SARTURIUS

Insight

Sartorius in Profile





Dear Readers,

Many serious diseases, such as cancer, rheumatism and Alzheimer's, are still incurable or treatable only to a limited extent. Although global medical knowledge has doubled within just a few years, the development of new drugs has become increasingly time-consuming and costly.

Successes in the fight against certain cancers and autoimmune diseases have been achieved with biopharmaceutical drugs, which have evolved from a medical novelty into a dependable therapeutic within a few decades. In the field of gene and cell therapy, recent breakthroughs promise further progress.

The prerequisite for these successes is that scientists and engineers are given the right tools and technologies to speed up the development of drugs and simplify production. This is where Sartorius comes in. Our brand promise puts this in a nutshell: Simplifying Progress. We help to translate new scientific discoveries into better patient care faster and give more people access to better medicine. You can find out how we do this, what motivates us and what our goals are on the following pages.

Dr. Joachim Kreuzburg Chairman of the Board





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Find our latest key figures and further information.

Mission

At Sartorius, we empower scientists and engineers to simplify and accelerate progress in life sciences and bioprocessing, enabling the development of new and better therapies and more affordable medicine.





Vision

We are a magnet and dynamic platform for pioneers and leading experts in our field. We bring creative minds together for a common goal: technological breakthroughs that lead to better health for more people.

Biopharmaceuticals in Focus

With its two divisions, Bioprocess Solutions and Lab Products & Services, Sartorius focuses on the biopharmaceutical industry. Offering solutions covering the entire biopharmaceutical value chain, the company supports its customers in increasing efficiency in drug development and simplifying production.

> Cell cultivation, media and cell culture components









Molecule Development



Cell Line and Process

Quality Control and Testing

Lab Products & Services Division

Lab instruments and consumables











Bioanalytical instruments







Bioprocess Solutions

Sartorius offers customers in biopharmaceutical production a broad product portfolio that covers all the steps in the manufacturing of a biopharmaceutical. In this way, the company helps ensure that biotech drugs and vaccines can be produced safely and efficiently. Sartorius is one of the leading manufacturers in filtration, fermentation, membrane chromatography and fluid management.



Bioprocess Solutions Division

Development

Upstream and Downstream Production

Lab Products & Services

Sartorius aims to simplify the complex and expensive development process for biopharmaceuticals and to speed up scientific advancement. To this end, the company provides innovative solutions for bioanalytics and premium lab products, consumables and services to laboratories in the pharmaceutical and biopharmaceutical industries, as well as academic research facilities. Sartorius is a market leader for laboratory balances, pipettes, and lab consumables.

Innovative Solutions for Better Medications

With its expert knowledge, ingenuity and understanding of customer needs, Sartorius has developed into a key partner of life science research and the biopharmaceutical industry in its more than 150-year history. Today, our employees worldwide are committed to ensuring that new medications can be developed faster and produced more efficiently, using Sartorius' innovative tools and technologies.



The Ambr^{*} 15 Microbioreactor Vessel determines optimal production conditions and is therefore an important tool for process development.





What are Biopharmaceuticals?

Traditional chemically manufactured drugs are based on small molecules of only a few atoms. The situation is different with biopharmaceutical active ingredients. They are produced using living organisms — such as bacteria, yeasts or mammalian cells — and consist of very large molecules with up to 20,000 atoms. Therefore, they cannot be administered as tablets, but by injection or infusion.

The advantages: biopharmaceuticals only bind to very specific cell receptors and thereby intervene in the body's own processes in a more targeted manner than other drugs. They open up new therapeutic options for patients with severe or rare diseases and are particularly promising candidates in the fight against cancer.

Whether cancer, dementia. diabetes, or rheumatism: many serious diseases are still incurable or can be treated only to a limited extent. To combat these diseases, biopharmaceuticals that are produced with the help of living organisms in complex research and production processes are playing an increasingly important role. Since the 1980s when the first biopharmaceutical human insulin was launched onto the market, the industry has been evolving at an exceptionally fast pace.

In 2020, six of the ten best-selling drugs worldwide were biologics; in the same year, biotechnologically produced active ingredients accounted for approximately one third of new drug approvals in the USA. Sartorius has contributed to this progress. With innovative tools and technologies that ensure more efficient processes

at every stage from research to production, Sartorius is helping to ensure that more people have access to affordable medicine.

Technologies for Every Phase of the Value Chain

Sartorius identified the potential of the biopharma sector at an early stage and subsequently aligned its product and service portfolio to this industry's requirements. Founded as a precision mechanical workshop for analytical balances in 1870, today's Sartorius Group is positioned as a strategic partner for life science research and the biopharmaceutical industry. The Sartorius Group supports its customers every step of the way from the initial idea to the market readiness of a new medication – a long, labor-intensive and expensive journey. On average, only one in 10,000 drug candidates actually makes it to the pharmacy counter.

Biopharmaceutical agent



Share of biopharmaceuticals in the top ten best-selling drugs

1 out of 10 | 2000



6 out of 10 | 2020





Sterile bags for cell culture processes and the storage and transfer of fluids are a safe, less expensive alternative to glass or stainless steel. Sartorius is one of the world's leading technology providers in this field.



Getting to this stage often takes more than a decade, with total costs of over two billion euros being the rule. Biopharmaceuticals are much more expensive to produce than drugs that are manufactured using chemical processes. This, in turn, puts mounting pressure on healthcare systems — and, thus, also on the pharma sector, which faces the challenge of designing its workflows and manufacturing operations as efficiently as possible. With its solutions available throughout the entire biopharmaceutical industry's value chain, Sartorius empowers its customers to accelerate drug discovery and development and simplify production. Premium laboratory instruments simplify meticulous and routine laboratory work and deliver reproducible results; innovative bioanalytical systems accelerate

the identification of suitable drug candidates; highly automated microbioreactors help to determine the optimal growth conditions for cell cultures in parallel experimental series; and a broad portfolio of scalable single-use products, such as bioreactors, filters and bags, is available for the actual manufacture and purification of pharmaceuticals. Compared with stainless steel systems, these single-use solutions have many advantages, particularly for production batches of up to 2,000 L. With a much lower capital outlay, they are faster to install, can be readily adapted to accommodate new production processes and are even more environmentally friendly than stainless steel systems, as single-use products eliminate the need

for labor-intensive and expensive cleaning procedures after every production run. At the same time, single-use systems minimize the risk of contamination by bacteria, fungi and viruses, which can sometimes survive even the most thorough cleaning protocols.

