sartorius stedim biotech

Your Guide to Upstream Processing Solutions From Research to Production

turning science into solutions

Our Solutions for Your 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 testing

Cell Line and Media Development

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

Test kits

cellca
is now part of the Sartorius Stedim Biotech Group

bio outsource
is part of the Sartorius Stedim Biotech Group




Production

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

Clarification

- Dynamic body feed filtration
- Crossflow filtration
- Depth filtration
- Steril filtration
- Virus filtration
- Membran chromatography
- Bags for fluid management (mixing and storage)

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

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


Your Guide to Upstream Processing Solutions

Sartorius: Your Partner for Bioprocess

Sartorius is a leading provider of cutting-edge equipment, consumables and services for the development and production of biopharmaceuticals, vaccines, regenerative medicine, and other biotech products.

Our integrated solutions for upstream and downstream processing have been supporting the biologics industry around the world for decades. Based on our expertise, we have been able to develop completely single-use process solutions that meet the requirements of future biomanufacturing.

Whether you just need a bioreactor or a single-use bag for media storage or are looking for a partner to build your completely single-use manufacturing facility, we will provide you with all the options, services and support you need.

Regardless of your preferences, we support you with a fully scalable and interchangeable range of single-use or glass and stainless steel bioreactor solutions. We understand that not every customer has the same needs, and your requirements can change over time.

Our array of automated multi-parallel mini bioreactors and classic benchtop bioreactors supports fast and reliable development and characterization of your processes throughout all phases.

Seamless transfer to pilot and production scale bioreactors is ensured by our thorough understanding of bioreactor design and scale-up principles, well-thought-out automation concepts and harmonized control strategies for oxygen, pH, temperature and feed addition.

Dr. Christel Fenge
Vice President Marketing and Product Management Fermentation Technologies

Moving your biopharmaceutical process towards production

Watch Video:
www.sartorius.com/video-integrated-solutions

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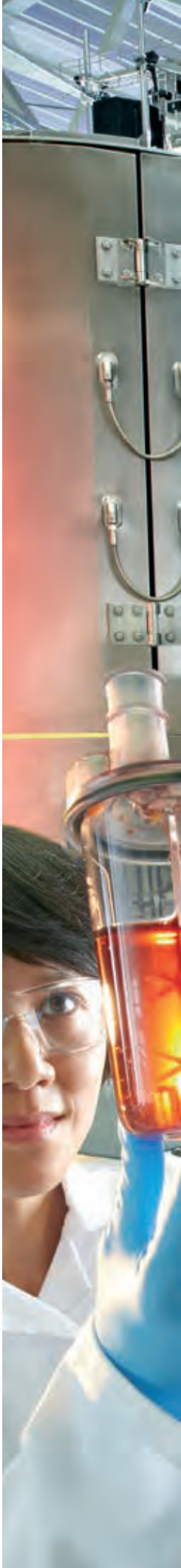


I. Cell Line

NEW Cell Line Development Services

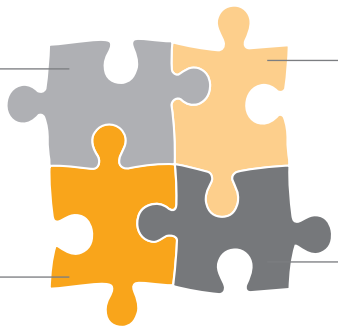
Cellca CHO Expression Platform

Sartorius Stedim Cellca is a leading provider of Cell Line Development Services for large-scale protein production of biopharmaceuticals in mammalian cells. Within 4 – 6 months the Cellca CHO 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.

Cellca CHO Expression Platform

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

Expression Vector
- DHFR system with high selection stringency
- Optimal signal peptide
- Freedom to operate



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

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

Your 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 40 successfully completed projects.

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

Performance
- 95% of our developed cell lines deliver protein titres exceeding 3 g/L in a 12 – 14 day standard fed-batch process.

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

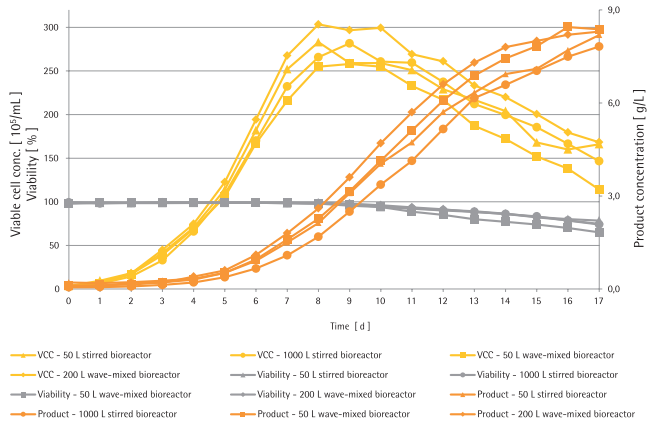
Vector Cloning → Transfection and Pool Generation → Single Cell Cloning → Clone Evaluation → RCB Preparation

From DNA to RCB in 4 Months

Products

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

Scalability and Robustness




BIOSTAT STR® 50 L


BIOSTAT STR® 1000 L


BIOSTAT® B with RM 50 Rocker


BIOSTAT® B with RM 200 Rocker

Scalability from shake flask to 1000 L with minimal process development

Proven Track Record

Product Concentration	2 g/L	3 g/L	4 g/L	5 g/L	6 g/L
Pre-clinic & Phase 1	4	21	9	4	2
Phase 2	1	1	–	–	1
Phase 3	1	–	–	–	–

Stability Study → Bioreactor Confirmation → Transfer & Documentation

3 – 4 Months

II. Media

Experience and Flexibility for Your Cell Culture Needs

Development of powerful cell culture media and feed strategies has dramatically changed our 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- and protein-free or even chemically defined media and feeds.

In collaboration with Lonza, 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.

Our 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.
- Two independent manufacturing sites in Europe and the U.S.
- 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

Are you looking for a partner that can manufacture your own cell culture media formulation? We can support you!

- Liquid media in containers ranging from 1 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

Do you want to optimize your cell culture medium? You have come to the right place.

- Expert support for your media optimization
- Lonza media optimization services
- CHOptimizer® Media Builder service

The Sartorius Media Team is looking forward to supporting you in making your projects a success!

Long-term Collaboration

sartorius stedim biotech | Lonza

Industry Leader

with
50 years of cell culture
experience

- Leading position in single-use applications that include fluid management, filtration and process analytical technology
- Pioneer in state-of-the-art micronization high-quality powder production processes
- Long-term relationships with dual-sourced raw material suppliers guarantees supply and quality
- Excellent regulatory dossier support
- 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 your core tasks and targets

Our Range of Cell Culture Media

A broad range of off-the-shelf media are available in liquid and powder format to provide you with maximum flexibility during early development.

Cells	Medium	Culture	NAO	Protein-free	Peptide-free	Primary application
CHO (e.g., DG44, CHO-S, CHO K1, DHFR$^-$)	UltraCHO	Suspension and adherent	No	No	No	Proteins
	ProCHO®-5	Suspension	Yes	Yes	No	
	PowerCHO®-2		Yes	Yes	No	
	PowerCHO®-3		Yes	Yes	No	
	PowerCHO® Advance	Suspension	Yes	Yes	No	
	ProCHO®-AT	Adherent	Yes	Yes	No	
CHOK1SV (GS platform)	PowerCHO®-GS	Suspension	Yes	Yes	Yes	Proteins
	Lonza GS V8 Media and feeds*		Yes	Yes	Yes	
Hybridoma	HL-1	Suspension	No	No	No	Proteins
	ProDoma-3		Yes	Yes	No	
	UltraDoma		Yes	No	No	
	UltraDoma PF		No	Yes	Yes	
NS0	ProNS0 2	Suspension	Yes	Yes	No	Proteins
Insect cells (e.g., Sf9, Hi 5)	Insect Xpress		No	Yes	No	Proteins | Vaccines
Vero	ProVero-1	Adherent	Yes	Yes	No	Vaccines
	PC-1		No	No	No	
MDCK	UltraMDCK	Adherent	No	No	No	Vaccines
	ProMDCK		Yes	Yes	No	
HEK 293	Pro293a	Adherent	Yes	Yes	No	Vaccines
	Pro293s	Suspension	Yes	Yes	No	
Per.C6®*	Permexcis*		Yes	Yes	No	Vaccines
PerC6 (and retinoblastoma cell lines)	ProPER1	Suspension	Yes	Yes	No	Vaccines
Hematopoietic cells (e.g., T, NK, DC)	X-Vivo 10	Suspension	No	No	No	Cell therapy
	X-Vivo 15		No	No	No	
	X-Vivo 20		No	No	No	
	HL-1		No	No	No	
Mesenchymal stem cells	MSCGM CD	Adherent	No	No	No	Cell therapy
Adult dermal fibroblasts	FGM CD	Adherent	No	Yes	No	Cell therapy
Adult and neonatal primary keratinocytes	KGM CD	Adherent	No	No	No	Cell therapy
hPSC and IPSCs	LY media	Adherent	No	No	No	Cell therapy

NAO: Non-animal origin
CD: Chemically defined

* License required


sartorius stedim
BIOSTAT B

High Performance CHO Media and Feeds

We offer a full range of products such as standard or customized CHO cell culture media with various features, such as serum-free, protein-free, chemically defined and non-animal origin.

A broad range of off-the-shelf media are available in liquid and powder format to provide you with maximum flexibility during early development. We offer special kits for cell line and media development as liquid (1– 20 L) and as powder versions (up to 5 kg).

Typical Components of our Cell Culture Media

Product	Glucose	Amino Acids	Lipids	Vitamins	Trace Elements	Hydrolysates	Proteins
ProCHO4	✓	✓	✓	✓	✓	✓	–
ProCHO5	✓	✓	✓	✓	✓	✓	–
PowerCHO™-1	✓	✓	✓	✓	✓	–	–
PowerCHO™-2	✓	✓	✓	✓	✓	–	–
PowerCHO™-3	✓	✓	✓	✓	✓	–	–
PowerCHO™ Advance™	✓	✓	✓	✓	✓	–	–
CHOptimizer*	✓	✓	✓	✓	✓	–	–

*More information on CHOptimizer®, our advanced media optimization tool box on page 20

Media Supply for Process Development

We offer expedited production of pilot batches of customer specific media to support process development.

Media Supply for GMP Production

Our media production facilities are ISO 9001 | 2008 and 13485:2012 compliant following cGMP 21CFR820 guidelines.

Homogeneous particle size of powder formulations	▶ Facilitated dissolution
Wide range of batch sizes and packaging formats – Up to 10,000 L for liquid formulations – Up to seven tons for powder formulations	▶ Simplify your scale-up and improve your supply chain risk mitigation through our dual manufacturing sites
Large range of off-the-shelf media with complementary feeds	▶ Fast and easy media selection for early process development

PowerCHO Advance

New High Performance CHO Medium

NEW

Applications
- CHO cell culture
- Fed-batch processes
- Antibody production
- Recombinant protein production

The PowerCHO™ media family provides you with a high performance, chemically defined media for antibody and recombinant protein production in CHO cells. The latest addition, PowerCHO™Advance™ demonstrates superior performance compared to leading CHO media on the market.

PowerCHO™Advance™ provides optimal conditions for early studies in shake flasks and well controlled conditions in bioreactors.

PowerCHO™Advance™ has been optimized for improved filterability. It´s innovative formulation ensures reliable performance from small liquid volumes used during early development to large scale powder preparations for commercial production.

You can maximize your cell densities and yields in fed-batch cultures using our Power Feed A or Xtreme Feed.

Chemically defined medium for CHO fed-batch culture	▶	Maximize your titers
Contains only fully traceable, non-animal origin raw materials	▶	Regulatory-friendly, suitable for clinical trials and commercial manufacturing
Available in liquid and powder formats	▶	Comparable performance provides flexibility in development and production
Easy filtration and handling	▶	Simplify scale-up and media prep from powder

NEW CHOptimizer®

The Media Builder

The CHOptimizer® Media Builder is a modern, Design of Experiments (DoE) based approach to media development and optimization for CHO based fed-batch processes. You can apply this approach in your own facilities supported by our media development experts.

Fast and easy to use approach for optimization of your medium and feeds in your own facilities, supported by our media developmet experts

- Significantly improve your titers and cost of goods
- Your cell line never leaves your facility
- Save valuable development time and cost
- Get access to your own media formulation

Increase titers by developing your own optimized medium and feed strategy in just 5 months.

Our CHOptimizer® media optimization tool box combines the ambr® 15 with an integrated DoE approach for efficient testing of different media mixtures. Our media experts will guide you through this process.

Starting from 4 chemically defined and animal origin free media mixtures, you will test 24 pre-qualified blends under controlled conditions using the ambr® 15. We provide you with spend media analysis and an optimized medium composition and feeds for your specific cell line.

Complementary Approaches to Media Optimization

Benchmarking

+ Standard media and feeds
+ Easy and fast (if it works)
- No optimization of media, feeds and process parameters
- Non optimal viability and titer

CHOptimizer®

+ Optimal medium, feeds and process for specific cell line
+ Fast optimization process
+ High titers
+ Access to final formulation

Media optimization service

+ High titers
+ Fully customized media
+ Access to final formulation
- Start from "scratch"
- Long process
- Cells "leaving" your control

Do it yourself

Media starting kit + Industry standard multiparallel micro bioreactor (ambr®15) with integrated DoE software and application specialist support

Fully outsourced process without in-house know-how building

CHOptimizer®

Our expert support

Definition of goals and milestones
Experimental planning according to DoE principles

Phase I

First run

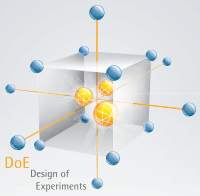
24 blends from basal media mixtures

Data analysis
Preparation of blends for phase II

Phase II

Second run

3 – 4 blends from phase I
2 – 3 replicates
Process parameter optimization

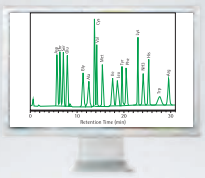


Data analysis
Spend media analysis
Preparation of final media and feeds

Phase III

Third run

Final media composition with feeds
Process | feed strategy optimization

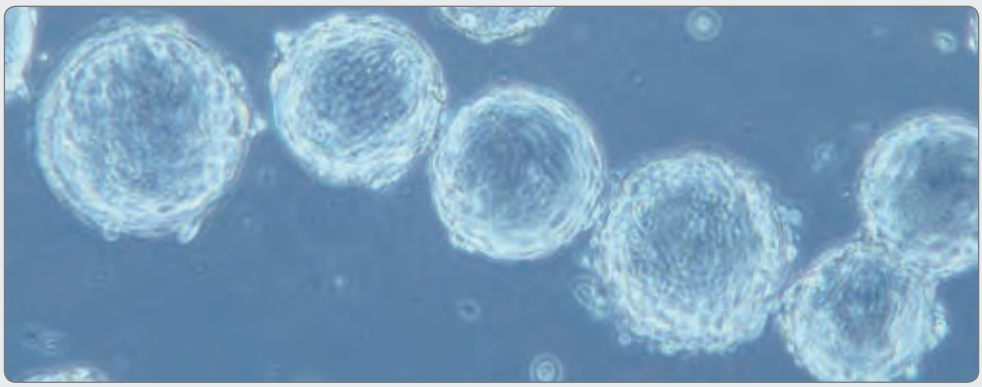


Data analysis
Final recommendation for custom media formulation and feeds

Optimized medium and feeds for your specific cell line

New, Improved Media for Viral Vaccine Production

A variety of cell lines are used for production of viral vaccines, such as HEK293, Vero, MDCK, and BHK21. More recently, also newly developed cell lines have been used, e.g. Sf9, EB66® and Per.C6®. Our media for vaccine production have been optimized for fast cell growth to optimal cell densities for best infection rate and virus production.



Vero cells grown on mycrocarriers

We offer media optimized for cell lines most commonly used for virus production.

Also, we provide license holders of Per.C6® cells with ProPer1 and Permexis media, specifically optimized for this cell line. Development is underway for a chemically defined medium for EB66® cells.

Our media support high density suspension culture and make infection easy.

For more information and to get the latest updates on Sartorius vaccine media please contact your local Sartorius representative.

Cell Line	Source	Medium	Culture
Insect Cells (e.g. Sf9, Hi 5)	Moth ovary	Insect Xpress	Suspension
Vero	African green monkey kidney	ProVero-1	Adherent
		PC-1	
		ProMDCK™	
MDCK	Canine kidney	ProMDCK™	Adherent
		UltraMDCK	
HEK 293	Human embryonic kidney	Pro293a	Adherent
		Pro293s	Suspension
Per.C6®	Human retinal	Permexcis®	Suspension
Per.C6® (and retino-blastoma cell lines)	Human retinal	ProPer1	Suspension

ProMDCK™

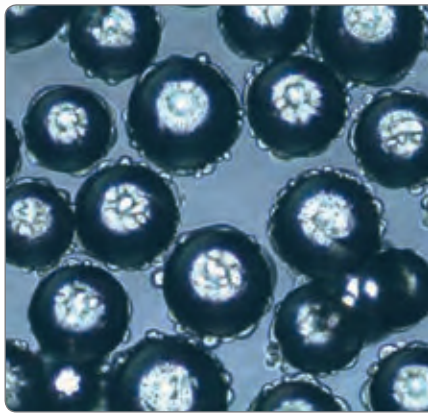
Serum free, protein free media for culture in flasks or on microcarriers

Applications
- Seed expansion, growth and infection of MDCK cells
- Suitable media formulations for adherent culture in T-flasks, roller bottles and on microcarriers in bioreactors
- Expansion of influenza virus (H1N1, H3N2, and B)

ProMDCK™ 2D and ProMDCK™ 3D are serum-free media specifically developed to support vaccine production with MDCK cells (Madin-Darby Canine Kidney cells).

ProMDCK™ media are optimized for expansion and virus infection of MDCK cells in static culture conditions such as roller flasks, trays and other 2D formats, as well as, in suspension in stirred tank bioreactors grown on micro-carriers (3D). Cells can be directly transitioned from ProMDCK™ 2D cultures onto micro-carriers with ProMDCK™ medium.

In addition, subculture of cells grown on microcarriers can be accomplished by adding fresh microcarriers directly to the cell culture in the bioreactor. Both versions of the medium have been demonstrated to support propagation of influenza virus (H1N1, H3N2, and B).



