Data in Pharma. Industry
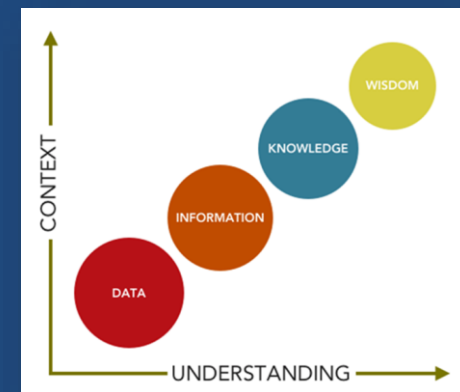
PDA
Parenteral Drug Association

CONNECTING PEOPLE SCIENCE AND REGULATION®

Data is the New OIL

You need to refine it to increase its value

*Adapted from. C. Undey; opening address IFPAC 2019, March 2019, Rockville (US)

Outline

- Why advanced data analytics

- Data in a regulated environment

- Model for processes

- Considerations for model validation
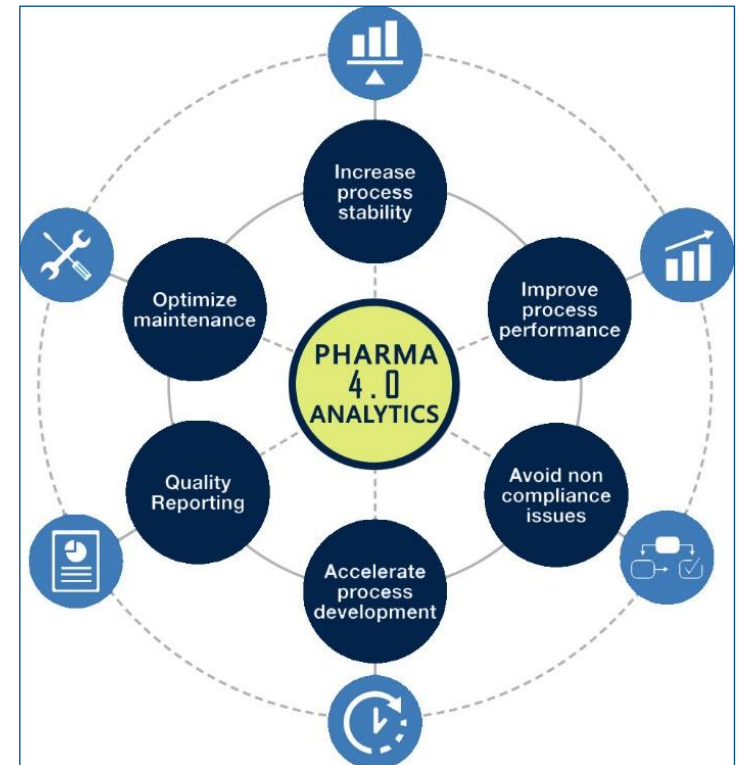
Why Advanced Data Analytics?

- The amount of data is exploding since more and more data is generated
    - 1.7MB of data is created every second by every person during 2020

- This means data is everywhere!
    - From professional life such as production floor (SCADA, analytics, Smart sensor) to your personal life such local grocery store and facebook!

- But how do we get *Value from data®*?

➔ use advanced data analytics, but what exactly is data analytics?

* https://techjury.net/blog/how-much-data-is-created-every-day/#gref

Why Data Analytics in Pharma?

