Deployment of the PI System and Advanced Analytics in Manufacturing

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Cork

Janssen In The World

At Janssen we work globally on the health of everyone

5,000
researchers
at various R&D centers

+ 37,000
employees
on a global scale

top10
fastest growing pharmaceutical company

15
new products
launched since 2009

33.5
billion USD
global turnover

6.9
billion USD
R&D investments in 2016

General process flow of Monoclonal antibody production

Preculture

Fermentation

Direct Product Capture

Purification

Final testing

Current vs Future State

Current

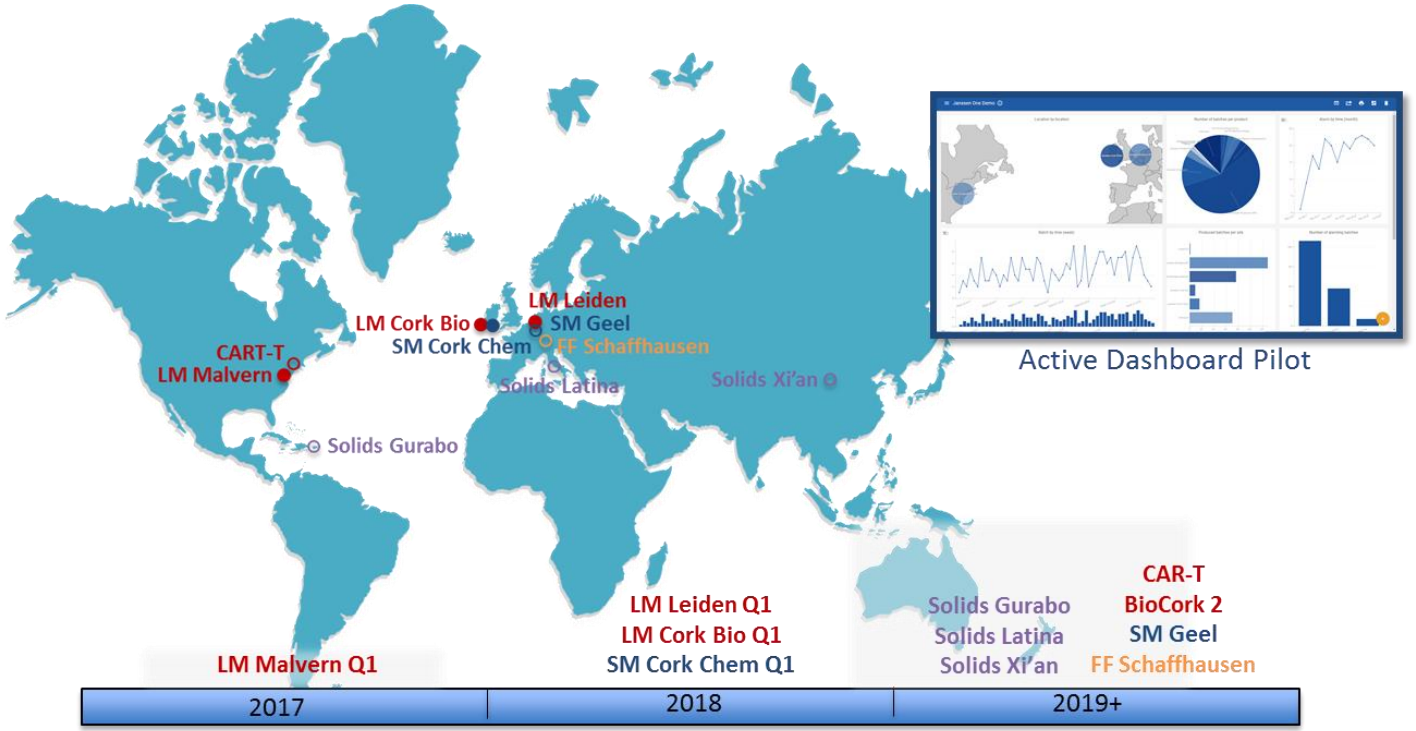
- Fixed batch recipes with few sensors
- Quality is “Measured” after the batch
- Limited real time awareness of batch performance

Multivariate Analysis & OSI PI

Future

- Dynamic control with multiplexed sensors
- Real time quality predication “right” time release
- Process monitoring and optimisation through advanced analytics