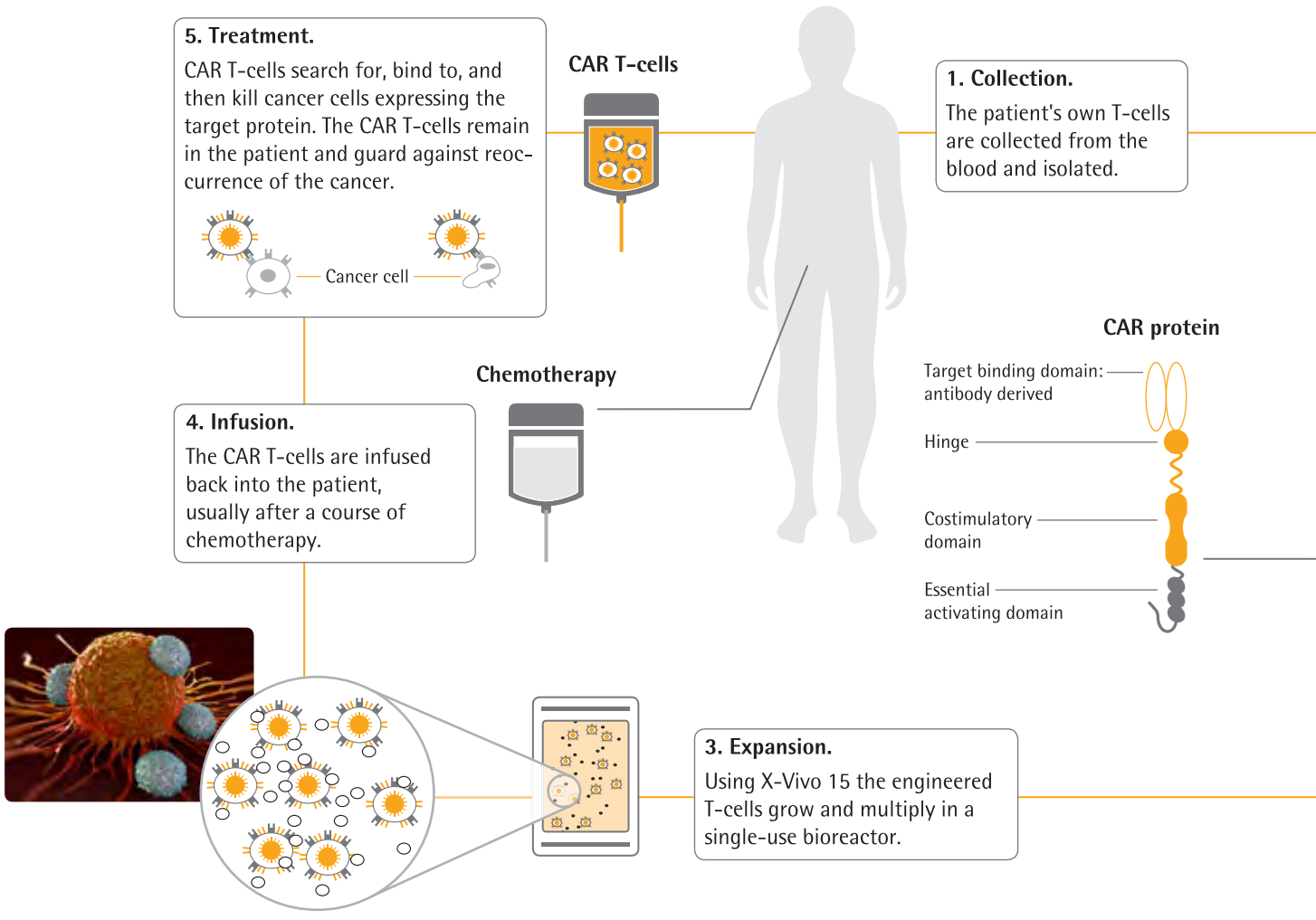
Easy to scale-up	▶ Provides suitable environment for MDCK cells from seed expansion in T-flasks, large scale growth on microcarriers in bioreactors and subsequent virus infection; no adaptation to changed culture format necessary.
Efficiency	▶ Reduces doubling time and virus productivity
Regulatory-friendly	▶ Serum-free media formulation, manufactured following cGMP guidelines (21CFR820) for maximum safety

Cell Therapy Media

Our chemically defined, serum-free cell therapy media provide nutritionally complete and balanced conditions for a variety of cells including lymphokine activated killer (LAK) cells, peripheral blood lymphocytes (PBL), and tumor infiltrating lymphocytes (TIL).

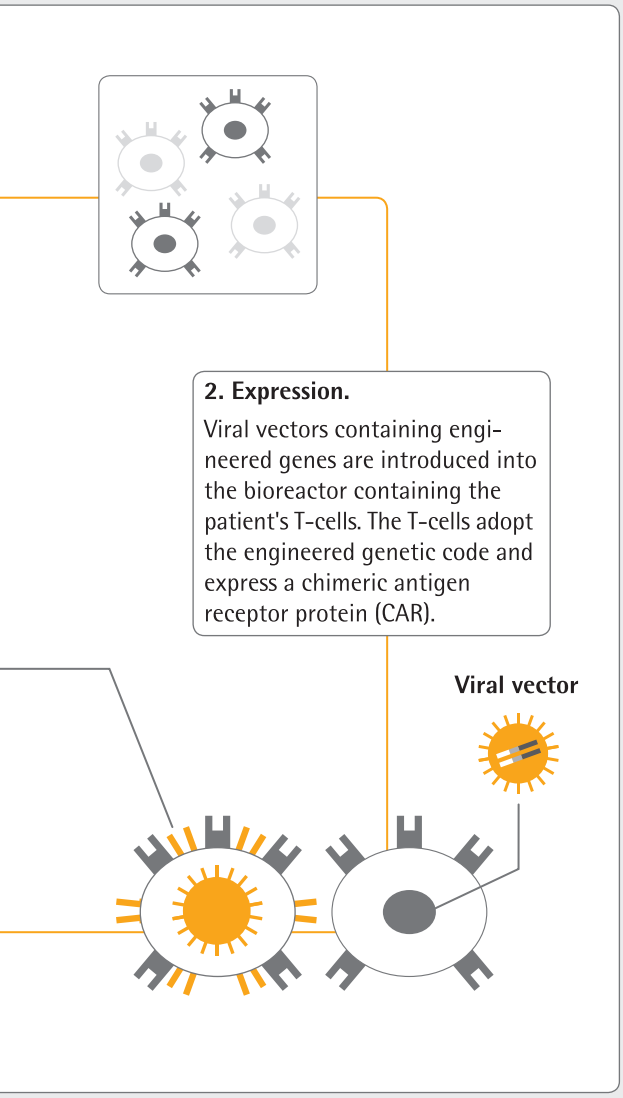
The X-Vivo cell culture media do not contain any growth factors, artificial stimulators of cellular proliferation, or undefined supplements. They are devoid of any protein kinase C stimulators and are suitable for the investigation of second messenger systems in the activation of human and murine lymphocytes. The formulations are complete and contain pharmaceutical grade human albumin, recombinant human insulin, and pasteurized human transferrin.

All media products are manufactured according to cGMP standards and drug master files are available to the FDA.



Schematic description of CAR-T therapy

Cell Type	Medium	Culture
Hematopoietic cells (e.g. T, NK, DC)	X-Vivo 10	Suspension
	X-Vivo 15	
	X-Vivo 20	
	HL-1	
Mesenchymal stem cells	MSCGM CD	Adherent
Adult dermal fibroblasts	FGM CD	Adherent
Adult and neonatal primary keratinocytes	KGM CD	Adherent



Applications

- Proliferation of peripheral blood lymphocytes
- Proliferation of tumor infiltrating lymphocytes
- Cryopreservation of human tissue
- Cultivation of human monocytes and macrophages
- Cultivation of stem cells
- Cultivation of dendritic cells

Solutions for Media Preparation

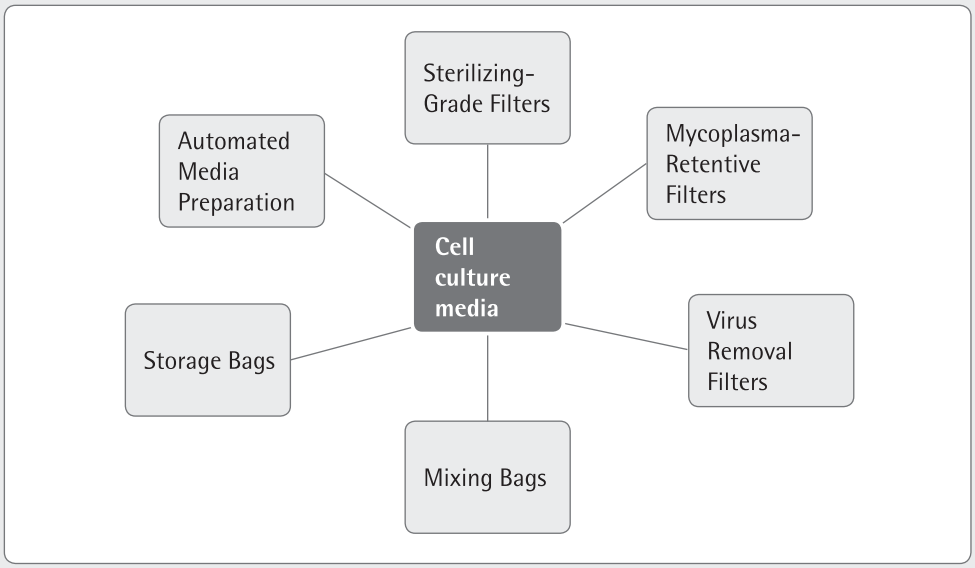
Sartorius offers:

- 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 your 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 your 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. While users initially converted individual production components to single use, the industry is now moving toward 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. Our validation experts will support you throughout qualification of your 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 CONFIDENCE® 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

Powder media ▶ Mixing ▶ Filtration ▶ Storage

Flexel® for Mixing

Single-Use Media Mixing Solution

Applications
- Media | feed preparation
- Buffer preparation

Flexel® for Magnetic Mixer[1] is a compact and non-invasive single-use mixing system for fast powder dissolution.

Flexel® for Magnetic Mixer offers powerful mixing performance for media preparation from 50 L up to 3,000 L. The high impeller speed of up to 300 rpm generates a strong vertical vortex due to the baffle effect of the cubical design. This provides instant dissolution even of high concentration media powders.

Cubical shape with front doors, front access to tubing and sensors and large 8" diameter top port	▶ Intuitive handling with quick start-up and simplified operation during bag installation
Strong vertical vortex combined with baffle effect of the cubical design enable fast powder dissolution	▶ Powerful high performance, mixer proven from 50 – 3,000 L
In-line monitoring and control of critical mixing process parameters (pH, conductivity, temperature, weighing, mixing speed and duration)	▶ Intelligent mixer providing consistent quality and process efficiency while meeting cGMP requirements
50 – 3,000 L working volume	▶ Scalable mixing technology
Dust-free powder addition via closed addition bag	▶ Protection of operators, meeting current health and safety regulations

[1] This product uses Pall patented Magnetic Mixer technology. All information on patents can be found at Pall.com/patents.

FlexAct® MP

Configurable Single-Use Solution for Media Preparation

Applications
- Automatic, contained media preparation

The FlexAct® MP is a standardized configurable system for convenient media preparation in biopharmaceutical processes.

The FlexAct® central operation module enables you to control and monitor all relevant process parameters during media preparation. Integrated weighing capabilities permit precise media dissolution using our Magnetic Mixer[1] technology. A fully automated, temperature-controlled pH adjustment is performed via a jacketed Palletank® for mixing and a temperature control unit (TCU). During fluid transfer and sterile filtration, pressure and flow are monitored and controlled to ensure safe operation.

Multi-functional central operating module	▶	Operator-friendly
Tailored bag configurations	▶	Flexible media supply
50 – 3,000 L working volume	▶	Fully scalable
Quick system set-up	▶	Increased efficiency
Integrated disposable sensors (pH, conductivity, temperature)	▶	Reliable monitoring of important parameters
Bi-directional operation	▶	Highly flexible

[1] This product uses Pall patented Magnetic Mixer technology. All information on patents can be found at Pall.com/patents.

Sartoguard Filter Family

Most Efficient Protection for Sartopore® 2 XL Filter Elements

Applications
- Prefiltration of cell culture media
- Protection of Sartopore® 2 XL final filters

The Sartoguard family consisting of Polyethersulfone (PES), Glass Fiber (GF) and PES Nano Fleece (NF) versions are all designed to extend the lifetime of Sartopore® 2 XL final filters by a factor of 3 to 4. Sartoguard filters ensure your final filter achieves the highest throughput and make your process more cost effective.

Sartoguard PES contains a PES double layer membrane, available in 0.1 or in 0.2 µm nominal pore size configurations. They are designed for cost-effective prefiltration of all types of cell culture media. The filters can be sterilized either by autoclaving or gamma irradiation.

Sartoguard PES filters and Sartoguard GF filters can be tested for integrity. Both match perfectly with Sartopore® 2 XL final filters.

Sartoguard GF contains a PES double layer membrane covered with a glass fiber fleece. It effectively protects the filter from clogging, especially when you need to filter serum and hydrolysate supplemented cell culture media.

The heterogeneous PES membrane double layer with or without fleece material
- provides optimal prefiltration for all types of cell culture media
- protects subsequent sterile filters and extend filtration capacity

Sartoguard prefilter family	▶ Protects subsequent sterile filters and extend filtration capacity
Sartoguard PES	▶ For prefiltration of all types of cell culture media
Sartoguard GF	▶ For prefiltration of complex media containing serum or hydrolysates

Sartopore® 2 XL Filter Family

Best Filtration Solutions for Cell Culture Media

Applications

- Sterilizing-grade filtration and mycoplasma-retentive filtration of cell culture media
- Sartopore® 2 XLG (0.8 | 0.2 µm) High speed and high capacity sterile media filtration for lowest filter consumption
- Sartopore® 2 XLM (0.2 | 0.1 µm) Unique combination of high retention and high capacity for sterile and mycoplasma free cell culture media

The Sartopore® 2 XL filter family is the best choice for sterilizing-grade filtration and mycoplasma-retentive filtration of cell culture media.

The unique range of PES double-layer membrane combinations perfectly serves the different cell culture media requirements.

Speed up your media preparation process using the Sartopore® 2 XLG sterilizing-grade media filter. You will benefit from highest flow rate | capacity with our unique 0.8 | 0.2 µm membrane combination.

The Sartopore® 2 XLM is the most advanced 0.1 µm rated filter with the highest mycoplasma retention. The special membrane structure with narrow pore size distribution provides exceptional safety in retention of various mycoplasma strains. The highly asymmetric pre-filter membrane maximizes your filtration capacity and gives you the most economic media filter.

Unique combination of different pre- and final filter membranes	▶ Ensures highly economic filter sizing and minimum filtration costs for all kinds of media
Low unspecific protein binding	▶ Excellent and reproducible cell growth
Reliable retention of mycoplasma by Sartopore® 2 XLM 0.1 µm	▶ Prevents mycoplasma contamination of your cell culture process
Available in a broad range of sizes and formats to provide linear scale-up from development to commercial-scale production	▶ Identical filtration performance at all scale-up levels of your media preparation process

Which Filter Solution Best Fits Your Needs?

Todays industrial cell culture media formulations can be very different, from serum and hydrolysate supplemented to chemically defined media. Based on our long standing experience in media filtration, we can recommend the best filter solution for your needs.
Our international team of application specialists helps you optimize your specific filtration process – just contact us 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	

Select Your Optimal Filter Combination for Effective Mycoplasma Removal

Contamination of cell culture media with mycoplasma is one major concern during media preparation. Combining maximum security for mycoplasma removal with lowest filtration cost for media preparation is the unique value of our Sartoguard and Sartopore® 2 XLM pre- and final filter media filtration solutions.

Our Mycoplasma Removal Kit contains all prefilters of the Sartoguard family and the Sartopore® 2 XLM final filters for small scale testing with our SartoScale 25 devices.
It has never been easier to identify the optimal filter combination for your media filtration needs!

Contact your local Sartorius representative to receive a Mycoplasma Removal Kit for free and ask for on-site application support to optimize your media filtration process.

SartoScale 25, Small Scale Test Devices

Sartocheck® 4 Plus Filter Tester

The Best-Selling Integrity Tester Worldwide

Applications
- Filter integrity testing

The Sartocheck® filter integrity tester reliably identifies whether your sterilizing-grade filters used in processes are actually intact – both before and after use.

Sartocheck® automated filter integrity tests are quick and easy to perform. A barcode scanner ensures user-friendly and error-proof selection of the appropriate pre-programmed filter test sequences. You can choose to print out test results or export test data for GMP-compliant documentation.

Automatic detection of operator mistakes, such as incorrect test set-up, ensures error-proof performance of filter integrity testing.

Automatic detection of incorrect set-ups	▶ Mitigates operator mistakes
Easy program selection with barcode scanner	▶ Prevents operator errors
Optimized backflow prevention via external valve	▶ Avoids cross-contamination
Patented cleaning function	▶ Allows decontamination of internal pneumatics
Robust technology	▶ Minimizes downtime

Virosart® Media

First Virus Retentive Filter for Cell Culture Media

NEW

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 (log10 reduction value) for small non-enveloped viruses and more than 6 LRV for larger enveloped viruses.

This newly developed media filter provides a cost effective solution with highest filter capacity for cell culture media. Through this high capacity it overcomes today´s bottlenects of virus filters originally developed for downstream applications.

In addition this filter is also qualified as a mycoplasma and leptospira retentive filter as well as a sterile filter based on the current ASTM guideline.

4 LRV for small non-enveloped viruses Mycoplasma orale: sterile (≥ 7) Leptospira licerasiae: sterile (≥ 7) Sterilizing grade filter based on current HIMA/ASTM guidelines	▶ Highest safety for your 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

Flexboy® Bags

The Original Single-Use Bioprocessing Bag

Applications
- Media and feed container
- Bulk harvest
- Sample collection
- Buffer, supplement and additive container

Flexboy® bags are designed for preparation, storage and transport of media, feeds and additives, intermediates and final bulk. They provide a single-use alternative to conventional glass, stainless steel and rigid plastic carboys in a large variety of applications.

Flexboy® bags are available in bag chamber volumes between 5 mL and 50 L. They are supplied sterilized and are ready-to-use.

Multiple configurations, with a broad range of tubing including thermoweldable TPE tubing, are provided to give you maximum process flexibility.

Multiple manufacturing sites	▶ High assurance of supply
100% bag chamber leak test	▶ Process safety and integrity
All connections extensively qualified	▶ Safe and robust
Full compliance with ISO11137	▶ The highest sterility assurance level
Standardized designs	▶ Most designs available from stock

Flexboy® Tray and Rack System

Easy and Safe Dispensing of Media and Feed Solutions

Applications
- Buffer and media dispensing and storage
- Bulk harvest dispensing and storage

The Flexboy® tray and rack systems are designed to facilitate handling of both individual and manifold Flexboy® single-use bioprocessing bags (5 – 50 L) within biopharmaceutical manufacturing processes.

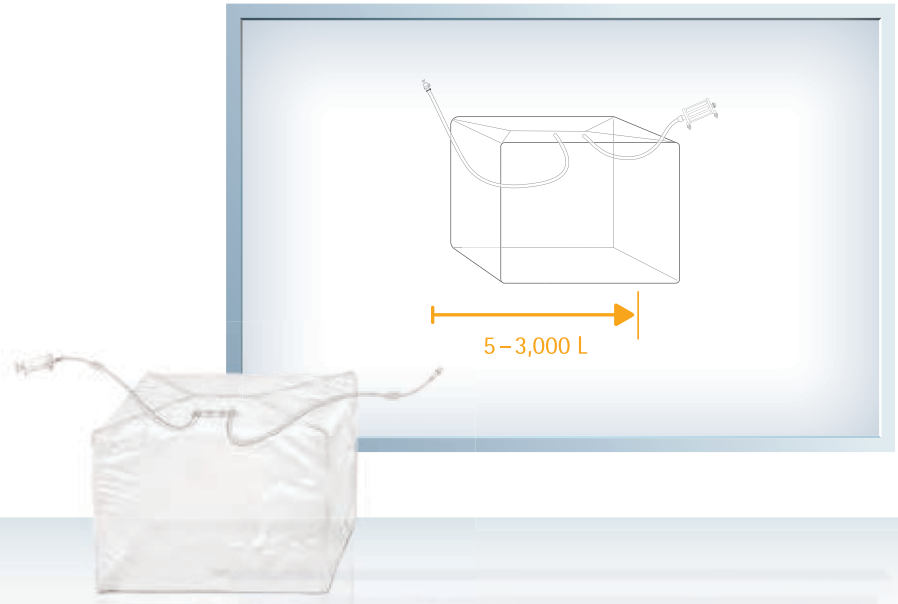
The tray and rack systems are available in a choice of ten times 5 L to 20 L and five times 50 L.

These systems provide you with an easy and safe solution for dispensing and aliquotation of media and bulk harvest.

Integrated wheels	▶ Facilitate maneuverability
Modular rack accommodates up to 20 trays	▶ Flexible
Dedicated area for storage	▶ Easy-to-use

Flexel® 3D Bags

3D Bioprocessing Bags for Palletank®



Applications
- Buffer storage
- Media storage
- Bulk harvest storage

Flexel® 3D bioprocessing bags ranging from 5 – 3,000 L are three-dimensional single-use bags.

These aseptic bags are made of our proven S40 polyethylene film and supplied pre-assembled with tubes, clamps, filters and connectors. They are presterilized and ready-to-use and available in a wide range of configurations.

