



The Value of the Novartis EA for San Carlos Site and **Novartis** Achievements/Goals of the Global PI System Strategy

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Agenda

- 1. Overview of Novartis and San Carlos Site
- 2. Enterprise Agreement with OSIsoft
- 3. Three Novartis Global PI System® accomplishments
- Two San Carlos Challenges that were met with the PI System
- 5. Future Plans
- 6. Summary



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Novartis overview

- Global Pharmaceutical Company, Headquartered in Switzerland
- 2016 Net Sales: 48 billion USD,
 ~118,000 Associates
- Portfolio: Innovative Medicines (small and large molecules), Generics, Eye Care
- NTO: 67 Mfg Sites in 27 countries

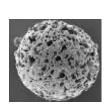




San Carlos site overview

- Small strategic site focusing on pulmonary diseases
- Main product: TOBI Podhaler
- Manufacturing process: spray drying and filling; with clean rooms and clean utilities





Powder (PulmoSphereTM)



Filled Capsule



Marketed Product



Novartis journey to OSIsoft EA

The value of OSIsoft Partnership for NOVARTIS over time:

- Strong need to leverage on edge technology and trustable partners to accomplish the High Quality Manufacturing required in Pharma
- Novartis recognized OSIsoft from the very beginning, as reference company/product for their stringent requirements
- Since 1999 the PI System[®] has been used in Novartis and gradually the PI System [®] has replaced all legacy Historians
- In 2013 the Enterprise Agreement with OSIsoft was signed
- Since the sign-off date many new sites joined the EA
- The journey towards the PI System as Event / Data Infrastructure fully in place NOW!!



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OSIsoft Services approach

Supporting Strategic Accounts as NOVARTIS is

 Utilize industry business acumen and a deep understanding of customers' Environment, People and Business Objectives to deploy services that impact business results

Integrate Services with Product Roadmap

 Align with Product Management to ensure an integrated product/ service launch which incorporates voice of the customer feedback

Seamless Customer Journey

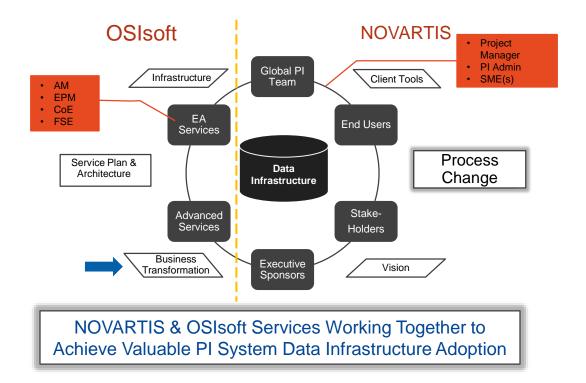
 Developed an agile services team that provides NOVARTIS with a consistent experience from co-authoring of business goals through delivery to drive adoption maturity

Envisioning Potential

Internal competency that can discover and position the possibilities of applying the PI System



Novartis + OSIsoft Services = Results





Some OSIsoft methodological tools in **Novartis EA**

EA Roadmap

It is to outline the activities, schedule, process and deliverables to be provided by OSIsoft's EA Services as part of the Enterprise Agreement. It is to serve as a guideline and roadmap for implementing these objectives successfully while focusing on maximizing NOVARTIS return on their Enterprise Agreement investment.

2. Business Impact Workshops

 A flexible framework to determine key business areas and the associated value that can be realized with the PI System as an enterprise data infrastructure and the adoption of new operational or business processes.

3. **Educational Workshops**

Designed to create first level of PI System awareness at user level. Then, presenting specific examples of Novartis business processes managed by the PI System.



