sartorius stedim biotech

Upstream Processing Solutions
From Research to Production

turning science into solutions

Solutions for Upstream Processing Needs

Sartorius offers a wide range of process solutions for cell culture and microbial production processes, as well as for cell line and process development activities.

SCADA system, process automation and chemometrics toolbox

Media and Media Preparation

- Ready-made liquid media in bottles and bags
- Powder media
- Platform system for media preparation
- Prefilters, sterile filters, mycoplasma-retentive and virus removal filters
- Bags for mixing and storage

Cells and Cell Banking

- CHO expression platform
- GMP dispensing systems
- Cell bank manufacturing and characterization

Cell Line and Media Development

- Automated multi-parallel mini bioreactors
- High throughput tools for media development

Test kits




Production

- Single-use bioreactors
- Stainless steel bioreactors
- In-line sensors and at-line analyzers
- Bulk harvest testing

Process Development

- Automated multi-parallel mini bioreactors
- Benchtop bioreactors with glass and single-use vessels
- Stainless steel bioreactors
- In-line sensors and at-line analyzers

Clarification

- Single-use centrifugation
- Depth filtration
- Sterile filtration
- Crossflow filtration
- Virus filtration
- Membrane chromatography
- Bags for fluid management (mixing and storage)
- Buffers in liquid or powder form

Tubings, connectors, disconnectors, SU sensors for flow | pressure and valves


Table of Contents

Cell and Gene Therapy Applications

Developers and manufacturers of cell and gene therapies require technologies and solutions with assured process integrity and a robust supply chain, which are critical to the successful development and manufacturing of these advanced therapies.

Sartorius is a global solution provider for the biologics industry, especially for antibody and vaccine production. Knowledge and experience gained with these proven products and services provide a strong foundation to support upstream and downstream processing of cells and viruses for allogeneic and autologous advanced therapies.

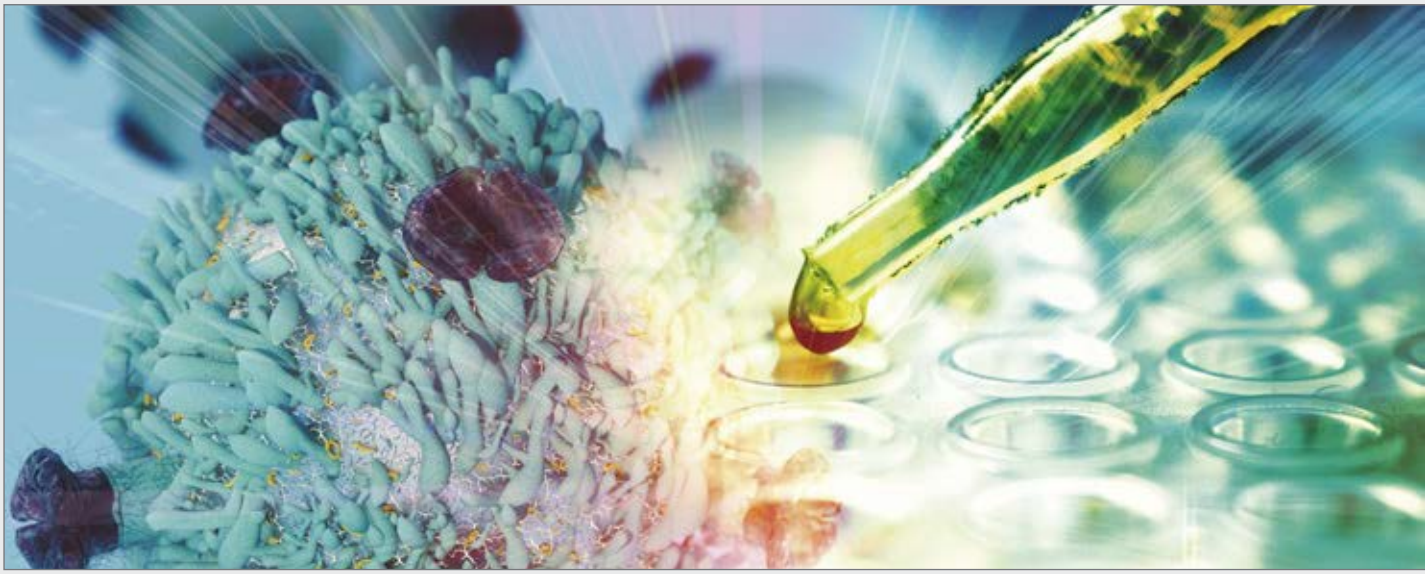
Therapy development can benefit from our single use systems, intelligent equipment and process analytical tools enabling accelerated process development and realization of therapy production goals. .

Highlighted here are some upstream solutions for research, process development and optimization, and production workflows for autologous and allogeneic advanced therapies:

- **Cellular Immunotherapy**
  Sartorius provides the cellular immunotherapy industry with a range of scalable single-use production technologies. Our portfolio supports immune cell expansion, viral vector production cell expansion, and downstream processing steps.

- **Gene Therapy and Viral Vectors**
  Viral vectors such as adenoviruses, adenoassociated viruses, lentiviruses and retroviruses are effective delivery systems for genetic material used in cell and gene therapies. Sartorius technologies are ideally suited for development and manufacturing processes for viral vectors. They allow end-to-end, single-use processing of virus batches at scales required for process development through to commercial manufacturing, up to 2,000L.

- **Cell Therapy**
  Cell therapies applications encompass the use of various types of stem cells such as mesenchymal stem cells (MSCs) or induced pluripotent stem cells (iPSC). MSCs are the most commonly used class of multipotent stem cells and are illustrative of production requirements of other cell therapies. Sartorius' portfolio of technologies supports scalable cell expansion and downstream processing steps including harvest, wash, and concentration of cells.



Technology Options Include

Stage of Development	Step	Cellular Immunotherapies	Viral Vectors for Cell & Gene Therapies	Cell Therapies
Research and Process Development	Expansion	• ambr® 15 › • ambr® 250 ›	• ambr® 15 & ambr® 250 › • Umetrics® MODDE® › • UniVessel® Glass › • UniVessel® SU ›	• ambr® 15 & ambr® 250 modular › • UniVessel® Glass › • UniVessel® SU ›
Production	Media Preparation	• Flexsafe® 2D Bags › • Single-use mixing systems • Sartorius Filter range ›	• Single-use mixing systems • Flexel® & Flexsafe® & Flexboy® Bags • Palletanks • Sartorius Filter range ›	• Single-use mixing systems • Flexel® & Flexsafe® & Flexboy® Bags • Palletanks • Sartorius Filter range ›
	Expansion	• BIOSTAT® RM TX & BIOSTAT® B Control Unit › • BioPAT® MFCS › • Flexsafe® RM TX Bags & › BioPAT® ViaMass ›	• BIOSTAT® RM or STR® › • BIOSTAT® B Control Unit › • BioPAT® MFCS ›	• BIOSTAT® RM › • BIOSTAT STR® › • BIOSTAT® B Control Unit › • BioPAT® MFCS ›

Please ask a Sartorius specialist for more information about the portfolio for any stage of individual process. Contact us on

regenmed@sartorius.com

I. Cell Line

Cell Line Development Services

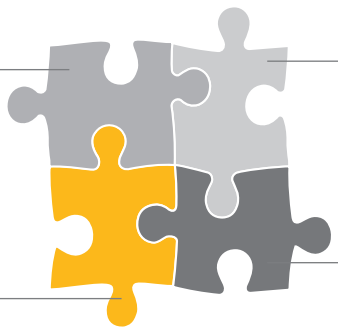
CellcaCHO Expression Platform

Sartorius Stedim Cellca is a leading provider of Cell Line Development Services for large-scale protein production of biopharmaceuticals in mammalian cells. Within 4 months the CellcaCHO Expression Platform can provide a stable well characterized Research Cell Bank (RCB) with titres consistently exceeding 3g/L in an easily scalable fed-batch process.

CellcaCHO Expression Platform

Host Cell Line
- CHO DG44
- Growth in suspension
- Long-term stability
- Fully documented history

Expression Vector
- DHFR system with high selection stringency without any MTX | MSX, antibiotics
- Optimal signal peptide
- Freedom to operate



Media System
- Chemically defined
- Free of animal components
- Free of proteins & peptones
- Optimized for Cellca cell lines

Upstream Process Design
- Robust
- Easy to scale
- Proven performance in various bioreactor systems

Key Benefits

Speed
- From DNA to high-titre RCB in 4 months. Save up to 3 months by omitting the need for scalability studies.

Track Record
- More than 90 successfully completed projects.

Scalability
- Processes can be easily transferred and scaled-up to a range of bioreactors.

Performance
- Up to 8 g/L in a ready-to use, unoptimized 12 – 14 day standard fed-batch process.

Customer Focus
- Committed project teams and dedicated client managers deliver service excellence and meet our clients requirements.

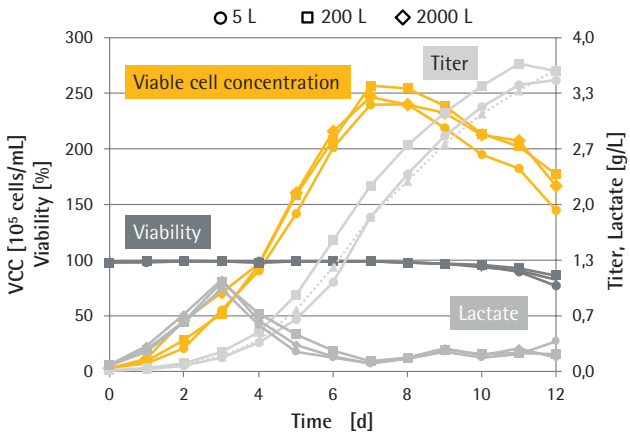
Vector Cloning → Transfection and Pool Generation → Single Cell Cloning → Clone Evaluation → RCB Preparation

From DNA to RCB in 4 Months

Products

- mAbs (IgG1, IgG4, IgG2)
- Fusion proteins
- Fab-related products
- Bispecifics
- Biosimilars

Scalability and Robustness – High Titer & Viability, Low Lactate Levels




UniVessel® Glass 5 L


BIOSTAT STR® 200 L


BIOSTAT STR® 2000 L

Scalability from shake flask to 1000 L with minimal process development

Cell Line Development: Track Record

	2 g/L	3 g/L	4 g/L	5 g/L	6 g/L	7 g/L	8 g/L
Pre-clinic & Phase 1	16	29	20	12	8	1	1
Phase 2	1	–	1	–	1	–	–
Phase 3	–	1	–	1	–	–	–
Market Approval	1	–	–	–	–	–	–

Un-optimized yields in a 12-14 fed-batch process with minimum 70% viability

Stability Study → Bioreactor Confirmation → Transfer & Documentation

3 – 4 Months

Cell Bank Manufacturing and Characterization

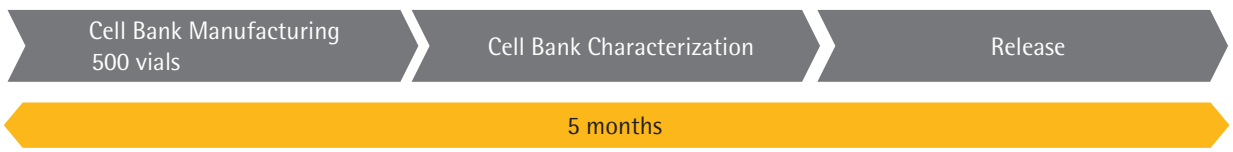
An Integrated Cell Banking and Characterization Package

To ensure safety and quality of any biological product, it is essential to have a fully characterized, well-documented, homogeneous, Master Cell Bank (MCB) and Working Cell Bank (WCB). The Cell Line and Testing Solutions portfolio now offers fully GMP cell bank manufacturing as well as cell bank characterization.

Cell Bank Manufacturing

- Closed, single-use manufacturing system with in line monitoring and control
- Dedicated facility to mammalian suspension cells, no serum or animal products, no bacteria or viral products
- Up to 500 vial cell banks at $1-3\times10^7$ cells per vial
- Automatic vial filling system and controlled rate cryopreservation
- Storage of filled vials in vapor phase LN2

From RCB to Released MCB in 5 months



Cell Bank Manufacturing and Characterization

Closed Cell Bank Manufacturing System

Cell Bank Manufacturing Process Flow

Initial cell recovery in Grade A system	Serial expansion in closed system	Aseptic connections via sterile welding	Cell harvest, concentration, centrifugation	Automated filling: 500 vials within 20 minutes	Controlled rate freezing; harvest to storage under 2 hours

Ultimate Safety Standards

- Closed & automated system
- Automated filling (fill-it)
- Dedicated facility for mammalian, suspension cell banks using serum-free & animal component free media
- Extensive environmental monitoring programme
- Manufacturing process broth qualified for sterility assurance

Regulatory Acceptance

- MHRA IMP (MIA) licenced manufacturing facility
- MHRA GMP Licenced Testing Facility
- Facilities and equipment validated to VMP
- Cell bank testing to global regulatory standards

Deliverables

- > 500 vial bank ~ 1×10^7 viable cells per vial
- Manufacturing Summary Report
- Certificate of GMP Compliance
- TSE | BSE Batch Certification
- Certificate of Analysis for each Release and Characterization Assay

Integrated Approach: DNA to Cell Bank Release

The Cell Bank Manufacturing Services can be easily combined with our Cell Line Development Services and Cell Bank Characterization Services for a de-risked and time-saving approach from DNA to MCB in 10 months.

From DNA to MCB in 10 Months

fill-it

Automated Cell and Strain Banking System

Applications
- GMP cell banking
- Cell banking for discovery purposes
- Strain banking under GMP and non-GMP requirements
- GMP liquid aliquotation

fill-it is an automated benchtop system for creating high-quality cell and strain banks in cryovials.

The system works with racks of branded 0.5 – 5.0 mL cryovials in 24-way, 48-way and 96-way formats.

The fill-it system decaps all cryovials simultaneously and then dispenses cells, strains or liquids into the cryovials before recapping, ready for transfer to freezers or other downstream activities. It is a proven system designed for easy installation on a laboratory bench or in a standard biosafety cabinet.

High-throughput system unlike slow manual processing	▶ Permits processing of large batches, significantly reducing QC costs and increasing productivity
Automated dispense module with peristaltic pump and an aseptic single-use tube set certified for compliance with GMP	▶ High-throughput aseptic transfer of cell, strains and liquids improves product consistency and reduces the risk of contamination
Validatable IQ | OQ processes for GMP	▶ Supports clinical development, regulatory approval and manufacture of biologics
System has a simple three-button user interface and fits on a laboratory bench or in a standard biosafety cabinet	▶ Easy-to-use flexible system with small footprint designed to fit in any laboratory
Automated decap | recap module	▶ Reduces risk of repetitive strain injury compared with manual processing


sartorius stedim biotech

II. Media


ambr 15
sartorius stedim
Cell Culture Media

Experience and Flexibility for Cell Culture Needs

Development of powerful cell culture media and feed strategies has dramatically changed the way of producing antibodies, recombinant proteins and vaccines. Today, antibody titers of up to 10 g/L and beyond can be achieved in intensified cultures using serum- or protein-free or even chemically defined media and feeds.

Sartorius offers a broad range of powerful cell culture media for the most common cell lines used for protein and virus production.

As selection and optimization is cell line dependent and a critical aspect of process development, we provide qualified application support and development services to our customers.

The cell culture platform media offering includes

- Serum-free media
- Protein-free media
- Animal-origin-free media
- Chemically defined media

▶

- No virus or prion concerns
- Simplified downstream processing
- Maximized yields

Experience and Quality

- Rely on a partner who understands the criticality of an appropriate quality system, quality control and assurance of supply.
- All raw materials are selected to comply with European and U.S. Pharmacopeia standards. If available, they are from a certified non-animal origin source.
- Powder media are produced in a controlled area at low humidity to prevent any inadvertent hydration. All liquid media are made from water for injection for the best microbiological quality.

Flexibility and Customization

Sartorius as partner can help to adapt cell culture media formulation to specific needs.

- Liquid media in containers ranging from 0.5 L bottles to 1,000 L bags; up to 10,000 L per batch
- Powder media in package sizes of up to 20 kg per unit; up to 7 tons per batch

Come to the right place to optimize your cell culture medium.

- Expert support for your media optimization
- Media optimization services

The Sartorius Media Team is looking forward to supporting customer specific projects in making it a success.

Industry with Cell Culture Media Solutions

- Leading position in single-use applications that include fluid management, filtration and process analytical technology
- Long-term relationships with dual-sourced raw material suppliers guarantees supply and quality
- Pioneer in state-of-the-art micronization high-quality powder production processes
- Risk minimization approach applied to powder | liquid solutions
- ISO certification with successful audit track record following Current Good Manufacturing Practices 21CFR820

Complete Solution

All liquid media filtered through Sartorius filters; full media qualification package and support	▶ Optimized media filtration and guaranteed successful scale-up and transfer into commercial production
Pre-weighed buffer and media powder in ready-to-use dispensing bags	▶ Simple and straightforward media and buffer preparation with Sartorius FlexAct® MP or mixing solutions
Advanced feeding and control strategies using Sartorius ambr® and BIOSTAT® bioreactors, sensors, MFCS supervisory control system and chemometrics tool box	▶ Fast track to optimized culture conditions and yields
Sartorius one-stop shop for integrated and optimized solutions for cell line, media and process development and production of cell culture derived products	▶ Full process support allows you to focus on customer core tasks and targets

For more information please contact:

CellCultureMedia.EU@Sartorius.com (for EU and Asia)
CellCultureMedia.NA@Sartorius.com (for Americas)
Info_CellCultureMedia@Sartorius.com

Broad Range of Cell Culture Media

Media Are Available as Liquid and Powder for Maximun Flexibility

Applications
- Mammalien and insect cell culture
- Process developpment and optimization
- Media preparation can be used with WFI-quality water in bags

With maximun flexibility different format can be provided. For media preparation, WFI quality water in bags can be used.

Cells	Culture	Primary Application
CHO (e.g., DG44, CHO-S, CHO K1, DHFR$^-$)	Suspension and adherent	Proteins
	Suspension	
	Suspension	
Hybridoma	Suspension	Proteins
NS0	Suspension	Proteins
Insect cells (e.g., Sf9, Hi 5)		Proteins | Vaccines
Vero	Adherent	Vaccines
MDCK	Adherent	Vaccines
HEK 293	Adherent	Vaccines
	Suspension	
Per.C6® *		Vaccines
Mesenchymal stem cells	Adherent	Cell therapy
Adult dermal fibroblasts	Adherent	Cell therapy
Adult and neonatal primary keratinocytes	Adherent	Cell therapy
hPSC and IPSCs	Adherent	Cell therapy

* License required

Custom Media Formulations

Adapted Solutions for Customer Requirements

Applications
- Vaccine production
- Therapeutic protein production
- Cell therapy

In addition to off-the-shelf media formulations, we support our customers with the manufacture of their own proprietary media formulation, either in liquid or powder format. The team of experienced media specialists can also assist with the development and optimization of cell line specific medium and feed formulations. Get a support about cell line and process development to clinical and commercial production.

Media Optimization Services and Support
The media specialists will develop or optimize customer specific media formulations designed for your unique cell culture requirements.

Media Supply for GMP Production
The media production facilities are ISO 9001 | 2008 and 13485:2012 compliant following cGMP 21CFR820 guidelines.

Media Supply for Process Development
An expedited production option for those that require high quality cell culture media for process development and non-GMP production.

Homogeneous particle size of powder formulations	▶ Reduces regulatory burden ▶ Facilitated dissolution
Two redundant manufacturing sites	▶ Security of supply globally
Wide range of batch sizes and packaging • Up to 10,000 L for liquid formulations • Up to seven tons for powder formulations	▶ Excellent partner for scale-up, matching needs from preclinical to commercial phase
Similar offering for buffers	▶ Products also for downstream processing

Media Services

In addition to a broad standard classical and chemical-defined portfolio, Sartorius media services team is able to provide custom cell culture solutions.

Quality

Sartorius is currently engaged in the manufacture of over 1,500 products for pharmaceutical and biotechnology applications such as disease diagnosis, biomedical research, production of diagnostics and therapeutics as well as quality control testing of pharmaceuticals and medical devices for the presence of bacterial contaminants.

Manufacture of these Sartorius products – specifically cell culture media, reagents, and buffers – follow the protocols and compliance specifications of the following industry regulations:

- 21CFR820
- ISO 9001: 2008 certified
- ISO 13485: 2003 certified

In order to maintain consistent quality in sterile cell culture media products, strict control of each production lot is essential. Written procedures in accordance with current Good Manufacturing Practice (cGMP) provide quality control from start to finish for each product.

To verify the conformity of material to established specification throughout the manufacturing process, inspections and testing are carried out during these four stages:

- Raw material receipt
- In-process manufacturing, labeling and packaging
- Finished product
- Post-manufacture for shelf life studies

Media Processes

Packaging

Sartorius' business units are industry-leading suppliers for the application they serve, such as filtration, fluid handling and fermentation. Combining forces enhances the strength of Sartorius Stedim Biotech. With decades of experience and a rich heritage in engineering, the packaging solutions will be answering the customer specific needs providing excellence in customer service, product quality and innovation solutions.

Sartorius wants to protect our products in the best possible way with high-quality packaging – on the inside as well as the outside. There is a particular value on the highest standards of safety and security, in order to offer efficient and flexible solutions in a market that is both challenging and constantly changing.

Shipping

Media & Buffer product storage and shipping conditions vary. While some can be stored at ambient temperature (uncontrolled), others might need to be stored at room temperature (15 – 30°C), refrigerated (2 – 8°C) or frozen (–10°C | –20°C). Appropriate packaging is provided to maintain optimal conditions during shipping. We have years of experience in shipping a broad range of volumes of our products (in liquid or powder form) at different temperatures all around the globe. Custom transportation solutions can be tailored to every specific need if required.

