

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

OUR PRIORITIES



GROWTH



INNOVATION



PRODUCTIVITY



PEOPLE

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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Our journey with OSIsoft

	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	
✓	PI installed at Sandoz Austria																
✓	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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Making Quality Medicine On Time, Every Time

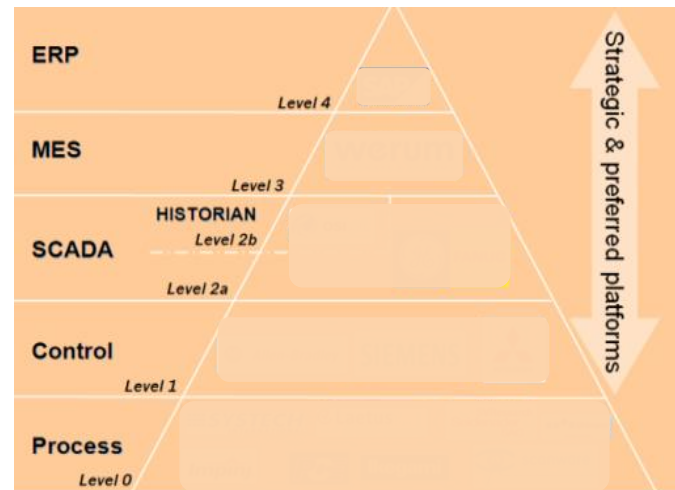
Technical operations strategy

- 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

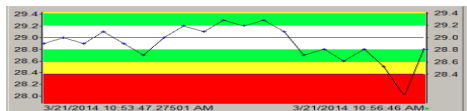
The right INFO, for the right USER, at the right TIME



The four automation business drivers

Automation strategy

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



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

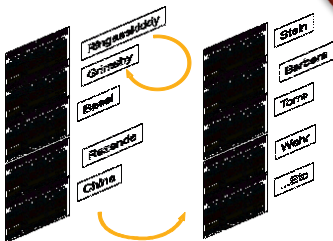


The right INFO, for the right USER at the right TIME

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

Tech. R&D to Commercial

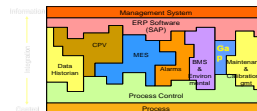
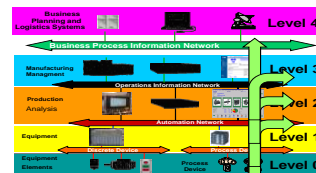
Supply Chain



4. Flexibility

3. Integrated Environment

- Systems are integrated
- Data flows from ERP to shop floor
- And viceversa



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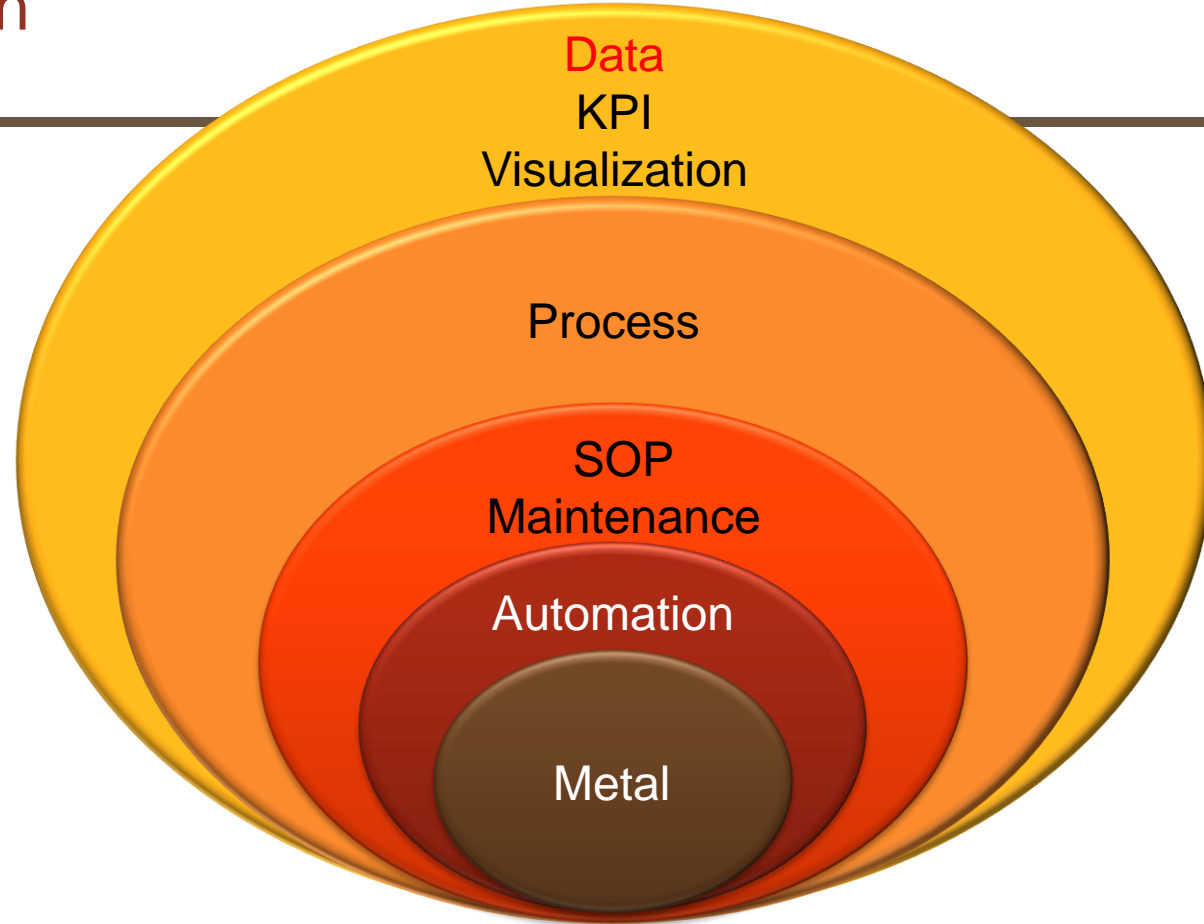
Equipment standardization program

Automation strategy three pillars

- 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 ?