Focus on Customer Benefits

The growth of the Group shows that Sartorius meets the qualitatively and quantitatively increasing needs of a demanding customer group. In recent years, Sartorius has increased its sales revenue by a significant double-digit percentage per year on average. In many product categories, the Group is among the global market leaders. The company plans to continue to grow strongly.

In addition to organic growth, especially in the Asian and American markets, acquisitions are expected to support the positive development. The primary objective of these acquisitions is to further increase customer benefits by expanding the product portfolio in a meaningful way. In this way, Sartorius is continuously strengthening its business with complementary acquisitions of technologies that can help the biopharmaceutical industry and research to achieve greater efficiency gains. With this strategy, over the last years, the company has acquired solutions for digitalization and automation, innovative processes in bioanalytics, and trailblazing technologies for novel treatments, including the takeover of selected life science businesses of the U.S. Danaher group, and the purification specialist BIA Separations that focuses on gene and cell therapies.

Application Knowledge as a Success Factor

To achieve success in a dynamically growing and highly complex environment, Sartorius needs one thing above all: employees who stay at the forefront of the rapid developments in the biopharmaceutical industry and who are able to implement the requirements and wishes of the customers in the best possible way. To better understand the challenges of the industry and to continuously expand its application know-how, Sartorius places great emphasis on close exchange with customers and relevant scientific institutions. Intensive cooperation agreements with the German Research Institute for Artificial Intelligence (DFKI), as well as Penn State University and the National Institute for

Innovation in Manufacturing Biopharmaceuticals (NIIMBL) in the U.S. have a very clear objective: to promote scientific advances in drug development and, in the long term, to reduce the costs of biopharmaceutical production so that more people can have access to better treatments.









Sartorius continuously expands its product portfolio through acquisitions of cost- and time-saving innovations in the biopharmaceutical and life science fields.





Sartorius generates a large portion of its revenue from membrane-based products. The filtration portfolio is among the most comprehensive in the industry.



Sartorius has its roots in weighing technology. The Cubis* II optimizes weighing results from experiments and test series in laboratories.



People at Sartorius

Sartorius unites ambitious people: They are life science enthusiasts, doers, risk takers, creative minds, and, above all, partners for our customers. They all share one ambition: translating scientific discoveries into medicine faster and more efficiently. As a listed company with global activities, Sartorius has retained the mindset that made it a pioneer in its industry as a startup more than 150 years ago: customer focus, can-do attitude, hands-on approach, and each individual's ambition to contribute.

Be Part of the Solution

Our customers are facing major challenges. Numerous diseases are still incurable; many are untreatable. New medications need to be developed and be made available worldwide. With its innovative technologies, Sartorius is part of the solution. For our employees, this purpose is both an opportunity and a commitment. To provide our customers with the right tools and achieve pioneering technological breakthroughs, we need technical expertise and customer knowledge as well as a strong sense of ambition and, quite often, a high level of persistence.

Grow With Us

Sartorius is one of the fastest-growing global players in its industry. We create and take opportunities, constantly integrating new technologies through acquisitions and partnerships. As a leading partner of life science research and the biopharmaceutical industry, we focus on dynamic sectors and highly innovative markets that will continue to grow for decades.

This opens up a world of options for those who have the drive to pursue them. We entrust our people with responsibility and, in return, expect them to have the courage to take risks and make bold decisions to move forward. Depending on personal goals and changing priorities in life, they can grow their careers in diverse ways — from technical to geographical aspects.

Add the Missing View

Sartorius offers the perfect size and culture for ambitious doers and diverse minds: every voice is heard. Each new perspective has the potential to be the missing piece for the next gamechanging discovery. Yet we believe that major challenges are best mastered together: when experienced specialists — many of them among the best in their fields — fuse their expertise and perspectives. That is why we foster exchange across fields, borders, cultures, and social backgrounds.







Thomas Kivela
Expert for single-use technologies;
develops biopharmaceutical
processes for customers

Making a Fresh Start

"I wanted a new start when Lioined Sartorius shortly before the pandemic. After 18 years in the biopharmaceutical industry, I had learned a lot about cost- and time-saving consumables. However, I wanted to have more freedom in the decision-making processes and to think more out of the box. From people in my field, I knew that Sartorius could offer me this. During the first weeks, I visited sites and customers, but then transitioned to working from home in March 2020. Thanks to the open culture at Sartorius, everyone is well connected. From day one, my colleagues involved me in ongoing projects. This allowed me to make a contribution from the very beginning. I have implemented various projects within the first year. Things couldn't be better."



Noushin Delmdahl
Protein biochemist; specializes
in filtration technologies for
laboratories

United by Shared Goals

"Before I joined Sartorius in

2001, I had mostly worked

on scientific projects and

spent a lot of time in the lab.

After switching to the company, I took on new teambased and customer-facing tasks. Today, I collaborate closely with colleagues all over the world and appreciate the dynamics that are generated in a team when you work towards achieving shared goals. I have experienced over and over again that borders and time zones play a minimal role when you want to talk to a colleague or ask someone for advice, for example, in India. In addition, because I've been able to further develop my skills and knowledge at Sartorius, the years have flown by. Yet, with our expansion into the field of bioanalytics, the scientist in me knows that the most exciting times are still to come."



Sandra Mei Specialist for Human Resources Management in Asia

Growing With Your Tasks

"'I can handle it', is what I thought when I was assigned responsibility for five additional Asian countries. Before that, I had spent three years exclusively dedicating my efforts to taking care of staffing for the strongly growing Chinese market. My new set of tasks turned out to be more complex than I had originally expected: the cultural differences between the countries are considerable, so handling job candidates requires a lot of tact, good instincts and skill. Since then, I have been learning something new every day. What I especially enjoy about my job is the freedom to define my work schedule and activities. As a result. I can fulfill my personal needs and continuously broaden my horizons. I can't think of a better way to be motivated than working like this."