Expected Business Impact

- Productivity & cost improvement

- Accelerated time-to-market

- Product quality & -similarity improvement

- Foundation of robust QbD strategy

Source: www.rdmag.com/article/2018/10/pharma-40-industry-40-applied-pharmaceutical-manufacturing
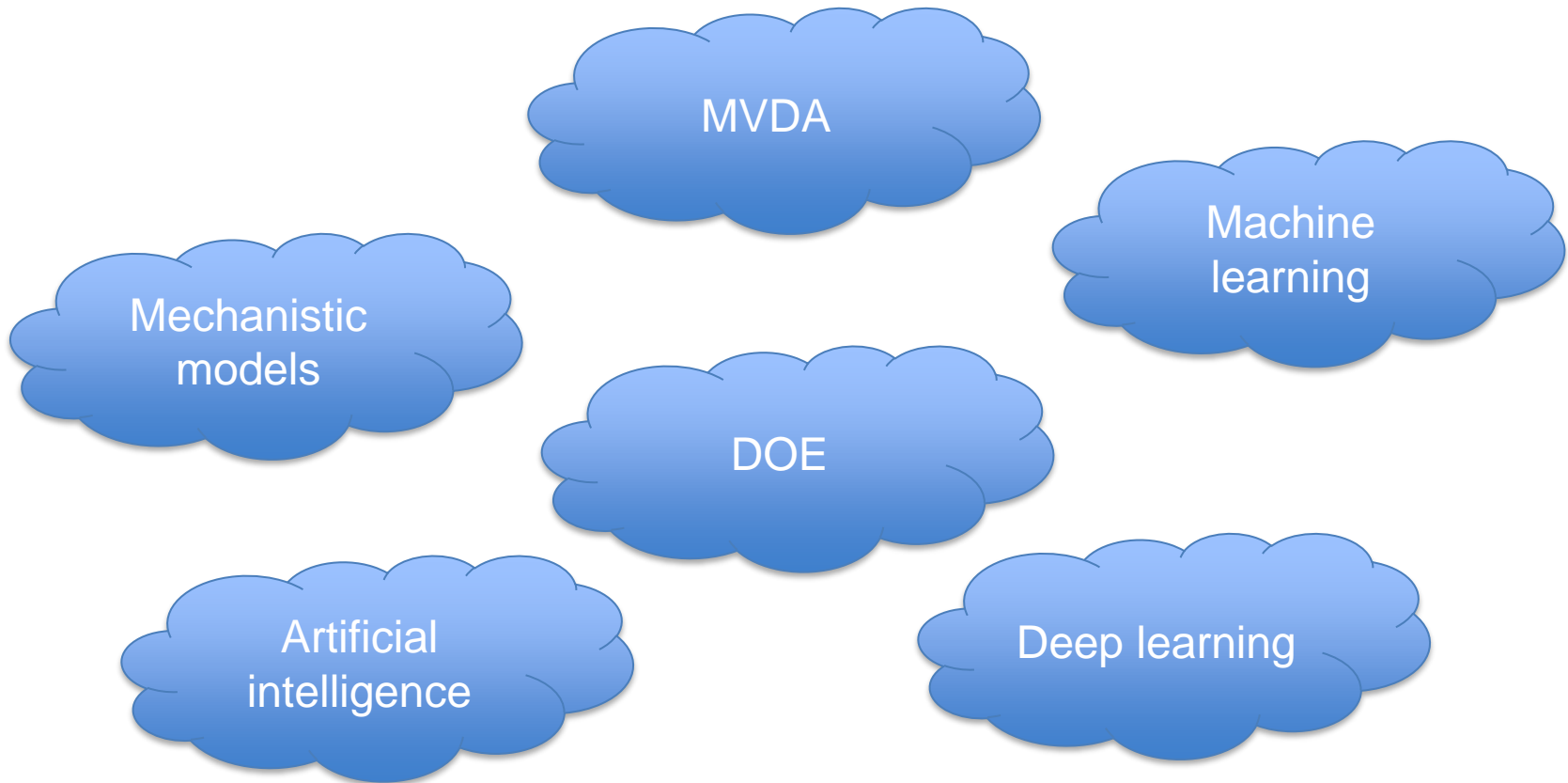
Digital & Analytics Trends

Pharma 4.0 will:

- leverage MVDA and process forecasting based on covariant CPP data

- drive the adoption of advanced MPC (model predictive control) as processing becomes more flexible, autonomous, and scalable

- provide a holistic representation of the entire manufacturing process across unit operations

- provide soft sensors: Real-time estimation of CPPs/CQAs based on measurements paired with online parameter estimations

- enhance chemometric models: Extract data from multidimensional spectra

- within Biopharma require to improve the mechanistic understanding of the underlying kinetics of advanced biotransformations as well as protein separation & purification

➢ *closed-loop adaptive model predictive control*

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What is Data Analytics?

Navigating through buzz words

What are all These Terms?

Artifical intelligence:
"the ability of a digital computer or computer-controlled robot to perform tasks commonly associated with intelligent beings."*
Such as "learning" and "problem solving.

