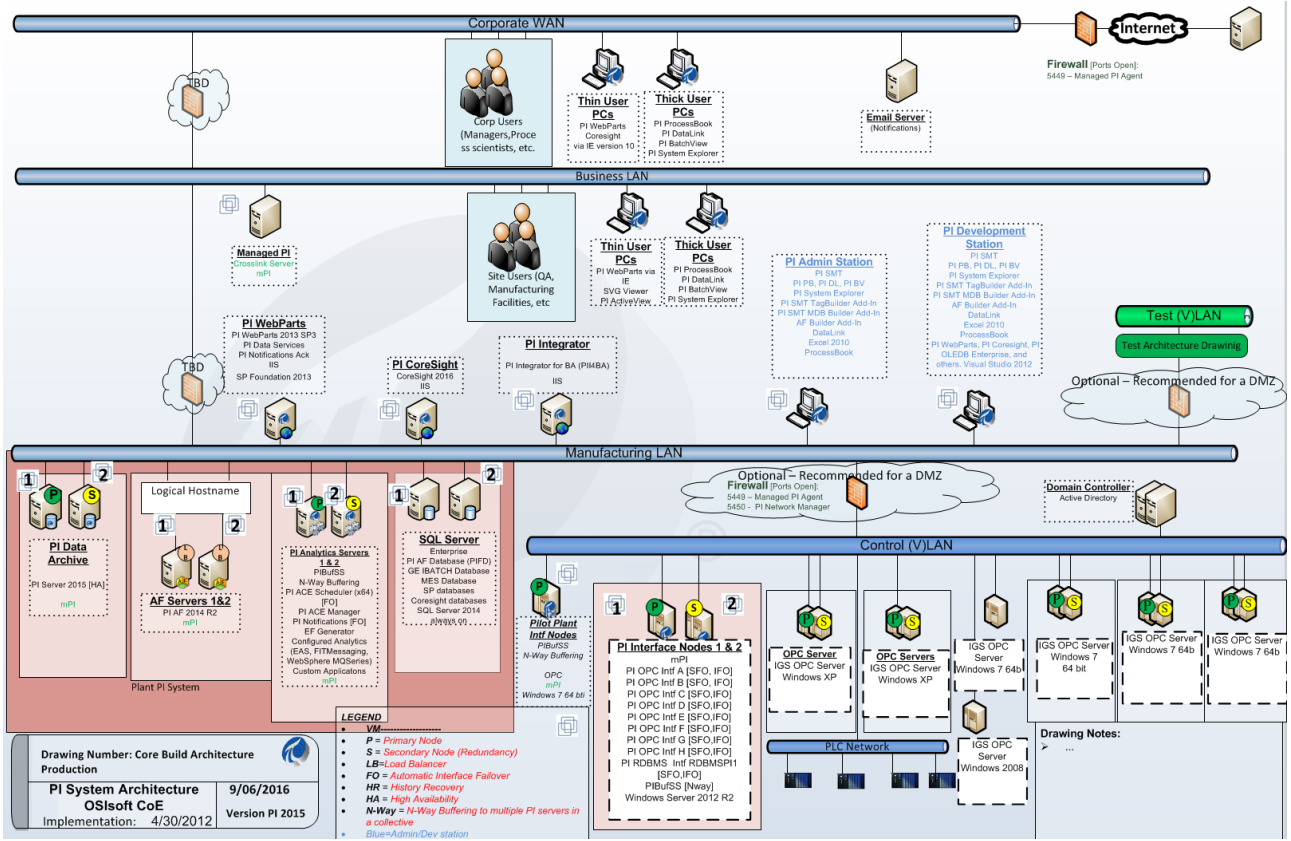
Center of Excellence Solutions Architecture