Shipping Solutions for Media & Buffers | Powder Form

	10 g to 2 kg	5 kg to 20 kg	2 kg to 20 kg	500 g to 2 kg
Bucket	•			
Drum		•		
Powder Bag			•	
Flexel Tankliner				•

Shipping Solutions for Media & Buffers | Liquid Form

	0.5 to 1 L	1 to 2.5 L	2 to 20 L	50 L	100 L	200 L	500 L	1000 L
Bottle	•	•						
LDPE 2D Pillow Bag		•	•					
Drum				•	•	•		
LDPE 3D Bag in Container					•	•	•	•
Stainless Steel Palletank					•	•	•	•
Plastic Palletank						•	•	

Solutions for Media Preparation

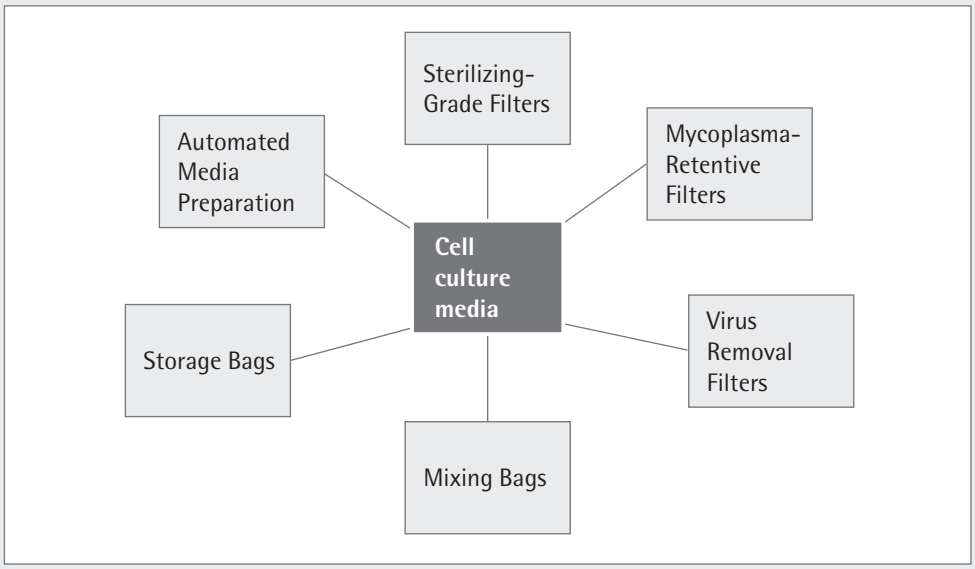
Sartorius offers:

- A broad portfolio of filters for various media types, including chemically defined or protein, serum or hydrolyzate-supplemented
- Safe solutions for mycoplasma risk mitigation; combining high retention efficiency with optimal throughput for cost-effective processing
- Prefilter portfolio with optimal protection of final filters to further reduce filtration costs
- All media filtration solutions are available both for single-use processing and media production in stainless steel equipment
- Industry leading system design with highest total throughput and economic filtration

Cell culture media are produced in large volumes and aseptically transferred into bioreactors. Key process steps involved in media preparation are the mixing of the powder media with water for injection (WFI), sterilizing-grade and mycoplasma-retentive filtration and media storage before use.

Continuous cost pressure, increased titers and reduced production volumes have led to the adoption of single-use technologies – both for bioreactors and media preparation. Sartorius has therefore developed the fully automated, easy-to-use FlexAct® MP system that helps reduce labor intensive steps to ensure higher productivity.

As leading partner for upstream processing, Sartorius provides integrated solutions that comprise cell culture media, bags, sterilizing grade filters, mycoplasma retentive filters and virus risk mitigation technologies.



Media Filtration Solutions

The choice of an appropriate filtration solution for media preparation highly depends on the composition of the cell culture medium. Often, 0.2 µm-rated sterilizing-grade filters are used for media preparation. However, reports of mycoplasma contamination of cell culture processes have put 0.1 µm-rated mycoplasma-retentive filters into the spotlight, again. Typical sources for mycoplasma contamination are animal-derived materials, such as trypsin or serum; plant-derived culture media supplements, such as soy-based supplements; and contamination caused by the operators themselves. Producers of cell culture media have to assess their potential risk for mycoplasma contamination in order to decide which filtration method to use. Sartorius media filtration solutions range from prefilters to sterilizing-grade and mycoplasma-retentive filters – tailored to the specific filtration needs of the various types of cell culture media.

Single-Use Media Preparation

Today, single-use systems for media preparation are available up to 3,000 L volume. While users initially converted individual production components to single use, the industry is now moving towards completely integrated systems for media preparation.

The Sartorius FlexAct® MP media preparation platform is a highly automated, fully closed system: It starts with powder dissolution in a single-use mixing system, which is followed by sterile filtration and the transfer of the ready-to-use media into a storage bag. To avoid errors, the entire media preparation process is supervised by a multi-functional central control unit. It monitors and records all relevant process data, such as operating pressure, pH, pump speed and fluid level.

Sartorius filters and single-use bags are supported by an industry-leading documentation package, which includes validation and extractables guides. The Sartorius validation experts support customer throughout qualification of single-use systems for biopharmaceutical production.

- Complete range of single-use bags for media preparation, mixing and storage from 50 L up to 3,000 L
- Magnetic mixing technology with universal mobile drive unit
- Fully integrated FlexAct® MP media preparation platform
- Comprehensive validation support for extractables | leachables by our dedicated validation team

Virus Risk Mitigation in Media Preparation

Virus risk mitigation in cell culture media preparation is a hot topic. Multiple bioreactor contaminations reported over the past several years have been caused by small, non-enveloped viruses like MVM and Vesivirus derived from raw materials.

Technologies such as high-temperature, short-time (HTST) treatment and virus removal filtration have been employed for virus risk mitigation in cell culture media preparation.

The new Virosart® Media filter is a unique solution for cost effective risk mitigation. It combines highest flux with superior capacity and is the method of choice for chemically defined cell culture media.

- Cost effective virus risk mitigation of chemically defined media with the new Virosart® Media
- Orthogonal and robust technologies for effective contamination control

FlexAct®

Single-Use Solution for Automated Media Preparation

Learn more about FlexAct® Solution

Applications
- Sterile Media Preparation
- Virus Mitigated Media Preparation

The FlexAct® configured to order solution brings together hardware, software, wetware and documentation into a ready to use package for single-use bioprocessing.

Media preparation can be configured within the offered application space making it capable of preparing single or up to 10 aliquots of media in 2D and 3D single-use bags. It uses pre-defined configurable software based on ANSI | ISA-S88 industrial standards for batch processing.

The software architecture allows easy interface to Distributed Control Systems (DCS) for plant-wide integration. The modular FlexAct® build and connection of sensor, actuator and holder components allows them to be shared between unit operations, enabling a single FlexAct® system to perform up to 6 distinct unit operations at various volumetric scales.

Flexible processing skids with multiple functionality for diverse unit operations	▶ Supports multi-product	adaptive-scale bioproduction
Easy to integrate into distributed control systems and manufacturing execution systems	▶ Speed and effort of system integration
Easy-to-use predefined application software based on flexible unit operation recipes	▶ No additional coding or programing of software
Reliable Single-Use sensor and actuator technologies	▶ Higher process accuracy and control
High degree of automation, user guidance, system diagnostic and process transparency	▶ A reduced risk of error and unplanned downtime

3. Media Sterile Filtration

Filter Selection Guide

Learn more about the Sartopore® 2 Filter Family

Learn more about the Sartoguard Filter Family

Todays industrial cell culture media formulations can be very different spanning, from serum and hydrolysate supplemented to chemically defined media. Sartorius has a long standing experience in media filtration. Based on this there are recommended filter solutions for each need. The international team of application specialists helps to optimize the customer's specific filtration process. Get in contact with Sartorius today.

Media Type	Serum, soy or yeast hydrolysate-supplemented cell culture media	Chemically defined cell culture media	Complex serum-free media
Sterile Filtrate Required			
Recommended Prefilter	**Sartoguard GF** 1.2 µm | 0.2 µm	**Sartoguard PES** 1.2 µm | 0.2 µm	**Sartoguard PES** 1.2 µm | 0.2 µm
Recommended Final Filter	**Sartopore® 2 XLG** 0.8 µm | 0.2 µm		
Mycoplasma Removal Required			
Recommended Prefilter	**Sartoguard GF** 0.8 µm | 0.1 µm	**Sartoguard PES** 0.8 µm | 0.1 µm	**Sartoguard PES** 0.8 µm | 0.1 µm
Recommended Final Filter	**Sartopore® 2 XLM** 0.2 µm | 0.1 µm		
Virus Removal Required			
Recommended Prefilter		**Sartopore® 2 XLM** 0.2 µm | 0.1 µm	
Recommended Final Filter		**Virosart® Media** 20 nm	

MaxiCaps® MR

Unique Large Scale Single-use Solution

Pre-assembled, pre-sterilized and self-contained: MaxiCaps® MR is designed for large-scale filtration in biopharmaceutical applications. It maximizes filtration capacity and minimizes risk.

Single-use filter capsules have been systematically replacing stainless steel filter housings and cartridges as an highly economical choice for the biopharmaceutical industry. From capsules to complex custom assemblies, the implementation of single-use filter assemblies provides shortened setup times and hardly any clean up time.

MaxiCaps® MR offers a single-use, large scale-filter system which can be configured with a filtration area between 5m^2 to 27m^2 and high quality Sartorius brand filters. Within the upstream process it is used for Media & Buffer Preparation, Cell Removal and Clarification applications.

90% less tubing	▶ Better handling and small footprint
90% less connections	▶ Highest safety
No assembly required	▶ Easy installation
Pre-sterilized system	▶ Ready-to-use
One integrity test only	▶ Saves up to 4 hours

Learn more about the MaxiCaps® MR

Applications

- Media & Feeds Filtration
- Large-Scale Buffer Preparation
- Post Cell Removal Bioburden Reduction for mAb's
- Clarification of Viral Vectors & Gene Therapy Products

Sartocheck® 5 Plus Filter Integrity Tester

Keeps Risk Factors Under Complete Control

Learn more about the Sartocheck® 5 Plus Filter Integrity Tester

Applications
- Integrity testing of filters pre and post use

The Sartocheck® 5 Plus perfectly meets today's key industry requirements for filter integrity testing in demanding GMP enviroments.

It sets a new standard for filter integrity testing devices:
- Surpass the Requirements of Quality Risk Management (QRM)
- Reach the Ultimate Level of Data Integrity
- Experience the Comfort of Intuitive Usability
- Discover the Simplicity of Health, Safety, and Environment (HSE)

Quality Risk Management	▶ Specific program parameters allowing detection of user errors and abnormal test conditions.
Data Integrity	▶ Flexible user matrix for generating individual roles, double data back up and a barcode scanner function.
Highest Safety for Operator, Drug & Environment	▶ The Sartocheck® 5 Plus is the only ex-proof integrity tester device on the market. This provides safety when testing alcohol wetted filters.
Usability	▶ Automatic test time for faster testing as well as attractive and intuitive industry rewarded user interface (iF Design Award 2018).

Virosart® Media

First Virus Retentive Filter for Cell Culture Media

Learn more about the virus risk mitigation strategy

Applications
- Media preparation of chemically defined cell culture media
- Addition of media feeds such as glucose

Virus-retentive filtration is a highly effective method for viral risk mitigation of cell culture media. Virosart® Media filter provides more than 4 LRV (log_{10} reduction value) for small non-enveloped viruses and more than 6 LRV for larger enveloped viruses.

This media filter provides a cost effective solution with highest filter capacity for cell culture media.

Through this high capacity it overcomes today's bottlenecks of virus filters originally developed for downstream applications.

≥ 4 LRV for small non-enveloped viruses ≥ 6 LRV for large enveloped viruses	▶ Highest safety for cell culture
New high-performance PES membranes	▶ Highest capacities and flow rates No impact on cell culture performance
Capsules and filter transfer sets delivered gamma irradiated	▶ Ready-to-use Easy implementation into single-use processes

III. Bioreactors and PAT


sartorius stedim
Flexsafe STR
BIOSTAT STR®
sartorius stedim
BIOSTAT STR®

Which Bioreactor Fits Your Needs?

Available for Cell Culture (CC) or Microbial (MO) Culture	Screening of Media, Clones or Expression Constructs	Small-Scale Protein Supply	Process Development Optimization, Characterization	Seed Expansion	Production	Product
CC	▢		(▢)			ambr® 15 cell culture Generation 2 >
MO						
CC						ambr® 15 fermentation >
MO	▢					
CC	▢	(▢)	▢			ambr® 250 high throughput >
MO	▢	(▢)	▢			
CC	▢	(▢)	▢			ambr® 250 modular >
MO	▢	(▢)	▢			
CC	(▢)	▢	(▢)	▢		BIOSTAT® A >
MO	(▢)	▢	(▢)	▢		
CC	▢	▢	▢	▢		BIOSTAT® B >
MO	▢	▢	▢	▢		
CC	▢	▢	▢	▢		BIOSTAT® B-DCU >
MO	▢	▢	▢	▢		
CC		▢	▢	▢	(▢)	BIOSTAT® Cplus >
MO	(▢)	▢	▢	▢	(▢)	
CC		▢	▢	▢	▢	BIOSTAT® D-DCU >
MO		▢	▢	▢	▢	
CC		▢		▢	▢	BIOSTAT® RM >
MO		(▢)		(▢)	(▢)	
CC			▢	▢	▢	BIOSTAT® RM TX >
MO						
CC		▢	▢	▢	▢	BIOSTAT STR® >
MO		(▢)	(▢)	(▢)	(▢)	

▢ Typical applications
(▢) Selected applications

ambr® 15 cell culture Generation 2

ambr® 15 fermentation

ambr® 250 modular

ambr® 250 high throughput

BIOSTAT® A

BIOSTAT® B

Product	Cultivation Chamber Type			Number of Parallel Vessels	Max. Vessel Working Volume
	Single-Use	Glass	Stainless Steel		
ambr® 15 cell culture Generation 2 >	✓			24 | 48	10 – 15 mL
ambr® 15 fermentation >				24	8 – 12 mL
	✓				
ambr® 250 high throughput >	✓			12 | 24	100 – 250 mL
	✓				
ambr® 250 modular >	✓			2 | 4 | 6 | 8	100 – 250 mL
	✓				
BIOSTAT® A >	✓	✓		1	1 – 5 L
		✓			
BIOSTAT® B >	✓	✓		2	1 – 10 L
		✓			
BIOSTAT® B-DCU >	✓	✓		6	1 – 10 L
		✓			
BIOSTAT® Cplus >			✓	1	5 – 30 L
			✓		
BIOSTAT® D-DCU >			✓	2	10 – 200 L
			✓		
BIOSTAT® RM >	✓			2*	0.5 – 100 L
	✓*				
BIOSTAT® RM TX >	✓			2	0.5 – 5 L
BIOSTAT STR® >	✓			2**	50 – 2,000 L
	✓*				

✓ Available
✓* Available for low cell density applications

* Twin versions available for RM Rocker 20 L and 50 L
** Twin versions available for BIOSTAT STR® 50 L and 200 L


BIOSTAT® B-DCU


BIOSTAT® Cplus


BIOSTAT® D-DCU


BIOSTAT® RM


BIOSTAT® RM TX


BIOSTAT STR®

ambr® 15 cell culture Generation 2

Advanced Microbioreactor System for Cell Culture Applications

Learn more about the new generation of ambr® 15 cell culture

Applications
- Clone selection
- Media and feed development
- Early process optimization
- Perfusion mimic processes
- DOE studies

Gas Supply Options > 68

ambr® 15 Individual Gas Supply

ambr® 15 cell culture is an automated, high throughput microbioreactor system that monitors and controls 24 or 48 cultures in parallel with working volumes from 10 – 15 mL.

ambr® 15 cell culture replicates laboratory scale bioreactor performance at the microscale. It comprises single-use cell culture vessels, automated workstation and powerful software, ambr® 15 cell culture is installed in a biological safety cabinet for aseptic operation.

The Generation 2 system offers improved performance, increased flexibility and extended capability to support more applications. It has been developed to answer the challenges faced as biotherapeutics become more complex, and processes more intensified.

New flexible operation with flexible deck layout and expanded tip bin capacity	▶	Increases walk-away time to maximize operator productivity
New rapid vessel drain functionality and process steps	▶	Enables clone stability studies, media exchanges and perfusion mimic processes to be performed
New liquid handler and culture station design	▶	Improves performance and allows lower stirrer speeds for sensitive cell lines
New ambr® clone selection software, 1 year license	▶	Simplifies the clone selection data workflow helping operators to select the best clones
Wide range of cell lines and processes	▶	Suitable for CHO, NS0, HEK293, T-cells, iPSCs, NK cells and many more

ambr® 15 fermentation

Advanced Microbioreactor System for Microbial Applications

Take a tour of the ambr® 15 fermentation workstation and microbioreactor vessel

Applications
- Strain selection
- Vector screening
- Media and feed development
- Early process optimization
- DOE studies

ambr® 15 fermentation is an automated, high throughput microbioreactor system that monitors and controls 24 cultures in parallel with working volumes from 8 – 12 mL.

ambr® 15 fermentation is dedicated to microbial applications. It provides a reliable microscale model for early stage microbial screening and optimization experiments. It comprises single-use microbial vessels, automated workstation and powerful software, ambr® 15 fermentation is installed in a biological safety cabinet for aseptic operation.

Fed-batch operation supports high density fermentations, improving early stage predictions of large scale bioreactor performance compared to shake flask or plate based cultures.

Now available with integrated online biomass measurement for real-time continuous growth measurement of microbial cultures.

Pumped pH reagent and feed addition	▶	Enables more predictive high cell density cultures
High k_La values	▶	Supports E.coli growth to over OD 200
Culture station stirrer control	▶	Representative conditions compared to lab scale bioreactors
Independent bioreactor control of pH, DO and temp	▶	More reliable and scalable results than shake flasks
Automated sampling and addition of liquid feeds	▶	Reduces hands-on operator time and cost

Gas Supply Options > 68

ambr® 15 Individual Gas Supply

ambr® 15 Vessels

Single-Use Microbioreactor Vessels for High Throughput Screening

Applications
- Clone or strain screening
- Media development
- Cell culture
- Microbial fermentation

ambr® 15 automated bioreactor systems use irradiated single-use microbioreactor vessels configured either for cell culture or microbial cultivations.

The ambr® 15 microbioreactor vessel design incorporates single-use pH and pO_2 sensor spots, integrated impellers, vessel port with cap for sampling and liquid additions, and entry for gas supply. Microbial vessels have additional lines for base and feed.

The microbioreactors are easily loaded into the culture stations prior to starting ambr® 15 cultivations.

Cell culture vessels for ambr® 15 cell culture include a pitched blade impeller, they can be supplied with or without gas sparge line for headspace gassing or gassing into the impeller mixing zone.

Microbial vessels for ambr® 15 fermentation include a Rushton impeller, gas sparge line, supply plate and lines for base and feed pumped liquid additions.

Integrated pH and pO_2 spots	▶ Provides highly predictive screening results under controlled bioreactor conditions
Integrated impeller and sparge tube	▶ Efficiently mixes liquid and gas, delivering scalable results
10–15 mL working volume (cell culture) 8–12 mL working volume (fermentation)	▶ Enables repeated culture sampling in a compact and cost-effective format
Robotic compatible cap	▶ Improves productivity and reduces errors by automating sampling, feeding and reagent addition
Irradiated single-use vessel	▶ Enables same-day turnaround of the ambr® 15 system, increasing throughput and reducing timelines


ambr 15
cell culture
sartorius stedim

ambr® 250 high throughput

Single-Use Multi-Parallel Bioreactor, Fully Automated for Accelerated Process Development

Find out about ambr® 250 high throughput

Applications
- Process development
- Scale-down model development
- Process characterization

Gas Supply Options > 68

ambr® 250 Individual Gas Supply

The ambr® 250 system is a high throughput, automated bioreactor system for process development with 12 or 24 fully featured single-use 100 – 250 mL mini bioreactors.

This is a completely integrated high throughput system with Easy Connect bioreactors and flexible software that enables scientists to manage many experiments at the same time while reducing the costs per experiment.

The ambr® 250 is ideal for scaling down processes based on its fully featured bioreactor design and provides a step change improvement in lab productivity.

Fully automated 12- or 24-way bioreactor system with liquid handling capability and intuitive control software	▶ Manage more experiments in parallel and reduce manual handling cost per experiment
Fully disposable, single-use Easy Connect mini bioreactors	▶ Fast turnaround of up to 24 bioreactors in less than one day
Classic stirred tank bioreactor design	▶ Provides excellent scalability to lab-scale bioreactors
Flexible software and individual control of all process parameters	▶ Enables DOE optimization of all parameters, ensuring implementation of QbD principles
Relatively small footprint and integrated biological safety cabinet	▶ Flexible system – fit 12 or 24 bioreactors in any laboratory
Positive displacement pumps and mass flow controlled gassing	▶ Highly accurate liquid and gas flow at low flow rates

ambr® 250 Vessels

Fully Featured Single-Use Mini Bioreactor Vessels

Applications
- Process development
- Scale-down model development
- Process characterization

Each ambr® 250 automated bioreactor system uses 12 or 24 single-use mini bioreactors with a working volume ranging from 100 – 250 mL.

The fully featured vessel design incorporates an integrated single-use pH electrode and pO_2 spot sensor. Each system is irradiated for supply as presterilized units.

You can choose between mammalian cell culture vessels with pitch blade impellers or microbial fermentation vessels with Rushton impellers.

A simple three-step Easy Connect process enables you to quickly hook up all the gas, liquid and sensor lines to each vessel and thus significantly reduce the time needed to set-up multiple bioreactor experiments.

Fully featured, classic stirred tank vessel	▶ Applicable as a scale-down model
Integrated Easy Connect gas and liquid in-line filters	▶ Simplifies the process of system set-up and results in fast turnaround between experiments
100 – 250 mL working volume with baffles	▶ Reduces reagent costs and supports enhanced off-line analysis
Polycarbonate vessel construction and integrated pH electrode and pO_2 spot	▶ Fully disposable with no need to clean between runs or refurbish probes
Robotic compatible cap for sampling	▶ Improves productivity and reduces errors by enabling automated inoculation, feeding and sampling

ambr® 250 high throughput perfusion

The Fast Track to Intensified Cell Culture Processes Development

Read about ambr® 250 high throughput perfusion

Applications
- Perfusion cell culture
- Process development
- Intensified fed-batch
- Continuous perfusion
- Seed train optimisation

The ambr® 250 high throughput perfusion system is a high throughput, automated bioreactor system for a range of applications in perfusion cell culture process development.

This next-generation perfusion bioreactor system can enable and enhance your perfusion process development in several key areas, including seed train optimisation, intensified fed-batch, and continuous perfusion.

Different process types can be run in parallel or in series, including both perfusion and fed-batch process types.

Integrated single-use perfusion bioreactors	▶ Reduce complexity and setup time
Fully automated parallel system	▶ Increase experiment size and consistency
Industry standard bioreactor and perfusion filter	▶ Results are predictive of larger scale performance
Lower media and labour costs	▶ Increased cost effectiveness
Enables larger perfusion studies and DOE	▶ Improve development timelines and process performance

ambr® 250 perfusion Vessels

Single Use Mini-Bioreactor Vessels with Perfusion Capability

Applications
- Perfusion cell culture
- Process development
- Intensified fed-batch
- Continuous perfusion
- Seed train optimisation

ambr® 250 high throughput single-use perfusion bioreactors include all key elements required for perfusion culture, in a simplified and user-friendly format.

