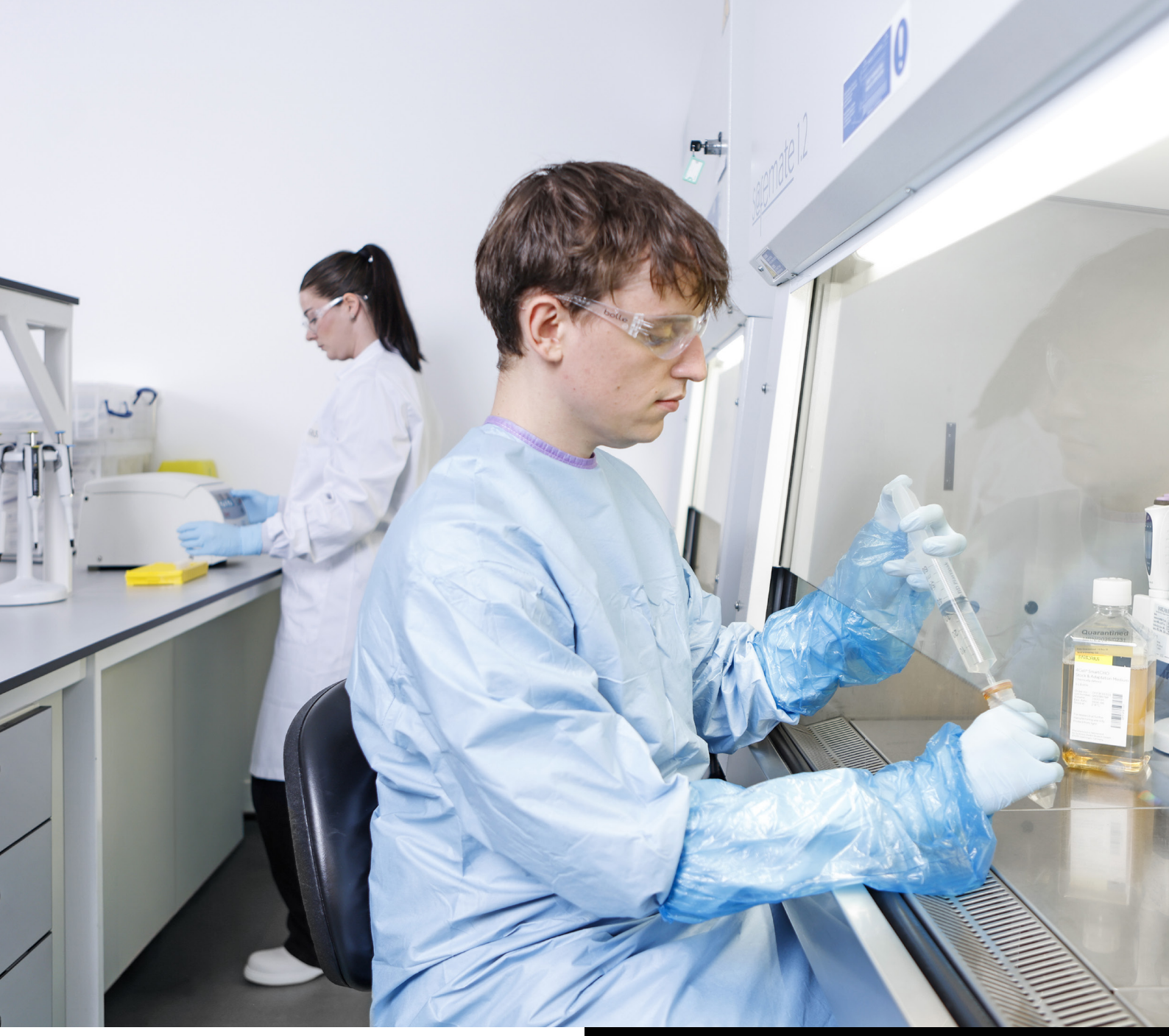


Testing and Cell Bank Manufacturing Services

Simplifying Progress

SARTORIUS

Introduction

Our Testing and Cell Bank Manufacturing Services support you throughout your entire drug development journey — across both traditional and advanced therapies — by providing testing services and cell banks to proceed with successful regulatory submissions.