Abbott Nutrition Standard PI System Architecture

Version 1.0

February 2015

A PI System Architecture Blueprint Diagram

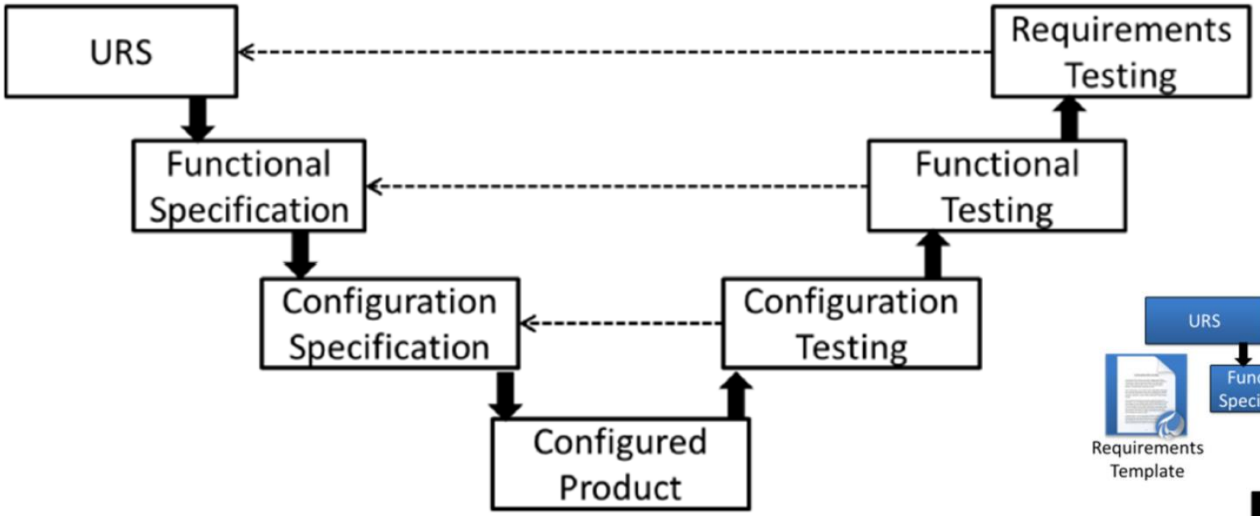


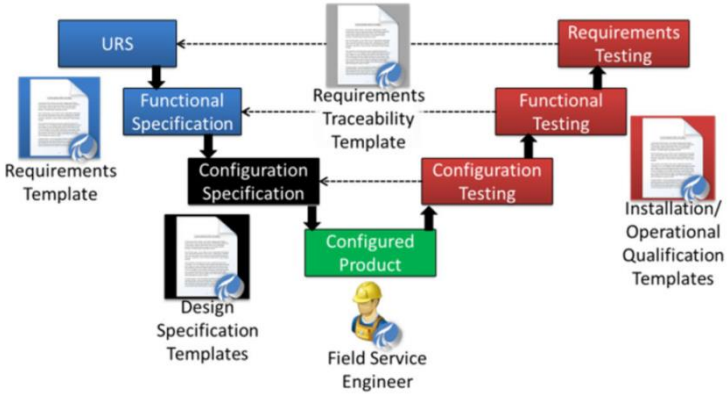
Validation Strategy for PI System Infrastructure at Abbott, Granada Plant

GAMP 5 Validation Approach

What does validating the PI System mean?

Requirements Testing also known as User Acceptance Testing, (UAT) or Performance Qualification (PQ)





Validation Approach – Abbott as Company

Any IT component must be validated.

The System Life Cycle (SLC) will be used defining all key deliverables and activities.

Deliverables and activities depending upon the criticality, complexity and regulatory requirements of the software application or business problem.

PI System Validation Strategy in Abbott

The PI System must be validated to its most critical use as a **repository of quality**.

We will leverage validation process by using **validation document templates**.

Site roadmap and the **Electronic Batch Record** project implementation support.