Digitalization/SIMCA Deployment

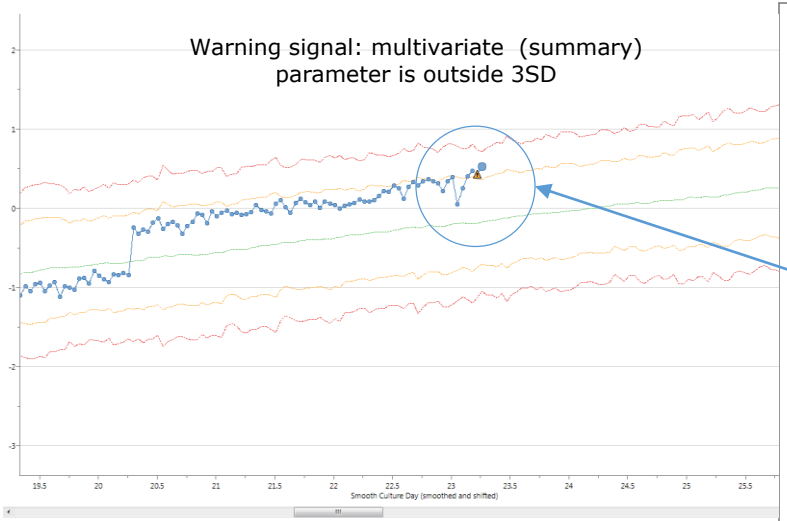


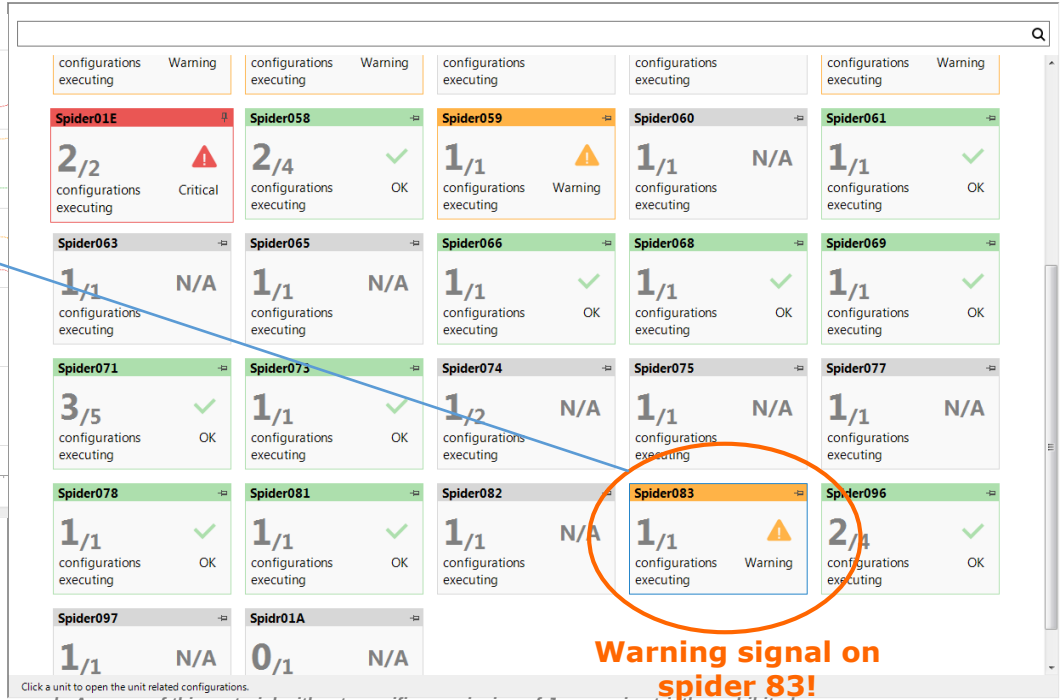
Digitalisation

Erik Klijn
Leiden, Netherlands

Last year

Advanced Analytics facilitates overview





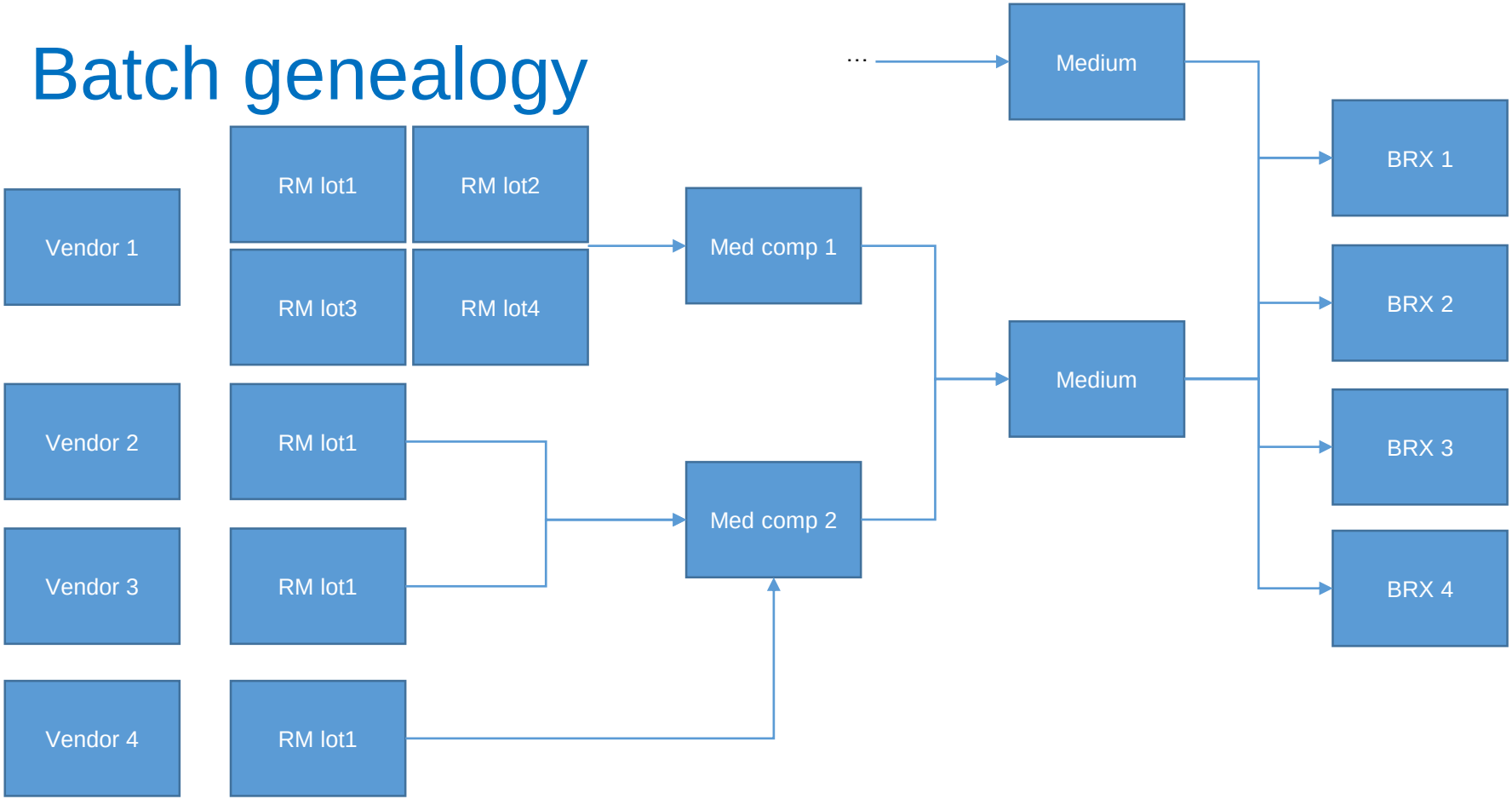
Leiden characteristics

- **30+ bioreactors running in parallel**