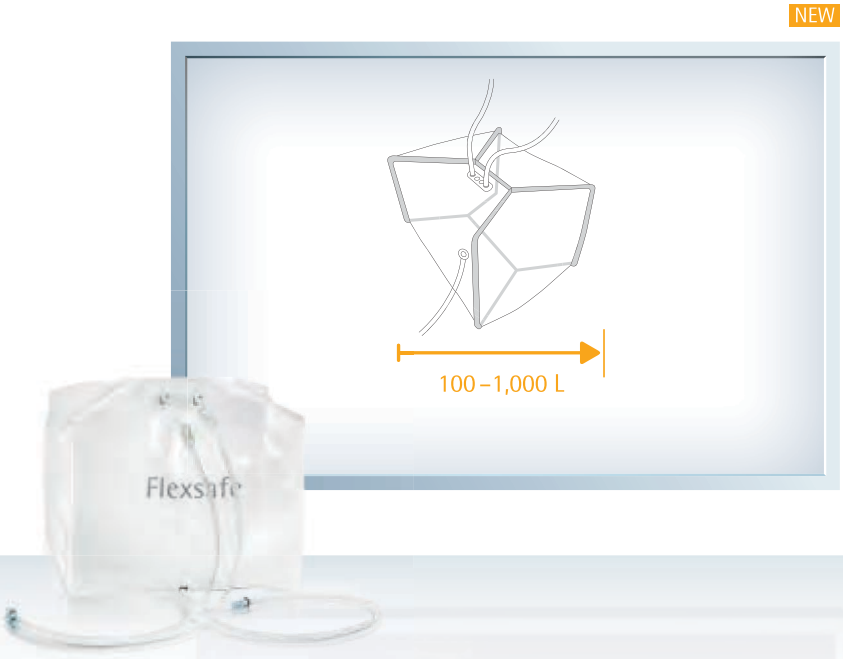
The Flexel® 3D bioprocessing bag range offers robust, reliable and sterile single-use solutions for processing, storage and transportation of large-volume media and intermediates. They provide you with a safe, cost-effective alternative to conventional stainless steel vessels.

Multiple manufacturing sites	▶ High security of supply
Full compliance with ISO 11137	▶ Highest sterility assurance level
Flexel® bags used in GMP production of commercial products	▶ Rely on proven track record
Various bag & filter sizes	▶ High flexibility

Flexsafe®
Pre-Designed Solutions

3D Bioprocessing Bags for Palletank®

NEW



Applications
- Buffer storage & shipping
- Media storage & shipping
- Bulk harvest storage

Flexsafe® 3D bioprocessing bags are made of our new S80 polyethylene film, the first film optimized for the bioprocessing industry. It offers outstanding robustness and assurance of supply. Full control of the resins, additives and extrusion process ensures excellent and reproducible cell growth and a consistent E&L profile.

A wide range of sizes, from 50 L to 1,000 L is available for safe and easy liquid storage. Flexsafe® 3D bags from 100 L to 500 L provide safe and robust liquid shipping solutions and have been validated under the most stringent international ASTM D4169 norms. Our Flexsafe® pre-designed solutions are available in designs optimized for every media, buffer, harvest, drug substance and drug product processing step.

For more information, download our digital brochure on www.sartorius.com/flexsafe.

Liquid shipping validation | ASTM D4169	▶ Proven robustness
Self-deploying bags for Storage Palletank®	▶ Ease of use
Process & application based designs	▶ Meet upstream application requirements
Process based quality control	▶ Best quality control and monitoring for bioburden, endotoxins and sub-visible particulates

Palletank® for Flexel® and Flexsafe® 3D Bags

In-Process Fluid Handling

Applications

- In-process intermediate and bulk product hold
- Storage and distribution of media and buffers
- Solution distribution in Flexel® 3D bag manifold
- Waste collection
- Feed and harvest container for bioreactors

Our range of movable and stationary Palletank® is perfectly matched to accommodate our array of Flexel® and Flexsafe® 3D bags.

Palletank® for in-process fluid handling are available in 200 L, 500 L, 1,000 L, 1,500 L, 2,000 L, 2,500 L and 3,000 L volumes.

The Flexel® and Flexsafe® 3D bags are manufactured according to a patented design that precisely fits the Palletank®.

Continuous processing without movement of the containers	▶ Easy operation
Double-hinged front door with safety latches	▶ Easy access
Lifting system for large-size containers	▶ Optimal bag unfolding and filling


sartorius

Transfer Sets, Filter Transfer Sets and Sensor Transfer Sets

Fluid Transfer and Filtration Solutions

Applications

- Transfer of inoculum from Flexboy® bags to Flexsafe® RM or STR® cell culture bioreactor bags
- Liquid transfer between single-use and stainless steel systems using a steam-through connector
- Liquid transfer and simultaneous particle reduction or sterile filtration
- Liquid transfer under flow- or pressure-controlled conditions
- Media and buffer filtration in a fully single-use set-up
- Sterile venting of single-use bioreactors

Single-use transfer sets and filter and sensor transfer sets can be configured for any liquid transfer application in upstream processing using silicone or TPE tubing to provide maximum flexibility.

Sartorius single-use transfer sets are gamma-irradiated and ready-to-use. They are widely utilized to securely connect different single-use and reusable containers to give you the flexibility you need: opt for quick connectors or TPE tubing and tube welding. These transfer sets can be easily designed to connect media bags to bioreactors, and bioreactors to bags to collect bulk harvest.

Easily sterilize your media and buffers by using our ready-to-use filter transfer sets. Your application-specific transfer sets will allow you to perform mycoplasma retention, sterile filtration, particle removal and bioburden reduction.

Sensor transfer sets will ensure maximum security by giving you full process control during liquid transfer operations.

Gamma sterilized	▶ Ready-to-use
Connection assembly qualified	▶ Robust connection
Large variety of qualified components Available with different types of filters and single-use sensors	▶ Highly flexible design to match process requirements

TuFlux® SIL Silicone Tubing

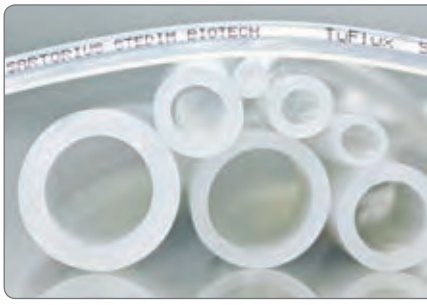
High-Purity, Platinum-Cured Silicone Tubing

Applications
- Media and buffer transfer
- Creation of filtration assemblies
- Bioreactor fluid transfer

TuFlux® SIL is designed for fluid transfer in biopharmaceutical manufacturing processes.

TuFlux® SIL is a highly resistant platinum-cured silicone tubing manufactured by Raumedic.

TuFlux® SIL is available today in seven different dimensions from 1/8" (3.2 mm) to 3/4" (19.1 mm) inner diameter and a wall thickness from 1.6 to 4.8 mm.



Platinum-cured silicone	▶ Compatible with weak acids and bases; extraordinarily resistant to heat and cold
Shore hardness A 60	▶ Excellent rupture strength in peristaltic pumps and reduced kink effect
Inner and outer diameter dimensions printed on the tubing	▶ Facilitates tubing identification
"Low-tack" significantly reduced surface friction	▶ Easy to handle when you are wearing gloves
Coils wrapped in double PE-bags	▶ Tubing protected and easy to introduce in cleanrooms
Low extractable profile and unique validation guide for TuFlux® SIL available	▶ Fast validation of TuFlux® SIL in your process

BioWelder® TC

Automated Connection of TPE Tubing

Applications

- Automated sterile connection of single-use assemblies
- Connection of media bag to bioreactor for feeding applications
- Sampling from media bag or bioreactor
- Sequential weldings are possible on the same TPE tubing section

The BioWelder® TC is a fully automated device for connecting thermoplastic tubing in a contained way outside a laminar airflow hood.

Featuring a new, compact design, this device makes it easy for you to make sterile connections of liquid-filled tubing with up to 1-inch outer diameters. BioWelder® TC is now also available for small diameter tubing down to ¼-inch outer diameter.

The innovative technology allows flexible, leak-free connection of bioreactor bags with media or feed bags or any other connection of disposable bags in a sterile welding operation outside a class A or B environment.

Liquid-filled tubing from ¼" to 1" outer diameters (⅛" to ¾" inner diameters)	▶ Flexible device and robust technology
Fully automated device	▶ Easy-to-use, reliable process
Standard programs	▶ Ready-to-use for other tubing
Extensively qualified	▶ Safe and robust connections
Short welding time	▶ Fast connections

BioSealer®

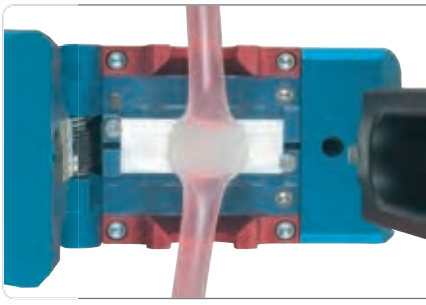
Automated Disconnection of TPE Tubing

Applications

- Sterile disconnection using TPE tubing
- Sterile disconnection of media and feed bags
- Sterile disconnection of Flexsafe® RM bags after inoculum transfer
- Any type of sterile disconnection, e.g., of sample

The BioSealer® is a fully automated device designed to produce permanent and consistent, leak-free seals on thermoplastic tubing.

There is no need for a laminar flow cabinet or similar environment to disconnect tubes aseptically from disposable bag assemblies.



Seals tubing between 1/4 – 3/4" outer diameters	▶ Automated and reproducible disconnection
Sealing times between 2 to 4 min	▶ Ready to start immediately
Programmable for several thermoplastic tubing	▶ Easy adaption to various space requirements due to removable sealing head

Opta® SFT

Mechanical Sterile Connection of Single-use Assemblies

Applications

- Sterile connection of media bag to bioreactors
- Sterile connection of venting line to Cultibag® or Flexsafe STR® bags
- Sterile connection of Flexsafe® RM bags to external cell retention device

Opta® SFT sterile connectors create a sterile fluid path between two pre-sterilized components in both classified and non-classified production environments.

Opta® SFT sterile connectors are quick and easy-to-use. They are backed by extensive validation and 100% in-house integrity testing performed on each connector. The validation of the connector itself and the connection encompasses a severe bacterial challenge test via immersion in Brevundimonas diminuta (> 10^6 CFU/mL).

You can purchase Opta® SFT sterile connectors either individually to assemble your own set or as pre-installed units on any Sartorius single-use assembly (e.g. Flexboy®, Flexel®, Flexsafe® 3D | RM | STR bags, Transfer Set, etc.).

Opta® SFT sterile connectors are validated to connect gamma-irradiated bags, such as Flexsafe STR® bags, to autoclaved assemblies, such as venting lines.

Male and female connector couplings sealed with sterilizing-grade membrane	▶ Sterile fluid transfer in non-classified and classified environments
Sterilizable by gamma irradiation and autoclave	▶ Flexible implementation of hybrid single-use and reusable equipment
100% integrity tested	▶ The highest security
Three-step operation	▶ Easy, robust, repeatable operations
Hose barb connections intensively qualified	▶ Safe and secure tubing connections

Clipster® Aseptic Disconnectors

Mechanical Sterile Disconnection

Applications
- Sterile disconnection of media bags after feeding
- Sterile disconnection of Flexsafe® RM bags after inoculum transfer
- Sterile disconnection of sample bags or containers

The Clipster® aseptic disconnector is a single-use device designed to perform aseptic disconnections of tubing.

The Clipster® aseptic disconnector is available as a stand-alone product or pre-assembled on single-use assemblies, such as media bags and transfer sets.

Safe and quick, the Clipster® disconnector is a hand-held tool that ensures easy and aseptic disconnection in any environment.

Mechanical disconnection, can be performed on silicone tubing and TPE tubing	▶ Flexible disconnection approach
Error-proof design and hand-held tool for safe disconnection, four-step operation	▶ Easy, quick, robust and reliable
Extensively qualified	▶ Safe and robust
Available for Flexboy®, Flexel®, Flexsafe® bags, Transfer Sets and as an option on Flexsafe STR® bags	▶ Flexible application
Three Clipster® sizes	▶ Compatible with five tubing diameter sizes (from ⅛" to 1" inner diameter tubing as standard)

III. Bioreactors and Fermenters

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
MO						
CC						ambr® 15 fermentation
MO	▢					
CC	▢	(▢)	▢			ambr® 250
MO	▢	(▢)	▢			
CC	▢	(▢)	▢			ambr® 250 modular
MO	▢	(▢)	▢			
CC	▢	▢	(▢)	▢		CERTOMAT® CTplus
MO						
CC	(▢)	▢	(▢)	▢		BIOSTAT® A
MO	(▢)	▢	(▢)	▢		
CC	▢	▢	▢	▢		BIOSTAT® B
MO	▢	▢	▢	▢		
CC	▢	▢	▢	▢		BIOSTAT® B-DCU
MO	▢	▢	▢	▢		
CC		▢	▢	▢	(▢)	BIOSTAT® Cplus
MO	(▢)	▢	▢	▢	(▢)	
CC		▢	▢	▢	▢	BIOSTAT® D-DCU
MO		▢	▢	▢	▢	
CC				▢	▢	Customized Stainless Steel Fermenters
MO				▢	▢	
CC		▢		▢	(▢)	BIOSTAT® RM
MO		(▢)		(▢)	(▢)	
CC		▢	▢	▢	▢	BIOSTAT STR®
MO		(▢)	(▢)	(▢)	(▢)	

▢ Typical applications
(▢) Selected applications


ambr® 15


ambr® 250 modular


ambr® 250


CERTOMAT® CTplus


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	✓			24 | 48	10 – 15 mL
ambr® 15 fermentation				24	8 – 12 mL
	✓				
ambr® 250	✓			12 | 24	100 – 250 mL
	✓				
ambr® 250 modular	✓			2 | 4 | 6 | 8	100 – 250 mL
	✓				
CERTOMAT® CTplus	✓			6 | 98	12.5 mL – 2.5 L
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
			✓		
Customized Stainless Steel Fermenters			✓	multiple	200 – 2,000 L
			✓		
BIOSTAT® RM	✓			2*	0.5 – 100 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


Customized Stainless Steel Fermenters


BIOSTAT® RM


BIOSTAT STR®

CERTOMAT® CTplus

Your CO_2 Incubation Shaker Designed for Cell Culture

Applications
- Cultivation of mammalian cells
- Clone propagation
- Clone selection
- Seed expansion

The CERTOMAT® CTplus has been designed for cultivation of mammalian cells in shake flasks under stringent control of temperature, CO_2 concentration and humidity.

The incubation chamber, mechanical drive and control unit are strictly isolated from one another. This prevents corrosion of the drive unit and other parts due to formation of carbonic acid in the incubation chamber. Separate heating systems for the air, for the doors and humidification pan effectively prevent condensation in the incubation chamber. Tight seals reduce CO_2 consumption and ensure control of humidity to even allow the use of multiwell plates.

Purpose-built shaker incubation chamber with effective insulation and temperature performance similar to CO_2 incubators	▶ Lowers CO_2 consumption; precisely controls temperature and ensures exceptionally even temperature distribution; easy to clean
Encapsulated drive	▶ Protects drive against humidity and CO_2, decreases wear
Variable mass compensation	▶ Reduces vibration of equipment; safe operation even at high shaker speed when three units are stacked; save valuable floor space
Water pan in front; no heatmat attached	▶ Enables easy removal of the water pan from the front for cleaning and refilling or autoclaving, if necessary
Expandable for data exchange and process monitoring	▶ Enables the same SCADA software to be used for CERTOMAT® CTplus data and those of your BIOSTAT® fermenters

ambr® 15 cell culture

High Throughput Automated Micro Bioreactor for Predictive Cell Line and Media Screening

Applications
- Cell line screening
- Early process development
- Bioreactor DoE studies
- Media development
- Small-scale perfusion mimic

ambr® 15 cell culture is a high throughput, automated bioreactor system for 24 or 48 parallel fed-batch cell cultures in a cost-effective 10–15 mL micro bioreactor format.

The system is used by most leading biopharmaceutical companies and has enabled large bioreactor DoE studies and integration of cell line screening and early process scouting.

ambr® 15 has been proven by industry leaders to provide better scalability than a shake flask and has transformed cell line development in many leading biopharma companies worldwide.

24 or 48 parallel cell cultures	▶ Large screening studies in bioreactor conditions
Single-use 10–15 mL micro bioreactors	▶ Reduce hands-on time and cost per experiment
Stable control of pH, pO_2, impeller and gas sparging	▶ More reliable and scalable results than shake flasks
Automated sampling and addition of liquid feeds	▶ Very consistent cultures, reduced labor time and cost
Fits in a standard biological safety cabinet	▶ Fast and easy to install in laboratories

Gas Supply Options: page 90

ambr® 15 Individual Gas Supply

ambr® 15 fermentation

High Throughput Automated Micro Bioreactor for High Density Fed Batch Strain Screening

NEW

Applications
- Microbial culture pH 6 – 8
- Biopharm E.coli processes
- Vector screening
- Strain selection
- Media development

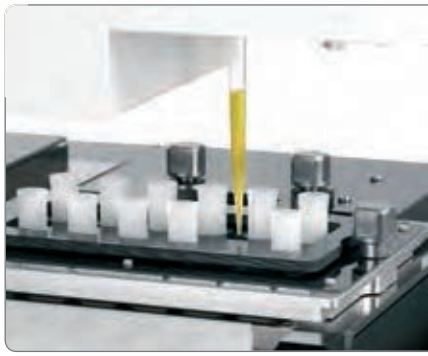
ambr® 15 fermentation is a high throughput automated bioreactor system for 24 parallel fed-batch microbial fermentations in a cost-effective 8 – 12 mL micro bioreactor format.

ambr® 15 fermentation is based on the gold standard ambr® 15 technology.

It provides a consistent microscale model for early stage microbial screening experiments with fed-batch culture capability.

Fed-batch operation supports high density fermentations, improving early stage predictions of large scale bioreactor performance compared to shake flasks or plates.

Pumped pH reagent and feed addition	▶	Enables more predictive high cell density cultures
High k_La values of up to 380 h^{-1}	▶	Supports E.coli growth over OD 200
8 – 12 mL liquid working volume	▶	Multiple samples can be taken during culture
Stable control of pH, impeller and gas sparging	▶	More reliable and scalable results than shake flasks
Automated sampling and addition of liquid feeds	▶	Very consistent cultures, reduced labor time and cost



Gas Supply Options: page 90

ambr® 15 Individual Gas Supply

ambr® 15 Vessels

Single-Use Micro Bioreactor Vessels for High Throughput Screening

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

Each ambr® 15 automated bioreactor system uses irradiated single-use micro bioreactor vessels with gas supply, impeller, pH and pO_2 sensor spots.

The ambr® 15 micro bioreactor vessel mimics the characteristics of classic lab-scale bioreactors, providing more predictive and scalable results compared to shaken culture systems.

Vessels for ambr® 15 cell culture (above, right) include a pitched blade impeller and a choice of sparged or headspace gassing options. Vessels for ambr® 15 fermentation (left) include a Rushton impeller, sparge tube and 2 pumped liquid supply tubes.

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
sartorius stedim

ambr® 250 high throughput

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

Applications
- Process development and process optimization
- Scale-down studies
- Cell culture and microbial fermentation

Gas Supply Options: page 90

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 more 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	▶ Enables you to 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 1 hour
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 and process optimization
- Scale-down studies
- Cell culture and microbial fermentation

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 so 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 Modular

Increased Productivity with Simplified Operation

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

Gas Supply Options: page 90

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

NEW

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

BIOSTAT® A

Your Professional Start to Controlled Cultivation

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

Gas Supply Options: page 90

Additive Flow

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.

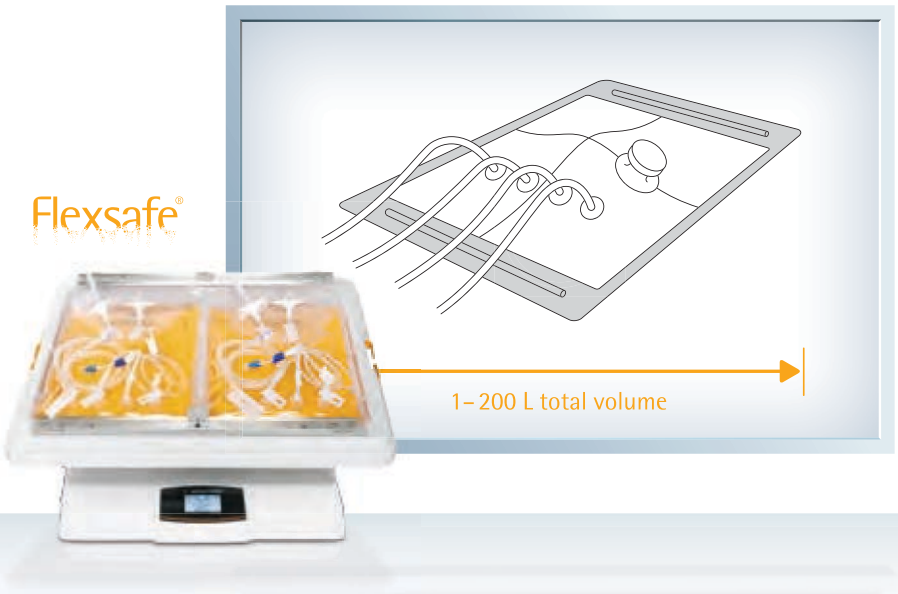
BIOSTAT® A is available in configurations for microbial fermentation and for cell culture applications.