Our offerings feature:

- Comprehensive testing packages for product and cell bank characterization, bulk harvest, stability studies, lot release (drug substances | drug products — both clinical and commercial), and more
- Hundreds of off-the-shelf, phase-appropriate testing methods that comply with regulatory requirements
- Method development and lifecycle management, including GMP qualification and validation
- Qualified person (QP)-released master cell banks (MCB) in < 5 months and working cell banks (WCB) in < 3 months
- Approval from the US FDA and UK MHRA to ensure GMP compliance

Testing services to support your successful regulatory submissions

A comprehensive biologics testing service supports drug developers and commercial manufacturers of biologics from discovery through to commercial manufacturing, and is an essential requirement of regulators across all modalities and product types.

Our global current GMP (cGMP) - compliant testing and cell bank manufacturing facilities are FDA- and MHRA-approved for manufacturing mammalian cell banks and biologics testing of viral vector gene therapies, cell therapies, viral vector vaccines, and protein-based therapeutics, including new biological entities and biosimilars.

Dedicated to simplifying your drug development journey

Through our dedicated focus on testing and banking requirements, we provide the optimal support service for our clients. We consistently review and monitor our capacities to reduce lead times and increase availability to clients.

We extensively monitor changes in regulatory guidelines and act quickly to make improvements to our processes and reduce our turnaround times wherever possible to ensure you receive your testing results and cell banks as quickly as possible.

Successful track record

- > 28 years' experience in cGMP biologics testing services and > 800 clients supported to global regulatory standards.
- ~50 successful regulatory submissions supported and named specifically on ~10 drug licences.
- > 300 testing methods available across various modalities, with extensive expertise in method development and cGMP qualification and validation.
- > 120 GMP cell banks manufactured, tested, and QP-released.

For more information, visit
www.sartorius.com/en/services/biologics-testing

Portfolio Overview

Our comprehensive solutions for successful regulatory submissions

Pre-clinical and process development

Our biologic testing services, available as platform methods and | or customized, are established and performed during early development stages (e.g., as part of the cell line development process).

Product characterization

- Product quality assessments
- Assay development expertise
- Full assay lifecycle management

Cell bank manufacturing

- cGMP MCB and WCB
- QP for cell bank release

Cell bank characterization

- Validated cGMP release assays
- Sterility, mycoplasma, and virus testing
- Genetic characterization

Clinical and commercial manufacturing

Our services can also be leveraged for in-process controls and final batch release.

Bulk harvest testing

cGMP testing to assess the safety of your batch

Stability and storage studies

Custom-designed studies tailored to your program

Lot release testing

A fully cGMP-compliant suite of lot release tests

Biologic testing services and mammalian cell bank expertise

Product testing
From non-regulatory early-stage testing to GMP-qualified and -validated release assays, for any biologic

Cell bank manufacturing
Master and working cell banks and adherent cell lines

Cell bank testing
For mammalian cell bank release, designed to meet ICH Q5A with GMP assays

Product Testing Services

As experts in method development and assay lifecycle management, we can take your methods from early-stage development through to GMP qualification and validation as your molecule passes through the clinical and commercial phases.

We offer hundreds of ready-to-use platform methods to support product characterization throughout all phases of your projects.

