



Simplifying Progress

Data Analytics Consultancy Service Packages

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SARTORIUS

Introduction

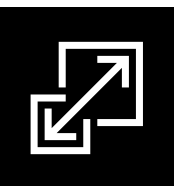
With over 30 years of data analytics expertise and a toolbox of advanced analytical solutions, Sartorius Data Analytics is ideally positioned to help you enhance your process understanding and meet your operational goals. Our Data Analytics Consultancy Service Packages are delivered by our highly qualified consultants and structured to help you overcome challenges and mitigate risk across the biopharmaceutical drug development and manufacturing process.

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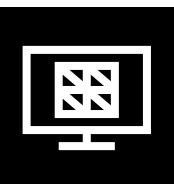
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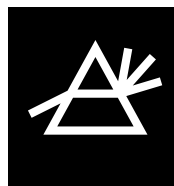
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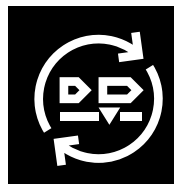


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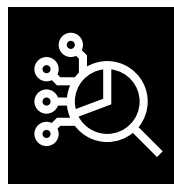
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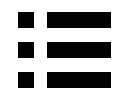
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Package overview and material numbers



Data Analytics Consultancy Service Packages

Our Data Analytics Consultancy Service Packages are designed both to address resource and expertise gaps and support you in developing the capabilities to unlock value independently.

What you bring

- Historical process data, or, for some packages, data generated within a defined period after project initiation
- Process knowledge
- Key project personnel and subject matter experts
- Prerequisites specific to each Consultancy Service Package

What Sartorius Data Analytics adds

- 30+ years of biopharmaceutical data analytics expertise
- A toolbox of advanced analytical solutions
- A range of standard service packages designed to achieve your objectives within a defined scope and cost

What you gain

- A strong foundation built on in-depth knowledge and data quality
- Time, cost, and resource savings by avoiding the need to execute the work internally
- Package-specific deliverables, e.g., data analysis, presentations, reports, guidance templates, and | or models

What is not included

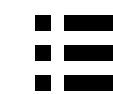
- Software products*
- Training courses*
- Consultant travel for on-site visits*
- Installation or connectivity (e.g., SimApi)
- Additional qualification support options

A statement of work is available for each Consultancy Service Package, outlining the scope, customer prerequisites, and deliverables in more detail. A statement of work signed by the customer and Sartorius is required before the start of service to confirm agreement of service scope and deliverables.

To order our Data Analytics Consultancy Service Packages, contact your sales representative and quote the service number listed under the relevant package.

*These items can be included on top of the Data Analytics Consultancy Service Packages as optional add-ons.





Overview

Data Analytics Consultancy Service Packages

Get support for your data analytics project with purpose-driven packages that have defined scope and pricing.

Fill resource and expertise gaps, or combine service packages with training add-ons to help your team unlock value independently.

Data analysis for process scaling and tech transfer packages

- Data Analysis for Process Scaling
- Data Analysis for Tech Transfer



SIMCA®-online packages

- SIMCA®-online Model Building
- SIMCA®-online Model Updates



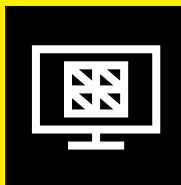
Data analysis for material conversion packages

- Data Analysis to Assess Equivalence Starter
- Data Analysis to Reduce Cost of Conversion Level 1



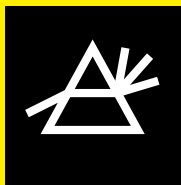
In silico simulation packages

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- Process Improvement: New Operating Mode



Raman spectroscopy packages

- Raman Spectroscopy Level 1
- Raman Spectroscopy Level 2
- Raman Spectroscopy Level 3



Downstream processing packages

- Direct Transition Analysis



Process optimization packages

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- Process Optimization Level 1
- Process Optimization Level 2
- Process Optimization Level 3



Life cycle and qualification packages

- GxP Validation Framework for SIMCA®-online



Sustainability packages

- Sustainability and Energy Mapping





Data Analysis for Process Scaling

Features

The Data Analysis for Process Scaling package leverages DOE and MVDA tools such as MODDE® and SIMCA® to assure product and process consistency across scales, for example:

- Bioreactor scale-up from process development to manufacturing (Ambr® 250 to Biostat STR® 2000)
- Bioreactor scale-down from manufacturing to process development for troubleshooting (Biostat STR® 2000 to Ambr® 250)

Benefits

- Assured product quality and process performance across scales
- Faster scale-up to accelerate time to market
- Rapid troubleshooting to support timely qualification of scaled models

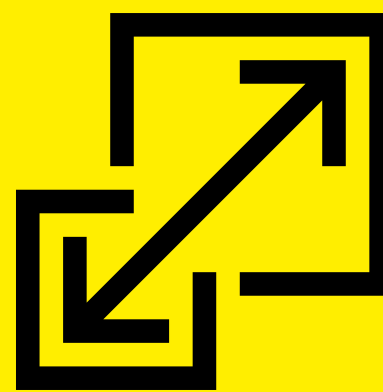
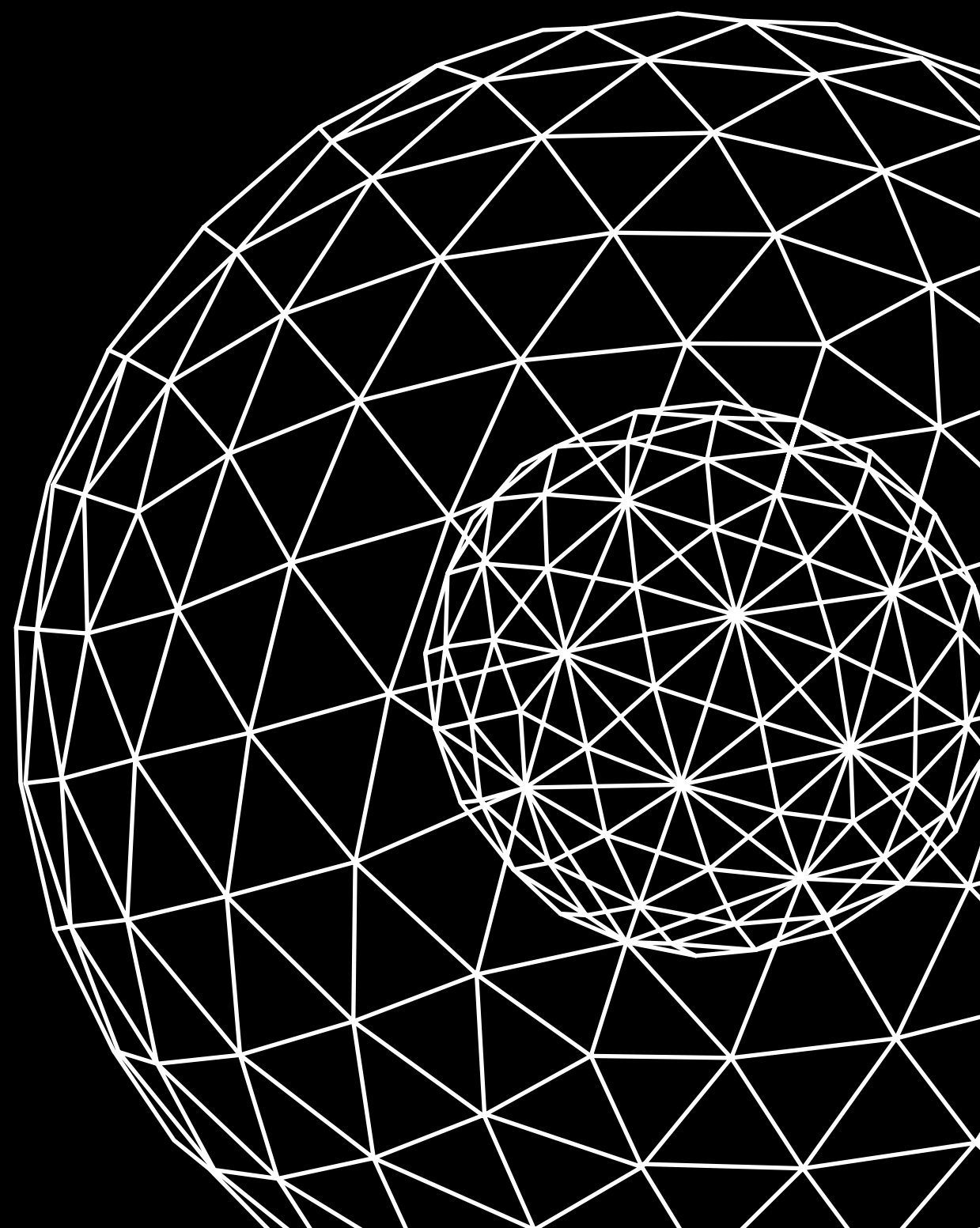
Customer prerequisites

