sartorius stedim biotech

BioPAT® Chemometrics Toolbox
New Opportunities for Efficient Bioprocess Development and Manufacturing

turning science into solutions

BioPAT® Chemometrics Toolbox

Increase Efficiency and Assure Quality

SYNCHRONIZED PAT SOLUTIONS

During the past few years, usage of multivariate methods in development and manufacturing processes has dramatically increased. Especially after the introduction of concepts like Process Analytical Technology (PAT) and Quality by Design (QbD), chemometrics is regarded as a central approach for increasing the efficiency of biotechnological processes and product development. In addition, it is a sophisticated tool for preventing or mitigating the risk of producing a poor quality product.

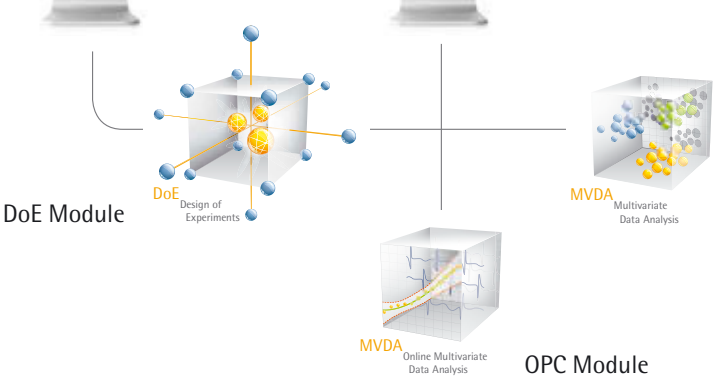
Design of Experiments (DoE) is considered best practice for knowledge building. Multivariate Data Analysis (MVDA) techniques are increasingly being used for scale- and batch-to-batch comparison investigations, and are making inroads into continuous real-time quality control and assurance.

Integrating and merging the capabilities of advanced chemometric methods into our scalable process control software BioPAT® MFCS/win enables both operators and management to look into systematic cost savings besides ensuring process reliability, safety and robustness.

DoE
BioPAT® MODDE

SCADA
BioPAT® MFCS

MVDA
BioPAT® SIMCA



DoE Module

MVDA Module

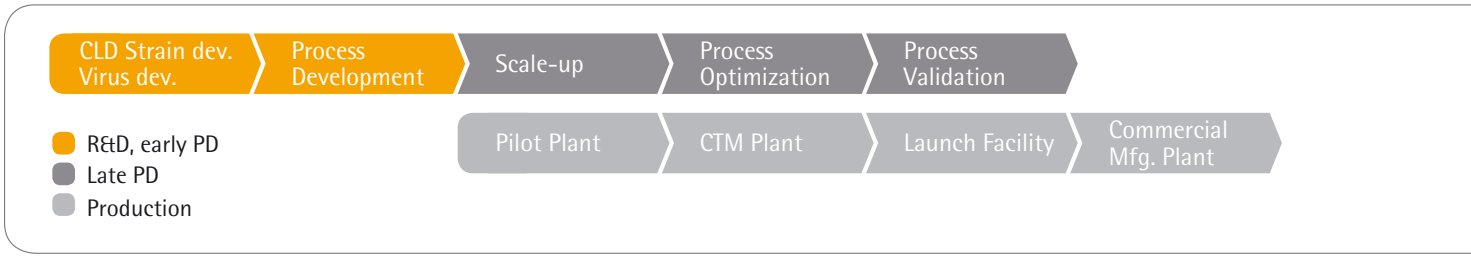
OPC Module

MVDA-online
BioPAT® SIMCA-online

Good to Know

- Choose between stand-alone or MFCS/win linked versions
- Special enterprise and university licenses available
- Free demo-versions for download at www.sartorius.com
- Comprehensive service and support solutions

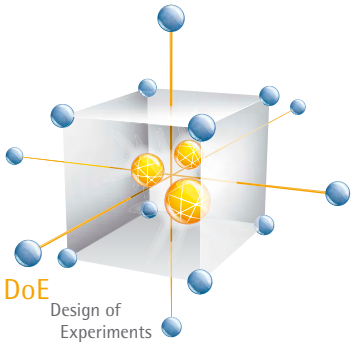
User-friendly Software
for Process Development, Scale-up and Production



Identify critical process parameters and their optimal ranges and estimate a Design Space

BioPAT® MODDE is a state-of-the-art DoE software package that is used by scientists, engineers and statisticians alike to help understand complex processes and products.