Single-use perfusion bioreactors significantly reduce staff time needed for set-up and cleaning, and enable rapid system turnaround. This increases system utilization efficiency and helps to reduces development timelines.

Integrated components further reduce set-up time and minimize risk of lost experiments. ambr® 250ht perfusion bioreactors are available in both alternating tangential flow (ATF) and tangential flow filtration (TFF) variants.

High efficiency sparger	▶	Supports very high cell densities
30 kDa or 0.2 µm filter	▶	For product retention or flow through
Single use pressure sensors	▶	Monitor transmembrane pressure
Perfusion pump system	▶	Performs crossflow and bleed functions
Integrated and irradiated	▶	Reduce complexity and setup time

ambr® 250 modular

Increased Productivity with Simplified Operation

Find out more about ambr® 250 modular

Applications
- Process optimization
- Process characterization
- Process scale-down model

Gas Supply Options > 68

ambr® 250 Individual Gas Supply

ambr® 250 modular is an innovative easy-to-use benchtop bioreactor system that can be expanded from a 2 to 8 bioreactor system, using fully integrated single-use 100 – 250 mL mini bioreactors.

The system utilizes the same advanced stirred tank bioreactor technology pioneered in the original ambr® 250 high throughput system. The system comprises a series of elegantly designed benchtop modules enabling 1 – 8 bioreactors to be operated in parallel and a control module with intuitive system software accessed via a user-interface screen.

Classic stirred tank bioreactors	▶ Provide excellent scalability to lab-scale bioreactors
Benchtop bioreactor system that is modular and expandable	▶ A flexible system that can be expanded to meet increased demand
Single-use bioreactors are fully integrated to reagent reservoirs and syringe pumps	▶ Increase productivity by enabling experimental set-up and turnaround to be carried out quickly and easily
Positive displacement pumps and mass flow controlled gassing	▶ Highly accurate liquid and gas flow at both high and low flow rates

ambr® 250 modular Vessel

Fully Integrated Single-Use Mini Bioreactor Vessels

Applications
- Process optimization
- Process characterization
- Process scale-down model

The ambr® 250 modular bioreactor is a single-use bioreactor vessel that is fully integrated to 5 reagent reservoirs and syringe pumps allowing for significant simplification of experimental set-up.

Each bioreactor is fully integrated with 5 liquid reservoirs and proprietary single-use syringe pumps.

The integration simplifies experimental set-up, eliminates any need for sensor or pump calibration, and significantly reduces any error due to manual handling.

Bioreactor fully integrated to reagent reservoir and syringe pumps	▶ Allows for rapid experimental set-up and turnaround
Single-use syringe pumps	▶ Enables highly consistent and accurate liquid delivery
Classical stirred tank vessel design	▶ Enabling accurate scale-down modelling
Single-use technology	▶ Eliminates need for sensor or pump calibaration ensuring easy and rapid experimental set-up


sartorius
sartorius stedim

BIOSTAT® A

Your Professional Start to Controlled Cultivation

See how easy it can be to control a bioreactor

Applications
- Microbial fermentation and cell culture
- Academic education and technical training
- Early-stage research and development

BIOSTAT® A is a minimum footprint and easy-to-use bioreactor | fermenter designed as an entry-level model for microbial fermentation and cell culture.

With its compact design, BIOSTAT® A saves valuable space in your laboratory. If you are looking for a bioreactor for training purposes or for scale-up from shake flask to controlled cell growth, BIOSTAT® A is the perfect fit.

BIOSTAT® A is available in configurations for microbial fermentation and for cell culture applications.

It can be combined with the UniVessel® Glass in a range of 1 L, 2 L and 5 L, as well as with the 2 L single-use UniVessel® SU. Using the advanced package, you can operate it by a tablet or a smartphone and can perform fed-batch processes.

Intuitive operation concept including operation via tablet and smartphone	▶ Speeds up training and reduces the risk of operating errors
Integrated, circulated cooling for microbial fermentation	▶ Allows fermentation in any lab and minimizes water usage
Simple and automatic aeration control	▶ No manual adjustment of flow meters and no pulsed aeration
Easy interchangeability between reusable and single-use culture vessels	▶ More flexibility every day
Fast Load pumps	▶ Easy, fast and safe handling of tubing

BioPAT® Sensor and Software Options:
- **MFCS:** Supervisory Control and Data Acquisition > 84

Gas Supply Options > 68

Additive Flow

BIOSTAT® B

The Multi-Talent for Research and Process Development

Check out the possibilities of BIOSTAT® B

Watch Video on Sartorius Benchtop Bioreactor Website

Applications

- Microbial, insect and mammalian cell culture
- Suspension and microcarrier cultivation
- Process development
- Process optimization
- Process characterization

The BIOSTAT® B is our universal benchtop controller for stirred and rocking motion systems.

With multiple thousand installations worldwide, the BIOSTAT® B is the market leading benchtop system for various R&D applications.

One BIOSTAT® B control tower controls up to two culture vessels completely independently, saving valuable bench space.

It is available with the UniVessel® Glass in a range of 1 L, 2 L, 5 L and 10 L, as well as with the 2 L single-use UniVessel® SU and with the RM Rocker in a choice of 20 L and 50 L.

Stirred and rocking motion, reusable and single-use culture vessels – all controlled with one DCU tower	▶ Flexibility of bioreactor system – suitable for various demands
Single or twin set-up for control of one or two culture vessels	▶ Saves valuable bench space
Configurable design thanks to variety of flexible and scalable options	▶ Fully configurable BIOSTAT® B meets customer specific needs
12" touch screen and stainless steel housing	▶ Simple to operate and easy to clean
Gassing system comparable to our BIOSTAT STR® with up to four mass flow controllers	▶ Straightforward process transfer to production-scale, single-use bioreactors

BioPAT® Sensor and Software Options:

- **ViaMass:** Viable biomass measurement > 74
- **Trace:** Glucose | Lactate measurement > 76
- **Fundalux:** Turbidity measurement > 77
- **Xgas:** Off-gas analysis > 88
- **MFCS:** Supervisory Control and Data Acquisition > 84

Gas Supply Options > 68

Additive Flow

Advanced Additive Flow

BIOSTAT® B-DCU

The Ultimate Tool for the Development of Intensified Bioprocesses

The BIOSTAT® B-DCU is designed to meet demanding requirements in process optimization and characterization – especially for intensified bioprocesses.

The BIOSTAT® B-DCU provides enhanced functionality and an unrivalled level of options to flexibly design process control strategies. It is the ideal scale-down bioreactor model for cell culture and microbial processes as it can emulate process strategies used at production scale. The unique system design enables the independent operation of up to six culture vessels and makes it an ideal tool for MSAT as well as process optimization and characterization teams.

The BIOSTAT® B-DCU can be combined with glass culture vessels, ranging from 1 L, 2 L and 5 L to 10 L, and with the 2 L single-use UniVessel® SU.

Advanced and precise control of multiple liquid lines for feed, bleed and permeate flow plus fully flexible aeration options make our BIOSTAT® B-DCU the ultimate tool for the development of intensified bioprocesses with ultra high cell densities.

Integration of advanced BioPAT® sensor and process control options	▶ Better process control and optimization options lead to improved titer and quality
Connectivity to third party supervisory software including DeltaV™ [1]	▶ Integration into existing supervisory control infrastructure reduces human error and improves data consistency
Large number of configuration options, based on decades of experience	▶ Reliability and flexibility for seamless scale-up and scale-down allows hassle-free process optimization and characterization
Superior gas mixing with up to six smart mass flow controllers with a 1:200 flow range	▶ Accurate oxygen control across large cell density range and precise down scalling of large scale bioreactors

Learn more about the BIOSTAT® B-DCU as Perfusion Bioreactor

Applications

- Perfusion & concentrated fed-batch processes
- Mammalian, microbial and insect cell cultures
- Process optimization
- Process characterization
- Process development

BioPAT® Sensor and Software Options:

- **ViaMass:** Viable biomass measurement > 74
- **Trace:** Glucose | Lactate measurement > 76
- **Fundalux:** Turbidity measurement > 77
- **Xgas:** Off-gas analysis > 88
- **MFCS:** Supervisory Control and Data Acquisition > 84

Gas Supply Options > 68

- O_2 Enrichment
- Additive Flow
- Advanced Additive Flow

[1] DeltaV™ is a trademark of Emerson Process Management

UniVessel® Glass

Multi-Purpose Glass Culture Vessel

Get more information about the features of UniVessel® Glass

Applications

- Perfusion and concentrated fed-batch processes
- Microbial fermentation (bacteria, yeast, fungi)
- Animal cell culture (mammalian, insect)
- Adherent cell cultures on microcarriers
- Process development and optimization
- Scale-up and scale-down studies

Bottom drain option

UniVessel® Glass culture vessels are specifically tailored to the needs of biopharmaceutical process development e.g. for such as monoclonal antibodies, recombinant proteins and vaccines.

The autoclavable UniVessel® Glass can be configured according to individual needs. Over 50 years of experience in designing scalable bioreactors have gone into the making of UniVessel® Glass. Numerous scientific articles on its scalability and reproducibility have meanwhile been published.

Our recently launched new design is lighter, easier to handle and dishwasher proof. The special bottom drain version makes it ideal for ATF and TFF based intensifed processes.

Configuration Examples

For microbial culture, with double-wall vessel, Rushton impellers, baffles, inoculation port and ring sparger

For cell culture, with single-walled vessel, 3-blade segment and Rushton impellers, micro-sparger and dip tube for gentle inoculation.

Lighter design, easier to handle and dishwasher proof	▶ Quick turnaround, easy to use
Classic stirred-tank design, characterization data available	▶ Straightforward scale-up
Fits into small autoclaves	▶ Saves investing in new autoclave
Choice of 1 L, 2 L, 5 L, 10 L working volumes	▶ Flexible interchangeability between vessel sizes without extra investments into a new controller
Fits to all BIOSTAT® benchtop systems	▶ Lowers the investment budget for new controllers as the available UniVessel® Glass can be used

UniVessel® SU

Single-Use Bioreactor, Proven Design, Ready for the Future

Turn the production process to single-use

Applications
- Mammalian and insect cell culture
- Suspension and microcarrier cultures
- Process development and optimization
- Seed expansion

The UniVessel® SU is a stirred-tank single-use bioreactor with a working volume range of 0.6 – 2 L. It is entirely single use from vessel to sensors and can easily be connected to existing bioreactor controllers.

It combines the proven, scalable design of glass bioreactors and the fast turnaround of single-use systems. UniVessel® SU can be easily integrated into both new and existing bioreactor controllers in customer's lab. The optical holder guarantees secure vessel stand and its built-in single-use measurements for pH and DO minimize vessel preparation time.

It can be used interchangeably with glass vessels to help efficiently manage peak workloads despite challenging timelines. Since discarding the complete vessel after one use, the user hasn't to bother with the hassle of cleaning, autoclaving and reinstallation.

All single-use from vessel to sensors	▶ Achieves turnaround in less than an hour
Compatible with your available bioreactor controllers	▶ Enables you to utilize your existing controllers with cutting-edge, single-use vessels and sensors; no additional investment in new controller needed
Interchangeable with glass vessels	▶ No more bottlenecks during peak workloads
Proven and scalable design	▶ Same design principles as glass bioreactors and BIOSTAT STR®, to reduce time and effort for process development, optimization and validation

BIOSTAT® RM TX with Flexsafe® RM TX Bags

Culturing Consistent Quality Products for Cell Therapy Applications

Learn more about the BIOSTAT® RM TX for cell therapy applications

Applications
- Process Development
- Immunotherapy
- Ex vivo expansion of patient-specific T-cells and | or T-cell subsets

The BIOSTAT® RM TX and Flexsafe® RM TX bag combination provides an automated, wave-mixed and closed environment suitable for optimal growth of cell products in working volumes up to 5 L.

The system supports the culturing of consistent quality cells and is perfect for small volume autologous processes with multi-parallel scale out needs. Using this system, one Flexsafe® RM TX bag can be controlled and monitored via the BIOSTAT® B control unit.

For scale-out, two Flexsafe® RM TX bags and two separate rocking platforms can be attached to a twin BIOSTAT® B control unit. Fed-batch, perfusion processes or a combination of culture modes are possible with the BIOSTAT® RM TX.

Fixed perfusion membrane at the bottom of the bag, for removal of cell free media during perfusion process	▶ Minimal loss or damage of the cells
Single-Use sensors for pH, DO and viable biomass	▶ To enable sophisticated process control with reduced sampling need
100% integrity tested, gamma-irradiatable and fully validated Sartopore® Air sterile filters	▶ Continuous protection of the culture from contamination
Unique gravity harvesting concept (see picture)	▶ To maximize cell recovery
Walk-away automated analysis and control	▶ For robust & consistent manufacturing
Complete qualification of the system	▶ For GMP use to support regulatory compliance

BioPAT® Sensor and Software Options:

- **ViaMass:** Viable biomass measurement > 74
- **MFCS:** Supervisory Control and Data Acquisition > 84

Gas Supply Options > 68

Advanced Additive Flow

BIOSTAT® RM 20|50

Easy-to-Use Rocker

Learn more about the BIOSTAT® RM as a fully GMP compliant wave-mixed bioreactor

Applications

- Mammalian, insect and plant cell cultures
- Suspension cells and adherent cells on microcarriers
- Low to medium density microbial cultures
- Expansion and differentiation of stem cells
- Rapid material supply for preclinical trials
- Production of recombinant proteins, mAbs and vaccines

The BIOSTAT® RM is a fully GMP compliant single-use, wave-mixed benchtop bioreactor. It is perfectly sized and suitable for stand alone use or in combination with a control tower (BIOSTAT® B).

It features an exchangeable bag holder to fit bags with a total volume of 1–50 L. The BIOSTAT® RM basic rocking platform with an integrated local controller, optional Air | CO_2 mixing module and load cells is the optimal choice for straight-forward applications, such as seed generation.

For more sophisticated process control the BIOSTAT® RM basic can be combined with the BIOSTAT® B tower to run fully automated and controlled batch, fed-batch or high cell density perfusion cultures.

Individual control of two bags on one platform	▶ Space-saving
Advanced alarming and safety features	▶ Safe cultivation
Automated sampling function	▶ Reduced manual handling
Basic configuration in combination with BIOSTAT® B controller	▶ Maximum process flexibility
Advanced process analytical sensor options in combination with BIOSTAT® B controller	▶ For increased process safety and reduced sampling need

BioPAT® Sensor and Software Options:

- **ViaMass:** Viable biomass measurement > 74
- **MFCS:** Supervisory Control and Data Acquisition > 84

Gas Supply Options > 68

Advanced Additive Flow

BIOSTAT® B with RM 200 Rocker

Large-Scale, Rocking-Motion, Single-Use Bioreactor

Learn more about the BIOSTAT® RM 200 rocker as a large-scale bioreactor

Applications

- Mammalian, insect and plant cell cultures
- Suspension and adherent cell cultures on microcarriers
- Low to medium density microbial cultures
- Shear-sensitive cells, such as stem cells
- Large-scale seed expansion
- Small-scale production of recombinant proteins, vaccines and mAbs

The BIOSTAT® B with RM 200 rocker is a single-use, rocking motion bioreactor for large-scale. Flexsafe® RM 100 L and 200 L bags are also available with a bag integrated perfusion filter. This solution is ideal for intensified seed supply without the need for an external cell retention device, e.g. ATF.

BIOSTAT® B with RM 200 rocker is the ideal choice for production-scale seed expansion and rapid material supply for preclinical and clinical studies using proven rocking motion technology.

The bag holder fits Flexsafe® RM bags providing working volumes up to 100 L.

Flexsafe® RM bags can be used in your seed train processes and scaled up to the BIOSTAT STR® single-use, stirred tank bioreactors equipped with Flexsafe STR® bags. Thereby the same polyethylene film material can be used across all cell culture steps.

Low consumable costs	▶ Economical alternative to stirred single-use bioreactors
Well-proven technology with intuitive design	▶ Easy to operate
Precise gravimetric harvest and feed controllers	▶ Reliable and efficient cultivation
Independent controller and rocking platform unit	▶ Flexible space-saving component arrangement

BioPAT® Sensor and Software Options:

- **ViaMass:** Viable biomass measurement > 74
- **MFCS:** Supervisory Control and Data Acquisition > 84

Gas Supply Options > 68

Advanced Additive Flow

Flexsafe® RM

Excellent Growth in Flexsafe® Bioprocessing Bags

Applications
- Mammalian cells
- T-cells
- Insect cells
- Plant cells
- Stem cells
- Microbial cells

The Flexsafe® RM is a single-use bioreactor bag available in multiple sizes and configurations. The control of the complete manufacturing process, from resin to the final bag, ensures consistent and reproducible quality of the Flexsafe® bioprocessing bags.

This has been proven by excellent and lot-to-lot consistent cell growth performance of this multilayer polyethylene film. Our BIOSTAT® RM bioreactors use rocking motion mixing technology which is ideal for cell cultivation with low shear stress. Flexsafe® bags are available in 1 L, 2 L, 10 L, 20 L, 50 L, 100 L and 200 L size as basic, optical and perfusion configurations, with or without BioPAT® ViaMass. Basic bags are designed for use in seed train and production applications without pH and DO control.

Optical bags feature integrated single-use opto-chemical pH and DO sensors, which are already pre-calibrated. Perfusion bags are available in two versions:

- with integrated 1.2 µm perfusion membrane (PES)
- ATF perfusion bags are designed for the convenient connection to an external cell retention device via OPTA connector.

BioPAT® Sensor and Software Options:

- **ViaMass:**
  Viable biomass measurement > 74

Strong and flexible film	▶ Ultimate process safety	fast & easy handling
Optimized and fully controlled film formulation	▶ Consistent cell growth, security of supply
Basic, optical or perfusion bag designs	▶ Wide range of standard bags is suitable for many different needs and applications
Integrated single-use sensors for measurement of viable biomass, pH and pO_2	▶ Reduced operator interaction enables higher automation level and thereby decreases contamination risk

BIOSTAT STR®

Perfect Match for True Scalability in Single-Use

Learn more about the BIOSTAT STR® bioreactor family

Applications

- Antibodies, recombinant proteins, vaccines, cell & gene therapy
- High cell density exceeding 150 million cells/mL
- Adherent cell culture on microcarriers
- Process development and scale-up
- Seed expansion

BioPAT® Sensor and Software Options:

- **ViaMass:** Viable biomass measurement > 74
- **Trace:** Glucose | Lactate measurement > 76
- **Xgas:** Off-gas analysis > 88
- **MFCS:** Supervisory Control and Data Acquisition > 84

Gas Supply Options > 68

Additive Flow

Advanced Additive Flow

The BIOSTAT STR® single-use bioreactor design is based on the gold standard of conventional stirred-tank bioreactors.

Simplify the scale-up and scale-down, minimize the risk of your process transfers and easily switch between stainless steel and single-use bioreactors.

BIOSTAT STR® makes all this possible thanks to its classic stirred-tank design, comparable mixing and gassing strategies and reliable single-use sensor platform.

Get the best solution for high cell density continuous cultures and microcarrier cultures. BIOSTAT STR® is available with working volumes of 50 L, 200 L, 500 L, 1,000 L and 2,000 L.

The latest generation design offers a number of features such as connectivity to our BioPAT® MFCS or 3rd party supervisory software like DeltaV™ [1].

Geometrical similarity of vessel design	▶ Straighforward scalability between scales and from multi-use systems
Proven stirrer design with two impellers on central shaft	▶ Excellent fluid flow dynamic – minimized mixing time
Advanced aeration concept	▶ Excellent oxygen transfer and CO_2 removal at minimized foaming
Advanced single-use pH and pO_2 sensors	▶ Low contamination risk; easy and quick handling
Easy integration into 3rd party distributed control system (e.g. Delta V™ [1])	▶ Reduce operator training and mitigate human error

[1] DeltaV™ is a trademark of Emerson Process Management

Flexsafe STR®

Single-Use Bags for BIOSTAT STR®

Learn more about the Flexsafe STR® single-use bags

Applications
- Suspension or adherent cell culture on microcarriers
- Mammalian, insect and stem cell culture
- Low to medium cell density microbial culture

Flexsafe STR® single-use bags for our BIOSTAT STR® bioreactor are a member of our bioprocessing bag family, combining outstanding cell growth, robustness and assurance of supply.

Flexsafe STR® facilitates single-use manufacturing there by meeting the most stringent customer needs for safe bioprocessing.

Flexsafe STR® bags are configurable, offering multiple options for tubing, connectivity to cell retention devices (ATF type), spargers and impeller combinations. The preferred single-use pH sensor can be choosen between the proven optical technology and the new dry-storage electrochemical solution.

Pre-configured standard bags are available from stock.

The same polyethylene film material can be used across all cell culture steps. Flexsafe® RM bags can be used in a seed train process, e.g. together with our BIOSTAT® RM bioreactors. For media storage, shipping and bulk harvest hold. Flexsafe® 3D bags can be used.

* Available bag working volumes:
50 L, 200 L, 500 L, 1,000 L, 2,000 L

BioPAT® Sensor and Software Options:

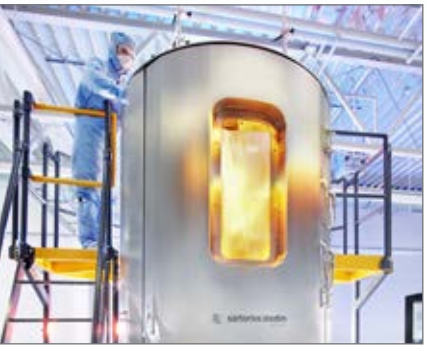
- **ViaMass:**
  Viable biomass measurement > 74

Robust bag with telescopic shaft	▶ Easy installation and reliable operation
Complete control of film raw materials	▶ Consistent lot to lot cell growth performance
Sterile connection and disconnection devices	▶ Safe liquid transfer
Needle-free sampling port	▶ Easy and convenient sampling

Flexsafe STR® Point-of-Use Leak Test

Process Safety with Bag Post-Installation, Pre-Use Testing

Learn more about the Integrity Testing incl. bag test



The innovative Sartocheck® 4 plus bag tester technology applied to Flexsafe STR® single-use bioreactors will secure processes in case the bag got damaged during transportation etc.

Intactness of Flexsafe STR® single-use bioreactors can be easily checked at point of use to ensure an optimal process and operator safety thanks to fully validated and qualified technology.

This non destructive method will prevent batch losses, time and money waste due to potential bag mishandling.

Post-installation, pre-use pressure decay testing	▶ Mitigate risk of batch losses ▶ Keep projects timelines on track
Test bag and connections until the first clamp	▶ Check bag intactness just before use
Patented, qualified non destructive technology	▶ Reliably and reproducibly detects leaks
Single-use and easy to use fleeces	▶ Low impact on process timeline

Holistic Safety Concept of BIOSTAT STR®

Sartorius has developed a holistic safety concept, from production site to post-use disposal, which brings ultimate safety to single-use bioprocessing.