- Completed assessment questionnaire
- Pre-consultation with stakeholders to align on scope, available data, and objectives
- Definition of current scale and target scale
- Characterization data from both scales
- Ability to generate data from at least one scale as needed

Deliverables

A Sartorius consultant will review the service, requirements, scope, and deliverables (virtually | remotely).

- **Part 1:** DOE design for scaling parameters
- **Part 2:** MVDA characterization of scales
- **Part 3:** Scaling strategy report and knowledge transfer



Data analysis for process scaling and tech transfer

Data Analysis for Tech Transfer

Features

The Data Analysis for Tech Transfer package leverages MVDA software (SIMCA®) to compare operations across equivalent-scale equipment (e.g., bioreactors and chromatography systems) and | or sites, to evaluate alignment and identify key parameters responsible for variation.

Optional add-on: Training to enable customers to take ownership of the models (requires SIMCA® as a prerequisite)

Benefits

- Assurance of product quality and process performance across equipment and | or sites
- Accurate duplication and | or transfer of processes
- Time, cost, and resource savings

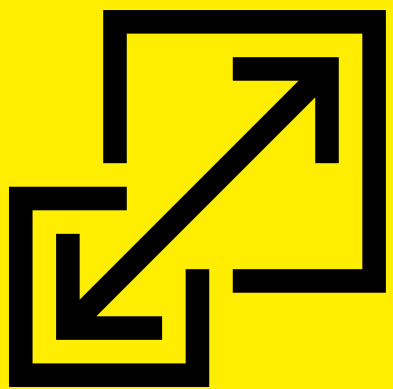
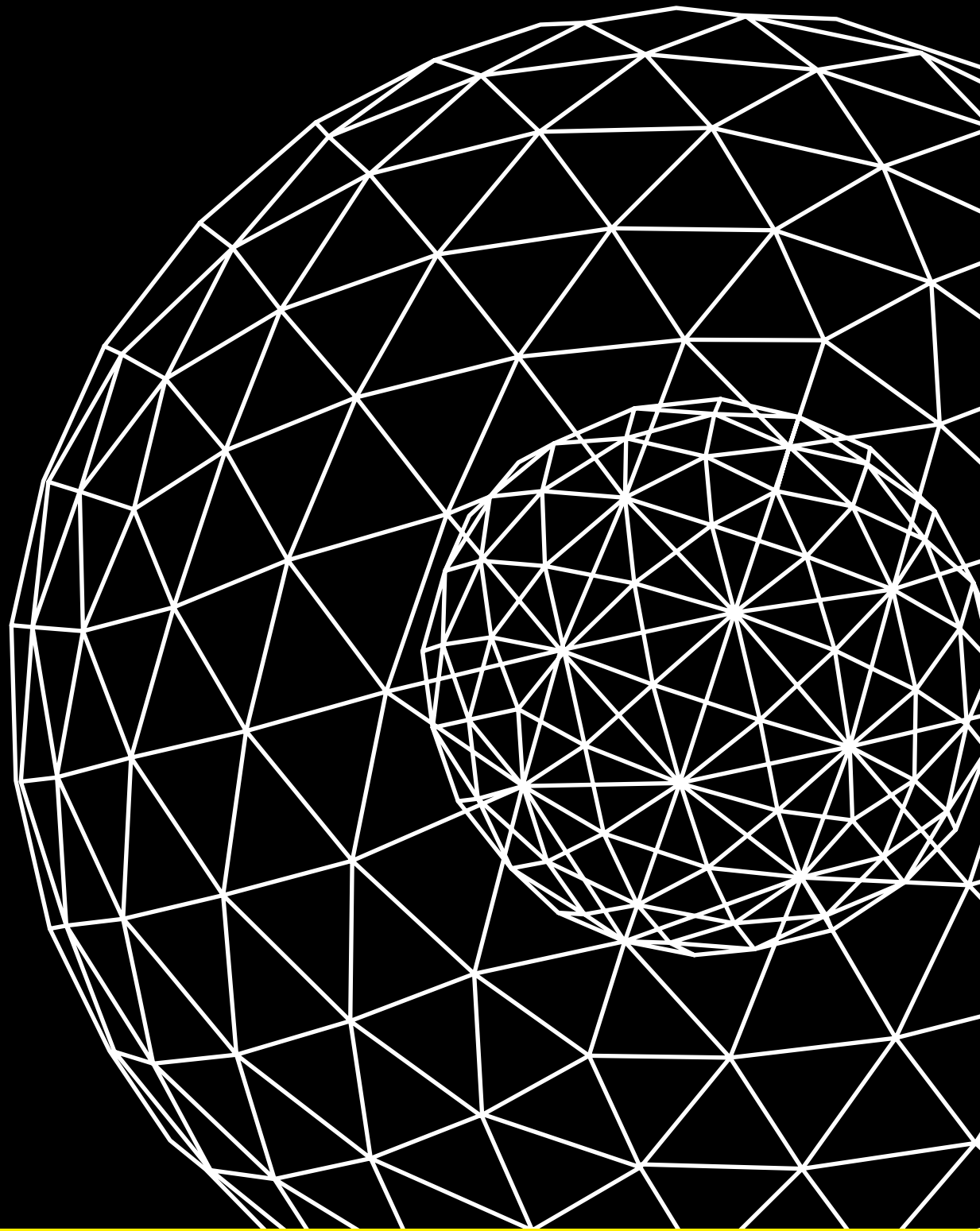
Customer prerequisites

- Completed assessment questionnaire
- Pre-consultation with stakeholders to align on scope, available data, and objectives
- Equivalent data from current and target processes
- Access to subject matter experts for consultation as needed

Deliverables

A Sartorius consultant will review the service, requirements, scope, and deliverables (virtually | remotely).

