



Implementation of CAMO Process Pulse to enable online multivariate data evaluation in real-time

Presented by

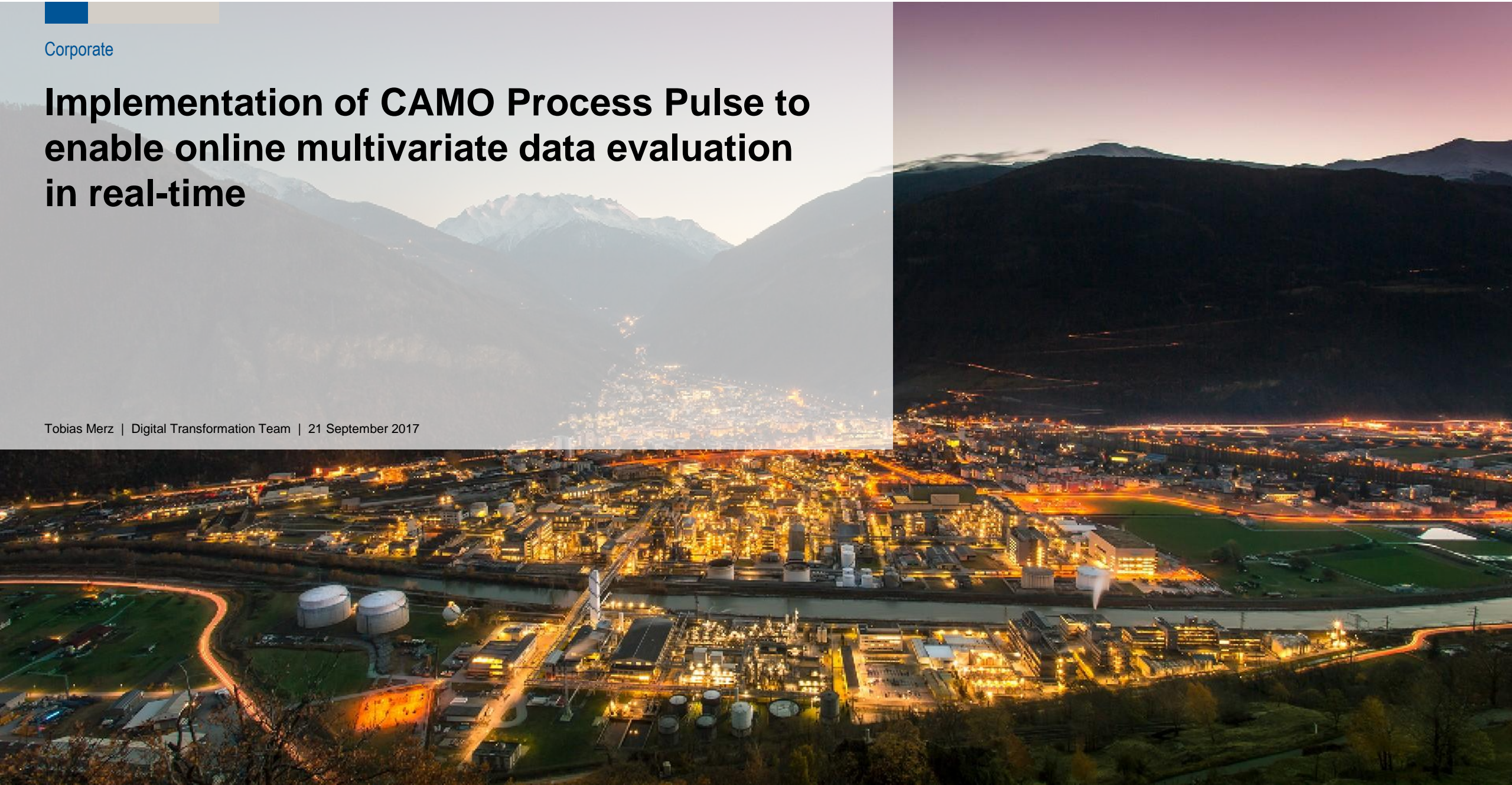
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Lonza

Corporate

Implementation of CAMO Process Pulse to enable online multivariate data evaluation in real-time

Tobias Merz | Digital Transformation Team | 21 September 2017



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- Introduction
- Motivation and Vision
- Current Challenges
- Roadmap Data Analytics
- Implementation Project
- Process Pulse Structure
- Pilot Project
- Summary

Lonza at a Glance

Adding Capsugel in June 2017

“A trusted supplier to the pharmaceutical, biotech and specialty ingredients markets”

Year Founded

1897

1963

Employees
End of 2016

~10 000

~3 600

Countries with
Offices / Sites

~30

14

Successful Product-
Related Audits in 2016
(Regulatory and Customer)