Production
- Incoming goods inspection
- ISO7 cleanroom bag assembly
- Qualified staff and manufacturing SOPs
- Stringent quality control

Transportation
- Innovative packaging concept protects bag until final installation

Installation
- System designed for convenient installation to reduce operator manipulation
- Detailed instructions in operating manual available
- Video installation guide available
- Aseptic connector technology
- Bag tester for point-of-use leak test

Operation
- Proven cell culture performance
- Extensive application-based robustness qualification
- Pressure measurement and control keeps bag pressure within permissible range
- Single-use exhaust cooler eliminates blockage of exhaust filter
- Overheating protection to maintain material properties
- Completely closed bag with non-invasive magnetic coupling and single-use sensors
- Spill tray with direct connection to kill tank

Deinstallation
- Aseptic disconnection
- Convenient disassembly

Flexsafe® Bag Family

Safe and Convenient Single-Use Processing

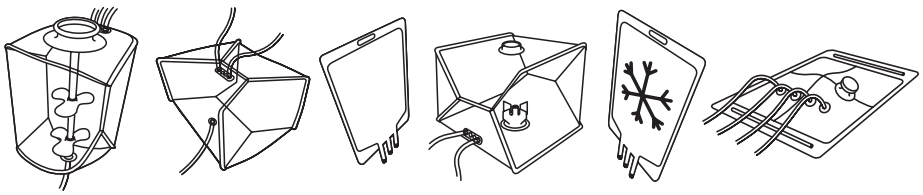
Flexsafe® – One Film Across All Single-Use Applications

Flexsafe® meets the requirements for outstanding robustness and ease of use throughout all steps of single-use processing – from rocking motion or stirred tank bioreactor cell culture, through to large-scale mixing to shipping of drug products. In addition, Flexsafe® reduces time and expense for process validation, extractable and leachable studies, toxicology assessment and stability studies.

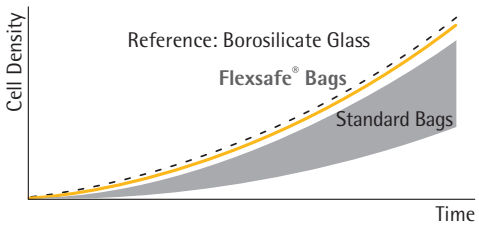
One for All

Learn more about the Flexsafe® bag family

Watch Video: New Bag Family



Cell Growth

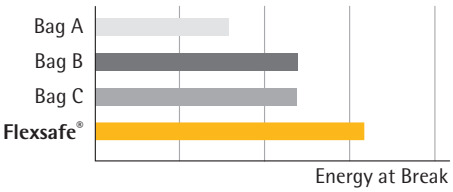


Flexsafe® ensures excellent and reproducible growth behavior of the most sensitive production cell lines. The complete control of our raw materials, the extrusion process and the bag assembly guarantees consistent lot-to-lot cell growth performance.

We optimized the resin and minimized the additive package, in collaboration with our resin and film suppliers.

Independent labs have confirmed that Flexsafe® bags are free of cytotoxic leachables. No bDtBPP is identified in WFI extracts of Flexsafe® bags.

Robustness



The thickness, strength and flexibility of the new polyethylene film enhances the mechanical robustness of Flexsafe® – making it ideal for all bioprocessing applications. The strength of Flexsafe® significantly reduces the risk of accidental damage to the bag due to inappropriate handling. Its flexibility enables convenient installation and self-deployment of the bag in its container.

Assurance of Supply

Flexsafe® provides you with an unprecedented assurance of supply and enables robust business continuity plans. Our strategic partnership with resin and film suppliers ensures full traceability of raw materials and control over the entire manufacturing process from the resins to the final assembled bags.

Rely on Proven Scalability – Accelerate The Development

Sartorius Stedim Biotech offers classic stirred-tank design in single-use bioreactors, from ambr® 250 to BIOSTAT STR® 2000.

- Geometrical similarity of vessel design
- Consistent mixing and gassing strategies
- Reliable single-use sensor platform

Simplify your scale-up and scale-down studies
Easily switch between reusable and single-use bioreactors
Mitigate risks during process transfers

ambr® 250
100 – 250 mL
working volume

UniVessel® SU 2 L
0.6 – 2 L
working volume

BIOSTAT STR® 50
12.5 – 50 L
working volume

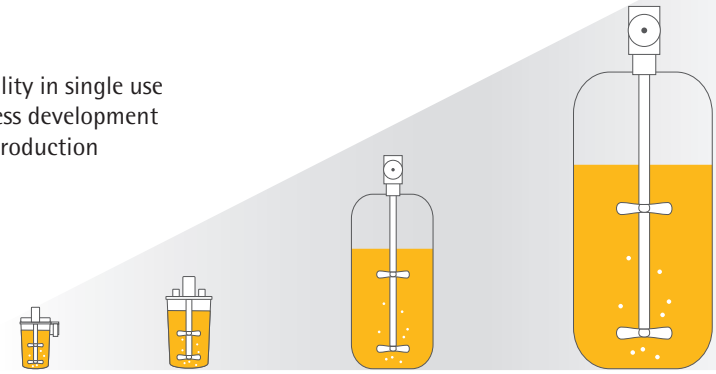
BIOSTAT STR® 200
50 – 200 L
working volume

BIOSTAT STR® 500
125 – 500 L
working volume

Cell line Development | Process Development | Production

- Mammalian, insect and stem cell culture
- High cell density cultures exceeding 150 million cells/mL
- Adherent cell culture on microcarriers
- Low to medium cell density microbial culture

Seamless scalability in single use
from early process development
to commercial production



250 mL | 2 L | 50 L | 2000 L

BIOSTAT STR® 1000
250 – 1,000 L
working volume

BIOSTAT STR® 2000
500 – 2,000 L
working volume

- Antibodies and recombinant proteins
- Vaccines
- Cell and gene therapy

For further details please have a look
at our website.

BIOSTAT® Cplus

The Stainless Steel Fermenter | Bioreactor for Your Laboratory

Learn more about the BIOSTAT® Cplus as a laboratory stainless steel fermenter

Applications
- Microbial and cell culture
- Suspension and microcarrier cultures
- Process development and scale-up
- Seed production
- Protein supply for research and development

BIOSTAT® Cplus is a fermenter | bioreactor developed for the fermentation of microorganisms and cultivation of animal cells.

The BIOSTAT® Cplus is available with a selection of culture vessels with working volumes of 10 L, 15 L, 20 L and 30 L. A benchtop version is available with a 5 L working volume culture vessel. The system can be flexibly integrated into an existing laboratory infrastructure. The culture vessel can be sterilized by electro or steam heating. The casters under the supply unit of the bioreactor enable it to be easily moved to another location. Extended functionality and ease of use is provided by a wide choice of in-line sensors and anaylzers with an integrated display of process values on the DCU screen. For enhanced system performance, the powerful SCADA software BioPAT® MFCS is available with an optional S88 recipe control module.

BioPAT® Sensor and Software Options:
- **Trace:** Glucose | Lactate measurement > 76
- **Fundalux:** Turbidity measurement > 77
- **Xgas:** Off-gas analysis > 88
- **MFCS:** Supervisory Control and Data Acquisition > 84

Gas Supply Options > 68

- O_2 Enrichment
- Additive Flow
- Advanced Additive Flow

Compact and mobile design	▶ Saves valuable laboratory space and easy to relocate
Closed loop temperature control system with a choice of steam or electrical heating	▶ Highly precise temperature control that matches your laboratory infrastructure
Automatic Sterilization In Place (SIP)	▶ Minimizes manual operation
Open frame piping skid	▶ Easy to access during operation and maintenance

BIOSTAT® D-DCU

"Fast Lane" to Production

The BIOSTAT® D-DCU is designed for demanding requirements in process development and small scale production.

The system offers an excellent solution for any budget and every need. Working volumes are available in a choice of 10 L, 20 L, 30 L, 50 L, 100 L and 200 L. Scalable BioPAT® MFCS S88 recipes provide a significant increase in process safety and reliability and result in improved batch-to-batch consistency.

Due to the bioreactor's modular design, various configurations are available – from basic to fully featured. The BIOSTAT® D-DCU can be equipped with an automated CIP system. It can be connected to a mobile unit for easy and convenient cleaning of the vessel and transfer lines. Alternatively, it can be powered and integrated into a hard piped system in your facility.

It is designed to interface single-use storage bags for media addition and harvesting, as well as the TAKEONE® single-use aseptic sampling systems. Further enhanced functionality and ease of use are provided by a wide selection of in-line sensors and analyzers and by integrated display of process values on the DCU screen.

Single or twin configuration	▶ Saves valuable space
Automatic Sterilization In Place (SIP) and Cleaning In Place (CIP) sequences	▶ Minimizes manual operation
Powerful industrial DCU control system	▶ Reliable and flexible to grow with your needs
Gear-free, low-noise agitation system	▶ For silent operation even at a high agitation speed
Fully configurable from basic batch set-up to sophisticated configurations supporting advanced gassing and feeding strategies	▶ Meets virtually all process requirements

Learn more about the BIOSTAT® D-DCU as the fast lane to production

Applications

- Microbial and cell culture
- Suspension and microcarrier cultures
- Process development and scale-up
- Seed production
- GMP Production

BioPAT® Sensor and Software Options:

- **Trace:** Glucose | Lactate measurement > 76
- **Fundalux:** Turbidity measurement > 77
- **Xgas:** Off-gas analysis > 88
- **MFCS:** Supervisory Control and Data Acquisition > 84

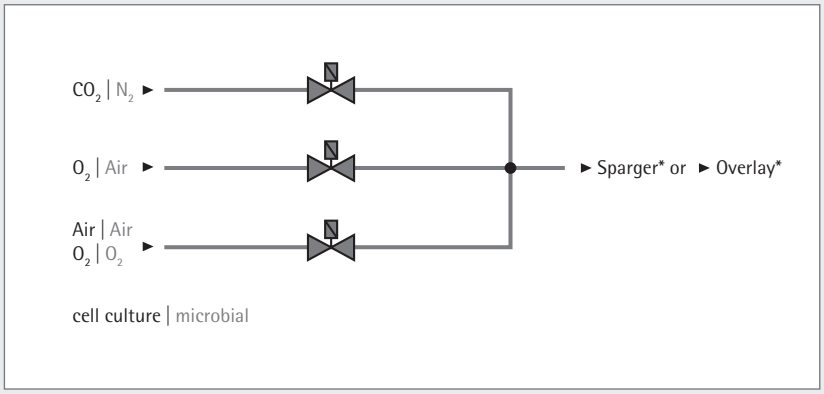
Gas Supply Options > 68

O_2 Enrichment

Additive Flow

Advanced Additive Flow

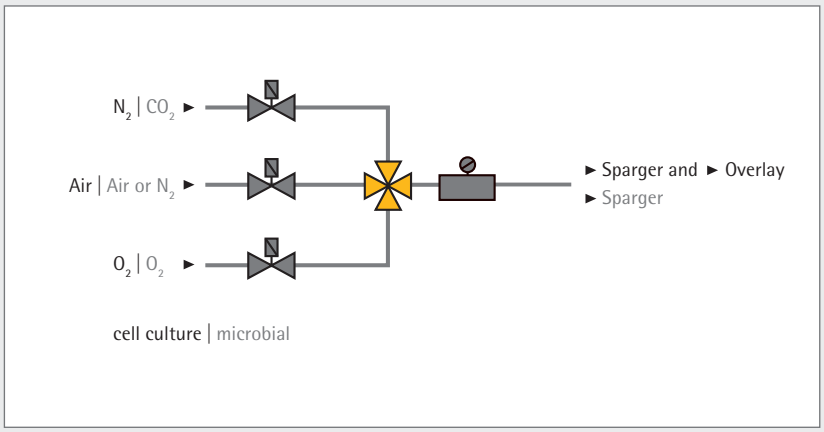
Gas Supply Options



* Depending on vessel type.

ambr® 15
Individual Gas Supply

Typical gases used are Air | O_2 | CO_2 for ambr® 15 cell culture and N_2 | Air | O_2 for ambr® 15 fermentation. Each gas is added individually into the supply line for each bioreactor vessel. The mixed gas is delivered to the culture via sparger or overlay according to the type of ambr® 15 vessel being used.



ambr® 250
Individual Gas Supply

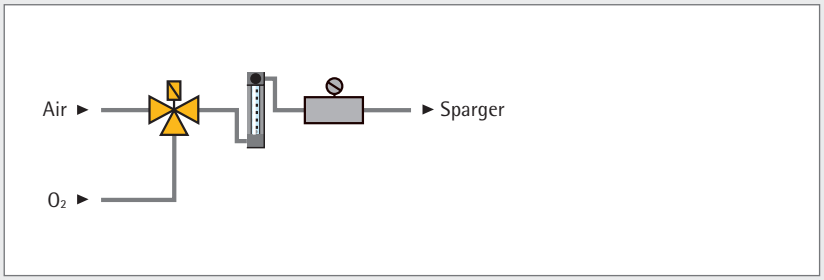
This advanced gassing strategy utilizes both mass flow controllers and valves to accurately control flow rates. The strategy directs any or all of the 3 gases (Air, O_2, N_2 | CO_2) to the sparger or overlay independently. Any two gases can be accurately mixed, for example when enriching gas with oxygen, either as a percentage of the total flow or as an addition to the current gas flow. Gas actual flow rates are monitored and controlled digitally via the user interface.

Switch valve
Dosing shutoff valve
Mass flow sensor

* The diagrams shown are examples.
The detailed design depends on the specific configuration of the ambr® gassing strategy.

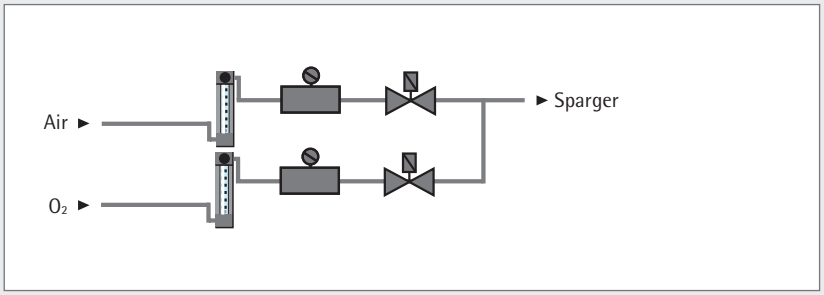
O_2 Enrichment

This gassing strategy uses a 3 | 2-way solenoid valve to direct either an air or O_2 flow to the sparger. A manual flow meter visually indicates and controls the flow rate. O_2 is pulsed via a solenoid valve, when required to maintain the dissolved oxygen setpoint. Air is not provided at this time. Optionally mass flow controllers can be integrated to measure and control the total gas flow rate via manual adjustment or automatically in conjunction with the controller, based on the signal of the pO_2 probe and the selected setpoint.



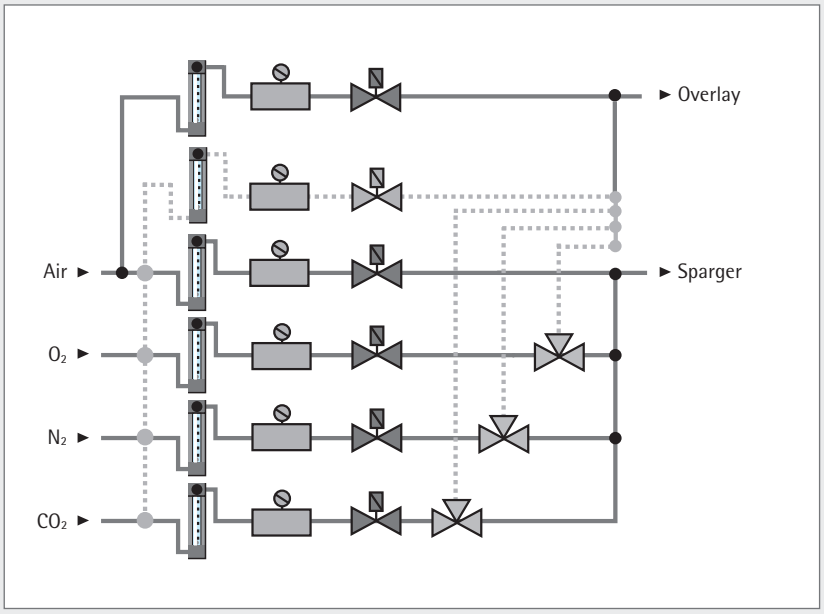
Additive Flow

Controls the flow rate of air and O_2 individually, (N_2 and CO_2 also possible but not shown) to a single output, either a sparger or overlay.



Advanced Additive Flow

Direct air, O_2, N_2 and CO_2 can be directed to the sparger and to the overlay. Flow meters visually indicate the flow rate for each gas. Add an additional gas flow path to the sparger or overlay outlet. Select optional mass flow controllers for each flow path, and switch gases between overlay and sparger.
The detailed design of the Advanced Additive Flow gassing approach depends on particular BIOSTAT® bioreactor system and configuration. Please contact your the Sartorius representative for further details.



Flow controller
Optional gas switch
Dosing shutoff valve
Optional dosing shutoff valve
3|2-way solenoid valve
Mass flow controller
Optional mass flow controller
Optional gas flow path

* The diagrams shown are examples.
The detailed design depends on the specific configuration of the BIOSTAT® gassing strategy.

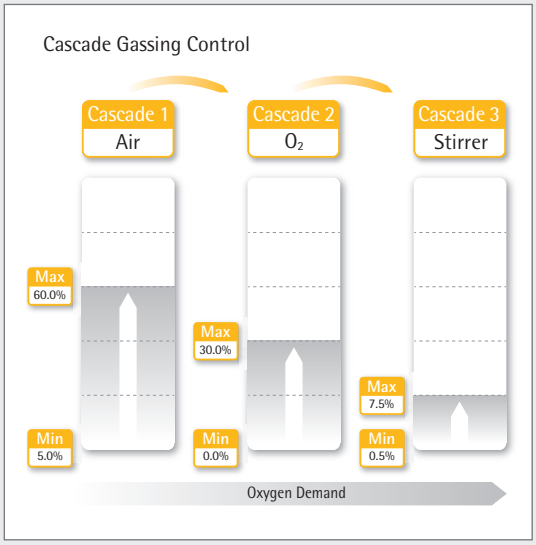
Oxygen Control Strategies

Solenoid Valves and Mass Flow Controllers

Choose between two options for controlling the gas flow into a BIOSTAT®: solenoid valves (SVs) and mass flow controllers (MFCs). SVs operate electromechanically, switching on or off and discontinuously dosing a fixed flow rate of gas when a specific electric current is applied. MFCs are designed and calibrated to a specific type of gas in a particular range, and use a proportional control valve to realize a continuous gas flow. The accuracy of a MFC is typically 10-fold better and offers increased flexibility for an oxygen control strategy.

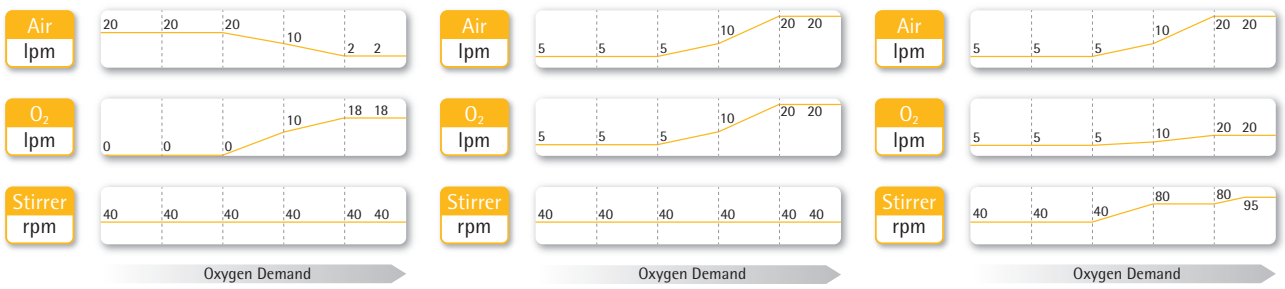
Cascade Gassing Control

Automatic pO_2 control is one of the most important functionalities of a bioreactor. It is designed to alter the volumetric oxygen transfer rate in order to meet process oxygen demands. As the measured pO_2 moves off the set point, the system will automatically change a parameter (over a defined range) in order to re-establish the pO_2 set point. Freely select between different control parameters such as stirrer speed, air flow or oxygen percentage. Each parameter is placed in a cascade order. Once the parameter's limit has been reached the BIOSTAT® controller will shift to the next cascade until reaching the set point.



Advanced pO_2 Control

Enable parallel modification of all physical parameters with the advanced pO_2 controller. Activate or change multiple parameters simultaneously such as stirrer speed, aeration rate for air | oxygen or other parameters. All oxygen control strategies can be realized and be resource efficient. For examples see below visuals:



Constant gas flow decreases the flow of air and simultaneously increases oxygen gas

Constant gas ratio, where both air and oxygen % are increased at the same rate

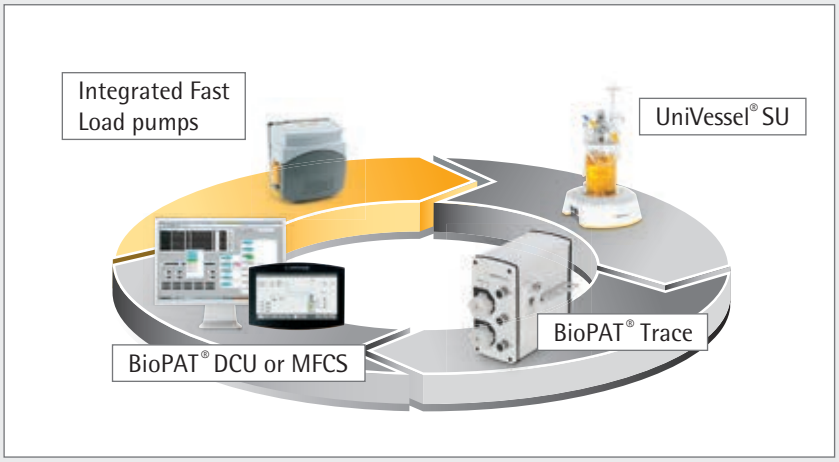
Bubble size optimization enables fine tuning of the oxygen % and gas-liquid interface area

lpm: litre per minute
rpm: revolutions per minute

Advanced Measurement and Control Loops

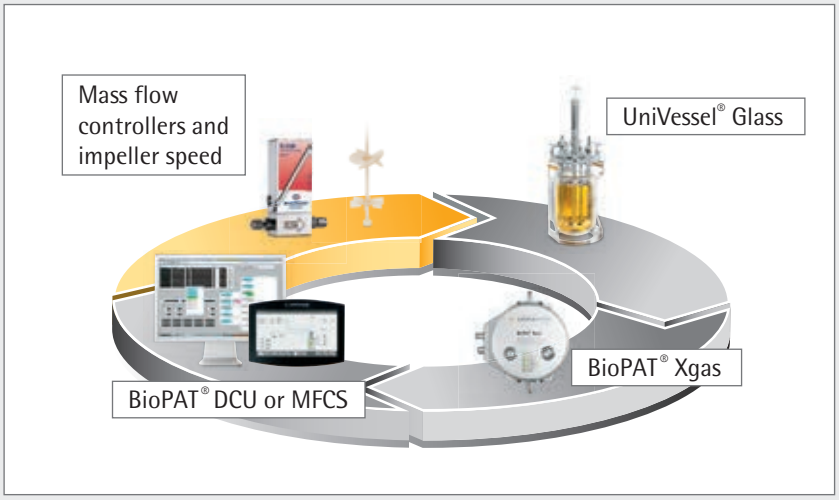
Glucose Feed Control

The BioPAT® Trace monitors glucose and lactate online in both microbial and mammalian cultivations. This analyzer combines single-use bio sensors and fluidic elements to provide real-time glucose concentration data which can be fed into the BioPAT® DCU or MFCS. From there the software enables control loops for automated glucose feeding to ensure virtually constant in-process glucose concentrations.



