The Factory of the Future ...is possible today ?

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Novartis automation strategy

The Factory of the Future ... is possible today?

- Novartis at a glance
- What is the Factory of the Future
- Novartis automation strategy
  - Standardization program
  - Technical infrastructure
  - Global data model
- User driven program
- Summary and conclusions

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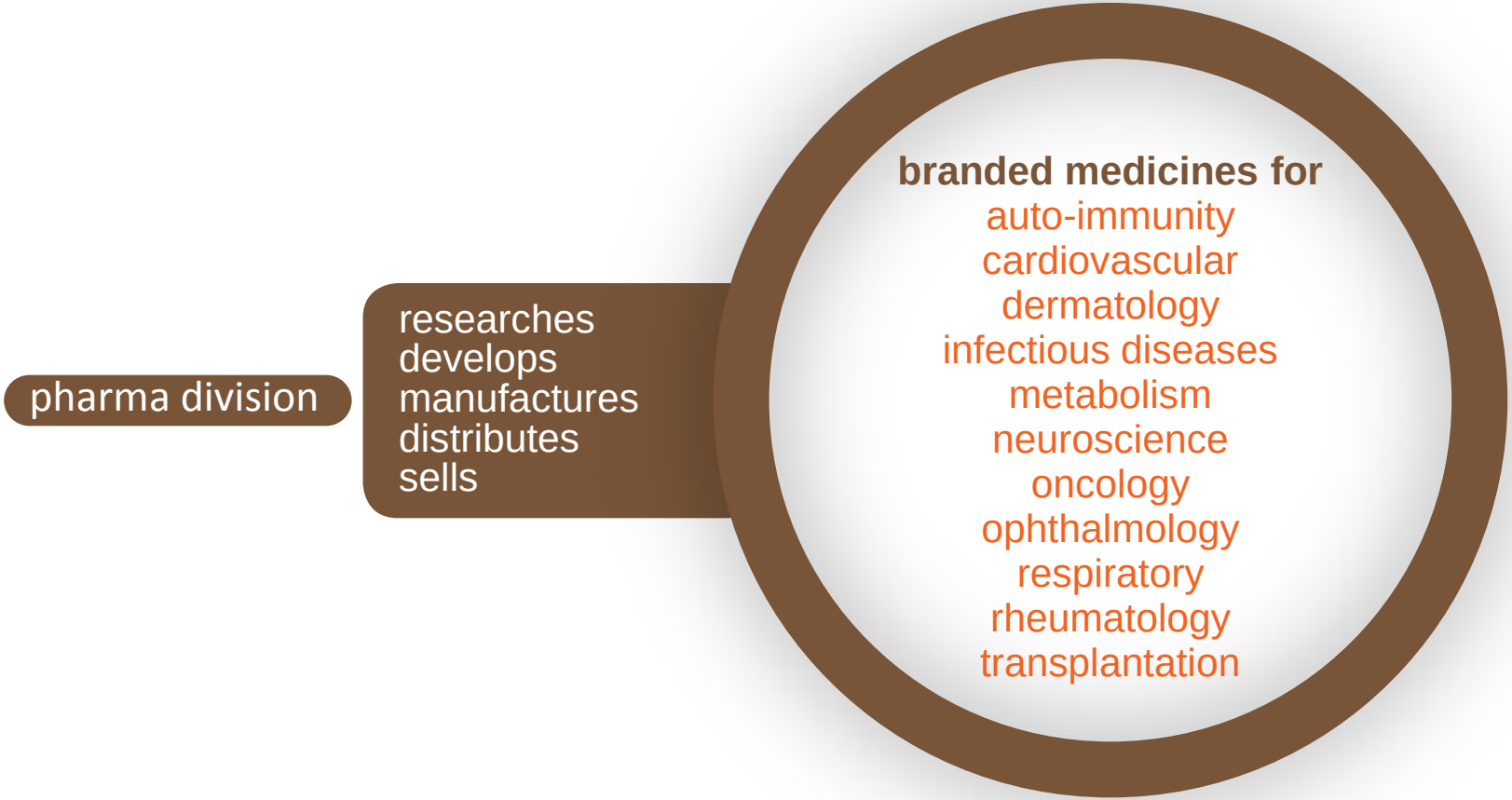
reached 1.2 billion patients in 2013



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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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Factory of the Future: A new concept
Trends

- 20th Century Automation: "Replace people"
  - Eliminate low added value tasks by automation, robotization and motion of mechanical devices.
- 21st Century Automation: "Help people to do their jobs"
  - Focus today is on Information and knowledge.
  - Key to know in our processes, equipment and manufacturing plants
    - what happened (historical information) & what is happening (real time monitoring)
    - what is going to happen (predictive analytics) & and WHY is that happening.
  - This will improve processes, remove sources of variability, increase productivity and build quality.
  - What we need is the ability to extract information from the equipment, aggregate, and consolidate at upper level and convert into meaningful information for the user (actionable information).
  - Each manufacturer tends to force its own "language" and we strive for common languages that allow the connectivity and communication across different brands and types of devices / equipment.

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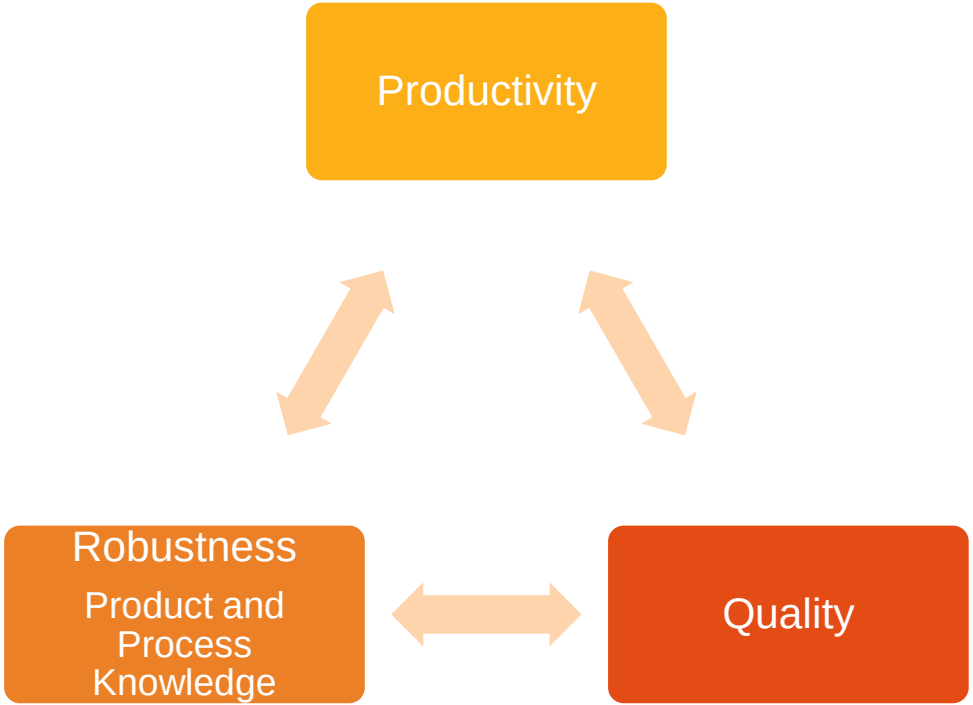
Factory of the Future: A new concept

The triangle



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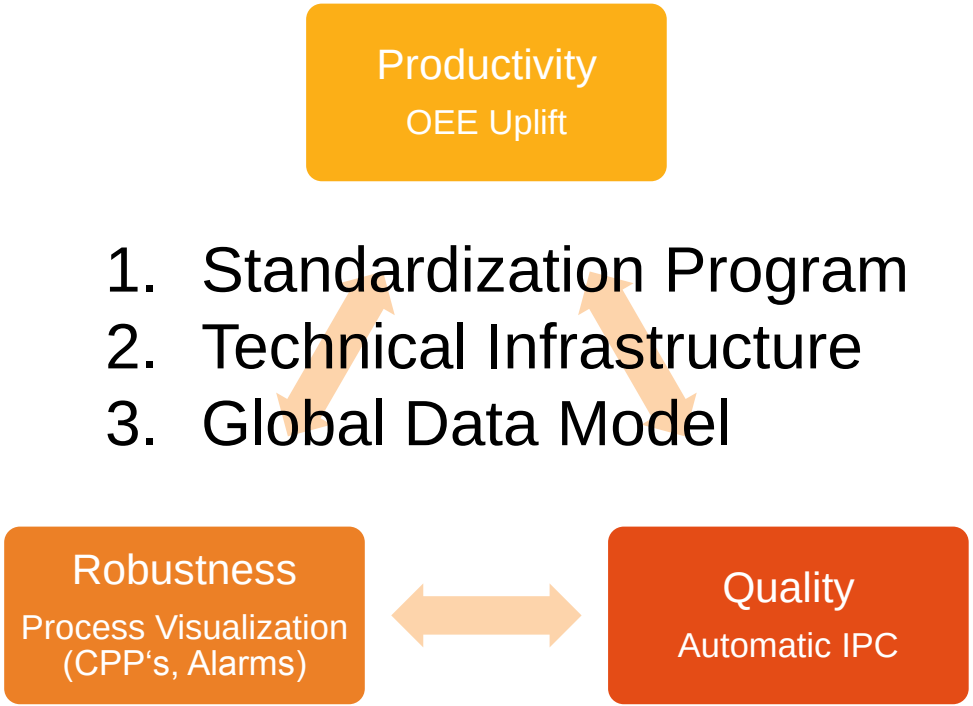
Factory of the future: a new concept

The triangle



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Equipment standardization program

Design one, build many

- 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»