Design ONE, Build MANY

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R.U.T.H concept vs island approach

Island approach

1. What is R.U.T.H ?

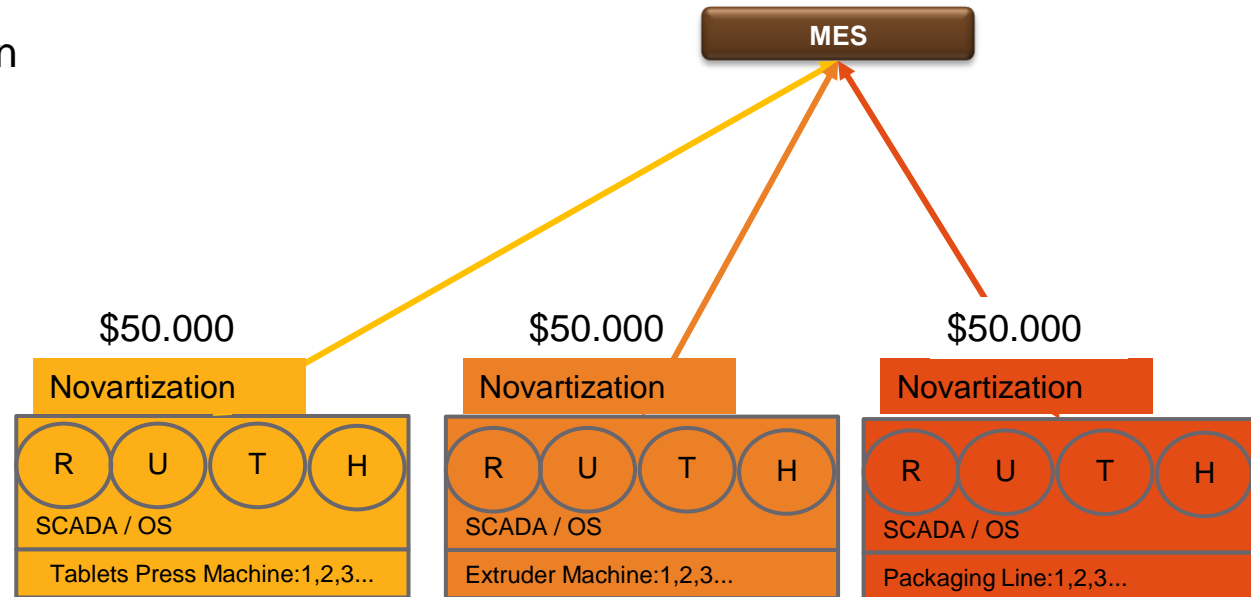
- a) Recipe management
- b) User management
- c) Time Synchronization
- d) Historian

Novartization:

Specific changes required to interface to MES

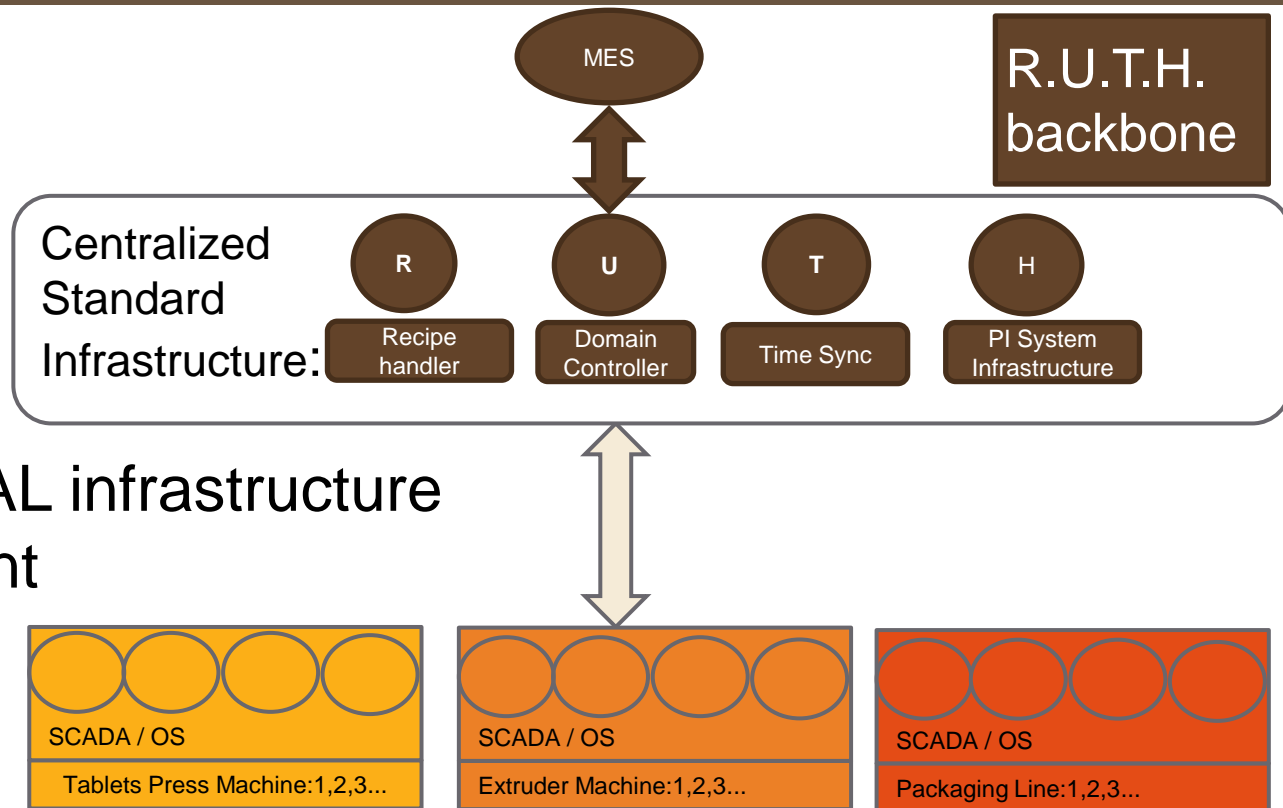
Example of URS:

