

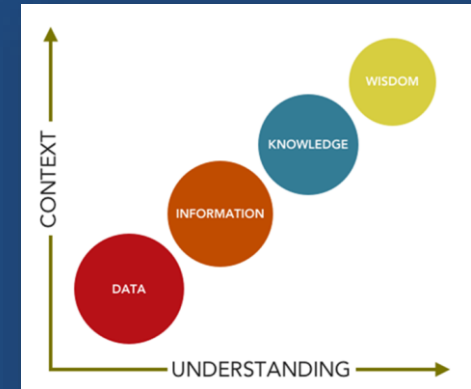
# *Data in Pharma. Industry*



# 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?

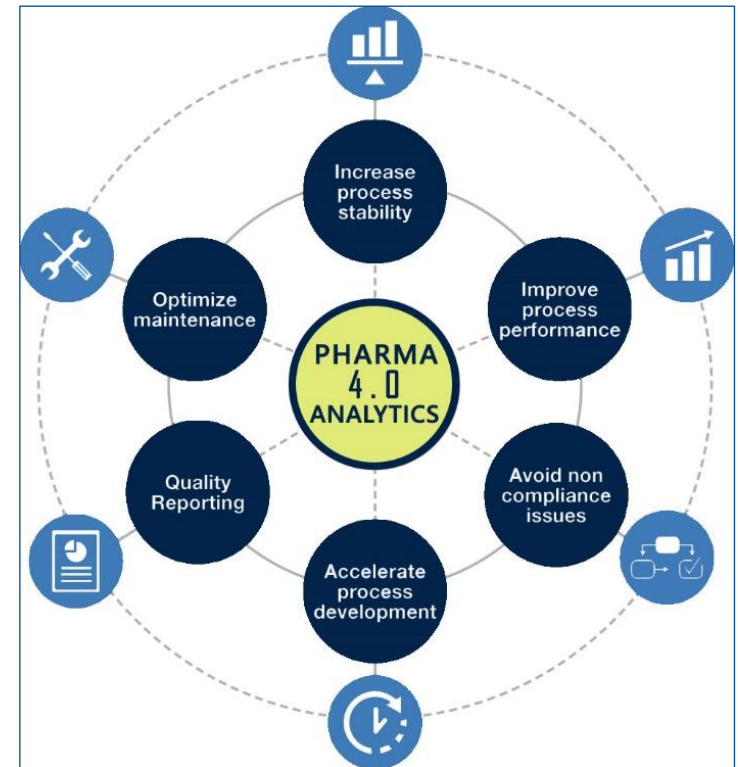
- The amount of data is exploding since more and more data is generated
    - 1.7MB of data is created every second by every person during 2020
  - This means data is everywhere!
    - From professional life such as production floor (SCADA, analytics, Smart sensor) to your personal life such local grocery 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](http://www.rdmag.com/article/2018/10/pharma-40-industry-40-applied-pharmaceutical-manufacturing)

