



Cell Culture Media
Services for Protein
and Viral Vector
Production

Simplifying Progress

SARTORIUS

Introduction

Sartorius Cell Culture Media Services provide drug developers and manufacturers with high-performing, tailored media formulations for protein and viral vector production.

Backed by decades of expertise in media development and manufacturing, the service provides you with access to our most experienced scientists, who will determine the best approach to match your process performance indicators.

Our offerings feature:

- Expertise with the most used cell lines and corresponding proprietary high-performing media libraries
- An iterative, rational, and research-driven development approach to learn and adjust at each step
- Broad analytical methods and advanced technologies to gain insights into process parameters
- Compendial-grade raw materials used to support large-scale manufacturing in GMP environments

Reaching optimal process conditions

Choosing the right cell culture media is key to enabling reproducibility, quality, and performance. Sartorius Cell Culture Media Services help identify the formulation best suited to each process through a comprehensive offering that includes benchmarking studies, media and process optimization, and de novo media development supported by advanced analytics.

Expedite your trials with prototypes, and scale up confidently to commercial scale by sourcing your media from our certified facilities, available as liquid (in bottles or single-use bags) or in powder format.

Successful track record

- Over 20 years of experience and more than 375 successfully developed media formulations for internal and external partners
- With cutting-edge equipment and 60+ validated analytical methods, media and processes are improved based on informed decisions
- Installed annual capacity exceeding 3 million liters and 200 tons, with continued investments to meet future demand

Expertise across diverse modalities

Whether you are working with adeno-associated viruses (AAVs), lentiviruses (LVs), proteins, monoclonal antibodies (mAbs), or biosimilars, our scientists have long-standing experience with the most commonly used cell lines, including HEK, CHO, BHK-21, MDCK, and Vero.

With a portfolio of 15+ standard, off-the-shelf lean media formulations, you will benefit from an in-depth understanding of cell culture media used to produce traditional and novel therapeutics.



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**4Cell® HEK293 VIP
NX CD Medium**

Chemically defined
1L Bottle

Order no.: 892-0001
Lot number: XHKX123456
Volume: 1L
Mfg. date: YYYY-MM
Store at: 2-8 °C

For research or further
manufacturing use only.
Protect from light.

Manufactured by Sartorius in Germany
for Sartorius Stedim Biotech GmbH
37079 Goettingen, Germany

892-0001

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**4Cell® HEK293 GM
CD Medium**

Chemically defined
1L Bottle

Order no.: 851-0001
Lot number: XHKG123456
Volume: 1L
Exp. date: YYYY-MM
Store at: 2-8 °C

For research or further
manufacturing use only.
Protect from light.

Manufactured by Sartorius in Germany
for Sartorius Stedim Biotech GmbH
37079 Goettingen, Germany

851-0001

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**4Cell® HEK293 VIP
NB CD Medium**

Chemically defined
1L Bottle

Order no.: 891-0001
Lot number: XHKB123456
Volume: 1L
Mfg. date: YYYY-MM
Store at: 2-8 °C

For research or further
manufacturing use only.
Protect from light.

Manufactured by Sartorius in Germany
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37079 Goettingen, Germany

891-0001

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**4Cell® HEK293 TF
CD Medium**

Chemically defined
1L Bottle

Order no.: 861-0001
Lot number: XHKT123456
Volume: 1L
Exp. date: YYYY-MM
Store at: 2-8 °C

For research or further
manufacturing use only.
Protect from light.

Manufactured by Sartorius in Germany
for Sartorius Stedim Biotech GmbH
37079 Goettingen, Germany

861-0001

SARTORIUS

**4Cell®
Feed**

Chemically defined
1L Bottle

Order no.:
Lot number:
Volume:
Exp. date:
Store at:

For research or further
manufacturing use only.
Protect from light.

Manufactured by Sartorius in Germany
for Sartorius Stedim Biotech GmbH
37079 Goettingen, Germany

861-0001

Media service offerings



Media benchmarking studies

Expediting comparative studies for media selection

We offer established standard approaches for proteins expressed in CHO cells and AAV and LV vectors expressed in HEK cells to expedite project execution and shorten qualification timelines.

