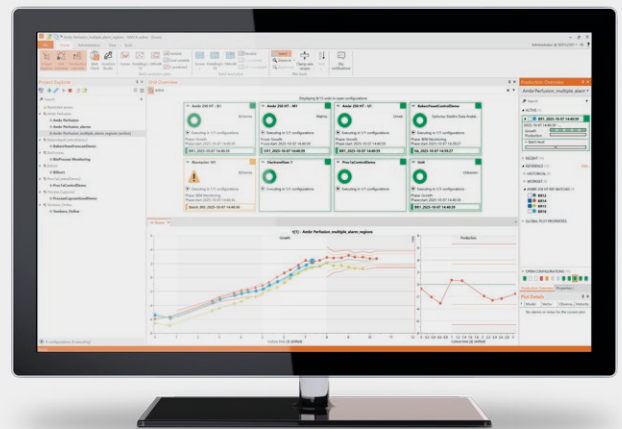


Umetrics® Digital Twin Deploy SIMCA®-online

Assure Manufacturing Success



Product Information

Harnessing the power of digital twins helps bioprocess scientists ensure precision, consistency, and product quality. With the automation of machine learning (ML) models, Sartorius delivers intelligent, efficient, reliable, interpretable, and proven solutions that optimize operations, reduce risks, and enhance productivity.

Umetrics® Digital Twin Deploy enables real-time process monitoring with an ML digital twin and provides early detection of deviations, allowing proactive rather than reactive responses to production and quality challenges. Optimizing controllable parameters in real time enables improved throughput, consistent quality, and minimum cost.

Features and Benefits

- Assert, optimize, and control production across batch, continuous, and hybrid processes
- Cut downtime with real-time alarms in both web and rich clients
- Speed compliant rollout with 21 CFR Part 11, SSO, and easy installation, maintenance, and support

Introduction

Relevant Applications

- **Visualize**— View process data anywhere
- **Monitor**— ML as a digital twin tracker for real-time early fault detection
- **Predict**— ML as a quality attribute soft sensor for results ahead of QC measurements
- **Control**— In silico process optimization for real-time process improvement

Relevant Process Steps

- Bioreactor production
- Bioreactor cleaning
- Predictive maintenance
- Chromatography

Overview

Advanced Process Control

Advanced process control (APC) with digital twins offers a transformative approach to managing complex production processes. The demand for low-cost and high-throughput products to an acceptable quality has never been more critical. APC systems based on digital twins are designed to address these needs by providing real-time monitoring, control, and optimization of manufacturing processes, ensuring that products meet stringent quality standards while maximizing operational efficiency.

The Importance of APC in Biopharma

Biopharmaceutical manufacturing processes are inherently complex, involving numerous variables and intricate interactions. Traditional control methods often fall short in managing these complexities, leading to variability in product quality and inefficiencies in production. APC systems, however, leverage advanced digital twin algorithms and data-driven insights to provide a more nuanced understanding of these processes. By continuously monitoring key parameters and the correlation patterns in the process and adjusting them in real-time, APC systems help ensure optimal conditions, reduce variability, and keep consistent product quality.

Benefits of Implementing APC

The implementation of APC in biopharma manufacturing offers several significant benefits:

Reduced quality variation

APC systems ensure that manufacturing processes remain within specified parameters and correlation patterns, reducing the risk of deviations that could impact product quality.

Increased efficiency

By optimizing process conditions, APC systems can improve yield and reduce waste, leading to more efficient resource use.

Predictive capabilities

APC systems can predict potential issues before they occur, supporting proactive interventions that prevent disruptions in production.

Regulatory compliance

APC systems help manufacturers adhere to regulatory standards by providing detailed documentation and traceability of process conditions.

Challenges and Considerations

While APC offers numerous advantages, its implementation in biopharma manufacturing is not without challenges. The complexity of biopharmaceutical processes requires sophisticated digital twin models and algorithms, which can be difficult to develop and maintain. Additionally, integrating APC systems with existing manufacturing infrastructure can be a complex task, requiring careful planning and execution. Manufacturers must also consider the cost of implementing APC systems, balancing the initial investment with the long-term benefits.