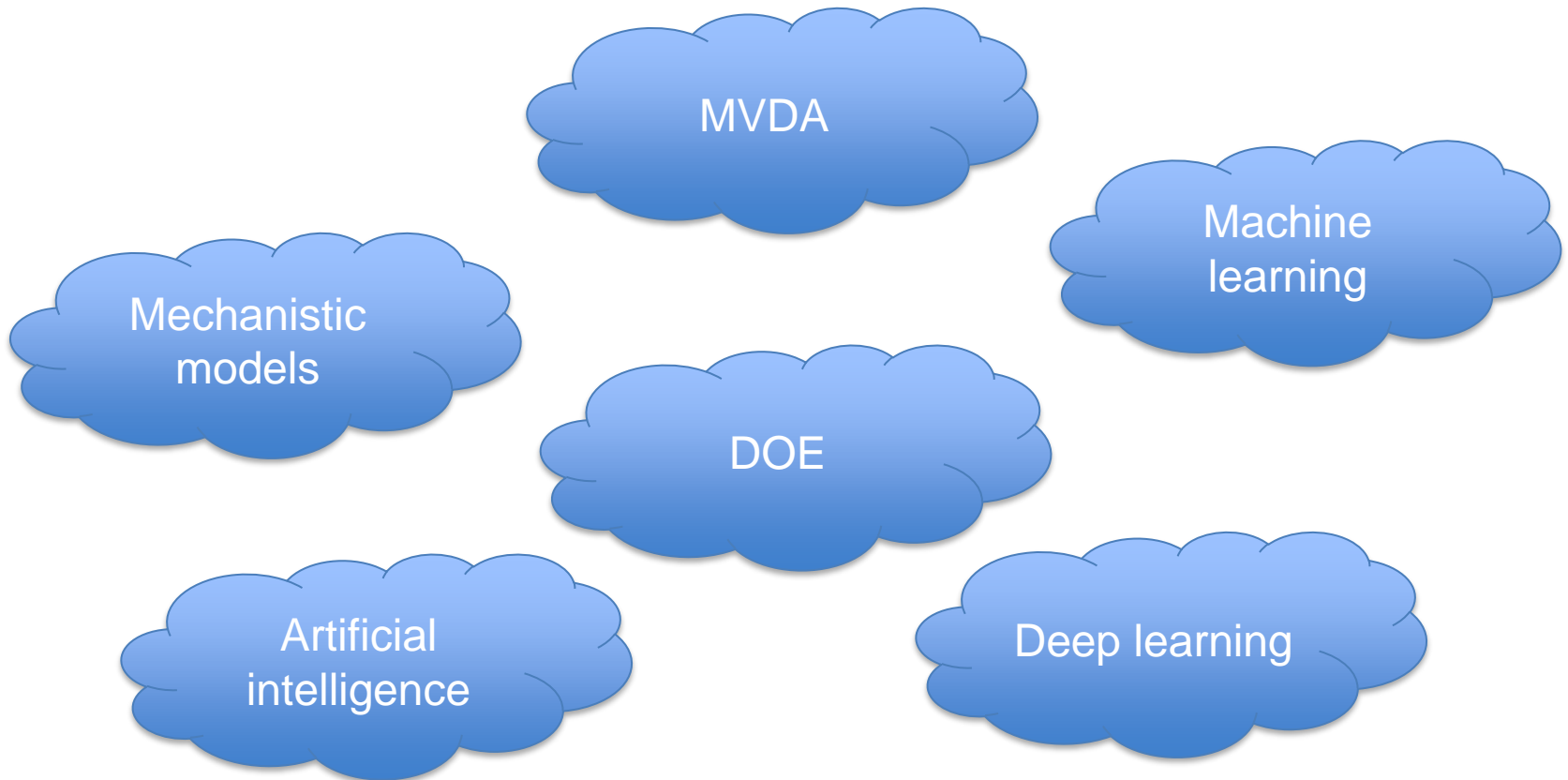
# Digital & Analytics Trends

## 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*

# What is Data Analytics?

Navigating through buzz words



# What are all These Terms?

Artificial 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\*\*\*