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

BIOSTAT® RM basic 20|50 and Flexsafe® RM Bags

Easy-to-Use Rocker and Excellent Growth with New Flexsafe® Bioprocessing Bags



Applications

- Mammalian, insect and plant cell culture
- 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

BIOSTAT® RM 20|50 basic is a perfectly sized, single-use, wave-mixed benchtop bioreactor for stand-alone use.

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, Air|CO_2 mixing module and load cells is the optimal choice for straight-forward applications, such as seed generation.

Individual control of two bags on one platform	▶ Space-saving
Advanced alarming and safety features	▶ Safe cultivation
Automated sampling function	▶ Reduced manual handling

Flexsafe® RM bags for wave-mixed bioreactors feature outstanding film quality in working volumes from 100 mL – 100 L.

Flexsafe® RM bags can be used in your seed train and scaled up to our BIOSTAT STR® single-use, stirred tank bioreactors equipped with Flexsafe STR® bags. Benefit from the same polyethylene film material across all your cell culture steps. Flexsafe® RM bags fit on rocking motion bioreactors of various brands.

Strong and flexible film	▶ Ultimate process safety ▶ Fast and easy handling
Optimized and fully controlled film formulation	▶ Optimal and consistent cell growth
Basic, optical or perfusion bag designs which can be customized	▶ Suitable for many different applications
Single-use pH and pO_2 sensors	▶ No contamination risk

Watch Video: youtube.com

Flexsafe® – Watch Video

BIOSTAT® B

The Multi-Talent for Research and Process Development

Watch Video: youtube.com

BIOSTAT® B – Watch Video

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.

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.

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

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 your 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 options:

Trace
Glucose | Lactate measurement
(page 96)

ViaMass
Viable biomass measurement
(page 94)

Fundalux
Turbidity measurement
(page 97)

Xgas
Off-gas analysis
(page 98)

Gas Supply Options: page 90

Additive Flow

Advanced Additive Flow

BIOSTAT® B-DCU

Fully Flexible for Advanced Process Development

NEW

The BIOSTAT® B-DCU is designed to meet demanding requirements in process optimization and characterization.

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

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 QbD studies.

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. Used together with our wide range of integrated sensors, MFCS and chemometrics tool box, the BIOSTAT® B-DCU is the ideal tool for advanced process optimization and characterization studies.

Integration in customer process landscape can be achieved by an OPC DA | AE or an optional DeltaV™ interface.

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	▶ Fully flexible gassing strategy to meet your process requirements

BioPAT® sensor options:


Trace
Glucose | Lactate measurement
(page 96)


Fundalux
Turbidity measurement
(page 97)


Xgas
Off-gas analysis
(page 98)


ViaMass
Viable biomass measurement
(page 94)

Gas Supply Options: page 90

O_2 Enrichment

Additive Flow

Advanced Additive Flow

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

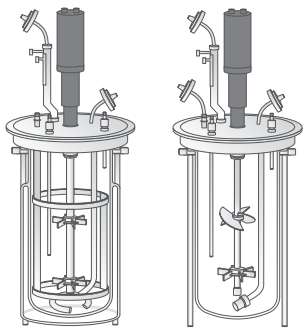
UniVessel® Glass

Multi-Purpose Glass Culture Vessel

Applications

- Microbial fermentation (bacteria, yeast, fungi)
- Animal cell culture (mammalian, insect)
- Adherent cell culture on microcarriers
- Process development and optimization
- Scale-up and scale-down studies
- Seed expansion

NEW



Configuration examples

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 your 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.

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

For continuous culture with integrated spinfilters for cell retention in perfusion applications

New, 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 your investment budget for new controllers as you can use your available UniVessel® Glass

UniVessel® SU

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

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 your 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 your lab.

It can be used interchangeably with glass vessels to help you efficiently manage peak workloads despite challenging timelines. Since you discard the complete vessel after one use, you no longer have 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

Benchtop Accessories

Anti-foam Disk

In fermentation applications, high oxygen transfer rates are achieved by high aeration and agitation rates. This often results in excessive foaming in the culture.

Our foam disk, a mechanical foam destroyer, solves problems with foaming where they start – directly at the liquid surface. The foam disk is installed on the stirrer shaft. This makes retrofitting fast and easy. It is a two-layer disk with four sections. Its lower layer has downward-positioned slots and paddles for foam skimming. The foam disk is available for all autoclavable UniVessel® glass culture vessels.

- Prevents problems with foaming
- Reduces the need for anti-foam agent
- Easy to retrofit

Flexible Adapter for Exhaust Cooler

Typically, the exhaust cooler and its fittings are at the highest point of the culture vessel. They have to be arranged vertically to enable condensate to flow back into the vessel. However, in the case of small autoclaves, the height of the fully equipped UniVessel® Glass can be challenging.

Using a flexible adapter reduces height requirements in an autoclave. The adapter is installed between the exhaust cooler and its top plate port at the culture vessel.

- Reduces the height of your UniVessel® Glass
- Makes your UniVessel® Glass fit into smaller, space-saving autoclaves
- No need to invest in a larger autoclave

STT Connector

STT quick-connect couplings enable fast and secure tube connections to link the culture vessel with medium and feed flasks, external cell retention devices, harvest containers and the like. They consist of a female connector with a slotted membrane and a male connector – both with blind plugs for autoclaving. STT connectors enable you to aseptically connect tubing with inner diameters of 1.6 – 2 mm and 3.2 – 5 mm.

- Fast and aseptic connection of tubing

TuFlux® SIL

TuFlux® SIL, Sartorius Stedim Biotech's platinum cured silicone tubing is available as an accessory for benchtop bioreactors in various dimensions. Benefit from the best extractable profile among all tested Si(Pt) tubing as well as the high kinking resistance during autoclaving due to 60 shore a hardness. The unique low tack treatment makes the tubing less sticky and easy to handle. Have a look at page 43 for more information.

Bypass Sampler

The bypass sampler permits sample removal from and additions of small amounts of additives to the culture vessel using a septum in combination with a syringe. Operation in a closed bypass loop enables dead volume free sampling and addition. It consists of a membrane holder with a septum and a 19 mm plug for connection to the lid of our glass culture vessels.

- Aseptic, dead volume free sampling

BENCHMARK™ Sampling System

Collect samples in a syringe and protect your bioreactor from external contaminates by using the BENCHMARK™ sampling system. BENCHMARK™ includes a needle-free septum and a one-way check valve. The needle-free septum is validated to maintain a microbial barrier after 140 actuations. The one-way check valve prevents fluid, air and contaminants from entering the sampling pathway and therefore from contaminating the vessel.

- High sampling capacity
- Cost-effective sampling
- Easy and safe to use

Spinfilter

Spinfilters, mounted on the stirrer shaft of our UniVessel® Glass culture vessels, enable the removal of cell culture supernatant during continuous perfusion culture of animal cells. They are available in a choice of different mesh sizes for suspension cell culture and cell culture on microcarriers.

- Easy to integrate into new or available BIOSTAT® bioreactors
- Cost-effective perfusion device
- No external loop

Sartorius Midisart® 2000 for Sterile Gas Filtration

Midisart® 2000 air|gas filters are ideally suited for particle removal and sterile filtration of bioreactor inlet and outlet air|gases. Its extremely hydrophobic PTFE membrane prevents water blockage of your filter caused by high humidity air streams even after prolonged use.

- Long-time operation even at high humidity air streams
- Reliable and validated separation of microorganisms

BIOSTAT STR®

True Scalability in Single-Use

Applications

- Vaccine, recombinant protein and mAb production
- High cell density continuous culture
- Adherent cell culture on microcarriers
- Process development and scale-up
- Seed expansion

BioPAT® sensor options:

Xgas
Off-gas analysis
(page 98)

Gas Supply Options: page 90

Additive Flow

Advanced Additive Flow

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

Simplify your 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.

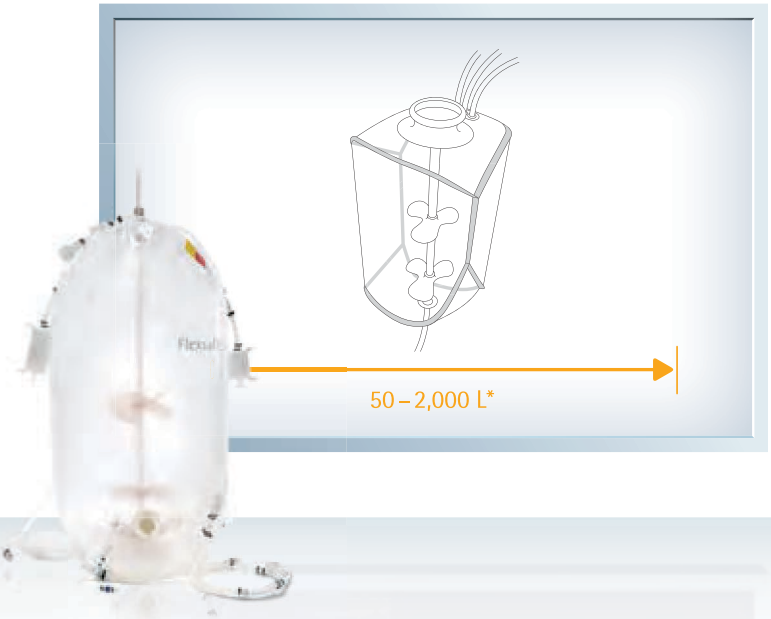
Get the best solution for high cell density continuous cultures and microcarrier cultures. You can choose from working volumes of 50 L, 200 L, 500 L, 1,000 L and 2,000 L.

Two impellers on central shaft	▶ Homogeneous mixing in a minimum of time
Innovative sparger element	▶ Excellent oxygen transfer and CO_2 removal at minimized foaming
Single-use pH and pO_2 sensors	▶ Low contamination risk; easy and quick handling
Single-use exhaust cooler	▶ Prevents exhaust filter blockage

Flexsafe STR® Bags

Single-Use Cultivation Chamber for BIOSTAT STR®

NEW



Applications
- Suspension and 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 new bioprocessing bag family, combining outstanding cell growth, robustness and assurance of supply.

Flexsafe STR® facilitates the way towards single-use manufacturing of the future. It meets the most stringent customer needs for safe bioprocessing.

Flexsafe STR® bags are configurable, offering multiple options for tubing, connectors, spargers and impeller combinations. Pre-configured standard bags are available from stock.

Benefit from the same polyethylene film material across all your cell culture steps. Use our Flexsafe® RM bags in your seed train, e.g. together with our BIOSTAT® RM bioreactors. Use Flexsafe® 3D bags for media storage and bulk harvest hold.

Robust bag	▶ 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

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

Sartocheck® 4 Plus Bag Tester

Post-Installation, Pre-use Testing Takes Safety to the Highest Level

Applications
- Post-installation, pre-use testing of bags

The Sartocheck® 4 plus Bag Tester is the first bag tester specifically designed to verify the intactness of bags installed in single-use BIOSTAT STR® bioreactors.

The Sartocheck® 4 plus Bag Tester incorporates patented technology for non-destructive point-of-use bag testing. This fast test method is fully validated, automatic and is based on pressure decay.

It is your most efficient risk mitigation tool to prevent batch losses due to operator errors and incorrect handling of bags.

Tests the bag as well as connections until the first clamp	▶ Verifies intactness of bag and connections as the final step before use
Post-installation, pre-use pressure decay testing	▶ Eliminates batch losses due to inadequate handling ▶ Keeps project timelines on track
Intuitive operation	▶ Less effort and training required
Patented, qualified non-destructive technology	▶ Reliably and reproducibly detects leaks

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

Single-Use Accessories

Single-Use Exhaust Cooler for BIOSTAT STR®

The exhaust cooler is a single-use device for the BIOSTAT STR® sizes 50 L to 1000 L. It is installed between the bag and the exhaust gas filter and thus within the sterile barrier. This exhaust cooler enables high cell density cultivations at high gas flow rates.

- Increases process safety
- Reduces aerosol load in off-gas
- Protects the exhaust filter from blockage

Exhaust Filter Line for BIOSTAT STR®

The 0.2 µm sterilizing-grade Sartofluor® exhaust gas filters come in a ready-to-use sterilized tube assembly with Opta® SFT sterile connectors (see page 46) for easy and safe connection to the exhaust line of our CultiBag STR® and Flexsafe STR® bags. They are designed to control the typical flow rates of high density cell culture processes. A heating element in the filter line prevents the filter from wetting out.

- Ready-to-use and easy to connect to STR® bags
- Back-up exhaust filter line for risk mitigation

BIOSTAT® B with RM 200 Rocker

Large-Scale, Rocking-Motion, Single-Use Bioreactor with New Flexsafe® RM Bags for Excellent Cell Growth

Applications

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

The BIOSTAT® B with RM 200 Rocker is a single-use, rocking motion bioreactor for large-scale cultivation.

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

The bag holder fits the Flexsafe® RM bags in a working volume range from 10 L up to 100 L.

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

Low consumable costs	▶ Economical alternative to stirred single-use bioreactors
Reliable single-use probes for measurement of pH, pO_2 and cell density	▶ Easy-to-use; low risk of contamination
With well-proven controller designed for automated batch and fed-batch processes	▶ Optimal solutions for fully controlled process
Precise gravimetric harvest and feed controllers	▶ Reliable and efficient cultivation
Independent controller and rocking platform unit	▶ Flexible space-saving component arrangement

BioPAT® sensor options:

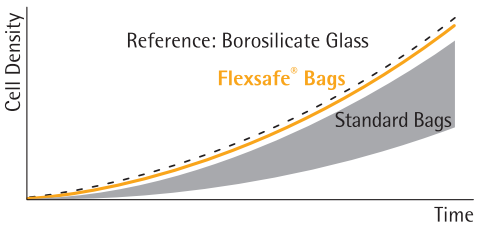
ViaMass
Viable biomass measurement
(page 94)

Gas Supply Options: page 90

Advanced Additive Flow

Flexsafe® Bag Family

Cell Growth



Optimized Resin and Additive Formulation
Flexsafe® bags are based on an optimized resin and minimized additive package of the polyethylene film, developed in collaboration with our resin and film suppliers. Flexsafe® bags are free of cytotoxic leachables as confirmed by independent labs. WFI extracts of Flexsafe® bags have been validated for the complete absence of bDtBPP.

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

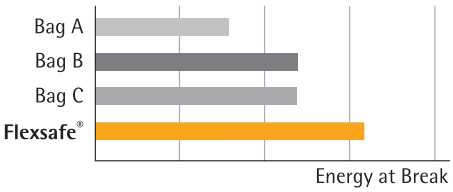
Assurance of Supply

Consistent Quality and Business Continuity
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 resins to the final, assembled bags.

New Bag Family

Watch Video:
www.sartorius-stedim.com/flexsafe

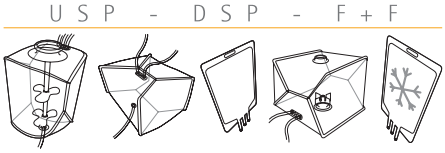
Robustness



Superior Strength and Flexibility of Film and Welds
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.

One for All



Safe and Convenient Single-Use Processing
Flexsafe® meets your 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.

Integrated Optical Single-Use Sensors from ambr® 15 to BIOSTAT STR® 2000

All our single-use bioreactor vessels are equipped with identical, integrated optical sensor patches for non-invasive pH and oxygen monitoring.

The measurement principle is based on fluorescent dyes that are exposed to the cell culture fluid in a specific location in the bioreactor. The dyes are stimulated by light and the pH or O_2 concentration dependent emission intensity is captured and converted into a pH or pO_2 concentration value.

Together with PreSens, we have optimized the sensor patches for reliable measurement. Specifically for our large-scale, stirred-tank BIOSTAT STR® we have developed a special single-use sensor port that protects the patches during gamma irradiation, thereby enhancing the robustness of the pH measurement.

Sensors are integrated and ready to use	▶ Reduction of contamination risk
Performance comparable to conventional sensors	▶ Reliable single-use measurements
Seamless scalability of measurements and controls	▶ Time and costs savings during scale-up

ambr® 15

ambr® 250

UniVessel® SU

	Single-Use pH Sensor	Multi-Use pH Sensor	Single-Use pO_2 Sensor	Multi-Use pO_2 Sensor
Measurement Method	Precalibrated dual lifetime fluorescence referencing method ▶ Excitation at 480 nm ▶ Emission at 570 nm	Combination electrode; potential measured against reference electrode	Precalibrated fluorescence quenching referencing method ▶ Excitation at 505 nm ▶ Emission at 630 nm	Method 1: Measurement of electrical current affected by partial pressure of oxygen Method 2: Oxygen dependent luminescence quenching (phase fluorimetry)
Measurement Ranges	pH 6 – 8	pH 2 – 12	0 – 110% at 37°C	0 – 100%
Accuracy | Resolution	0.1 pH at ± 0.50 pH units near the value of 1-point calibration	± 0.1 pH units	< 1% air saturation at 37°C within 0 – 100% air saturation	0.1%
Preparation Time	None	2 – 3 hours	None	2 – 3 hours
Sterilization Method	Gamma irradiated together with single-use bioreactor	Autoclaved and aseptically inserted into bioreactor	Gamma irradiated together with single-use bioreactor	Autoclaved and aseptically inserted into bioreactor

BIOSTAT® RM

BIOSTAT STR®

Scalability in Single Use

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

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

Our rigid-wall and bag bioreactor vessels featuring a single-use, stirred-tank design are based on proven engineering principles:

- Central stirrer shaft
- Choice of Rushton turbine and low-shear 3-blade segment impellers
- Geometric similarity of vessel and impeller dimensions
- Comparable ring- and microsparger designs
- Torospherical vessel and bag design

We support your scale-up and -down activities with extensive process engineering data on mixing time, oxygen transfer and power input determined for all our glass, stainless steel and single-use bioreactors, covering all available impeller and sparger configurations. Contact your local application specialist for further information and additional data on CFD modelling.

Our local controller for intuitive operation provides you with standard control strategies to align your batch, fed-batch, and continuous culture approach for all our ambr® and BIOSTAT® bioreactors. You decide whether you prefer to work with conventional pH and pO_2 probes or whether you wish to benefit from fully single-use optical pH and pO_2 probes across our entire range of UniVessel® SU and STR® disposable bioreactors.

Our Range of Stirred-Tank Single-Use Bioreactors

ambr® 15

ambr® 250

UniVessel® SU 2L

BIOSTAT STR® 50

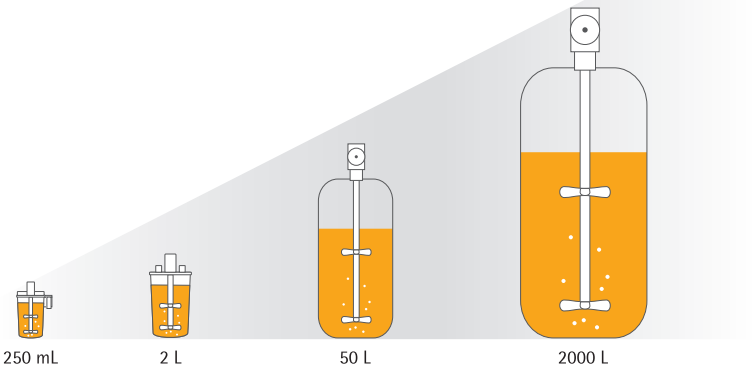
BIOSTAT STR® 200

Benefit already during cell line and media development from a stirred bioreactor design using our ambr® 15 system. It helps you to generate meaningful data and supports manufacturability at scale right from the beginning.

Then continue your process development using our ambr® 250 multi-parallel mini bioreactor systems and run Design of Experiments studies to determine your process optimum in the most effective, fast and highly predictive way.

Next, move to material supply for toxicological studies and prove your process at scale in our BIOSTAT STR® single-use bioreactor. You can rely on our new BIOSTAT STR® 2000 for late-phase clinical and commercial production and flexibly adapt your capacity to your market needs.

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



Classic, stirred-tank design and geometric similarity of our range of single-use bioreactors from ambr® 250 to BIOSTAT STR® 2000.