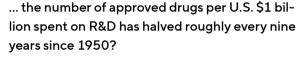
Did You Know That...?

... company founder Florenz Sartorius already successfully brooded over inventions of which the basic ideas are still used today in biopharmaceutical production?

Sartorius developed heating devices that were used for bacteriological purposes and as incubators in poultry breeding. Thermostats regulated the ambient temperature so precisely that the cultivation and incubation process could be accurately controlled. The technology — a precursor of today's bioreactors — sold successfully throughout Europe.



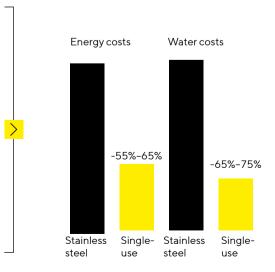
Number of medications 100 10 Eroom's Law 0.1



As paradoxical as it may seem and despite many technological and medical advances, the development of new drugs is becoming increasingly inefficient. This is why we speak of "Eroom's Law," a reversal of the concept coined by Intel co-founder Gordon E. Moore in 1965, according to which the performance of processors doubles every two years. Sartorius is helping to reverse this trend and shorten the time to results.

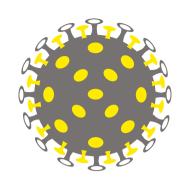
... single-use technology is more environmentally friendly than reusable products?

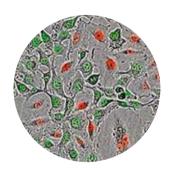
Single-use products, such as bags, filters and centrifuges, eliminate the need for costly cleaning procedures. Therefore, during their use, they have less of an ecological impact than reusable product solutions — energy and water consumption are more than 50 percent lower. After use, the energy-rich single-use materials are incinerated to generate energy. In this way, Sartorius supports its customers in making production processes greener and more efficient.



... biotechnology can reduce our dependence on drug sources?

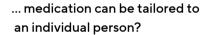
The vast majority of flu vaccines are produced with the help of serum eggs. About half a billion of these are needed each flu season. The production method has long lead times and is subject to risk, such as not enough eggs being available in the event of a pandemic. The World Health Organization (WHO) therefore advocates for a diversification of processes through, for example, cell-based production.





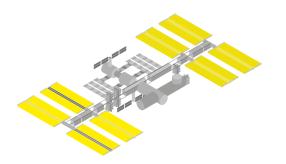


With the Incucyte® S3, researchers can observe living cells in real time directly in the incubator to analyze how active pharmaceutical ingredients attack and destroy cancer cells. Until now, it was only possible to photograph cell cultures at certain times and document the changes afterwards. The Incucyte® S3 reduces the effort compared with the manual method and provides better results without disturbing sensitive cultures.



In CAR-T cell therapy for the treatment of certain forms of leukemia, the body's own immune cells are removed, genetically modified, multiplied and returned to the patient. This process is complex and expensive — and results in a drug that can only be administered to one person. Sartorius' solutions speed up development and ensure reliable production.





... even serious scientific research sometimes transcends earthly things?

NASA used the Sartorius Air-Port MD8 air sampler on the International Space Station (ISS) to learn more about airborne microbial contamination and its possible effects on the crew. The device filters up to 125 L of air per minute and collects viruses, fungi and bacteria for subsequent cultivation and microbiological analysis.

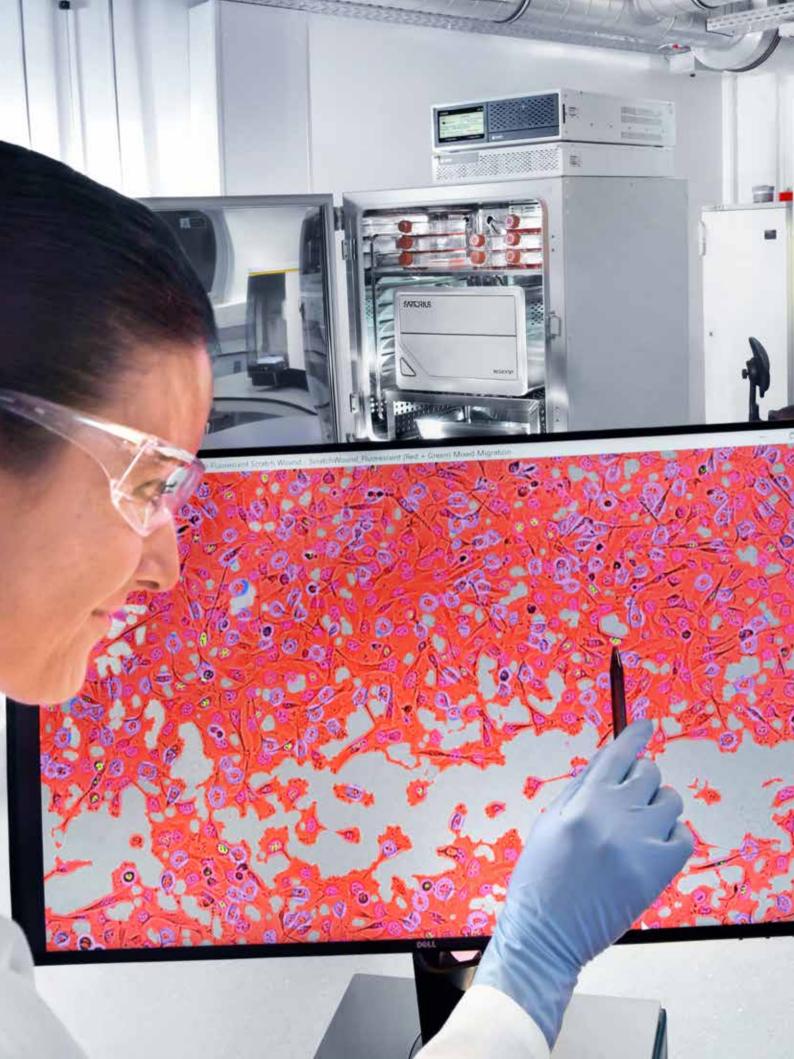
Faster to Market

Biopharmaceutical research and development can be likened to looking for a needle in a haystack. With groundbreaking analytical technologies and premium laboratory instruments, Sartorius is providing researchers with the tools that help to identify new active drug compounds faster.