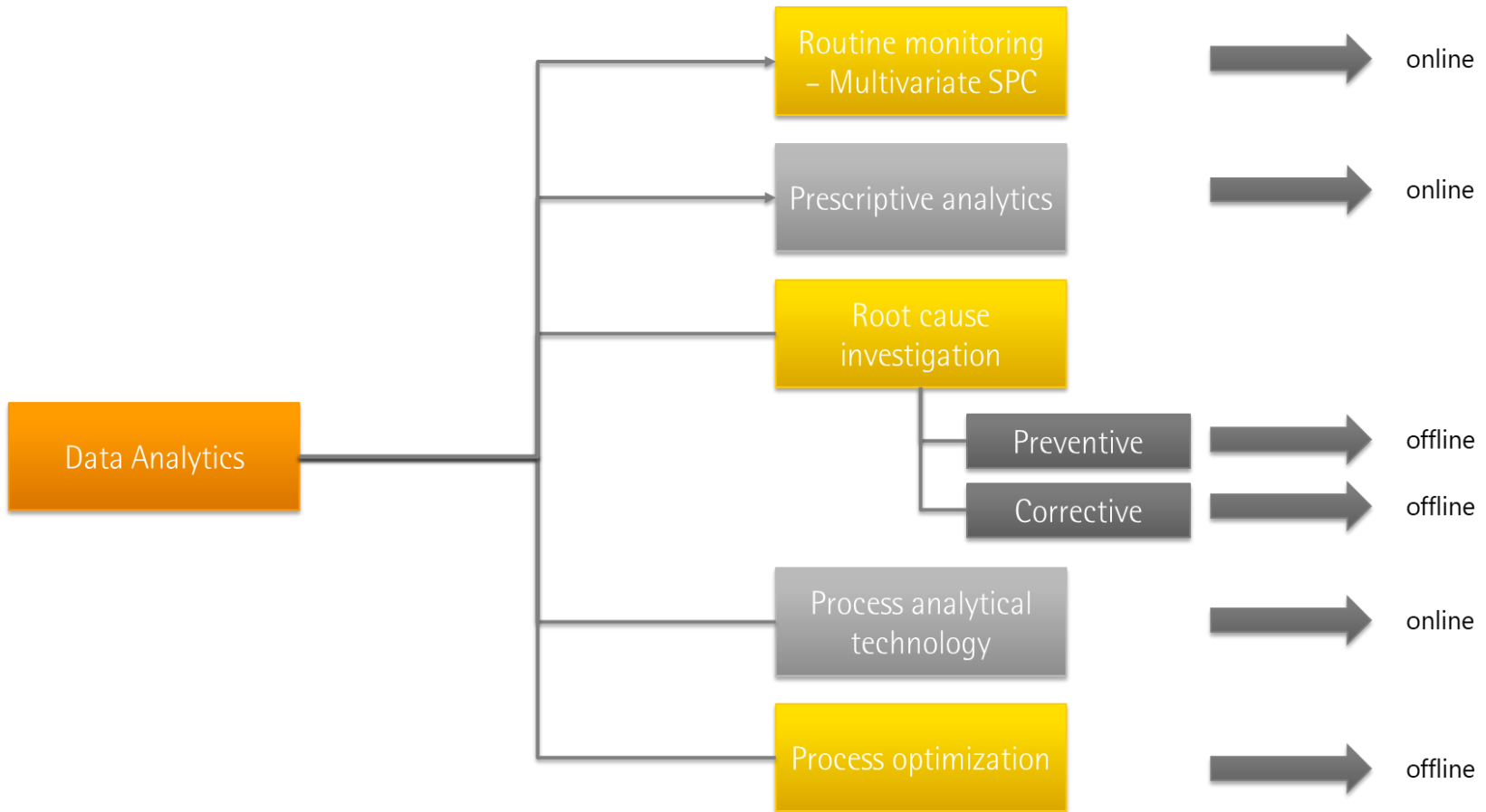
**MVDA**  
is based on the statistical principle of multivariate statistics, which involves observation and analysis of more than one statistical outcome variable at a time\*\*

What cannot be achieved with these techniques?

