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Maximizing the Value of Novartis' GMP PI System with the Enterprise Agreement: San Carlos Site Case Study

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Hervé Bajolle



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OSIsoft UC 2015

San Carlos Case Study

The Novartis Company and the San Carlos Site at a Glance

OSIsoft/Novartis Enterprise Agreement

Business Challenge

San Carlos PI System Upgrade Project

Business and Operational Value Achieved

Future Plans



Global Pharmaceutical Company

Headquartered in Switzerland

2014 Net Sales: 58 billion USD

Three Main Divisions:

- | | | |
|-----------------------|------------|------------------|
| 1. Pharma | 2. Sandoz | 3. Alcon |
| (branded
products) | (generics) | (vision
care) |

pharma division

researches
develops
manufactures
distributes
sells

branded medicines for
auto-immunity
cardiovascular
dermatology
infectious diseases
metabolism
neuroscience
oncology
ophthalmology
respiratory
rheumatology
transplantation

There are Manufacturing Sites in over a dozen countries

San Carlos, California Site

Home of TOBI Podhaler

- Novartis acquired the pulmonary business of Nektar (San Carlos) in 2009
- TOBI Podhaler was approved by the FDA in 2013
 - Approved for use in 68 countries
- Helps prevent chronic lung infections for cystic fibrosis patients

TOBI™ Podhaler™
Tobramycin Inhalation Powder 28 mg per capsule

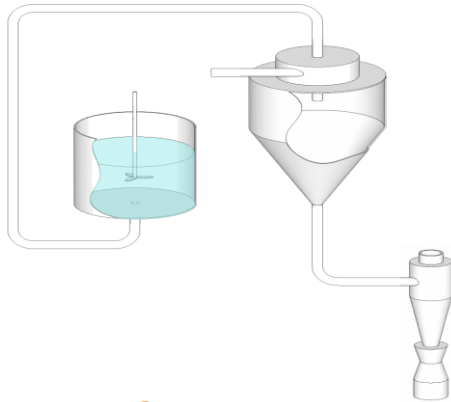


San Carlos, California Site

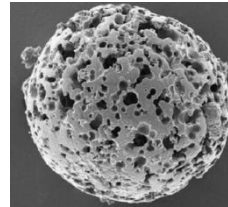
Manufacturing Capabilities

- 6 Spray Drying Systems
- 4 Filling Systems
- Clean Utilities and General Building Utilities

R&D, Clinical & Commercial
Manufacturing Activities



Spray Dryer



Powder (PulmoSphere™)



Filled Capsule

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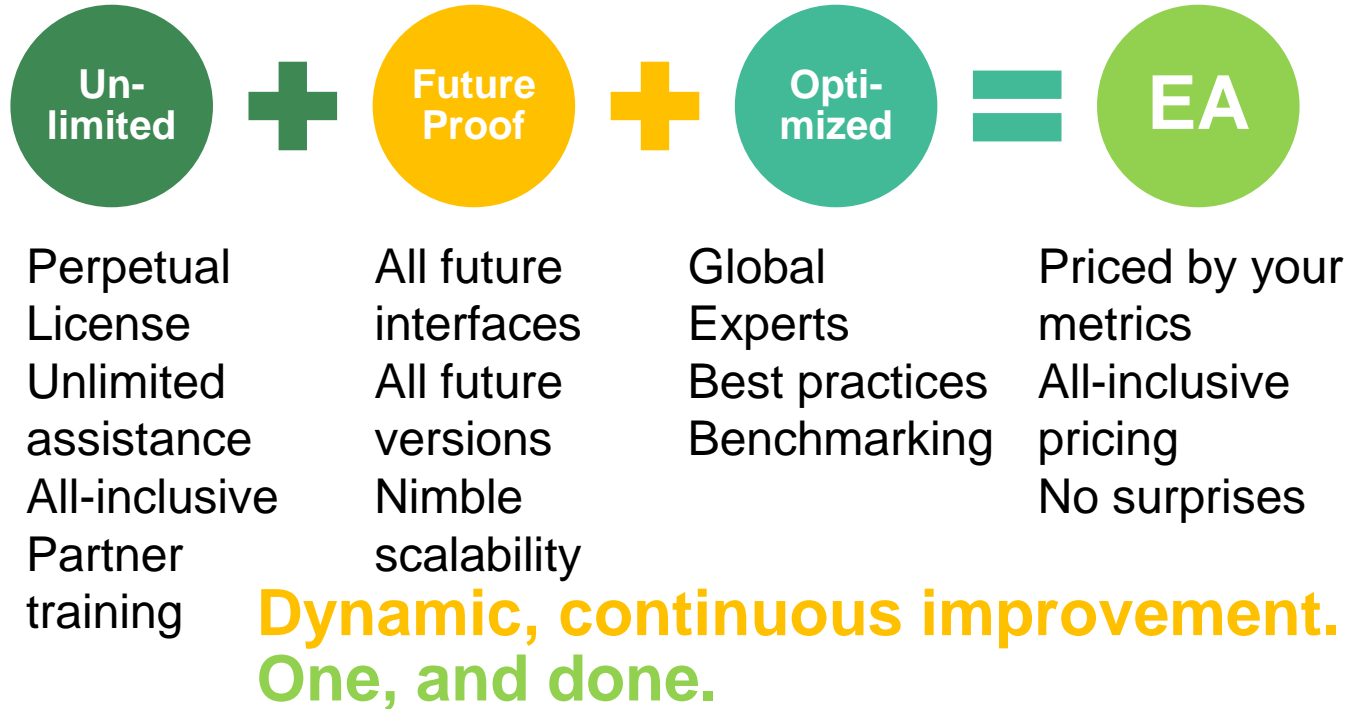
Business and Operational Value Achieved