BIOSTAT STR® 500

BIOSTAT STR® 1000

BIOSTAT STR® 2000

BIOSTAT® Cplus

The Stainless Steel Fermenter | Bioreactor for Your Laboratory

Applications

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

BioPAT® sensor options:

Trace
Glucose | Lactate measurement
(page 96)

Fundalux
Turbidity measurement
(page 97)

Xgas
Off-gas analysis
(page 98)

Spectro
Multi-variant bioprocess monitoring
(page 99)

Gas Supply Options: page 90

O_2 Enrichment

Additive Flow

Advanced Additive Flow

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.

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

Your "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

Applications

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

BioPAT® sensor options:


Trace
Glucose | Lactate measurement
(page 96)


Fundalux
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Xgas
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Spectro
Multi-variant bioprocess monitoring
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Gas Supply Options: page 90

O_2 Enrichment

Additive Flow

Advanced Additive Flow

Customized Stainless Steel Fermenters | Bioreactors

Fit for Purpose Process Solutions

Applications
- Microbial, insect and mammalian cell culture
- Suspension and microcarrier culture
- Pilot-scale production
- Commercial production

Sartorius offers process-scale stainless steel bioreactors and fermenters based on an engineering platform approach.

The large scale stainless steel fermenter | bioreactor platform of Sartorius is based on decades of engineering experience and detailed understanding of biopharmaceutical manufacturing processes and specific customer requirements. This platform virtually eliminates time-consuming engineering efforts that are normally required for establishing P&IDs, 3D designs and implementation of control software.

This results in shorter project execution timelines combined with better control of costs and timelines right from the beginning.

Moreover, high operational safety is ensured by using industrially proven and reliable components, designs and a PLC software library. Design platforms are available in incremental sizes of working volumes from 200 L to 2,000 L.

Standardized designs, components and PLC software library	▶ Backed by 50 years of experience
Proven hardware designs and control software	▶ Fully functional right after commissioning
Fully flexible and modular design	▶ Cost-effective fit for purpose process solutions
Standardized components	▶ Minimal downtime during preventive and corrective maintenance

In-Situ Accessories

Mobile CIP Unit

A mobile Cleaning In Place (CIP) unit is your ideal solution when you require maximum flexibility, experience space limitations or an investment into a hard piped CIP installation is not an option. Our mobile CIP system perfectly integrates with the BIOSTAT® D-DCU controller and ensures an automatic cleaning process. CIP headers integrated in the fermenter vessel guarantee effective and reliable cleaning of the complete bioreactor system including the culture vessel, gas inlets, exhaust lines, addition lines and transfer groups.

- Mobile CIP intergrated with bioreactor control system
- Fully automated CIP process
- Flexible installation

SACOVA

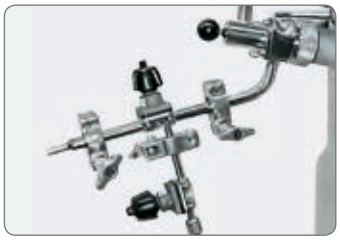
The SACOVA is an addition valve designed to add sterile liquid to an in-situ sterilizable fermenter or bioreactor. The SACOVA is easy to remove from the culture vessel for autoclaving together with the connected bottle for addition of media or thermoweldable tubing – for later connection to a single-use bag. After autoclaving, SACOVA is then inserted in the vessel lid or side port and sterilized together with the culture vessel. After sterilization SACOVA is ready to use. In summary, SACOVA is an easy, safe and inexpensive alternative for sterile addition of agents, feeds or media to the culture vessel.

- No open flame needed for aseptic connection
- Safe handling due to needle-free operation
- Three-channel version for multiple additions in a single port

Sampling Valves

Sampling valves are specially engineered for aseptic sampling of the culture vessel. Two different versions are available – the SVC 25 and the Keofit W9. Both sampling valves are resterilizable and reusable during the fermentation. On the BIOSTAT® D-DCU, the sampling valve can be sterilized either by a manual method or a fully automatic procedure. The SVC 25 fits into a 25 mm side port, and the Keofit W9 is designed to fit into a sanitary flange. Both sampling valves can be supplied for sampling into an open bottle or into a contained sampling bottle.

- Precise dosing of sampling volume
- No dead volume; ensures representative sampling
- Resterilizable and safe



Resterilizable Addition Port

Addition port (AP) kits are designed for sterile connections of containers with corrective agents, feed and media or for connection of smaller scale fermenters | bioreactors to inoculate the culture vessel. In addition, the AP can be resterilized and reused during fermentation. AP kits are available in two versions; 1) for a 19 mm lid port, and 2) for a 25 mm side port. When equipped with a dip tube, it can be used for harvesting or for additions below the liquid surface.

- No open flames needed for aseptic connection
- Resterilizable connections process
- Different adjacent additions via a single port

Containment Sampling Kit

Used in combination with the SVC 25 or Keofit W9, the containment sampling kit is ideal for removing an aseptic and aerosol-free sample from the culture vessel. It consists of an autoclavable silicone-jacketed glass bottle, a stainless steel lid with a vent filter and a diaphragm valve, as well as a condensate line. On the BIOSTAT® D-DCU, the containment sampling kit can be sterilized either by a manual method or by a fully automatic procedure. This kit is excellently suited for use in typical applications requiring operator protection according to biosafety regulations and those in which the sample will be used for further processing under aspetic conditions.

- Aseptic sampling
- Aerosol-free sampling for operator protection
- Safe silicone-jacketed sampling bottle

TAKEONE® Single-Use Sampling System

The TAKEONE® aseptic sampling system is single-use so you can immediately start sampling "right out of the box". While traditional sampling devices require cleaning, preparation and sterilization after each use, TAKEONE® eliminates these steps, saving valuable time. The system's QUICKSEAL® aseptic tube sealing unit enables safe and reliable disconnection of the sampling bag – without the need for any utilities.

- Fully single-use; eliminates cleaning, preparation and sterilization
- Reliable performance as all sampling lines are 100% integrity tested at the factory
- Easy and safe aseptic sampling bag disconnection

Internal Spinfilters

Spinfilters, mounted on the stirrer shaft of the culture vessels, enable the removal of cell culture supernatant during continuous perfusion cultivation of animal cells. They are available in a choice of different mesh sizes for suspension cell culture as well as cell culture on microcarriers.

- Easy to integrate into new or available BIOSTAT® bioreactors
- Cost-effective perfusion device
- No external loop

Sartofluor® Mini Cartridges for Sterile Gas Filtration

Sartofluor® mini cartridges rated to 0.2 µm are sterilizing-grade filter elements for air and gases in the pharma | biotech industry. Their unique hydrophobic PTFE membrane is ideally suited for particle removal and sterile filtration. The membrane also prevents water blockage of your filter caused by high humidity air streams even after prolonged use.

- Long-time operation even at high humidity air streams
- High-steam cycle lifetimes
- Reliable and validated separation of microorganisms

BioPAT® DCU

Intuitive Local Control for Your BIOSTAT® Bioreactors

The robust, intuitive-use and industry-proven DCU (digital control unit) control technology is now available in its fourth generation. It is our standard local control platform for our BIOSTAT® bioreactors, SARTOFLOW® crossflow filtration units and FlexAct® configurable systems available for a large number of unit operations. Transfer of local data, PID control settings and recipes for advanced automation is easy and secure when the DCU is connected to our BioPAT® MFCS SCADA system.

- 12" to 18.5" touch-screen with closed frame; protected against water splashes and dust
- Easy-to-use and reliable operation due to advanced touch-screen technology – even while you are wearing protective gloves
- Process parameter monitoring and alarm messaging, control loops and automated sequences – for total control at a glance

Common local control platform with intuitive design of the human machine interface – for all our BIOSTAT® bioreactors and other process equipment

- Minimizes training and enables you to start your process right away
- Increases operator flexibility
- Mitigates human error

Plug-and-play connection to Sartorius SCADA system BioPAT® MFCS

- Reduces engineering efforts for faster and cost-effective commissioning
- Integration in customer process landscape can be achieved by an OPC DA | AE or an optional DeltaV™ interface

Advanced options for process monitoring and control

- Unmatched performance backed by Sartorius

Build your own automation network from lab to production scale – based on bioprocess optimized and preconfigured solutions from Sartorius.

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

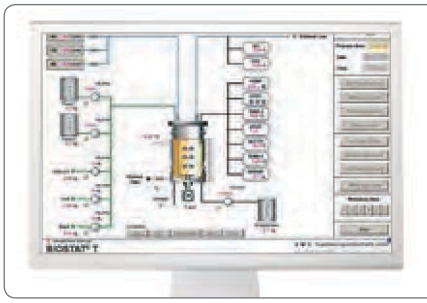
BIOSTAT® T

Interactive Training Simulator

Applications

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

The BIOSTAT® T training tool enables virtual training of your operators on real bioprocesses to mitigate the risk of human error and prevent batch losses.

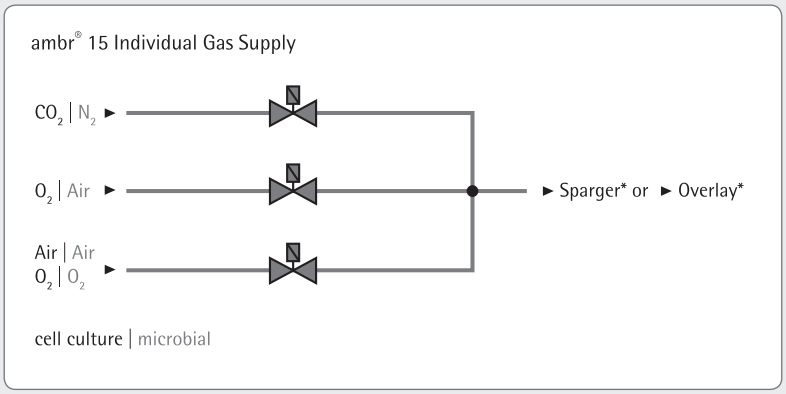


BIOSTAT® T combines the intuitive user interface of the BioPAT® DCU with a powerful bioprocess data simulation engine.
It effectively teaches you how fermentation processes work by running through a virtual batch, from vessel preparation, probe calibration and sterilization to inoculation, process parameter monitoring and control.

In addition, you can try out various controller settings to determine their effect on culture performance. The tool offers simulation of a 20 L batch, fed-batch or continuous Baker's yeast process.

Similar look and feel as the BioPAT® DCU	▶ Fast transfer of learning into real-world environment
Virtual training on real bioprocesses	▶ Time- and cost-effective training of operators
Study effects of control loops and settings on batch, fed-batch and continuous process behavior	▶ Reduction of the impact of human error

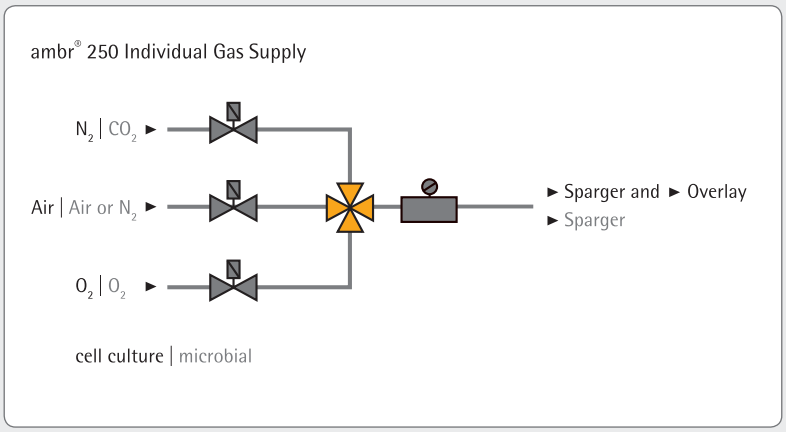
Gas Supply Options



* Depending on vessel type.

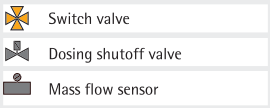
ambr® 15 Individual Gas Supply

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

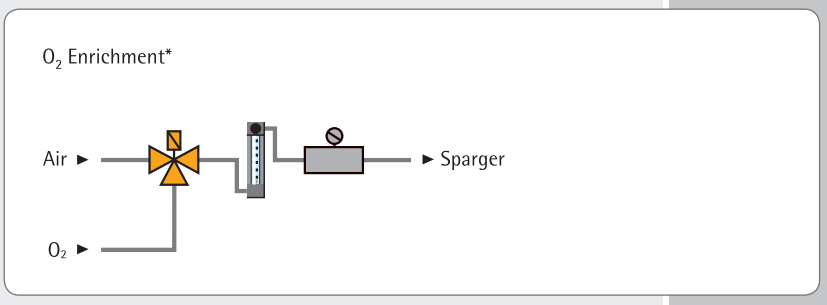
This advanced gassing strategy utilizes both mass flow controllers and valves to accurately control flow rates. The strategy directs any or all of the 3 gases (Air, O_2, N_2 | CO_2) to the sparger or overlay independently. Any two gases can be accurately mixed, for example when enriching gas with oxygen, 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.



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

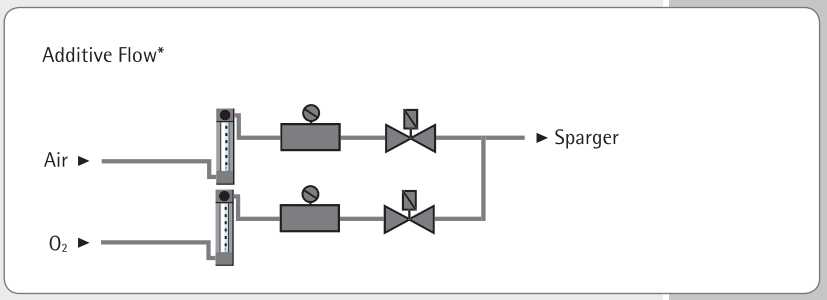
O_2 Enrichment

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. You can optionally integrate mass flow controllers 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.



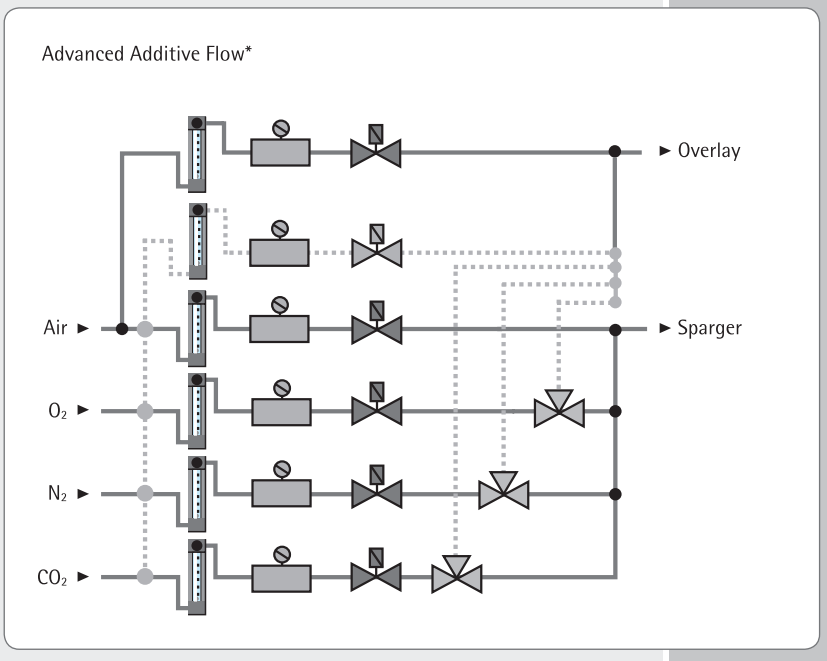
Additive Flow

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.

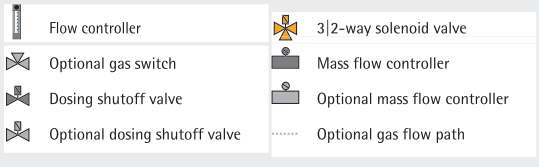


Advanced Additive Flow

You can direct air, O_2, N_2 and CO_2 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 your particular BIOSTAT® bioreactor system and configuration. Please contact your local Sartorius representative for further details.



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



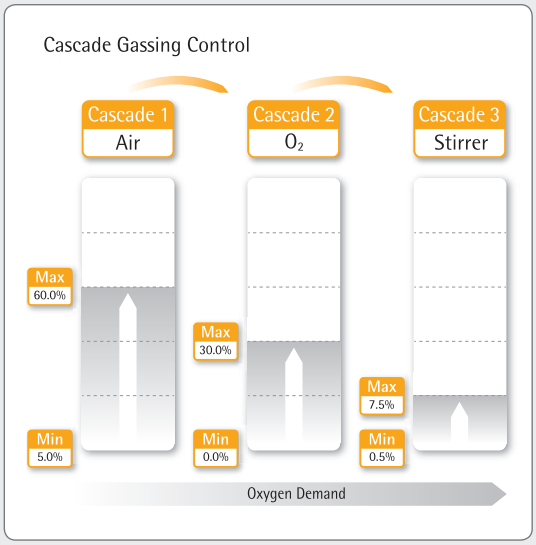
Oxygen Control Strategies

Solenoid Valves and Mass Flow Controllers

You can 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

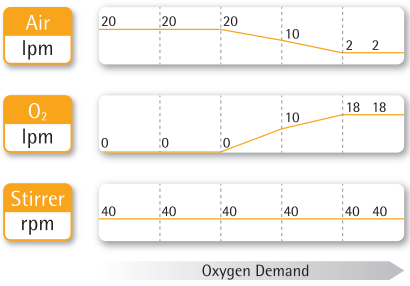
Automatic pO_2 control is one of the most important functionalities of a bioreactor. It is designed to alter the volumetric oxygen transfer rate in order to meet process oxygen demands. As the measured pO_2 moves off the set point, the system will automatically change a parameter (over a defined range) 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

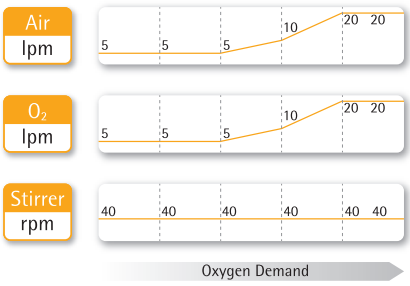
Enable parallel modification of all physical parameters with the advanced pO_2 controller. Activate or change multiple parameters simultaneously such as stirrer speed, aeration rate for air | oxygen or other parameters. You can realize all oxygen control strategies and be resource efficient. For examples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

Constant Gas Flow



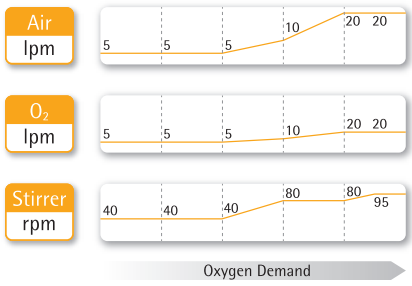
Constant gas flow decreases the flow of air and simultaneously increases oxygen gas

Constant Gas Ratio



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

Bubble Size Optimization



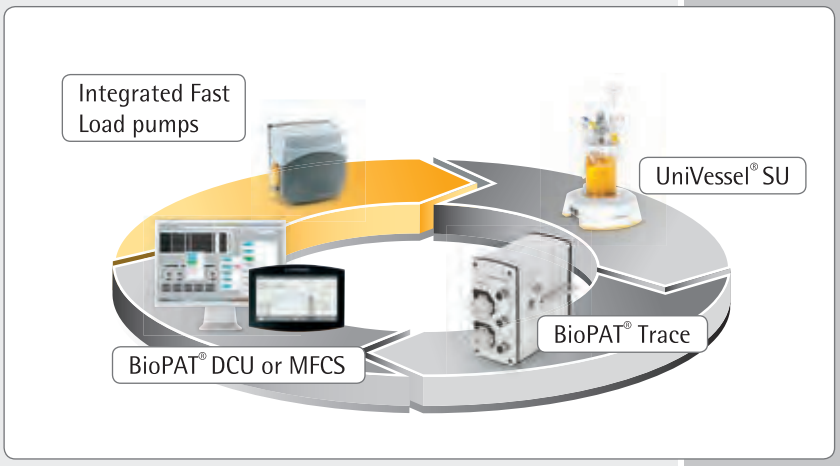
Bubble size optimization enables fine tuning of the oxygen % and gas-liquid interface area

lpm: litre per minute
rpm: revolutions per minute

Advanced Measurement and Control Loops

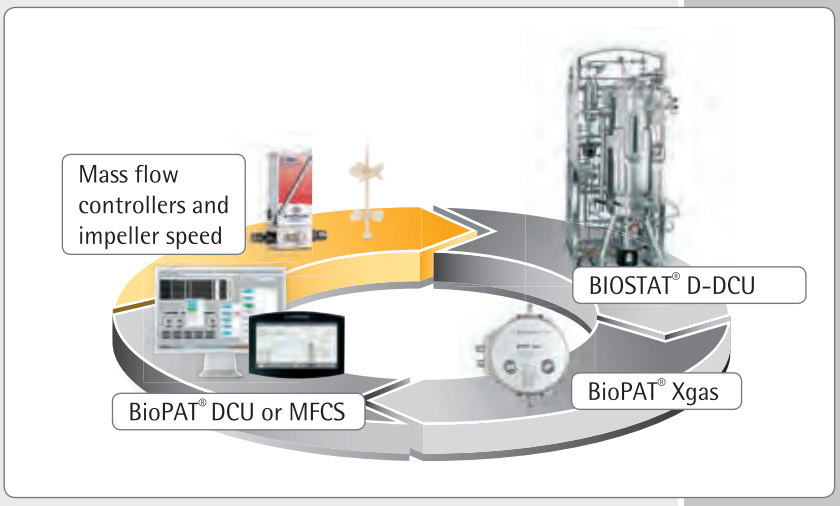
Glucose Feed Control

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.