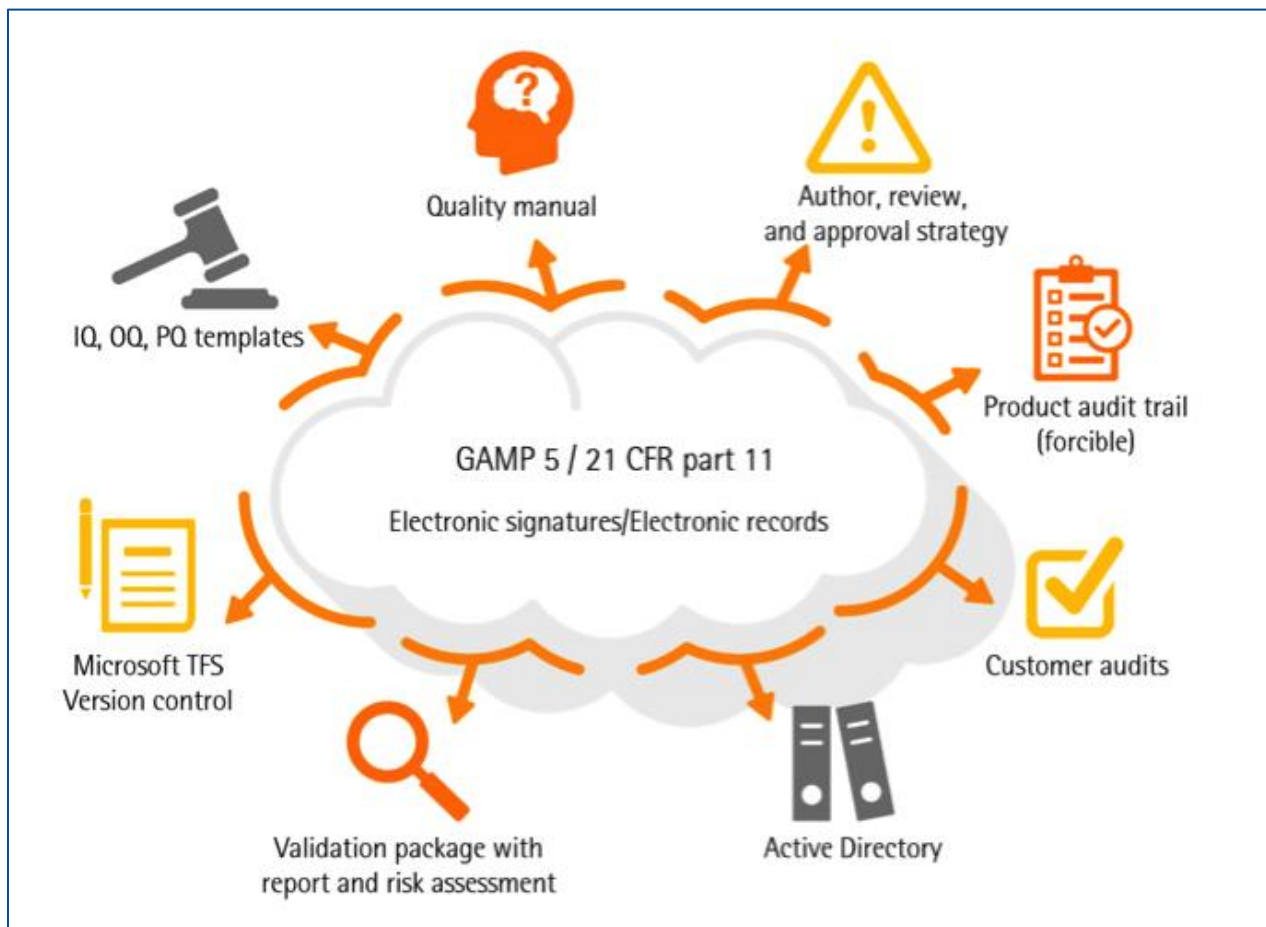
These tools will find correlation but no cause and effect relation