RG-00067							
BluePrint Infrastructure (RG-00067)							
1. Quality Planning Phase							
Change Request	Closed	25/Aug/2015	12/Jul/2016	2010	Quality	Critical	CN=Julio Lopez/OU=GRANAD.
Main Project Form	Closed	n/a	n/a	2015	Quality	Critical	Jose Nogales
Project Plan	Approved	16/Dec/2015	n/a	2015	Quality	Critical	Jose Nogales
Risk Assessment	Approved	14/Dec/2015	n/a	2015	Quality	Critical	Jose Nogales
User Requirements	Approved	14/Dec/2015	n/a	2015	Quality	Critical	Jose Nogales
2. Requirements Analysis Phase							
Functional Requirements	Approved	24/May/2016	n/a	2015	Quality	Critical	Jose Nogales
Migration Conversion Plan	Approved	20/May/2016	n/a	2015	Quality	Critical	Jose Nogales
3. Design Phase							
Configuration Management (Production)	Approved	14/Dec/2015	n/a	2015	Quality	Critical	Jose Nogales
Configuration Management (Production)	Approved	17/May/2016	n/a	2015	Quality	Critical	Jose Nogales
Configuration Management (QA/Test)	Approved	20/Jun/2016	n/a	2015	Quality	Critical	Jose Nogales
Detailed Design Description	Approved	02/Jun/2016	n/a	2015	Quality	Critical	Jose Nogales
Detailed Design Description	Approved	08/Jun/2016	n/a	2015	Quality	Critical	Jose Nogales
Detailed Design Description	Approved	20/Jun/2016	n/a	2015	Quality	Critical	Jose Nogales
Detailed Design Description	Approved	20/May/2016	n/a	2015	Quality	Critical	Jose Nogales
Detailed Design Description	Approved	24/May/2016	n/a	2015	Quality	Critical	Jose Nogales
System Architecture Description	Approved	14/Dec/2015	n/a	2015	Quality	Critical	Jose Nogales
System Architecture Description	Approved	20/May/2016	n/a	2015	Quality	Critical	Jose Nogales
Validation Plan	Approved	20/May/2016	n/a	2015	Quality	Critical	Jose Nogales
4. Construction and Coding Phase							
Unit Testing	Approved	12/Dec/2015	n/a	2015	Quality	Critical	Jose Nogales
5. Test Phase							
Test Protocols	Approved	24/May/2016	n/a	2015	Quality	Critical	Jose Nogales
Traceability Matrix	Approved	20/Jun/2016	n/a	2015	Quality	Critical	Jose Nogales
6. Operation and Maintenance Phase							
Installation & Operational Qualification (Production)	Approved	12/Jul/2016	n/a	2015	Quality	Critical	Jose Nogales
Installation & Operational Qualification (Production)	Approved	12/Jul/2016	n/a	2015	Quality	Critical	Jose Nogales
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Installation & Operational Qualification (QA/Test)	Approved	12/Jul/2016	n/a	2015	Quality	Critical	Jose Nogales
System Certification Summary	Approved	12/Jul/2016	n/a	2015	Quality	Critical	Jose Nogales
System Certification Summary	Approved	12/Jul/2016	n/a	2015	Quality	Critical	Jose Nogales

Validation Principles - CoE Best Practices Adoption

- Focus on PI System Infrastructure
- Streamline Requirements
- Target Optimum Validation Level
- Eliminate Non-Value Add Errors

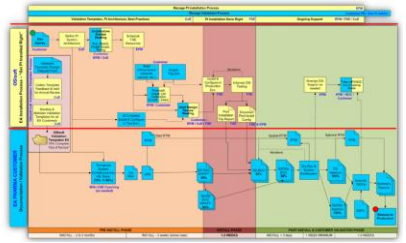
PI System Validation Process and Validation Templates are intended **to reduce the customer's validation burden.**

PI Validation Best Practice

Based on the principles defined in the previous section, the CoE designed this best practice, which is composed of two deliverables, the PI Validation Process and the PI Validation Templates. These two deliverables are the keys to significantly reducing customers' validation burden and are covered in this section.