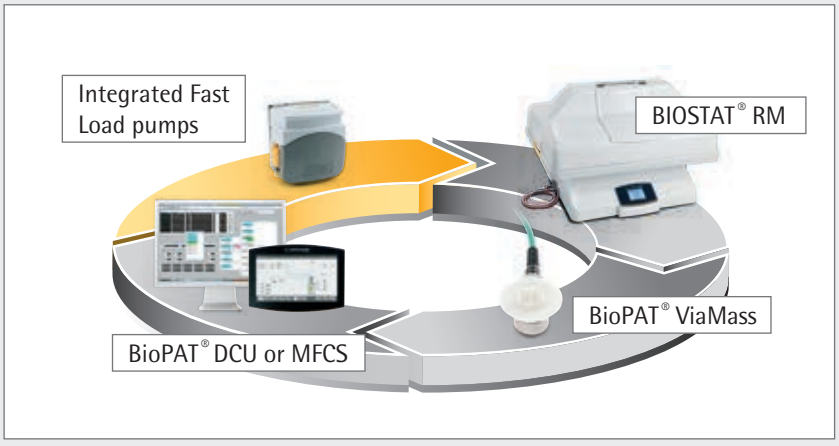
Metabolic Respiration Control

The BioPAT® Xgas off-gas sensor and MFCS software with the S88 recipe module can automatically adjust the aeration, agitation and oxygen percentage to the respiration requirements of individual cells. As a result, this upstream control loop enables optimal growth conditions, ultimately increasing the productivity of customer process.



Viable Biomass Feed Control

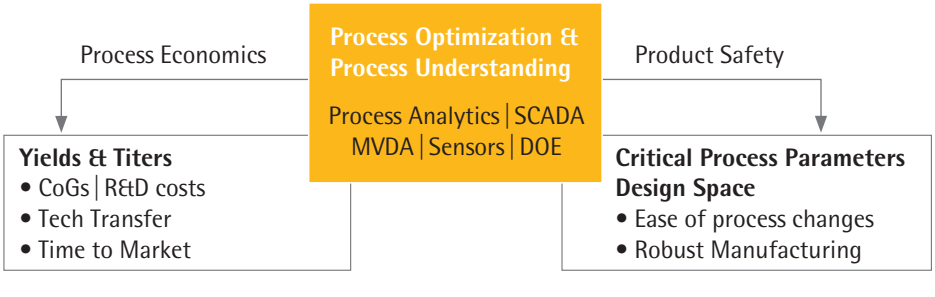
Collecting real-time data about viable cell volume enhances process understanding and control capabilites. It allows continuous adjustment of feed pumps and perfusion rates as the biomass changes. As the BioPAT® ViaMass is fully integrated, the BIOSTAT® can be configured to indicate trigger points at desired viable cell volumes rather than using a set cultivation time. This considerably improves the consistency and reproducibility of batches.



Sartorius Process Analytical Technologies

Biopharmaceutical production processes have changed significantly due to overall titer improvements and the increasing deployment of single-use technologies. The introduction of robust and reliable single-use sensors further enhances the benefits of single-use processing concepts. They enable you to use Process Analytical Technology (PAT) approaches for effective automation and optimization.

Implementation of process analytical technologies results in risk mitigation, simplified process changes and cost savings.



Process Analyzers and Sensors

Collect real-time data for advanced process control strategies, which will ultimately improve the economy and safety of your processes. Sartorius provides a comprehensive range of process analyzers and sensors for your process needs.

Single-use sensors for pH and pO_2; fully integrated into our BIOSTAT® bioreactors	▶ Enable real-time monitoring and control
Process analyzers for online measurement of glucose, lactate and other metabolites	▶ Ensure consistent process and product quality
Automated biomass measurement for single-use, glass and stainless steel bioreactors	▶ Ensures batch-to batch consistency

Process Control and Software Tools

Stable and robust processes require automated control of critical process parameters based on reliable data acquisition, storage and evaluation capabilities. Process control and software tools further pave the way towards a knowledge-based approach to biopharmaceutical production to mitigate risk.


STR
SYNCHRONIZED
PAT
SOLUTIONS

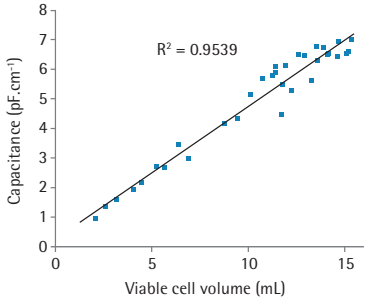
BioPAT® ViaMass

Inline Biomass Measurement for Process Control

Learn more about the BioPAT® ViaMass as biomass measurement sensor

Applications

- 24|7 monitoring of viable cell volume
- Automated feeding based on biocapacitance
- Viral processes: Determination of infection and harvest time point
- Cell therapy: Process monitoring without contamination risk and volume reduction
- Intensified processing: Automated cell bleed control based on biocapacitance



BioPAT® ViaMass measures the viable cell volume using the principle of biocapacitance, which is selective to viable cells only. The SU sensor is fully integrated in Flexsafe STR® and Flexsafe® RM bags and comes presterilized with a plug-and-play integration. For easy process development, the sensor is also available as a multi-use stainless steel probe for all our UniVessel® benchtop reactors. BioPAT® ViaMass is fully integrated in the Sartorius control unit and feedback loops can easily be implemented.

Process understanding requires monitoring of critical process parameters, such as viable cell density. However, manual sampling reduces the bioreactor volume, is laborious and increases the contamination risk. BioPAT® ViaMass measures the viable cell volume inline without the need of sampling and without contamination risk.

It can be used for event-based automation, such as bleed control, feed control, as well as harvest point and infection point detection.

Fully integrated SU sensor	▶ Ease of use, no contamination risk
Available as reuseable probe for benchtop bioreactors	▶ Covers all scales of process development
Feedback loops easily established	▶ Automated process control, such as cell bleed or feeding
Biocapacitance is selective to viable cells	▶ Direct access to viable cell volume

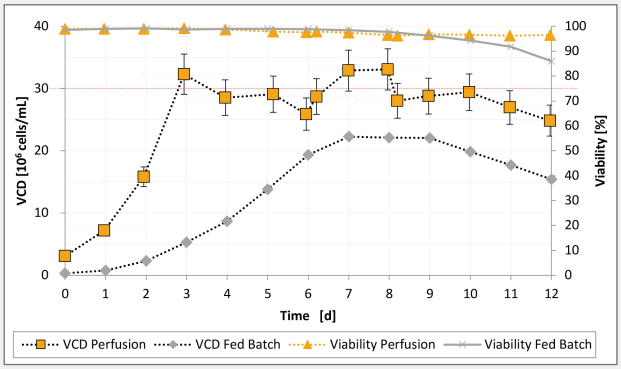
Advanced measurements on these Bioreactors:

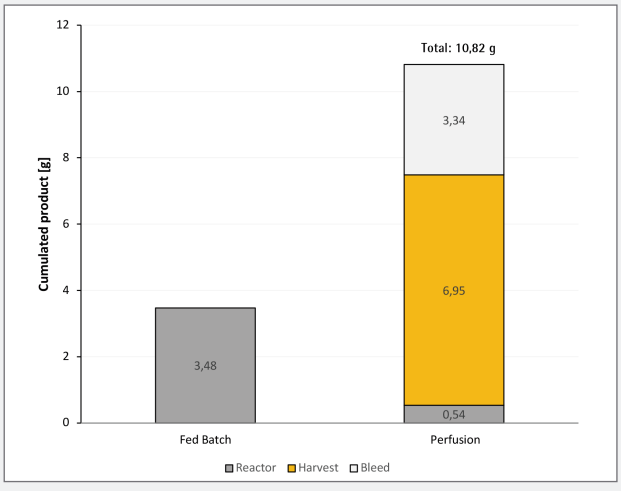
- BIOSTAT® B > 50
- BIOSTAT® B-DCU > 51
- BIOSTAT® RM > 55
- BIOSTAT STR® > 58

Automated Cell Bleed in Intensified Processes Through BioPAT® ViaMass

Viable biomass is one of the most important critical process parameters in upstream bioprocesses. For accessing biomass in Sartorius BIOSTAT® bioreactors, we offer BioPAT® Viamass, a capacitance sensor that measures viable cell volume. BioPAT® Viamass delivers special value for intensified processing in SU bioreactors. While intensified processing delivers the advantage of increased productivity, they come with the challenge of being much more complex than conventional processes and require tighter monitoring and control.

BioPAT® Viamass can be used to automate cell bleed in perfusion cultivations. The graphs to the right demonstrates a perfusion cultivation with automated cell bleed based on the online ViaMass® signal, performed in BIOSTAT® RM system. The viable cell density could be controlled at 30 million cells per mL in a fully automated fashion. The product yield was 3-fold higher in the intensified process compared to a conventional fed-batch process.





Source: Sartorius R&D Bioprocessing USP – Gerhard Greller, Jens Matuszczyk and Johannes Lemke

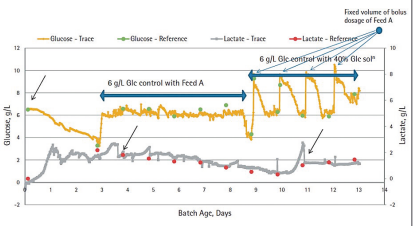
BioPAT® Trace

Inline Glucose and Lactate Measurement

Learn more about the BioPAT® Trace as glucose and lactate sensor

Applications

- 24|7 glucose and lactate monitoring without volume loss
- Enables automated feed control
- Capable of low glucose control (<1g/L) with a sampling rate of up to 30 per h



BioPAT® Trace is a glucose and lactate sensor capable of inline integration into bioreactors. The measurement principle is a biosensor based on glucose and lactate oxidase generating an amperometric signal. BioPAT® Trace probes make use of a dialysis principle, which does not require sampling.

The glucose concentration in an upstream process is one of the most relevant critical process parameters in biopharma manufacturing. Too little glucose results in starvation, while too high levels result in lactate generation, which affects the pH and inhibits cell growth. Furthermore, it has been shown that keeping the glucose concentration stable positively affects product glycosylation.

Manual glucose control based on sampling is highly laborious, comes with contamination risks and is often too infrequent to achieve stable control. BioPAT® Trace can measure and control glucose and lactate concentration in an automated fashion without volume loss with an accuracy of 0.1g/L.

24|7 glucose and lactate monitoring & control	▶ Working range 0.1 – 20 g/L glucose, accuracy 0.1 g/L
Capable of low glucose control below 1 g/L	▶ Low glucose control can increase mAB titer by 30%
Biosensor based on glucose and lactate oxidase	▶ Unparalleled level of glucose control
Inline dialysis sampling without volume loss	▶ Safe operator time, reduce contamination risks
Self-calibrating during the process; available for BIOSTAT® single-use and benchtop bioreactors	▶ Easy to use system

Advanced measurements on these Bioreactors:

- BIOSTAT® B > 50
- BIOSTAT® B-DCU > 51
- BIOSTAT® Cplus > 66
- BIOSTAT D-DCU® > 67

BioPAT® Fundalux

Inline Monitoring of Total Biomass

Implement a continuous OD600 measurement with BioPAT® Fundalux

Applications
- Inline monitoring of total biomass based on turbidity e.g., in microbial cultures
- Inline and continuous OD600 measurement (BioPAT® MFCS required)
- For stainless steel and glass vessels

The BioPAT® Fundalux system is based on an integrated absorption-based probe using near infrared light for turbidity measurement. It can be used in all glass and stainless steel bioreactors.

Especially in microbial culture, manual sampling can be highly time-consuming and inconsistent. The BioPAT® Fundalux probe continuously monitors cell growth in your culture by measuring the turbidity in a defined optical path based on near infrared light. This inline turbidity measurement can be correlated directly to laboratory analysis methods for cell count and OD600 optical density.

The BioPAT® Fundalux amplifier comes integrated into BioPAT® DCU. Automatically converted the turbidity reading of a Fundalux sensor into an OD600 reading by combining it with BioPAT® MFCS.

BIOSTAT® bioreactor integration	▶ All-in-one BioPAT® DCU, data collection and control
12 and 25 mm probe connection	▶ Flexible entry into your fermenter
Range of optical path lengths (1, 5 and 10 mm)	▶ Optimal total biomass coverage for your bioreactor
Online OD600 measurement in combination with BioPAT® MFCS	▶ Provides real-time knowledge to optimize bioprocess runs ▶ Makes sampling for OD600 measurement redundant
Reliable, continuous inline measurement	▶ Eliminates laboratory sampling ▶ More sensitive & cost-effective than offline sample data

Advanced measurements on these Bioreactors:

- BIOSTAT® B > 50
- BIOSTAT® B-DCU > 51
- BIOSTAT® Cplus > 66
- BIOSTAT D-DCU® > 67

BioPAT® Xgas

Online Off-Gas Analysis of O_2 and CO_2

Develop perfusion feeding strategies facilitated by BioPAT® Xgas

Applications

- Development of perfusion feeding strategy based on OUR
- Batch record of % O_2 | CO_2 in off-gas
- Automatic calculation of metabolic data
- Optimization of microbial and high cell density cell culture processes
- Measure critical process parameters for scale-up

The compact BioPAT® Xgas precisely tracks changes in respiratory gas emission from a cultivation vessel. It can be integrated as an option into all BIOSTAT® bioreactors for real-time calculation of metabolic data, such as oxygen uptake and carbon dioxide emission rate.

The precise measurement of input and output metabolic gases by mass flow controllers and offgas analysis yields insights into critical metabolic changes during the cultivation process.

This enables the user to apply reliable, advanced gassing or feeding strategies to improve production rates and reduce cultivation time. Develop a perfusion feeding strategy in one go, facilitated by BIOSTAT® B-DCU and BioPAT® Xgas.

Standardized integration into all BIOSTAT® bioreactors	▶	All-in-one BioPAT® DCU, data collection and control
Parallel measurement of O_2 and CO_2 by one sensor	▶	Reduces footprint and exhaust piping requirements
Wide detection range	▶	Analyzes O_2 enrichment and CO_2 headspace gassing
Automatic moisture and pressure compensation	▶	The highest accuracy and precision ensured
Compact, mountable design	▶	Safe, ergonomic and space-saving in lab and production areas
Fast and easy 1-point calibration to air	▶	Less time needed for initialization and setup

Advanced measurements on these Bioreactors:

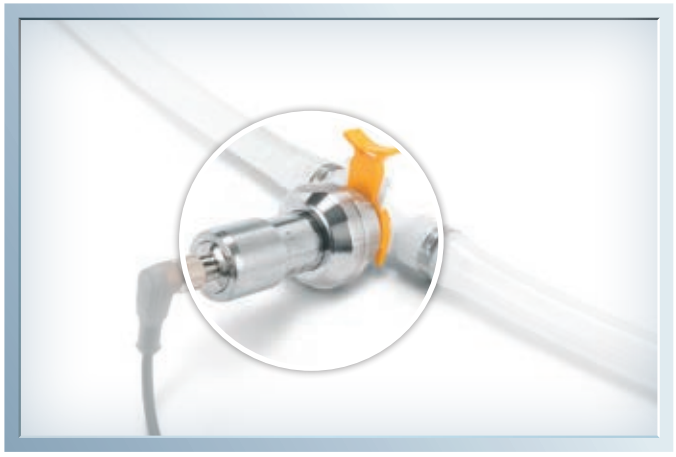
- BIOSTAT® B > 50
- BIOSTAT® B-DCU > 51
- BIOSTAT STR® > 58
- BIOSTAT® Cplus > 66
- BIOSTAT D-DCU® > 67


sartorius stedim
BioPAT® Xgas
sartorius stedim
BioPAT® Trace

BioPAT® Pressure

Inline Pressure Measurement

Applications
- Monitor pressure controlled processes, e.g. perfusion or cross-flow filtration
- Detection of filter fouling
- Guarantee appropriate back pressure during washing step in preparation for filter integrity testing



The BioPAT® Pressure sensor combines a multi-use transmitter and a single-use flow pipe. The new design allows for more flexibility, with better longevity, handling and accuracy

The BioPAT® Pressure sensor uses piezoresistive effect to accurately and quickly determine the pressure inline. The single-use pipes can be integrated into any assembly (from ¼" up to 1" inner diameter) and include a fixing mechanism for easy and robust coupling of to the multi-use transmitter.

Once both are assembeld together the measurement can take place. The pressure sensor measures reliably over a wide temeprature range (4 – 40°C) thanks to a pre-programmed temperature compensation. The analog outlet signal (4 – 20 mA) can be directly transmitted to a control untit or shown in a benchtop display.

Single-use flow pipe: • Integrated fixing mechanism • Chemical resistance	▶ Easier installation and reliable connection to transmitter
One transmitter for all sizes	▶ Appropriate for ADC applications
Factory adjustment procedure	▶ Flexibility in the process scale
Benchtop display	▶ Higher accuracy ▶ For at-line monitoring of the flow rate or not controlled stand-alone applications
Multi-use electronics	▶ No electronic waste

BioPAT® Flow

Inline Flow Rate Measurement

Applications
- Monitor flow rate in any inlet or outlet streams
- Determine total volume of liquid transfered

The BioPAT® Flow sensor is the world's only ultrasonic flow sensor that combines a multi-use clamp-on and a single-use flow pipe. This combination assures highest accuracy and flexibility.

The BioPAT® Flow sensors use the ultrasonic transit-time technology to accurately and quickly determine the flow rate. The single-use pipes can be integrated into any assembly (from ¼" up to 1" inner diameter), independent of the tubing type and without introducing bends or changing the inner diameter. Once the multi-use clamp-on is assembled around the pipe, the measurement can take place.

The effect of temperature is accounted for by using three standard calibration tables, which cover 4 – 37 °C. The measurement is not affected by the viscosity of the fluid or the pressure of in the system. Data read-out can be done with a benchtop amplifier box or a DIN-Rail module suitable for electrical cabinets. Both analog (4 – 20 mA) and digital (RS-232) signals are available as output.

Single-use flow pipe: • Precise and straight flow path • Hard plastic with thermoplastic elastomer overmolding • Fixed measurement position • Chemical resistance	▶ Higher reproducibility and accuracy ▶ Pressure independent measurement without compromising on coupling quality ▶ The calibration is independent of the type of tubing and minimizes operator errors ▶ Appropriate for ADC applications
Multi-use electronics	▶ No electronic waste
Analog and digital outputs	▶ Interface flexibility for integration into control unit
Benchtop amplifier box	▶ For at-line monitoring of the flow rate or not controlled stand-alone applications

Automation is Key

Process Automation is one key component to ensure consistency and reproducibility of bioprocesses.

Local control on the single unit-operation does not stand alone and integration ability is key. The basis of an integration with ease is heavily relying on a thorough S88 implementation. Furthermore recipe management to build time & condition based decision are important modules to reach the required consistency. Embedded in the recipe execution, user guidance reduces human error during setup of consumables & process execution.

Based on customer specific process & set-up, Sartorius offers a range of solutions, starting with purely out of the box instruments to highly customized solutions well integrated in customer's IT network.

Standard

Digital Control Unit (DCU)
The *Digital Control Unit* (DCU) is Sartorius standard for local control automation for BIOSTAT® bioreactors. It is well recognized in the industry for its ease of use and intuitive HMI interface.

Furthermore DCU is fast and easy to implement, so the customer is ready to start the process right away under control of an efficient and GMP ready automation.

Also the extension of the DCU with BioPAT® MFCS SCADA solution is plug-and-play. Doing so, customer's process is now empowered with batch management, historization, trends and report, rich GMP ready features and a powerfull S88 advanced recipe management.

Adapted

Adapted Modular Process Units
In cases, where standard solutions can not cover custom specific requirements, Sartorius can offer solutions, which adapt hardware, consumable and automation to the specific process.

Based on 300+ projects executed, Sartorius offers an automated system composed of well tested standard functions with customized changes, to allow faster project execution and robust system in comparison to other engineering approaches.

Fully supported by industrial components and software (Siemens); connectivity to SCADA, DCS & historian systems are available out of the box hence enabling either stand-alone process unit as well as a fully integrated solution in the existing infrastructure.

GMP and data integrity requirements are met by a consistent and documented engineering approach and proven GMP functionality (e.g. user management and batch reporting).

Customized

Automation Consistency From Sensor to Batch
If your brownfield or greenfield installation requires automation consistency down to the field level (sensors & actuators), Sartorius will provide a full native solution together with local partners. Common automation systems are based on Emerson and Rockwell, but other can be arranged on request.

In this approach, very specific requirements of installation, automation and process request can be realized.

BioPAT® MFCS

SCADA Software for Reliable Data Acquisition, Monitoring and Control

Learn more about BioPAT® MFCS

Applications

- Reliable data acquisition, monitoring and control
- For upstream and downstream unit operations, e.g., BIOSTAT® bioreactors, Sartoflow® and FlexAct® systems
- Across all scales from early process development to commercial manufacturing
- Incorporating Sartorius and 3rd party equipments

Microsoft Partner
Gold Independent Software Vendor (ISV)

BioPAT® MFCS is the central platform for your online and offline process and analytical data, from cell line and process development to production scale.

Designed as a "plug-and-play" solution, it is ideally suited for capturing, storing and visualizing process data of our Sartorius bioreactors and other process equipment including 3rd party units. This software enhances your ability to build your own SCADA network using our preconfigured and bioprocess optimized solution.