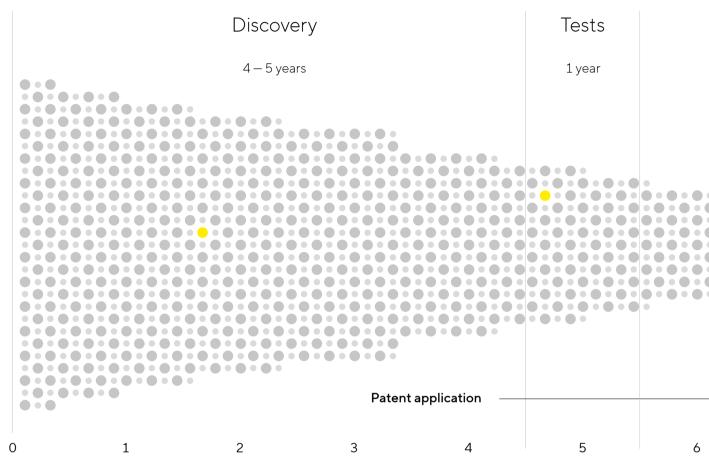


The Incucyte® enables complete visual monitoring and analysis of cell reactions and interactions directly in the incubator without disturbing sensitive cell cultures.





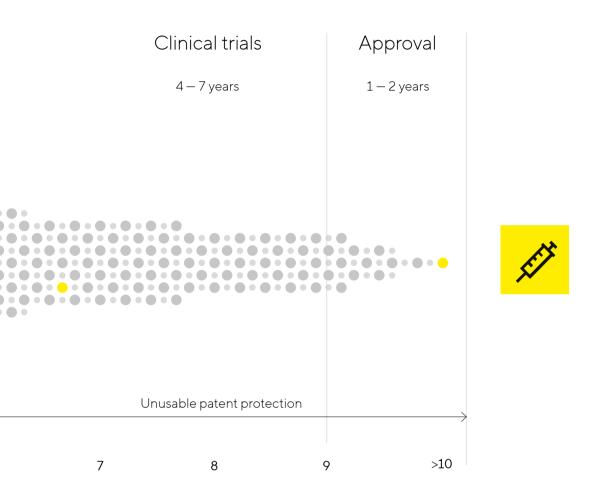
Only One in 10,000 Drug Candidates Reaches the Market



^{*} Schematic visualization based on data from the Association of the British Pharmaceutical Industry

The rate of finding a successful candidate gives even the uninitiated among us an idea of how complex and laborious biopharmaceutical research and development is: only one in 10,000 potential drug candidates makes it to the market as a new treatment. Getting there is a long haul, involving thousands of experiments, sample preparation procedures and analyses. Therefore, one of the biggest challenges in

biopharmaceutical research and development is to significantly shorten the drug discovery timeline. This is all the more true because active ingredients have to be patented early in the R&D process. With a patent protection period of 20 years from the filing date, only about twelve years of market exclusivity remain on average after final approval of the drug. Sartorius technologies help to achieve results faster.





An expensive and time-consuming path

Pharmaceutical companies invest more than two billion euros to bring a new drug to market. In many cases, development takes more than ten years.

Technologies from Sartorius speed up the research process and reduce costs.



Octet[®] systems allow scientists to analyze molecular interaction in real time without the need for markers.



The Turbo in Biopharma Research

In the search for new therapies, researchers must first find a gateway to combat the disease, such as a specific type of cancer. Unlike chemotherapy or radiotherapy, biopharmaceuticals often use a patient's own immune system. For instance, monoclonal antibodies (mAbs) are of great importance in this therapeutic approach. These proteins, produced by living organisms and developed in the lab, are designed so that they specifically bind to sites on cancer cells, marking them for destruction by the immune system. What sounds simple in theory is, in fact, a long and painstaking process in the laboratory.

Sartorius offers innovative bioanalytical systems to simplify and accelerate the selection of drug candidates. For example, Incucyte® and iQue® Screener deliver answers to essential questions, such as: Is the cell alive? Is it dividing? Is it producing the desired antibody? How does my active pharmaceutical ingredient interact with diseased or healthy cells? While Incucyte® enables the continuous visual monitoring and analysis of cell reactions and interactions directly inside an incubator with its live-cell imaging, the advantages of the fully automated iQue® Screener platform lie in the combination of data depth and high speed.





Microsart* Kits enable the detection of mycoplasmas in just a few hours and are used in every process phase of biopharmaceutical research and production.



The comprehensive functions of Sartorius laboratory balances simplify complex applications and guarantee compliance with the required standards.



A simultaneous feed of up to 1,536 samples, analysis, data evaluation and even cleaning of the instrument are performed without further assistance from the laboratory staff. The smallest sample volumes of only one microliter are sufficient to obtain meaningful and multi-layered data on a wide range of cell parameters. As a result, iQue® Screener not only accelerates analysis tenfold, but also protects valuable cell cultures and reduces the use of expensive reagents.

A key challenge in drug development is the ability to identify molecules that bind to biomolecular structures on the surface of cells or pathogens. To avoid undesired effects, researchers must seamlessly analyze and understand these bonding events. Do molecules bond at all? How strong is their binding interaction and how long does it last? With the Octet® platform acquired from Danaher in 2020, Sartorius has added a key technology for accelerated analysis of molecular interactions to its portfolio. It is based on the patented biolayer interferometry technology and enables label-free, real-time analysis of biomolecular interactions.

Better Results, Less Effort

Manual and therefore time-consuming and error-prone processes still characterize everyday laboratory work today. Here too, Sartorius products ensure that better results can be obtained reproducibly, faster and safer. Premium laboratory instruments, such as high-precision balances with intelligent assistance systems, ergonomic pipettes to minimize muscle and joint strain, and ultrapure water systems reduce manual effort and set the foundation for reliable sample preparation and analyses. For microbiological quality control, Sartorius offers a wide array of products, such as filtration systems, sterility testing units and solutions for airborne microbe sampling, virus quantification and for the detection of mycoplasmas. They are used not only for pharmaceutical research, but also in the quality control laboratories of the food and beverage industry, to test clinical products and for monitoring both water and wastewater. Yet, regardless of where our products are used, they consistently help to prevent errors, simplify workflows and reduce physical workloads.