> 150

> 275

Major Manufacturing and
R&D Facilities Worldwide

> 40

13



Market-Focused Segments:
Specialty Ingredients
and Pharma&Biotech

2

Sales in 2016
in CHF

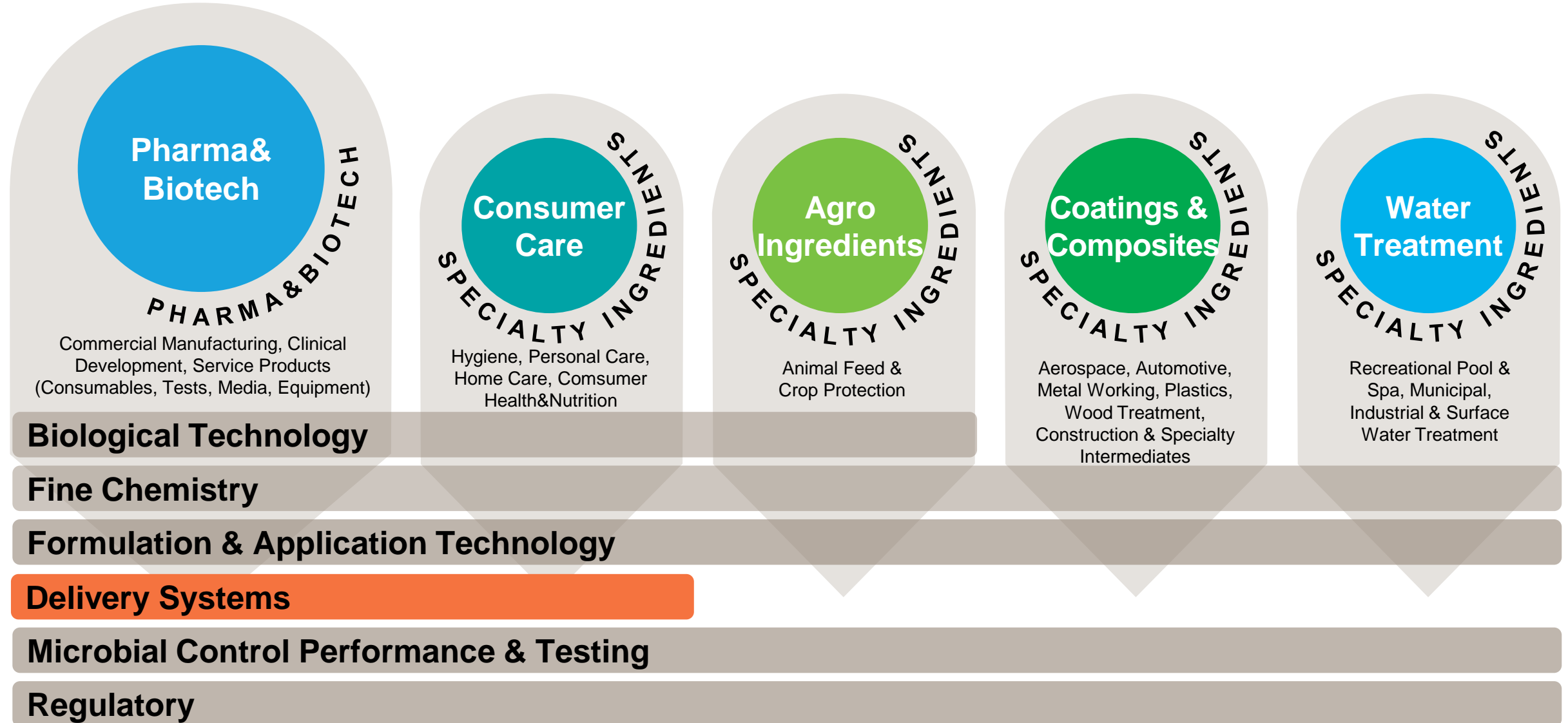
~4.13 bn

Empty Two-Piece
Capsules Produced
in 2016

~200 bn

Lonza's Target Markets

and Technology Platforms with Addition of Capsugel



Process Analytical Technology at Lonza

Guidance for Industry
PAT — A Framework for
Innovative Pharmaceutical
Development, Manufacturing,
and Quality Assurance

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research, CDER
Center for Veterinary Medicine, CVM
Office of Regulatory Affairs, OIRA
Pharmaceutical CGMPs
September 2014

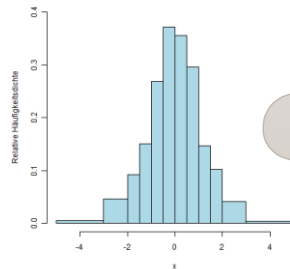
PAT Definition (FDA)

... a system for designing, analyzing and controlling manufacturing through timely measurements of critical quality and performance attributes of raw and in-process materials and processes, with the goal of ensuring final product quality.