Novartis EA major achievements

- 1. Roll-out and Training Programs
- 2. Standardization
- 3. Global AF Model
- 4. CPV and PAT
- 5. IT-OT Integration
- 6. MES Integration
- 7. DCS Integration
- 8. Supporting Site-Specific Projects



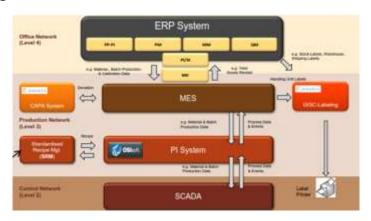
DCS integration: Embedded PI Server

- Embedded PI Servers installed in three DCS
- Easier to manage because they are consistent with other PI servers
- Plant staff use the embedded PI Server for monitoring & troubleshooting
- Office staff use the site PI System for reports (PI to PI interface)



MES Integration: PI System as a Data Bus

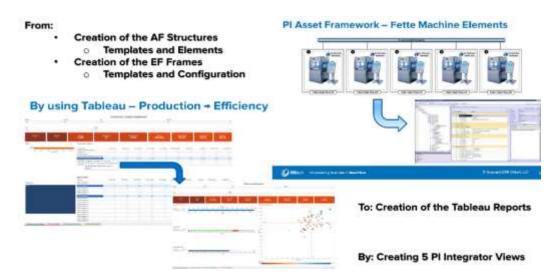
- Handshaking between MES & PI System and between PI System & standard SCADA validated globally once
- Templates can be re-used by sites to interface with similar equipment
- Helps speed up integration of new machines





IT-OT integration: Proof of concept for **Equipment Efficiency Metric System**

- PI Integrator for Business Analytics used to connect to BI data visualization software
- With BI software, data can be sliced and diced to find root causes of machine stoppages





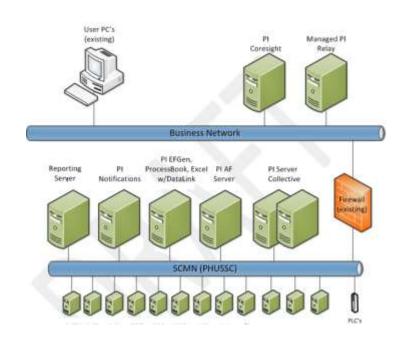
San Carlos PI System use cases introduction

- Upgraded the PI System in 2014 according to the global standardization process defined at HQ
- San Carlos attends regular global PI System meetings, and communicates with other sites and with OSIsoft
- Two recent challenges that were met with the PI System are described next:
 - 1. Monitoring of Stability Chambers
 - 2. Multi-Batch Trend Report



San Carlos PI System

- PI Server Collective
- PI AF and Analytics
- Managed Pl
- ~12 OPC interface nodes
- ~10,000 tags
- GMP compliant (with sandbox dev. env. - all virtual machines)





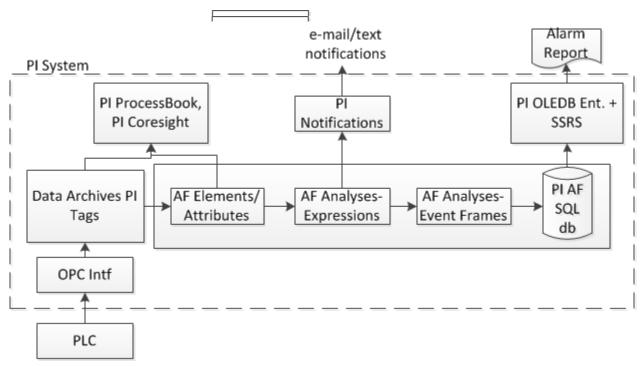
Challenge #1: Monitoring of stability chambers

Need to monitor Temperature and RH of new Stability Chambers

- Stab. Chamb. are used to test and store products in specific temperature and/or humidity conditions
- Two options considered are described in next slide