- **Highly flexible plant**
  - A lot of small moveable equipment
  - Multiple processes in one bioreactor hall
  - Many products in parallel
- **Hard to keep overview**

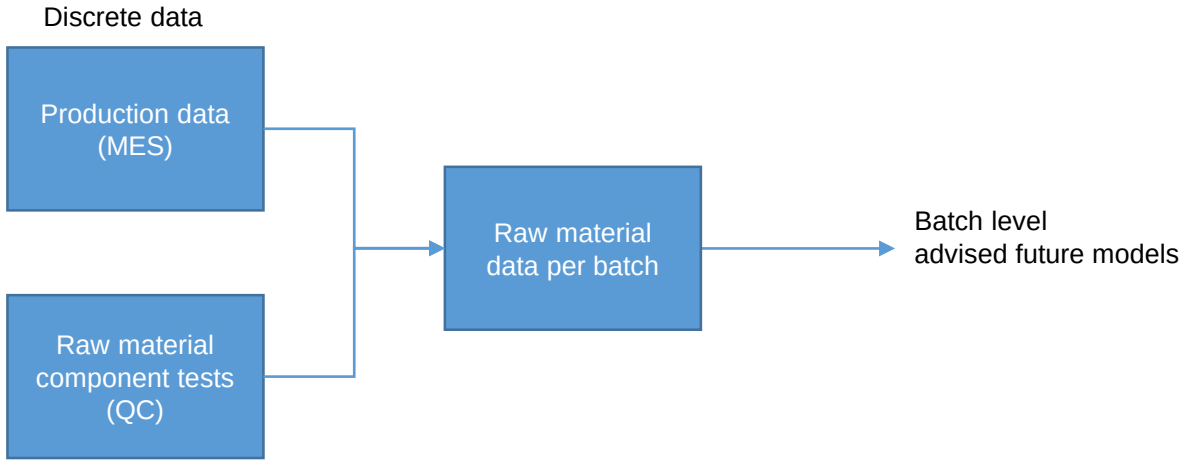
This year

- Optimization of raw material components
- Complex batch genealogy
- Complex cellular interactions with raw material components