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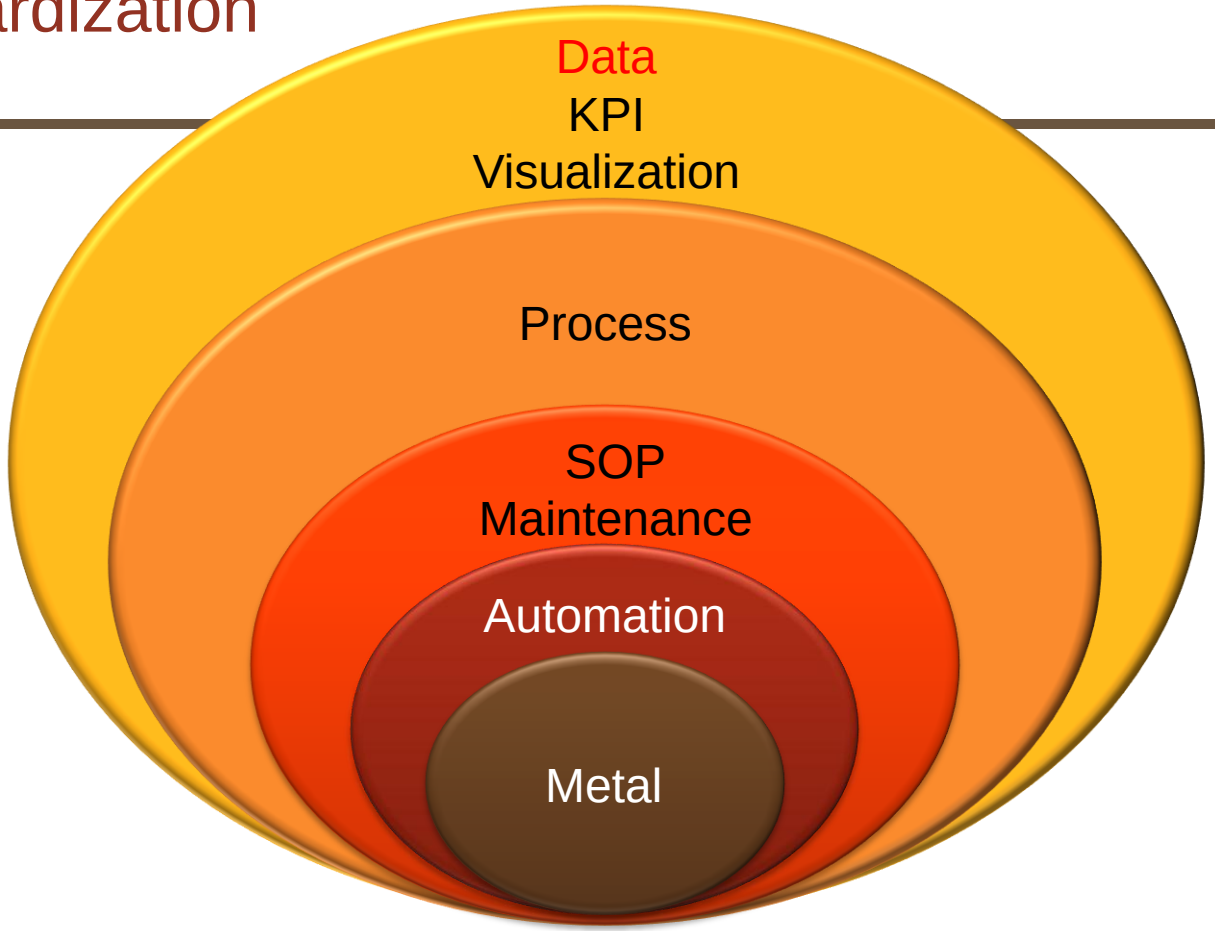
Equipment Standardization

What is a standard?



Design ONE, Build MANY

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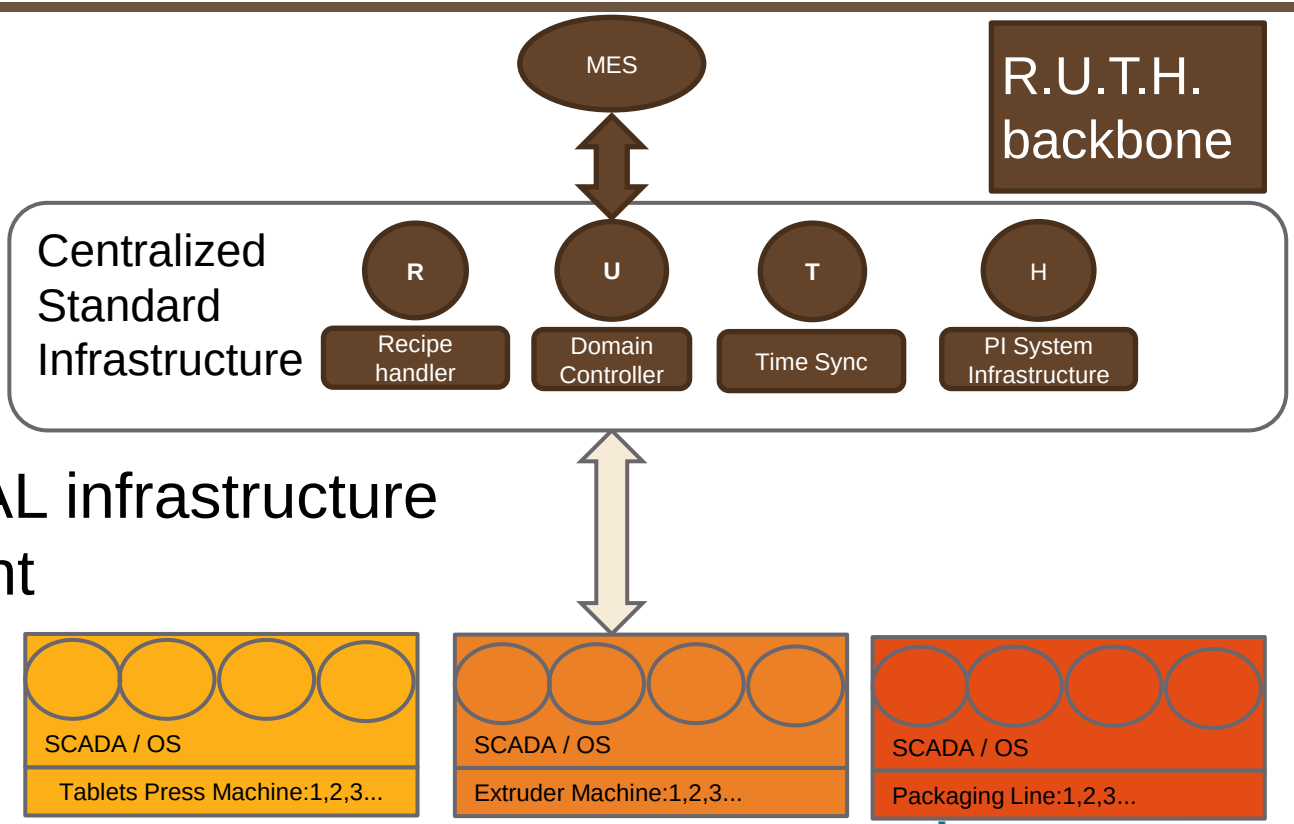
Equipment Connectivity

R.U.T.H. backbone



- Create a CENTRAL infrastructure
- Simplify Equipment
- ~~Data~~ Integrity

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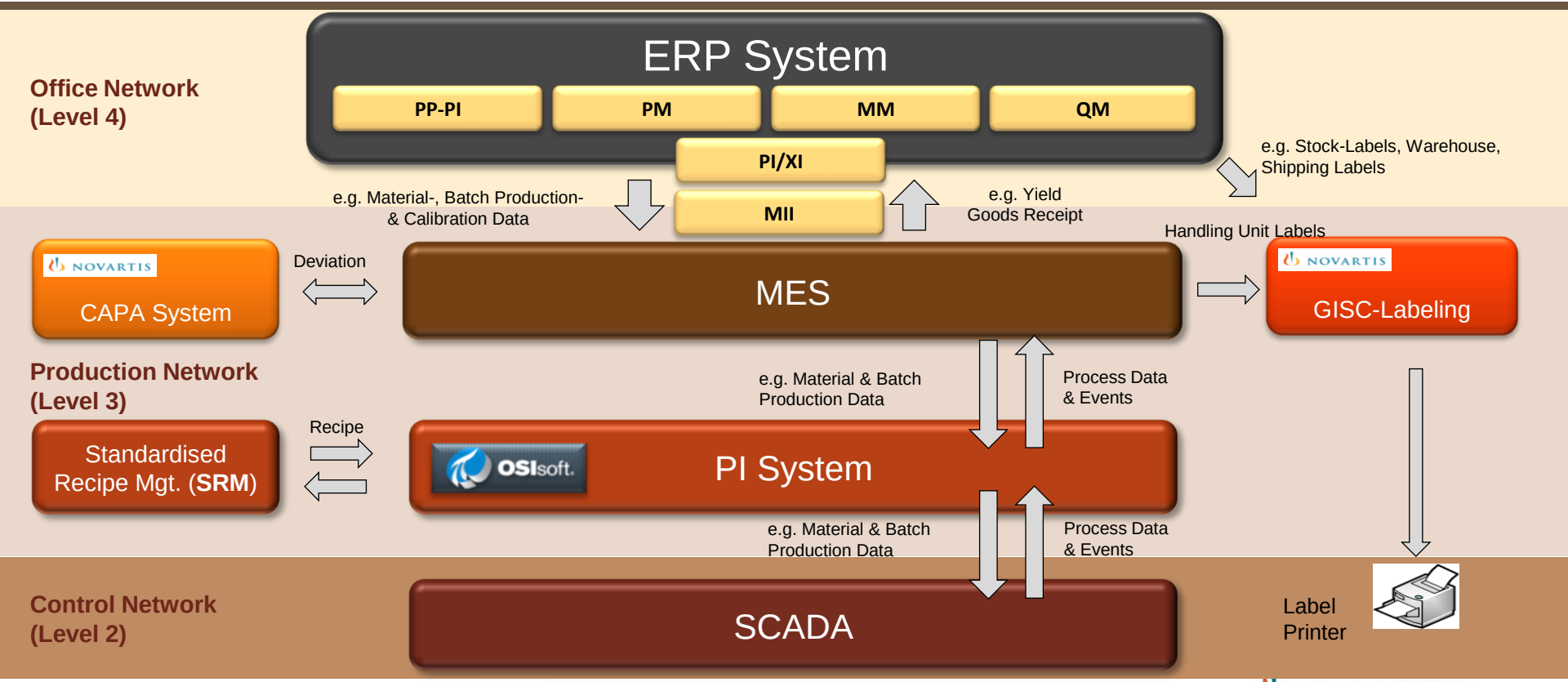
Global architecture