# Application Areas of Data Analytics



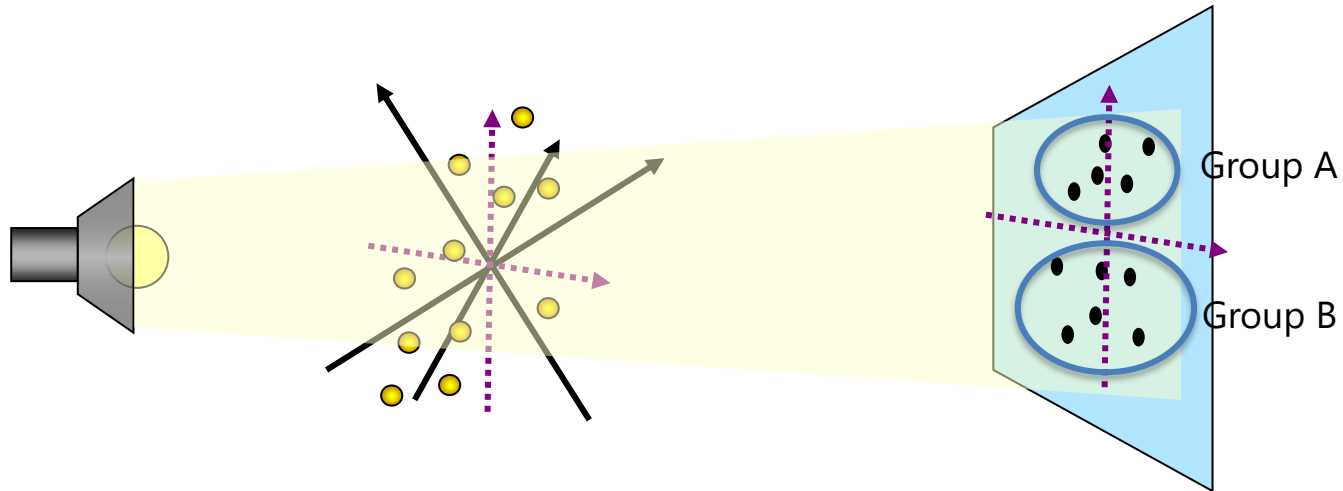
# Data in a Regulated Environment



# Back to Data Analytics

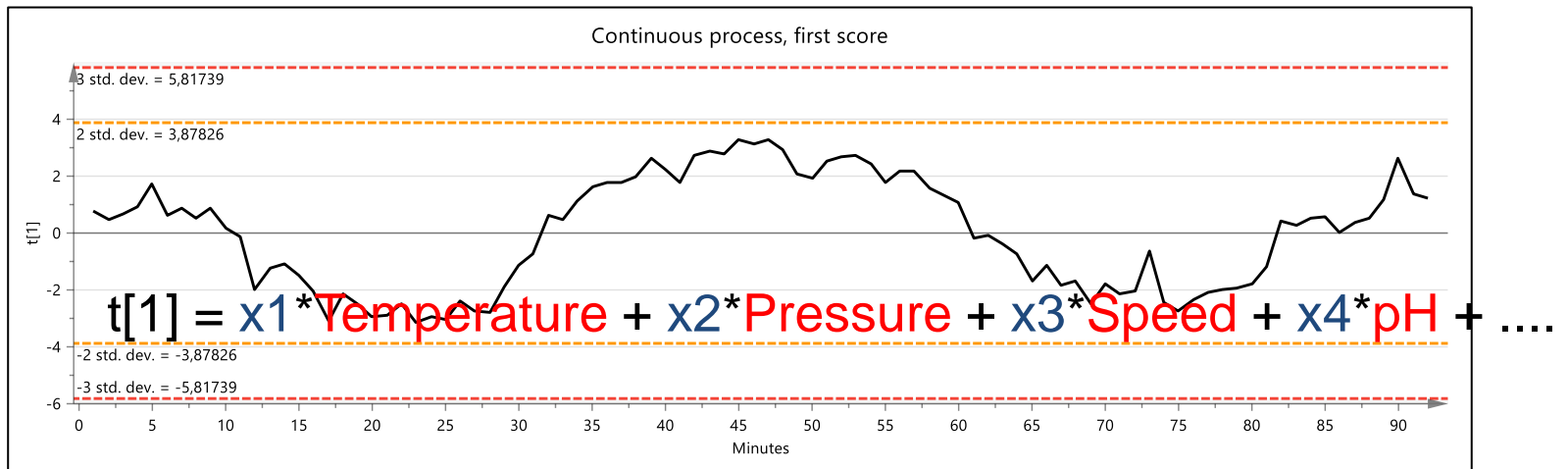
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# MVDA for Process Models