Batch genealogy



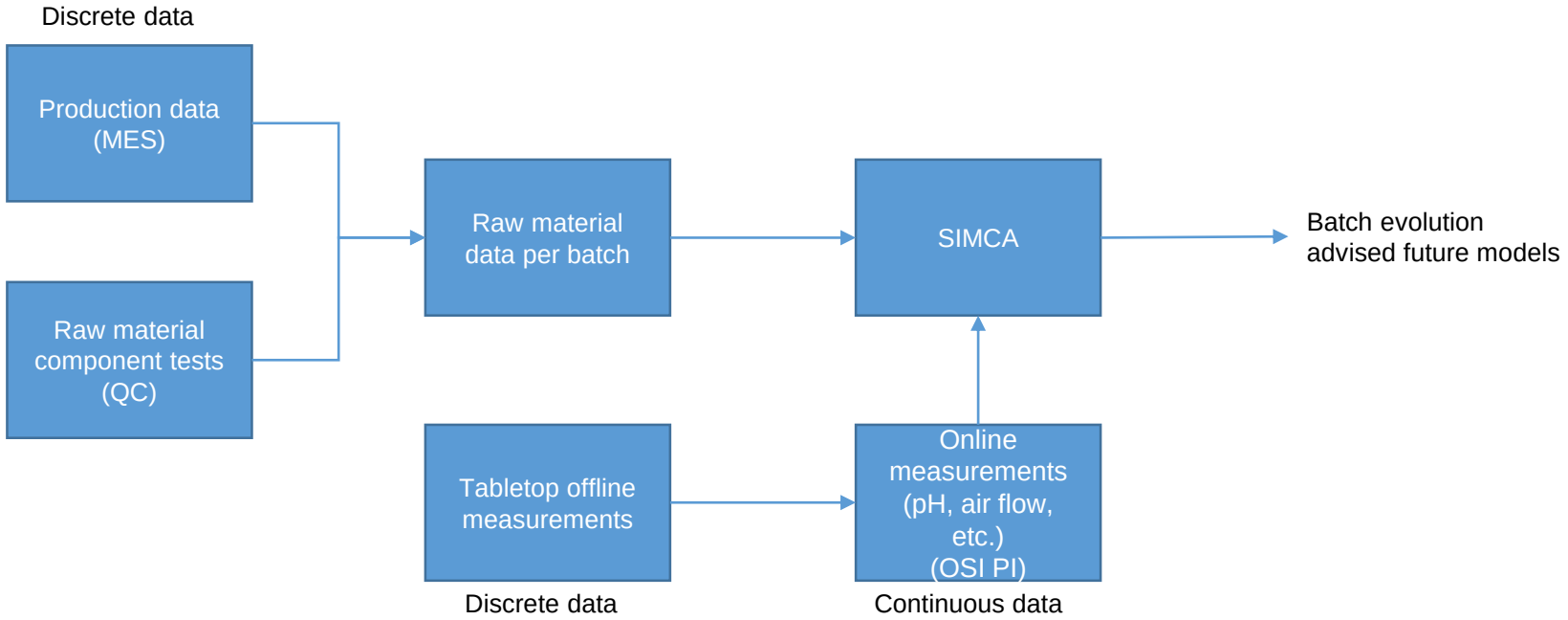
Optimization of raw material components



Drawbacks:

- Only considers batch averages for all continuous parameters
- Raw material component criticality & optimal levels differs over duration of batch

Optimization of raw material components

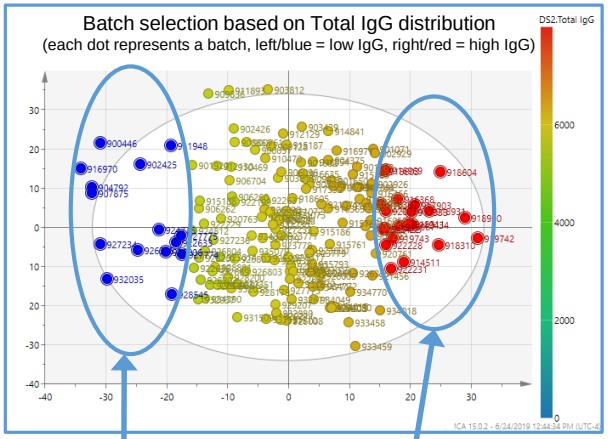


Advantages:

- Consider real parameters at the right time
- Differentiate between criticality & optimal levels differs over duration of the batch

Optimization of raw material components

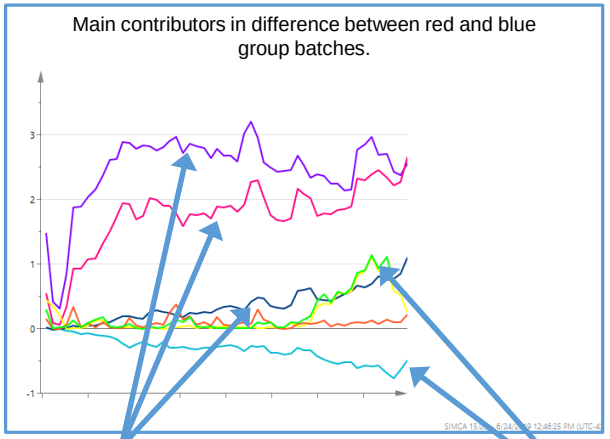
Batch Overview Model



Group 1 (Blue): Low production

Group 2 (Red): High production

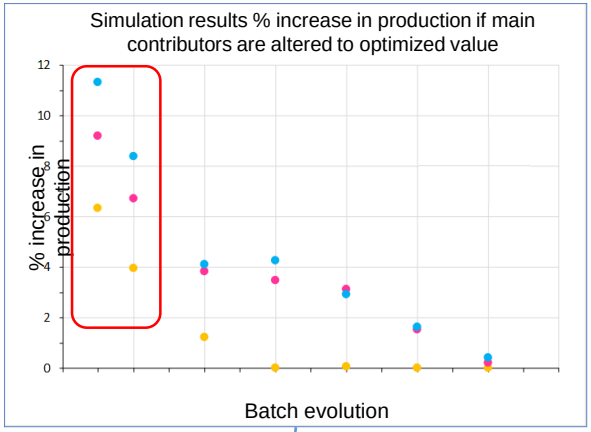
Culprit variables



Top 3 sources of variation (for the entire duration of the batch)

Additional sources of variation (at the end of the batch)