The Role of SIMCA®-online in APC

SIMCA®-online, part of the Umetrics® Digital Twin AI Ecosystem, is a leading software solution that exemplifies the capabilities of APC in biopharma manufacturing, with a long list of customer success stories. It provides real-time insights through process monitoring that enables manufacturers to detect deviations, predict outcomes, and implement corrective actions swiftly.

By utilizing advanced ML models, SIMCA®-online facilitates proactive process control, ensuring that manufacturing operations remain within optimal parameters and that any potential issues are addressed before they impact product quality.

In summary, advanced process control is an essential component of modern biopharmaceutical manufacturing, offering the tools and insights needed to optimize production processes, ensure product quality, and enhance operational efficiency. As the industry continues to evolve, APC systems like SIMCA®-online will play a crucial role in driving innovation and maintaining competitiveness in the global market.

More Than Software

Sartorius' Umetrics® Digital Twin AI Ecosystem provides end-to-end support through biopharma processes and provides rapid results. Users gain access to supporting documents, templates, training, and consultation to address specific business challenges. Our courses and webinars help over a thousand people every year develop expertise and confidence in getting value from their data.

A Complete AI Ecosystem for Business Growth

The Umetrics® Digital Twin AI Ecosystem is a family of proven data analytics, advanced process control, and application

innovation solutions that work seamlessly together.

Powered by core data-preparation tools—retrieval, wrangling, contextualization, and exploration—and lifecycle management of ready-made digital twins, the system's toolkit is the glue for smooth transitions between Ecosystem products.

■ Umetrics® Digital Twin Build

Tools for empirical ML models in SIMCA®, for mechanistic models in Cell Insights, and for generating and exploring systems with DOE in MODDE®.

■ Umetrics® Digital Twin Deploy

Tools for visualizing the process, ensuring process consistency, and predicting and forecasting the product quality through ML models.

■ Umetrics® Digital Twin Innovate

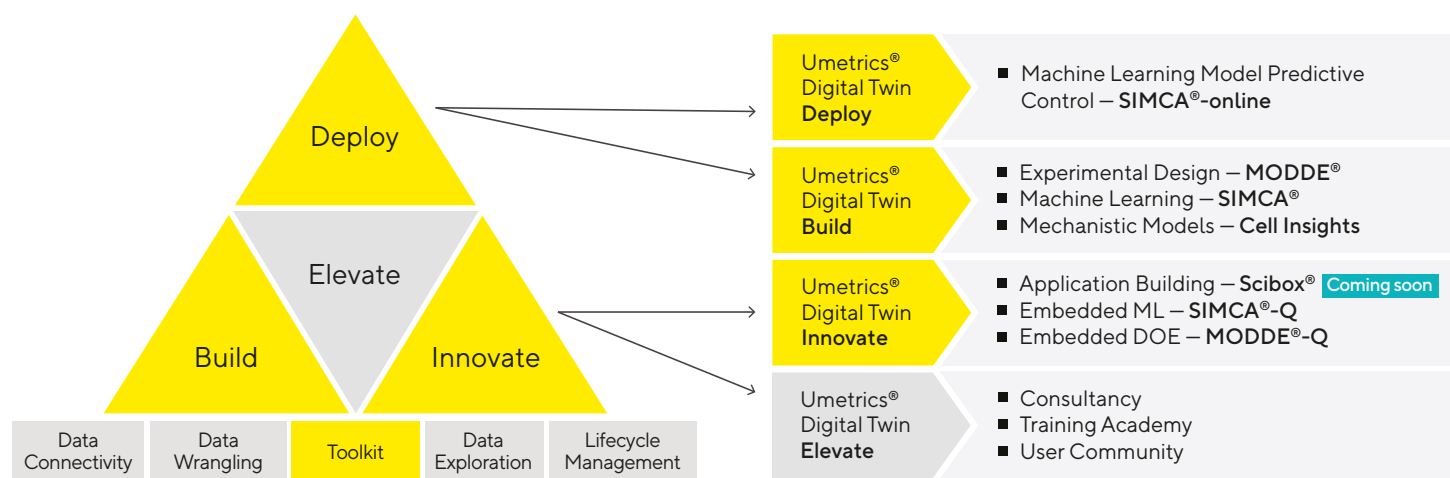
Tools for self-service rapid prototyping, creation, and deployment of streamlined workflows in Scibox® and built-in ML in SIMCA®-Q, and DOE in MODDE®-Q.