Product testing is required at multiple stages of drug development

Lead candidate selection	Pre-clinical and process development	Clinical and commercial manufacturing
Developability and manufacturability assessments	**Product characterization**	**Bulk harvest lot release**
▪ Establish early candidates with developability and | or manufacturability assessments ▪ Mitigate risks at later stages of development, regulatory filings, and clinical and commercial phases ▪ Characterize candidates using analytical methods to assess structure, physicochemical properties, and biological activity ▪ Inform suitability for scale-up to production and clinical readiness, accelerating the candidate selection process	▪ Assess selected candidates in greater detail using analytical methods, including evaluation of structure, physicochemical properties, and biological activity ▪ Generate data to support drug development progression and successful IND | IMPD filings	▪ Select, qualify, and validate appropriate lot release methods to generate data required for successful regulatory submissions ▪ Assess the safety profile of bulk harvest samples taken at the end of the production process through detection of process-related contaminants ▪ Perform final-stage release testing to confirm the identity, purity, potency, and biosafety of the drug substance and final drug product

Product testing must be performed on a variety of products and modalities to confirm the identity, potency, purity, and safety of a drug candidate

Protein-based therapies
- We have developed a variety of methods to assess critical quality attributes of monoclonal antibodies, bi-specifics, fusion molecules, and other protein-based therapeutics
- These services can be integrated with our Cell Line Development Services and are also available as standalone services
- Extensive experience in both new biological entities and biosimilars (>250 individual projects); can assess attributes such as N-glycan profiles, charge variants, size variants, intact mass, purity, heterogeneity, target binding, potency, and Fc binding and can perform peptide mapping
- We support clients during the clinical and commercial phases through unprocessed bulk harvest and lot release testing

Viral vector vaccines
- Testing packages available at every stage, from starting materials (master virus seed stock, working virus seed stock) to final viral product release (unprocessed bulk harvest, drug substance, drug product)
- Numerous ready-to-use methods established; we also have the capability to develop and validate specific methods
- Methods are based on ICH | FDA guidelines; client-specific packages can be developed if specific methods can be excluded based on risk
- Packages related to microbiological and viral safety, identity, purity, and potency are available — please contact us to discuss your requirements

AAV-based gene therapies
- The regulatory landscape for AAV-based gene therapy is complex and evolving as authorities constantly release new guidance; even small missteps can make approvals more time-consuming and costly. We work with you to develop, establish, and validate your methods for characterizing crucial AAV metrics, including biosafety, identity, purity, and potency
- Both non-regulated and cGMP-qualified methods are available to determine microbiological safety, viral safety, AAV replication competence, and capsid identity, as well as peptide mapping and genome sequencing
- Methods also available for titers (infectious, genomic, viral particle, capsid), full:empty capsid ratio, aggregation and stability, and residuals (e.g., HCP, DNA, BSA, FectoVIR-AAV® transfection reagent and PEIpro® transfection reagent, plasmid, AVB ligand, Benzonase® nuclease)

Bulk harvest testing
- UBH, obtained at the end of production before downstream processing (as a single or combined harvest of cells and media), is tested for sterility, mycoplasma, adventitious agents, species-specific viruses, and retroviruses to detect potential contamination and help ensure batch safety
- Standard (35 days) and accelerated (21 days) timelines tailored to your schedule
- Regulatory guidelines (ICH Q5A) state every batch of UBH for clinical and commercial use should be tested

Lot release testing
- Leverage our pre-clinical development work to speed up establishment of robust lot release testing of drug substances and drug products
- Integrated services from CHO cell line development to batch release, including protein characterization and comprehensive biosafety assays for efficient GMP qualification and validation assays for product release
- Methods used in pre-clinical testing may also be employed for lot release, but are GMP-qualified and -validated
- Once release criteria are defined, tailored testing release packages can be created to ensure consistent, on-time release of your clinical and commercial batches

Stability and storage
- Custom stability and storage programmes to assess shelf life, quality, and safety and to demonstrate how drug substance | product quality varies over time and under the influence of environmental factors, such as temperature and humidity
- Custom stability, quality, safety, and storage programs and protocols designed to your specific needs and ICH guidelines
- On-site (or client site) storage and sample management in dedicated stability suites (5°C, -20°C, and -80°C) to determine long-term storage conditions
- Shelf-life established using variable temperature and humidity chambers under stress and accelerated conditions
- We can support transfer or development and qualification | validation of product-specific assays for product release and subsequent stability testing

If your product type is not listed above, please contact us to discuss a custom work package.