Simulated increase in production



Savings up to 2.5 Million Euro / year

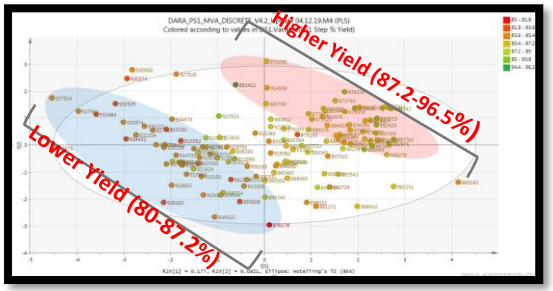
Patrick T. O’Sullivan
Cork, Ireland

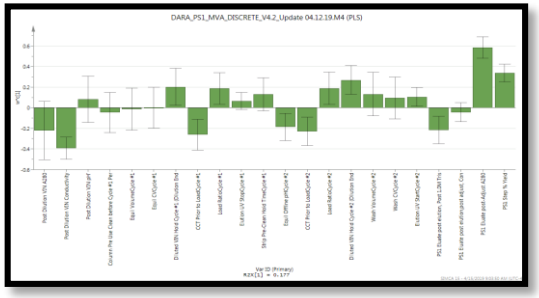
Cork, Ireland

- 5 main products
- 3 1000L BRX
- Set manufacturing
- 600million expansion
- 4 additional 15K
- Clinical Suite

DARA PS1 (Cork)

SIMCA®



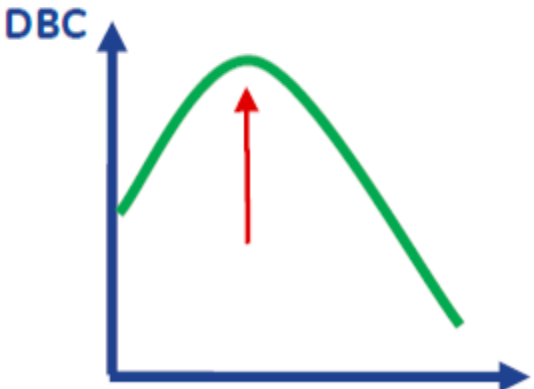


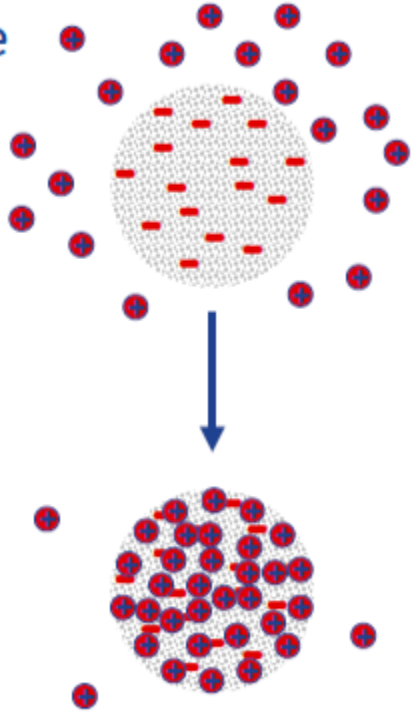
2-4% Yield

Why: Non-traditional IEX Behavior

Exclusion hypothesis – *optimal conductivity*

- Equilibrium shifted towards unbound state
- Facilitated mass transport into the pore network
- Reduced thickness of electric double layer



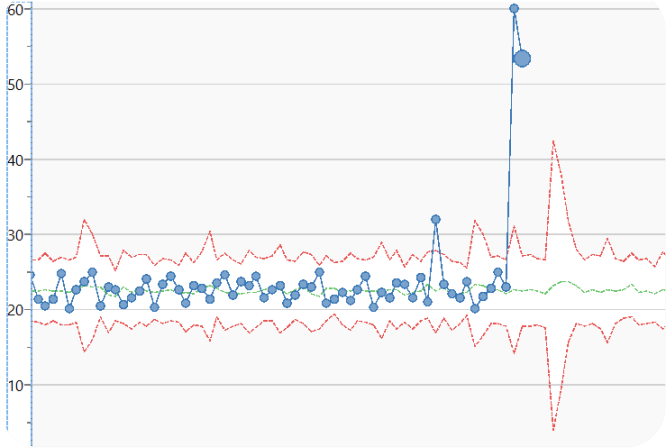


Harvest break tank weight isn't something routinely monitored

MVA Identified the harvest filtrate weights was abnormally high

Using SIMCA-online, the process SME identified that it was overfilling

Event Prevention



$200,000

Challenges

- Non GMP validated PI system → Data gaps
- Continuous PI data integrated with Discrete Manufacturing and Quality Data
- Transitioning of control systems → Data architecture must be recreated
- Scalability of SIMCA software for multiple models running at one time
- SIMCA-online introduction to Production Areas

Next Steps

- Transition to PI AF/EF to accommodate for DeltaV
- Introduction of PI vision
- Completion of data architecture and Integration of Azure Data Factory into Mfg Data Hub.

Summary

- Real Time monitoring, Forecasting & Simulation Modelling
- Currently active across Janssen's Large Molecule Platform
- Several process optimisation and yield improvements achieved from MVA
- OSI PI continuous data essential to Batch Evolution Model construction and implementation