The advanced 21 CFR Part 11 compliant BioPAT® MFCS suite is a feature-rich, GAMP category 4 software package capable of supporting the most demanding research or production environment. Besides the core functionality of a full-fledged SCADA system, BioPAT® MFCS in combination with the BioPAT® DCU is the most cost-effective and flexible platform specifically tailored for bioprocessing applications.

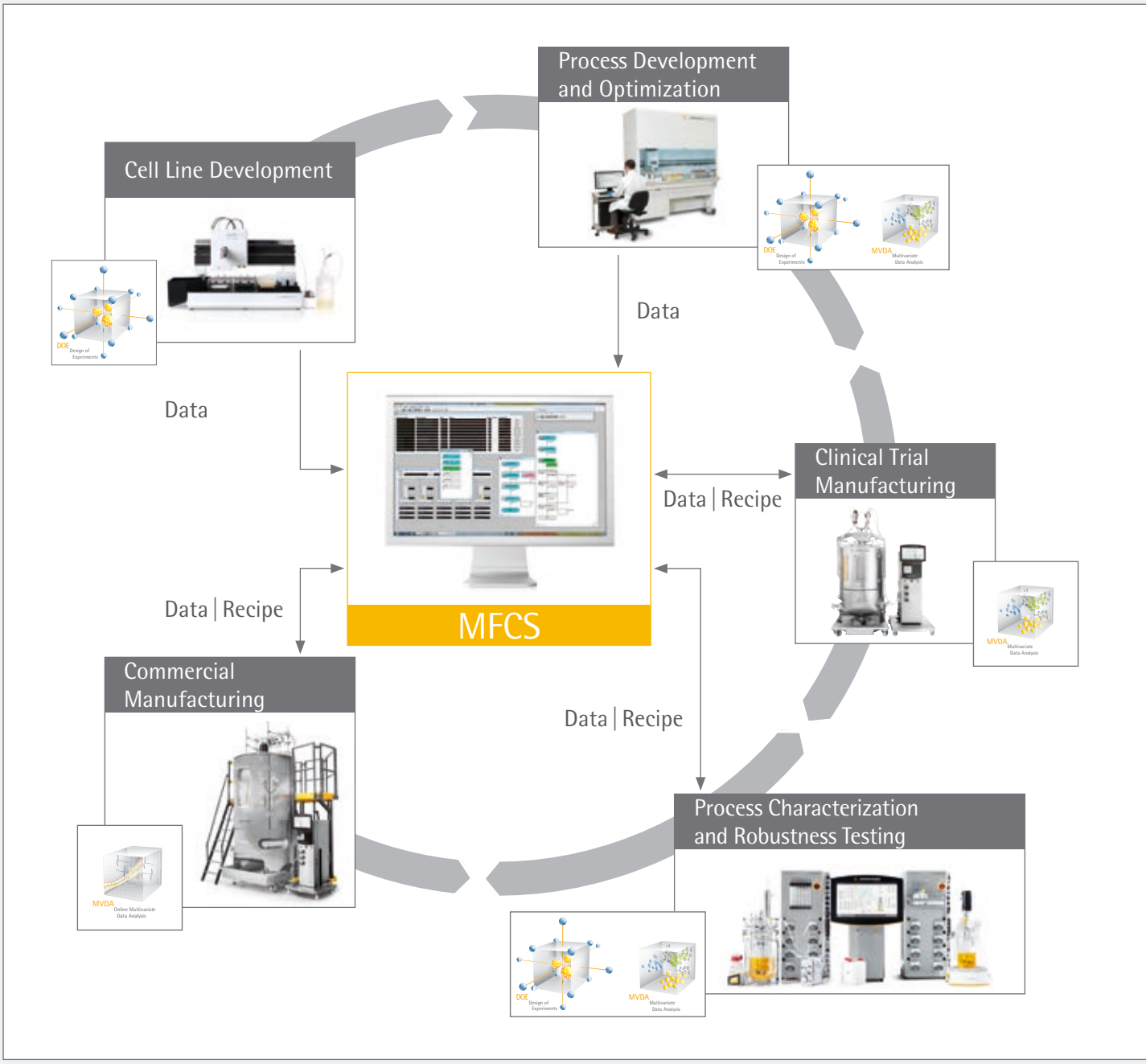
Scalable software for nearly all bioprocess applications	▶ Reduced training efforts and improved data consistency
Fully user configurable and upgradable with specific modules	▶ Unique customization level and flexible investment costs
Proven track record of over 25 years application in bioprocess development and production	▶ Reliable and robust system performance
Installation, configuration, validation and engineering services	▶ Technologically and economically optimized solutions
Central platform for real-time and historical analysis of process, analytical and sampling data	▶ Full transparency and accessibility for advanced process control and understanding

Advanced measurements on these Bioreactors:

- BIOSTAT® A > 49
- BIOSTAT® B > 50
- BIOSTAT® B-DCU > 51
- BIOSTAT® RM > 54
- BIOSTAT STR® > 58
- BIOSTAT® Cplus > 66
- BIOSTAT D-DCU® > 67

Seamless Scalablity and Data Consistency with BioPAT® MFCS

Seamless scalability, integration of chemometrics tools and consistent controls across all scales for accelerated process development and process transfers.



Software Modules BioPAT® MFCS

Your Choice for Advanced Features

Specialized for bioprocesses, BioPAT® MFCS provides preconfigured modules enabling plug-and-play setup of advanced SCADA functionalities, saving you in-house resources for engineering, maintenance and training. BioPAT® MFCS and its advanced modules were strictly developed according to a sustainable software lifecycle design. As a result, you will receive high-quality software for safe and worry-free operation – every time, all the time. These software modules are compatible with the latest off-the-shelf hardware and software technology.

Connectivity
When today's automation challenge is native connectivity and interoperability, BioPAT® MFCS provides a flexible Plug&Play device connectivity with Sartorius equipments, true interoperability with major third-party softwares and full support of the OPC Standard to enable a 24 | 7 monitoring of your processes.

Network
MFCS can run a single unit process system to 24 process units with multi-clients installation. This is ensured by the Multi-User Option that brings virtualization and RDS support reducing IT maintenance, securing the system and bringing remote availability.

S88 Recipe Control
Reproducible batches are a must-have for process development and pilot manufacturing. The ANSI | ISA-88 compliant Recipe Control Module for BioPAT® MFCS enables this by easy configuration of recipes following automated batch execution.

21 CFR Part 11
Meeting cGMP and 21CFR part 11 requirements is complex and crucial in bioprocessing. BioPAT® MFCS 21 CFR part 11 module supports you with user management, audit trail, electronic signatures and reporting capabilities bringing all features to achieve full compliance.

Optimization
The BioPAT® MFCS DOE module will ease your start into Design of Experiments, supported by user-friendly wizard guidance. Automatic transfer of the experimental design into a specific recipe allows for reliable and seamless integration into existing control strategies.

Analysis
The BioPAT® MFCS MVDA module supports easy and fast multivariate data analysis – saving you cumbersome and error-prone transfer of your process data to stand-alone software tools for statistical analysis.

Trainings
Join Sartorius training program for BioPAT® MFCS! Different level of trainings will give the necessary practical skills to perform the work safely and efficiently with BioPAT® MFCS. On site trainings can also be adapted to special needs and help the user get up to speed with BioPAT® MFCS!

Service & Support
Benefit from our international and experienced service team that offers a wide range of services including installation and configuration, computer system validation (CSV), hotline, remote and onsite maintenance.

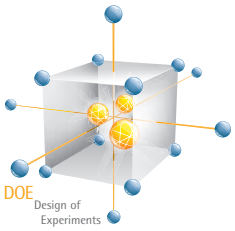
Umetrics® Chemometrics Toolbox

New Opportunities for Efficient Bioprocess Development and Manufacturing

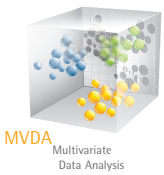
Take advantage of the Chemometrics Toolbox and integrate the capabilities of advanced multivariate methods into your existing process control software BioPAT® MFCS | win.

SCADA
BioPAT® MFCS

DOE Module



MVDA Module



OPC Module

DOE
Umetrics® MODDE®

Identify critical process parameters and their optimal ranges and estimate a design space

MVDA
Umetrics® SIMCA®

Identify normal operation space and understand reasons for process upsets, prepare models for real-time monitoring in SIMCA-online.

MVDA-online
Umetrics® SIMCA®-online

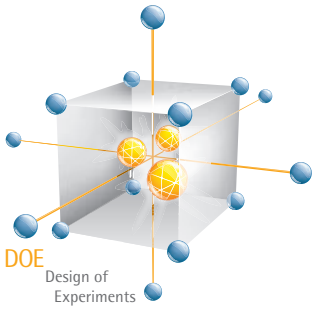
Monitor the manufacturing processes in real-time and save batches by early fault detection

Umetrics® MODDE®

DOE – The Efficient Way of Bioprocess Optimization

Applications

- Optimization of cell and microbial culture media composition and feed strategies
- Screening and optimization of process parameters
- Design Space Estimation (DSE) and validation



Umetrics® MODDE® is a state-of-the-art Design of Experiments software package that will help you understand complex processes and products.

Umetrics® MODDE® enables rapid process optimization with a reduced number of experiments. Forget time-consuming, traditional trial- and error optimization. You will benefit from unique design space tools to visualize the most reliable operating range for the investigated parameters considering risk analysis specifications.

Use the Umetrics® MODDE® software to speed up your development work, to increase productivity and elucidate primary effects and interactions of potential critical process parameters and critical quality attributes.

Visual user guidance with a multitude of automated functions	▶ Tool for beginners and experienced users alike
User-friendly design and one click analysis wizard	▶ Easy setup and reliable data evaluation of experiments
Graphic-rich presentation of results and reports	▶ Decision-making based on statistically verified statements
Unique connection to BioPAT® MFCS	▶ Reliable and seamless integration of DOE procedures into existing control strategies

Umetrics® SIMCA®

MVDA – Discover Hidden Process Information

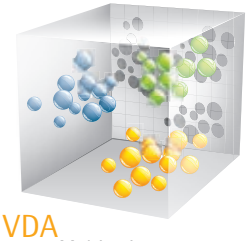
Applications

- Analyse and identify reasons for process deviations and upsets
- Classification of batches and process predictions
- Scale and batch-to-batch comparisons
- Identification of key trends, correlations, patterns, and relationships in your process data

Multivariate Data Analysis (MVDA) with Umetrics® SIMCA® supports and unlocks process understanding to ultimately improve the manufacturing consistency and secure throughput by identifying process behaviour that causes risks.

For many years, Umetrics® SIMCA® has been the standard tool for scientists and engineers, enabling them to manage considerable amounts of data. Umetrics® SIMCA® enables you to effectively explore your data, analyze your process and interpret the results. Use Umetrics® SIMCA® to transform data into information, allowing you to make the right decisions – quickly and confidently.

The unique Umetrics® MFCS MVDA module is specifically matched to communicate with and deliver data to Umetrics® SIMCA® in order to reduce effort associated with data management and comparison of current and historical batches.



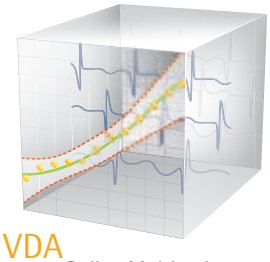
MVDA
Multivariate Data Analysis

Easy interpretation and analysis of large process data sets	▶ Improved process performance resulting in yield improvements and impurity reduction, among other benefits
Tech-transfer and batch-to-batch comparisons	▶ Generate process understanding to ultimately improve the quality, safety and efficacy of your drug product
Summary of all process information, all in one data model	▶ Control and assurance of overall process and product quality
Unique connection to BioPAT® MFCS	▶ Reduce the effort of data management and transfer

Umetrics® SIMCA®-online

Manufacturing Intelligence Simplified

Applications
- Early fault detection
- Golden batch comparison
- Real-time multivariate statistical process monitoring



MVDA
Online Multivariate Data Analysis

Umetrics® SIMCA®-online software performs real-time multivariate monitoring of your manufacturing processes and provides effective tools for early fault detection and diagnosis.

Umetrics® SIMCA®-online uncovers hidden information in your processes. It is a highly efficient software tool for real-time process monitoring and control. Predictive analytics and soft sensor models can be applied using process parameters and spectral data.

Supplied with data from BioPAT® MFCS, this software permits identification of inconsistencies before they result in a process deviation and provides user guidance to identify potential root causes. This results in enhanced control and assurance of your overall process and product quality.

Early detection of process deviations with guidance to identify potential root causes	▶ Save batches before they reach a critical stage, reduce cost of goods if batch cannot be saved. ▶ MVDA identifies inconsistencies in process behavior earlier than univariate monitoring.
Process trajectories for real-time process monitoring	▶ Enhanced process reliability due to easy-to-understand graphics
Standard interface to BioPAT® MFCS via OPC	▶ Easy implementation into existing IT infrastructures

ambr® clone selection powered by Umetrics®

Software for Consistent Screening and Ranking

Learn more about the ambr® clone selection software

Applications

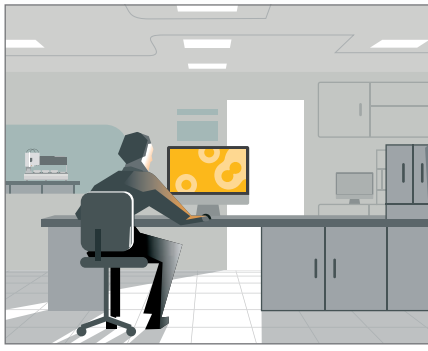
- A new standalone software application for use with data from ambr® 15 and ambr® 250 systems
- ambr® clone selection simplifies the data analysis workflow for cell line screening and ranking
- ambr® clone selection can also be used for strain, media and feed screening and ranking

ambr® clone selection is a new standalone software application for use with data from ambr® 15 and ambr® 250 systems to simplify the data analysis workflow for cell line screening and ranking.

Users define the selection criteria such as cell density, product titer and key product quality attributes and assign priority weightings in order to screen and rank clones.

The software application uses a unique multivariable desirability assessment feature for clone ranking.

Automation of the clone selection process	▶	Improves speed and consistency, frees up scientist time
Selection criteria profiles can be stored and shared within the same server	▶	Can be applied to new data sets for consistent selection by other team members
A report is generated to record the selection criteria and details of the selected clone candidates	▶	Possible to view and understand the selection comprehensively
Re-evaluate at any time	▶	If selection criteria change during your project, it is fast and straightforward to run the calculation again.
Data can be mined to the full to extract many key insights	▶	Maximizes use of data from ambr® experiments



Advanced functionality for these ambr® bioreactors:

- ambr® 15 cell culture > 38
- ambr® 15 fermentation > 39
- ambr® 250 high throughput > 42
- ambr® 250 modular > 46


BIOSTAT® B-DCU
sartorius stedim
sartorius stedim
biotech

BIOSTAT® T

Virtual Bioreactor Training Tool

Click here to request a personal software license

Applications

- Virtual training on BioPAT® DCU functionality and controller settings based on real process data

The BIOSTAT® T is an interactive software training tool and ideally suited to educate students and operators in bioprocess control. It enables users to learn about bioprocess engineering and to practice with menu navigation and control of a bioreactor prior to operating an actual bioreactor.

The BIOSTAT® T mimics the human machine interface and functionalities of a single-use or stainless steel bioreactor. It is based on actual cultivation batch data data that were collected under normal process conditions. This database enables the software to derive cell growth curves for the mentioned process conditions algorithmically.

The software enables users to gain insights into the characteristics of a CHO or Yeast cultivation. Users have to utilize the broad variety of software features to determine the optimal parameters for cell growth and antibody yield.

Integrative learning	▶ Theoretical principles of bioprocess engineering can be applied and verified
Close to reality	▶ Based on the human machine interface of a single-use or stainless steel bioreactor and contains real cultivation data
Completely virtual introduction to the operation of a bioreactor	▶ Achieving high quality results when using a bioreactor in real life from the very beginning
Time and cost saving	▶ Risk mitigation of human error and the prevention of batch losses

Sartorius Services for Maximized Process Security

Keeping a biopharmaceutical process robust and reliable, Sartorius provides a comprehensive range of services to ensure the highest reliability and uptime of your equipment, regulatory compliance and best quality of results. From installation and qualification to regular preventative maintenance: The instrument service team will be happy to assist customer on site and will be with him quickly thanks to the worldwide service network.

Installation and Commissioning

Safe and proper operation of your equipment – right from the start

Qualification (SAT)

Compliance with GMP requirements, easy integration into your quality management system

Operator Training

Quality through greater expertise: Sartorius trains the personnel operating our equipment

Installation Phase

Utilization Phase

Repairs and Spare Parts

In the event of service requests, we are quickly at your side with the necessary spare parts – worldwide

Maintenance and Contracts

Optimal equipment operation and protection against potential downtimes

Calibration

Accurate results in the long term and compliance with regulatory requirements

Key Benefits

- Process stability and minimized downtime
- Maximized system uptime, higher profitability
- Optimized total cost of ownership

Service Contracts for the Entire System Lifecycle

With the Bioprocess Service Program, Sartorius offers service contracts to protect customer's equipment through its entire lifetime. Based on the specific risk assessment and requirements, customers can choose between three Service Level Agreements: Essential, Advanced and Comprehensive. Protect equipment by choosing the appropriate service contract.
For maximum productivity and minimum downtimes.

Essential
Benefit from:

- A plannable annual maintenance
- A fast support at the technical helpdesk within one business day and priority on-site-response
- In case of repair:
  A discount on all time and material based cost elements

Advanced
Benefit from:

- A plannable annual maintenance
- Technical helpdesk reaction time within 8 hours and 72 hours on-site response
- In case of repair: labor and travel costs are covered, a discount of 10% on spare parts

Comprehensive
Benefit from:

- A plannable annual maintenance
- Technical helpdesk reaction time within 4 hours and 48 hours on-site response
- In case of repair: all costs are covered

For further details and the dedicated datasheets, please have a look at our website.

IV. Clarification


sartorius stedim
sartorius stedim
FlexAct

FlexAct® Solution

Single-use Automated Cell Removal | Clarification

Learn more about FlexAct® Solution

Applications

- Automated mammalian cell removal from production bioreactor
- Clarification of bioreactor supernatant for capture column loading
- Post centrifuge filtration of supernatant

The FlexAct® configured to order solution brings together hardware, software, wetware and documentation into a ready to produce package for single-use bioprocessing.

Cell Removal | Clarification enables the direct processing of a 2,000 L bioreactor in a single 8 hour shift. It uses pre-defined configurable software based on ANSI | ISA-S88 industrial standards for batch processing.

The software architecture allows easy interface to Distributed Control Systems (DCS) for plant-wide integration.

The modular FlexAct® build and connection of sensor, actuator and holder components allows them to be shared between unit operations, enabling a single FlexAct® system to perform up to 6 distinct unit operations at various volumetric scales.

Flexible processing skids with multiple functionality for diverse unit operations	▶ Supports multi-product	adaptive-scale bioproduction
Easy to integrate into distributed control systems and manufacturing execution systems	▶ Speed and effort of system integration
Easy-to-use predefined application software based on flexible unit operation recipes	▶ No additional coding or programing of software
Reliable Single-Use sensor and actuator technologies	▶ Higher process accuracy and control
High degree of automation, user guidance, system diagnostic and process transparency	▶ A reduced risk of error and unplanned downtime

Sartoclear® Depth Filters

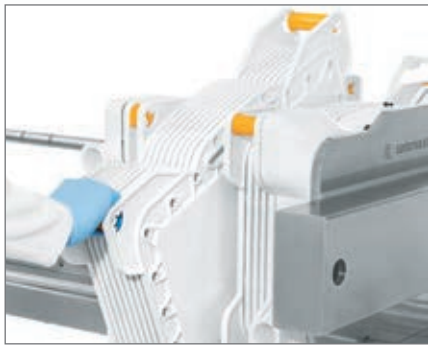
Cell and Contaminant Removal Technologies

Learn more about Sartoclear® Depth Filters

Applications

- Clarification of moderate cell density cultures (<5% wet cell weight)
- Post centrifuge filtration
- Mammalian cell culture harvests
- Microbial lysates
- Removal of precipitates from sera and plasma
- Particle and colloid removal from process intermediates

Sartoclear® filters are cellulose-based depth filters developed for demanding clarification applications in the biotechnological and pharmaceutical industries. Cellulose based depth filters protect subsequent membrane filters from premature blockage by retaining particles and contaminants originating from the host organism.



The wide range of grades offers a solution for a variety of applications such as post centrifuge filtrations, perfusion processes, and direct harvests with moderate cell densities.

Various filter sizes and formats are available to meet the process requirements from early development throughout clinical phases and up to large scale manufacturing while always keeping the same filter material.

Big variety of device formats	▶ Serves customer from the lab up to large scale commercial manufacturing with the same depth filter grade
Three different sizes per grade	▶ Linear scale up & flexible filtration areas
Availability in double layer and single layer formats	▶ Easy optimization with different applications
Lower pre-flushing volume (50 L/m^2)	▶ Reduces costs, water | buffer and saves time
Use the same accessories to run two depth filter grades in series	▶ Run primary and secondary clarification in one step
Ergonomic design	▶ Safe and easy dismantling of filled cassettes

kSep® Systems

Robust & Scalable Single-Use Centrifugation

Learn more about single-use centrifugation

Applications
- Harvest | Clarification
- Cell Therapy
- Vaccine Manufacturing

Sartorius kSep® systems provide robust, single-use bioprocessing solutions in the areas of recombinant therapeutics, cell therapy, vaccine manufacturing, and blood processing.

kSep® systems solve the problems of traditional centrifugation and filtration based technologies by handling very high cell densities while providing high recoveries and product quality.

Patented kSep® systems technology is the only current technology that provides significant advantages for users that want to either harvest cells as product or discard cells as by-product during manufacturing.

Only bowl centrifuge that does not stop rotating while discharging	▶ Integrates and	or reduces processing steps and time
Through the balance of centrifugal and fluid flow forces, the kSep® retains particles such as cells or microcarriers, as a concentrated fluidized bed under a continuous flow of media or buffer.	▶ Constant cell viability due to low shear
The system can be operated under sterile Conditions.	▶ All consumables are delivered pre-sterilized


sartorius stedim
biotech
A B C D

V. Bioanalytics and Biosafety

Product Characterization and Biosafety Testing Services

Physicochemical and Biological Analytical Comparability for Biosimilars

Demonstrating biosimilarity is a complex process that presents some unique challenges for developers and manufacturers. As an industry leading expert in supporting biosimilar development, BioOutsource offer a comprehensive testing package including structural, physicochemical and biological analysis. Our testing package includes off-the-shelf assays and platform methods to deliver cost efficiences and reduce development timelines.