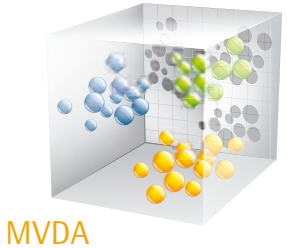
BioPAT® MODDE enables fast and effective identification of critical process parameters (CPPs) and, subsequently, establishment of a Design Space, resulting in reduced bio-process complexity and increased process understanding. This, in turn, facilitates process transfers. The Design Space tools provided by BioPAT® MODDE present a region of operability that meets risk analysis specifications and that guides engineers in determining how likely it is that their experiments will truly identify the most reliable operating region.



Compare batches and scales, identify key trends, correlations, patterns, and relationships

Multivariate Data Analysis (MVDA) techniques are being increasingly used for scale- and batch-to-batch comparison investigations to support or derive process understanding and to ultimately improve the quality, safety and efficacy of a drug product.

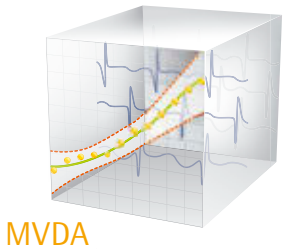
BioPAT® SIMCA is the benchmark software tool for scientists, engineers, researchers, product developers and others striving to gain information from large quantities of data. This software tool enables easy post-batch interpretation and analysis of large process data sets, gives a summary of all types of process information, key trends, correlations and patterns all in one convenient data model and permits faster troubleshooting. As a result, this reduces the risk of costly downtime.



Save batches by early fault detection and online-monitoring of the Design Space

Continuous real-time quality control and assurance is a highly desired state in biopharmaceutical manufacturing, which can be achieved by sophisticated process control strategies that use multivariate monitoring techniques to prevent or mitigate the risk of producing a poor quality product.

BioPAT® SIMCA-online is a highly efficient software release for realtime multivariate statistical process monitoring and control of previously established Design Spaces based on current process parameters and (spectro-) analytical data. The software permits early detection of process deviations and provides user guidance for identifying potential root causes by displaying easy-to-understand graphics. This not only results in improved health, safety and environmental (HSE) performance, but also in enhanced control and assurance of the overall process and product quality.

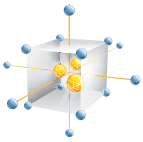


Upstream Applications

Accelerate Development and Optimize Production

CERTOMAT® CTplus

DoE for optimization of growth and production culture media to identify a better selection and quantitative composition of medium factors

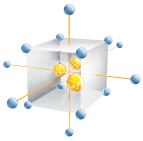


ambr™ 250

DoE for screening and optimization of basic process variables to define a better physical environment for cell growth and improved protein production

BIOSTAT® B

BIOSTAT® B-DCU II



BioPAT® MFCS

MVDA on historical production data for troubleshooting, understanding limitations of available data and seeing the opportunity for improvements

BIOSTAT® RM

BIOSTAT® STR

MVDA for scale-up evaluation and comparison of cell culture systems to mitigate risk of different scale-up performance and verify the findings of the small-scale studies for generation of process signatures

BIOSTAT® STR

BIOSTAT® D-DCU

BioPAT® Spectro

Process trajectories for real-time cultivation monitoring with MVDA-online for early detection of process deviations with guidance to potential root cause

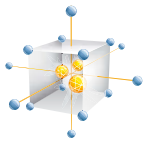
Downstream Applications
Optimize Purification and Establish Robustness