Future Plans

Novartis and OSIsoft / EA Contract

- Need to leverage on edge technology and trustable partners to accomplish the High Quality Manufacturing required in Pharma
- Novartis recognized OSIsoft/PI System 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 Server has replaced all legacy Historians
- In 2006 OSIsoft became the Pharma preferred supplier for 4 sites for 3 years
- In 2013 the Enterprise Agreement (EA) with OSIsoft was signed

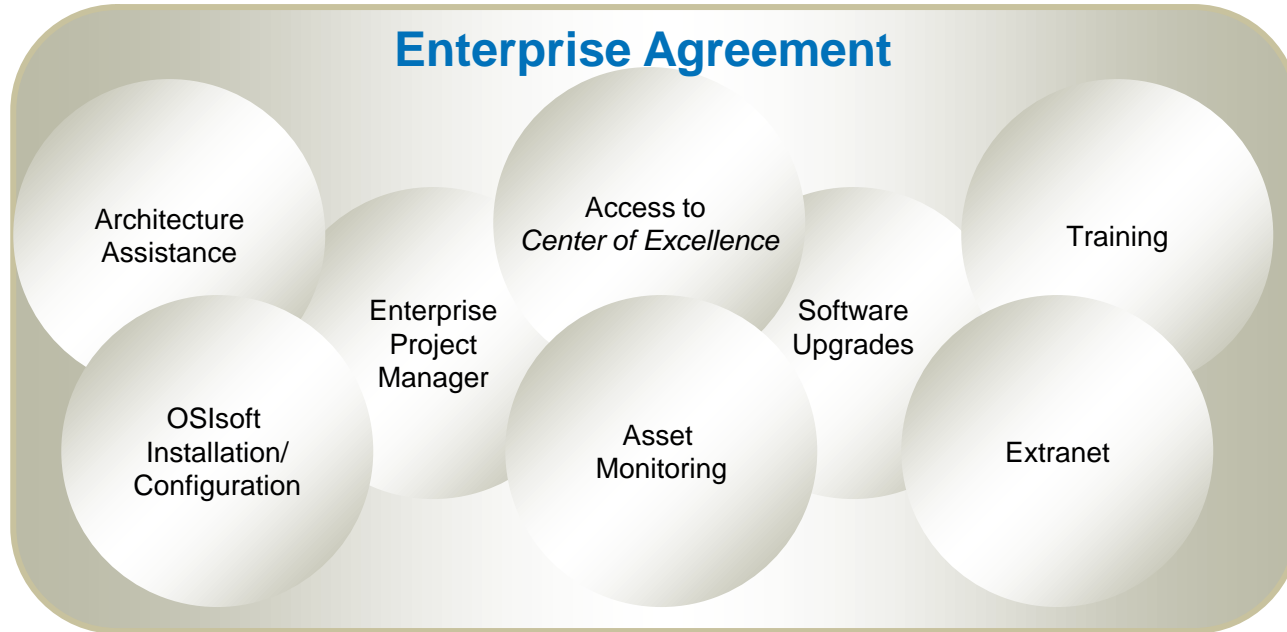
Special Aspects of an EA



Enterprise Services

Under an executed Enterprise Agreement, customers have access to a cumulative knowledge base built upon 30+ years as an industry leader.