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



R.U.T.H backbone

Back to the basics



- Create a CENTRAL infrastructure
- **Simplify** Equipment
- **17% Savings**

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R.U.T.H. concept

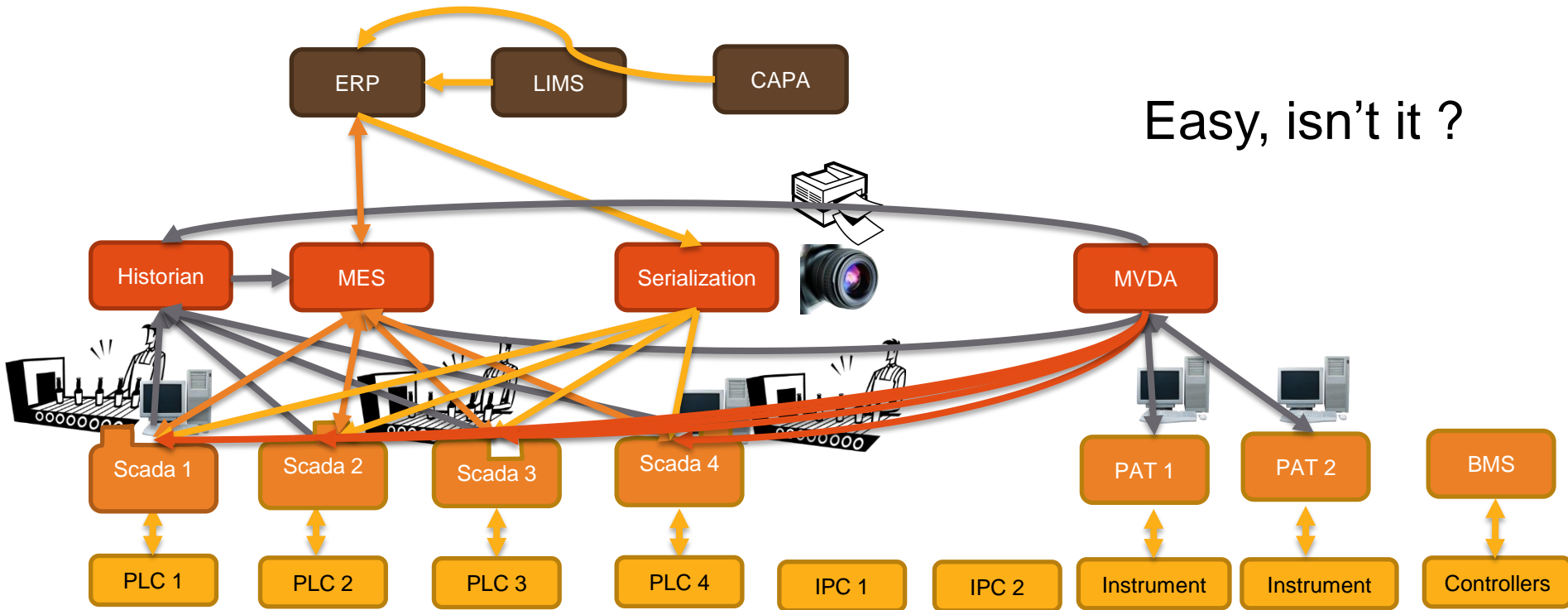
Interface strategy

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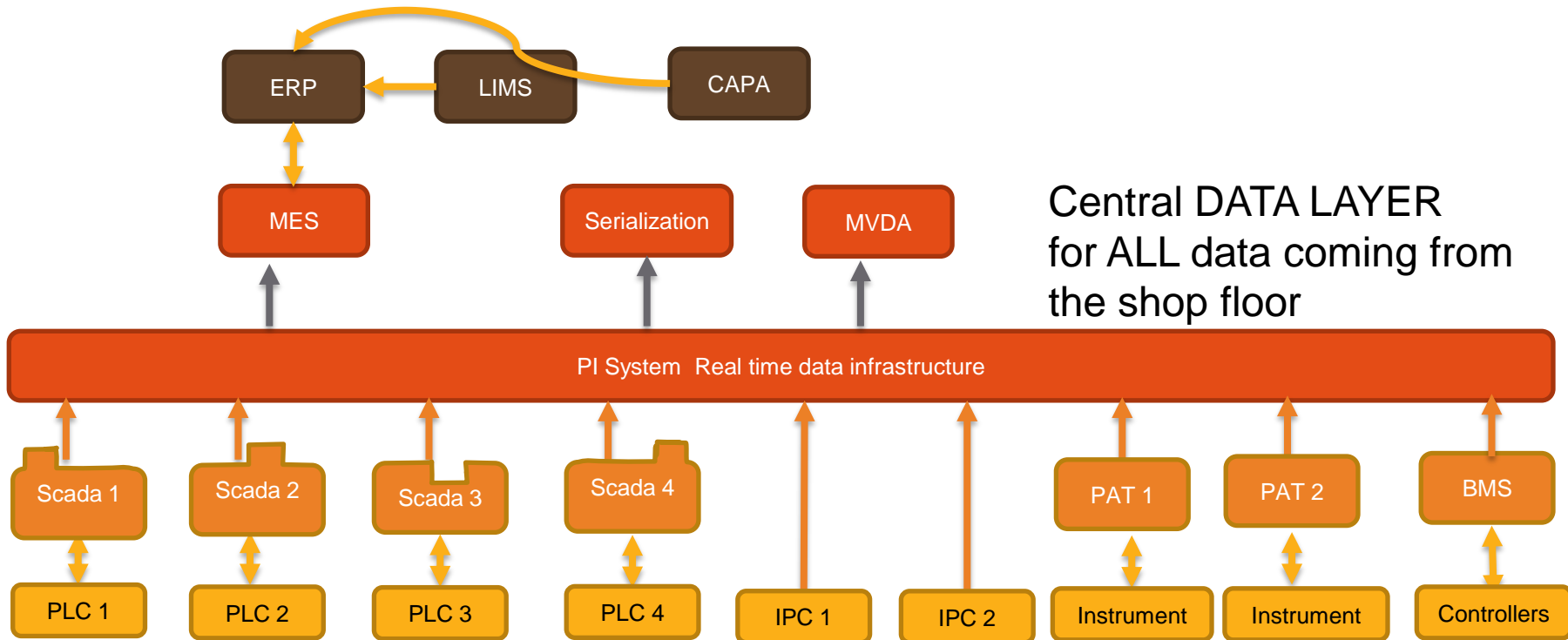
Traditional interface strategy