The fluorescence-based iQue® Screener platform rapidly examines many thousands of samples in a short time and provides multivariate analysis of cells and proteins in suspension.



Efficiency in Drug Production

In biopharmaceutical production, a combination of the most diverse factors is decisive for the quality and cost-effectiveness of the final drug. It's no coincidence that experts claim that "the process is the product." With scalable single-use technologies for bioreactors, filters and bags, as well as tools for process development and monitoring, Sartorius helps its customers to obtain the best possible results from their manufacturing processes, in terms of both quality and quantity.



Single-use technologies offer a safe and flexible alternative to conventional containers made of stainless steel or glass.





With the automated microbioreactor system Ambr[®] 15, researchers can conduct up to 48 independent cell culture experiments in a very small space.



The cell line used, the composition of the cell culture medium, oxygen and pH, temperature, stirring speed: the list of factors governing the success or failure of a biopharmaceutical production process is long. Why? Cells are demanding and require optimal conditions to grow and produce the desired drug in the largest possible quantity. Sartorius, with its broad-based portfolio of products, covers nearly every stage of biopharmaceutical manufacturing — from cell line development, cultivation and multiplication of cells, to cell harvesting and purification, to filling of the final product.

High-Tech Solutions That Fit in a Shot Glass

To ensure successful commercial-scale manufacturing, a production process is initially tested at a much smaller scale. Similar to the research phase, digitalization and automation solutions from Sartorius also help to achieve higher-quality results in less time during process development. The Ambr* is an automated bioreactor platform with vessel sizes of 15 mL or 250 mL, which can be used to perform up to 48 experiments simultaneously in a very small space. For each of these miniature bioreactors, the individual parameters, such as nutrient composition or pH, are set individually.





The fully preassembled UniVessel® single-use bioreactor for volumes of up to 2 L reduces the time and effort required to develop, optimize and validate cell culture processes.



Sartobind® membrane chromatography systems were developed to purify biomolecules. They are used to remove impurities, such as DNA, endotoxins, host cell proteins and viruses, quickly and reliably.





Multivariate software for modeling and monitoring cell culture processes helps to improve product quality and increase drug yield.



The system regularly takes samples to monitor and document cell development, autonomously maintaining stable cell cultivation conditions.

Once the ideal interaction between parameters has been established, it is important to be able to reproduce the same conditions independently of the size of a bioreactor. Sartorius technologies enable processes to be scaled from 250 mL to 2,000 L. But this isn't their only advantage. For many of the industry's challenges, such as time and cost pressures, hygienic and regulatory requirements, and the trend toward smaller production batches, they are a flexible, safe and cost-effective alternative. Compared with stainless steel systems, the initial investment in single-use equipment is much lower, the time needed for planning and commissioning is less, single-use systems are easier to change over to

manufacture other products, and the risk of contamination by bacteria, fungi or viruses is considerably reduced. This is achieved because after each production run, any part that comes into contact with the liquid cell broth is replaced by completely new, sterile-packaged components. The procedures required to clean stainless steel systems using chemicals and steam sterilization are eliminated entirely. This is not only more environmentally friendly, but also reduces the time needed to prepare the system for the next production process to just a few hours. Therefore, it's no surprise that single-use technologies are being increasingly used in biopharmaceutical research and production, especially for relatively small drug batches. Sartorius, with its broad and innovative array of products, is actively contributing to this trend and is the leading global provider of single-use bioreactors and bags.





Sartoclear® depth filters were developed for demanding clarification applications in the biotechnological and pharmaceutical industries. The modular devices provide linear scalability from small to large scale processes.





The preassembled Maxicaps*
MR single-use filter configuration for the filtration of large volumes requires 90% fewer hoses and connections than comparable stainless steel systems.

Precise Control of Sensitive Processes

What succeeds during cell culture cultivation and subsequent volume expansion should not malfunction during the actual production in the 2,000 L bioreactor. As cell cultures are highly sensitive and react to the slightest changes, strict monitoring of the production process is vital. In this phase, Sartorius uses process measurement technology and software for multivariate data analysis to ensure that relevant parameter measurements can be collected. documented and evaluated in real time. The system reveals correlation patterns between the individual parameters so that the right conclusions can be drawn and countermeasures taken in good time in the event of process deviations. This ensures that each batch meets the highest quality requirements and reduces the risk of losing a complete production batch.

Purification Expertise From the Source

Once the cells have produced the desired amount of antibodies, the complex downstream process begins, in which the active ingredient is gradually separated from impurities and unwanted components of the cell broth. Membranes and chromatography systems play an important role in this process. Sartorius' extensive filtration portfolio is based on about a century of experience: back in 1927 Sartorius, together with Richard Zsigmondy, the Nobel Prize winner for chemistry, developed a method for the industrial production of the synthetic membrane filters that Zsigmondy had invented. More recently, the company has expanded its purification expertise considerably with the acquisitions of the chromatography portfolios of U.S.-based Danaher and French company Novasep — the aim is to offer customers individual and flexible solutions for expensive downstream processing.





Celsius* Pak enables consistent, reproducible freezing and thawing of biopharmaceutical liquids and is suitable for long-term frozen storage.

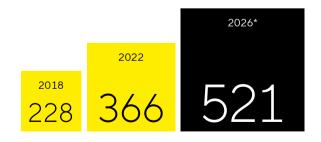


Every production process is different. Sartorius, in collaboration with its customers, develops and implements individual solutions from the development phase through to industrial production.

Sartorius is now one of the leaders in the global market for filtration solutions and has one of the most extensive purification portfolios in the industry.