Reliable & fully integrated solution as «best-practice»



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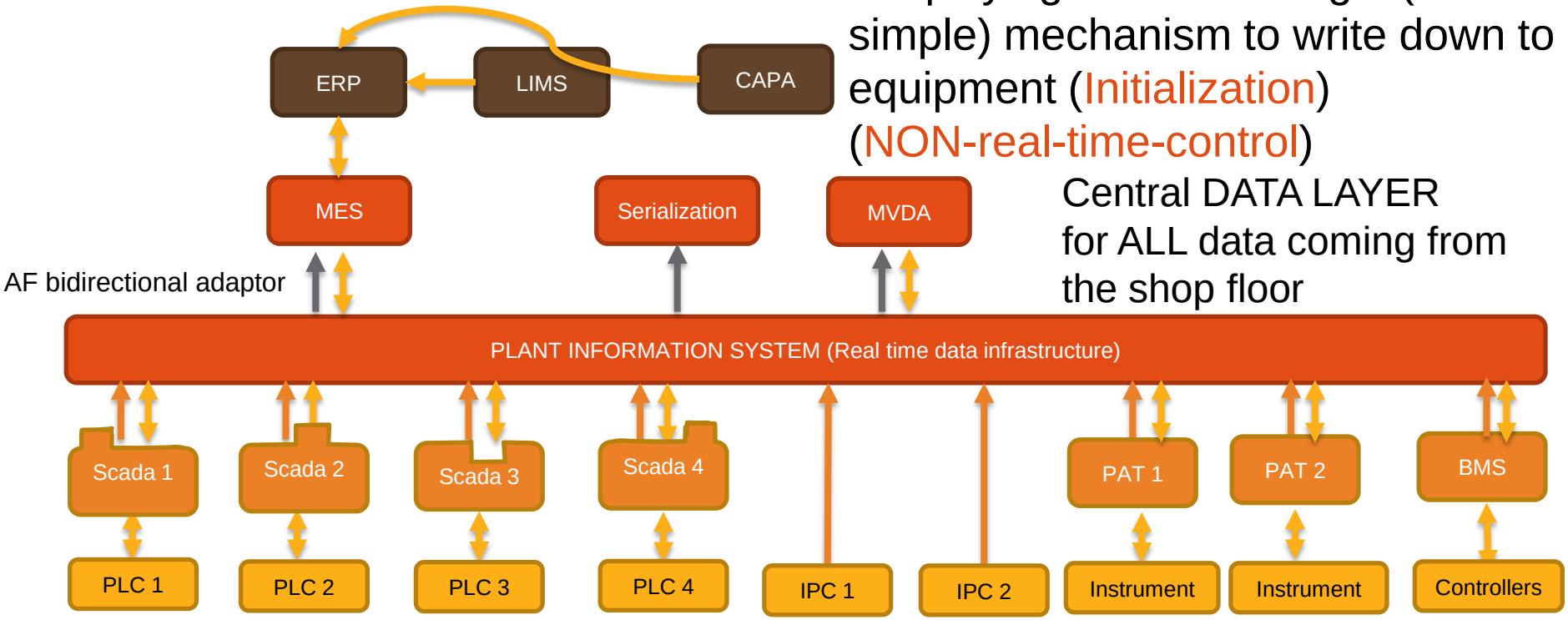
And also ...building a central data GATEWAY

Using a central infrastructure to write down



Simplifying to have a single (and simple) mechanism to write down to equipment (Initialization) (NON-real-time-control)

Central DATA LAYER for ALL data coming from the shop floor

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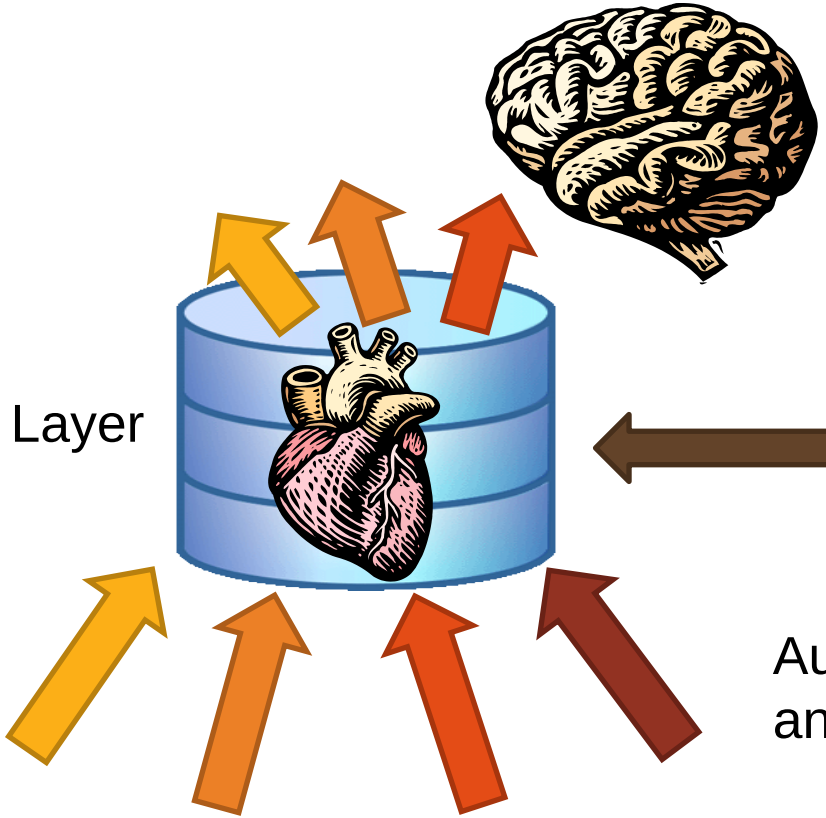
Simplification: a single data layer and data GATEWAY

Data at the core



Operational Intelligence

Central Data Layer
(heart)

MES
(muscle)

Automation systems
and field devices

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Global data model

What is a data model?

- Do we need structured data?
  - Structured Data vs. Google / Big Data approach
  - Big Data or...Smart Data?
- How to build a data model?
  - Two dimensions:
  1. **Process**: Simplified S88 view
     - Phases of the process
     - What is important? (Alarms, CPP's, key performance indicators...)
     - When everything is important, nothing is important
  2. **Asset hierarchy**. Aggregation levels

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Global data model

1. Process view

Activity Cycle of a Machine

Machine Operation Modes

Machine Status

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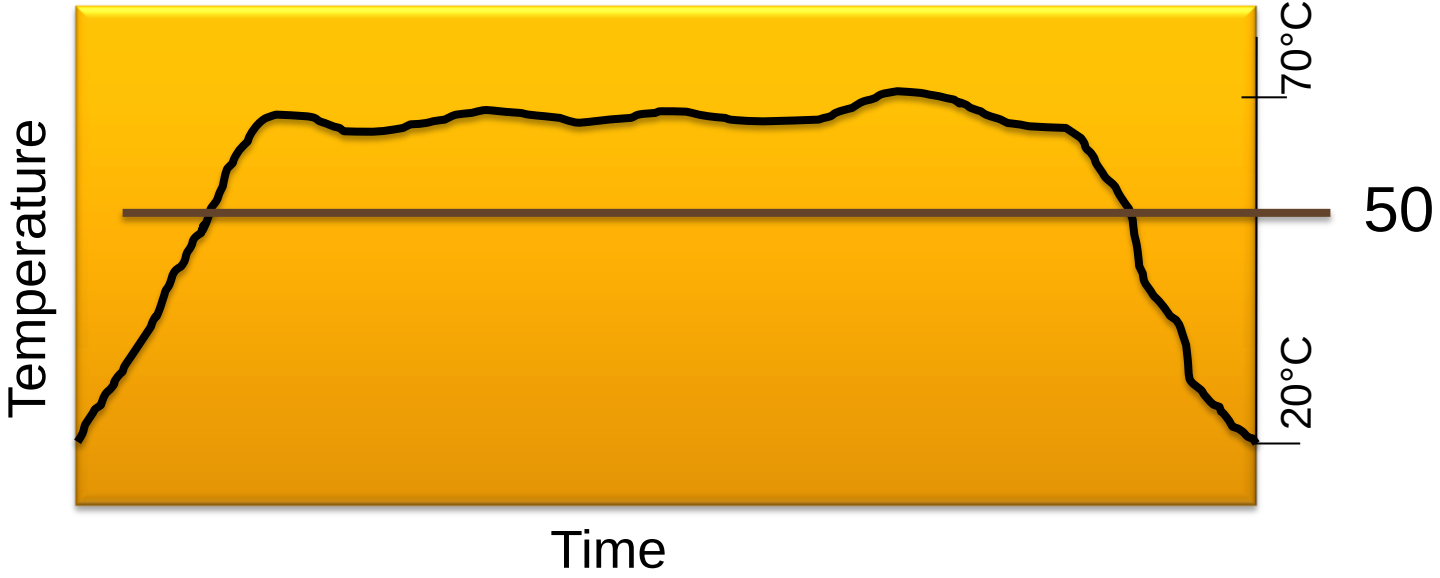
Global data model

1. Process view Example: coating (warming and cooling)



What is the average?