Available services include:



EA Goals Methodology

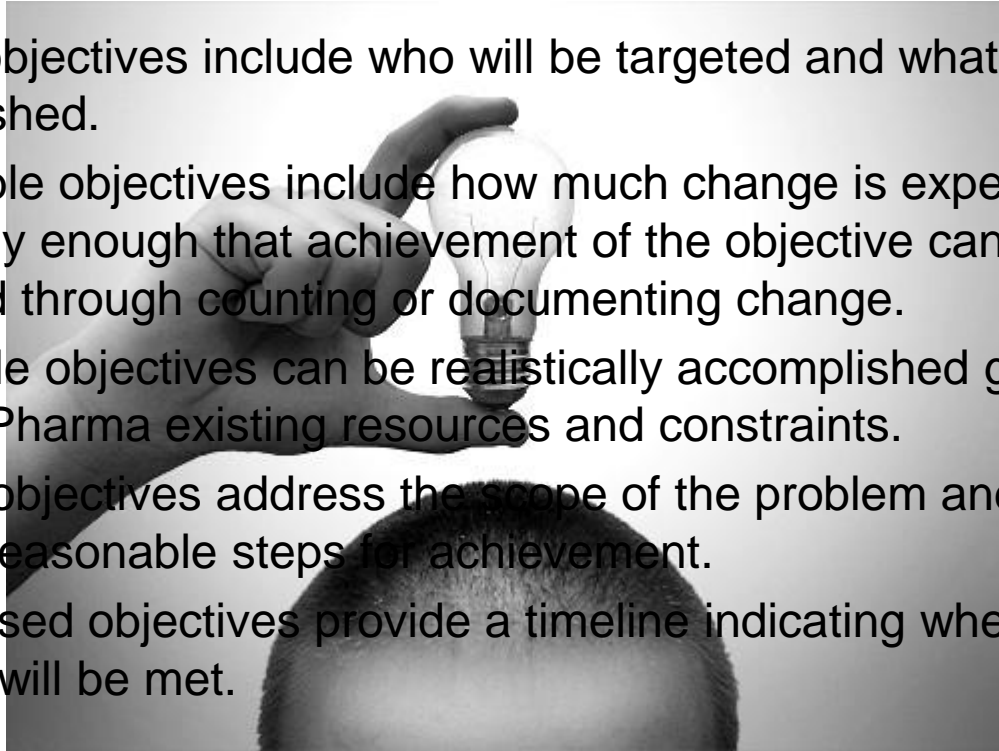
Specific objectives include who will be targeted and what will be accomplished.

Measurable objectives include how much change is expected, specifically enough that achievement of the objective can be measured through counting or documenting change.

Achievable objectives can be realistically accomplished given Novartis Pharma existing resources and constraints.

Realistic objectives address the scope of the problem and propose reasonable steps for achievement.

Time-phased objectives provide a timeline indicating when the objective will be met.