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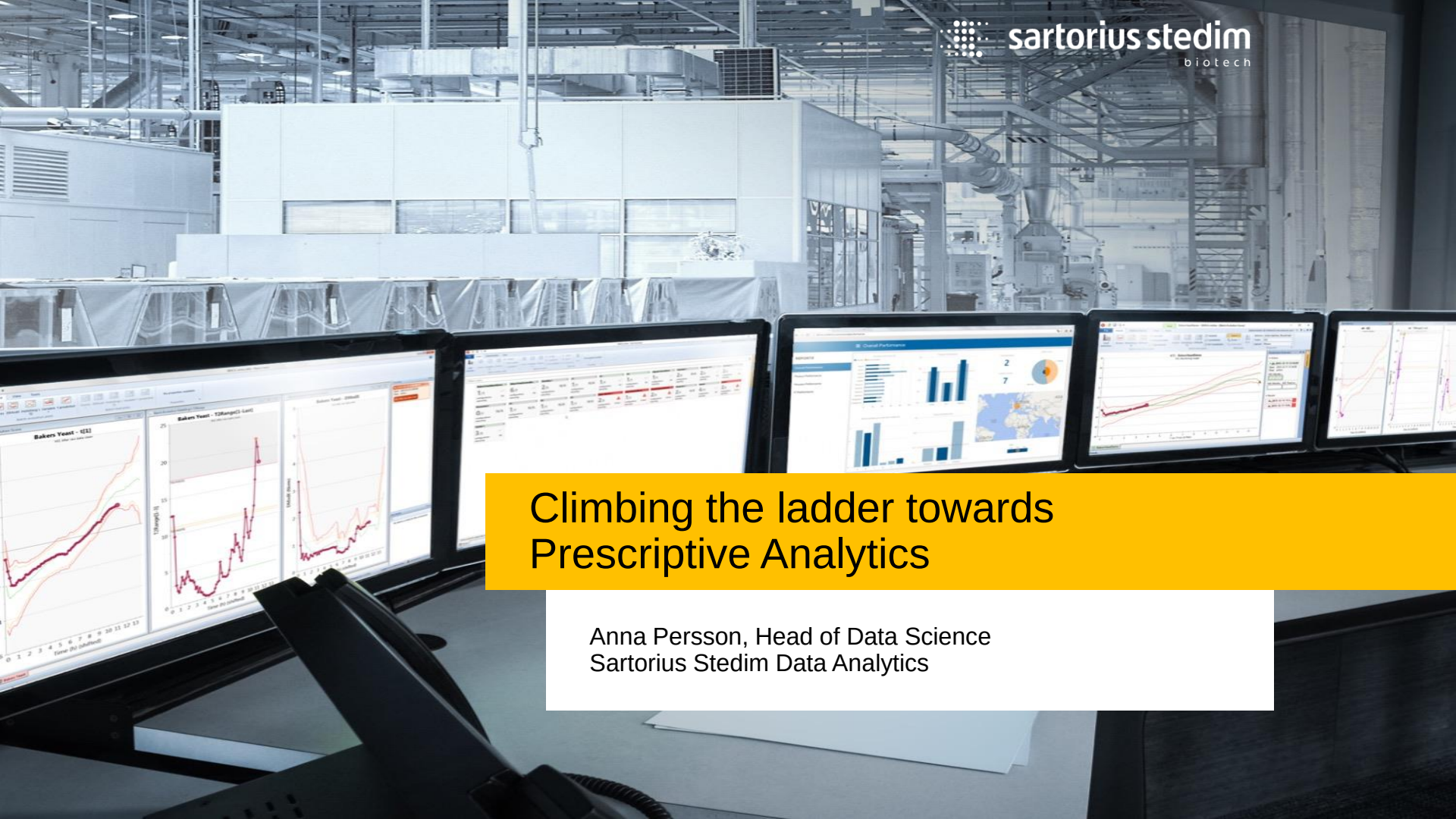
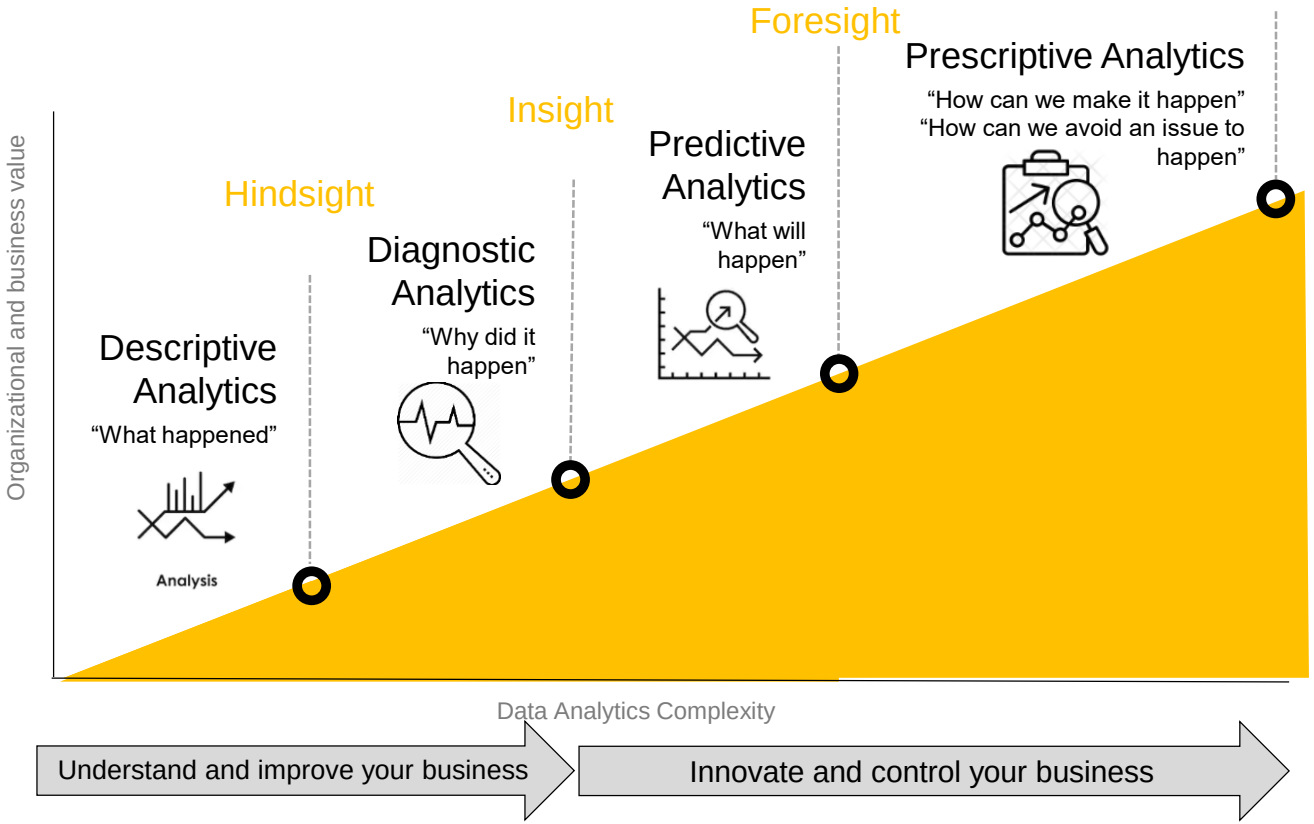


