

# SIMCA®

Application Note

## Consolidate Process and Spectroscopy Data for Multivariate Process Modeling and Monitoring

---

### Introduction

Industrial manufacturing today has very high requirements on efficiency and product quality. To be able to meet these demands it is important to have a good understanding of the process. This includes the information about the critical process parameters and how raw material and energy are used in the most effective way [Ref 1]. In biopharmaceutical manufacturing it is common to monitor process parameters to receive information and knowledge about the status of the process. To maximize the understanding of the processes the use of new, alternative sensors are increasing. Typically, these sensors are based on spectroscopic techniques (or similar), where the sensor data are used for building multivariate calibration models. The large amount of data and the diversity of data sources used in process monitoring require fast and flexible solutions.

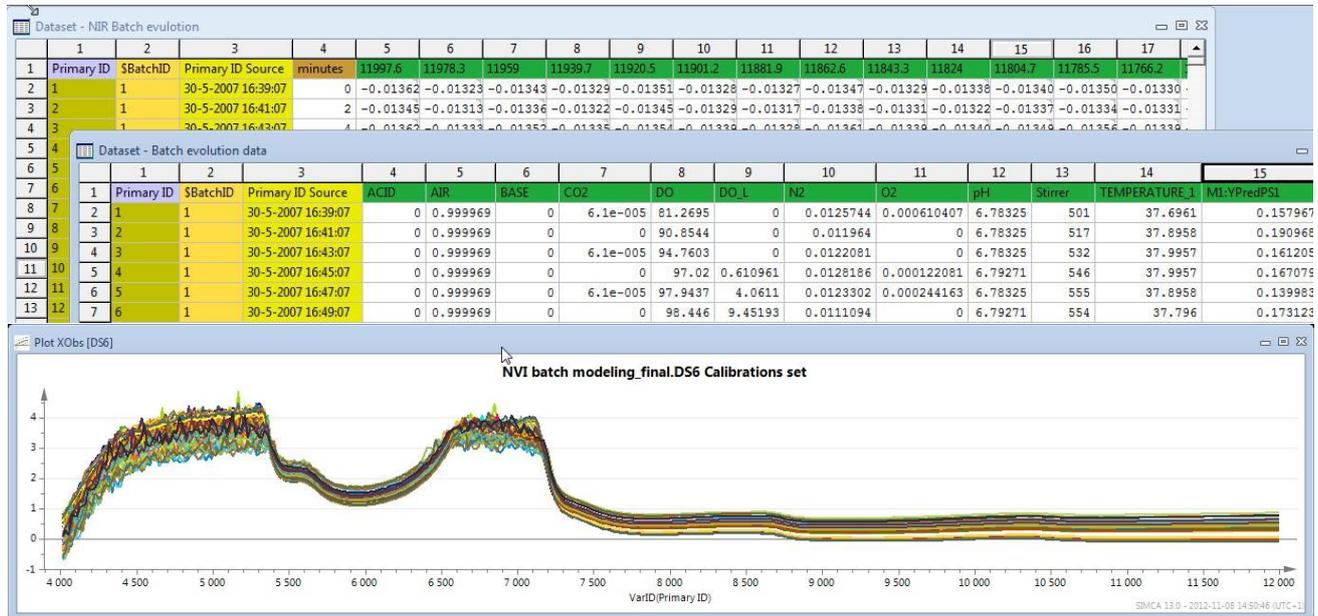
Multivariate monitoring of the collected process data will lead to

- Reduction of rejected batches by early fault detection [Ref 2]
- Informed decisions by straight forward interpretation of process deviations
- Ensure product quality by verifying that the process stays inside the design space or process envelope
- Stronger operator ownership by intuitive visualization of process status
- Increased process understanding from direct process interaction