- **Part 1:** SIMCA® modeling to assess reproducibility of process data
- **Part 2:** Report on findings and suggestions for root cause if variation is found



Data analysis for process scaling and tech transfer

Intensified Clone Selection

Features

The Intensified Clone Selection package supports the identification of high-performing CHO and HEK-293 clones under intensified process conditions using in silico simulation and mechanistic models (Perfusion Cell Line Selection workflow in Umetrics® Cell Insights).

Benefits

- Lower material and resource requirements through screening for the top-performing clones in silico before moving to in vitro studies
- Reduced process development timelines by up to 50%
- More informed decision-making

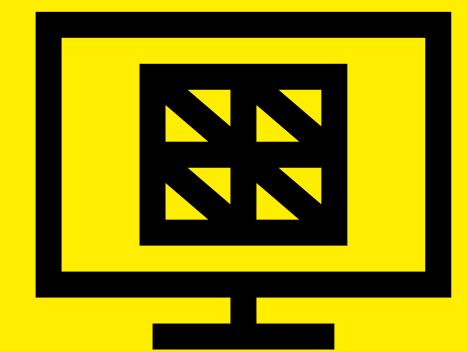
Customer prerequisites

- Data from at least one fed-batch run per clone of interest capturing variations in growth provided in .csv or Excel (.xlsx) format; ideally, screening data from three or more runs per clone (maximum 12 batches) and batch evolution (time-series data)
- Qualitative distinctions of each of the runs (e.g., the different clones)
- **Required variables:** Batch ID, time, viable cell density, viability, and volume
- **Optional variables:** Titer and composition of media and | or feed

Deliverables

A Sartorius consultant will review the service, requirements, scope, and deliverables (virtually | remotely).

- **Part 1:** Development of selection model(s) for clones of interest
- **Part 2:** Milestone meeting
 - Knowledge transfer of how perfusion cell line selection models are built
 - Agreement that model fit is acceptable
 - Definition of setpoints: average trajectory based on 1 – 3 individual batches for each clone and statistical limits
- **Part 3:** Presentation of process simulation and handover of a summary report



In silico simulation

Process Improvement: New Operating Mode

Features

The Process Improvement: New Operating Mode package supports the conversion of processes to new operating modes (e.g., batch to intensified processing) for CHO and HEK-293 cell applications using in silico simulation and mechanistic models (Perfusion Cell Line Selection and Virtual Bioreactor Workflows in Umetrics® Cell Insights).

Benefits

- Reduced process development timelines (up to 50%)
- Lower resource and material requirements
- More informed decision-making
- Identification of optimal operating conditions prior to in vitro studies

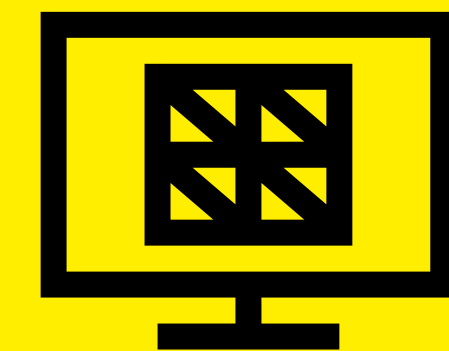
Customer prerequisites

- At a minimum, 1 – 5 historical datasets, capturing variations in growth in .csv or Excel (.xlsx) format and batch evolution (time-series data)
- Qualitative distinctions of each of the runs (e.g., the different clones)
- Required variables: Batch ID, time, viable cell density, viability, and volume
- Required variables for virtual bioreactor: Critical process parameters and metabolites from 3 – 5 datasets for each clone
- Optional variables: Product concentration, titer, and composition of media and | or feed

Deliverables

A Sartorius consultant will review the service, requirements, scope, and deliverables (virtually | remotely).

- **Part 1:** Development of perfusion cell line selection models with good fit
- **Part 2:** Milestone meeting
 - Knowledge transfer of how perfusion cell line selection models are built
 - Agreement that model fit is acceptable
 - Definition of setpoints and mode of intensified process
- **Part 3:** Presentation of process simulation and handover of a summary report



In silico simulation



Proof-of-Value Process Optimization Starter

Features

The Proof-of-Value Process Optimization Starter package provides a rapid assessment to identify potential optimization targets and deliver a high-level summary of improvement opportunities.

This package focuses on a single objective (batch loss avoidance, the reduction of variability, improving product quantity and | or quality, DOE design optimization, or early fault detection) applied to one unit operation and scale. The equivalent fixed consultancy time for this service is three days.

Benefits

- Fast, cost-effective access to Sartorius expertise and experience
- Early identification of potential process gains

Customer prerequisites

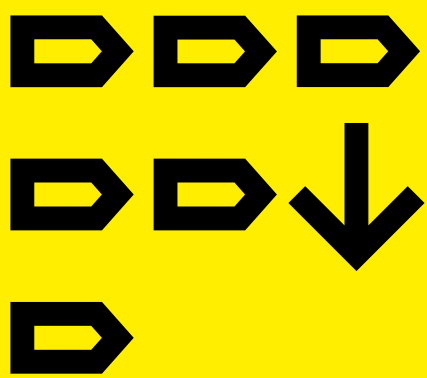
- Defined objective (e.g., yield improvement, reduced variability, or improved product quantity and | or quality), unit operation, and scale.
- Description of any known issues or concerns with the current process and any previous optimization efforts.

- Confirmation of data types and formats (e.g., historian, MES, LIMS), as well as any process or material changes within the historical batch range.
- Data from a minimum of three good (or acceptable) batches and three bad | variable batches, ideally more; if only the minimum is provided, there must not be any process or material changes across these batches.
- Datasets should contain the critical process parameters and quality attributes relevant to the chosen objective. For a bioreactor, these would typically include temperature, pH, dissolved oxygen, working volume, viable cell density, cell viability, product quantity and | or quality.

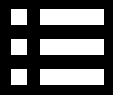
Deliverables

A Sartorius consultant will review the service, requirements, scope, and deliverables (virtually | remotely).

- **Part 1:** Data collection and review
- **Part 2:** Proof-of-value evaluation
- **Part 3:** Presentation of high-level findings and handover of a summary report



Process optimization



Process Optimization Level 1

Features

The Process Optimization Level 1 package supports process optimization for a specific objective, or for a proof-of-concept assessment, at a defined unit operation and scale.

This package focuses on a single objective (batch loss avoidance, the reduction of variability, improving product quantity and | or quality, building a golden batch model, or early fault detection) applied to one unit operation and scale. The equivalent fixed consultancy time for this service is 10 days.

Benefits

- Process improvement aligned with defined objectives
- Reduced internal resource use and analysis effort
- Enhanced process understanding through Sartorius expertise
- If applicable, simulation of a golden batch model

Customer prerequisites

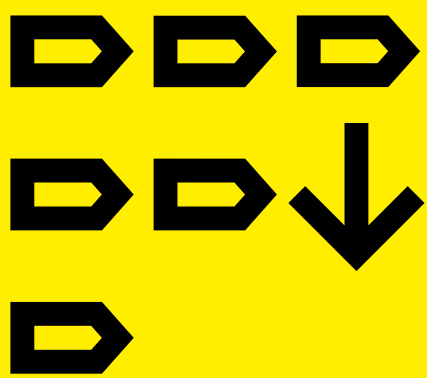
- Defined objective (e.g., yield improvement, reduced variability, or improved product quantity and | or quality) for one unit operation and scale.
- Description of any known issues or concerns with the current process and any previous optimization efforts.