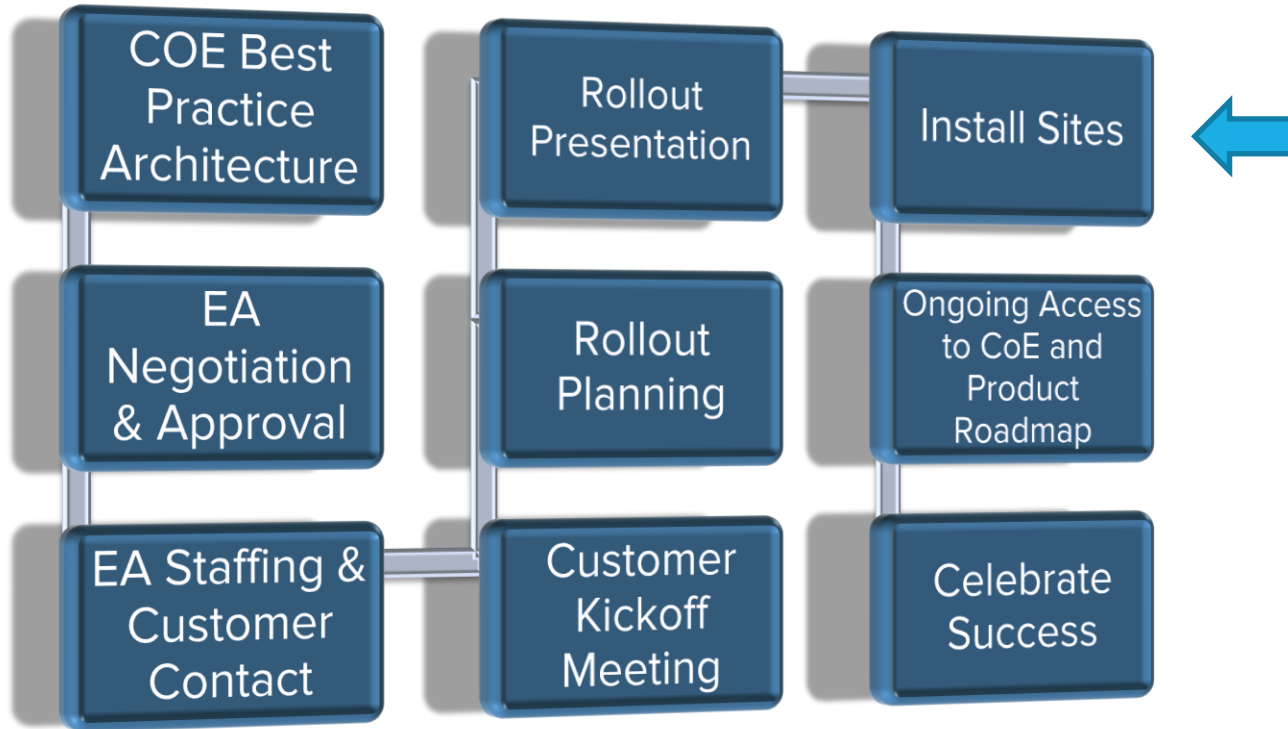


NOVARTIS EA Objectives

EA Objective	Value	Timeline
Enterprise Agreement Success	Capture and clearly articulate the success of the Enterprise Agreement program	2Q 2018
Value of the Global Rollout	Clearly articulate the value and benefits of the enterprise infrastructure to each global site.	1Q 2016
Deployment and Rollout Planning	Develop a rollout plan that addresses the structure for the rollout and support model	1Q 2015
Technology and Interface Design	Develop a robust, highly available infrastructure	1Q 2016
Data Model Design	Support critical manufacturing, continuous operations and without the reasonable loss of data	1Q 2016
MES Integration Design	Design and integrate MES and PI to reduce and simplify the data integration	4Q 2015
Continued Process Verification (CPV)	The ability to verify the stability and capability of the production process.	2Q 2016
Process Analytical Technology (PAT)	Provide timely data, identify weak points and prevent process deviations	4Q 2015
Operational Solution Cases	Develop potential enterprise value areas that Novartis can realize.	1Q 2016



Progress to Date



Novartis PI System Roll Out Plan

Site	Assessment	Installation Scheduled	Installation Complete
Novartis Ringaskiddy			
Novartis Grimsby	Done	Done	Done
Novartis ChemOps Switzerland	In Progress		
Novartis TRD Switzerland	In Progress		
Novartis Huningue	Done	Done	Done
Novartis PharmOPS Stein	Done	Done	Done
Novartis Urunleri PharmOps Kurtkoy			
Novartis Singapore PharmaOps	Done	Done	Done
Novartis NSPM BiopharmOps Singapore	Done	Done	Done
Novartis San Carlos	Done	Done	Done
Novartis Farmaceutica, Barbera del Vallés	In Progress		
Novartis Pharma Germany Wehr	In Progress		