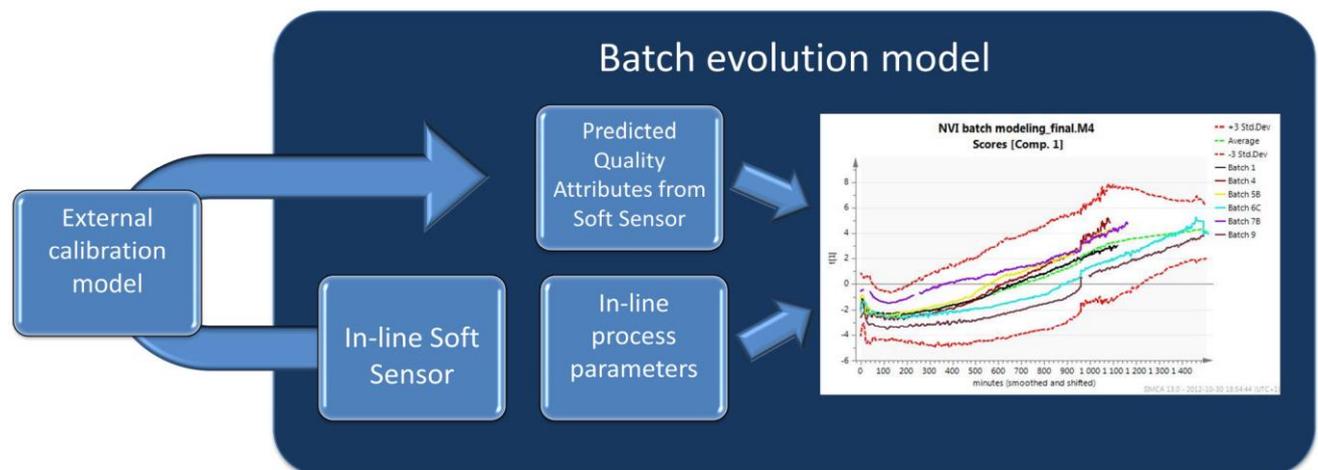


## Complete solution for real time process monitoring

Umetrics SIMCA product family offers a complete solution for real time process monitoring applicable in most industrial areas. It can connect to data both from direct sensors such as pH, temperature etc as well as spectroscopic data. Using multivariate data analysis all process data are combine into a mathematical model which present the key result in a real time environment [Ref 3]. Figures below show example of raw data from Inline process measurements and spectra from a NIR probe.