However, Sartorius is not, and never will be, content to rest on the laurels of its past successes. With a great understanding of its customers' needs, the company works continuously on improving its solutions and expanding them across the entire biopharmaceutical value chain. For instance, since the acquisition of BIA Separations in 2020, Sartorius also has technologies for complex purification of gene and cell therapies. The corporate objective is clearly defined: Sartorius aims to use its innovations to accelerate research, simplify production and contribute toward giving more people access to better medicines

Worldwide Expenditure on Biopharmaceuticals in billions of U.S. \$



^{*} Forecast; Source: Evaluate Pharma, World Preview 2021 Outlook to 2026, July 2021







Everything From a Single Source

Today, monoclonal antibodies represent one of the most successful strategies in the fight against various cancers. They are developed and produced using living, genetically modified mammalian cells in sophisticated processes. Sartorius' innovative solutions are used in nearly all steps of



Incucyte® real-time analysis system for living cells



Minisart® syringe filters



iQue® Screener Plus high-throughput screening



Cubis[®] high-performance laboratory balance



Octet® systems for marker-free analysis of molecular interactions



Picus[®] NxT multichannel electronic pipette

Molecule Development

Identification of Target Molecules

Drug development begins with the search for a therapeutic target. The focus is on the question of which signaling pathways the disease is based on and what role the target plays in this. The Incucyte® cell analysis platform allows end-to-end monitoring of living cells directly in the incubator and provides detailed insights into the biological mechanisms in real time.

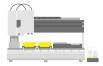
Library Screening

Screening identifies the most promising antibodies. To do this, antibody libraries, containing millions of different candidates, are used. On average, around 1,000 of them are shortlisted. The iQue® Screener highthroughput flow cytometer helps to analyze cells and their products. It combines speed with great data depth and can quickly identify and characterize drug candidates. With a combination of data depth and high speed, it is capable of quickly identifying and screening drug candidates.

Optimization and Characterization of Candidates

The antibody candidates are analyzed in more depth and optimized. The Octet® systems are based on biolayer interferometry and provide important information about the bonding capabilities of the molecules. One advantage of this label-free method is that no dyes are required. As a result, the sample being investigated remains unaltered. The next step involves analyses to provide a complete description of the antibody. This includes its efficacy and toxicological properties. The aim is also to discover whether changes to the molecule could have an adverse effect on patient safety.

biopharmaceutical research and manufacturing — from molecule and cell line development to cell growth, to purification and filling of the final product.



Ambr[®] 15 fully automated microbioreactor system



Arium° ultrapure lab water system



Mycap[®] aseptic fluid transfer system for bottles



Sartoclear® Dynamics Lab for clarification and sterile filtration of cell cultures



Fill-It automated highthroughput filling system



Microsart[®] mycoplasma kit for rapid mycoplasma detection

Cell Line and Process Development

>

Gene Cloning and Transfection

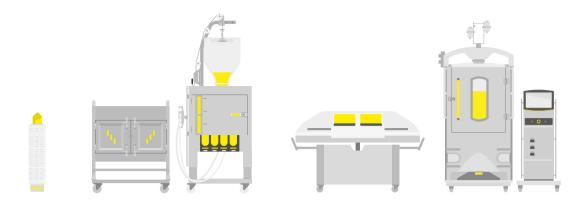
A stable cell line that reliably produces the antibody in large quantities is required for the production of the active compound. A DNA sequence that is cloned millions of times with the help of bacteria and serves as a construction manual for the protein is inserted into the DNA of the host cells. However, this process, known as transfection, succeeds in only some of the cells. The respective cell populations are selected and cultivated using a special procedure.

Cell Line Selection and Identification

The cells from the most promising cultures are isolated for further propagation. This creates the monoclonal populations required for industrial production. Performance is assessed using parameters such as cell growth, productivity, viability, and the quality of the mAbs produced. The search for the optimum clones is accelerated by the fully automated Ambr* 15 microbioreactor system system, which performs up to 48 experiments simultaneously.

Cell Line Characterization and Cell Banking

Prerequisites for the further use of cell lines are their complete characterization and the creation of a master cell bank. For this purpose, clones of a single cell culture are deep frozen for later use. This allows each production process to be started with "fresh" cells. Sartorius supports the complete process from cloning the DNA sequence to creating the cell bank.



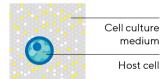
Media | Storage and mixing bags | Virus filter cartridges

Bioreactors | Sensors for process analysis

Upstream

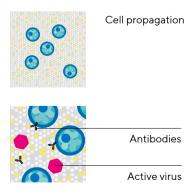
Cell Culture Media Production & Cultivation

For optimal division of the cells, they need perfect conditions. The culture medium — adapted to the respective cell culture — plays a critical role. It contains nutrients, such as proteins and sugars, and provides the cells with everything they need to thrive.



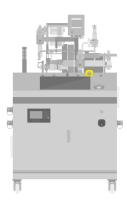
Scale-Up and Production

To produce large quantities of antibodies, the cells are transferred step by step to ever-larger bioreactors. There, they grow only when the conditions are ideal; influencing factors here include oxygen content, pH and temperature. During this phase, the cells begin to release the required antibodies into the cell culture medium. To prevent contamination with bacteria or viruses, production takes place under sterile conditions.









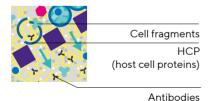
Depth filters | Centrifuges

Sterile filters | Tangential flow filtration systems (ultrafiltration)

Downstream

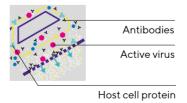
Separation and Centrifugation

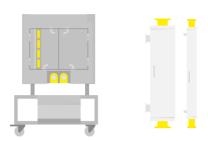
The cells are harvested at the end of a production run. The multivariate analysis software Simca*, which can be used to model and predict production processes, helps to determine the optimal time for this. During cell harvesting, the antibodies in the suspension are freed of cells and cell fragments — for example, by filtration or centrifugation.

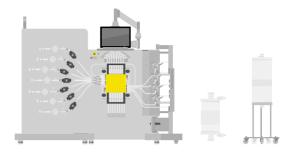


Filtration

After the harvest, the antibodies are purified to isolate them from other components of the solution. A combination of chromatography and Tangential Flow Filtration (TFF) is used to achieve the desired purity. In TFF, the liquid is pumped across a membrane and pulled out across the direction of flow to remove water, salts and small proteins. Sartorius has one of the most extensive TFF portfolios in the industry. The fully automated, closed-loop single-use systems not only ensure more flexibility in production, they also reduce the risk of contamination by viruses and bacteria.