San Carlos PI System Use Case Introduction

- San Carlos joined the EA on January 2014
- It was selected for rolling out the PI System in adherence with the global standardization process defined in the HQ
- San Carlos started very soon to work in a very cooperative way with EPM, COE, FSE and TS
- We executed rollout per phases managing the project with a very methodological approach
- The overall goal of the rollout was to address the business challenges that the San Carlos site was presenting to the project team

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San Carlos Site

Business Challenge

San Carlos Business Challenge:

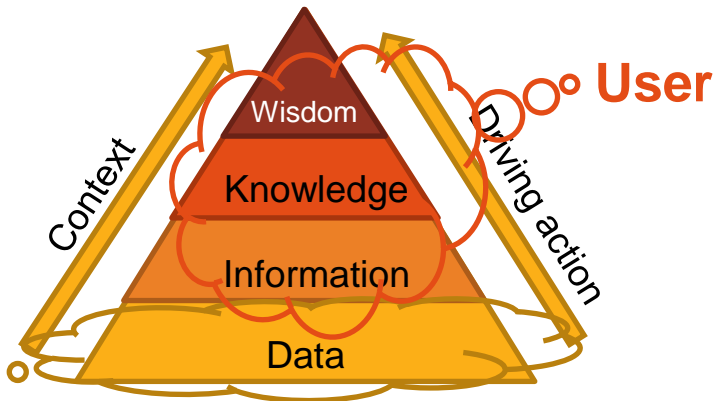
- 1) Need bigger and better PI System (site expansion)
- 2) Need to Align with Novartis Automation Strategy

Novartis Automation Strategy:

It's All About The Data

*“The right
information, for
the right **user**, at
the right **time**”*

Technical • • •



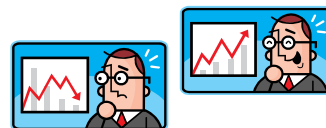
The Novartis Automation Strategy

The Four Business Drivers

- Is my process in control ?
- How can I improve my process ?



- What is the yield ?
- Why are machines stopping ?



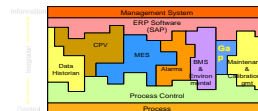
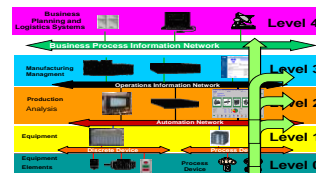
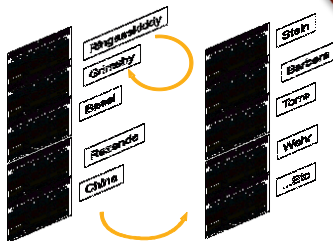
The right INFO, for the right USER at the right TIME