- Confirmation of data types and formats (e.g., historian, MES, LIMS), as well as any process or material changes within the historical batch range.
- A minimum of 30 batches, mostly good | acceptable, with some bad | variable data.
- Datasets showing batch performance (good and bad) containing critical process parameters and quality attributes relevant to the chosen objective and unit operation. For a bioreactor, these would typically include temperature, pH, dissolved oxygen, working volume, viable cell density, cell viability, product quantity and | or quality.

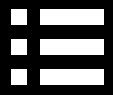
Deliverables

A Sartorius consultant will review the service, requirements, scope, and deliverables (virtually | remotely).

- **Part 1:** Support for data collection, contextualization, exploration, transformation, and review
- **Part 2:** Evaluation of optimization opportunities aligned with defined objectives
- **Part 3:** Presentation of optimization scenarios (areas for process improvement), including guidance for implementation or, where applicable, simulation of golden batch and handover of a summary report outlining the data flow from equipment for process improvement



Process optimization



Process Optimization Level 2

Features

The Process Optimization Level 2 package is identical to Process Optimization Level 1 but designed for large datasets (> 100 batches).

Select one objective for this service package from the list: batch loss avoidance, the reduction of variability, improving product quantity and | or quality, building a golden batch model, or early fault detection. The equivalent fixed consultancy time for this service is 15 days.

Benefits

- Process improvement aligned with defined objectives
- Reduced internal resource use and analysis effort
- Enhanced process understanding through Sartorius expertise
- If applicable, simulation of a golden batch model

Customer prerequisites

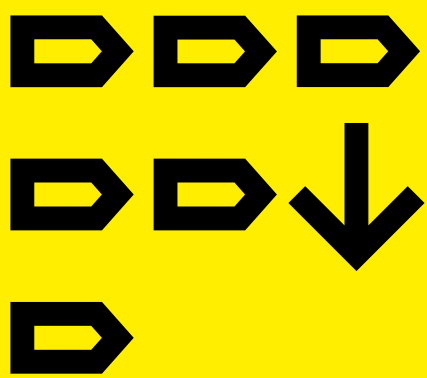
- Defined objective (e.g., yield improvement, reduced variability, or improved product quantity and | or quality) for one unit operation and scale.
- Description of any known issues or concerns with the current process and any previous optimization efforts.

- Confirmation of data types and formats (e.g., historian, MES, LIMS), as well as any process or material changes within the historical batch range.
- A minimum of 100 batches is required, mostly good | acceptable, with some bad | variable data.
- Datasets showing batch performance (good and bad) containing critical process parameters and quality attributes relevant to the chosen objective and unit operation. For a bioreactor, these would typically include temperature, pH, dissolved oxygen, working volume, viable cell density, cell viability, product quantity and | or quality.

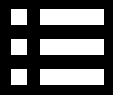
Deliverables

A Sartorius consultant will review the service, requirements, scope, and deliverables (virtually | remotely).

- **Part 1:** Support for data collection, contextualization, exploration, transformation, and review
- **Part 2:** Evaluation of optimization opportunities aligned with defined objectives
- **Part 3:** Presentation of optimization scenarios (areas for process improvement), including guidance for implementation or, where applicable, simulation of golden batch and handover of a summary report outlining the data flow from equipment for process improvement



Process optimization



Process Optimization Level 3

Features

The Process Optimization Level 3 package supports process optimization for a defined unit operation and scale in a new facility. Objectives may include batch loss avoidance, reduction of variability, or early fault detection and root cause analysis. The service includes development of SIMCA®-online models (one .usp file) for monitoring the process step. The equivalent fixed consultancy time for this service is 30 days.

Benefits

- Process improvement aligned with defined objectives
- Accelerated implementation of a state-of-the-art, Industry 4.0-ready facility
- Enhanced process understanding through Sartorius expertise

Customer prerequisites

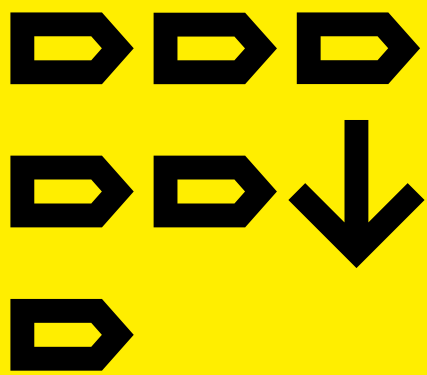
- Defined objective (e.g., batch loss avoidance, reduced variability, or early fault detection | root cause analysis) for one unit operation and scale.
- Commitment to complete the minimum required data generation and provide data within nine months from the start of service.

- A minimum of 10 batch runs, with 30 batches preferred. Data from the first 3–4 runs should be provided to the consultant for a preliminary assessment aimed at reducing observed variation and minimizing the total number of batches required.
- Connection to Biobrain® Supervise or another supported historian (required to run the yield regression model).
- SIMCA®-online version 17 or later in place, actively and correctly connected to the process data source for data collection.

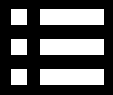
Deliverables

A Sartorius consultant will review the service, requirements, scope, and deliverables (virtually | remotely).

- **Part 1:** Evaluation of optimization opportunities aligned with defined objectives
- **Part 2:** Initial data assessment (3–4 runs) to reduce any observed variation
- **Part 3:** Optimization analysis, including development of a real-time golden batch model
- **Part 4:** SIMCA®-online monitoring models for the unit operation (one .usp file), presentation of optimization scenarios with implementation guidance, and a summary report outlining the data flow from equipment for process improvement



Process optimization



SIMCA®-online Model Building

Features

The SIMCA®-online Model Building package is designed for existing SIMCA®-online users seeking to expand to a new unit operation or facility. The service includes development of up to ten batch evolution models and four batch level monitoring | prediction models for a single physical unit operation. Model development is based on predefined criteria specifying the data to be included, along with testing for good | bad batch detection.

Out of scope:

- Model deployment and | or validation; validation of the model and | or determination of fit remains the responsibility of the customer under their quality management system.
- Software licenses and | or training required for the customer to take ownership of the models.
- Forecast and Control models.
- Installation and configuration of SIMCA®-online and | or SimApi connectivity.

Benefits

- Maximized value from model development through Sartorius expertise
- Reduced reliance on internal resources for model building

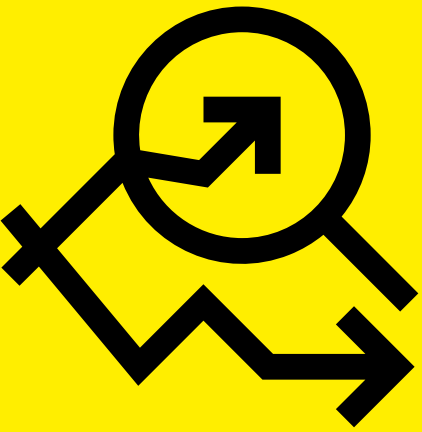
Customer prerequisites

- Overview of the data available, variation, and a test for good | bad batch detection
- Confirmation that sufficient historical data is available and can be provided in a SIMCA®-ready format at the start of the service
- SIMCA® and SIMCA®-online version 16 or later in place
- At least one model deployed and operational in SIMCA®-online

Deliverables

A Sartorius consultant will review the service, requirements, scope, and deliverables (virtually | remotely).