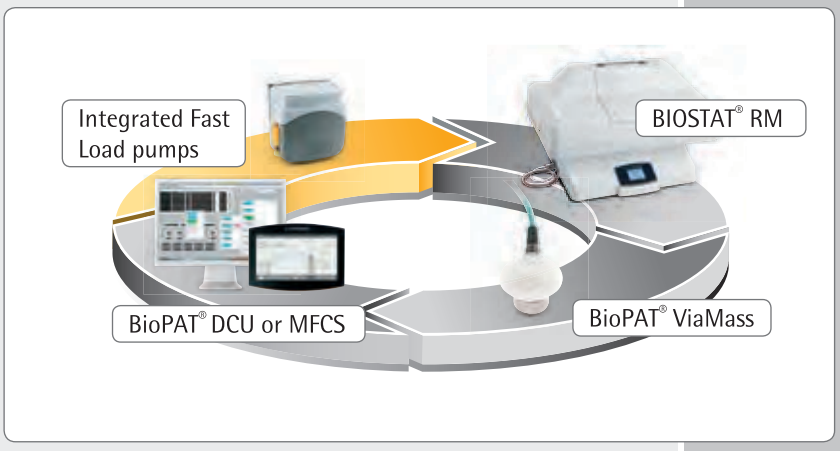
Metabolic Respiration Control

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 your cells. As a result, this upstream control loop enables optimal growth conditions, ultimately increasing the productivity of your process.



Viable Biomass Feed Control

Collecting real-time data about your 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, you can configure your BIOSTAT® 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.



BioPAT® ViaMass

Inline Monitoring of Viable Biomass

BioPAT® sensor:

ViaMass
Viable biomass measurement

Applications

- Inline real-time measurement of biomass concentration and growth rate
- Biomass monitoring of microcarrier cultures in vaccine and regenerative medicine
- Stable cell concentration via perfusion control
- Consistent time of virus infection
- Viable cell volume based glucose feed control

BioPAT® ViaMass brings inline viable biomass monitoring to our single-use, glass and stainless steel bioreactors. This capacitance measurement technology is fully integrated into the BIOSTAT® local control and vessel configuration for easy process development and control.

The integrated probes permit non-invasive and operator independent measurement of viable biomass inside our multi-use and single-use bioreactor vessels. The full integration prevents interface issues and reduces footprint for an easy plug and play set-up. The technology reduces the need for off-line sampling and enhances the batch-to-batch consistency with improved process control strategies based on real-time inline measurement of biomass.

Unique in the market, Sartorius offers integrated single-use non-invasive measurement of viable biomass in our RM and STR bags.

Mechanical, electrical & software integration to BIOSTAT® bioreactors	▶ Reduced footprint, digital communication issues and set-up complexity
Data & control integration to BioPAT® DCU	▶ Easy user interaction, calibration and establishment of biomass based control loops
Inline measurement reduces cell count sampling need	▶ Reduced contamination risk and operator effort
Gamma irradiated qualified sterile single-use bags with integrated biomass sensor discs	▶ Reduced risk of contamination and easy set-up, calibration and disposal
Aber Instruments industrially developed technology	▶ Known market leader in biomass measurement assuring quality and performance

Inline Biomass Measurement for all BIOSTAT® Bioreactors

Inline Probe Design

- Annular and flush design for glass and stainless steel
- Single-use sensor disc integrated into Flexsafe® RM and Flexsafe STR® bags
- 4 electrodes made of 100% Platinum for radio frequency (RF) field generation

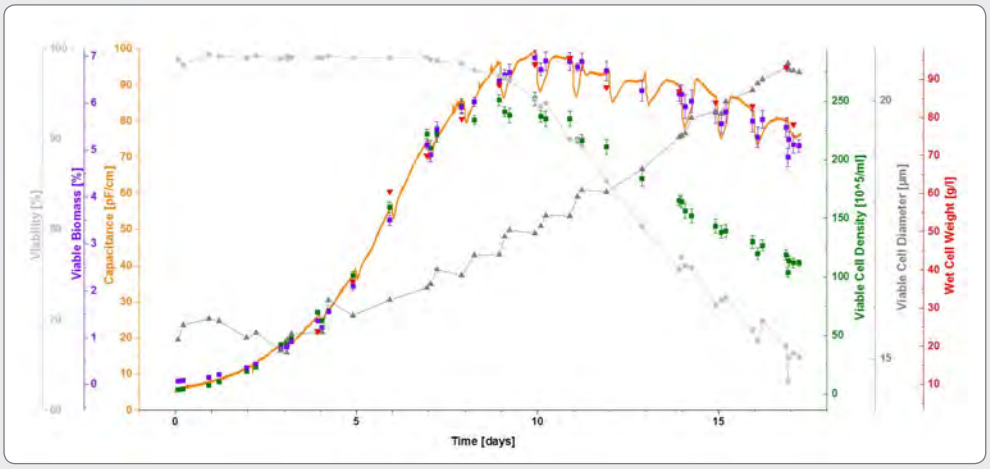
Capacitance Measurement Principle

- All living cells are polarized by the RF field generated from the sensor disc
  – more cells – higher signal
  – bigger cells – higher signal
- Dead cells, microcarriers and protein invisible to measurement field
- Measurement range 0 to 400 pF/cm – 10^3 cells/mL to 10^7 cells/mL for CHO cells with a ~25 µm diameter

Process Control Capabilities

- Automatically pause or switch feed on desired cell concentration
- Consistent seed transfer concentration
- Viable biomass based feed control
- Maintain perfusion cell concentration setpoint

Manufactured under the license from HAMILTON



Inline monitoring of viable biomass now available in our single use bioreactors

BioPAT® Trace and Multi Trace

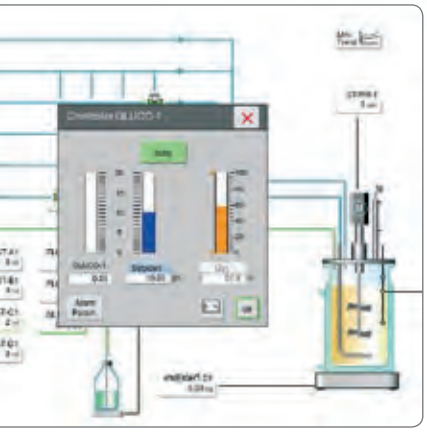
Online Measurement of Glucose | Lactate or Ethanol | Methanol

BioPAT® sensor:

Trace
Glucose | Lactate and Alcohol measurement

Applications

- Measurement of key nutrients during cell culture and microbial fermentation
- Automated Glucose feed control
- Automated alcohol induction feed rate control
- Nutrient | metabolite perfusion rate control



The BioPAT® Trace[1] and Multi Trace[2] analysis systems are ideal for simultaneous online monitoring of glucose, lactate and alcohol during batch, fed-batch and continuous cultures of microorganisms or animal cells.

The measurement range of the BioPAT® Trace spans typical microbial and cell culture processes. Based on your control requirements, up to 60 measurements per hour can be performed. The system's easy-to-operate design allows routine analysis functions just after brief training. Combined with our BIOSTAT® B-DCU you can easily create glucose control loops and monitor your control loop and process values on the BioPAT® DCU screen.

The measurement principle for the small molecules concentrations is based on a combination of enzymatic conversion and electrochemical detection. The sensor system can run up to 5,000 measurements and a maximum of 30 days continuous operation.

[1] Connects one vessel
[2] Connects up to four vessels

Automatic and self-calibrating measurement of glucose | lactate or ethanol | methanol	▶ Online monitoring of key metabolites, nutrients and inducers
Fully disposable sensor and fluidics set	▶ Easy setup for immediate use
Implementation of automatic control loops	▶ Automated control strategies based on glucose or alcohol concentration
Analogue outputs, ethernet and OPC connectivity	▶ Direct integration into your automation architecture via multiple options
Sampling modes: filtration and dialysis	▶ Sample volume can be adapted to the bioreactor volume – from small laboratory scale to large scale production

BioPAT® Fundalux

Inline Monitoring of Total Biomass

BioPAT® sensor:

Fundalux
Turbidity measurement

Applications

- Inline monitoring of total biomass based on turbidity e.g., in microbial cultures
- 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. You can use it 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 tool lets you conveniently control nutrient feeds, gas flow and other critical process parameters to optimize yield.

The BioPAT® Fundalux amplifier comes integrated into our BioPAT® DCU. To have strain-specific data converted automatically to any optical density measurement, just use BioPAT®Fundalux with BioPAT® MFCS software.

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
Robust LED light source	▶ Up to 10-year lamp lifetime
Product contact materials and surfaces are certified and traceable	▶ Calibrate, for example, your pH and pO_2 probe with certified absorption filters ▶ Biocompatibility and quality assured

BioPAT® Xgas

Online Off-Gas Analysis of O_2 and CO_2

BioPAT® sensor:

Xgas
Off-gas analysis

Applications

- 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
- Early warning of pO_2 probe error

The compact BioPAT® Xgas precisely tracks changes in respiratory gas emission from a cultivation vessel. You can integrate it 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 spectroscopic analysis yields insights into critical metabolic changes during your cultivation process.

This enables you to apply reliable, advanced gassing or feeding strategies to improve production rates and reduce cultivation time.

Standardized integration into all our 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

BioPAT® Spectro

Online Multivariate Bioprocess Monitoring

BioPAT® Spectro conveniently integrates into your stainless steel bioreactor | fermenter to provide real-time feedback on the status of your process.

Through a standard Ingold port, the BioPAT® Spectro scans the visible and near infrared spectrum, tracking changes in absorption and linking them to parameter concentrations. In combination with the BioPAT® SIMCA online software tool, the BioPAT® Spectro data are transformed into meaningful process data, minimizing your need for offline sampling.

The monitored spectrum is converted into a real-time process trajectory and overlaid with previous golden batches. Any unexpected parameter shift is detected instantly, enabling you to take guided corrective action within a window of operation. This helps to prevent process deviations and simplifies subsequent root cause analysis and assessment of impact on product quality and safety.

Seamless data transfer to our MVDA tool BioPAT® SIMCA-online	▶ Cost savings thanks to less offline analytics and reduced manual effort
Integration into BIOSTAT® Cplus and BIOSTAT® D-DCU through standard Ingold port	▶ No bioreactor adaptation required
Intuitive visual software; sophisticated filtering of air bubble effects	▶ Reduced need for operator training
Batch recording of process stages based on process trajectories	▶ Early error detection prevents loss of expensive batches
Automated GMP-compliant documentation via BioPAT® MFCS	▶ Easy access to all batch related information

BioPAT® sensor:

Spectro
Multi-variant bioprocess monitoring

Applications

- Golden batch comparison in late phase clinical trials and commercial production
- Multiple parameter monitoring, e.g., nutrients, metabolites, cell parameters, titers
- Media quality fingerprinting

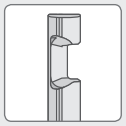
Risk is Inverse to Process Understanding

BioPAT® ViaMass

Viable biomass measurement

BioPAT® Trace

Glucose | Lactate and Alcohol measurement

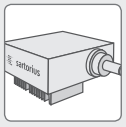


BioPAT® Fundalux

Turbidity measurement

BioPAT® Xgas

Off-gas analysis



BioPAT® Spectro

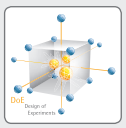
Multi-variant bio-process monitoring

BioPAT® DCU

Local Monitoring and Control

BioPAT® MFCS

Supervisory Control and Data Acquisition



BioPAT® MODDE

Design of Experiments

BioPAT® SIMCA

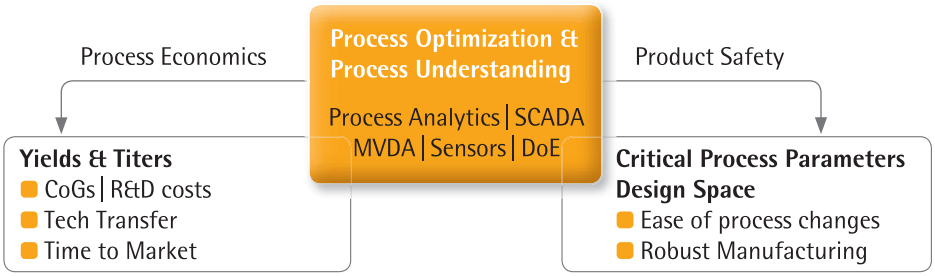
Multivariate Data Analysis

BioPAT® SIMCA-online

Online Mulitvariate Data Analysis

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, pO_2 and biomass; 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
Multivariate process monitoring based on NIR spectroscopy	▶ Ensure consistent process and product quality

Process Control and Software Tools

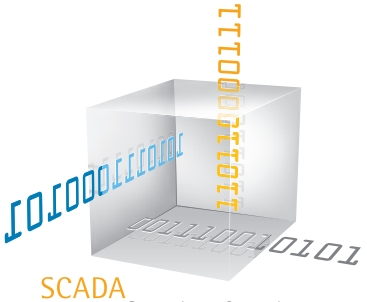
Stable and robust processes require automated control of critical process parameters based on reliable data acquisition, storage and evaluation capabilities. Process control and software tools further pave the way towards a knowledge-based approach to biopharmaceutical production to mitigate risk.

BioPAT® MFCS

SCADA Software for Reliable Data Acquisition, Monitoring and Control

Applications

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



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.

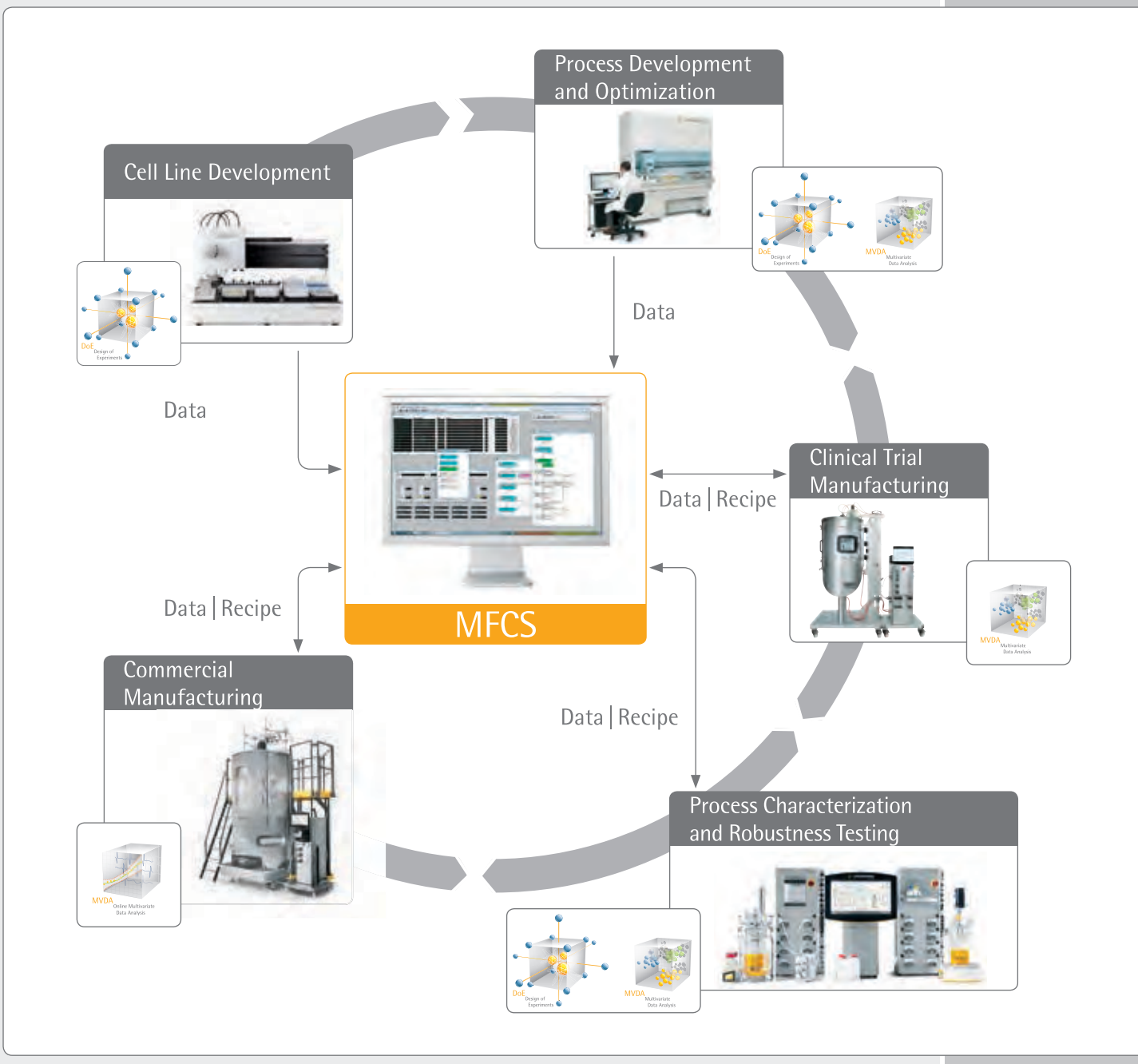
BioPAT® MFCS provides configurable modules and customization options to meet your particular requirements. Designed as a "plug-and-play" tool, it is ideally suited for capturing, storing and visualizing process data of our BIOSTAT® and ambr® bioreactors and other process equipment including 3rd party 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

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.

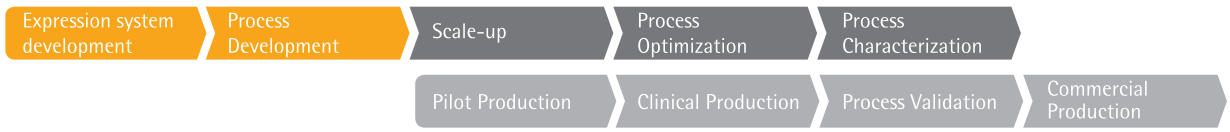


Software Modules BioPAT® MFCS

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, such as multi-core processors for fast data processing and Windows® 8 operating systems.

Drug development process



Connectivity
BioPAT® MFCS provides flexible connectivity to Sartorius devices and true interoperability with major third-party products. "Plug-and-play" communication to analytical instruments enables 24 | 7 monitoring of measurement data and facilitates feedback control loops.

Network
BioPAT® MFCS can be easily integrated into your existing IT architecture by distributed operator workstations with access authorization. If required, the SCADA environment can also be isolated from your company's network.

Automation
BioPAT® MFCS allows you to mirror each step of your process by selection of recipes complying with the ANSI/ISA-88.01 standard for computerized batch control.

Validation
BioPAT® MFCS supports all requirements to achieve full compliance with 21 CFR Part 11. Your process can be evaluated, reviewed, approved and archived without a single sheet of paper – and without the risk of interference with process data and electronic signatures.

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.

Training
Sartorius provides different levels of training sessions designed to ensure that each participant acquires the necessary, practical skills. On-site training courses can be adapted to your special needs so that you will get the most of your new BioPAT® MFCS.

Service & Support
Benefit from our team of experienced service engineers who have successfully delivered on a large number of projects worldwide, which include computer system validation as well as qualification of automated process equipment.