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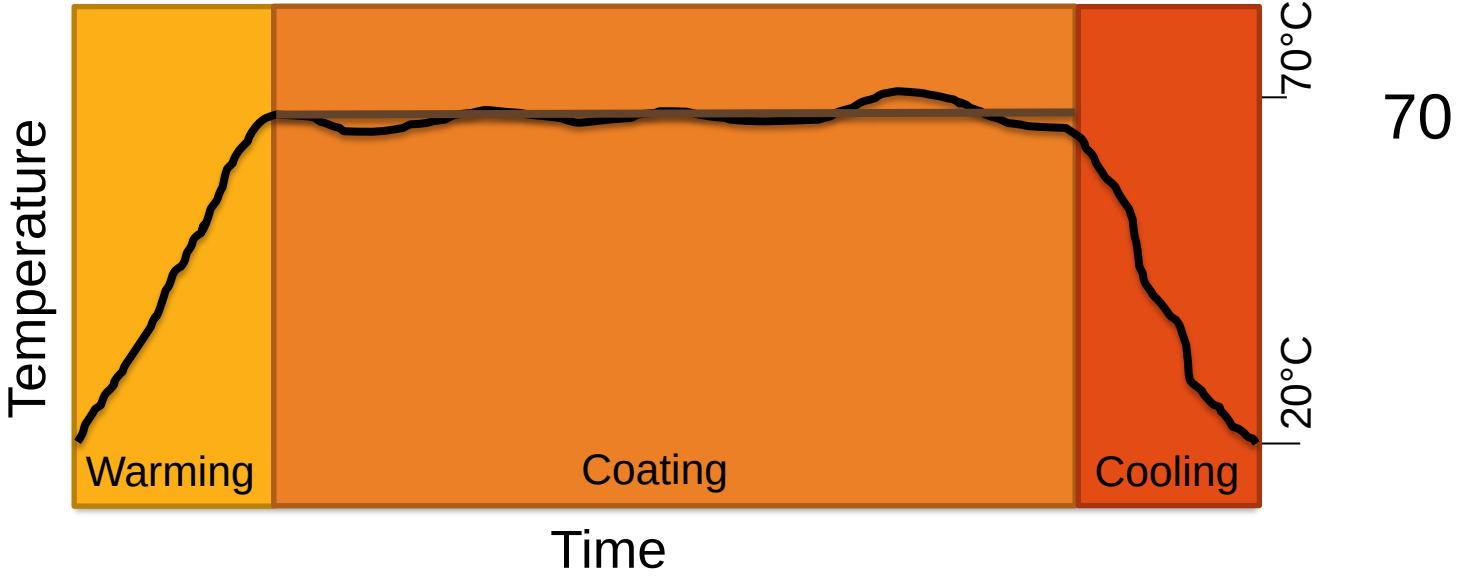
Global data model

1. Process view Example: coating (warming and cooling)



Establish process phases

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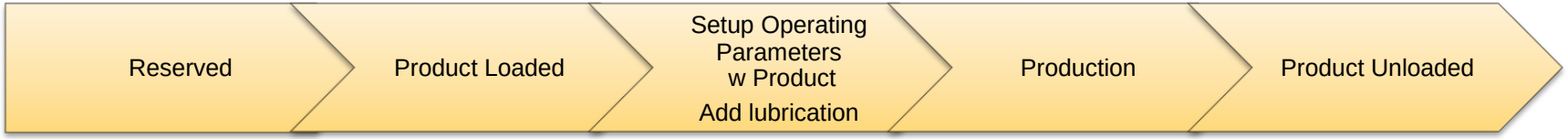
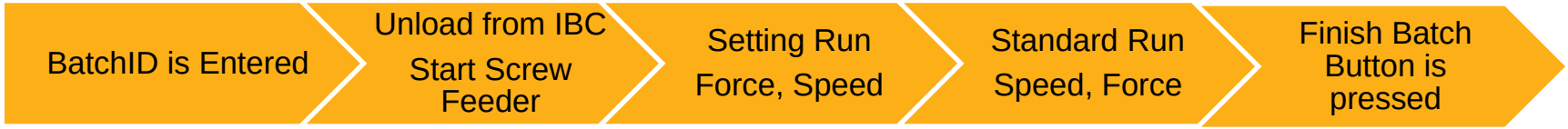
Global data model

1. Process view Example: Tablet compression with I.P.C.

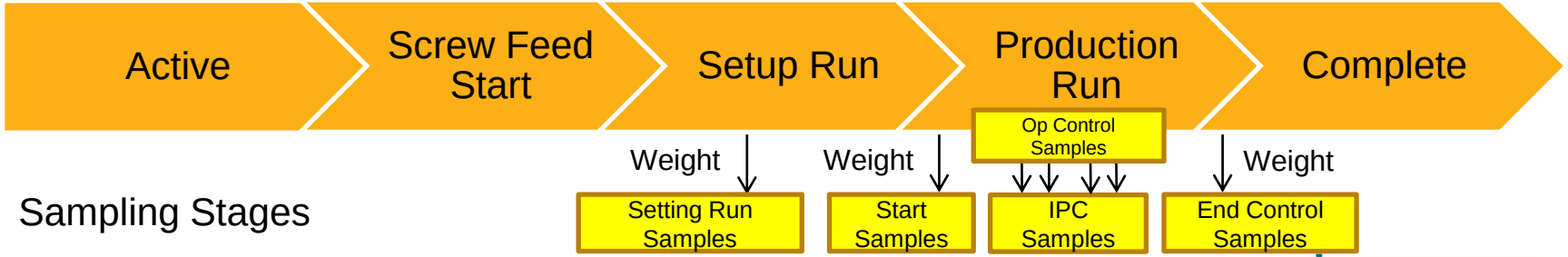
Activity Cycle of a Machine



Machine Modes



S88 Batch Unit Operation (Compression) Phases



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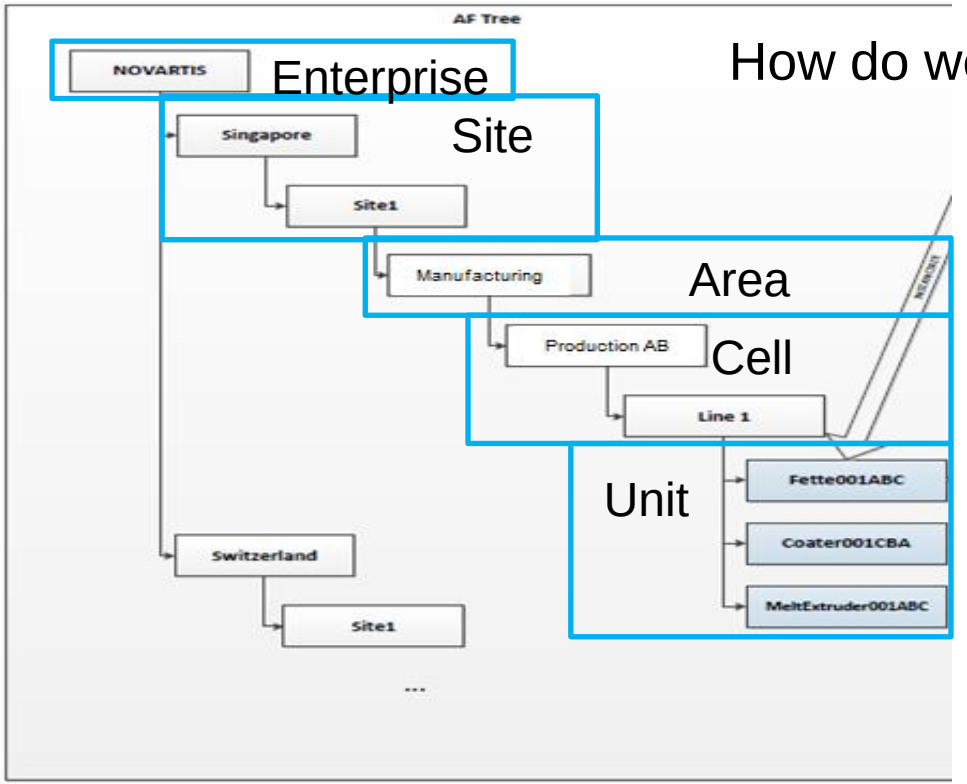
Global data model

2. Asset view



How do we want to aggregate our assets?

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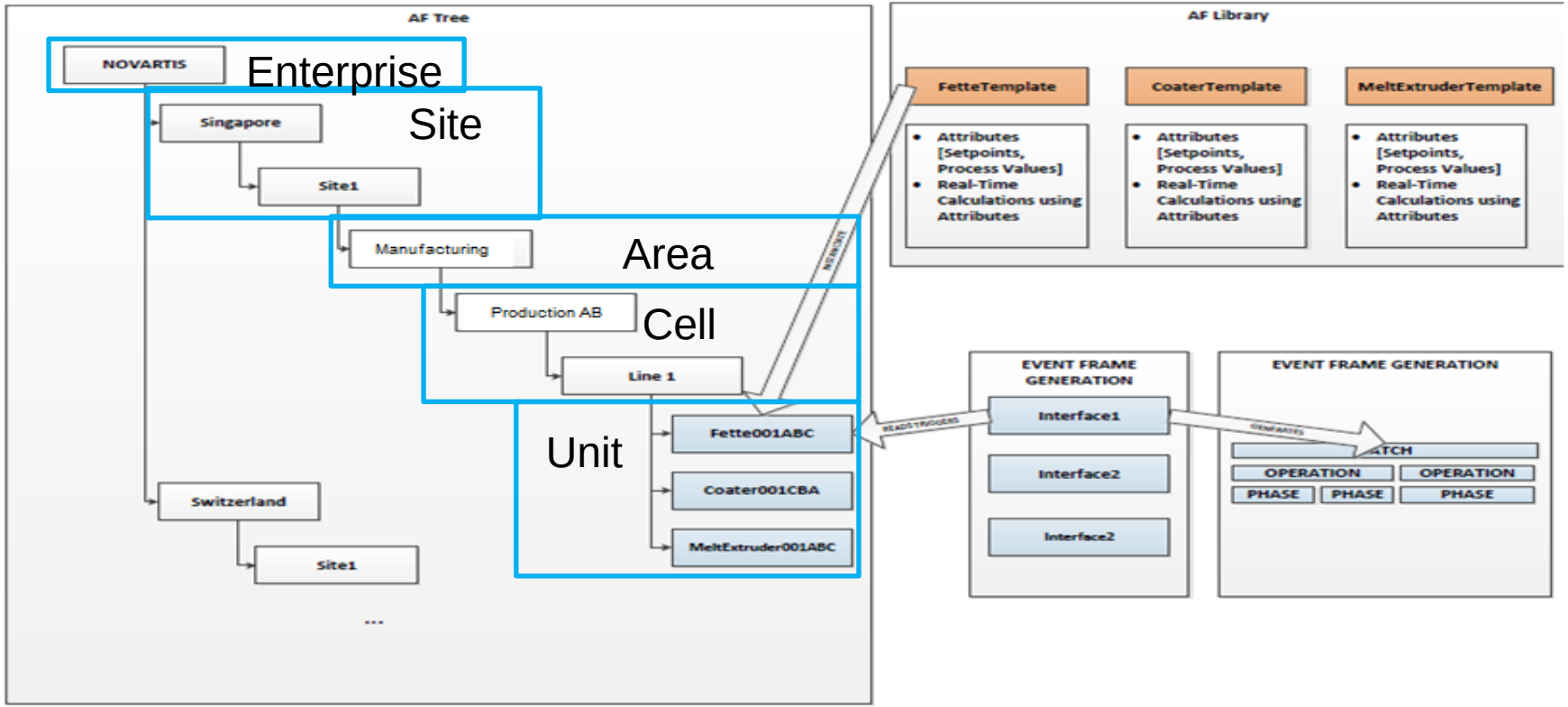
Global data model