- **Part 1:** Description of the workflow or data structure
- **Part 2:** Agreed strategy for building models (classifying good | bad batches)
- **Part 3:** Up to ten batch evolution models and four batch level monitoring | prediction models for one unit operation and a summary report



SIMCA®-online modeling

SIMCA®-online Model Updates

Features

The SIMCA®-online Model Updates package includes updates to up to 12 manufacturing SIMCA®-online process models for a physical unit operation at one scale, e.g., a production bioreactor or a chromatography column. The service is based on predefined criteria specifying the data to be included, along with testing for good | bad batch detection.

Out of scope:

- Model deployment and | or validation; validation of the model and | or determination of fit remains the responsibility of the customer under their quality management system.
- Continuous method verification or detection of when a model should be replaced.
- Software licenses and | or training required for the customer to take ownership of the models.

Benefits

- Reduced reliance on internal resources for manual model updates
- Optimized model performance through expert support

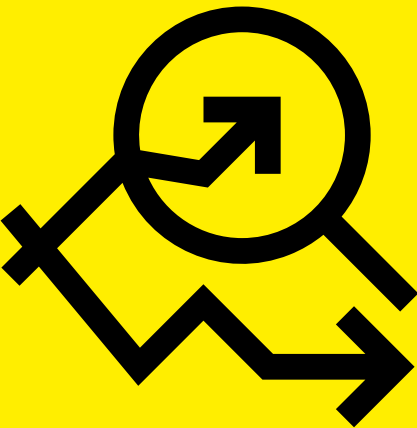
Customer prerequisites

- Overview of the data, variation, and models to be updated
- SIMCA® and SIMCA®-online version 16 or later installed and connected to data sources
- Deployed models with available historical prediction data for updating

Deliverables

A Sartorius consultant will review the service, requirements, scope, and deliverables (virtually | remotely).

- **Part 1:** Description of the workflow or data structure
- **Part 2:** Agreed strategy for updating existing models (classifying good | bad batches)
- **Part 3:** Up to 12 updated models for the specified unit operation and a summary report



SIMCA®-online modeling

Raman Spectroscopy Level 1

Features

The Raman Spectroscopy Level 1 package provides guidance templates supporting internal workflows for Raman spectroscopy calibration models, enabling the prediction of critical quality or material attributes. An optional SIMCA® MVDA spectroscopy training course is also available (at additional cost).

Out of scope:

- Consultancy for model development and calibration (if required, please see Level 2 and | or Level 3 service packages)
- Consultancy for model deployment and validation

Benefits

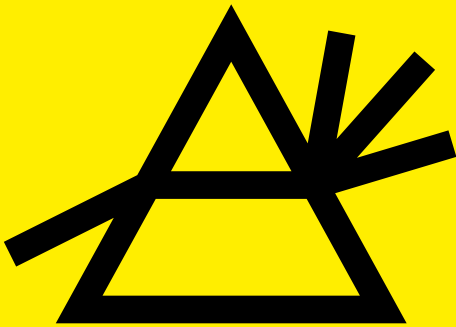
- Streamlined method development achieved using templates that capture the key aspects of model building with spectral data
- Reduced time and effort through ready-to-use templates that eliminate the need for de novo protocol development
- Improved project quality enabled by expert-designed protocols

Customer prerequisites

- SIMCA® software license, version 16 or later

Deliverables

- Method development protocol template for chemometric models, including example experimental plans and relevant USP, ICH, FDA, and EMA guidelines
- Method development report template including outlines of relevant data analyses, key model statistics to support development, and validation decisions



Raman spectroscopy



Raman Spectroscopy Level 2

Features

The Raman Spectroscopy Level 2 package includes development and delivery of optimized Raman spectroscopy models in SIMCA®. Sartorius-built calibration models enable the prediction of up to two selected analytes (glucose, lactate, glutamine, glutamate, and titer). An optional SIMCA® MVDA spectroscopy training course is also available (at additional cost).

Out of scope:

- Consultancy for model deployment and validation

Benefits

- Access to spectroscopy expertise, saving in-house resources
- Faster model development timelines

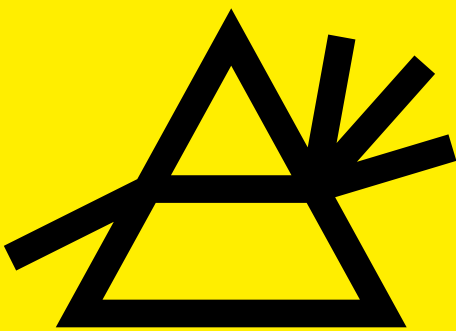
Customer prerequisites

- Quality spectroscopic data that covers the range of values and analytes for prediction
- Data for a training and prediction set (calibration | verification)
- Summary of any DOE or process variations used for creating spectral data
- Systems in place with native support for SIMCA® models, e.g., Bruker (Tornado) and Endress+Hauser (Kaiser)

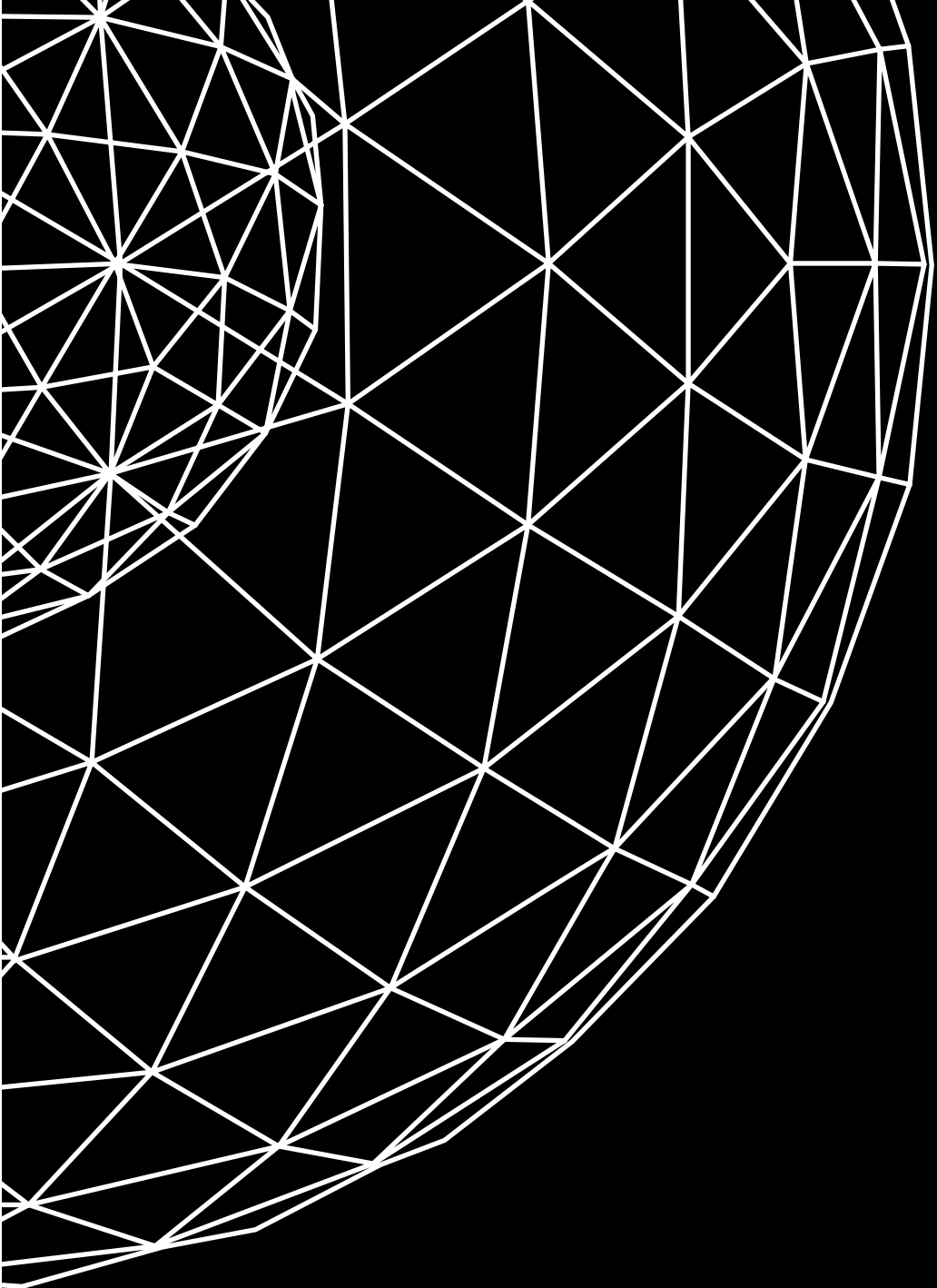
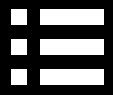
Deliverables

