Novartis automation strategy: The Workcenter of the Future (WoF)

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Novartis automation strategy
The Workcenter of the Future

Novartis at a glance

Our journey with OSIsoft

WHY a Novartis automation strategy

HOW:
- Standardization program
- Equipment connectivity (R.U.T.H)
- Interface strategy

WHAT: The Workcenter of the Future (WoF)

KEY questions and summary
reached 1.2 billion patients in 2013
pharma division

- researches
- develops
- manufactures
- distributes
- sells

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

> 11,000 associates working in 25 manufacturing sites in 15 countries on 4 continents

~ 2,400 tons drug substance produced each year

~ 30 billion patient doses tablets, capsules and vials for 250 different brands made each year
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KEY questions and summary
## Our journey with OSIsoft

### Long relationship

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1999</td>
<td>PI installed at Sandoz Austria</td>
</tr>
<tr>
<td>2000</td>
<td>First pilot at Ireland. Legacy OEM historian needed replacement</td>
</tr>
<tr>
<td>2001</td>
<td>Retired all legacy historians and standardised on PI across Irish site</td>
</tr>
<tr>
<td>2002</td>
<td>PAT projects needed a historian</td>
</tr>
<tr>
<td>2003</td>
<td>Technical and commercial comparison</td>
</tr>
<tr>
<td>2004</td>
<td>OSI became a Pharma preferred supplier for 3 Years - 4 sites</td>
</tr>
<tr>
<td>2005</td>
<td>Enterprise agreement</td>
</tr>
</tbody>
</table>

- First pilot at Ireland. Legacy OEM historian needed replacement
- Retired all legacy historians and standardised on PI across Irish site
- PAT projects needed a historian
- Technical and commercial comparison
- OSI became a Pharma preferred supplier for 3 Years - 4 sites
- Enterprise agreement
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KEY questions and summary
Making Quality Medicine On Time, Every Time

Technical operations strategy

- AUTOMATION STRATEGY

- Can we have an automation strategy?

- Goal is to support the TechOps strategy

- Making Quality Medicine On Time, Every time

- How?
What is the 21st century automation about?

Automation strategy

- What is the 21st century automation about?
- It is not about ....
  - Robotization?
  - Uniformity? Same brands? Same PLCs?
  - Vertical integration?
- It is all about..
  - DATA
  - The right information, for the right user, at the right time
Why / What / How of the strategy

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

**WHY**
- What are the Business Drivers?

**WHAT**
- What to do?
- What to deliver?
- How will the work-center of the future look like?

**HOW**
- Technology
- Methodology

The right INFO, for the right USER, at the right TIME
The four automation business drivers

**Automation strategy**

1. **Quality**
   - Is my process IN control?
   - How can I improve my process?
   - What are the sources of variability?

2. **Productivity**
   - What is the OEE, how to improve it?
   - What is the yield?
   - Why are machines stopping?
   - Visual management

3. **Integrated Environment**
   - Systems are integrated
   - Data flows from ERP to shop floor
   - And viceversa

4. **Flexibility**
   - Product transfer across sites
   - Visibility of supply chain
   - Transfer from R&D to commercial

**The right INFO, for the right USER at the right TIME**
Novartis automation strategy

The Workcenter of the Future

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KEY questions and summary

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Novartis is standardizing manufacturing equipment to

- Deliver procurement savings
- Simplify & reduce Engineering and qualification with their implementation
- Simplify product transfers and better demonstrate comparability
Avoid novartization

What is an standard?
Novartis automation strategy

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KEY questions and summary
R.U.T.H concept vs island approach

Island approach

1. What is R.U.T.H?
   a) Recipe management
   b) User management
   c) Time Synchronization
   d) Historian

Novartization:
Specific changes required to interface to MES

Example of URS:
Data storage of product batches for 10 years of lifetime after last batch is produced.