Cell Bank Manufacturing Service

Robust, reliable supply of your cell lines for clinical and commercial manufacturing

By leveraging our experience in single-use technologies and relevant technical and regulatory expertise, our GMP Cell Bank Manufacturing Service provides a closed, semi-automated process to mitigate risks related to manual handling, contamination, shear stress, and cytotoxicity due to overexposure to cryoprotectants.

Our Cell Bank Manufacturing Service is integrated with our Cell Bank Testing Service and can provide tested and QP-released MCB in <5 months and WCB within <3 months.

Flexible approach:

- More than 40 cell bank manufacturing slots available per year
- Platform or tech transfer possible (pilot | engineering runs)
- Flexible manufacturing options available, including shake flasks, bioreactors, and custom high-cell-density banking services for intensified seed trains
- Mammalian suspension and adherent cell bank manufacturing available at dedicated sites, ensuring animal component-free status for suspension manufacturing sites

Closed, broth-qualified manufacturing process for assured sterility

Vial recovery	Cell culture	Harvest, concentration, centrifugation	Automated filling	Controlled-rate freezing
				
Grade A isolator Bioquell QUBE®	**Aseptic processes** Sterile welding and sealing (MYCap®) **Flexible manufacturing options** Shake flasks or Biostat® RM	**Automated cell counting** NucleoCounter® **Centrifugation** Rotixa® 500RS	**>500 vials in <20 mins** Fill-It automated cryovial filling system	**Harvest to storage in <2 hours** CryoMed® automated freezing device

Note. High cell density (HCD) cell banks available using Biostat® RM with perfusion processes. Monitored using BioPAT® Viamass system and 7-day cell counting to assess feed rate of media to achieve desired cell densities.

Cell Bank Testing

Platform cGMP testing methods to ensure safe release of your cell banks

Biosafety testing	Research cell bank	Master cell bank	Working cell bank	End-of-production cell bank
Sterility and mycoplasma testing	✓	✓	✓	✓
Adventitious agents	-	✓	✓	✓
Retroviruses	-	✓	-	✓
Species-specific viruses	Optional	✓	-	-

Characterization	Research cell bank	Master cell bank	Working cell bank	End-of-production cell bank
Genetic analysis	✓	✓	-	✓
Identity	✓	✓	✓	✓

Standalone cell bank testing packages completed in < 10 weeks (MCB) and < 6 weeks (WCB) enable faster release of cell banks and accelerate time to manufacturing.