Climbing the ladder towards Prescriptive Analytics

Anna Persson, Head of Data Science
Sartorius Stedim Data Analytics

The Data Analytics Continuum

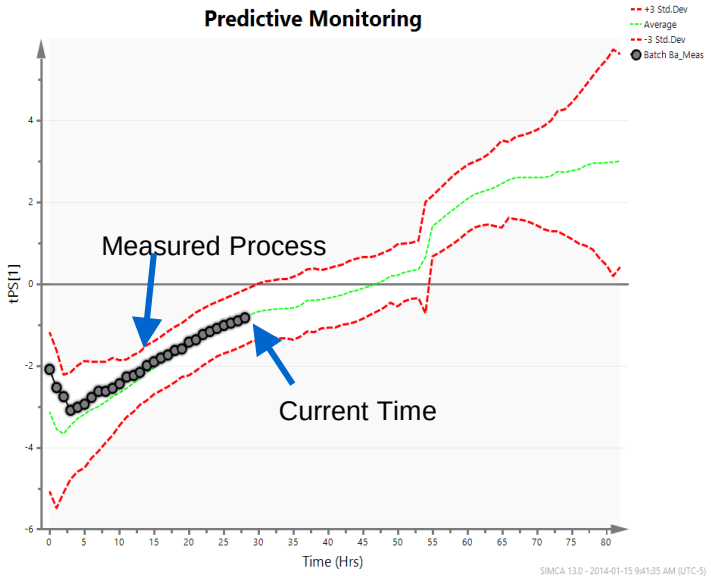


Umetrics Suite - Connectors to OSIsoft PI

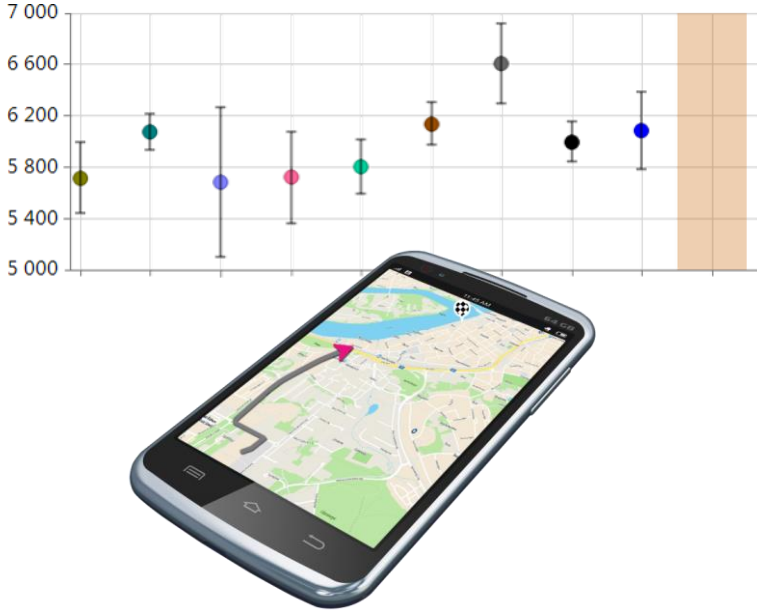
- PISimBatchOL
  - PI Server and PI Batch Systems
- PIAFSimApi
  - PI Server and PI EventFrames

Multivariate Statistical Process Control (MSPC)