↓

Machine learning:
Using computer to apply algorithm or statistical models on data in order to perform a specific task effectively without using explicit instructions, relying on patterns and inference instead**
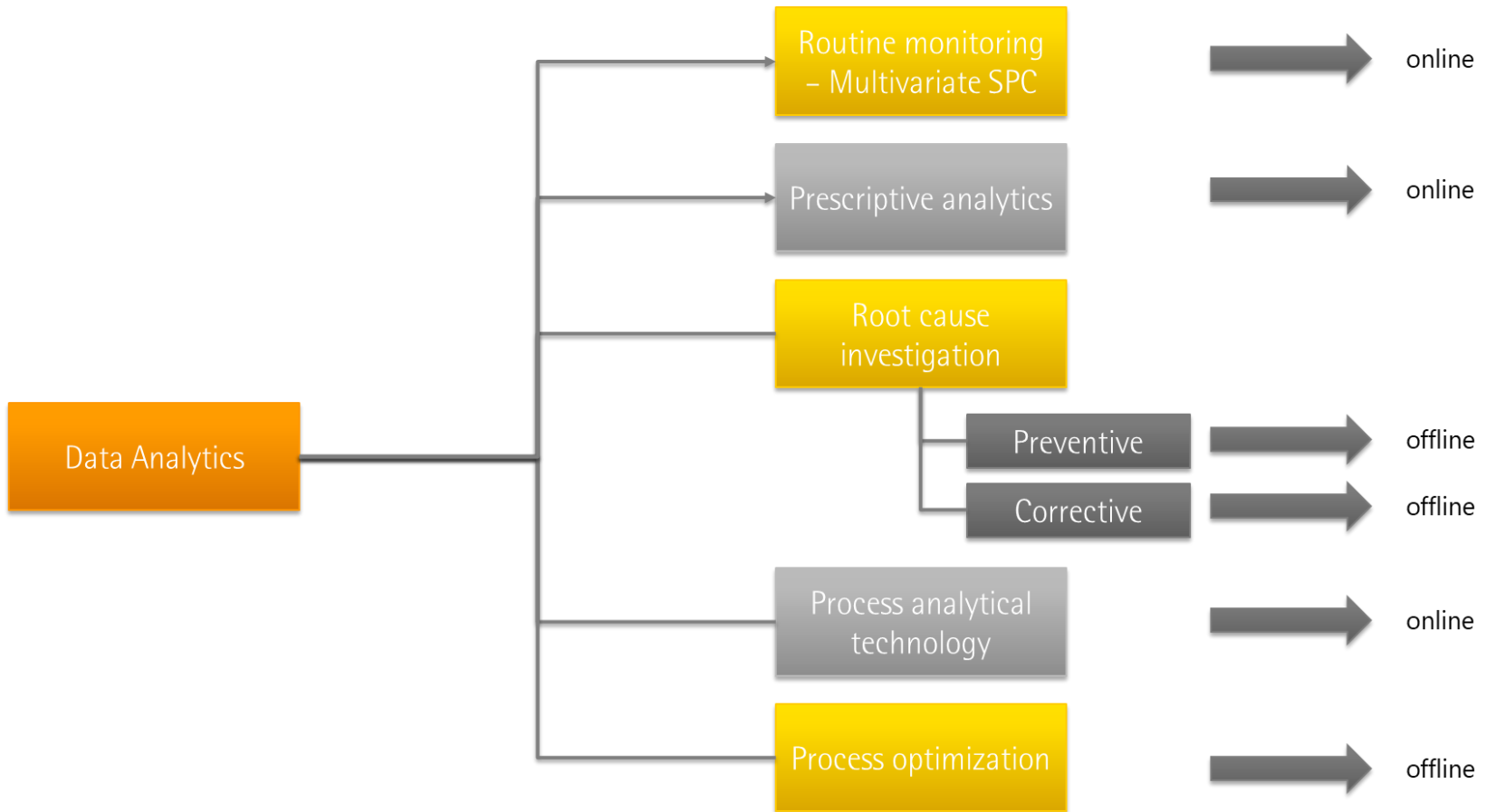
Deep learning
Deep learning is an AI function that mimics the workings of the human brain in processing data for use in decision making***