- Product transfer across sites
- Visibility of supply chain

- Systems are integrated
- Data flows from ERP to shop floor and vice versa

Tech. R&D to
Commercial

Supply Chain



The Novartis Automation Strategy

The Workcenter of the Future

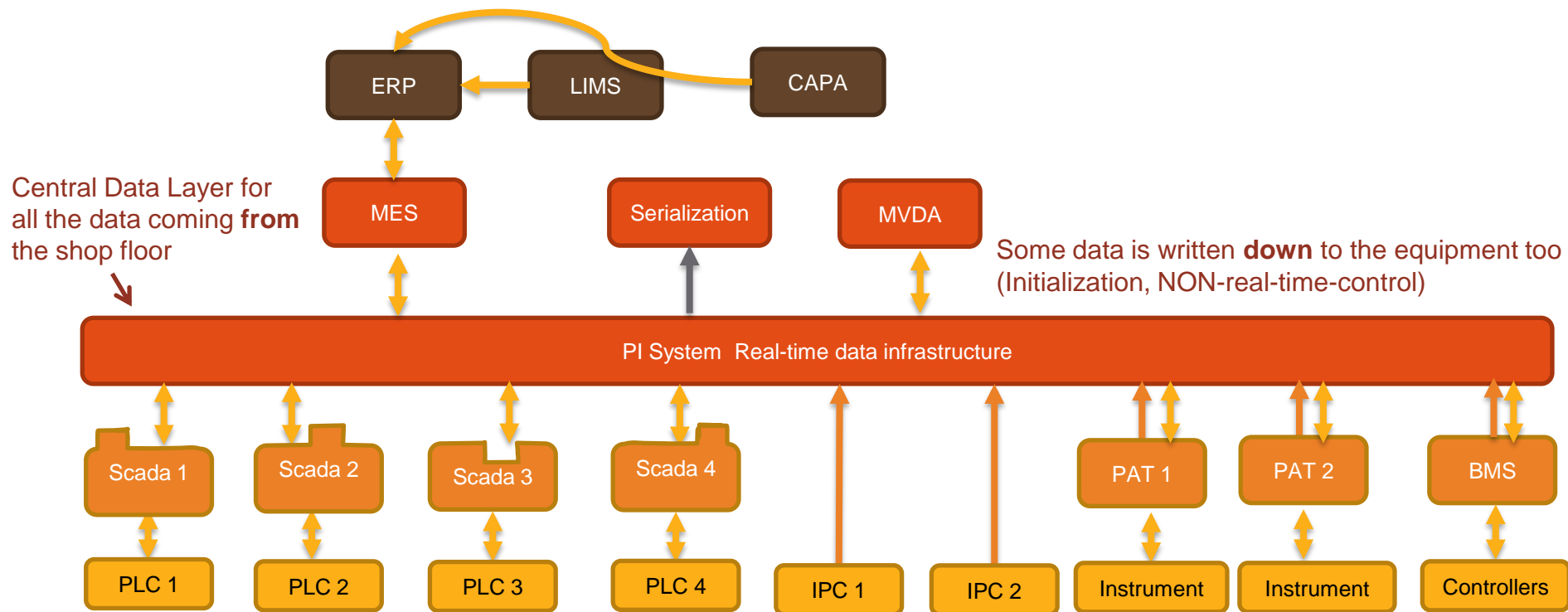
Objectives

1. “Lights out” Manufacturing
 - High visibility of process without entering the room
2. Paperless Manufacturing
 - MES
3. User Cockpits
 - Information needed to drive the operation



The Novartis Automation Strategy

Simplified Architecture: The PI System as the Central Data Layer



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The San Carlos PI System Upgrade Project

Project Objectives

1. Improve PI System robustness and data access
 - » Existing PI System had no PI Collective, no mPI, no AF, no PI Coresight
 - » PI DataLink and PI ProcessBook are behind firewall

2. Lay the foundation for Novartis data infrastructure for future MES
 - » San Carlos equipment was already networked, with remote access capability

The San Carlos PI System Upgrade Project

High-Level Project Strategy

- Rollout the “latest & greatest” PI System software
- Rollout the OSIsoft/Novartis standard PI System architecture
- Leverage EA for preparation, s/w installation, and basic s/w config.

The San Carlos PI System Upgrade Project

Project Scope

1. Install following applications:

- » PI Collective
- » Asset Framework (AF)
- » PI Coresight
- » Managed PI
- » Notifications
- » Event Frames (EF)
- » PI ProcessBook and PI DataLink
- » OPC interfaces and OPC Servers

Existing system must keep running while new system is being implemented

2. Migrate data from old PI Server

3. Document and Qualify System

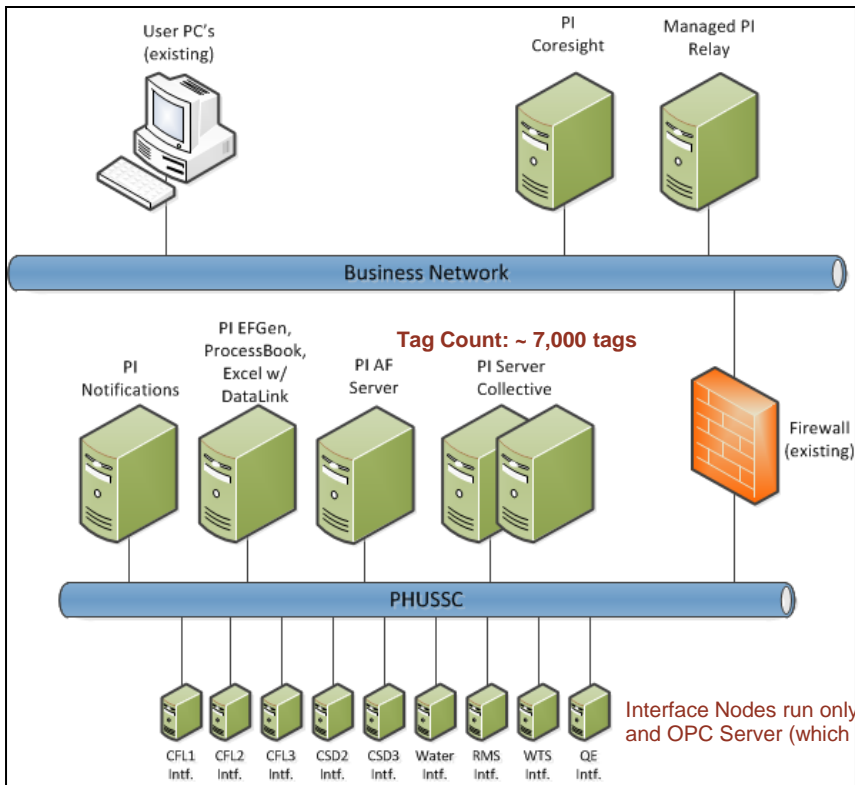
The San Carlos PI System Upgrade Project