FDA, 2004

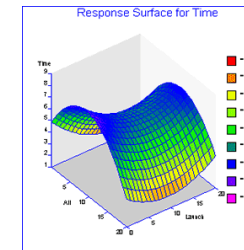
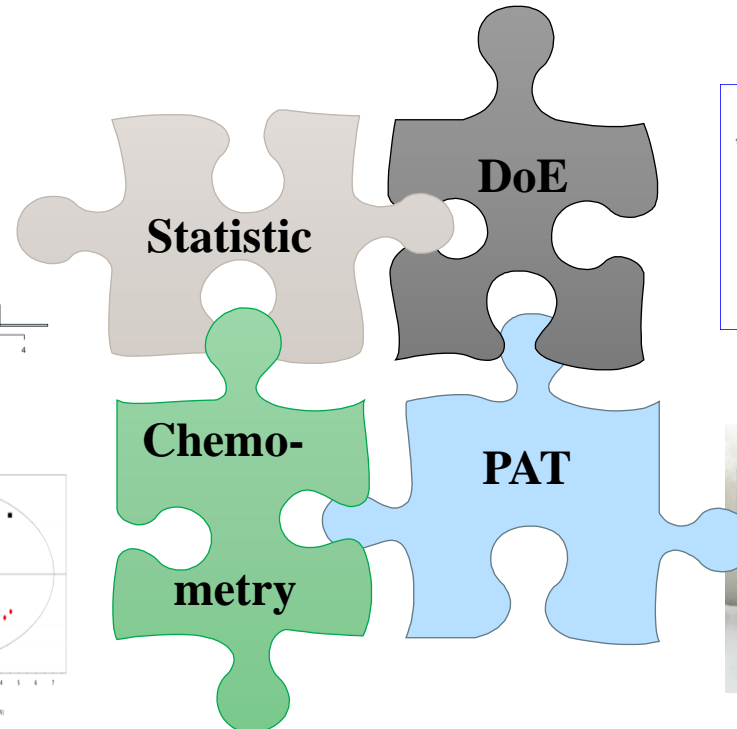
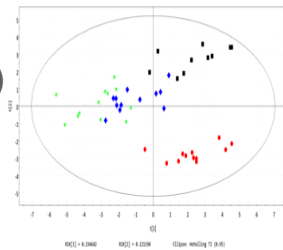
Statistic Tools

- statistical Process control (SPC)
- explorative Data analytics (EDA)
- Excel Tools



Multivariate Tools

- Principal component analysis (PCA)
- Regression methods (PLS)
- Multi-Curve Resolution (MCR)



Design of Experiments

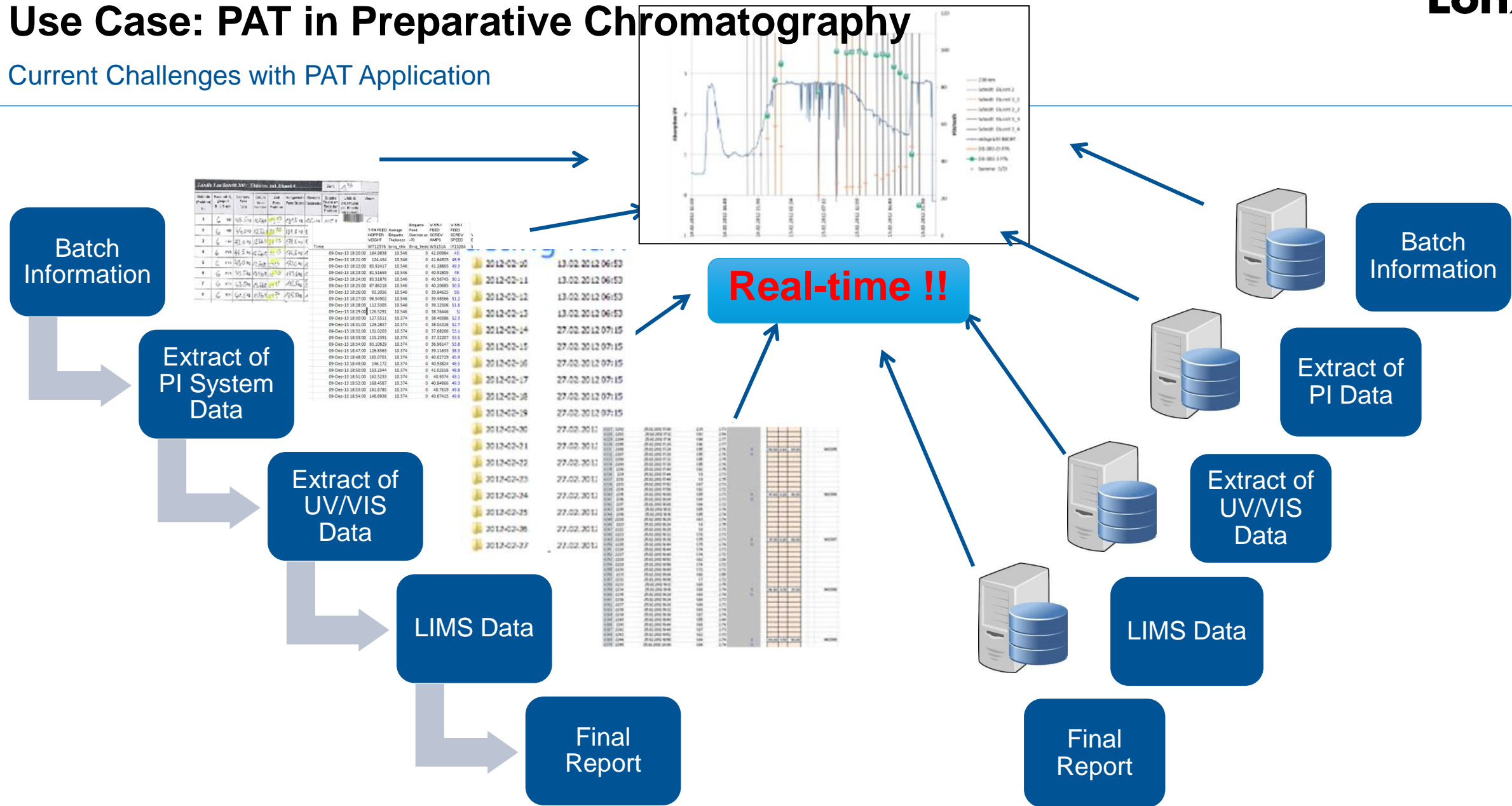
- Screening plan
- Response-Surface Plan
- Evaluation
- Process optimization