MVDA
is based on the statistical principle of multivariate statistics, which involves observation and analysis of more than one statistical outcome variable at a time**
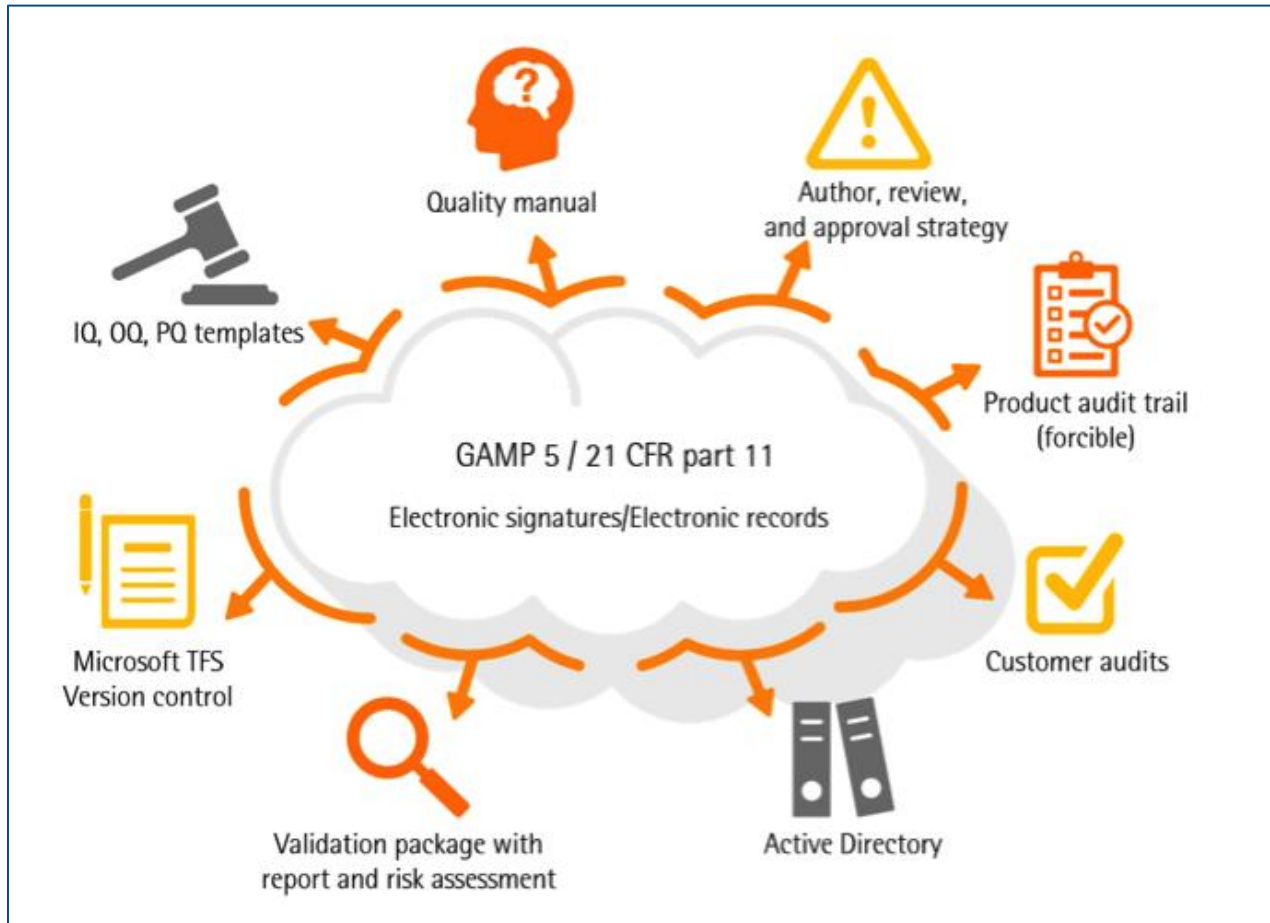
What cannot be achieved with these techniques?