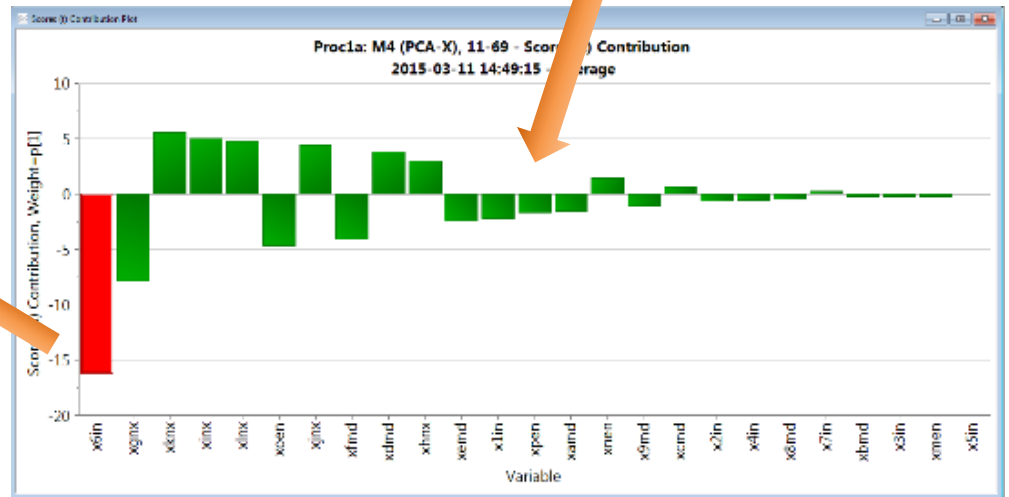
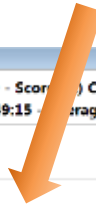
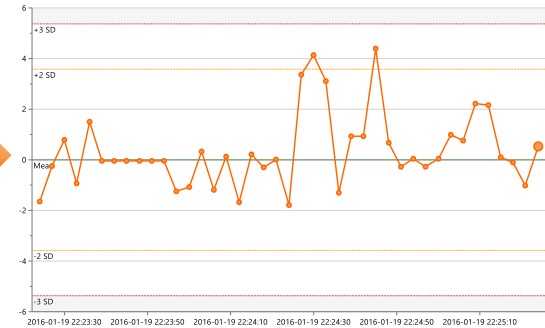
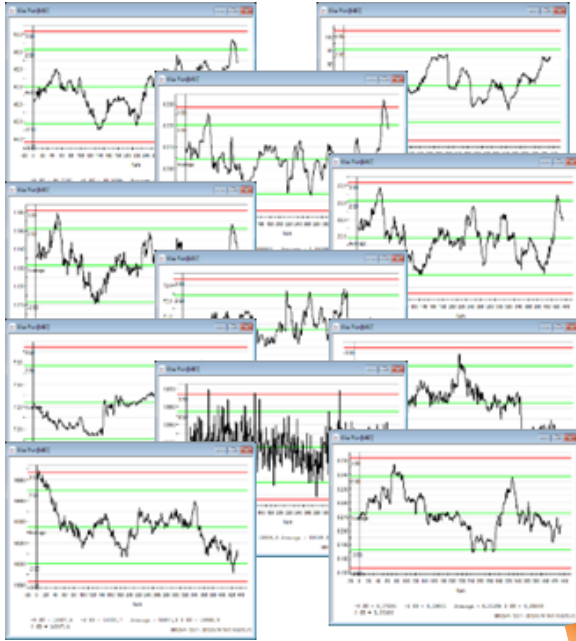