Technical Project Strategy

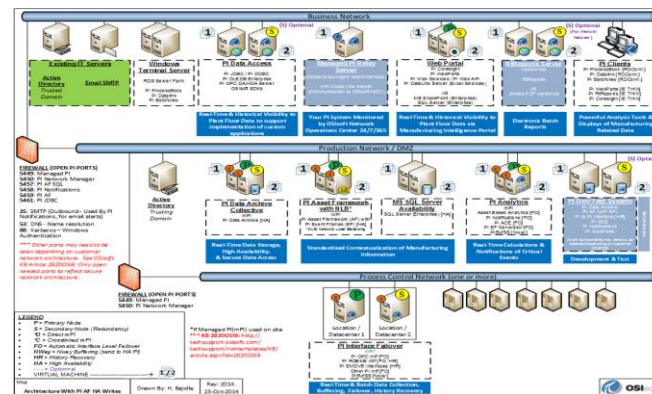
- Use VM's (HA) for all servers and interface nodes
- Build separate system in parallel with existing one
- Have OSIsoft engineers perform remote installation
 - Using Bomgar sessions in presence of System Admin
- Execute project internally, except for one validation contractor

The San Carlos PI System Upgrade Project

San Carlos System Architecture



Novartis Standard PI Architecture (developed with OSIssoft COE)



The San Carlos PI System Upgrade Project

Project Noteworthy Highlights

- ✓ Remote installation worked very well (but took slightly longer)
- ✓ Use of VMs allowed quick turnaround for changes

The San Carlos PI System Upgrade Project

Project Noteworthy Highlights (cont'd)

- ✓ Minor issue during Data Migration:
 - Lost the newly created interface health tags, Notification & EF history tags
 - Had to be re-created

- ✓ Qualification went very well
 - » Risk-based approach for Quality-Critical tags
 - » Some Non-Quality-Critical functionality (eg Notifications) was not OQ'd

- ✓ Project Completed in 8 months



The Novartis Company and the San Carlos Site at a Glance

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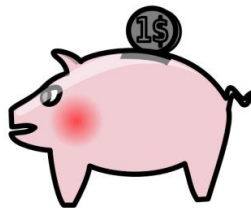
Business and Operational Value Achieved

Future Plans

The San Carlos PI System Upgrade Project

Business Value Achieved

- ✓ Realizing EA Value:
 - San Carlos is the first site to rollout standard architecture with latest software
- ✓ Architectural foundation is laid out for 'Workcenter of the Future'
- ✓ Project direct costs were very low
 - Most of it covered by EA, or done by internal staff



The San Carlos PI System Upgrade Project

Operational Value Achieved

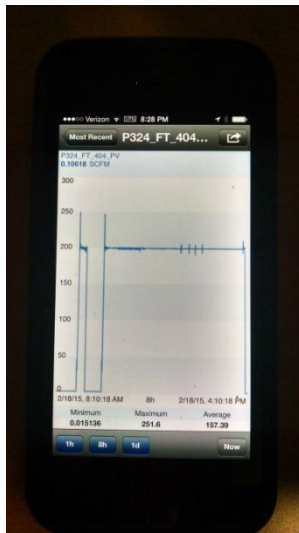
- ✓ PI Coresight dramatically improves access to data
 - » Application available on business network
 - » Users can browse AF Elements to find data
 - » Can teach a new user in 5 minutes
 - » No more data request to Automation Engineers!