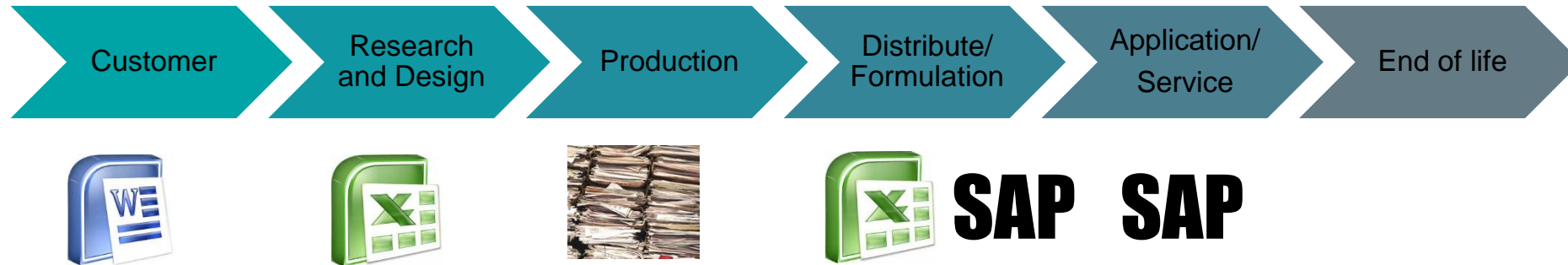
Process Analytical Technology

- Online Analytics
- Process understanding
- Process monitoring
- at-line / on-line / in-line Analyzer
- NIR, MIR, UV, Raman,
- Lasentec, MS etc.

Use Case: PAT in Preparative Chromatography

Current Challenges with PAT Application





- No standardization (within groups, file formats, sensors, ...)
- No interfaces of sensors
- No infrastructure for data
- No common data evaluation tools
- No interfaces to other systems e.g. LIMS, CDS, OSI-PI
- No data integrity, data availability, data accessibility

1. PAT Data Management

- Integration of MVA data
- Common data storage
- Raw data 21part11 compliant
- Data recording
- Audit trail

2. Control

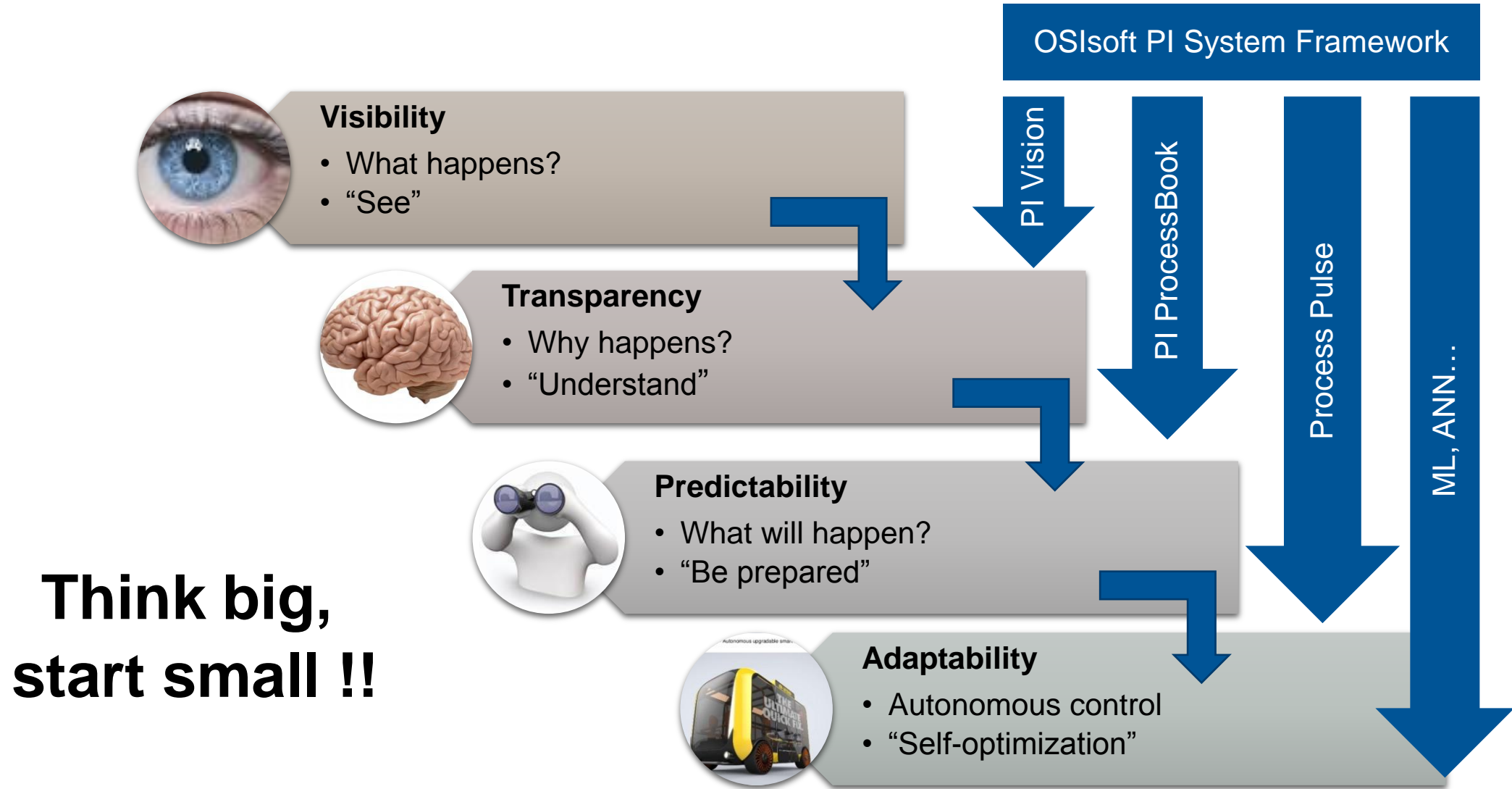
- Common interface for instruments
- Triggering start/stop of data recording
- Traceable reference measurements