These tools will find correlation but no cause and effect relation

Application Areas of Data Analytics

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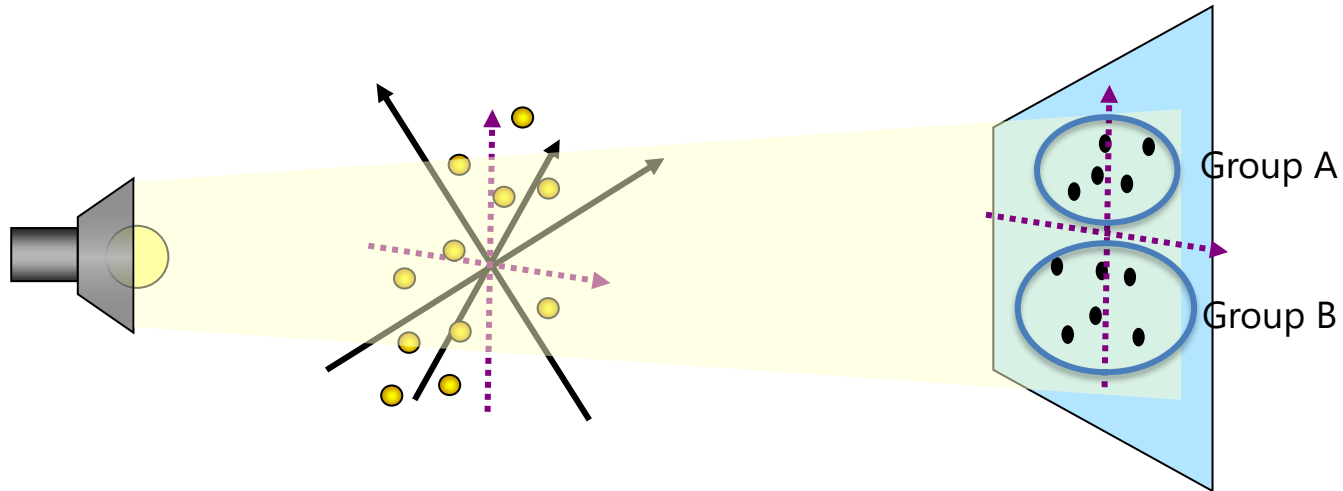# Data in a Regulated Environment