The San Carlos PI System Upgrade Project

Operational Value Achieved (cont'd)

- ✓ Users are using PI Coresight iPhone app
 - Facilities team can check status of utilities (water, steam, etc)
 - Engineers & Management can check status of manuf. equip.



The San Carlos PI System Upgrade Project

Operational Value Achieved (cont'd)

- ✓ 'Managed PI' frees up internal resources
- ✓ Implemented a risk-based approach to managing Quality-Critical tags vs. Non-Quality-Critical tags

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Business and Operational Value Achieved

Plans for the Future

The San Carlos PI System

Plans for the Future

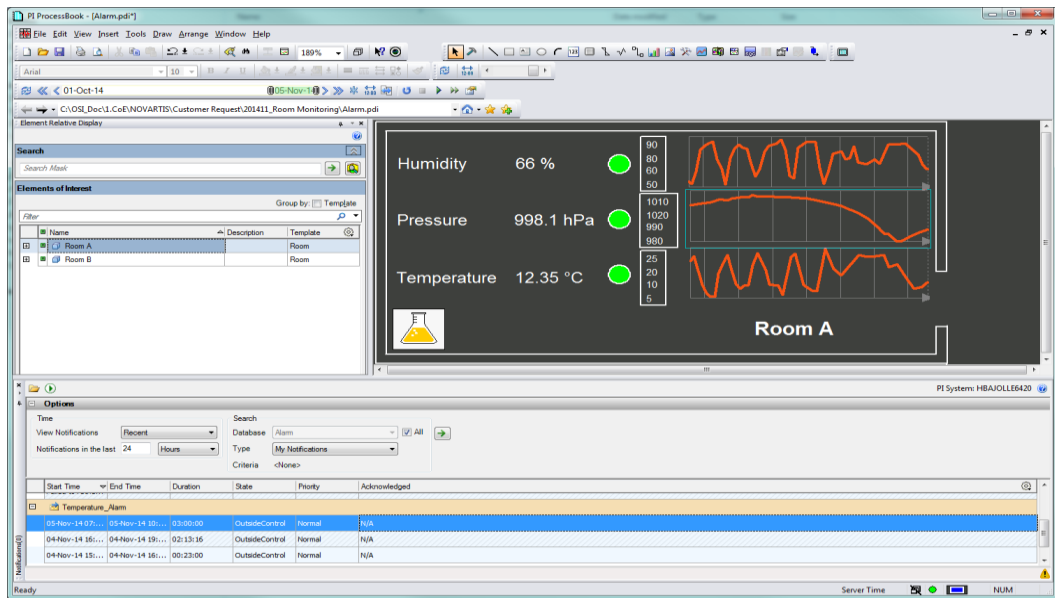
- Store data from BAS and from three remaining Process Units in PI Server



The San Carlos PI System

Plans for the Future

- Monitor QC Equip. with PI ProcessBook and Notifications



Will use templates from 'Monitoring & Alarming System' developed at Singapore site

The San Carlos PI System

Plans for the Future (cont'd)

- Create dashboard showing the status of every major equipment on site
- Use Event Frames to analyze/compare Spray Dryer batches



Maximizing the Value of Novartis' GMP PI System with the Enterprise Agreement: San Carlos Site Case Study

“We fully leveraged the EA to upgrade the San Carlos Site PI System. The project was extremely successful, and we are now well-positioned to implement the rest of the Novartis Automation Strategy”

The right INFO, for the right USER at the right TIME

Serge de Grandpré
Novartis Pharmaceuticals Corp.



Business Challenges

- A. Need bigger and better PI System due to site expansion
- B. Need to align with Novartis Automation Strategy
- C. Users find it difficult to access PI data

Solution

- A. Leverage EA for software and installation services to upgrade aging PI System
- B. Implement new state-of-the-art and robust PI System, and migrate historical data
- C. Use PI Coresight to improve access to data

Results and Benefits

- A. Extremely successful implementation (fast and with no issues)
- B. Productivity is increased as users have much easier access to data to make GMP decisions
- C. Foundation is laid out to implement MES (part of 'The Workcenter of the Future' initiative).

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Questions

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

State your
name & company





THANK
YOU