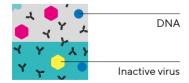


Mixing tanks | Virus filter cartridges

Chromatography (membrane and gels)

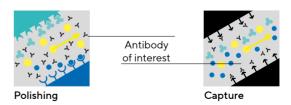
Viral Clearance

Viruses that may be present in the liquid are removed and inactivated by virus removal filters, adsorption or by lowering the pH. Manufacturers must use at least three different methods for a drug to be approved. The different viral clearance processes must be able to remove a specific total amount. Sartorius' portfolio contains products to cover all of these virus removal methods.

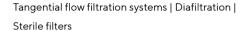


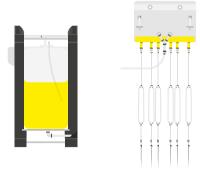
Polishing | Capture

Polishing removes any remaining contamination, such as DNA or host cell proteins. Unlike filtration, which uses membranes to filter according to particle size, polishing is a chromatographic purification process. In this step, properties such as charge, hydrophobicity or the binding affinity of the proteins are used to purify the target molecule. MAbs are primarily purified using protein A affinity chromatography and then rinsed out for the next process step using buffer solutions (capture). Sartorius' product range includes resines, chromatography membranes and monoliths, as well as stainless steel and single-use systems in the hardware sector.









Freeze and thaw systems | Filling systems



Concentration and Sterile Filtration

As with all biopharmaceuticals, antibodies used in cancer therapy are too fragile to pass through gastric acid without being damaged. To obtain an injectable drug, the antibody solution is calibrated to the final concentration, its pH is adjusted, and the necessary excipients are added. Before filling, the product once again undergoes sterile filtration.



Deep-Freeze Storage and Final Filling

Sartorius has developed innovative freeze & thaw systems so that manufacturers do not have to fill the drugs into their final containers immediately after production. With these systems, intermediates and ready-to-use drugs can be frozen, stored and transported quickly and evenly in sterile bags and then be thawed out again later. This allows manufacturers to produce and stockpile large quantities of an active ingredient to respond flexibly to changes in demand.

In the final production step, the drug is sterilely filled into syringes or ampoules.



Strong Company Values

Sustainability, openness and enjoyment are the values that shape our work with colleagues, customers and business partners alike. By incorporating them into our thinking and actions on a daily basis, we create a positive corporate culture, which is an important source of long-term economic success, lasting motivation and above-average performance.







Sustainability

Growing profitably and acting responsibly towards all stakeholders

For Sartorius, sustainability means working towards positive and all-around successful relationships with various stakeholders in all business activities. Customer orientation, excellence and innovation form the basis for this. We rely on lasting relationships based on trust with our customers and business partners, enabling both sides to benefit. We offer our employees a working environment in which they can continuously develop, both professionally and personally. Investors can expect a corporate policy that is geared to continuous and sustainable value enhancement. We are committed to being a responsible member of society and a good neighbor at our sites around the world.



Openness

A source of change and progress

It's well known that "the better is the enemy of the good." We regard openness – both internally and externally – as a basic prerequisite for leveraging our great Group-wide potential, for questioning the tried and true, and for recognizing the better in the new. Combined with our technological know-how, openness is key to developing innovations that really make a difference and create value for our customers.



Enjoyment

A working environment with freedom and appreciation

At Sartorius, hard work and pleasure go hand in hand because our employees not only work with their minds, but also with their hearts. In return, Sartorius offers them plenty of freedom and tasks that allow them to grow and realize their personal potential. The company appeals to people who like working in international teams, who enjoy taking on responsibility and who appreciate breaking new ground and celebrating their success together. This team-oriented and open manner is also how we work together

with our customers.



Intelligently Combined

The pressure to innovate in (bio)pharmaceutical research and production is intense. For Sartorius, this means improving existing solutions in a user-oriented way, quickly recognizing the potential of new technologies, forging partnerships and transforming technologies into ground-breaking innovations through intelligent integration. The Biostat STR* bioreactor family is the result of successfully integrating proprietary core technologies, acquisitions and the products of strategic partners.

Aseptic bags | With the acquisition of Stedim Biosystems, the "inventor" of bags for biopharmaceutical applications, Sartorius paved the way in 2007 for the development of fully scalable single-use bioreactors with properties that matched those of traditional stainless steel stirred vessels. The sterile, three-dimensional bags form the core of the reactor and are disposed of after production, including all tubes.

Bioreactor technology | In 2000, Sartorius acquired B. Braun Biotech, the world's leading provider of fermentation technology, to expand its portfolio to include the central process step in biopharmaceutical production. Although customers with large-volume applications continue to rely on stainless steel equipment from Sartorius, the trend for smaller product batches is driving the use of flexible and cost-effective single-use solutions. The reusable bag holder, which does not come into contact with the cell culture, carries the temperature control system, the drive motor for the stirrer and the filter holder.





Filter technology | Filtration has been one of the core technologies of Sartorius for about a century. In addition to product quality, simple use is also important for reliable filtration processes. With presterilized filters in capsules or preassembled units with hoses and connectors, Sartorius reduces the risk of user error and contamination.

Control and analysis software | The continuous monitoring and control of critical parameters are crucial for bioprocess efficiency and the quality of the end product. In cooperation with Siemens, Sartorius developed the cross-product automation platform Biobrain* that makes it easier for customers to integrate their systems into higher-level automation solutions.

The multivariate data analysis software by Umetrics, a company acquired in 2017, enables customers to model and optimize biopharmaceutical development and production processes. The real-time analysis of production data provides deep insights into an ongoing process and ensures consistently high product quality.

Sensors | The sensors of our collaboration partners continuously provide precise information about critical process parameters — such as pH, oxygen content, temperature, glucose, lactate value, living biomass — without having to interfere with the sensitive cell culture process.



At Home Worldwide

Customer proximity begins with short distances. As a global player, Sartorius is represented in more than 110 countries with its own production facilities, sales offices, and local commercial agencies.

Customers benefit from this geographical presence through short delivery times, fast order processing and personal service. In turn, Sartorius uses its many years of close contact with its customers to gain a precise understanding of their processes and requirements.