3. Combine asset view (hierarchy) and process view



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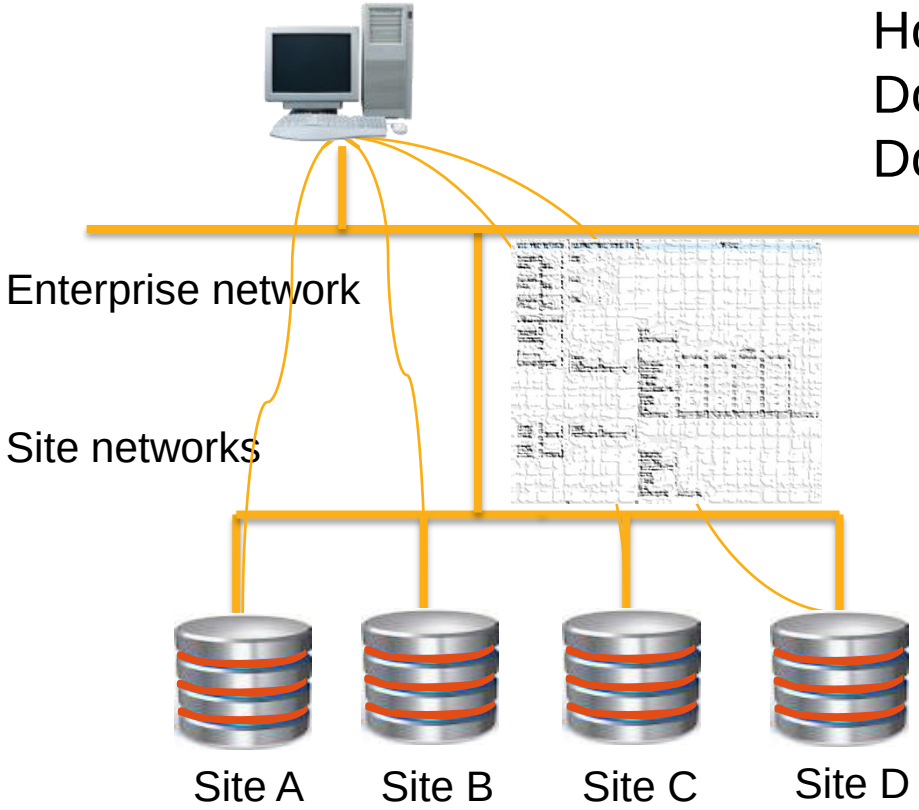
From site to enterprise: Federated model

Local data instance / Global data model



How to move to the enterprise level?
Do we need a Global Historian?
Do we need a Global Data Warehouse?

NO

We need a:

- Common naming convention
- Common data structure
- Common DATA MODEL
- Common KPI and visualization

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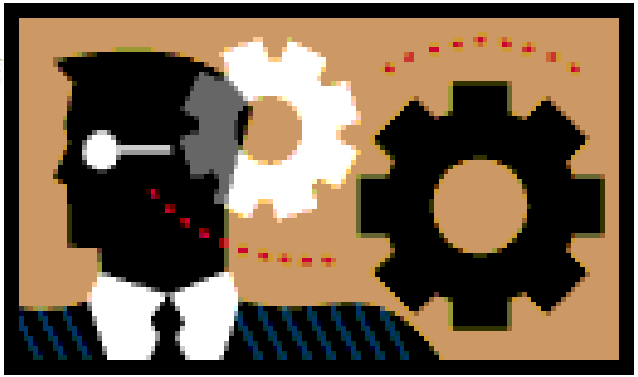
What's in it for me?

The user view

What's in it for me?

Who am I?
(Who is the user?)



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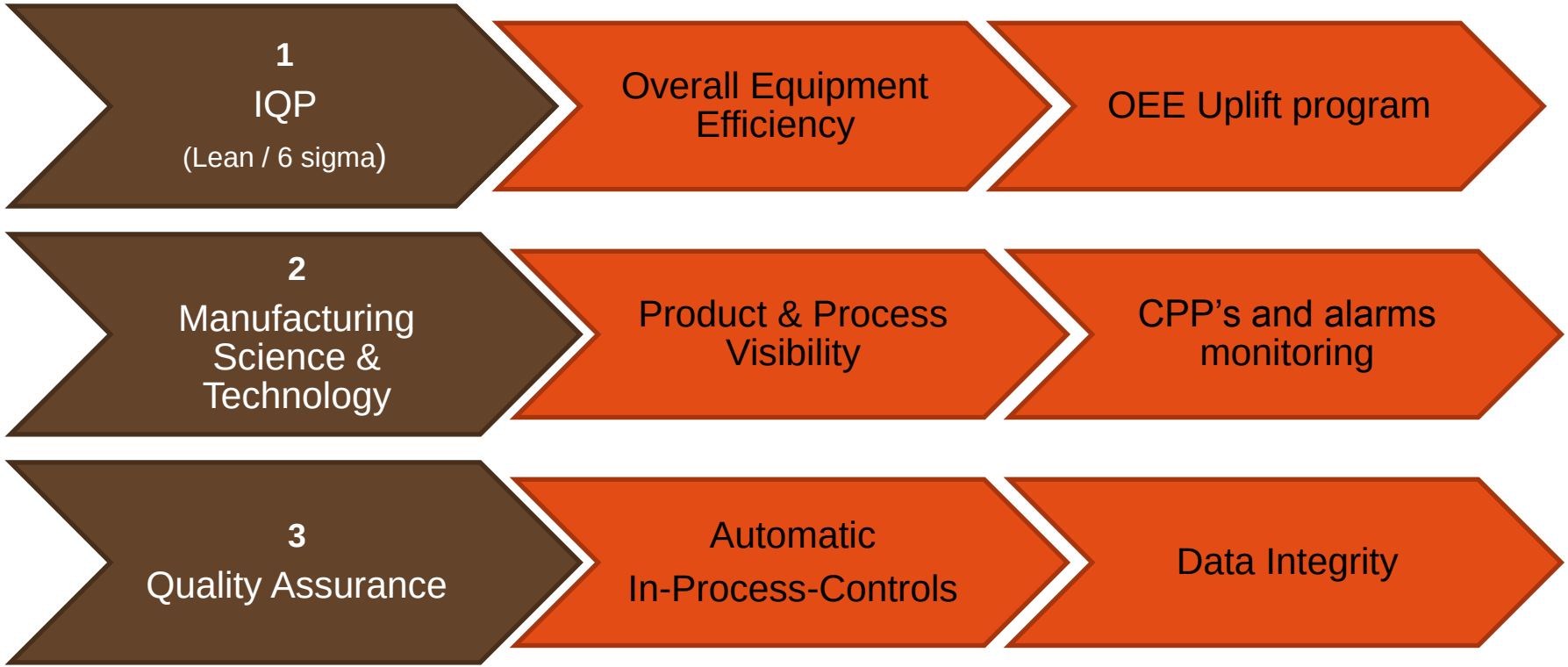
Summary: Main business benefits

The Factory of the Future



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1. OEE (Overall Equipment Efficiency)

Options and possibilities

Provide information on WHAT is happening and WHY

- Site performance and bottleneck (2017)
- Process Unit performance (2016)
- Campaign
- Batch
- Equipment
- Phases
- Microstoppages