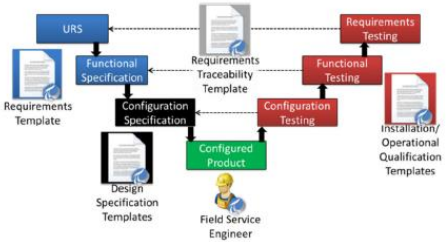
Figure 3 - PI Validation Best Practice Deliverables

Abbott Validation Process (‘V’ Model)



Quality planning phase

Change request
Project plan
Risk assessment
User Requirements



~~Performance Qualification~~

Operation and maintenance phase

IOQ execution
System certification summary

Requirement analysis phase

Functional Specification Requirements
Configuration management
System architecture design
Validation Plan
Design specs

Design phase

Functional requirements
BluePrint definition
Migration plan

Construction phase

System installation

Test phase

Test protocols
RTM

Results and Benefits

- Complete validation process in 2 weeks with an ongoing OSIsoft support.
- Best practices and continuous follow-up between FSE and AG Solution a big contribution to the infrastructure validation scope.
- 33 deliverables (Prod/Test) required by the change request, just 3 (PP/VP/SCS) were created by Abbott.
- 2015.a version was used in the majority of the products with some exceptions.

Document	Document Template	Production	Test
Project Plan	AQ09-05-T013 Project Plan Template v5.0	1	
Validation Plan	AN09-05-T024 Validation Plan Template v2.1	1	
Requirements	OSI_PISYS_RS_v2015.a	1	
PI System Requirements Traceability Matrix	OSI_PISYS_RTM_v2015.a	1	
PI Server Design Spec (DS)	OSI_PISVR_DS_v2015.a	1	1
Primary PI Server Installation and Operational Qualification (IOQ)	OSI_PISVR_IQOQ_v2015.a	1	1
Secondary PI Server Installation and Operational Qualification (IOQ)	OSI_PISVR_IQOQ_v2015.a	1	1
PI AF Server Design Spec (DS)	OSI_PIAF_DS_v2015.a	1	1
PI AF Server Installation and Operational Qualification (IOQ)	OSI_PIAF_IOQ_v2015.a	1	1
PI Analytics Server Design Spec (DS) (ACE/Notifications)	OSI_PIANA_DS_v2010.a	1	1
PI Analytics Server Installation and Operational Qualification (IOQ) (ACE/Notifications)	OSI_PIANA_IOQ_v2010.a	1	1
PI RtReports Design Spec (DS)	N/A		
PI RtReports Installation and Operational Qualification (IOQ)	N/A		
PI WebParts Design Spec (DS)	OSI_PIWP_DS_v2010.a	1	1
PI WebParts Installation and Operational Qualification (IOQ)	OSI_PIWP_IQOQ_v2010.a	1	1
PI Coresight Design Spec (DS)	OSI_PICO_DS_v2015.a	1	1
PI Coresight Installation and Operational Qualification (IOQ)	OSI_PICO_IOQ_v2015.a	1	1
PI Interfaces Design Spec (DS)	OSI_PIINTF_DS_v2015.a	1	1
PI Interfaces Installation and Operational Qualification (IOQ)	OSI_PIINTF_IOQ_v2015.a	1	1
PI Client Tools Installation and Operational Qualification (IOQ)	OSI_PICLI_IQOQ_v2015.a	1	1
PI Batch Interface Installation Operational Qualification (IOQ)	N/A		
Certification Summary	AN09-05-T017 System Certification Summary Template v1.4	1	

Lessons Learned

- Validation Plan must be shared with OSIsoft in advance.
- Important to have an architecture and software versions guideline (Blue Print) defined at **group level**
- Ask OSIsoft about the template release roadmap
- Collaboration with a good partner is the critical path in the PI System validation cost reduction
- Interesting to unify documents (URS,DS,IOQ,RTM) and functionalities

Next steps in Validation

- Validate the recent Asset Framework, Asset Analytics and Coresight 2016 release taking advantage of the OSIsoft services.
- Working globally and sharing information with OSIsoft.
- Evaluate along with Abbott Compliance the needs of Abbott deliverables, asking to OSIsoft if they can assist us.
- Align the business need with the resources available being aware in the template update cycle.