■ Umetrics® Digital Twin Elevate

Training and consulting services to support knowledge building, usage, and maximization of value from the full AI ecosystem.

These solutions give you control and confidence in your processes at every stage—from development to manufacturing.

Umetrics® Digital Twin AI Ecosystem



Change a Little – Grow a Lot

The Umetrics® Digital Twin AI Ecosystem supports organizations in generating value from their data. It provides tools for data analytics that can help identify key factors influencing research, development, and manufacturing outcomes. By enhancing process understanding and product consistency, the solution enables reduced risk and accelerated time to market. The offering includes software, training, support, and project management. As part of Sartorius, a global company with more than 10,000 employees, the ecosystem is backed by an international presence and infrastructure.

Technical Specifications

System Requirements for Clients and Servers

- Any x64 computer hardware supported by the Windows versions listed below
- Supported versions of Microsoft Windows Server 2022, Windows Server 2019, Windows Server 2016, Windows Server 2012, Windows Server 2012 R2, Windows 11, and Windows 10
- Microsoft.NET Framework 4.6.2 or later. The latest available version is recommended
- 500 MB available hard disk space for a full installation
- Any graphics card. Performance is not improved with more advanced cards
- SIMCA® projects built with SIMCA® 13.0.3 or later.
To use the latest features, we recommend SIMCA® 18.0

See the Knowledge Base for more information:
[sartorius.com/en/products/process-analytical-technology/data-analytics-software/support/knowledge-base/](https://www.sartorius.com/en/products/process-analytical-technology/data-analytics-software/support/knowledge-base/)

Database With Historical and Current Data

SIMCA®-online needs a commercial process data source. This source provides the right logic and data structures for process data and batches, and it is optimized for the kinds of data requests SIMCA®-online generates.

To access the data, SIMCA®-online uses a SimApi – a software layer that translates SIMCA®-online requests into a protocol the data source understands.

Ready-to-use SimApis are available for common data sources, including:

- ODBC (for databases such as Microsoft SQL Server)
- AVEVA PI System
- OPC UA

Developers can also build their own using the full SimApi specification.

Learn more:

- SIMCA®-online Implementation Guide: requirements and best practices for data sources and SimApis
- Download SimApis and see available features: [sartorius.com/umetrics-simapi](https://www.sartorius.com/umetrics-simapi)
- SimApi Guide: installation steps and technical details

Ordering Information

Peripherals and Accessories

Consultancy Service

Description	Order Number
GxP Validation Framework For SIMCA®-online (guidance templates)	UT-110060005
SIMCA® -online Model Updates Package	UT-110060020
SIMCA® -online Model Building Package	UT-110060021

Training Courses

Description	Order Number
SIMCA®-online Admin Course	UT-OC-ADM
SIMCA®-online Operator eLearning Course	n/a

Germany

Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen
Phone +49 551 308 0

USA

Sartorius Stedim North America Inc.
565 Johnson Avenue
Bohemia, NY 11716
Toll-Free +1 800 368 7178

Experience the benefits for your business today

Find out how our solutions can help your business to grow, whatever industry you are in.

Visit [sartorius.com/umetrics](https://www.sartorius.com/umetrics) for details or to download a free 30-day trial.

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