What — Management

Why — Root Cause analysis. Problem solving

Granularity

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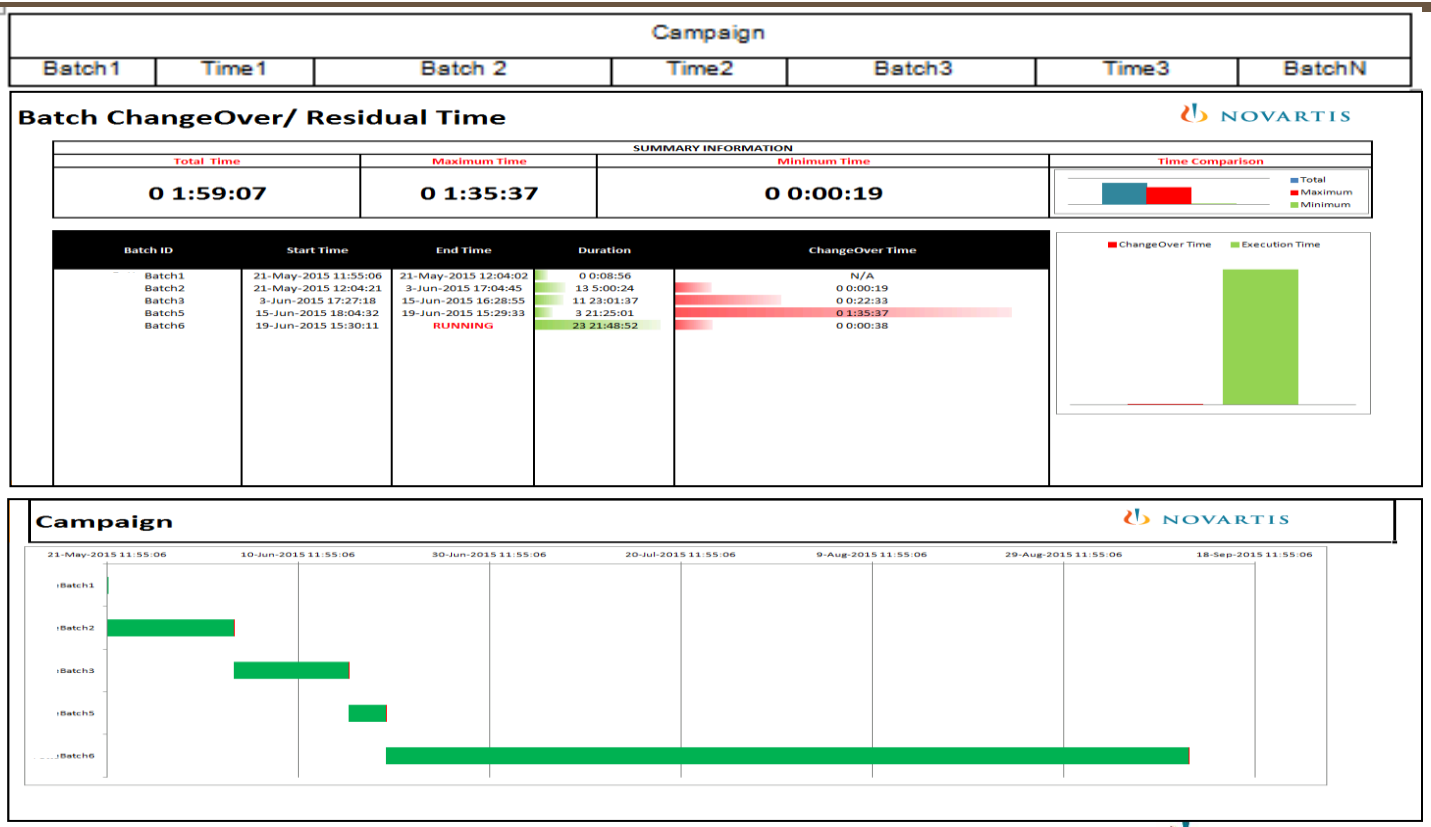
1. OEE: Campaign

Idle time interval between batches of ONE campaign

Process unit
Site
Campaign
Batch
Equipment
Phases
Microstoppages



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1. OEE: Batch

Batch efficiency: Compare across batches or machines

Process unit
Site
Campaign
Batch
Equipment
Phases
Microstoppages

Machine Efficiency Comparison By Batches Within Campaign

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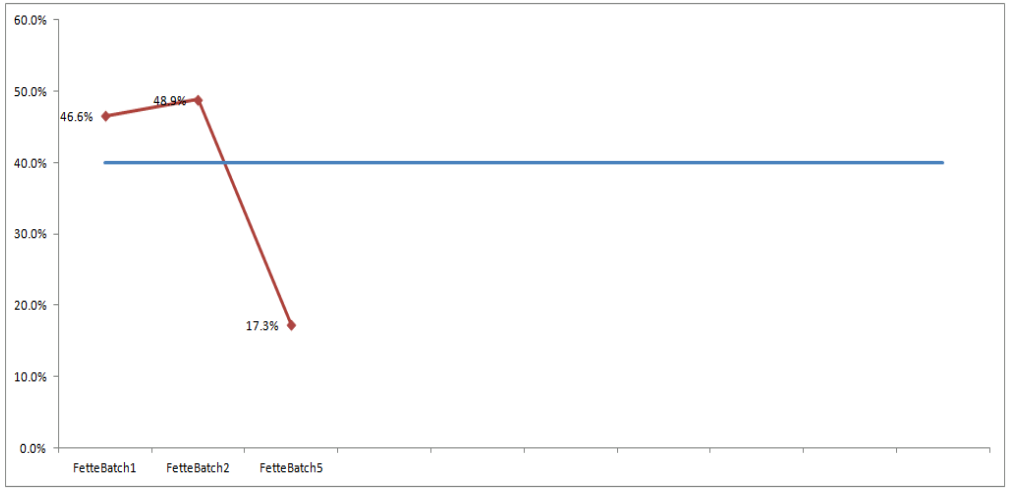
Efficiency Target	40%

Batch	Machine Efficiency
Batch1	46.6%
Batch2	48.9%
Batch5	17.3%
	#N/A
	#N/A
	#N/A
	#N/A
	#N/A
	#N/A
	#N/A

Drilldown

Refresh



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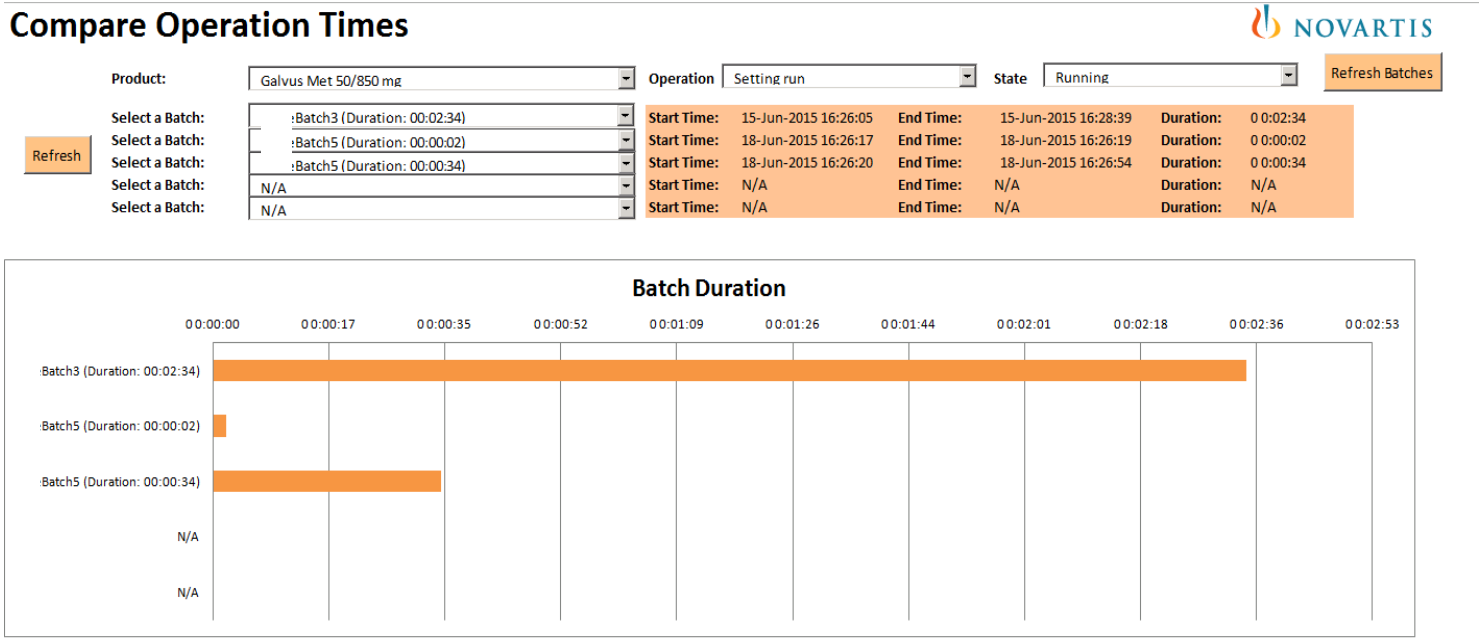
1. OEE: Equipment

Machine cycle time: Compare batch-to-batch

Process unit
Site
Campaign
Batch
Equipment
Phases
Microstoppages



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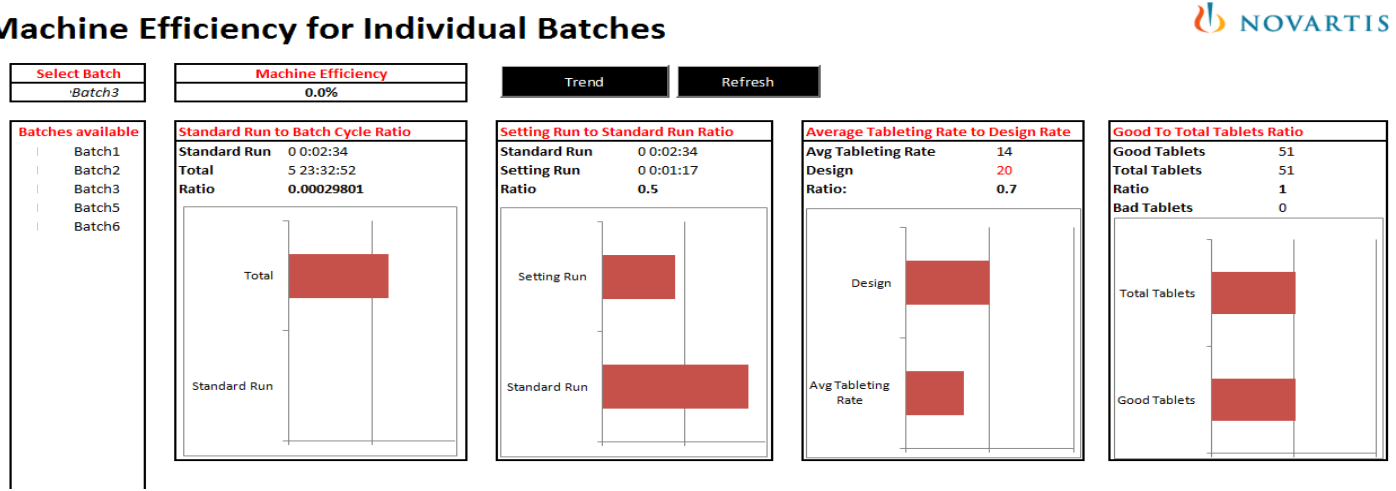
1. OEE: Phases. Machine efficiency

Factors: Setting run, standard run, tableting rate, good tablets

Process unit
Site
Campaign
Batch
Equipment
Phases
Microstoppages



What is available now:

- ✓ Tableting rate
- ✓ Tablets produced
- ✓ Current time

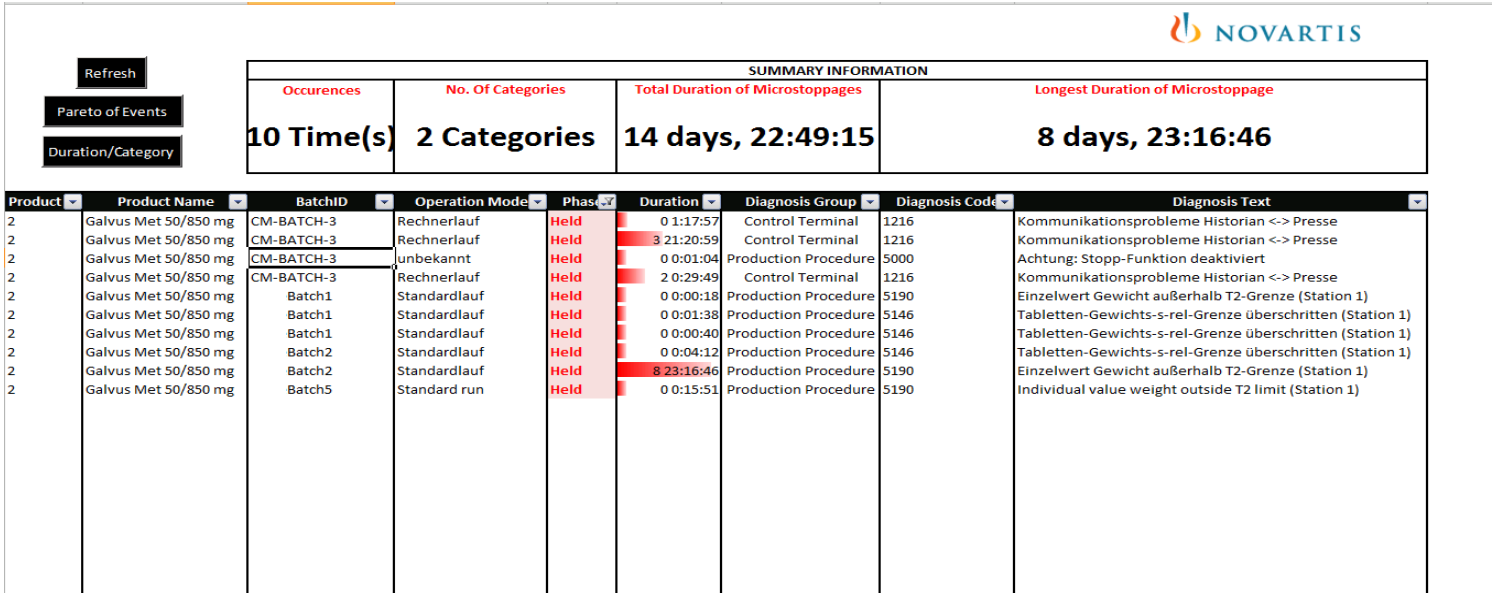
Next steps:

- ❖ Target production
- ❖ Projected production complete time
- ❖ You know @ Real time – Production will be on time or delayed

1. OEE: Micro-stoppages

Drilldown to causes of stoppages

Process unit
Site
Campaign
Batch
Equipment
Phases
Microstoppages



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Refresh

Pareto of Events

Duration/Category

SUMMARY INFORMATION

Occurences	No. Of Categories	Total Duration of Microstoppages	Longest Duration of Microstoppage
10 Time(s)	2 Categories	14 days, 22:49:15	8 days, 23:16:46

Product	Product Name	BatchID	Operation Mode	Phase	Duration	Diagnosis Group	Diagnosis Code	Diagnosis Text
2	Galvus Met 50/850 mg	CM-BATCH-3	Rechnerlauf	Held	0 1:17:57	Control Terminal	1216	Kommunikationsprobleme Historian <-> Presse
2	Galvus Met 50/850 mg	CM-BATCH-3	Rechnerlauf	Held	3 21:20:59	Control Terminal	1216	Kommunikationsprobleme Historian <-> Presse
2	Galvus Met 50/850 mg	CM-BATCH-3	unbekannt	Held	0 0:01:04	Production Procedure	5000	Achtung: Stopp-Funktion deaktiviert
2	Galvus Met 50/850 mg	CM-BATCH-3	Rechnerlauf	Held	2 0:29:49	Control Terminal	1216	Kommunikationsprobleme Historian <-> Presse
2	Galvus Met 50/850 mg	Batch1	Standardlauf	Held	0 0:00:18	Production Procedure	5190	Einzelwert Gewicht außerhalb T2-Grenze (Station 1)
2	Galvus Met 50/850 mg	Batch1	Standardlauf	Held	0 0:01:38	Production Procedure	5146	Tabletten-Gewichts-s-rel-Grenze überschritten (Station 1)
2	Galvus Met 50/850 mg	Batch1	Standardlauf	Held	0 0:00:40	Production Procedure	5146	Tabletten-Gewichts-s-rel-Grenze überschritten (Station 1)
2	Galvus Met 50/850 mg	Batch2	Standardlauf	Held	0 0:04:12	Production Procedure	5146	Tabletten-Gewichts-s-rel-Grenze überschritten (Station 1)
2	Galvus Met 50/850 mg	Batch2	Standardlauf	Held	8 23:16:46	Production Procedure	5190	Einzelwert Gewicht außerhalb T2-Grenze (Station 1)
2	Galvus Met 50/850 mg	Batch5	Standard run	Held	0 0:15:51	Production Procedure	5190	Individual value weight outside T2 limit (Station 1)

Longest time machine was stopped / most frequent causes of stoppages are best visualized in **Pareto Charts**

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2. Product and Process robustness

Options and possibilities

Alarm information, aggregated view

- Impact analysis
- Duration
- Max. excursion
- Aggregated and pareto view
- Etc.

Process and Product robustness

- Critical Process Parameters (CPP's) monitoring
- Early warnings
- Increased knowledge about Process and Product
- Yield

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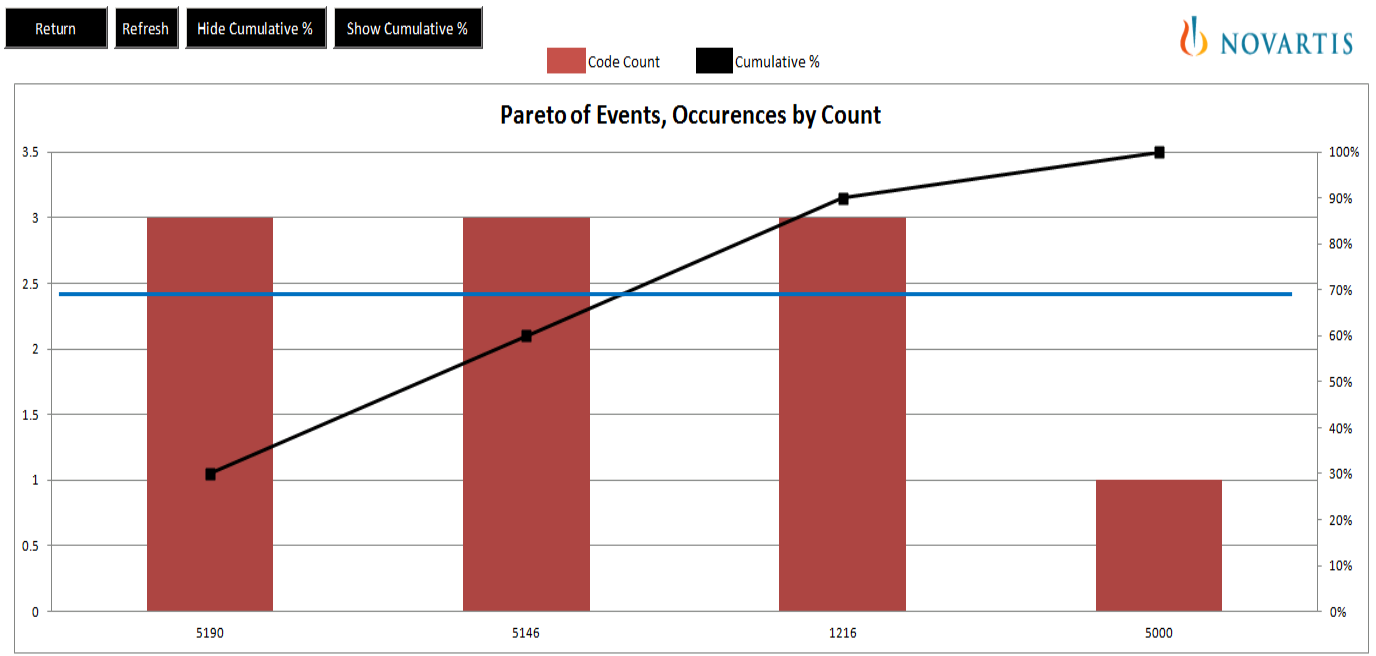
2. Product and Process robustness: Alarm pareto chart