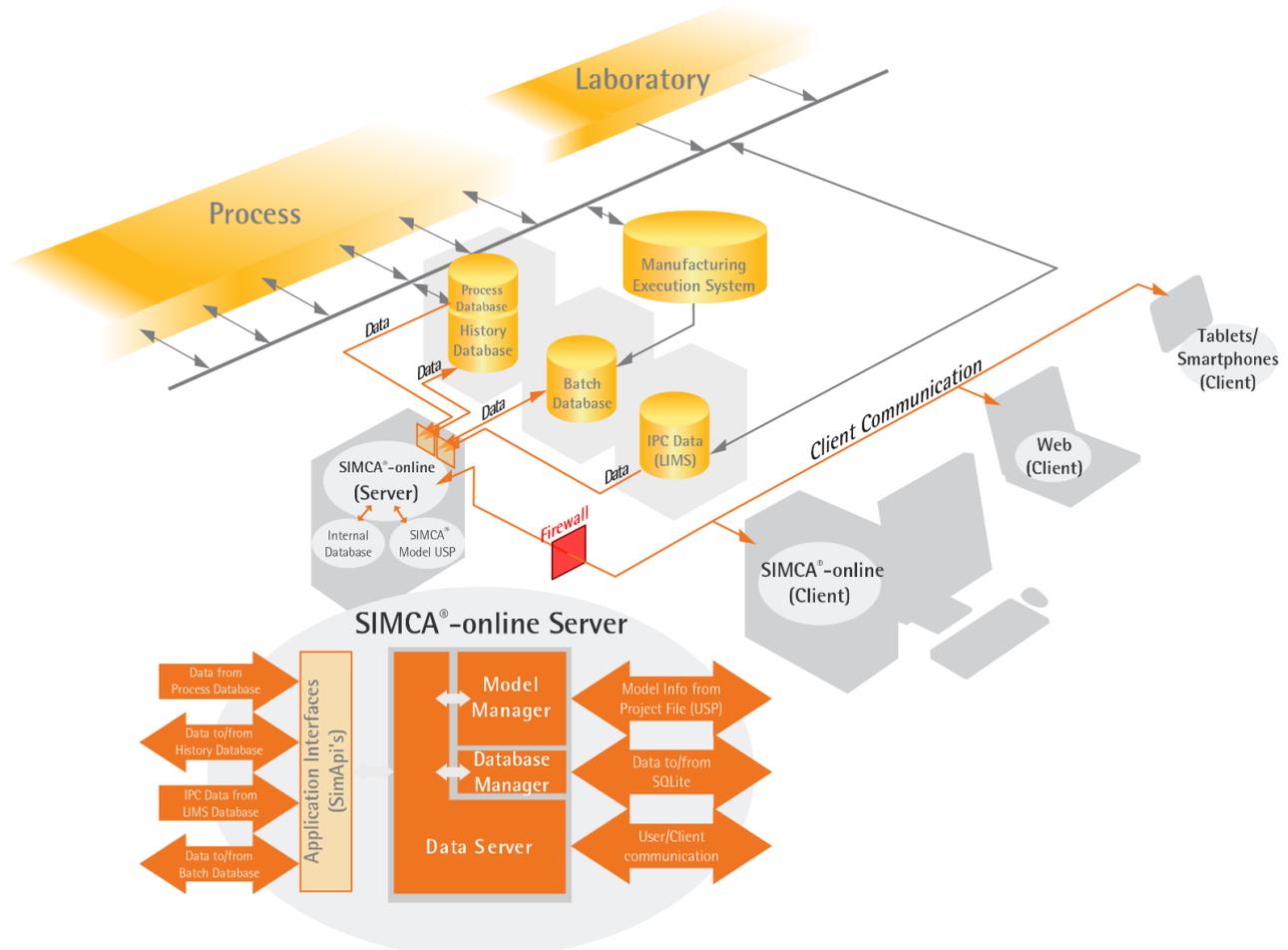


SIMCA offers the ability for real time prediction of process parameters from in-line Near Infrared spectroscopy (or other type of sensor) measurements with the help of an external MVDA calibration model. Both the at-line calibration model and the in-line NIR and process data are modeled in one single SIMCA project (usp file). These parameters are integrated into the overall MVDA model, which compresses all measured process parameters into one key parameter plot for real time monitoring of the process evolution.



## Integration of SIMCA-online

The figure below shows a schematic overview of a process system with SIMCA-online connecting to both the process historian and the spectrometer. It shows how model management is handled by the SIMCA-online server and the usage of the clients. The interface that enables communication between SIMCA and SIMCA-online and other external systems is an Application Programming Interface (API). SIMCA-online can both read data and write back results to the historian(s). Depending on the source different API's are used [Ref 4].



## References

1. FDA, Guidance for industry: PAT – A framework for innovative pharmaceutical development, manufacturing, and quality assurance; September 2004
2. Benefits and Challenges of Implementation of MSPC in the Pharmaceutical Industry, Charles E. Miller, Louis Obando, John P. Higgins, Gert Thureau, Merck Sharp and Dohme, Process Analytical Technologies, West Point PA, IFPAC 2013 Conference, Baltimore MD, January 2013
3. A Practical Approach for Exploration and Modeling of the Design Space of a Bacterial Vaccine Cultivation Process, M. Streefland,1 P.F.G. Van Herpen,1 B. Van de Waterbeemd,1 L.A. Van der Pol,1, E.C. Beuvery,2 J. Tramper,3 D.E. Martens,3 M. Toft, Biotechnology and Bioengineering, Vol. 104, No. 3, October 15.
4. SimApi describing the sources that can be accessed with SIMCA and SIMCA-online. [www.umetrics.com/simapi](http://www.umetrics.com/simapi)