PI System Validation

COMPANY and GOAL

Abbott Nutrition wanted to **validate PI System** to its most critical use as a repository of quality.

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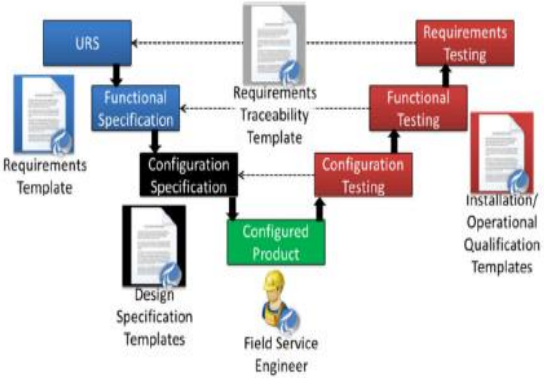
AG Solution
Process Automation & Industrial ICT



CHALLENGE

OSIsoft does not validate its system directly.

Installation was made long time ago.

Abbott templates available 2010.a and 2012.a.

- Quality cannot use batch and process data to release product.
- Know-how in the PI System validation process.

SOLUTION

OSIsoft recomends to partner with a System Integrator.

CoE/EPM engagement and FSE ongoing support.

Abbott policy deliverables and activities.

- OSIsoft Validation Templates 2015.a
- 33 deliverables required by the change request just 3 created by Abbott.
- FSE and AG Solution collaboration a big contribution to the infrastructure validation scope.

RESULTS

Successful system certification Summary according to the Abbott QA compliance

AG Solution a big contribution to the infrastructure validation scope.

“One team, one voice, one goal”

- Validation achieved in 2 weeks.
- QA Repository ready to feed the EBR initiative.

Collaboration Use Cases

Migration to a Modern PI System: from PI Batch to Event Frames

COMPANY and GOAL

As part of the transition to a **Modern PI System**, Abbott Nutrition requires a **more flexible, more powerful** and an integrated **highly available** infrastructure.

Migration from PI Batch to Event Frames is a requirement.

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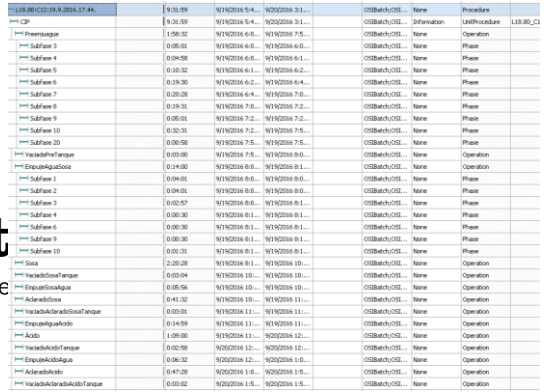

CHALLENGE

Migration required to implement Reporting and Visualization of batch processes as PI Event Frames.

PI System Roadmap focuses on Event frames.

Visualization based in PI Batch.

- QA needs PI Batch information
- Development based in PI Batch and PI Webparts.
- PI Coresight limited usage as never supported PI Batch

SOLUTION

Replica of production environment in a Test System.

On Site Field Service Support to perform PI Batch to Event Frames migration, including interfaces.

- Asset Framework
- PI EFGEN
- PI Coresight
- PI Datalink
- PI System to PI System

RESULTS

All data migrated successfully.

Batch hierarchy maintained in Event Frames.

Event Frames tracks and reports batches 10 times faster than PI Batch.

"I will make timely, fact-based decisions"

- PI Batch migration goal achieved.
- Event Frames based information.
- Event Frames attributes as RCA information.
- Investigating reporting techniques.

PI Event Frames Visualization in PI Coresight 2016 R2.

COMPANY and GOAL

Abbott Nutrition is looking for a **Standard Visualisation Platform** across the company based on Asset Framework and Event Frames.