A Sartorius consultant will review the service, requirements, scope, and deliverables (virtually | remotely).

- **Part 1:** Top three optimized models for the initial dataset per analyte | critical quality attribute in one SIMCA® file
- **Part 2:** Report on the details of the models generated, pre-processing applied, model quality statistics (RMSEE, R², Q²), and verification of predictive ability and quality (RMSECV, RMSEP)



Raman spectroscopy



Raman Spectroscopy Level 3

Features

The Raman Spectroscopy Level 3 package comprises the development and delivery of optimized Raman spectroscopy models in SIMCA®, including:

- A method development report and protocol to support the building of calibration models.
- Best practice recommendations for experimental plans (DOE) to aid in the development of robust models.
- Calibration models to enable the prediction of up to two selected analytes (glucose, lactate, glutamine, glutamate, and titer).
- Optional add-on: MVDA spectroscopy training course (at additional cost).

Out of scope:

- Consultancy for model deployment and validation

Benefits

- Access to spectroscopy expertise, saving in-house resources
- Faster model development timelines
- Reduced experimental effort by focusing calibration model development on relevant spectral data and process parameters

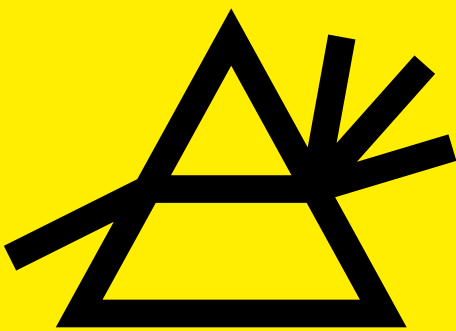
Customer prerequisites

- Quality spectroscopic data that covers the range of values and analytes for prediction
- Commitment to complete experiments and generate data for training and prediction sets (calibration | verification) within six months from the start of service
- Systems in place with native support for SIMCA® models, e.g., Bruker (Tornado) and Endress+Hauser (Kaiser)

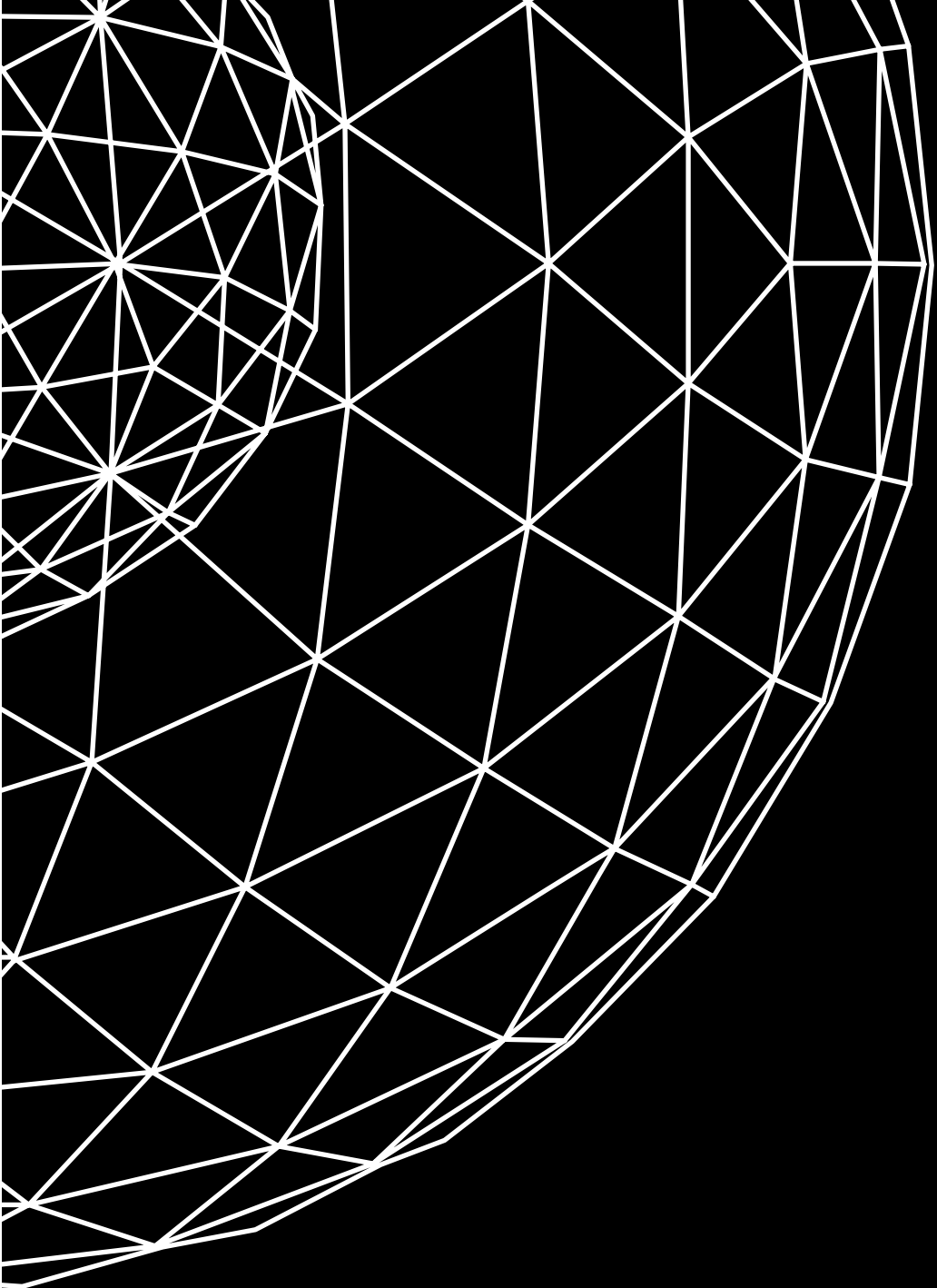
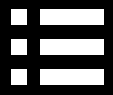
Deliverables

A Sartorius consultant will review the service, requirements, scope, and deliverables (virtually | remotely).