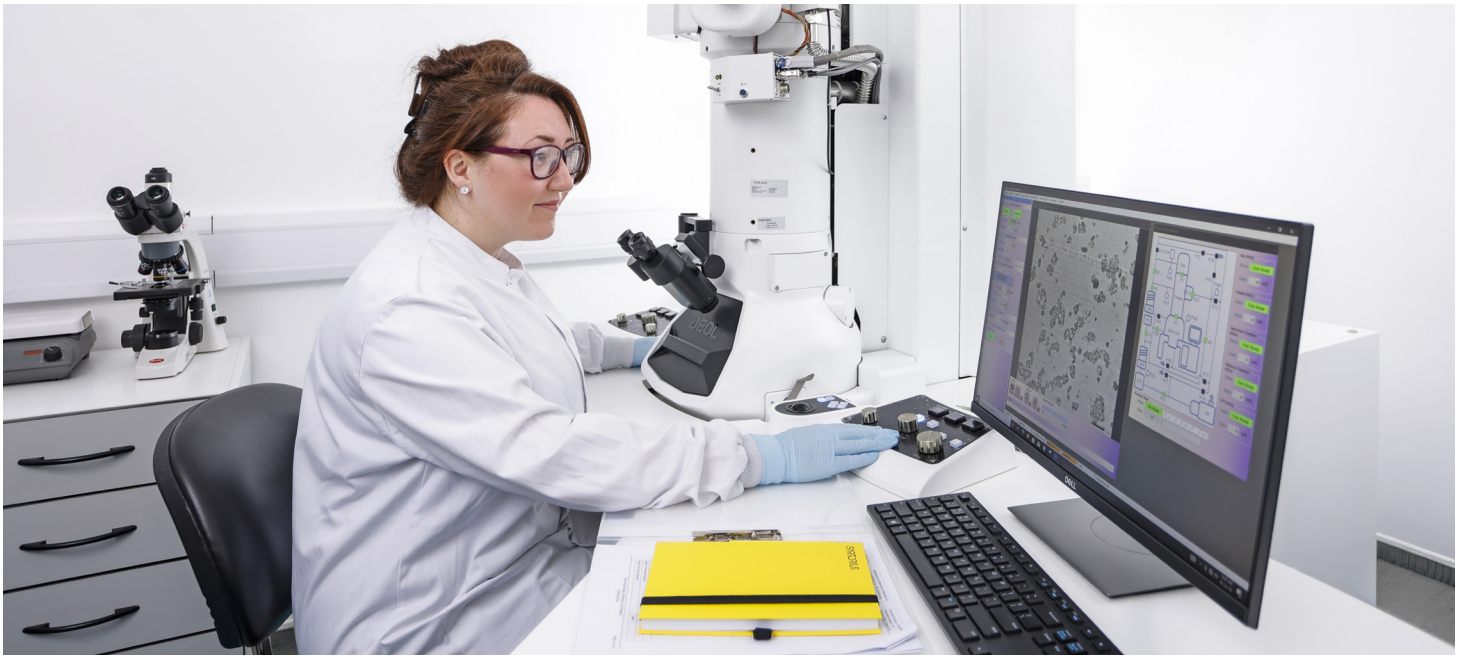
Cell bank testing

Stringent cGMP biosafety testing is required for all banks to confirm absence of contaminants, including bacteria, mycoplasma, and viruses.

Regulations

The regulations outlining the testing of cell banks can be extensive. We have developed cGMP platform methods for testing cell banks that align with ICH Q5A guidelines.

Note. RCB = Research cell bank, MCB = Master cell bank, EoPCB = End of production cell bank, QP = Qualified person



Example packages for cell bank testing

Cell bank testing

Biosafety testing		Characterization	
Microbiological safety	Sterility, mycoplasma	**Genetic analysis**	Transgene confirmation (gene copy number, sequencing)
Viral safety	Species-specific virus (vesivirus, bovine and porcine, MVM, MAP, and HAP) Retrovirus (TEM, S+L- assay) Adventitious agents (in vitro assays)	**Identity**	DNA barcoding

MDCK cell banks

Biosafety testing		Characterization	
Microbiological safety	Sterility, mycoplasma	**Genetic analysis**	Transgene confirmation (gene copy number, southern blot)
Viral safety	▪ Species-specific virus (bovine and porcine ; MVM optional) ▪ Retrovirus (TEM, PERT) ▪ Adventitious agents (in vitro and in vivo assays)	**Identity**	Morphology (if adherent), DNA barcoding

HEK293 cell banks

Biosafety testing		Characterization	
Microbiological safety	Sterility, mycoplasma and mycobacteria	**Genetic analysis**	Sequencing, gene copy number (custom development)
Viral safety	▪ Species-specific virus (human and simian viruses, bovine and porcine, optional; SARS-CoV-2, MVM) ▪ Retrovirus (TEM, PERT) ▪ Adventitious agents (in vitro assays)	**Identity**	Morphology (if adherent), DNA barcoding

Stem cell banks

Biosafety testing		Characterization	
Microbiological safety	Sterility, mycoplasma, and mycobacteria	**Genetic analysis**	Custom packages available, depending on application
Viral safety	▪ Species-specific viruses (human virus panel by PCR; SARS-CoV-2 optional) ▪ Retroviruses (TEM) ▪ Adventitious viruses (in vitro assays)	**Identity**	DNA barcoding, fingerprinting