- Reducing of the dimensionality by project using correlation pattern
- Separating structure variation (information) from noise
- Generate easy to understand plot to illustrate your data effectively for analysis

# MVDA for Process Models

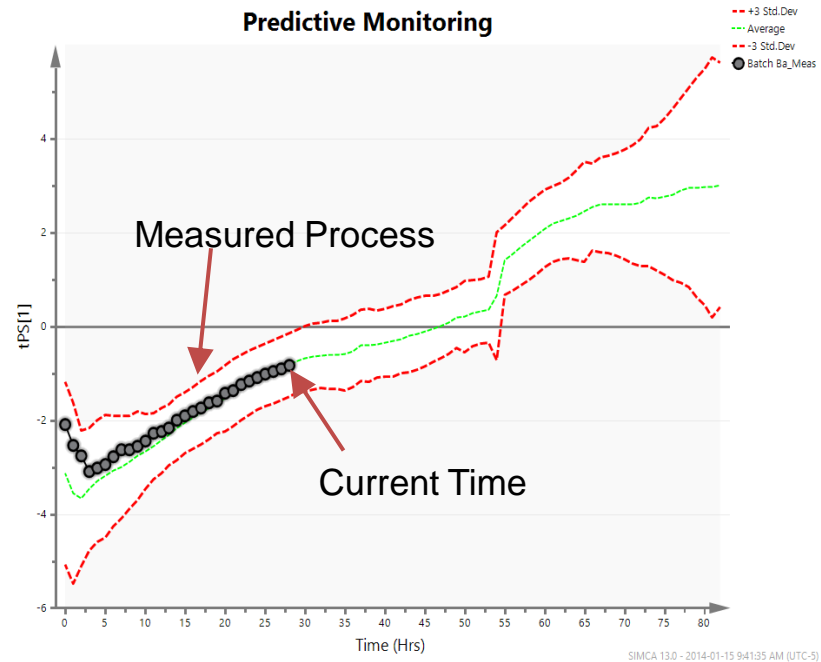


# MVDA for Process Models



# Forecast and Advised Future

## Batch evolution

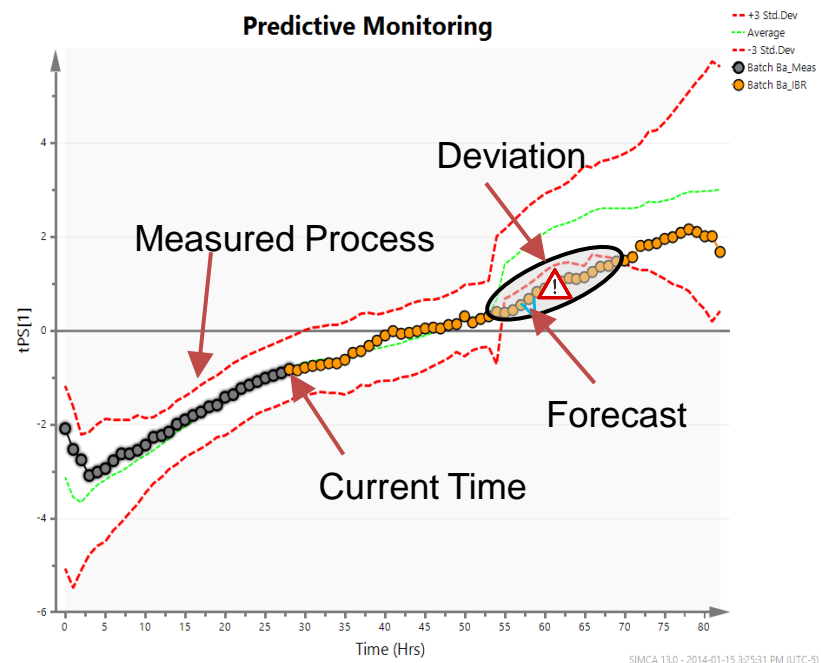


## Batch level



# 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 standard line data (in total 11 variables)
- Predictive model to forecast the product formation of product phase based on growth phase.