3. Evaluation

- Online evaluation possible
- Integration of univariate models
- Integration of multivariate models
- Model management

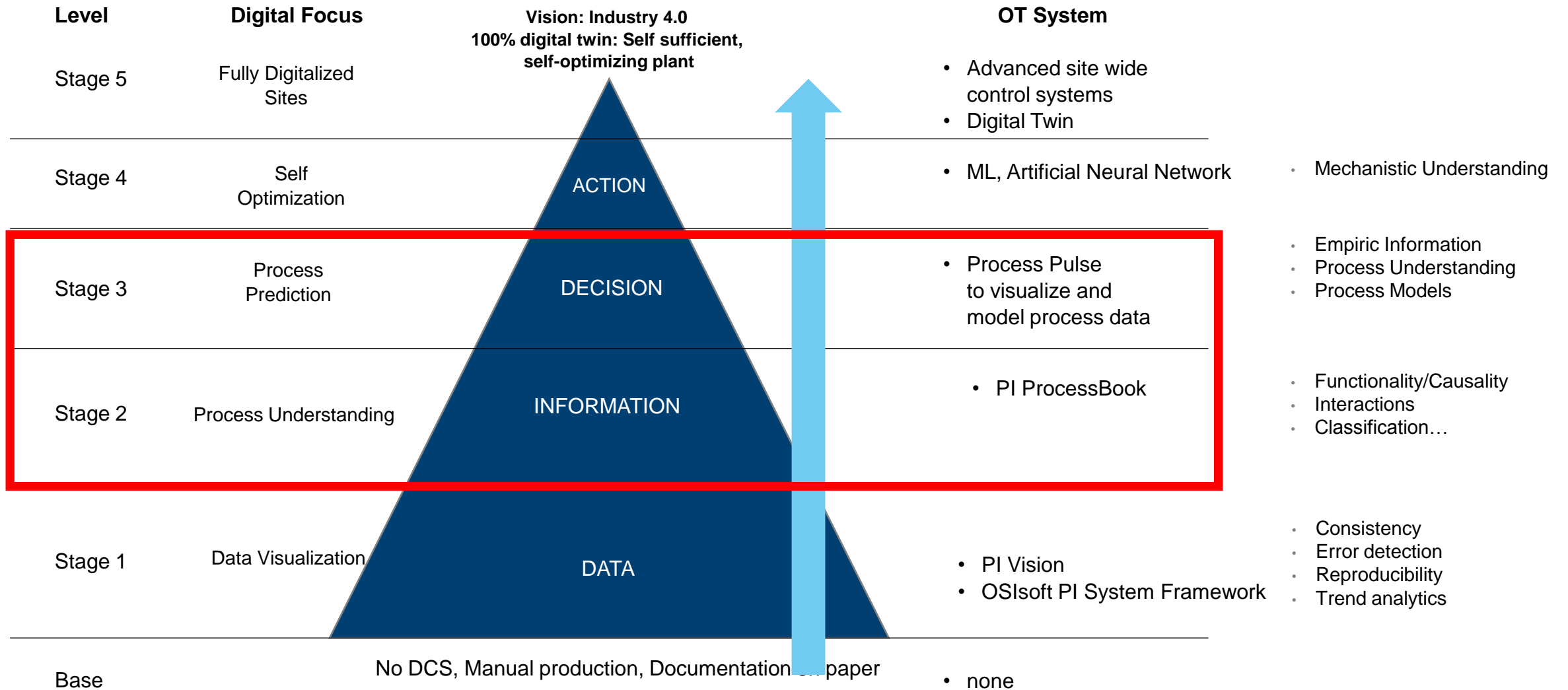
4. Export/Reporting

- Easy extraction of experimental data
- Export of graphics
- Link with other systems (GDM, PI, LIMS,...)
- Sharing Information via Web