Data at the core



The PI System as the central DATA layer

Simplified interface strategy

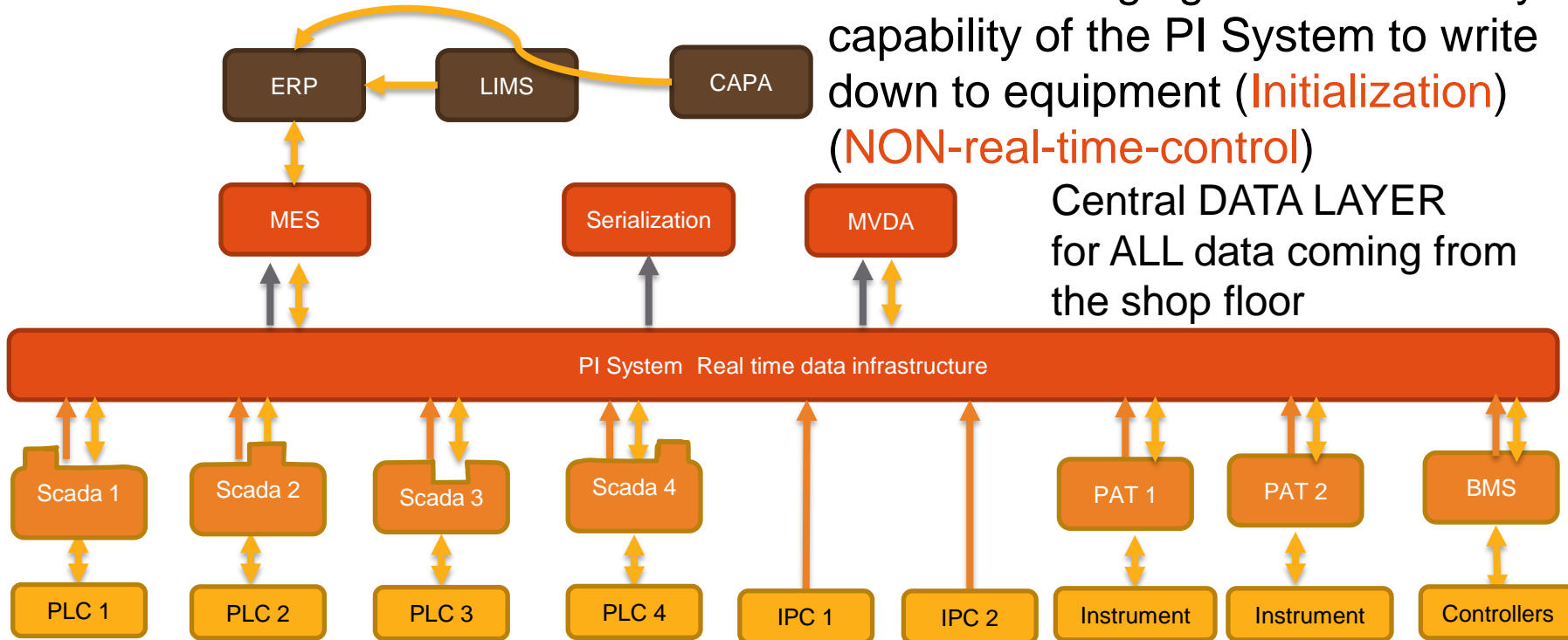


And also ...The PI System as the data GATEWAY