Sartobind® Pico

DoE for optimization of purification conditions to identify best binding capacity for impurities

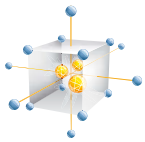
Sartobind® 96-well plates

Sartobind® Nano



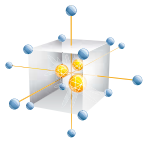
SARTOFLOW® crossflow systems

DoE for robustness studies of crossflow filtration conditions together with MVDA for multi-variate statistical purification monitoring



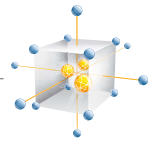
UVivatec®

DoE and MVDA for robustness and validation studies of virus inactivation with focus on product quality and safety



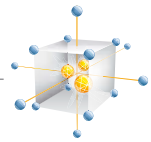
Zero-T system

DoE for filterability studies to optimize flow rates for an optimum filtration scheme and material compatibility



Celsius® S3

DoE for optimization of freeze and thaw rates for process development and stability studies using a minimal amount of product



BioPAT® MODDE

" Naturally it is most important for researchers and engineers when developing new products, but we also see it as a way of structuring our experiences and minimising the number of experiments.

Are you concerned about risk mitigation?

- Create knowledge around process and quality assays to demonstrate product and process comparability for manufacturing
- Define design space as "window of operation" for efficient scale-up qualification and ensure a drug product meeting the defined quality
- Science- and risk-driven process optimization to determine a manufacturing processes that will ensure production of a high quality product

Do you want to reduce costs?

- Speed up development of new therapeutics with less effort due to smaller number of experiments needed to determine critical process parameters
- Optimize many parameters at the same time which allows reduction of development costs and time-to-production
- Statistical analysis and evaluation result in less variation and costly deviation handling due to understood operating range

Do you strive for seamless transferability?

- Establish acceptance criteria for process and product comparability between the sending and receiving site
- Improve process robustness to reduce the chance of surprises during the qualification campaign
- Less process validation effort due to reduced number of critical process parameters which must be monitored or controlled

BioPAT® SIMCA

"During process development, MVDA contributes significantly in a structured way to evaluating and visualising data stemming from lab and pilot scale.

- Assessment, control and ongoing process reviews with focus on product quality and patient safety
- Establish scale-up strategies based on process and equipment knowledge to mitigate the risk of different performance
- Improved process understanding and reduced ambiguity mitigates risks associated with uncertainty

- Shorten the timelines for validation and comparability of analytical assays, procedures and equipment
- Evaluate and visualize data from lab and pilot scale in a structured way supports a better understanding and increases efficiency e.g. in terms of throughput time
- Easy post-batch interpretation and analysis of large process data sets permits faster troubleshooting and reduces risk of costly downtime

- Verify the findings of the small-scale studies for generation of process signatures
- Evaluate full-scale process performance at the receiving site while minimizing process changes as to avoid impact on process performance and product quality
- Assess the readiness of the receiving site for the qualification campaign to ensure a high degree of confidence that the qualification campaign will be successfully executed

BioPAT® SIMCA-online

"We had the most successful experience applying MVDA in a retrospective way. Overall, a 40% increase of yield have been gained. Now, due to this success the installation of an online MVDA control system is planned for the next months.

- Ensure that a process is under control and, consequently, that it meets the quality specifications
- Easy-to-understand graphics minimize the risk of overlooking errors, which can have serious consequences
- Immediate fault detection and diagnosis, e.g. process deviation or sensor failure, enables operators to react as early as possible

- Time resolved design space verification enables real time release which in turn saves testing time and unblocks resources
- Early fault detection and isolation saves batches and prevents expensive post-process deviation handling
- Real-time quality assurance without subject matter experts, so that shop floor teams are able to respond immediately to ongoing challenges

- Standardized process analysis across sites and scales facilitates flexible workforce
- Assess process comparability with respect to the most significant process parameters, e.g. product quality and titer

SYNCHRONIZED PAT SOLUTIONS

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