Sartorius concentrates its business activities on the three core markets of Europe. North America and Asia, with the most closely knit network being located in Europe due to the company's history. Since the company's foundation in 1870, the university city of Göttingen in Lower Saxony has been the headquarters and the largest manufacturing and development location. This is where Sartorius develops and produces two of its core technologies: membrane filters and laboratory instruments. Bags and tubing are manufactured at the plant in Aubagne, France. Sartorius serves North America, the world's largest pharmaceutical and laboratory market as well as the headquarters of many major customers and the source of numerous innovations, through its sales and distribution center in Bohemia, New York. The most important production facility in the region is the plant in Yauco, Puerto Rico. Sartorius supplies its American biopharmaceutical customers with membrane filters and sterile bags from this site.

Sartorius is active in the dynamically growing Asian market from its sales headquarters in Shanghai, China. Beijing and Bangalore are important production sites, where Sartorius manufactures stainless steel bioreactors, single-use bags and laboratory balances, among other products. To further expand its foothold in the region, Sartorius is building a new plant for cell culture media and selected single-use products in the biopharma hub of Songdo in South Korea.







Find a current list of the Sartorius locations worldwide here







More Than 150 Years of Innovative Strength

The products have evolved, but what drives Sartorius at its core has remained unchanged since 1870: the goal of simplifying, accelerating and improving methods, processes and results based on the latest scientific findings. In this tradition, we contribute to providing more people with access to better medicine today.



The company's success began with short-beam analytical balances, yet over the years, the firm has evolved from a precision engineering workshop into an international group.



Company Foundation

In 1870, at just 24 years old,
Florenz Sartorius founds the
"Feinmechanische Werkstatt
F. Sartorius" in Göttingen. The
company soon focuses on a
technology Florenz had learned
about during his apprenticeship
and continued to develop: his
short-arm analytical balances
reduced the time required
for precise measurements in
pharmacies and laboratories.
They win numerous awards at
international trade fairs.

1900

New Generation

In the 1890s, his craftsmanship and scientific curiosity lead Florenz Sartorius to develop incubators for poultry breeding. They are followed by heating cabinets for bacteriological purposes. Sartorius uses profits from the balance manufacturing business to buy companies, expanding his portfolio with their technologies. Florenz Sartorius' sons join the business from 1906.

1920

Developments for the Future

In 1927, Sartorius co-founds a company to manufacture novel synthetic membrane filters that completely retain particles, bacteria or other pathogens above a certain size. The company develops a process for large-scale manufacturing. With the advent of biotechnology at the end of the 20th century, membrane filter technology proves to be the core of today's bioprocessing business.







World War II

During World War II, production increasingly switches to armaments, such as automatic devices for releasing sticks of bombs from aircraft. Sartorius profits from these orders. The company also uses forced labor and prisoners of war. Sartorius later had independent researchers examine its role during the Nazi era; the results were published in November 2019.

1950

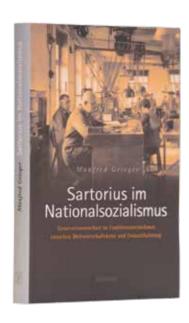
The German Economic Miracle

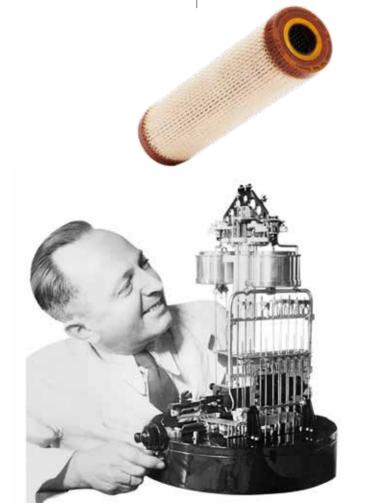
With its traditionally highly skilled workforce, Sartorius plays its part in the German "Wirtschaftswunder" (economic miracle): production is resumed shortly after the end of the war. Against the backdrop of postwar reconstruction, the demand for high-performance equipment increases. The Selecta balance series is a great success at home and abroad. Various industries discover applications for membrane filtration.

1970

Pacesetters

After the successful Apollo 11 mission in 1969, Sartorius employees analyze 20.2 milligrams of precious lunar rock to determine its absolute surface. In the 1970s, electronics finally make their way into balances and simplify the weighing process. The portfolio of single-use products in membrane filtration grows. Pleated filter cartridges are launched on the market, providing a large filter surface in a compact design.





Worldwide Network

Since its foundation, Sartorius has been operating internationally, advertising at trade fairs abroad and concluding business deals in the USA, France and the UK. First with sales offices and later – from the 1980s onward – through its own production sites, the company expands its global presence to be close to its customers.

1990

Focus on Biopharmaceuticals

To facilitate sustainable growth and broaden its financial base, Sartorius goes public in 1990. Since the mid-1990s, Sartorius has been focusing on biotechnology, still a new technology at that time. As the first biopharmaceuticals – such as human insulin – reach market maturity, industrial-scale production facilities are needed for the first time.

2000

Single-Use Technologies

Single-use technologies not only make pharmaceutical production more environmentally friendly; lower initial investments and more flexible processes also accelerate the production of biologics, making it less expensive. In 2007, Sartorius merges its biotechnology division with French Stedim Biosystems S.A. into Sartorius Stedim Biotech — thus becoming a global technology leader for the biopharmaceutical industry.







Total Solutions Provider

With in-house developments, strategic acquisitions and a steadily growing product range, Sartorius evolves into a total solutions provider for the entire process chain in the biopharmaceutical industry: from molecule development to production to final filling of medical drugs. Milestones, especially with regard to the field of advanced therapies, include the acquisition of selected parts of Danaher's life science business and the acquisition of BIA Separations in 2020.

2020+

Simplifying Progress

In the future, automation, digitalization, and networking will increasingly shape processes in biopharmaceutical research and production. Sartorius is developing solutions centered around artificial intelligence and is working on assistance and automated data management systems to enable technological breakthroughs in biopharmaceuticals and life sciences more quickly and efficiently.











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Simplifying Progress