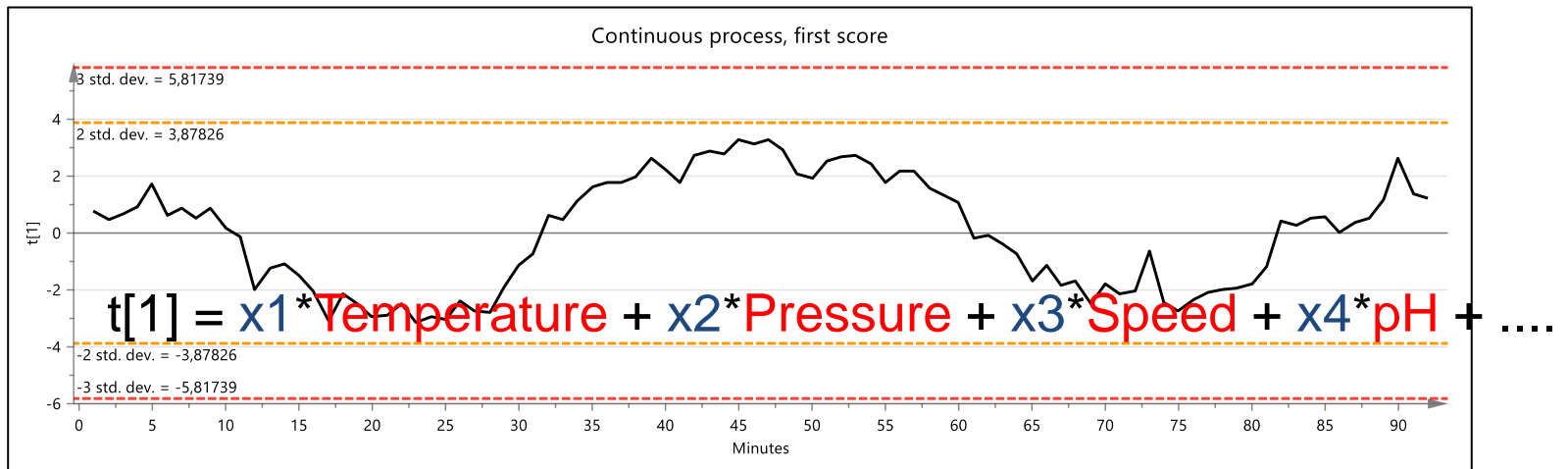# Data Integrity by Dominic Parry

Subtitle here

Back to Data Analytics

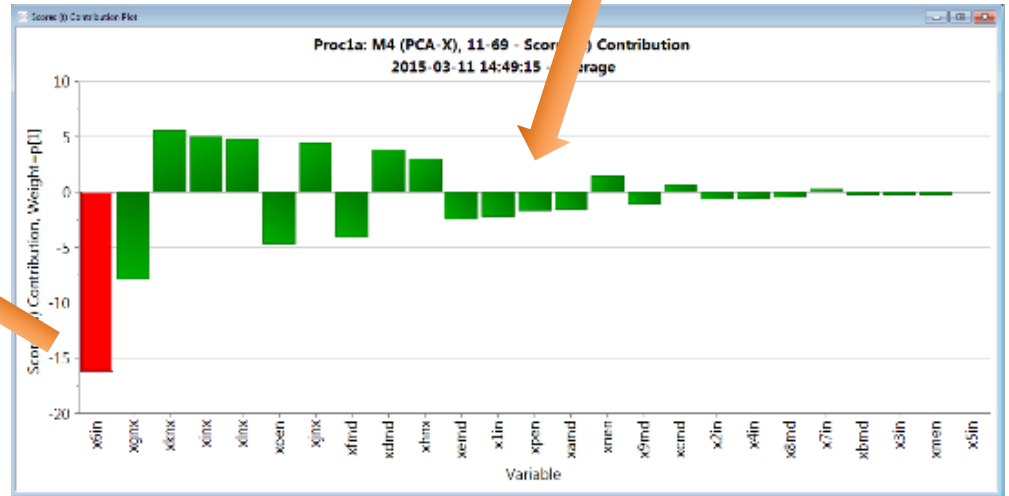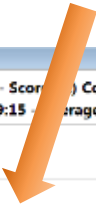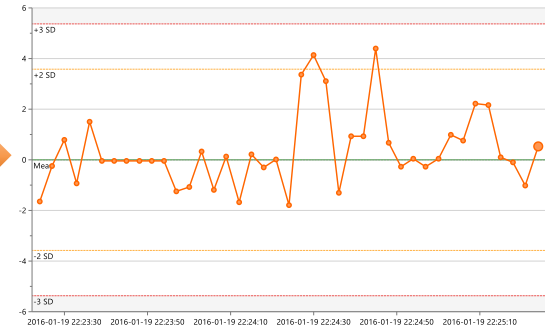Subtitle here

MVDA for Process Models
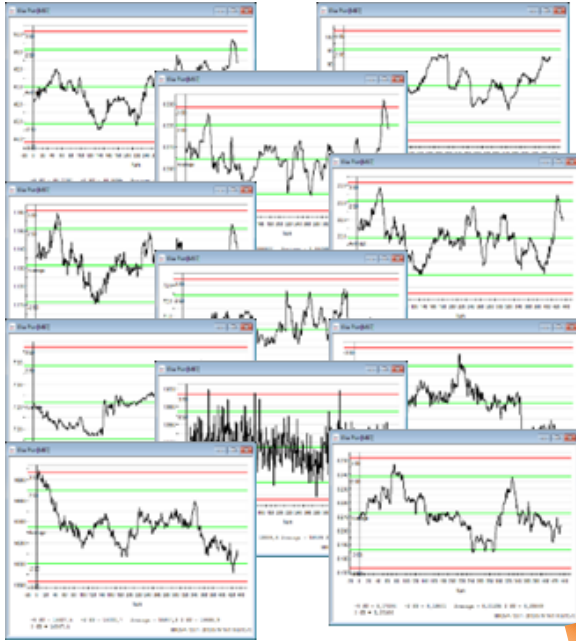

Group A

Group B

- Reducing of the dimensionality by project using correlation pattern

- Separating structure variation (information) from noise

- Generate easy to understand plot to illustrate your data effectively for analysis

MVDA for Process Models

Dow Jones = x1*GSK + x2*J&J + x3*Pfizer + x4*DuPont + ….