Using the PI System to write down

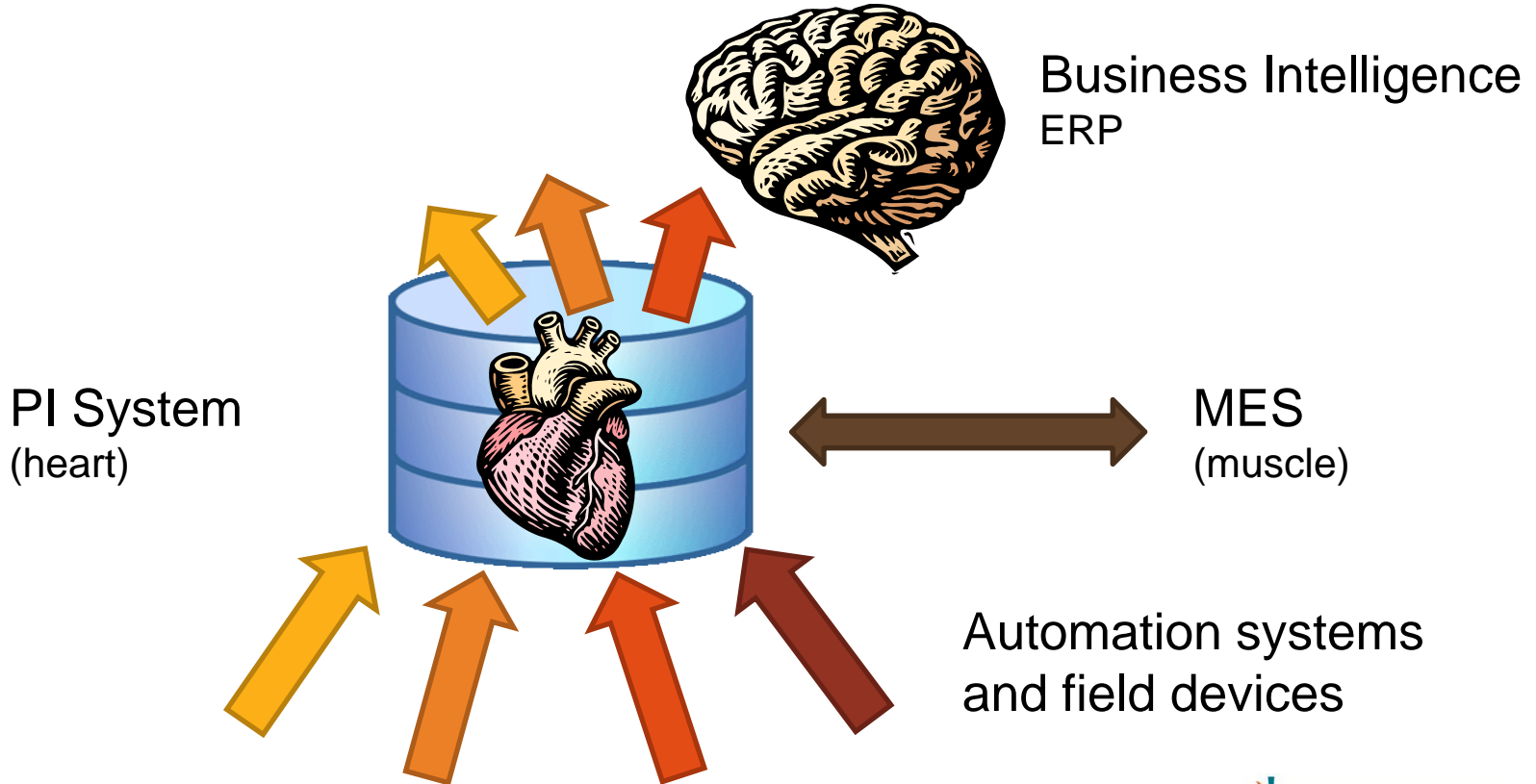
We are leveraging the connectivity capability of the PI System to write down to equipment (**Initialization**) (**NON-real-time-control**)