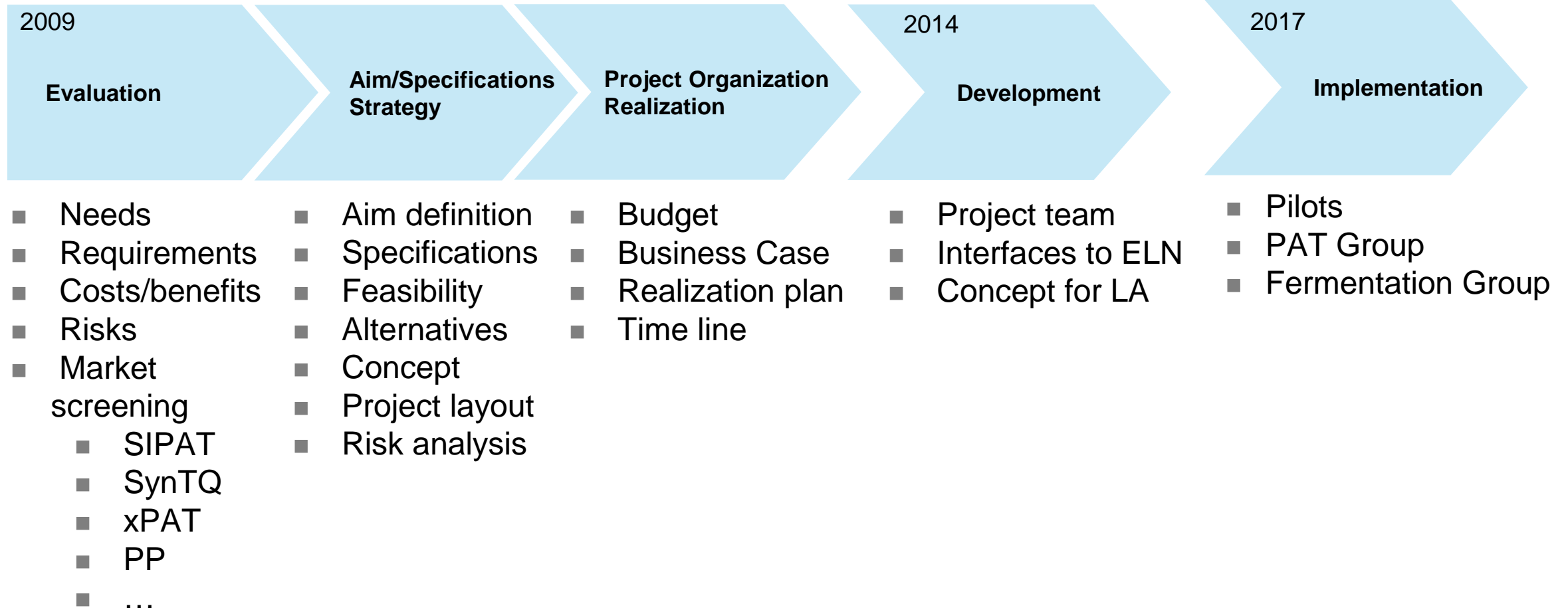
Operations Digitalization Pyramid

Following a Maturity Level Approach

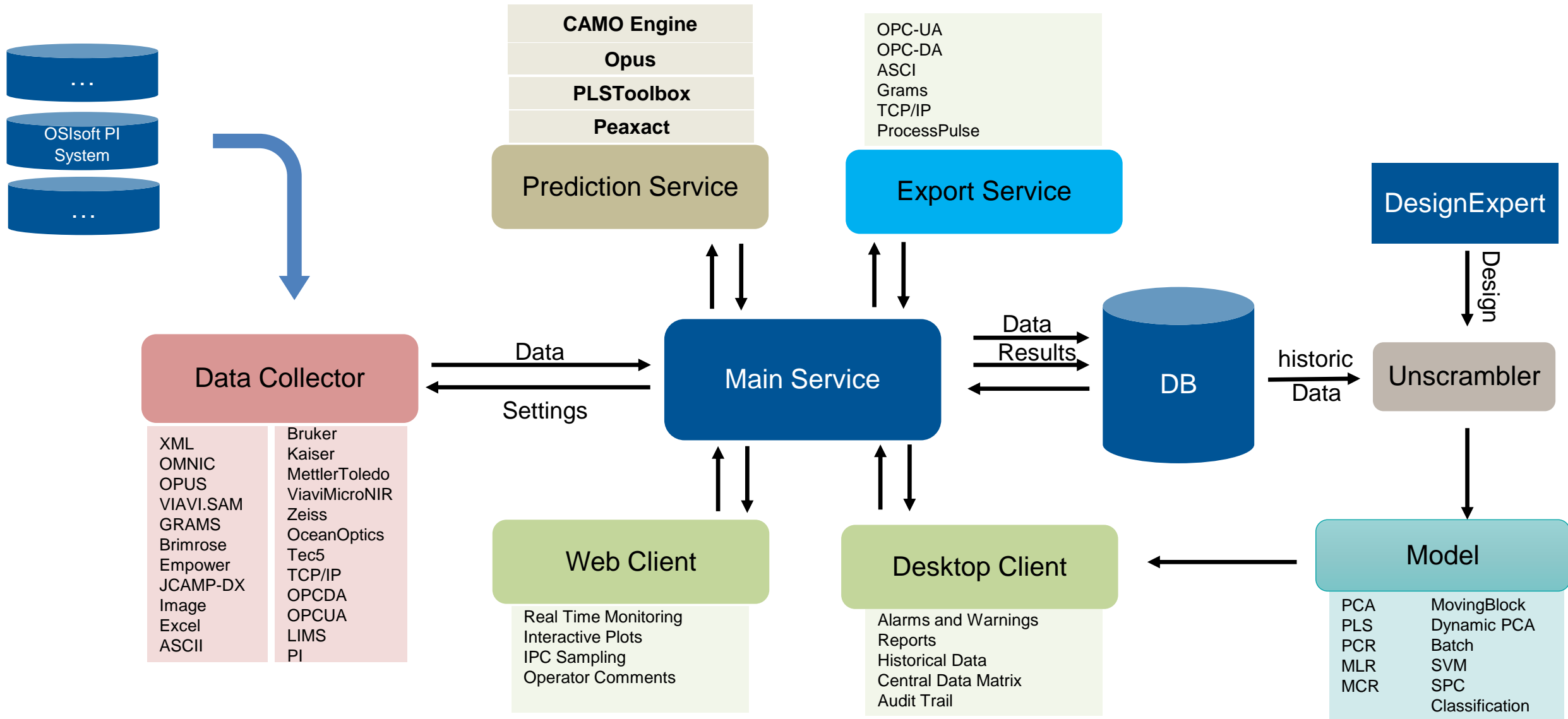


Road Map

Process Pulse

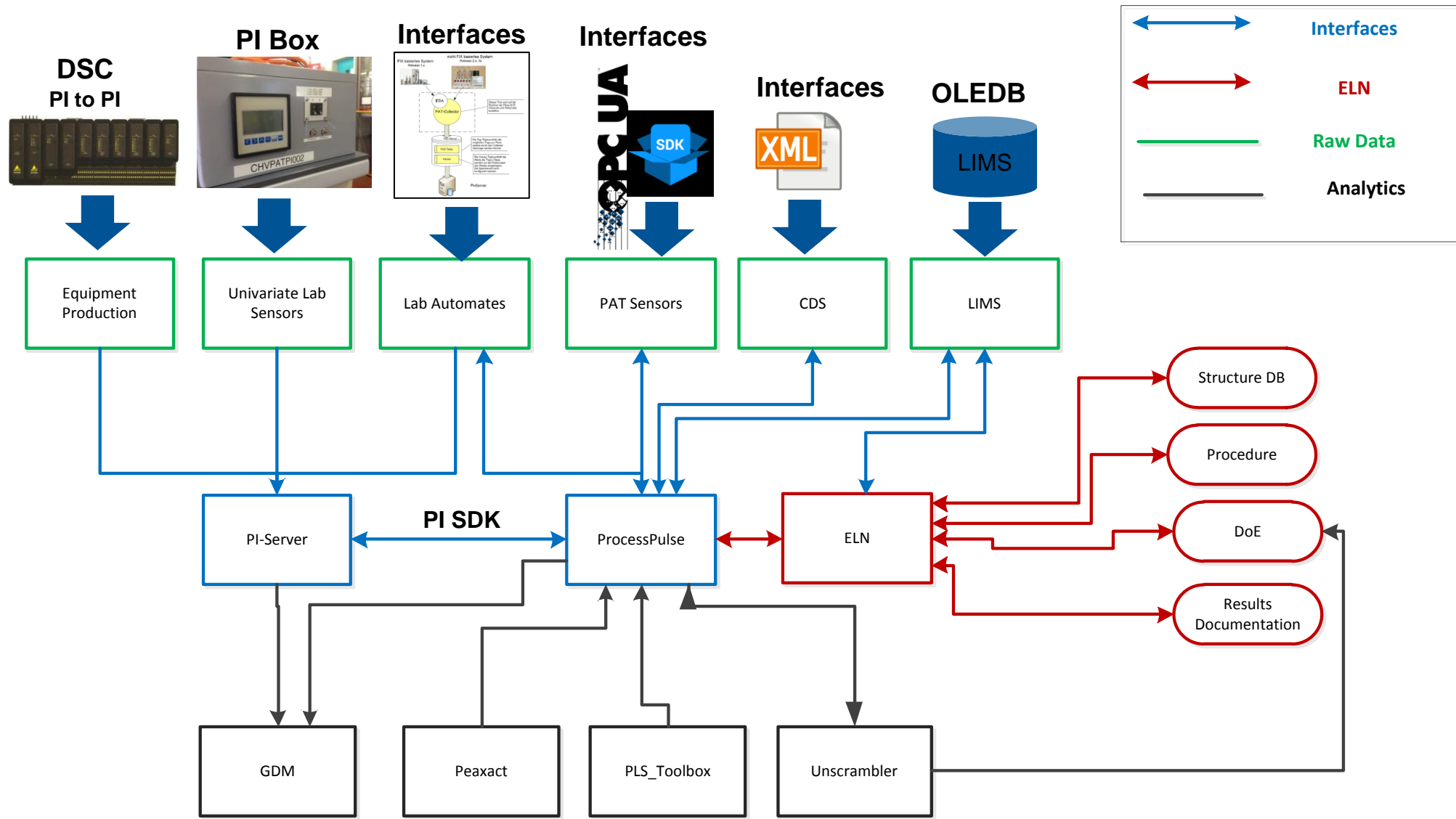


Concept of Process Pulse



Architecture in R&D

Development of Interfaces

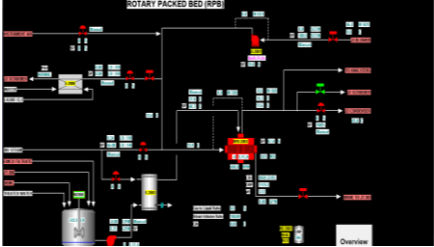


Use Case: Pilot Study in Production Scale

Combining Multivariate Data with Process Data

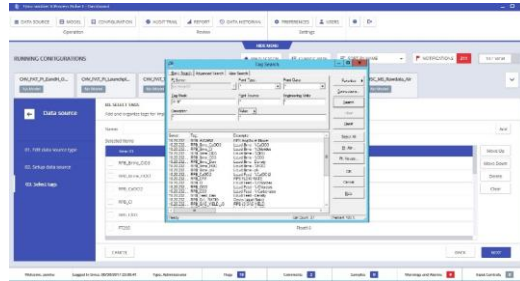
Multiple Process Parameter

- Raw Data written to the PI System



Data Interface

- PI to Process Pulse



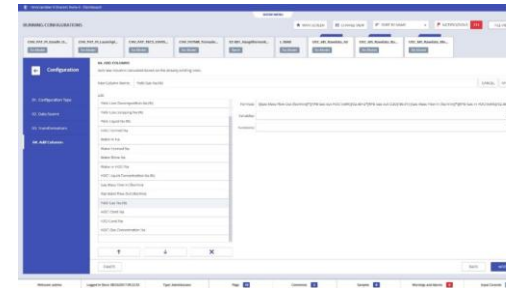
Calculations

- Mol Concentrations A/B
- Gas Yield
- Liquid Yield
- ...

Online Dashboards

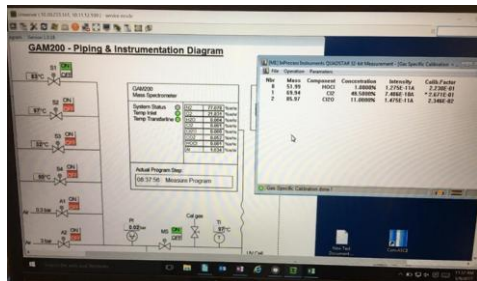


Process Pulse Data Integrator



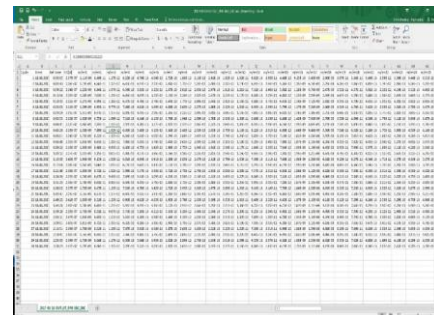
Process Mass Spectrometer

- 0-100 AU Mas Spectra



Data Converter

- Raw data to ASCII



Meta Data

- DoE Run No.
- Operator
- Initial Concentration
- ...

Use Case: Pilot Study in Production Scale

Solution with Process Pulse

Problem:

Running a pilot of a gas reaction with online mass spectrometry needs to be optimized