- **Part 1:** Method development protocol template for chemometric models, including example experimental plans and relevant USP, ICH, FDA, and EMA guidelines
- **Part 2:** Top three optimized models for the initial dataset per analyte | critical quality attribute in one SIMCA® file
- **Part 3:** Method development report including an assessment and summary of the models generated, details of the models generated and the pre-processing applied, model quality statistics, and verification of predictive ability and quality



Raman spectroscopy



GxP Validation Framework for SIMCA®-online

Features

The GxP Validation Framework for SIMCA®-online package provides system and validation documentation templates to support the validation of SIMCA®-online for GxP use.

Out of scope:

- Model validation execution
- Customization | execution of documentation
- Deployment of SIMCA®-online systems
- Process modeling
- Development of non-supported SimApis
- Validation of SIMCA®-online | SIMCA® across multiple sites
- Software licenses and training
- Integration into a quality system

Benefits

- Right-first-time model development enabled by guidance and document templates, minimizing timelines and resource requirements
- GxP-compliant use of model outputs

Customer prerequisites

- SIMCA® and SIMCA®-online installed in a development environment at a minimum (current versions are recommended)
- SimApi installed and connected
- Dedicated resources from quality, system admin, business admin, testing, and, ideally, including process domain experts

Deliverables

Quick-start service by a consultant to provide guidance on the use of the package. Customization is not included.

- SOPs for modeling, users, and IT admin
- Best practice guide for modeling
- SIMCA®-online user guide
- Templates for the validation plan, URS, FDS, TDS, IQ, and OQ protocols, traceability matrix, test and validation summary report



Life cycle and qualification



Data Analysis to Assess Equivalence Starter

Features

The Data Analysis to Assess Equivalence Starter package supports the assessment of process equivalence after conversion to a new material. Materials may include raw materials (e.g., media), process consumables (e.g., filters), or other process equipment. The new process state is compared to the original for a single unit operation using consistent assessment criteria and objectives.

Benefits

- Demonstration of equivalence or improved performance of new materials across normal operating conditions
- Increased internal capacity through offloading of equivalence assessment activities
- Deeper insights from results with knowledge transfer through Sartorius expertise

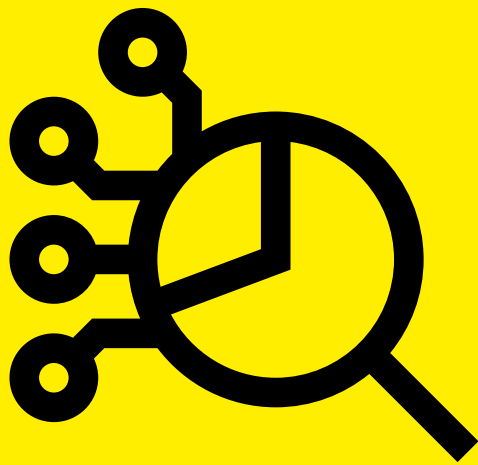
Customer prerequisites

- Agreed assessment criteria for comparison of the two materials and determination of equivalence. This may include matching or improving critical quality attributes within a specified tolerance (confirmed with a two one-sided t-test), demonstrating improved process control (through reduced variability using MVDA), or other similar assessments.
- Relevant historical data from completed experiments comparing the materials; at a minimum, three good batches from studies directly comparing Material A with Material B using the same methodology and analytical tests (process, materials, equipment, sampling time, and analyzers). The more batches available, the better the representation of the data.

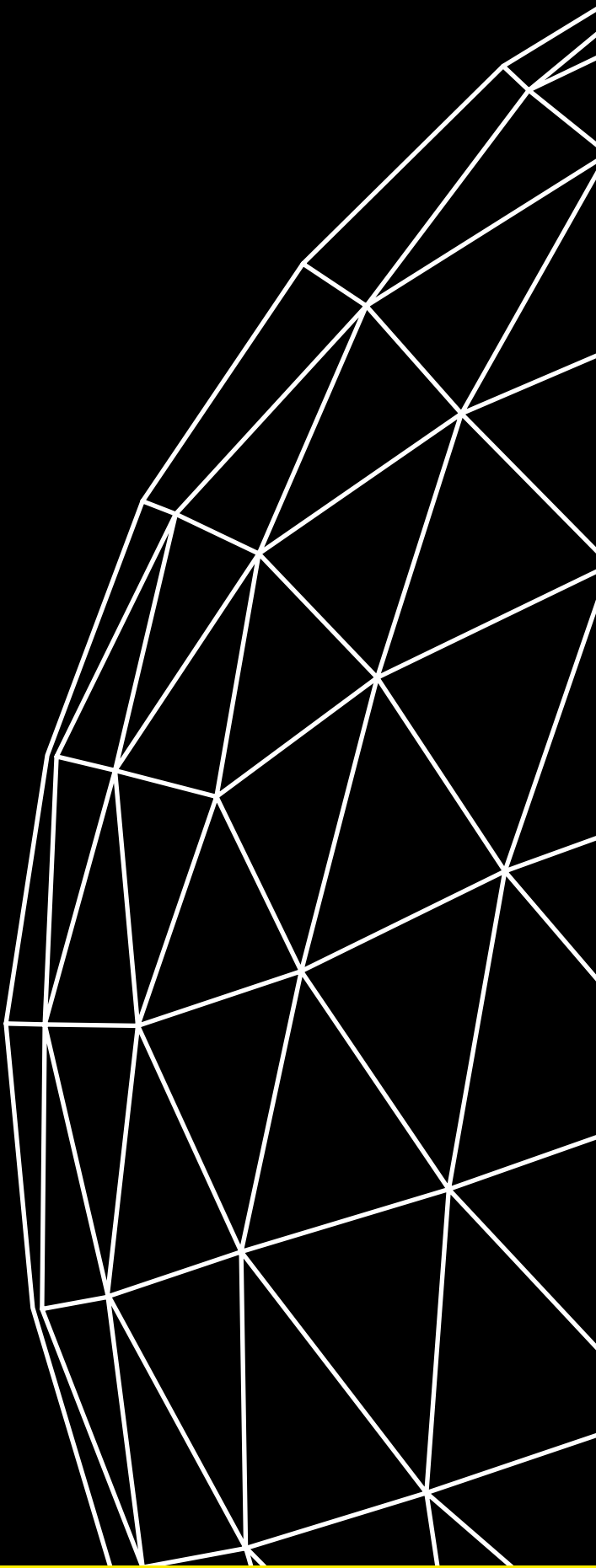
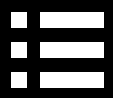
Deliverables

A Sartorius consultant will review the service, requirements, scope, and deliverables (virtually | remotely).