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



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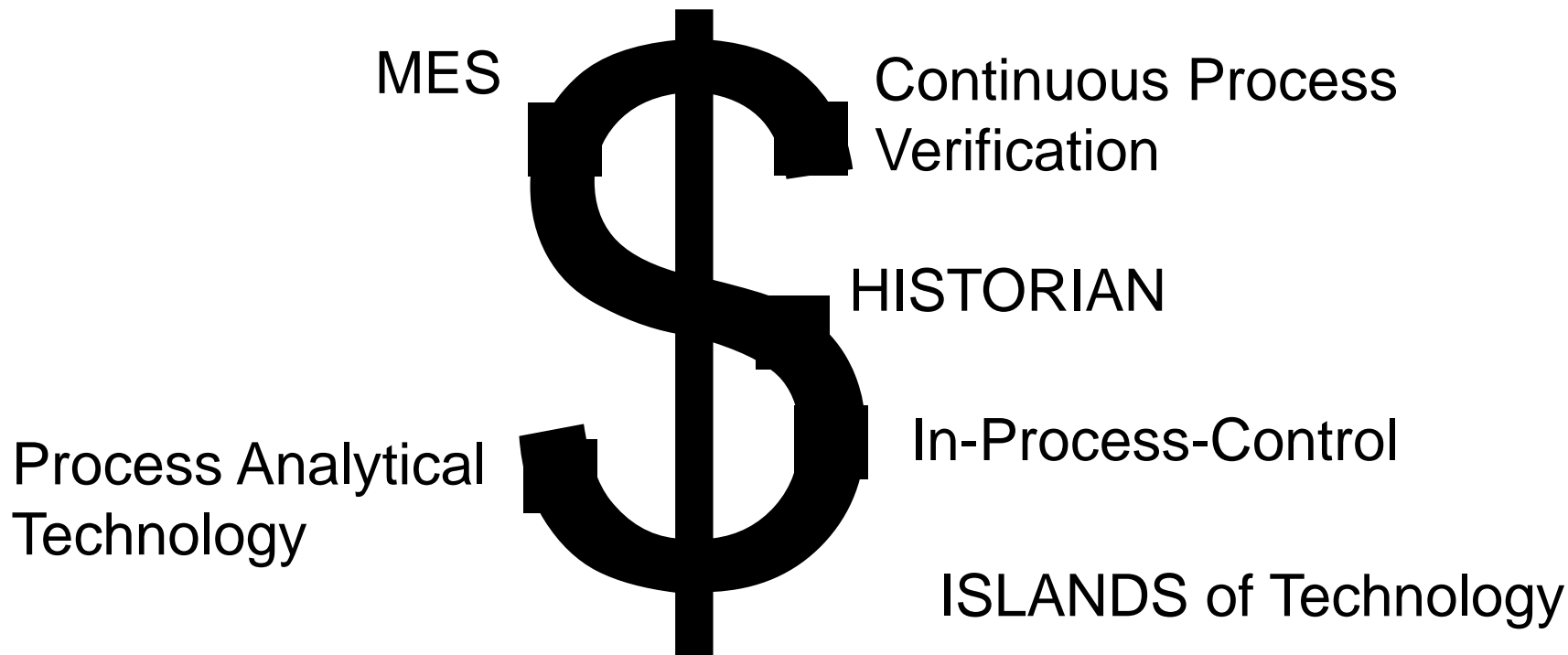
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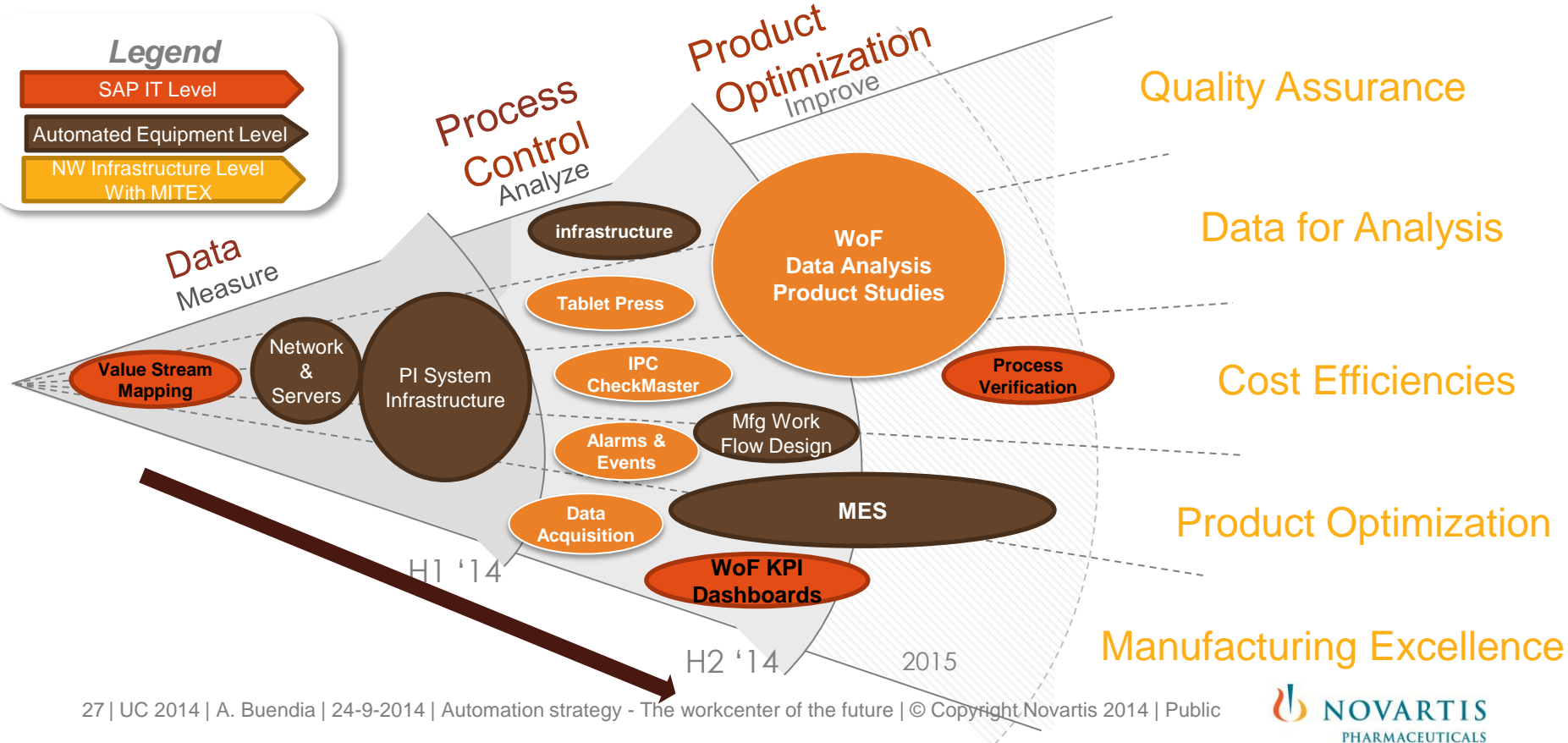
The Workcenter of the Future