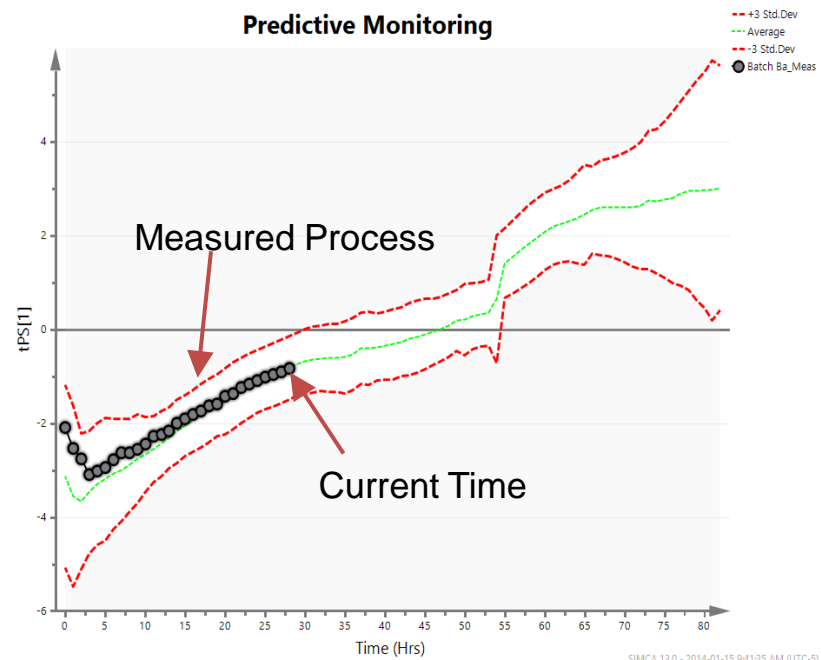t[1] = x1*Temperature + x2*Pressure + x3*Speed + x4*pH + ….
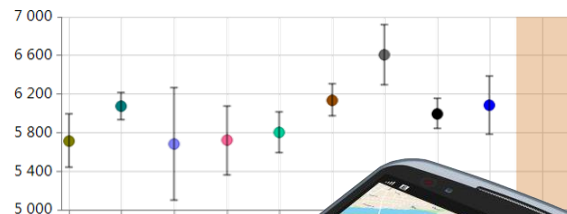
MVDA for Process Models

Forecast and Advised Future
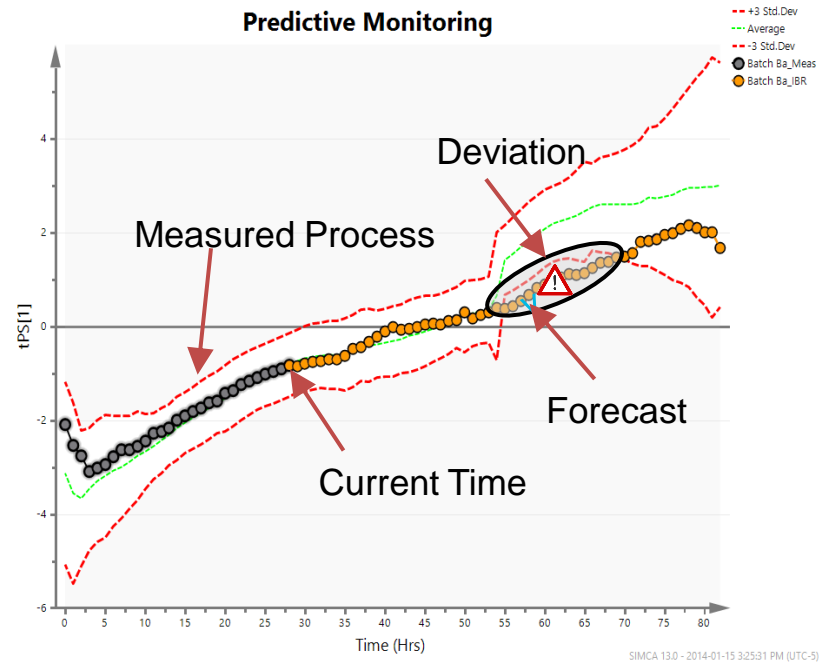
Batch evolution