Apply 80/20 rule to identify stop diagnostics activated by occurrence

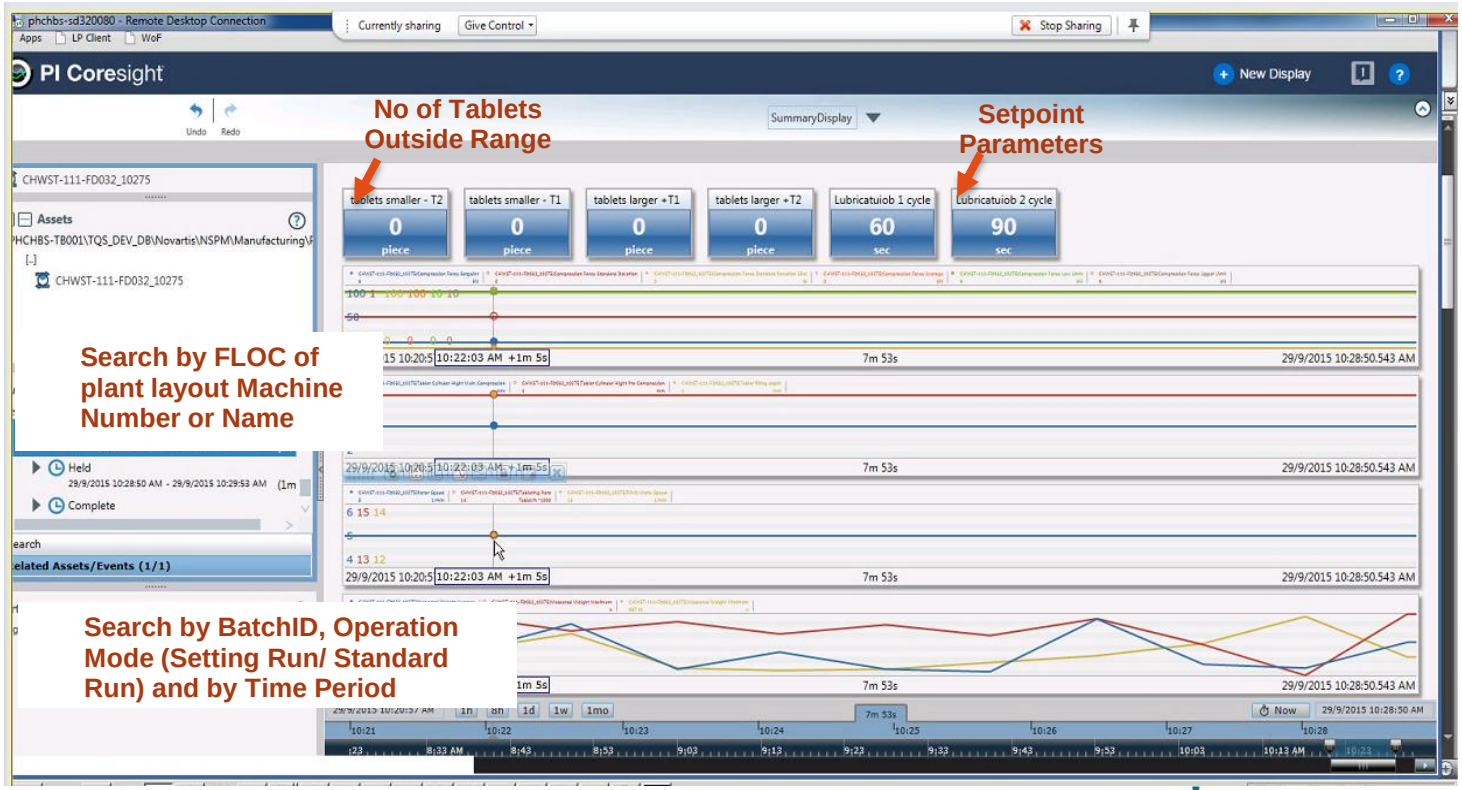
Alarms
CPP's



2. Product and Process robustness: CPP's view

Compression force, filling depth, cylinder height, average weight

Alarms
CPP's



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3. Automatic in-process-controls

Options and possibilities

Goal

- Eliminate manual sampling
- Feedback loop with sampled values
- Minimize operator presence in the room
- (What causes the deviatons: equipment or people?)
- Eliminate paper

- PAT?
- Many machines have «embedded» PAT sensors we are not using («PAT ready»)
- Crawl before running!!

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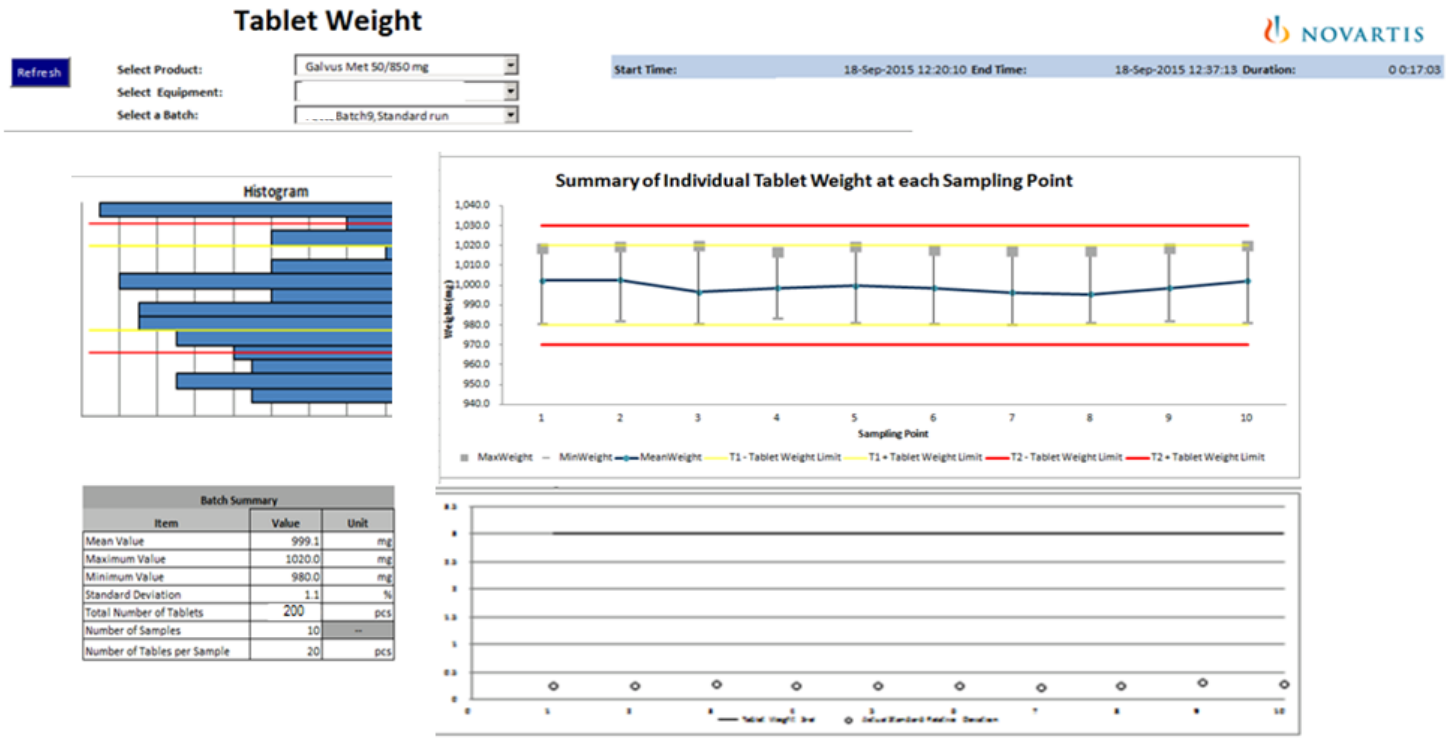
3. Automatic in-process-controls

Tablets weight aggregated and statistical view

Aggregated
Detailed



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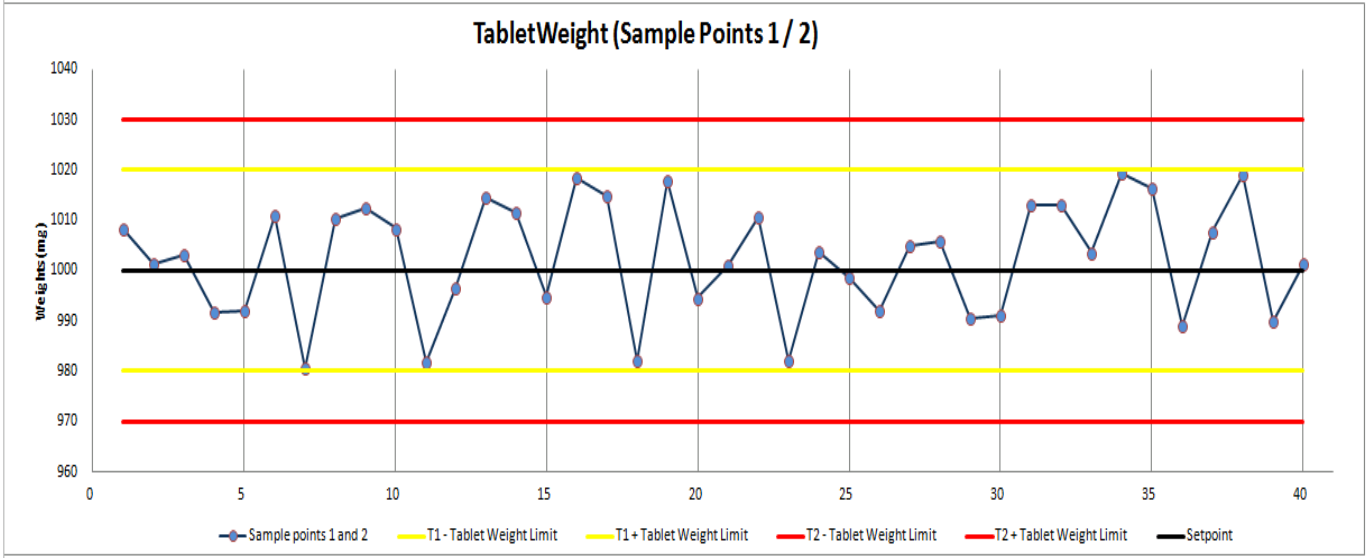
3. Automatic in-process-controls

Tablet weight detailed view

Aggregated
Detailed

Select Sample Number: TabletWeight (Sample Points 1/ 2)



Samples	Target	UCL	LCL	USL	LSL	ActMin	ActMean	ActMax	StdDev
Sample 1	No Data	1030	970	1020	980	980.6	1002.35	1018.5	1.23
Sample 2	No Data	1030	970	1020	980	982.1	1002.68	1019.4	1.09

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The Factory of the Future ... is possible today?

The Factory of the Future:

- What does it mean?
- Is it possible today?

Solution	Business Challenge	Anticipated Results
Standardization initiative	Identify the USER	**Increase OEE,** and drive it in a consistent manner
Right infrastructure, partnership and commercial agreements	Provide a Role based information	Increase **product and process robustness** and knowledge
Global data model	Engage the User by providing actionable information	**Increase productivity.** Avoid manual in-process-controls. Avoid paper.
		Increase quality. Robust automatic In-process-controls

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Thank You

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