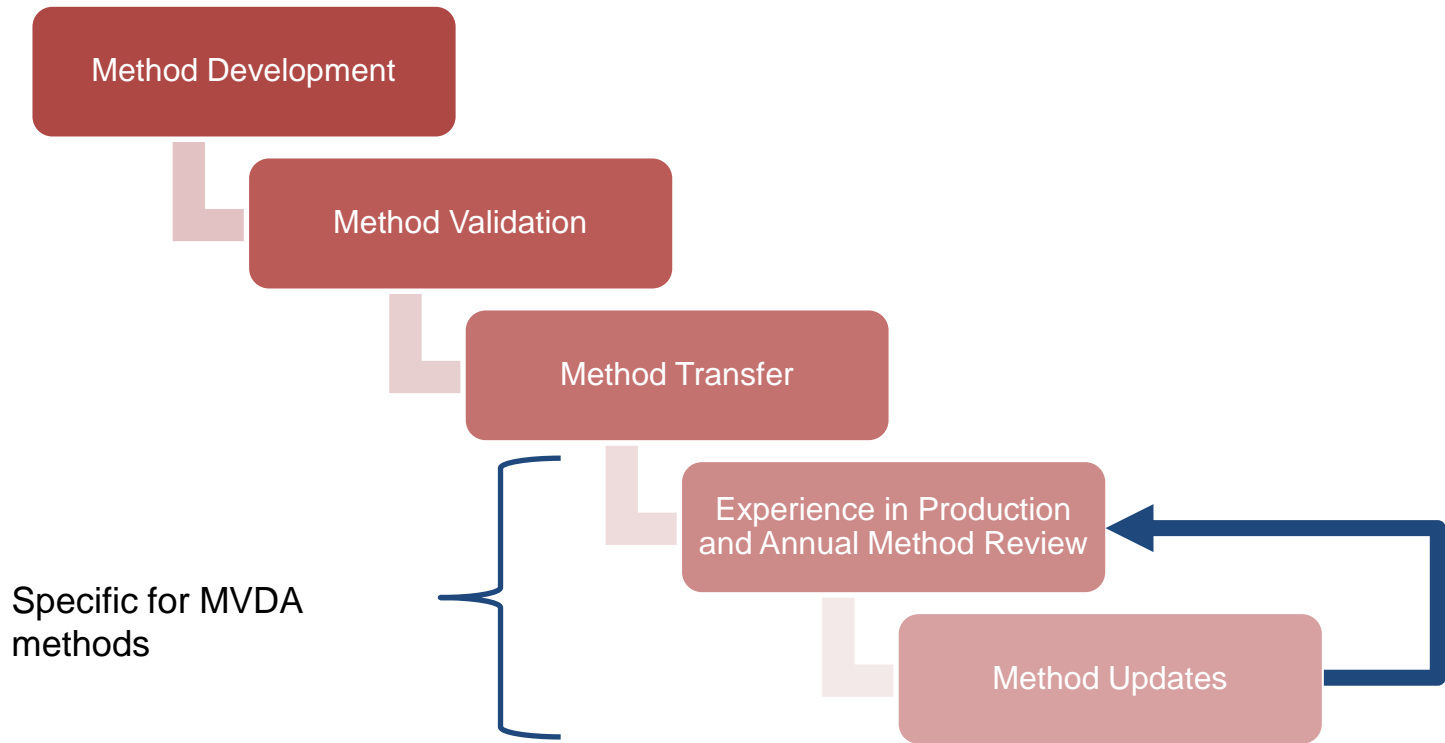
# Looking at a Process Model

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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



# 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?