- **Part 1:** Review and analysis of historical data from experiments comparing the materials for one unit operation to assess equivalence based on the defined criteria
- **Part 2:** Delivery of report and knowledge transfer



Data analysis for material conversion



Data Analysis to Reduce Cost of Conversion Level 1

Features

The Data Analysis to Reduce Cost of Conversion Level 1 package helps reduce the cost of material conversion in a process through design and execution of an experimental plan that minimizes the number of experiments required to demonstrate equivalent or superior performance of new materials across normal operating conditions.

Materials may include raw materials (e.g., media), process consumables (e.g., filters), or other process equipment. The new process state is compared to the original for a single unit operation using consistent assessment criteria and objectives.

Benefits

- Cost, time, and resource savings achieved by minimizing experimental burden
- Increased internal capacity through offloading of analysis activities
- Deeper insights from results with knowledge transfer through Sartorius expertise

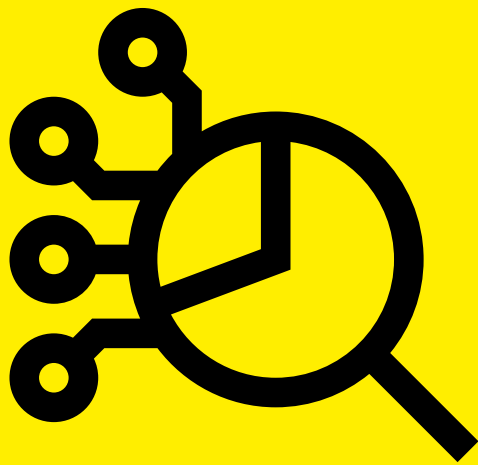
Customer prerequisites

- Agreed assessment criteria for comparison of the two materials and determination of equivalence. This may include matching or improving critical quality attributes within a specified tolerance (confirmed with a two one-sided t-test), demonstrating improved process control (through reduced variability using MVDA), or other similar assessments.
- With support from the Sartorius consultant, selection of 1 – 4 factors, target values, and normal operating ranges for the DOE. These factors include parameters that are varied in the process such as setpoints, seed densities, and pressures. The experimental design ensures assessment of process equivalence across the defined operating range.
- Commitment to complete data generation from experiments and confirmation runs within three months from the start of service.

Deliverables

A Sartorius consultant will review the service, requirements, scope, and deliverables (virtually | remotely).

- **Part 1:** Experimental design
- **Part 2:** Model building and evaluation using DOE and MVDA
- **Part 3:** Comparison of performance and equivalence of the materials based on the defined assessment criteria
- **Part 4:** Report and knowledge transfer



Data analysis for material conversion

Direct Transition Analysis

Features

The Direct Transition Analysis (DTA) package supports the implementation of automated chromatography column assessment using DTA, enabling real-time monitoring of column health using SIMCA®-online. The service is available at the batch level for a single downstream processing line with one target molecule at one site.

Benefits

- Improved process efficiency and product yield by automated classification of good | bad transitions
- Early detection of resin overuse and column lifetime limits
- Increased column operational lifetime through confirmation of packing robustness
- Reduced process variability through identification of optimal packing conditions

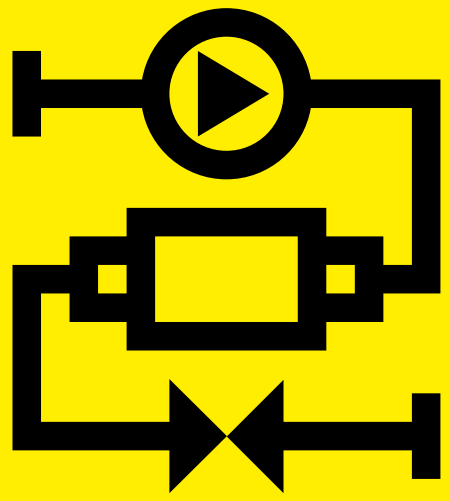
Customer prerequisites

- SIMCA®-online (version 18.1 or higher) installed with connectivity to live data from SCADA | process historian
- Admin access to the SIMCA®-online server (if guidance support is required to install the DTA SIMCA® extension)
- DTA SIMCA® Extension downloaded using the link provided at the start of the package

Deliverables

A Sartorius consultant will review the service, requirements, scope, and deliverables (virtually | remotely).

- **Part 1:** Data review to identify operational phases where assessment methods are applicable
- **Part 2:** Support for method implementation in SIMCA®-online, specifically by implementing the DTA SIMCA® Extension



Downstream processing

Sustainability and Energy Mapping

Features

The Sustainability and Energy Mapping package provides a quantitative report identifying opportunities to improve sustainability through power and waste reduction, based on an assessment of historical and projected financial and process information. An optional training add-on (at additional cost) is available to support customer ownership of the models (requires SIMCA®).

Benefits

- Deep insights to guide sustainability initiatives and improve overall resource efficiency
- Lower energy consumption and waste supporting carbon emissions reduction

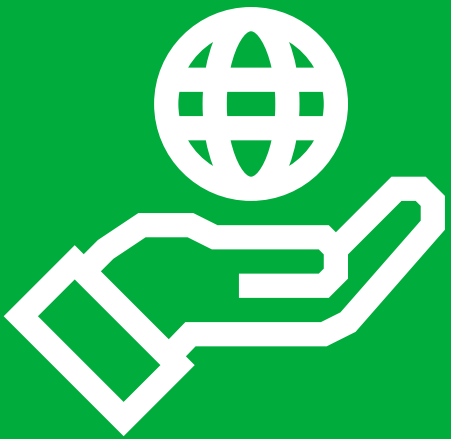
Customer prerequisites

- Pre-consultation with stakeholders to define scope, available data, and objectives
- Minimum of two years of power use and process data captured in a historian or database; identification of waste resources
- Two years of future power contract obligations and any plans for expansion

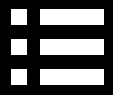
Deliverables

A Sartorius consultant will review the service, requirements, scope, and deliverables (virtually | remotely).

- **Part 1:** Guidance on assembly of financial and process information
- **Part 2:** Creation of SIMCA® models based on provided data
- **Part 3:** Report providing a quantitative assessment and recommendations for sustainability improvements through power and waste reduction



Sustainability



Package Overview and Material Numbers

Material number	Consultancy service package
UT-110060001	Data Analysis for process scaling
UT-110060002	Data Analysis for tech transfer
UT-110060010	Intensified clone selection
UT-110060011	Process improvement: New operating mode
UT-110060013	Proof-of-value process optimization starter
UT-110060014	Process optimization level 1
UT-110060015	Process optimization level 2
UT-110060016	Process optimization level 3
UT-110060021	SIMCA®-online model building
UT-110060020	SIMCA®-online model updates
UT-110060017	Raman spectroscopy level 1
UT-110060018	Raman spectroscopy level 2
UT-110060019	Raman spectroscopy level 3
UT-110060005	GxP validation framework for SIMCA®-online
UT-110060004	Sustainability and energy mapping
UT-110060007	Direct transition analysis
UT-110060023	Data analysis to assess equivalence starter
UT-110060024	Data analysis to reduce cost of conversion level 1
UT-993750	Fixed daily travel rate for travel expenses*

**Please contact your local Sartorius representative
to discuss these packages and receive a quote.**

*A Sartorius consultant will perform the service and prepare the service deliverables remotely. These Data Analytics Consultancy Service Packages do not include consultant travel. If the Sartorius consultant is requested by the customer to be on-site to perform a part of the service, a fixed daily rate will be added to cover travel expenses incurred.



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