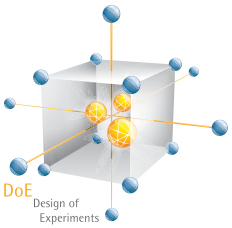
BioPAT® Chemometrics Toolbox

New Opportunities for Efficient Bioprocess Development and Manufacturing

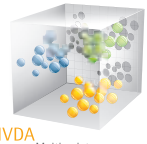
Take advantage of the BioPAT® Chemometrics Toolbox and integrate the capabilities of advanced multivariate methods into your existing process control software BioPAT® MFCS | win.

SCADA
BioPAT® MFCS

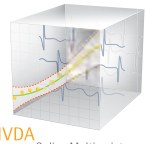
DoE Module



MVDA Module



OPC Module



DoE
BioPAT® MODDE

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

MVDA
BioPAT® SIMCA

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

MVDA-online
BioPAT® SIMCA-online

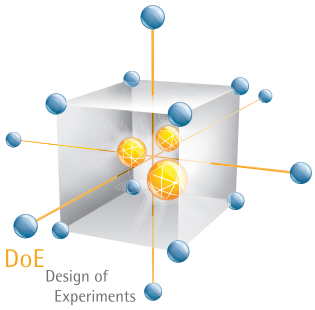
Monitor the design space online and save batches by early fault detection

BioPAT® 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



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

BioPAT® 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 BioPAT® 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 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

BioPAT® SIMCA

MVDA – Discover Hidden Process Information

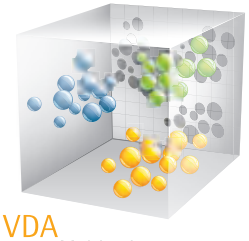
Applications

- 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 BioPAT® SIMCA supports and unlocks process understanding to ultimately improve the quality, safety and efficacy of your drug product.

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

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



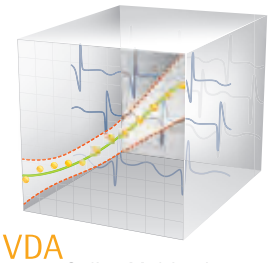
MVDA
Multivariate Data Analysis

Easy interpretation and analysis of large process data sets	▶ Improved process performance resulting in yield improvements and impurity reduction, among other benefits
Scale 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

BioPAT® SIMCA-online

Real-time Design Space Monitoring

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



MVDA
Online Multivariate Data Analysis

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

BioPAT® 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	▶ Faster troubleshooting
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


BioPAT® MFCS
sartorius stedim
ADMINISTRATION
MONITORING
ANALYSIS
BioPAT® MFCS
HELP

Instrument Services

Providing Peace-of-Mind While Maintaining Peak Equipment Performance

In order to keep your biopharmaceutical process robust and reliable, we provide a comprehensive range of services to ensure highest reliability and uptime of your equipment and best quality of results.

Trouble-free Operation

- Peace-of-mind that your equipment will run efficiently throughout its entire lifetime.
- Optimal equipment performance and avoidance of unnecessary interruptions or need for corrective action with our preventive maintenance.
- Professional service handling and minimized equipment downtime thanks to our experienced service engineers.

Trained Operators

- Train your operating staff as part of each installation and IQ|OQ to put necessary knowledge and skills into practice
- Our application specialists and training centers offer seminars that will show you how to work even more efficiently and confidently.

Regulatory Compliance

- Use our installation and operational qualification (IQ|OQ) services to ensure that your equipment can be used in a highly regulated environment.
- Documented quality and traceability of your measurement results in compliance with ISO 17025, GLP|GMP and FDA regulations as part of our calibration services.
- Our ISO 17025-accredited certificates are accepted worldwide and enhance your recognition as a qualified operator.

Optimized System Performance

- Ensure full performance right from the start and for the entire equipment lifecycle with our professional system installation.
- Get the most out of your equipment with our individual configuration and on-site adaption.

Quality of Results

- Trust the accuracy and precision of your analytical results with regular equipment calibration. Sartorius will perform and document this service for you.
- We offer a variety of accredited and ISO calibration certificates which meet the requirements of the pharmaceutical and regulated industry.

Lifecycle Management: Maximize Efficiency and Prolong the Lifespan of Your Systems

Robust and efficient process operation based on the Sartorius Instrument Service

Installation and Commissioning

Our factory-trained service engineers ensure up and running equipment individually configured and perfectly adapted on-site for full system performance right from the start.

Qualification

Qualification services (IQ|OQ and SAT) at Sartorius testing standards and with comprehensive documentation ensure operating your systems fully in compliance with cGMP.

You can choose between four different levels of qualification.

- **Level 1:**
  We provide you with material certificates.
- **Level 2:**
  You receive Sartorius test documentation templates (IQ|OQ documents, which enable you to perform the system qualification).
- **Level 3:**
  We prepare the test documentation for your individual system and perform the documented execution of the factory acceptance test at our manufacturing facility.
- **Level 4:**
  Includes the site acceptance tests at your facility.

Preventive Maintenance & Service Contracts

Professional regular maintenance safeguards robust system performance and reliability of results.

Select one of our worry-free service agreements with regular preventive maintenance visits that include the correct configuration, calibration and adjustment for your process at fixed, plannable annual operational budgets.

Contract Types

Content	Standard	Advanced	Customized
Annual preventive maintenance visit	✓	✓	*
Travel expenses	✓	✓	*
Wearing parts and consumables	✓	✓	*
Calibrations incl. certificates	✓	✓	*
Technical phone support	✓	✓	*
10 % discount on spare parts	✓	✓	*
One emergency call out per year incl. expenses		✓	*
Repairs during maintenance visit		✓	*
10 % discount on additional repair work		✓	*
Priority handling of emergency calls		✓	*

* Individual agreement

Protect your Equipment with Sartorius Instrument Service and ask for your Specific Service Offer!

- Maximum productivity over the complete lifetime unlock the full potential of your equipment
- Highest reliability and continuous, robust and precise operation
- Maximum operation uptime through a global network of experienced service engineers with in-depth knowledge of the bio-pharmaceuticals industry
- Risk mitigation by ensuring regulatory compliance and confidence in your results

IV. Clarification

Sartoclear Dynamics®

Single-Use Clarification of High Cell Density Cultures

Applications
- Clarification of high cell density fed-batch cultures

Sartoclear Dynamics® is a new single-use technology developed for the clarification of high cell density animal cell culture. Robustness, ease of use and scalability are key characteristics of this technology.

Sartoclear Dynamics® is based on the principles of body feed filtration and uses highly purified diatomaceous earth as a filter aid. The addition of the porous diatomaceous earth keeps the filter cake on the filters permeable for fluids.

This enables a continued filtration until the Sartoclear Dynamics® cassettes are completely full. The result is a highly efficient and constant clarification performance in a single step.

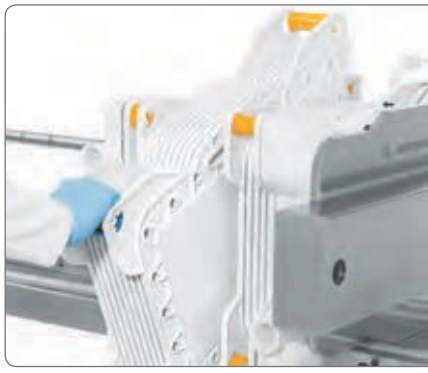
Single-use clarification solution for high cell densities	▶ Avoids high investment costs for centrifuges
Insensitive to viability changes and differences in cell densities	▶ Prevents oversizing of filtration area and makes process development predictable
Amazingly fast	▶ Saves time and reduces the exposure time to proteases

Sartoclear® Depth Filters

Cell Clarification and Contaminant Removal Technologies

Applications
- Post centrifuge filtration
- Clarification of moderate cell density cultures (<5% wet cell weight)

Sartoclear® filters are cellulose-based depth filters developed for demanding clarification applications in the biotechnological and pharmaceutical industries.



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

The single-use Sartoclear® depth filter cassettes and Sartoclear Dynamics® are two complementing technologies using the same holder and manifold plates.

Depending on your process needs you either select Sartoclear® depth filters for applications with lower solid contents (i.e. post centrifuge filtrations, perfusion processes, moderate cell densities) or Sartoclear Dynamics® for applications with solid contents higher than 5%. Both Sartoclear® technologies can be installed in series or parallel, offering a maximum of flexibility.

Big variety of device formats	▶ Serves you from the lab up to large scale commercial manufacturing with the same depth filter grade
One platform for two different technologies	▶ Select the best technology for your application without changing the equipment

Sartopure® | Sartoguard | Sartopore®

Most Economic Solutions for Post-Cell Removal Filtration

Applications
Filtration post-cell removal:
- Particle removal
- Bioburden reduction
- Sterile filtration

Complete your cell removal process. Any remaining debris is effectively removed by subsequent filtration steps. Different membrane and fleece filters or combinations are available.

Sartopure®
Sartopure® filters are the ultimate choice for your particle removal providing lowest filtration costs per liter. The exceptional total throughput performance combined with unmatched particle retention makes the Sartopure® filter unique.

Sartoguard
There is always a Sartoguard filter type matching your bioburden reduction requirements. Due to the combination possibilities of PES membranes with different fleeces, your post-cell removal filtration step can be downsized significantly reducing your total filtration costs.

Sartopore®
Due to the special 0.8 | 0.2 µm PES membrane combination and the large filtration area Sartopore® 2 XLG provides unmet capacity especially for sterilizing filtration after cell removal.


FLEXBOY®
20 L

V. Analytics

Microsart® RESEARCH | ATMP | AMP Mycoplasma

Rapid Real-time PCR Mycoplasma Detection Kits

Applications

- Microsart® RESEARCH Mycoplasma – Testing of cell culture materials in research and development
- Microsart® ATMP Mycoplasma – Testing of Advanced Therapy Medicinal Products (ATMPs)
- Microsart® AMP Mycoplasma – Regulated in-process and lot-release testing

Microsart® Mycoplasma detection kits reduce your testing time from weeks to just three hours.

The earlier you detect a mycoplasma contamination, the higher your long-term savings. Early detection means more time to react, saving you valuable time and considerable expense.

Microsart® Mycoplasma test kits offer a fast and easy-to-use solution for early detection at all stages of your process, no matter if you screen ATMPs or test samples from R&D or in your GMP production plant.

If you perform a prior enrichment step using the Sartorius Vivaspin® 6 or Vivaspin® 20 ultrafiltration devices, you will have the flexibility to use sample volumes of up to 18 ml.

With this concentration step you have the possibility to increase your sensitivity. The kits contain all essential components – lyophilized primers | nucleotides | probes | polymerase | internal amplification control | positive control furthermore rehydration buffer and PCR grade water.

Flexible sample volumes. Protocols for testing 2 µl, 200 µl or up to 18 ml are available	▶ The level of security can be adapted to your needs
Microsart® RESEARCH | ATMP | AMP Mycoplasma kits are based on real-time PCR technology using highly specific TaqMan® probes	▶ Easy-to-use and fast: results within hours – not days
Microsart ATMP | AMP Mycoplasma kits are validated according to EP 2.6.7 in combination with EP 2.6.21, with detection limit less than 10 CFU/ml	▶ Open system, no hardware bundle – take advantage of the qPCR you already own and keep your investment low

Sterisart

For Sterility Testing in Pharma | Biotech

Applications

- Sample and media transfer to Sterisart NF consumables for sterility testing
- Reliable media and buffer transfer into Flexboy® bags

Sterisart universal pump and consumables help ensure full compliance with international GMP guidelines in your microbial monitoring and batch release procedures for intermediates and drug substance.

The Sterisart universal pumps are specially designed for media and liquid transfer in cleanroom environments class A, B and C. They can also be used for safe transfer of media, feeds or samples to Flexboy® bags. Two pump versions are available: a basic version and an advanced with display and an integrated barcode scanner for convenient traceability of the equipment you use.

In combination with Sterisart NF consumables, sterility testing can be performed according to pharmacopeia requirements (USP<71> and Eu. Ph. 2.6.1).

For this purpose, the pumps can either be operated in a clean bench or installed countersunk in the working surface of isolators. Closed and ready-to-use Sterisart NF consumables minimize the risk of false-positive results. For (re)-validation, stasis testing, dilution and analysis of microbes, special septum versions are available.

No ventilation and no particle release	▶	The highest safety and reliability
Foot switch available	▶	Convenient operation
Integrated barcode scanner	▶	Easy traceability of every batch
More than 20 different Sterisart NF consumables	▶	High flexibility
Unique septum for aseptic sampling	▶	Minimized risk of getting a secondary contamination

Microsart® @filter

Touch-free Membrane Transfer Concept for Microbial Enumeration

Applications

- For microbial limit testing according to USP (Chapter <61>) and EP (Chapter 2.6.12)
- Innovative membrane transfer concept for microbial enumeration
- Enhanced safety of microbiological quality control
- For final quality control and release of non-sterile products

Filter your samples via Microsart® @filter units mounted on a ventable Combisart® manifold using the Microsart® e.jet vacuum pump.

Do you still use forceps for transferring membranes onto agar plates? Use Microsart® @filter in combination with Microsart® @media and enjoy the brand-new membrane transfer concept. Choose your membrane colour between white, green and black according to the microorganisms to be counted.

After filtration, remove the funnel, take the lid off the agar plate, place it onto the membrane and back onto the agar plate. The set is now ready for incubation and the risk of secondary contamination is reduced to an absolute minimum.

Touch-free membrane transfer	▶ Minimizes the risk of secondary contamination; outstanding recovery rates and reliable results
Choose membrane colour white, green or black	▶ Reliable results due to better visibility of colonies
Ready-to-use	▶ Preparation- and sterilization-free procedure accelerates workflow
Liftable lid inside exterior lid eliminates the need to open the complete dish	▶ Easy access to colonies for further analysis with minimum risk of secondary contamination

fill-it

Automated Cell and Strain Banking System

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

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

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

Bioanalytical Services for Biosimilars

Biosimilar Characterization and Comparability

Biosimilars are a relatively new field in the biopharmaceutical industry and present some unique challenges for developers and manufacturers. BioOutsource is an industry leading expert in the characterization and comparability of biosimilar monoclonal antibodies, reducing customer's development timelines and delivering cost efficiencies with a unique and comprehensive range of off-the-shelf assays to support biosimilar comparability studies.

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

Cell Line Development → Process Optimization → Clinical Trials Manufacture → Process Characterization → Process Validation → Comparability Studies → Commercial Manufacture

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)
- Yervoy (ipilimumab)
- Stelara (ustekinumab)
- Orencia (abatacept)
- Synagis (palivizumab)
- Actemra (tocilizumab)

Fab Binding

- ELISAs (Indirect, Competition, Blocking, Cell Based)
- FACs
- SPR

Fab Functional

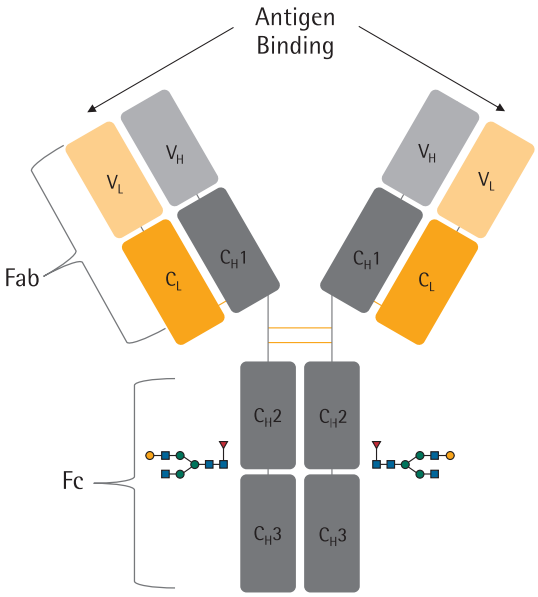
- Various Direct, Blocking, Neutralising MOAs

Fc Binding

- C1q (ELISA)
- FcRn
- Fcγ Receptors

Fc Functional

- ADCC
- Surrogate ADCC
- CDC



Your 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 30 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

Biosafety Testing Services

Safety Testing of Biologics and Vaccines

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

From early stage development to commercialisation of the product.

Cell Line Development → Cell Line Characterization → Process Optimization → Process Characterization → GMP Lot Release

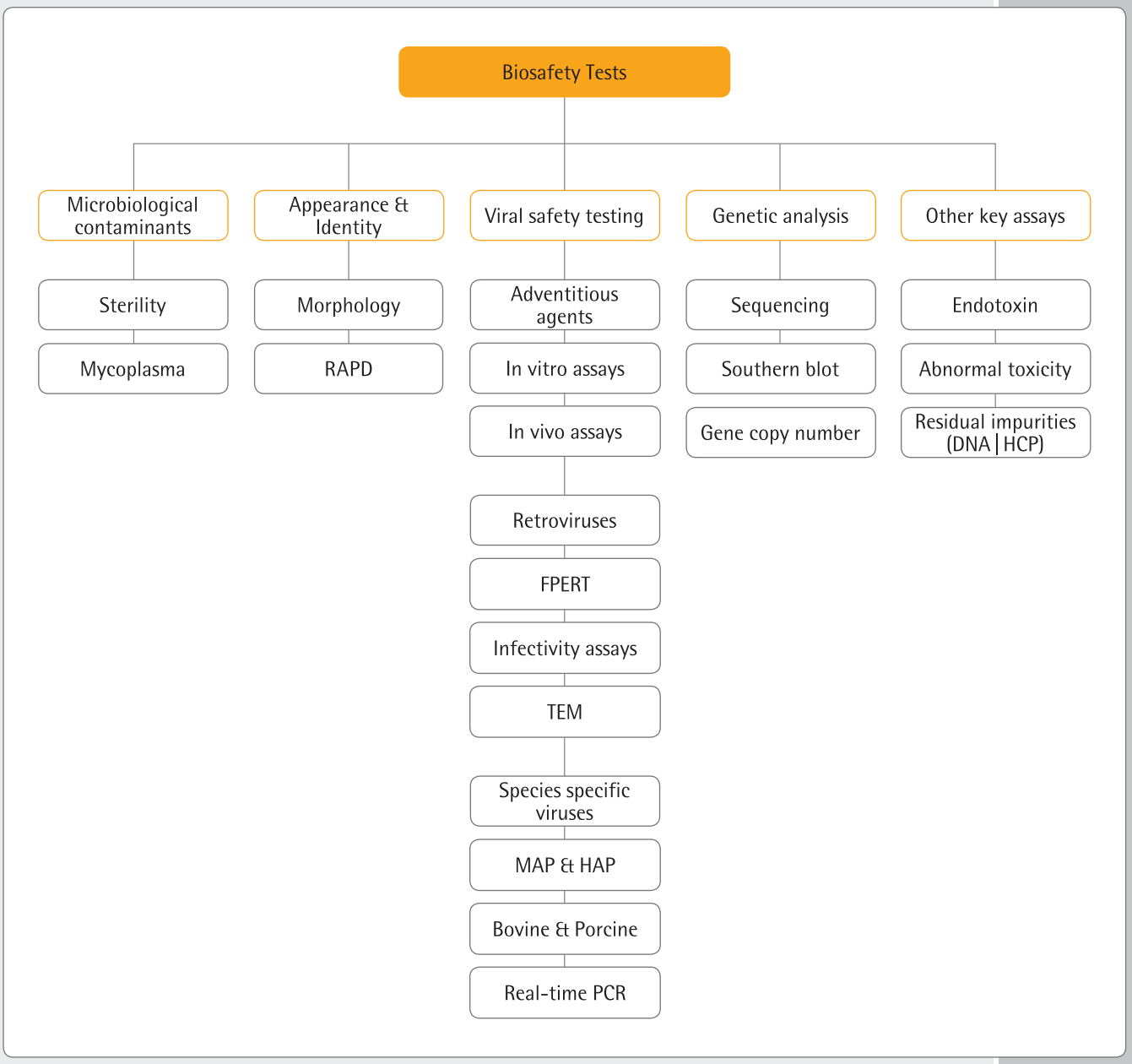
BioOutsource offer a range of validated assays to characterize cell banks from different species including murine, hamster, human and primate.