- Large number of process variables has to be managed
- Online Mass spectra has to be integrated
- Online Yield calculations from different data streams
- Calculations of yield are based on initial parameter set
- Project team is located on four different sites

Preprocessing of signals

Complex calculation

Combining different results in one dashboard

Integrate MVA models

Sharing the dashboard

Benefits:

- Visualization of theoretical and current yield from reaction
- Identifying steady state of reaction
- Online optimization of reaction
- Sharing the results for all project members on four different sites

Business Case

1. Increase efficiency and higher data quality by avoiding “copy-paste”
2. Speed up data evaluation for science based decisions
3. Early detection of unforeseen events
4. Modeling of steady-state behavior
5. Providing process information (for process optimization in R&D and production)
6. Enabling a team approach over different Sites



1. Combining multivariate and univariate data streams in one system
2. Enable data evaluation “on-the fly”
3. Documentation of all meta data
4. “Single point of truth”
5. Automation in data analytics
6. First pilots are successfully implemented

The PI System as a fundament for Process Analytical Technology Applications

COMPANY and GOAL

Serving today's and tomorrow's market needs by bringing biotech and specialty chemical expertise to our customers.

Lonza



CHALLENGE

No infrastructure for multivariate - and process data to enable multivariate data analytics

- Spectral data stored in silos
- Models integrated only in the proprietary systems
- No link with process data

SOLUTION

Process Pulse is a platform to connect to different data sources and enable online multivariate data analytics

- One common storage for spectral data
- One GUI for all PAT instruments

RESULTS

Increase efficiency and higher data quality by avoiding “copy-paste”

- Instead spending 80% time for data gathering, now is 80% time for data evaluation
- “Playing with the dashboards makes fun”

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Questions

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

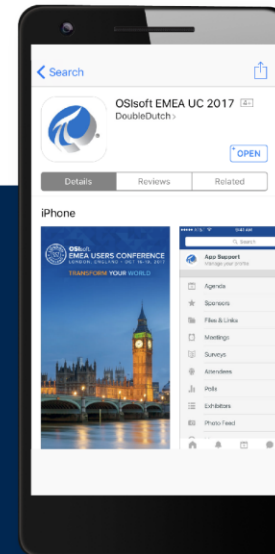


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감사합니다

Danke

谢谢

Merci

Gracias

Thank You

ありがとう

Спасибо

Obrigado