BioOutsource partner with biosimilar clients at the following stages of drug development:

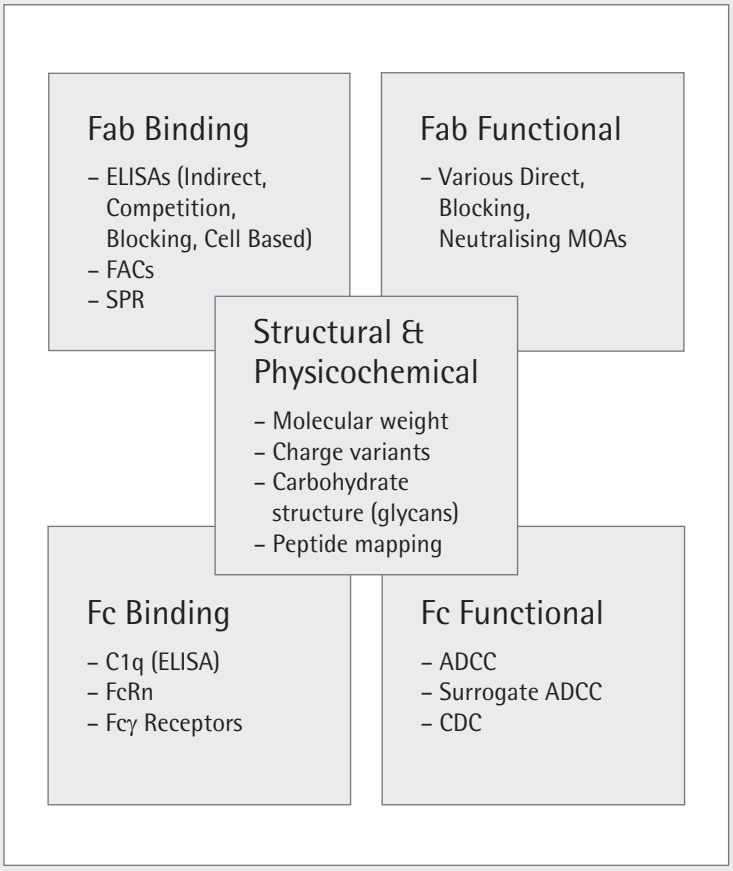
Cell Line Development → Clone Selection → Process Optimization → Process Characterization → Product Characterization → Comparability → Commercialization

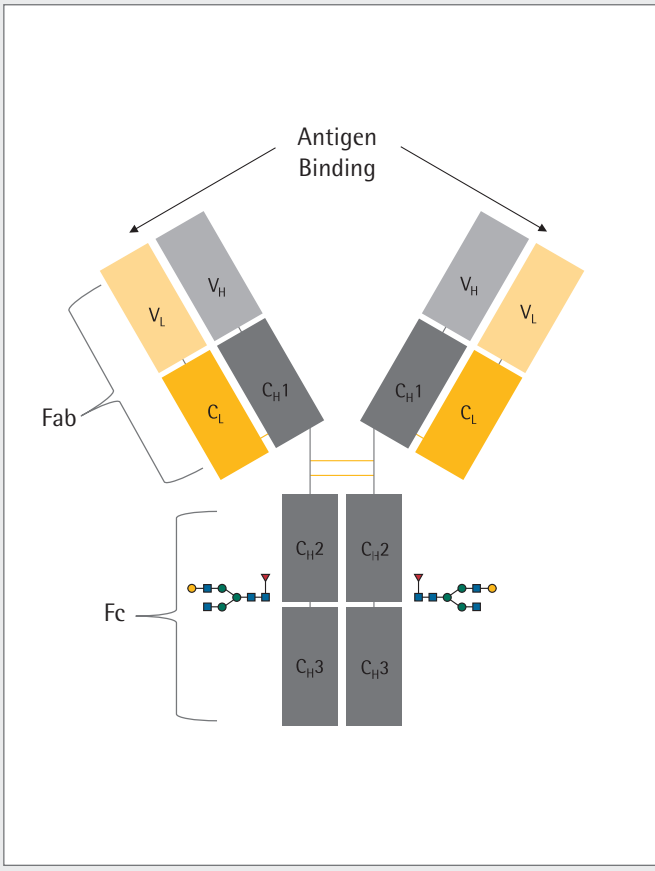
BioOutsource offer a variety of methods to support the testing of a wide range of biosimilar monoclonal antibodies including:

- Herceptin (trastuzumab)
- Humira (adalimumab)
- Enbrel (etanercept)
- Avastin (bevacizumab)
- Lucentis (ranibizumab)
- Rituxan (rituximab)
- Remicade (infliximab)
- Simponi (golimumab)
- Stelara (ustekinumab)
- Prolia (denosumab)
- Actemra (tocilizumab)

Currently, in our R&D pipeline we are developing methods to support assessments of biosimilarity for the following molecules:

- Erbitux (cetuximab)
- Synagis (palivizumab)
- Eylea | Zaltrap (aflibercept)
- Xolair (omalizumab)
- Opdivo (nivolumab)
- Tysabri (natalizumab)
- Yervoy (ipilimumab)
- Orencia (abatacept)





Key Benefits

Speed
- Reduce assay development time by accessing BioOutsource's off-the-shelf assays

Cost Reduction
- Reduce assay development costs using off-the-shelf assays

Technical Expertise
- Leverage BioOutsource's experience of working with over 50 biosimilar developers

Quality
- Greater quality assurance with sensitive methods and comprehensive data reporting

Regulatory
- Excellent regulatory insights for generating data required for regulatory submissions

Research & Development
- In-house R&D team works closely with clients to ensure that new methods are readily available for the next generation of biosimilars

Physicochemical and Biological Characterization of Novel Biological Entities

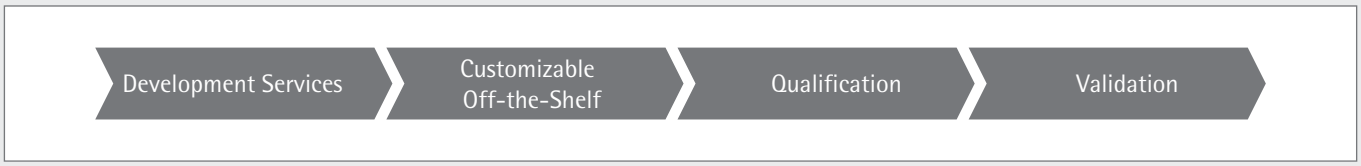
Our off-the-shelf Targets

We have extensive expert knowledge to support your New Biological Entity (NBE) with our off-the-shelf & custom assays, as well as regulatory compliant biosafety testing in the following areas:

- Bioassays
- Cell-based Potency Assays
- Binding Assays
- Physicochemical & Structural Analyses
- Qualification & Validation

Our Approach = Your Success

Speed	Faster assay development to shorten your timeline IND submission
Flexibility	Tailored testing packages
Expertise	Extensive experience & full range of platform methodologies
Compliant	Fully cGMP compliant laboratories
Integrated	Full service package available



Our method lifecycle approach takes you from pre-clinical development through to phase III validation and commercial lot release, with a smooth transition to cGMP services from our fully compliant laboratories.

Early Assay Development & Screening

- Custom Assay Development (DoE)
- Tech Transfer
- Optimization (DoE)

Structural and Physiochemical Analytical Package

- Supporting your development process from pool | clone selection -> assessments of product stability
- Methods to meet regulatory standards

Analytical Methods Qualification

- ICH Q6B Specifications: Test Procedures and Acceptance Criteria for Biotechnological | Biologcal Products
- ICH Q2B Validation of Analytical Procedures

Our panel of off-the-shelf monoclonal antibody characterization assays are ready to go for a range of targets (TNF, CD20, VEGF, HER2, EGFR, PD-1, PD-L1, IgE, IL-12/23, RANKL. etc). Our assays have been qualified with commercially available innovator mAbs such as Humira, Rituxan, Herceptin, Avastin etc. – Ask for our qualification reports today.

Fab Binding
- ELISA Methods
- Flow Cytometry
- SPR Methods

Structural Analysis
- LC-MS Methods
- N-glycan Analysis
- Intact Mass
- Peptide Mapping

Fab Functional
- Various direct
- Blocking
- Neutralizing
- MOAs

Fc Binding
- C1q (ELISA & SPR)
- Fcγ Receptor SPR
- FcRn

Fc Functional
- ADCC
- ADCP
- CDC

Don't see your target? Don't worry.
Contact us today to discover our possibilities.

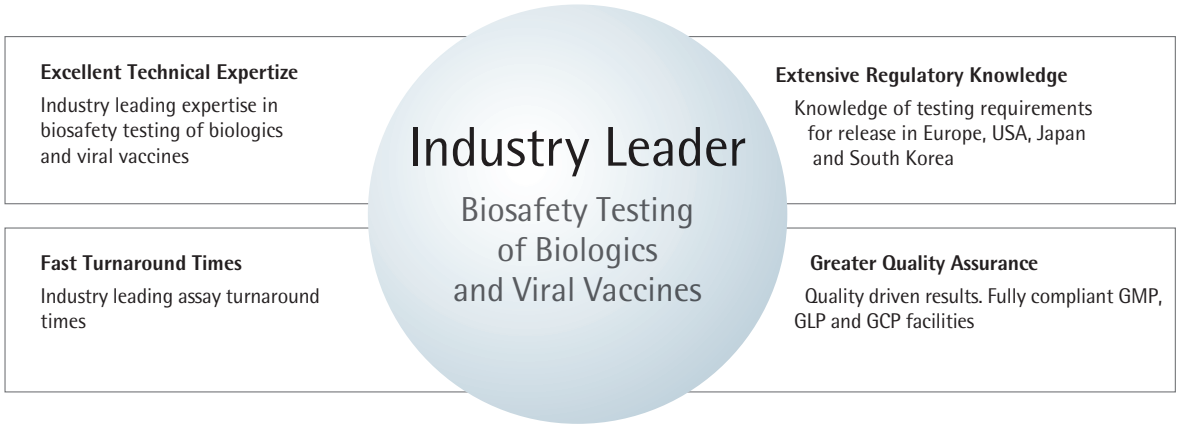
Full Range of Fc Effector Binding & Functional Assays
- Protein therapeutics: Characterization of immunological and biological properties
- Experience in Fc characterization assays including, binding to C1q, Fc receptors, ADCC & CDC

GMP Method Validation
- Product specific validation supporting stability studies & lot release
- USP1033, Ph. Eur. & ICH Q2B specifications

Biosafety Testing Services

Our Capabilities

All biopharmaceutical and biotechnology products must undergo stringent safety testing throughout development and manufacture to ensure the products and host cell lines are characterized and free from contamination.



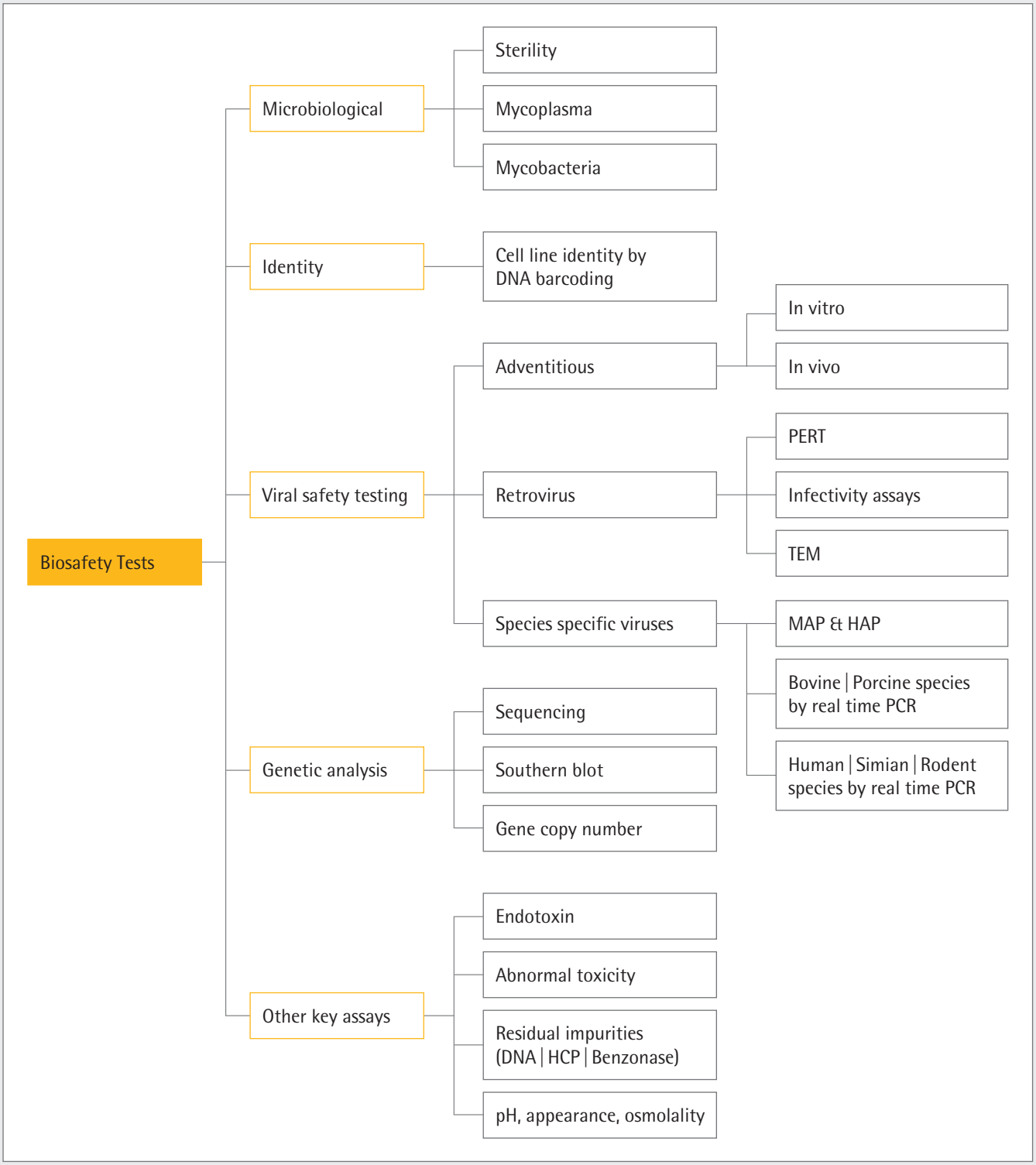
Biosafety testing within the manufacturing process should be established in the early stages of drug development. Before clinical trials, the cell banks (Master, Working, and End of Production) require comprehensive testing to characterize the bank, demonstrate purity and confirm that the banks are free from contamination and adventitious agents. We have developed and validated a range of assays to characterize cell banks originating from different species including murine, hamster, human and primates.

BioOutsource also supports the testing of bulk harvests and final product and have experience working with the following products:

- Biosimilar (monoclonal antibodies)
- Recombinant proteins
- Viral vaccines
- Gene therapy vectors
- Oncolytic virus products
- Plasma-derived therapies
- Cell therapies

BioOutsource partners with clients from early stage development through to commercialization of the product:

Cell Line Development → Clone Selection → Process Optimization → Process Characterization → Product Characterization → GMP Lot Release

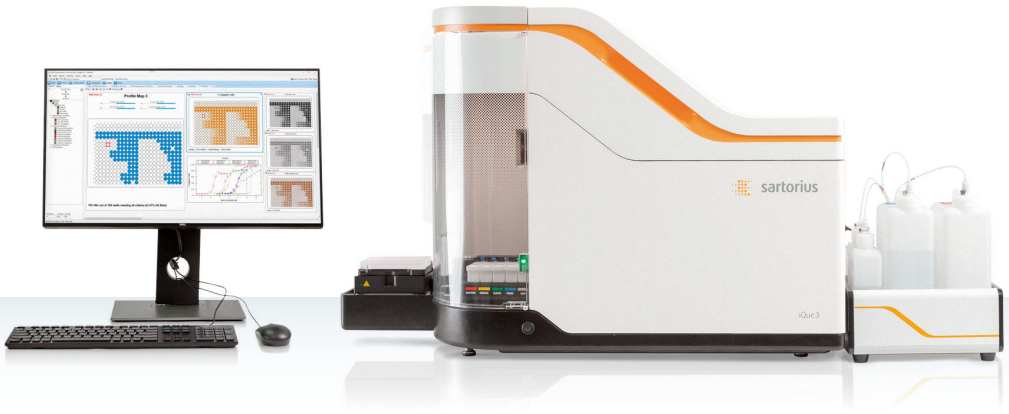

Biosafety Tests
Microbiological
Sterility
Mycoplasma
Mycobacteria
Identity
Cell line identity by DNA barcoding
Viral safety testing
Adventitious
In vitro
In vivo
Retrovirus
PERT
Infectivity assays
TEM
Species specific viruses
MAP & HAP
Bovine | Porcine species by real time PCR
Human | Simian | Rodent species by real time PCR
Genetic analysis
Sequencing
Southern blot
Gene copy number
Other key assays
Endotoxin
Abnormal toxicity
Residual impurities (DNA | HCP | Benzonase)
pH, appearance, osmolality

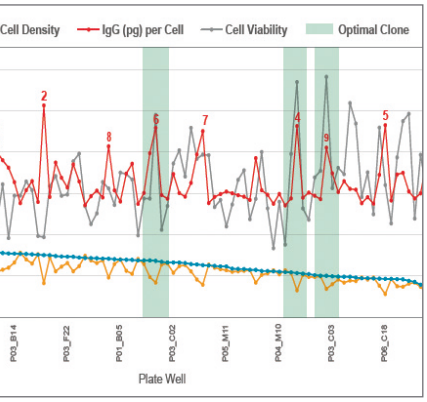
Cy-Clone PLUS™ Kit

The Fastest Way to Identifying Clones

Applications

- Identifies optimal clones with more critical productivity attributes
- Provides fast and easy clone selection
- Assesses IgG production on a per cell basis
- Provides cell viability and count assessment





The Cy-Clone PLUS™ kit along with the iQue3 and and ForeCyt® Software correlates IgG quantitation per cell with cell health readouts and cell density in a single, cost-effective assay that can migrate through the entire workflow from screening to scale up.

Cell number is an important variable to consider when ranking clones. It is helpful to understand how many cells are producing the IgG titer to get a better picture of whether a particular clone is growing well and whether it is an optimal producer or not. Assessing IgG production on a per cell basis, in addition to cell density and total IgG production measurements, gives a much different picture as to which clones are the optimal producers. Cy-Clone PLUS™ multiparametric readout (IgG titer, IgG titer per cell, cell density and cell viability) offers more critical productivity attributes from each clone, a comprehensive assessment of which clones are healthy and will be the optimal producers for further evaluation.

Content – More critical productivity attributes from each clone	▶ More relevent data, clone numbers, viability, how the clones are performing
Speed – More clones screened in less time	▶ Evaluate 3.5 × more clones than legacy methods
Usability – More user-friendly workflow, templated analysis and easy visualization	▶ The Profile Map feature in ForeCyt® Software, automatically defines the the desired clones from user-defined criteria
Insight – More insight for better clone selection	▶ Insight leads to actionable results to drive cell line development forward

Virus Counter® Platform

Biologically-Relevant Total Virus Particle Quantification

Learn more about Virus Counter® Platform

Applications

- Optimization of growth conditions in process development
- Monitor viral titer in near real-time
- Increased yields and shortened timelines by harvesting with precision
- Early identification of challenges

The Virus Counter® platform is purpose-built for virus quantification. The instrument, reagents and software are optimally suited to quantify total viral particles in near real-time.

The Virus Counter® platform offers an emerging approach to enable direct, biologically-relevant quantification of viruses in minutes, rather than the days or weeks required by more historical methods. The platform features multiple detection systems, the versatile Combo Dye® reagent and the antibody-based ViroTag® reagents.

Both approaches use a simple, no wash workflow to stain virus samples, offering the right solution for individual quantification needs. The platform allows users to optimize growth conditions for viral production, track viral titers in bioreactors, and precisely determine optimal harvesting times.

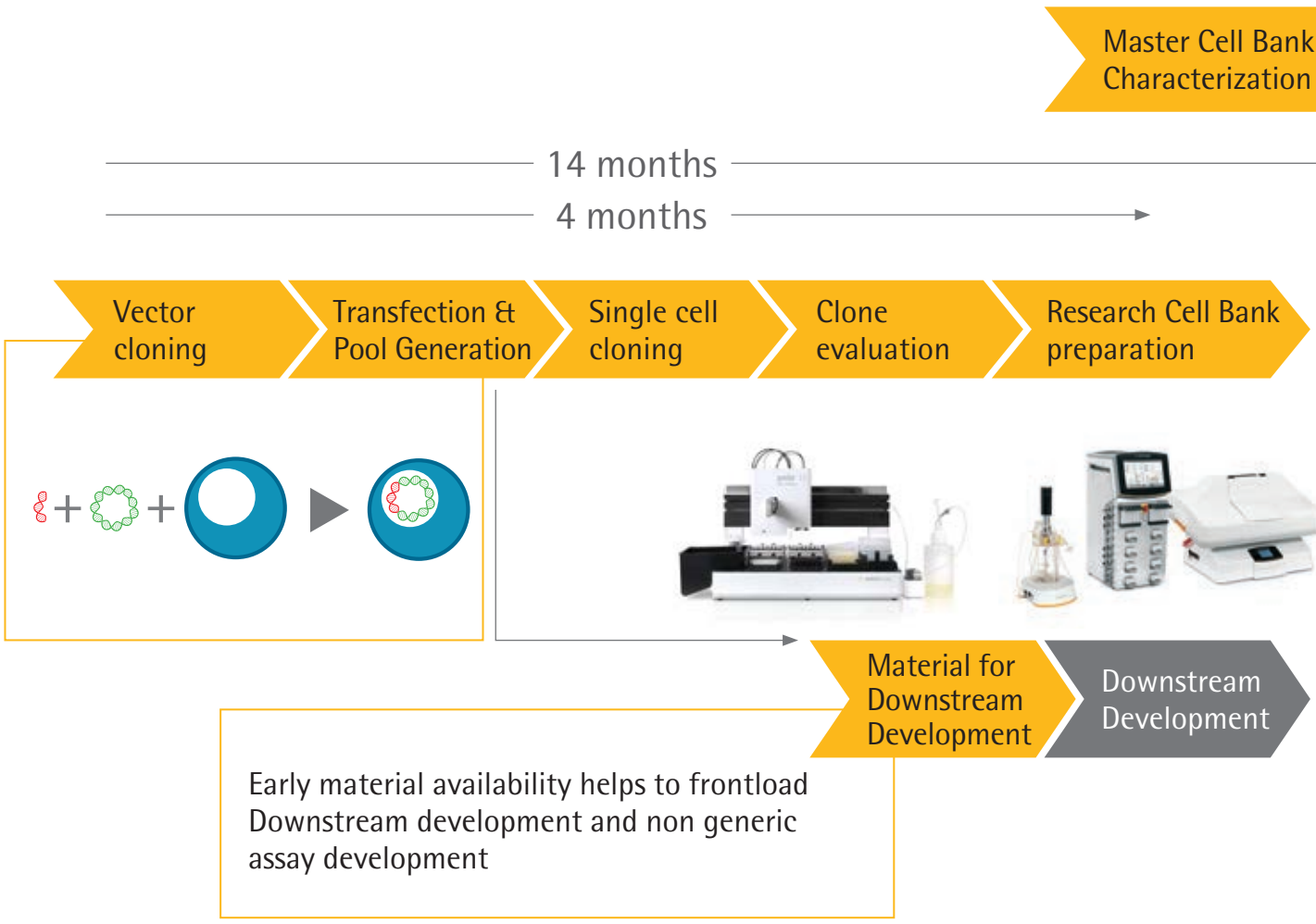
Flow-based, no wash assay	▶	Unrivaled speed to results
Virus-specific reagents	▶	Biologically-relevant and specific readout
Direct binding of fluorescent reagents	▶	Total virus particle quantification
Software-assistend operation and analysis	▶	Ease-of-Use

VI. Application and Engineering Services

Accelerate The Early Phase Drug Development

Sartorius Process Development Consultants Guide Through Process Design

Sartorius provides a free process development consultancy service to support the integration of your early phase development activities ensuring speed to clinic and commercial manufacturing with robust, cost-effective processes.