Note. MVM = minute virus of mice; MAP = mouse antibody protein; HAP = hamster antibody protein; TEM = transmission electron microscopy; PERT = product enhanced reverse transcriptase

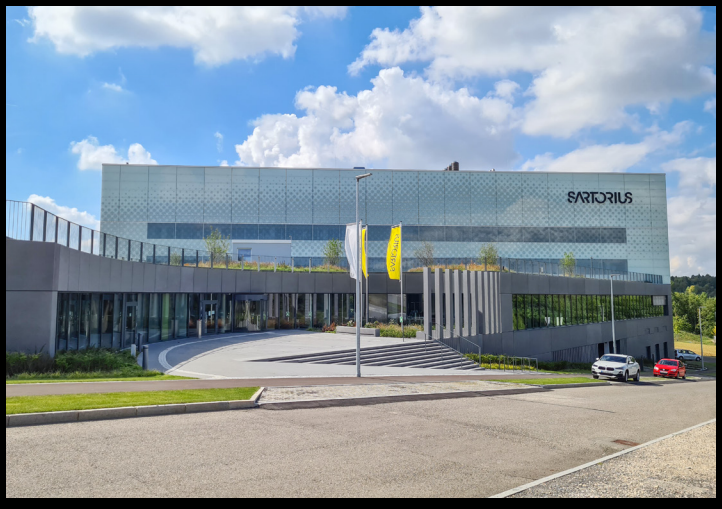
Beyond our testing and cell bank manufacturing services

Benefit from dedicated products and services for your CHO- or HEK-based processes to simplify and accelerate the development of your biologics.

CHO Cell Line Development Service
Maximize the potential of your cell line using our reliable platform, proprietary technologies, and industry-leading instruments. Achieve higher yields without compromise by leaning on our proven track record.

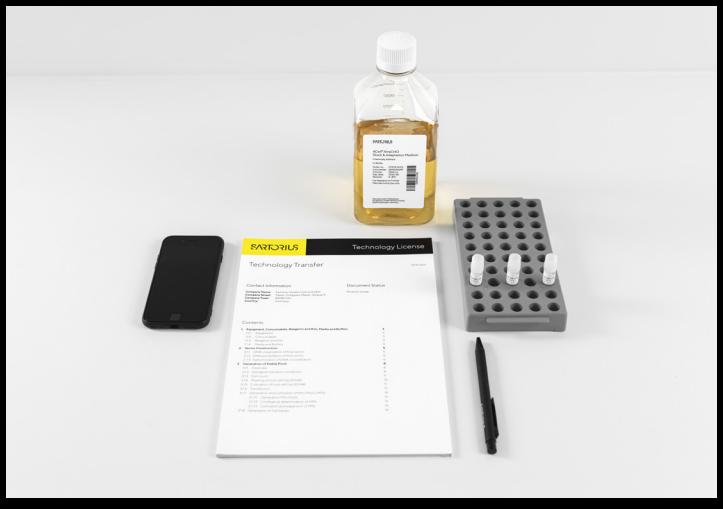
Media services
Our vast array of cell culture services accelerate process development through extensive media benchmarking, optimization, and custom formulation development. Scale confidently by sourcing your media from our certified manufacturing sites.

Customizable service packages to suit your cell line development strategy



Outsourced cell line development
Partially or entirely outsource your cell line development process to Sartorius as your extended laboratory bench and trusted drug development partner.

- DNA to pool (feasibility | manufacturability assessment)
- DNA to research cell bank (RCB)
- DNA to MCB



In-house cell line development
Access our cell line development technology for your in-house development, including our established host cell line, vector, media, and methodologies.

- Research technology license (DNA to pool)
- Commercial technology license (DNA to RCB)

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For details on the registrations please refer to https://www.sartorius.com/en/patents-and-trademarks

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