Connecting the dots



Manufacturing information process control technology

Our Novartis' critical success factors



An integrated pilot for pharma operations

The goals of the WoF

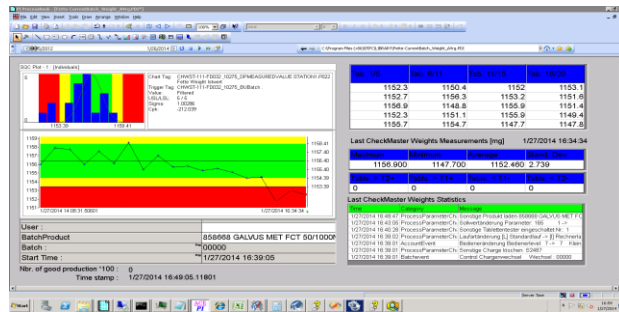
Three objectives

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

Lights out manufacturing

The goals of the WoF

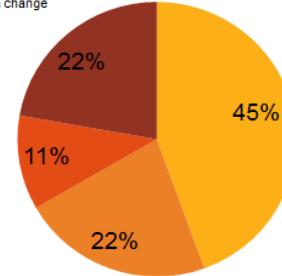
- High visibility of process without entering the room
- Integrated automated In-process-controls
- Minimum manual intervention increase product quality
- Ideally, the light in the production room can be switched off



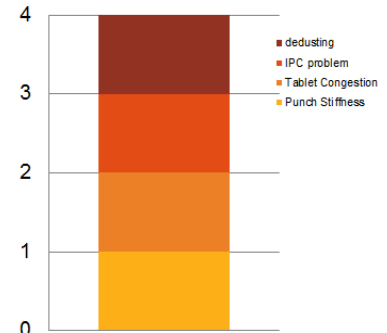
Control charts
Alarms & Events

Manual Activities & Interventions

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



Major Causes of Stoppage



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)



Manufacturing cockpit of the future

The vision

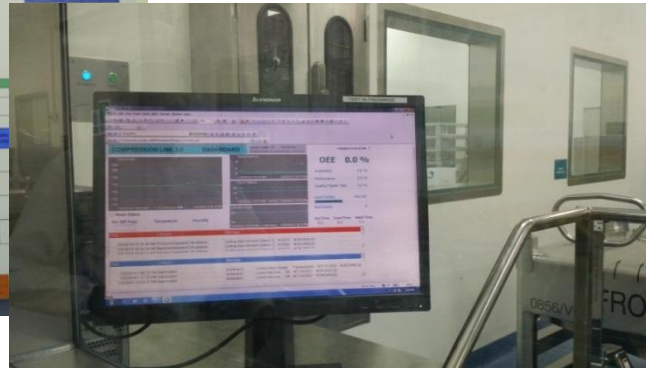
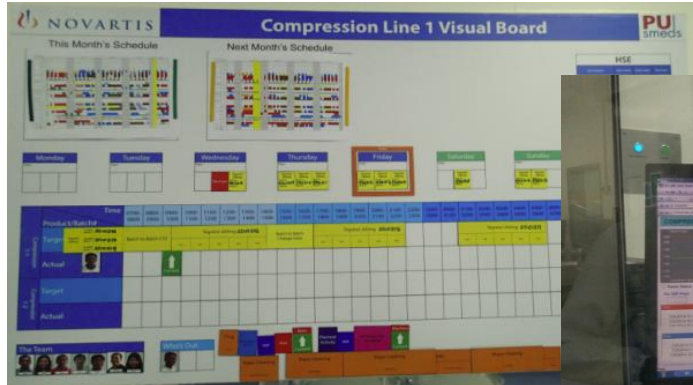


What information do we need **to drive** operations ?

Operator cockpit

The Workcenter of the Future

- 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**”



Quality

Process

Productivity

Environment

Alarms

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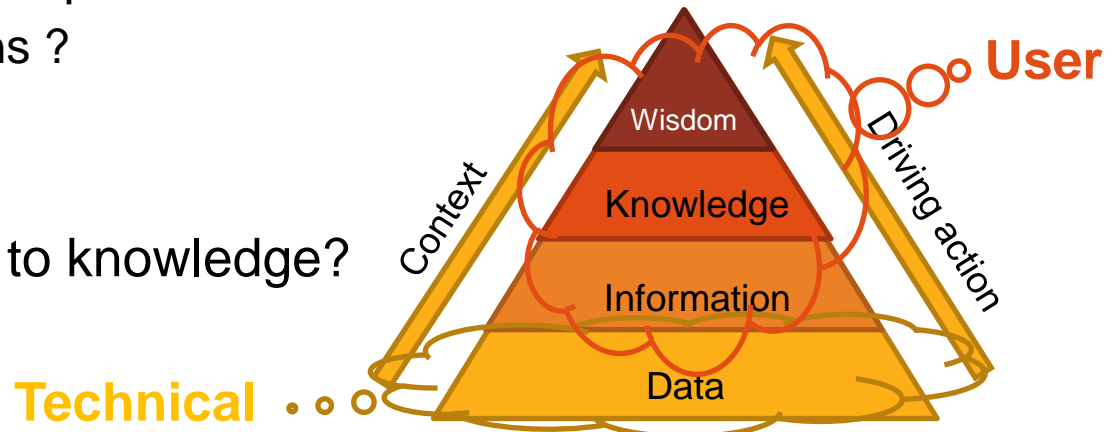
WHAT: The Workcenter of the Future (WoF)