"As scientific innovation in healthcare expands rapidly, biotech companies are aggressively looking to move their products in to the clinic quickly. Sartorius' Process Development Consultants will advise on an optimal PD strategy every step of the way and help build a rapidly scalable process around your molecule."

Drug Substance & Drug Product CoA

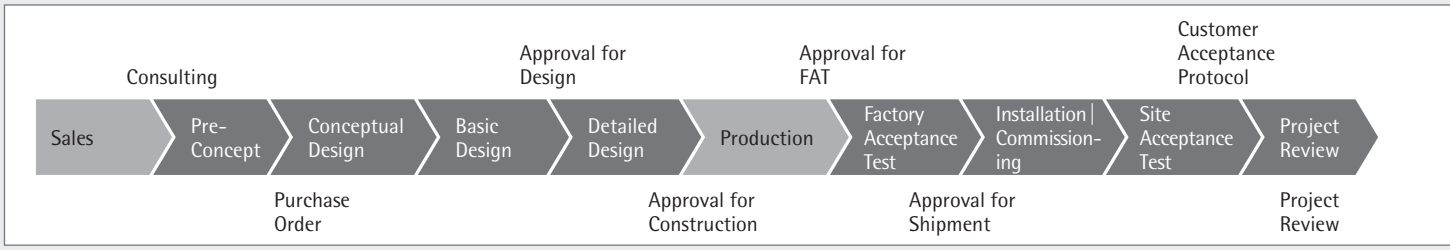
Confirmation run | Downstream Development | Tox Production | Clinical Production

Flexible, Scalable and Cost Efficient Bioprocess Facility Solutions

Rapid and Flexible Biomanufacturing

The Sartorius Integrated Solutions team works with the customer and designs the entire biomanufacturing process based on single-use or hybrid solutions. Sartorius delivers and implements rapid and cost-effective biomanufacturing solutions from early phase development through scale-up to commercial manufacturing. Benefit from the most comprehensive bioprocess technology portfolio coupled with Sartorius' expertise in single-use technologies. The global bioprocess engineering teams are available to discuss development and manufacturing requirements.

Bioprocess consultancy services for optimized process design and best technology selection



Visit the Integrated Solution Website.

Discover companies who have found success with Integrated Solutions. From contract manufacturing organisations to pharma companies, producing monoclonal antibodies, antibody drug conjugates, vaccines or blood and plasma products.

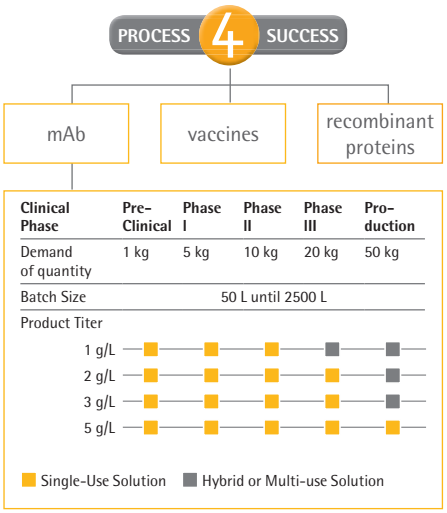
Watch Video:
Moving your biopharmaceutical process towards production

Customer specific BIOSTAT STR® 2000 Twin design

SARTOFLOW® 150 Crossflow System

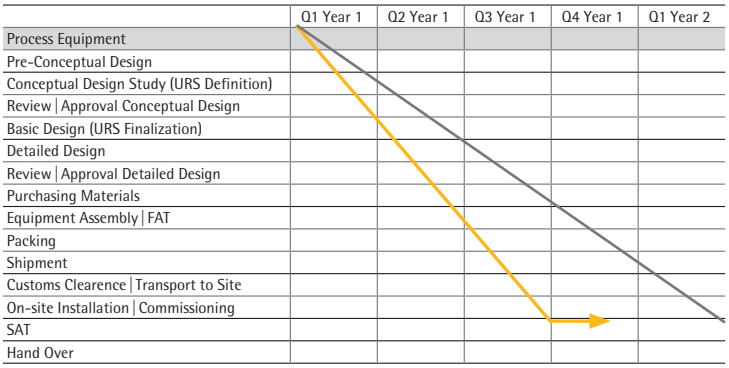
Over 100 Successful Fully Single-Use and Hybrid Project Implementations

Mitigate Investment Risks due to Strong Attrition Rates in Bioprocess Development
We design a bioprocess solution with maximum flexibility in mind to facilitate changing requirements. We tailor our offering around your business scenario along your short and long term goals. We have experience of process design and engineering from implementing a wide variety of different products and processes at different scales. With over 100 successful process implementations we understand the implication on bioprocess design when working with single-use and hybrid solutions.



Project execution timeline for a monoclonal antibody process (1000 L, 3 g/L titer)

Using our mAb process platform approach based on pre-defined solutions, you reduce engineering efforts and deliver your project at a considerably shorter timeline compared to conventional stainless steel approaches.



- Process4Success (Single-use Platform Process)
- Classic Stainless Steel

Visit Your Closest Sartorius Application Center!

Experience hands-on how our single-use bioprocess solutions work and improve customer specific operations. Visit one of Application Centers in the USA, Germany or China. For further information, follow the links below or contact the local sales representative. We are looking forward to welcoming you soon.

Key Benefits

- Projects can be discussed with Sartorius experts to identify the best solution for every specific need based on Sartorius' broad experience
- Experience flexible, reliable and smart equipment for specific applications
- Look beyond the obvious and see further systems that might simplify the daily work

Bohemia, NY, USA
https://www.sartorius.com/en/knowledge/application-center/application-center-new-york-usa

Goettingen, Germany
https://www.sartorius.com/en/knowledge/application-center/application-center-goettingen-germany

Shanghai, China
https://www.sartorius.com/en/knowledge/application-center/application-center-shanghai-china

Glossary

ADCC	Antibody-Dependent Cellular Cytotoxicity
ASTM	American Society for Testing and Materials
bDtBPP	Bis (2,4-di-tertbutylphenyl) phosphate
CAR	Chimeric Antigen Receptor
CC	Cell Culture
CD	Chemically Defined
CDC	Complement Dependent Cytotoxicity
CFD	Computational Fluid Dynamics
CHO	Chinese Hamster Ovary (cells)
CIP	Cleaning in Place
DCU	Digital Control Unit
DNA	Deoxyribonucleic Acid
DOE	Design of Experiments
DSE	Design Space Estimation
FAT	Factory Acceptance Test
FDA	Food and Drug Administration
FPERT	Fluorescent Product Enhanced Reverse Transcriptase
GAMP	Good Automated Manufacturing Practice
GF	Glass Fiber
GLP	Good Laboratory Practice
GMP	Good Manufacturing Pratice
HAP	Hamster Antibody Production
HCP	Host Cell Protein
IQ | OQ	Installation Qualification / Operational Qualification
ISO	International Organization for Standardization
LAK	Lymphokine Activated Killer
LED	Light Emitting Diode
lpm	Litre Per Minute
mAb	Monoclonal Antibodies
MAP	Mouse Antibody Production
MCB	Master Cell Bank
MDCK	Madin-Darby canine kidney (cells)
MFC	Mass Flow Controller
MLV	Murine Leukemia Virus

MO	Microbial Culture
MVDA	Multivariate Data Analysis
MVM	Minute Virus of Mice
NIR	Near Infrared
NAO	Non Animal Origin
OPC	Open Platform Communications
PAT	Process Analytical Technology
PBL	Peripheral Blood Lymphocytes
PCR	Polymerase Chain Reaction
PES	Polyethersulfone
PID | P&ID	Piping and Instrumentation Diagram
PLC	Programmable Logic Controller
PPV	Porcine Parvovirus
PTFE	Polytetrafluoroethylene
QbD	Quality by Design
QC	Quality Control
R&D	Research and Development
RAPD	Rapid Amplification Polymorphic DNA
RCB	Research Cell Bank
RF	Radio Frequency
RM	Rocking Motion
rpm	Revolutions per Minute
SAT	Site Acceptance Ttest
SCADA	Supervisory Control and Data Acquisition
SIP	Sterilization In Place
SOP	Standard Operating Procedure
SPR	Surface Plasmon Resonance
SU	Single Use
SV	Solenoid Valve
TEM	Transmission Electron Microscopy
TIL	Tumor Infiltrating Lymphocytes
USP	U.S. Pharmacopeial Convention
WCB	Working Cell Bank
WFI	Water for Injection

Solutions for Downstream Processing Needs

Sartorius offers a wide range of process solutions for purification of monoclonal antibodies, recombinant proteins, vaccines and antibody drug conjugates.

SCADA system, process automation and chemometrics toolbox

Harvest

- Single-use centrifugation
- Depth filters
- Sterile filtration
- Crossflow filtration
- Biosafety testing

Buffers

- Platform system for buffer preparation
- Bags for mixing and storage
- Ready-made liquid buffers in bottles and bags

Virus Inactivation

- ■ Platform system for low pH virus inactivation

Concentration | Diafiltration

- ■ Crossflow systems and cassettes

Capture

- ■ Membrane adsorption chromato-graphy solutions

■ Production ■ Process development & scale-down devices

Polishing

- Membrane adsorption chromatography solutions

Virus Filtration | Clearance

- Virus filtration systems and filters

Bulk Drug Substance Preparation

- Crossflow systems and cassettes
- Freeze-thaw bags
- Controlled freeze-thaw solutions
- Sterile filters and integrity testers

Pre- and sterile filters, integritiy testers, bags for mixing and storage, tubings, connectors, disconnectors

Overview Weblinks

Page	Description	Link
28	Learn more about FlexAct® Solution	https://www.sartorius.com/en/products/process-filtration-purification/flexact-single-use-automated-solutions
30	Learn more about the Sartopore® 2 Filter Family	https://www.sartorius.com/shop/ww/en/usd/sartopore%c2%ae-2/c/M_Sartopore_2
30	Learn more about the Sartoguard Filter Family	https://www.sartorius.com/shop/ww/en/usd/sartoguard%c2%ae/c/M_Sartoguard
31	Learn more about the MaxiCaps® MR	https://www.sartorius.com/en/products/process-filtration-purification/process-sterile-filtration/filter-transfer-sets/maxicaps-mr
32	Learn more about the Sartocheck® 5 Plus Filter Integrity Tester	https://www.sartorius.com/en/products/process-filtration-purification/process-filtration-hardware/integrity-testing/sartocheck-5
33	Learn more about the virus risk mitigation strategy	https://www.sartorius.com/en/products/process-filtration-purification/virus-filtration/virosart-media
38	Learn more about the new generation of ambr® 15 cell culture	https://www.sartorius.com/en/products/fermentation-bioreactors/ambr-multi-parallel-bioreactors/ambr-15-cell-culture
39	Take a tour of the ambr® 15 fermentation workstation and microbioreactor vessel	https://www.sartorius.com/en/products/fermentation-bioreactors/ambr-multi-parallel-bioreactors/ambr-15-fermentation
42	Find out about ambr® 250 high throughput	https://www.sartorius.com/en/products/fermentation-bioreactors/ambr-multi-parallel-bioreactors/ambr-250-high-throughput
44	Read about ambr® 250 high throughput perfusion	https://www.sartorius.com/en/products/fermentation-bioreactors/ambr-multi-parallel-bioreactors/ambr-250-high-throughput-perfusion
46	Find out more about ambr® 250 modular	https://www.sartorius.com/en/products/fermentation-bioreactors/ambr-multi-parallel-bioreactors/ambr-250-modular
49	See how easy it can be to control a bioreactor	https://www.sartorius.com/en/products/fermentation-bioreactors/benchtop-bioreactors/biostat-a
50	Check out the possibilities of BIOSTAT® B	https://www.sartorius.com/en/products/fermentation-bioreactors/benchtop-bioreactors/biostat-b
50	Watch Video on Sartorius Benchtop Bioreactor Website	https://www.sartorius.com/en/products/fermentation-bioreactors/benchtop-bioreactors
51	Learn more about the BIOSTAT® B-DCU as Perfusion Bioreactor	https://www.sartorius.com/en/products/fermentation-bioreactors/benchtop-bioreactors/biostat-b-dcu
52	Get more information about the features of UniVessel® Glass	https://www.sartorius.com/en/products/fermentation-bioreactors/benchtop-bioreactors/univessel-glass
53	Turn the production process to single-use	https://www.sartorius.com/en/products/fermentation-bioreactors/benchtop-bioreactors/univessel-su
54	Learn more about the BIOSTAT® RM TX for cell therapy applications	https://www.sartorius.com/en/products/fermentation-bioreactors/single-use-bioreactors/biostat-rm-tx
55	Learn more about the BIOSTAT® RM as a fully GMP compliant wave-mixed bioreactor	https://www.sartorius.com/en/products/fermentation-bioreactors/single-use-bioreactors/biostat-rm-flexsafe-rm

Page	Description	Link
56	Learn more about the BIOSTAT® RM 200 rocker as a large-scale bioreactor	https://www.sartorius.com/en/products/fermentation-bioreactors/single-use-bioreactors/biostat-rm-flexsafe-rm
58	Learn more about the BIOSTAT STR® bioreactor family	https://www.sartorius.com/en/products/fermentation-bioreactors/single-use-bioreactors/biostat-str-flexsafe-str
59	Learn more about the Flexsafe STR® single-use bags	https://www.sartorius.com/en/products/fermentation-bioreactors/single-use-bioreactors/biostat-str-flexsafe-str
60	Learn more about the Integrity Testing incl. bag test	https://www.sartorius.com/en/products/process-filtration-purification/process-filtration-hardware/integrity-testing
62	Learn more about the Flexsafe® bag family	https://www.sartorius.com/en/products/fluid-management/liquid-storage-shipping/flexsafe-liquid-storage-shipping
62	Watch Video: New Bag Family	https://www.sartorius.com/en/products/fluid-management/liquid-storage-shipping/flexsafe-liquid-storage-shipping
66	Learn more about the BIOSTAT® Cplus as a laboratory stainless steel fermenter	https://www.sartorius.com/en/products/fermentation-bioreactors/stainless-steel-bioreactors/biostat-cplus
67	Learn more about the BIOSTAT® D-DCU as the fast lane to production	https://www.sartorius.com/en/products/fermentation-bioreactors/stainless-steel-bioreactors/biostat-d-dcu
74	Learn more about the BioPAT® ViaMass as biomass measurement sensor	https://www.sartorius.com/en/products/process-control-data-analytics/prozess-analyzers
76	Learn more about the BioPAT® Trace as glucose and lactate sensor	https://www.sartorius.com/en/products/process-control-data-analytics/prozess-analyzers
77	Implement a continuous OD600 measurement with BioPAT® Fundalux	https://www.sartorius.com/en/products/process-control-data-analytics/prozess-analyzers
78	Develop perfusion feeding strategies facilitated by BioPAT® Xgas	https://www.sartorius.com/en/products/process-control-data-analytics/prozess-analyzers
84	Learn more about BioPAT® MFCS	https://www.sartorius.com/en/products/process-control-data-analytics/automation/biopat-mfcs
91	Learn more about the ambr® clone selection software	https://www.sartorius.com/en/products/fermentation-bioreactors/software-apps-for-bioreactors/ambr-clone-selection
93	Click here to request a personal software license	https://www.sartorius.com/en/products/fermentation-bioreactors/software-apps-for-bioreactors/biostat-t
98	Learn more about FlexAct® Solution	https://www.sartorius.com/en/products/process-filtration-purification/flexact-single-use-automated-solutions
99	Learn more about Sartoclear® Depth Filters	https://www.sartorius.com/en/products/process-filtration-purification/process-filtration-harvesting/sartoclear-depthfilters
100	Learn more about single-use centrifugation	https://www.sartorius.com/en/products/process-filtration-purification/process-filtration-harvesting/ksep-systems
111	Learn more about Virus Counter® Platform	https://www.sartorius.com/en/applications/quality-control-testing/virus-quantification

Sales and Service Contacts

For further contacts, visit www.sartorius-stedim.com

Europe

Germany
Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen

Phone +49.551.308.0

Sartorius Stedim Systems GmbH
Robert-Bosch-Strasse 5 – 7
34302 Guxhagen

Phone +49.5665.407.0

France
Sartorius Stedim FMT S.A.S.
ZI des Paluds
Avenue de Jouques – CS 91051
13781 Aubagne Cedex

Phone +33.442.845600

Sartorius Stedim France SAS
ZI des Paluds
Avenue de Jouques – CS 71058
13781 Aubagne Cedex

Phone +33.442.845600

Austria
Sartorius Stedim Austria GmbH
Modecenterstrasse 22
1030 Vienna

Phone +43.1.7965763.18

Belgium
Sartorius Stedim Belgium N.V.
Rue Colonel Bourg 105
1030 Bruxelles

Phone +32.2.756.06.80

Hungary
Sartorius Stedim Hungária Kft.
Kagyló u. 5
2092 Budakeszi

Phone +36.23.457.227

Italy
Sartorius Stedim Italy S.r.l.
Via dell'Antella, 76/A
50012 Antella-Bagno a Ripoli (FI)

Phone +39.055.63.40.41

Netherlands
Sartorius Stedim Netherlands B.V.

Phone +31.30.60.25.080

filtratie.nederland@sartorius-stedim.com

Poland
Sartorius Stedim Poland Sp. z o.o.
ul. Wrzesinska 70
62-025 Kostrzyn

Phone +48.61.647.38.40

Russian Federation
LLC "Sartorius Stedim RUS"
Vasilyevsky Island
5th line 70, Lit. A
199178 St. Petersburg

Phone +7.812.327.53.27

Spain
Sartorius Stedim Spain, S.A.U.
Avda. de la Industria, 32
Edificio PAYMA
28108 Alcobendas (Madrid)

Phone +34.913.586.098

Switzerland
Sartorius Stedim Switzerland AG
Ringstrasse 24 a
8317 Tagelswangen

Phone +41.52.354.36.36

U.K.
Sartorius Stedim UK Ltd.
Longmead Business Centre
Blenheim Road, Epsom
Surrey KT19 9 QQ

Phone +44.1372.737159

Ukraine
LLC "Sartorius Stedim RUS"
Post Box 440 "B"
01001 Kiev, Ukraine

Phone +380.44.411.4918

Africa

Republic of South Africa
Sartorius South Africa (Pty) Ltd
Unit 4, Alphen Square South
853 16th Road
Midrand 1685, RSA

Phone +27.11.315.5444

Americas

USA
Sartorius Stedim North America Inc.
565 Johnson Avenue
Bohemia, NY 11716

Toll-Free +1.800.368.7178

Argentina
Sartorius Argentina S.A.
Int. A. Ávalos 4251
B1605ECS Munro
Buenos Aires

Phone +54.11.4721.0505

Brazil
Sartorius do Brasil Ltda
Avenida Senador Vergueiro 2962
São Bernardo do Campo
CEP 09600-000 - SP- Brasil

Phone +55.11.4362.8900

Mexico
Sartorius de México, S.A. de C.V.
Libramiento Norte de Tepotzotlan s/n,
Colonia Barrio Tlacateco,
Municipio de Tepotzotlan,
Estado de México,
C.P. 54605

Phone +52.55.5562.1102

leadsmex@sartorius.com

Asia | Pacific

Australia
Sartorius Stedim Australia Pty. Ltd.
Unit 5, 7-11 Rodeo Drive
Dandenong South Vic 3175

Phone +61.3.8762.1800

China
Sartorius Stedim (Shanghai)
Trading Co., Ltd.
3rd Floor, North Wing, Tower 1
No. 4560 Jinke Road
Zhangjiang Hi-Tech Park
Pudong District
Shanghai 201210, P.R. China

Phone +86.21.6878.2300

Sartorius Stedim (Shanghai)
Trading Co., Ltd.
Beijing Branch Office
No. 33 Yu'an Road
Airport Industrial Park Zone B
Shunyi District, Beijing 101300

Phone +86.10.8042.6501

Sartorius Stedim (Shanghai)
Trading Co., Ltd.
Guangzhou Branch Office
Room 1105
Xing Guang Ying Jing Building
No. 119, Shui Yin Road
Yue Xiu District, Guangzhou 510075

Phone +86.20.3836.4193

India
Sartorius Stedim India Pvt. Ltd.
#69/2-69/3, NH 48, Jakkasandra
Nelamangala Tq
562 123 Bangalore, India

Phone +91.80.4350.5250

Japan
Sartorius Stedim Japan K.K.
4th Fl., Daiwa Shinagawa North Bldg.
8-11, Kita-Shinagawa 1-chome
Shinagawa-ku, Tokyo, 140-0001 Japan

Phone +81.3.4331.4300

Malaysia
Sartorius Stedim Malaysia Sdn. Bhd.
Lot L3-E-3B, Enterprise 4
Technology Park Malaysia
Bukit Jalil
57000 Kuala Lumpur, Malaysia

Phone +60.3.8996.0622

Singapore
Sartorius Stedim Singapore Pte. Ltd.
10 Science Park Rd
The Alpha #02-13/14
Singapore Science Park II
Singapore 117684

Phone +65.6872.3966

South Korea
Sartorius Korea Biotech Co., Ltd.
8th Floor, Solid Space B/D,
PanGyoYeok-Ro 220, BunDang-Gu
SeongNam-Si, GyeongGi-Do, 463-400

Phone +82.31.622.5700

www.sartorius-stedim.com

Publication No.: S--1526-e191007 · Order No.: 85037-541-65 · Ver. 10|2019