Batch level

Forecast and Advised Future

Batch evolution

Batch level

What You See in Demonstration

- Process model for a cell cultivation
- The process has 2 phases: a growth phase and a stationary phase
- model was based on standart line data (in total 11 variables)
- Predictive model to forecast the product formation of product phase based on growth phase.
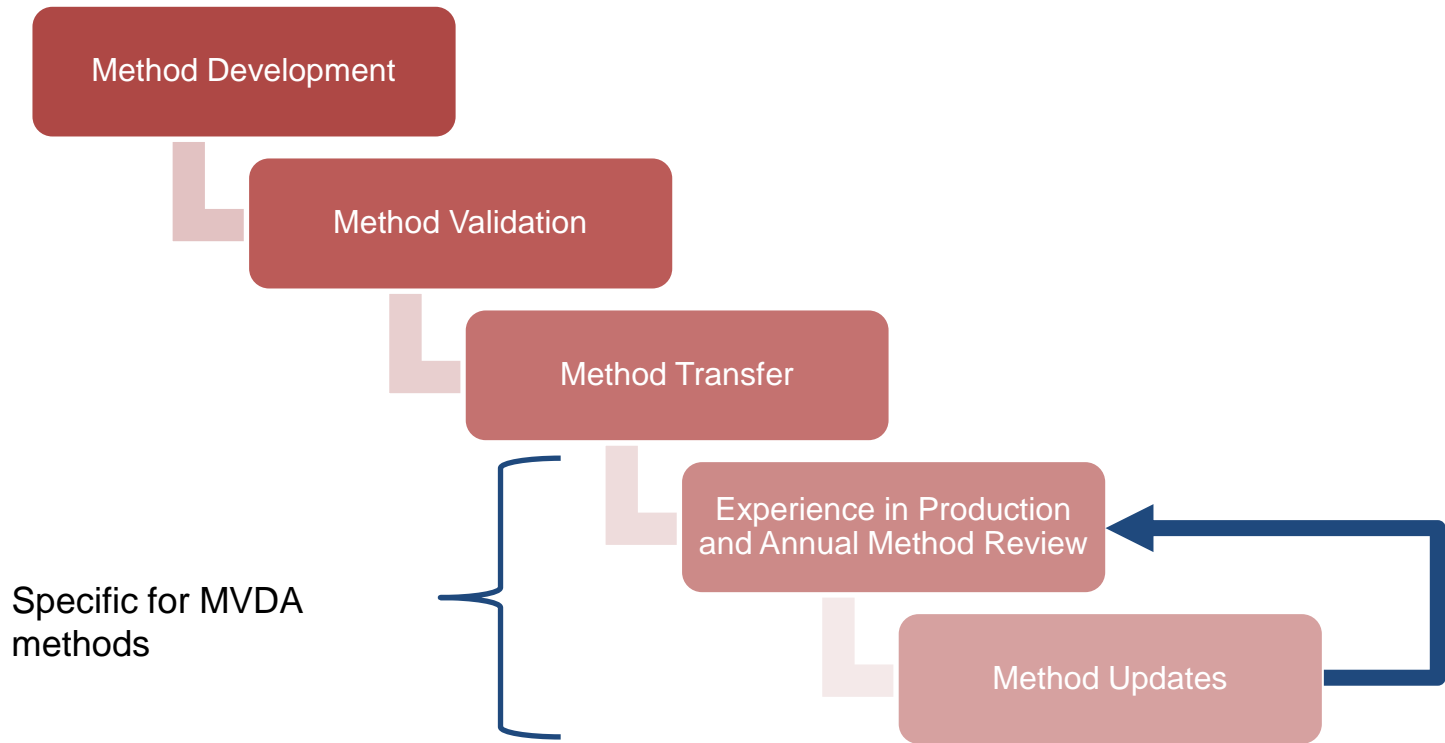
Looking at a Process Model

Subtitle here

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Considerations for Application

- The context of use for the model
  - What is the contribution of the model to the decision relative to other available evidence?
  - What is the significance of an adverse outcome resulting from an incorrect decision
  - Are there any limitations of the model based on the assumptions?

- Model validation strategy

- Model maintenance
  - MSPC models can require verification or an update upon changes in
    - Process conditions
    - Equipment
    - Material characteristics
  - Monitoring and trending of model performance will be a component of continuous process verification

Considerations for Model Validation

Method Development

Method Validation

Method Transfer

Experience in Production and Annual Method Review

Method Updates

Specific for MVDA methods

Considerations for Model Validation in a Regulated Environment

- Model Quality
    - Is the model complexity correct?
    - Is the model capable to differentiate between good and bad?
    - Is my model capturing a sufficient amount of variation?
    - In case of a prediction model additional aspects such as robustness, precision

- Administrative Part
    - What is the user concept?
    - How is the alarm acknowledgement strategy?
    - What SOPs are needed?