Batch evolution

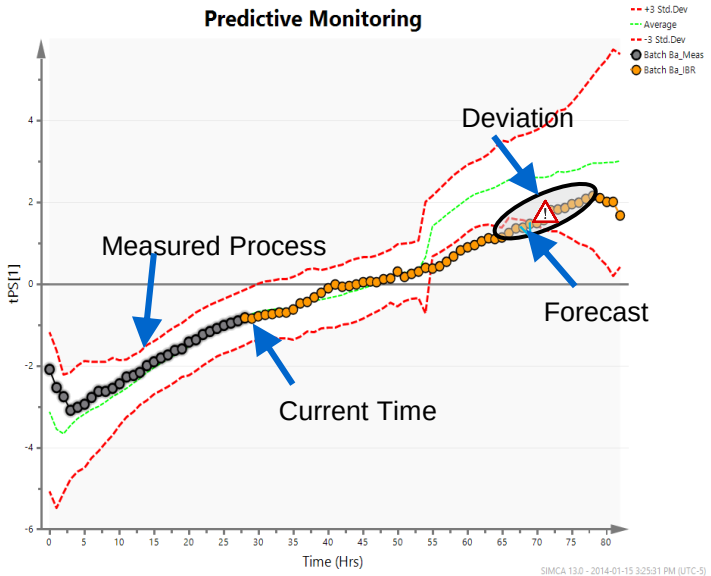


Final properties



MSPC & Process Forecasting

Batch evolution



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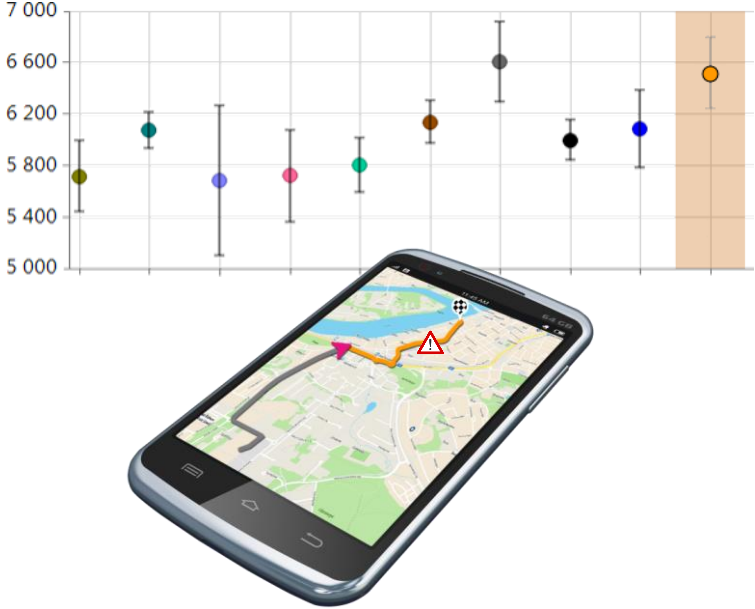
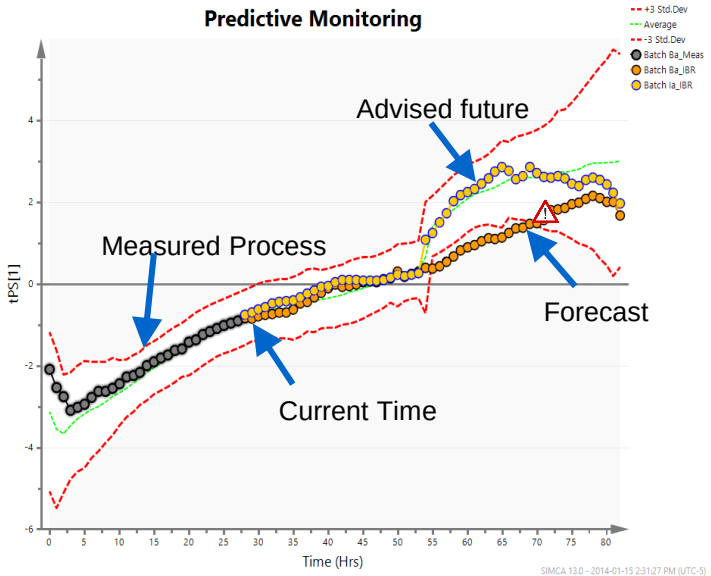


MSPC, Forecast and Advised future

Supervisory Control

Batch evolution



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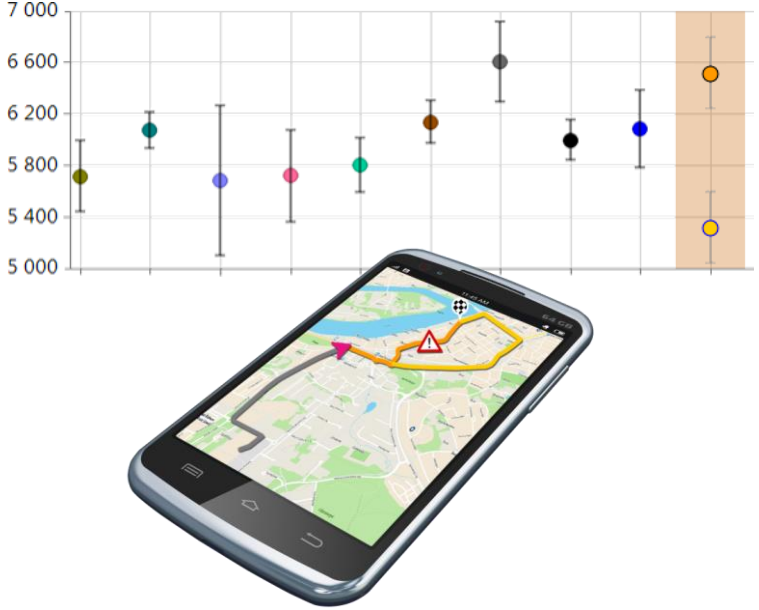

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