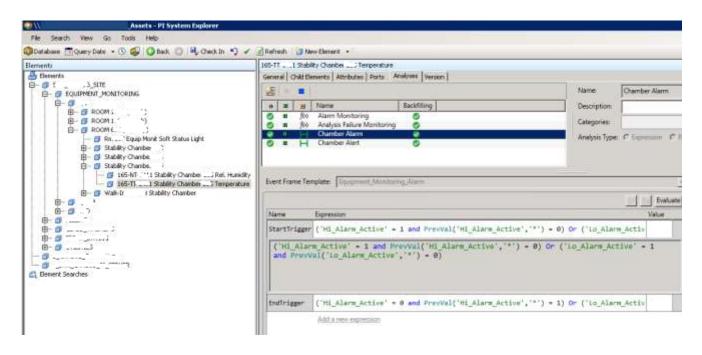


Solution architecture



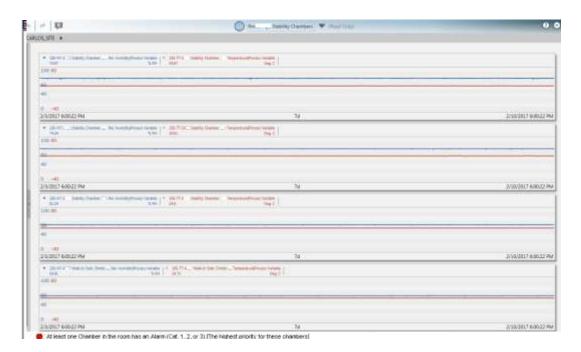


Technical solution: Asset Analytics for Notifications and Event Frames



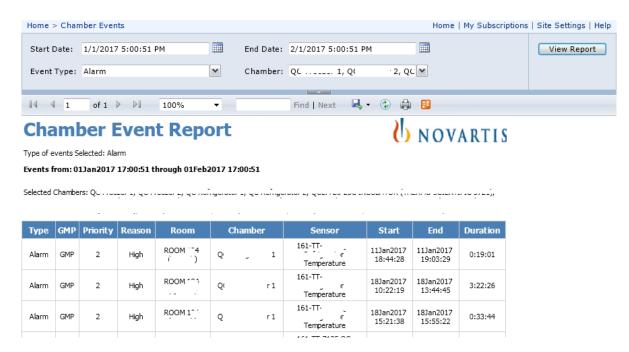


PI ProcessBook and PI Coresight displays





Alarm Report with PI OLEDB Enterprise and SSRS





Solution benefits

- All logic and data is in the PI System
- No need to create SCADA graphics
- No need for additional SCADA licenses
- PI OLEDB Enterprise included in EA



Challenge #2: Process parameter multi-batch trending/monitoring

Need to automate periodic CPV report that takes too long

Old process:

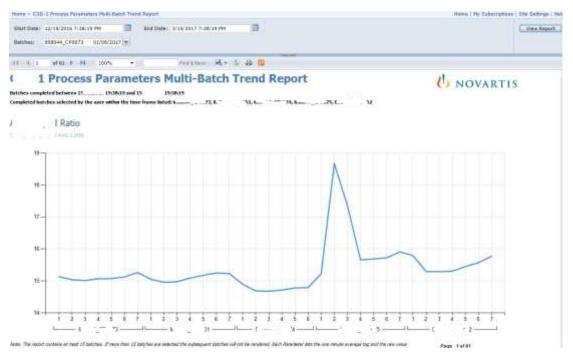
- 1. Query SQL database to find start and end time of each batch & subbatch
- 2. Query PI Server with PI DataLink for raw data for each batch & subbatch and calculate aggregate values and create charts

New process:

1. Select Batch ID's, click 'View Report'.



Process parameter multi-batch trend report





Technical solution: new PI tags, EF, PI OLEDB Enterprise & SSRS

- 1. 1-min average PE tags to ensure all sub-batch have same amount of data points
- 2. Event Frames w/ attributes for aggregate data: avg, min, max, standard deviation (built-in calculations)
- 3. Query AF database via PI OLEDB Enterprise and returns result in SSRS report

Solution benefits

- Validated PDF report saves approx. 150 man-hour/year
- Easy to export csv data into statistical tool for further analysis
 - Due to "rectangular" dataset made up of 1 min. avg data points



Future Plans

San Carlos:

- Create more reports via PI **OLEDB Enterprise and SSRS**
- Upgrade PI Coresight to be able to acknowledge Event **Frames**

Global:

- Silent Install of PI System
- Global AF Model
- Alarm Notifications
- PAT and OPC UA
- Keep working on projects previously mentionned



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COMPANY and GOAL

Novartis is a major global pharmaceutical company and wants fully leveraging its Enterprise Agreement (EA) with OSIsoft







CHALLENGE

Novartis wants to leverage the EA to meet various business challenges



Prototypes and various projects executed with OSIsoft support



- Equipment monitoring, Reporting
- Leveraged EA for downloads, installations, support/escalation

RESULTS

Increase productivity and compliance

- Lower cost of integrating equipment
- Single version of the truth for monitoring, alarming, reporting
- One example saves 150 man-hr/yr









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Merci

Danke

谢谢

Gracias

Thank You

ありがとう

Спасибо

Obrigado