PI Coresight with Event Frame support and Overlay Trending investigated as a feasible solution

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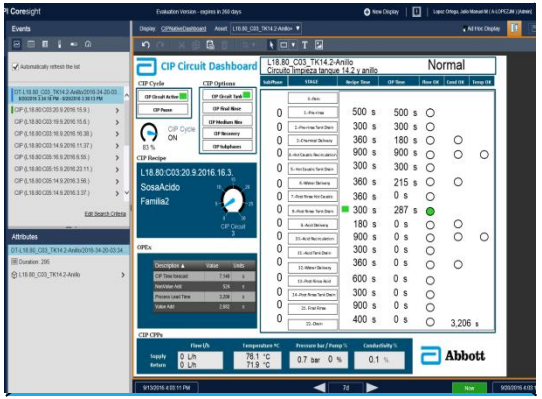

CHALLENGE

Difficulties to find out a good standard visualization platform.

Abbott Nutrition used PI Coresight for real time data, and PI WebParts for process data and batch information.

- Replace PI WebParts with PI Coresight after batch to Event Frame migration.
- Developed a non-real time dashboard for Event Frame visualisation - Requires developing skills, difficult to deploy in all sites.

SOLUTION

PI Coresight 2016 R2 installed.
Event Frame Overlay Trending Testing.
On Site Field Service Support.
Guidance and feedback to PI Coresight Product Management

- PI Coresight 2016 R2 (Beta)
- EA relationship: EPM, CoE, Field Service, Product Management support.

RESULTS

Win-Win initiative
Asset Framework Modeling best practices.
PI Webparts and PI Batch decommissioning roadmap

"I am a leader"
"I will make timely, fact-based decisions"

- PI Coresight as main RCA tool.
- CIP Process at-a-glance.
- Event comparison used to evaluate time loss and bad CIP cycles.

PI Integrator PoC

COMPANY and GOAL

Abbott wanted to **improve the process efficiency leveraging BI tools** to reduce SQL server programming work and real time visualization across all plant departments.

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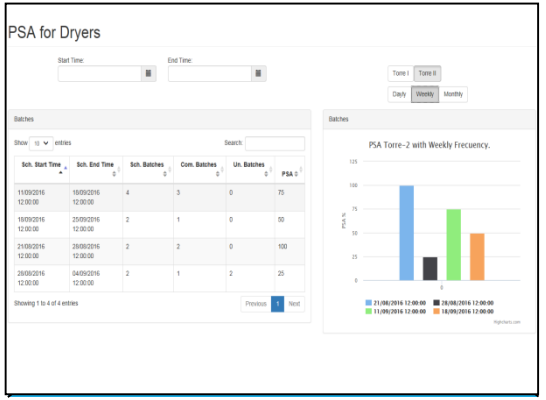

CHALLENGE

SQL Server based implementation.

Difficulties to access to the Event Frame information.

Costly replication.

- Development overload.
- Hard maintenance.
- IT strong dependence

SOLUTION

Install and publish attributes and PSA calculation using PI Integrator.

View and edit PI Integrator output using MS Excel and BI tools.

View PSA metric using PI Coresight 2016 and PI Coresight 2016 R2.

- PI Integrator
- Asset Analytics
- Asset Framework

RESULTS

Successfully publish key attributes and calculated data using PI Integrator at a defined frequency.

Successfully consume PI Integrator output with defined BI and visualization tools.

“I drive continuous improvement”

- Quick replication.
- Asset Framework Standardization.

Contact Information

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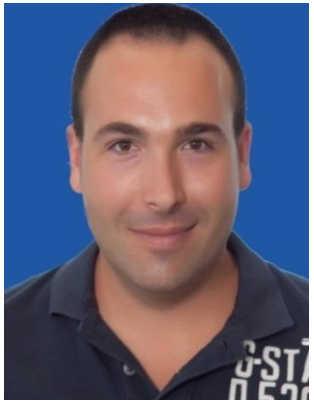

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Questions

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

State your **name & company**

Please remember to…

Complete the Online Survey for this session

http://ddut.ch/osisoft

감사합니다

谢谢

Danke

Merci

Gracias

Thank You

ありがとう

Спасибо

Obrigado

The sum of all of these efforts give us **business-value** across all manufacturing sites.