Cell Bank Testing:
- Master Cell Bank (MCB)
- Working Cell Bank (WCB)
- End of Production Cell Bank (EPC)

Other Biosafety Testing:
- Bulk Harvest
- Genetic Stability
- Final Product Lot Release

BioOutsource has experience working with the following products:

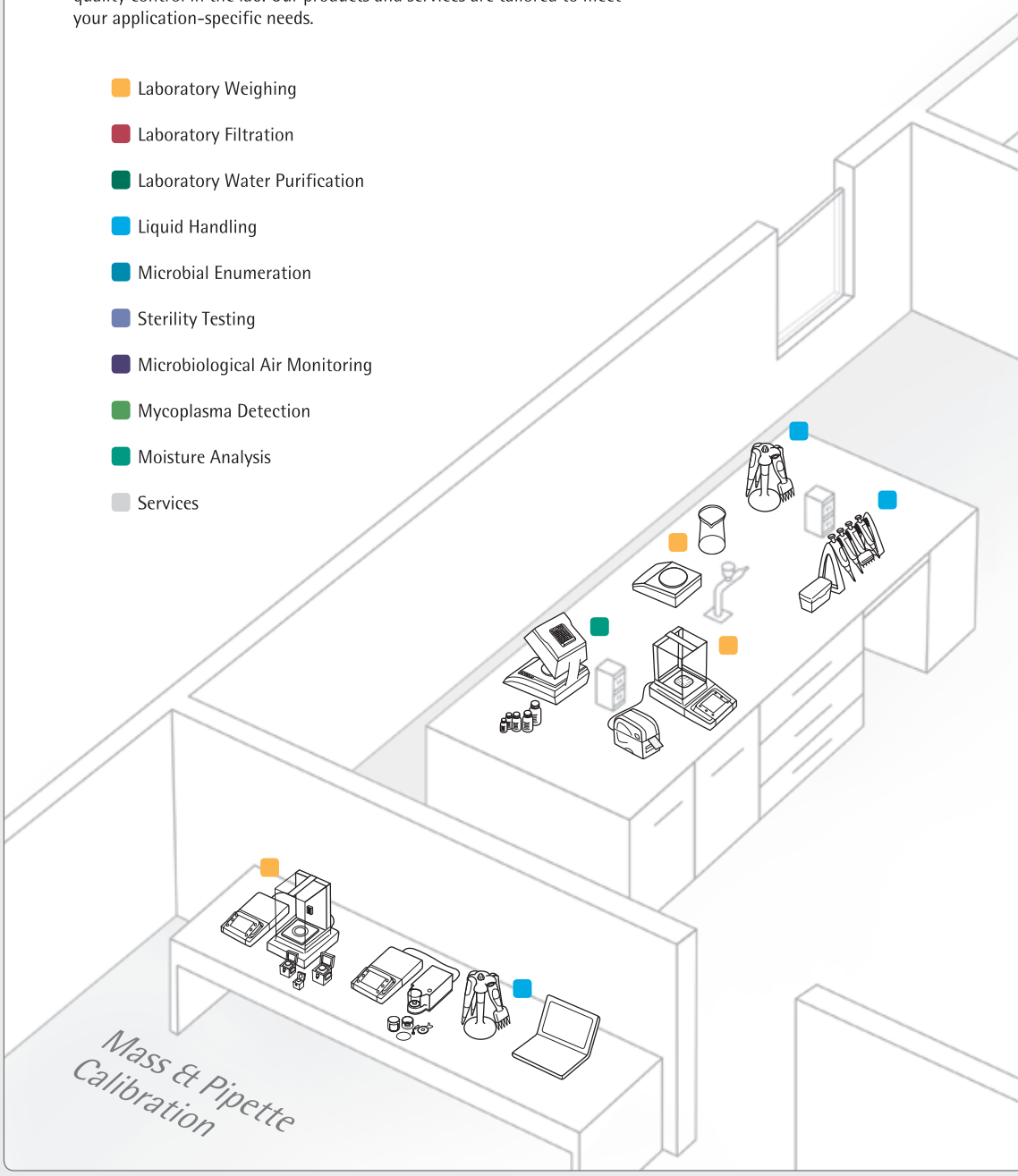
- Biosimilar monoclonal antibodies
- Monoclonal antibodies
- Recombinant proteins
- Vaccines
- Gene therapy vectors
- Regenerative medicine

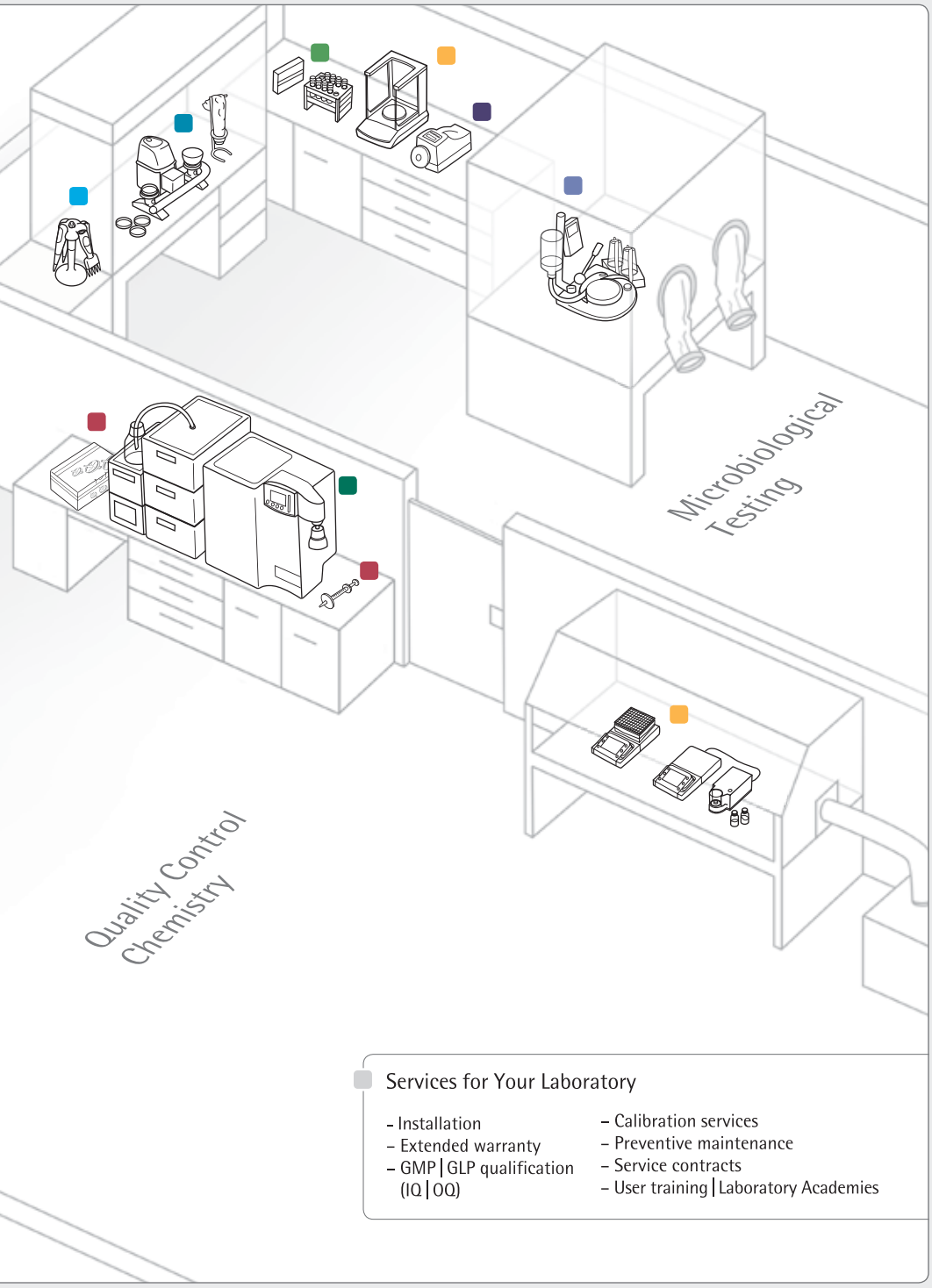

Biosafety Tests
Microbiological contaminants
Appearance & Identity
Viral safety testing
Genetic analysis
Other key assays
Sterility
Morphology
Adventitious agents
Sequencing
Endotoxin
Mycoplasma
RAPD
In vitro assays
Southern blot
Abnormal toxicity
In vivo assays
Gene copy number
Residual impurities (DNA | HCP)
Retroviruses
FPERT
Infectivity assays
TEM
Species specific viruses
MAP & HAP
Bovine & Porcine
Real-time PCR

Sartorius Solutions for Quality Control Laboratories

Whatever your area of expertise, Sartorius offers unique solutions for quality control in the lab. Our products and services are tailored to meet your application-specific needs.

- Laboratory Weighing
- Laboratory Filtration
- Laboratory Water Purification
- Liquid Handling
- Microbial Enumeration
- Sterility Testing
- Microbiological Air Monitoring
- Mycoplasma Detection
- Moisture Analysis
- Services





Services for Your Laboratory

- Installation
- Extended warranty
- GMP | GLP qualification (IQ | OQ)
- Calibration services
- Preventive maintenance
- Service contracts
- User training | Laboratory Academies

VI. Application and Engineering Services

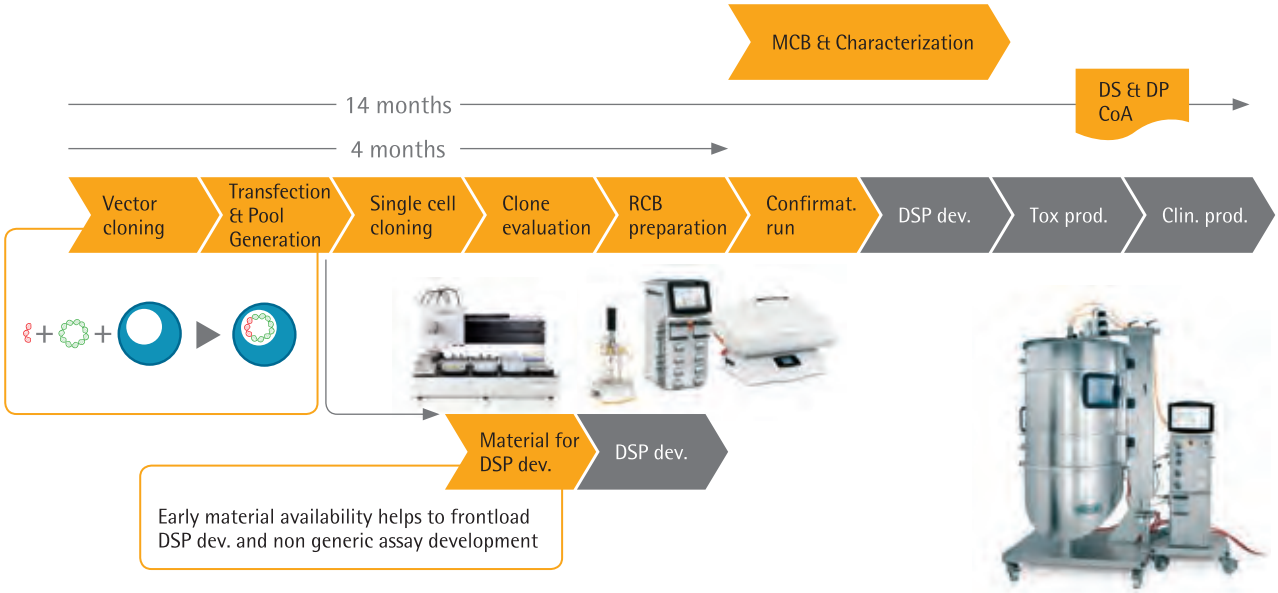
Integrated Process Development Services

Let Us Help You Bring It All Together

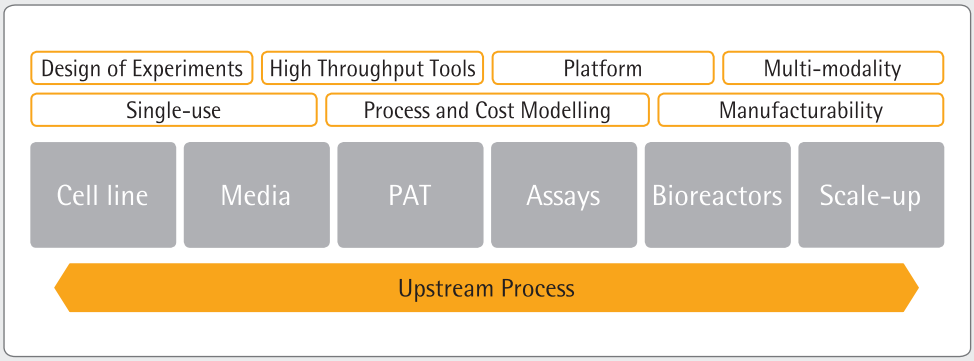
"As scientific innovation in healthcare expands rapidly, biotech companies are aggressively looking to move their products in to the clinic quickly. Sartorius' Process Development Consultants will advise on an optimal PD strategy every step of the way and help build a rapidly scalable process around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

Bioprocess technologies are used to facilitate the rapid development and manufacturing of biopharmaceutical processes and as such need to interface accordingly.

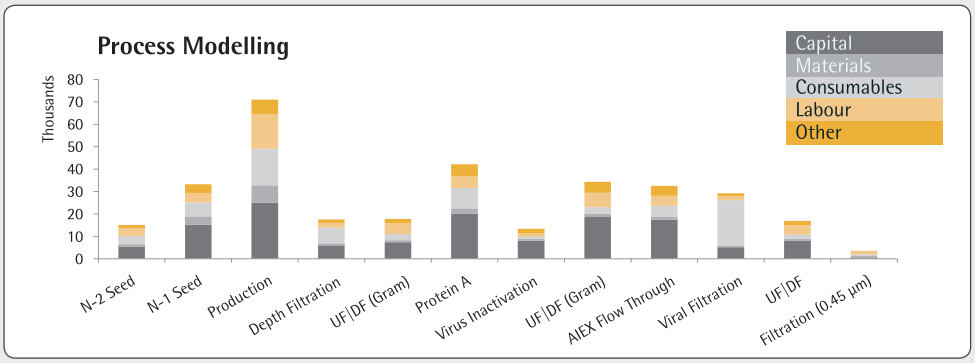
bio outsource
is part of the
Sartorius Stedim Biotech Group



cellca
is now part of the
Sartorius Stedim Biotech Group



Our Process Development Consultants act as a single point of contact and advise the client on the use of technologies from across our portfolio to develop scalable, fully characterized, and robust processes early in the drug development cycle through the application of high throughput tools, cell line development and analytical services, process analytical technologies, advanced scaling concepts and process modeling software – seamlessly integrated from upstream to downstream.



We support you with cost modelling of your potential processing scenarios to understand the expected costs involved and breakdown into cost categories. A detailed cost analysis of each processing step guides your decision on where to invest most resources into process optimization efforts, the introduction of new technolgies or process intensification.

This will help you make smart choices in this fiercely competitive filed where time to market is key and cost pressure is increasing.

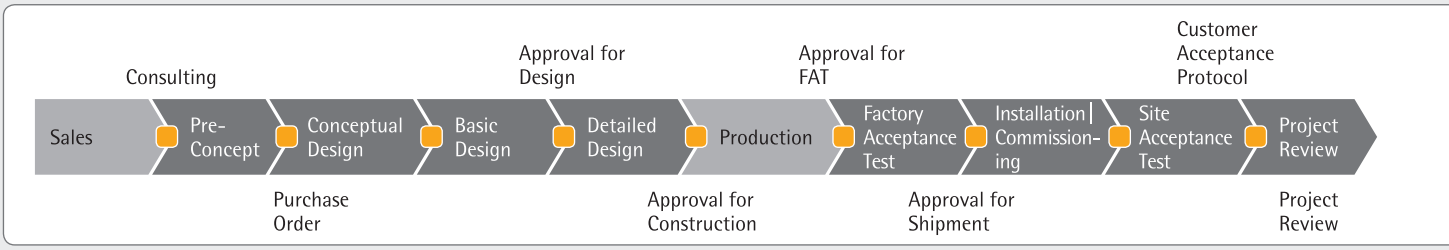
Sartorius Process Development Consultants help to shorten the development and tech transfer timeline for successful cGMP manufacturing of biologics and deliver the most highly optimized processes.

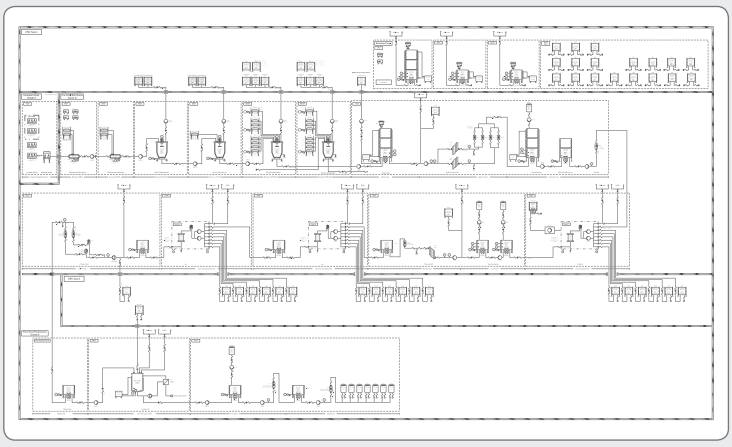
Flexible, Scalable and Cost Efficient Bioprocess Facility Solutions

Rapid and Flexible Biomanufacturing

The Sartorius Integrated Solutions team works with you and designs your entire biomanufacturing process based on single-use or hybrid solutions. We deliver and implement 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 our expertise in single-use technologies. Our global bioprocess engineering teams are available to discuss your development and manufacturing requirements.

Bioprocess consultancy services for optimized process design and best technology selection



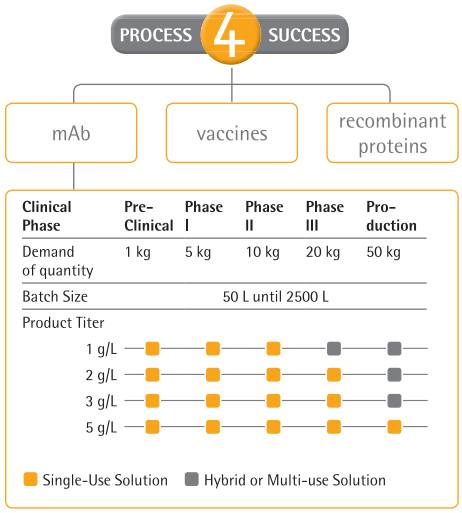


Customer specific BIOSTAT STR® 2000 Twin design

SARTOFLOW® 150 Crossflow System

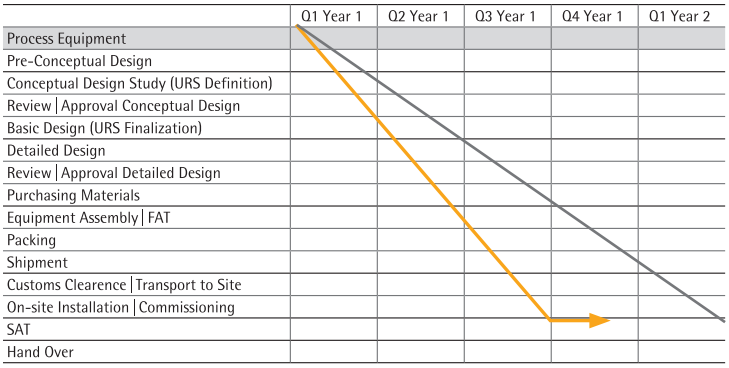
Over 100 Successful Fully Single-use and Hybrid Project Implementations

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 our Website:
www.sartorius.com/en/integrated-solutions

Discover companies like yours 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.

Visit Your Closest Sartorius Application Center!

Experience hands-on how our single-use bioprocess solutions work and improve your operations. Visit our Application Centers in the US, Germany or China. For further information, follow below links. We are looking forward to welcoming you soon.

Your Benefits

- Experience flexible, reliable and smart equipment for your application
- Discuss your specific needs with our experts and identify the best solution based on our broad experience and services for your specific needs
- Hands-on training of your staff of all aspects of operating our single-use process solutions

Bohemia, NY, USA
www.sartorius.com/application-center-usa

Goettingen, Germany
www.sartorius.com/application-center-germany

Shanghai, China
www.sartorius.com/application-center-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
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
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
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
WFI	Water for Injection

Our Solutions for Your 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

- Dynamic body feed filtration
- Crossflow filtration
- Depth filters
- 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, bags for mixing and storage, tubings, connectors, disconnectors

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