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R.U.T.H backbone

Back to the basics

Centralized Standard Infrastructure:

- Recipe handler
- Domain Controller
- Time Sync
- PI System Infrastructure

- Create a CENTRAL infrastructure
- Simplify Equipment
- 17% Savings
Novartis automation strategy
The Workcenter of the Future

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**WHAT:** The Workcenter of the Future (WoF)

**KEY questions and summary**

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Traditional interface strategy

Data at the core

Easy, isn’t it?
The PI System as the central DATA layer

*Simplified interface strategy*

Central DATA LAYER for ALL data coming from the shop floor
And also ... The PI System as the data GATEWAY

Using the PI System to write down

We are leveraging the connectivity capability of the PI System to write down to equipment (Initialization) (NON-real-time-control)

Central DATA LAYER for ALL data coming from the shop floor
The PI System as the data layer and data GATEWAY

Data at the core

- Business Intelligence
- ERP
- PI System
  (heart)
- MES
  (muscle)
- Automation systems and field devices
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Connecting the dots

Continuous Process Verification

HISTORIAN

In-Process-Control

MES

Process Analytical Technology

ISLANDS of Technology
Manufacturing information process control technology

Our Novartis’ critical success factors

Legend
- SAP IT Level
- Automated Equipment Level
- NW Infrastructure Level With MITEX

Data for Analysis
- Process Control
- Data Acquisition
- Tablet Press
- IPC CheckMaster
- Alarms & Events
- Data Analysis
- Product Studies
- WoF KPI Dashboards
- MES
- Mfg Work Flow Design
- WoF
- Data Analysis
- Product Studies
- Product Optimization
- Cost Efficiencies
- Quality Assurance
- Manufacturing Excellence

Value Stream Mapping
- Network & Servers
- PI System Infrastructure

Process Verification

SAP IT Level
Automated Equipment Level
NW Infrastructure Level With MITEX

Network & Servers

Process Control
- Analyze
- Improve

Data Measure

PI System Infrastructure

H1 '14

H2 '14

2015

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An integrated pilot for pharma operations

The goals of the WoF

Three objectives

1. “Lights out manufacturing”
2. “Paperless manufacturing”
3. Cockpits (operator and process experts)
Lights out manufacturing

*The goals of the WoF*

- High visibility of process without entering the room
- Integrated automated In-process-controls
- Minimum manual intervention increase product quality
- Ideally, the light in the production room can be switched off

Control charts
Alarms & Events

**Manual Activities & Interventions**

- Aspect Check
- Fabrication cycle
- Manual IPC for Check master breakdown
- Bin change

**Major Causes of Stoppage**

- 45%
- 22%
- 22%
- 11%

**Causes**
Paperless manufacturing

*Understanding the meaning*

- **What it is:**
  - All instructions / information is available and automatically provided electronically to the right user, at the right time, every time.
  - All data is captured, stored, analyzed, visualized, reviewed, approved and distributed electronically in a compliant manner.

- **What it is not:**
  - No information captured manually on paper
  - Scanned paper records (paper on glass)
What information do we need **to drive** operations?
Operator cockpit

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- Operator cockpit
  - Information point for operators to access all information and controls required for them to operate the machine.
  - “The right information, to the right user at the right time, every time”
Novartis automation strategy

*The Workcenter of the Future*

- **Novartis at a glance**
- **Our journey with OSIsoft**
- **WHY a Novartis automation strategy**
- **HOW:**
  - Standardization program
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- **WHAT:** The Workcenter of the Future (WoF)
- **KEY questions and summary**
The THREE KEY questions

The Workcenter of the Future

- Who is the USER?
  - It is not the president or the HQ
  - Role based information
  - Strong focus on OPERATIONS

- Do we want to solve past problems or...?
  - To drive operations?

- How to move from data to knowledge?

![Diagram showing the relationship between Data, Information, Knowledge, and Wisdom]

Technical
Customer workstream

The Workcenter of the Future

- «Customer» workstream
  - WHAT to do
  - What information do you need
  - Who has to see it
  - Where do you want to see it
  - Which format
The Workcenter of the Future: SUMMARY

**WHY**
- Quality
- Productivity
- Integrated Env.
- Flexibility

**WHAT**
- Lights out mfg.
- Paperless
- Operator Cockpit
  - Actionable Info.
  - (Avoid rear mirror)

**HOW**
- Standardization
- Eqp. connectivity (RUTH)
- Simplified Interface
  (PI System as the data heart)
- From data to Information
- Customer DRIVEN

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*The right INFO, for the right USER at the right TIME*
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- NOVARTIS PHARMA AG
THANK YOU