KEY questions and summary

The THREE KEY questions

The Workcenter of the Future

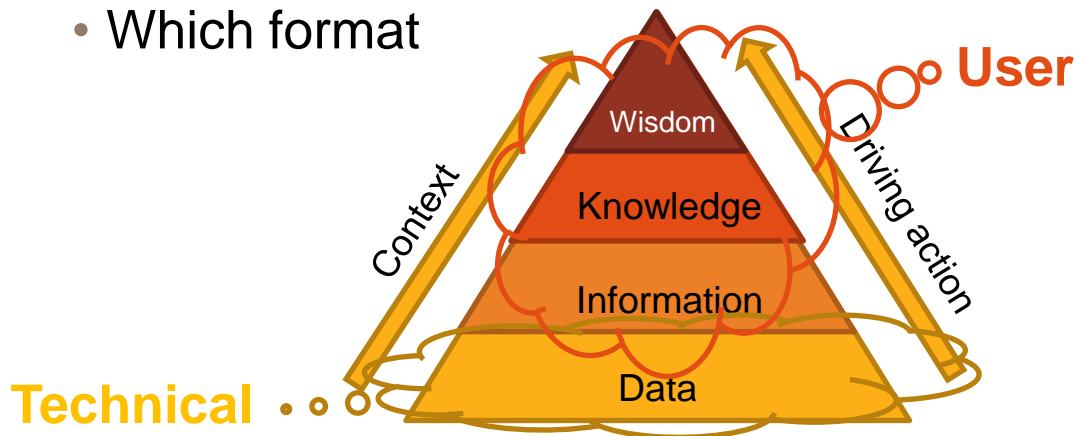
- Who is the USER ?
 - It is not the president or the HQ
 - Role based information
 - Strong focus on OPERATIONS
- Do we want to solve past problems or...?
 - To drive operations ?
- How to move from data to knowledge?




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



 **NOVARTIS**

MIPROC Work Center of the Future (WoF) Questionnaire

Department: MS&T Work Center: Compression Line

Site : _____ Date: _____

General Instruction: Please answer *All* questions; select *All* options that are relevant.

Section A : Real Time Data

1 What are the CPPs and parameters of the Tablet Press you want to see?

☐ Thickness
☐ Hardness
☐ Diameter
☐ Compression Force
☐ Extraction Vacuum
☐ Others, Please specify: _____

2 What control strategy is needed when a CPP is out of Control Limits (Alarm limits)?

☐ Immediate machine stop
☐ Alarm informing operator his presence
☐ Others, Please specify: _____

3 Where do you want to see information related to the Compression Line?

☐ In a control room
☐ Distributed in the production floor
☐ Others, Please specify: _____

4 In what form do you want to see real time parameters related to question 1?

☐ Pie chart
☐ Bar chart
☐ Line chart
☐ Process Control Chart
☐ Others, Please specify: _____

Section B - Reports

How often do you need summary information for your use?

☐ Real-Time / 10 minutes
☐ End of each shift / 1 day
☐ End of each week / 1 week
☐ Others, Please specify: _____

2 In what format do you need to include in the reports?

☐ Statistical information (e.g. range, mean, std dev, etc.)
☐ Compression data (e.g. Compression settings, filling depth setting, punch stiffness)
☐ Alarms and Alerts generated
☐ Others, Please specify: _____

Page 1 of 2

Why / What / How

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

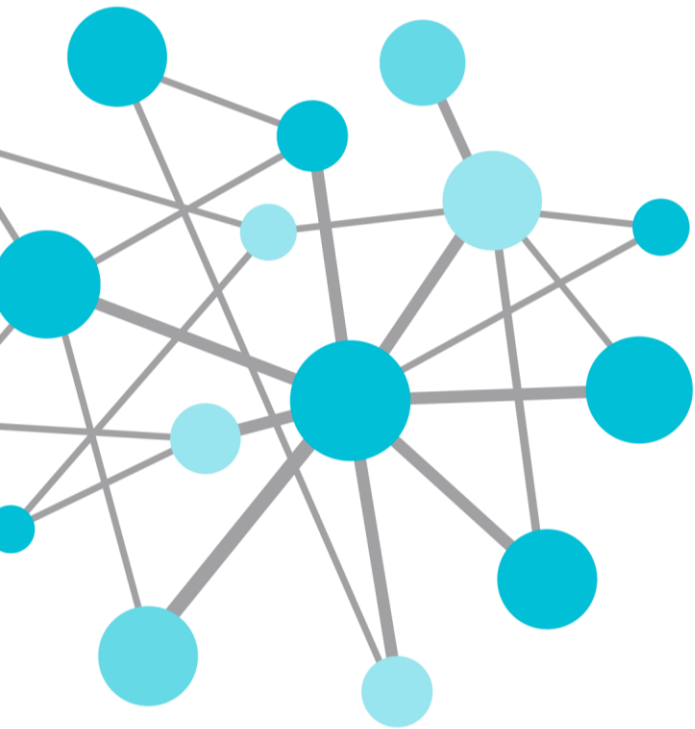
- Standardization
- Eqp. connectivity (RUTH)
- Simplified Interface
(PI System as the data heart)
- From data to Information
- Customer DRIVEN

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



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YOU

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