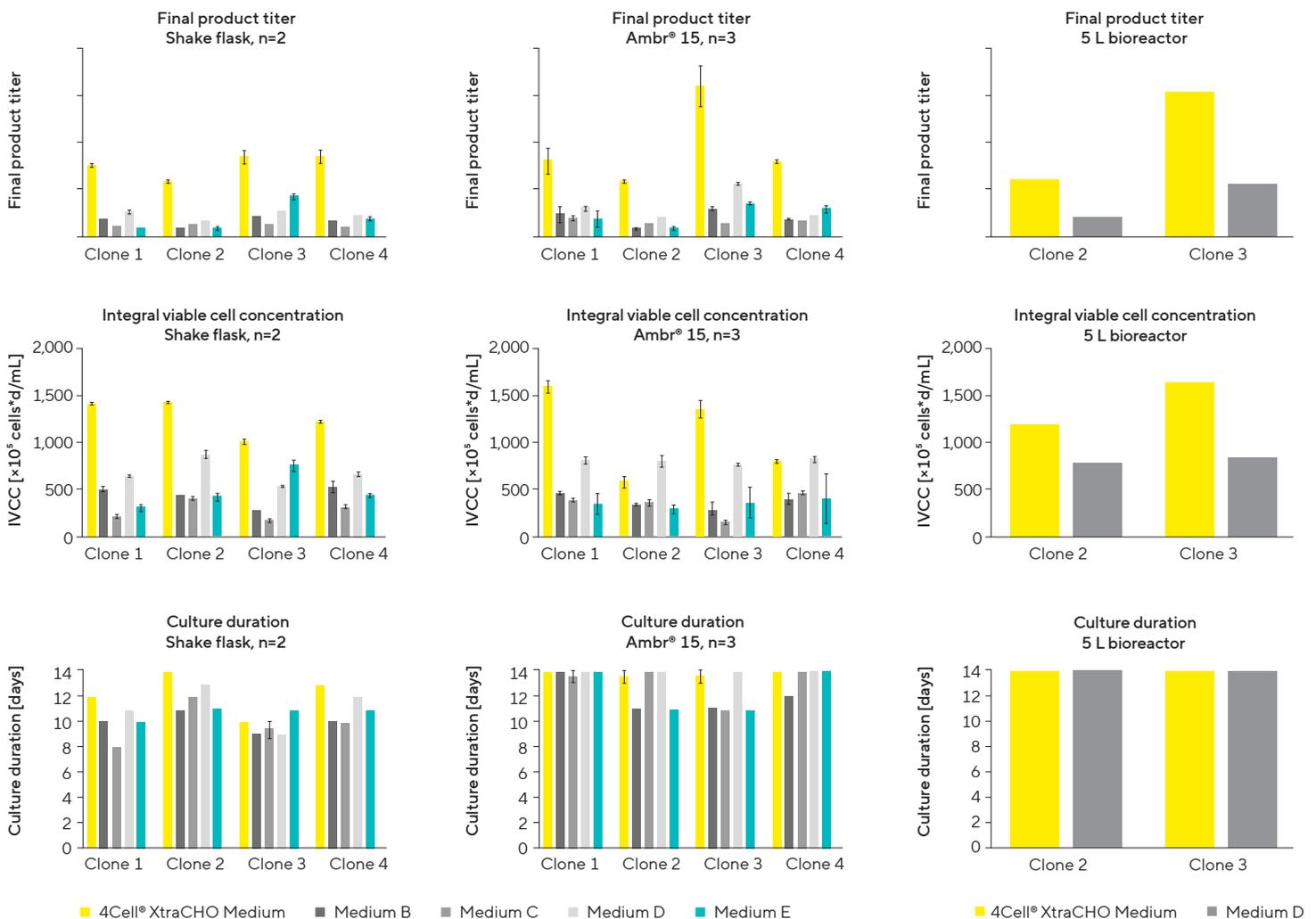
Each study includes the following:

- Tech transfer from your lab to ours to replicate your process
- Screening of our relevant proprietary formulations* against your reference materials in shake flasks or Ambr® 15 bioreactors
- Analytical measurements, including viable cell density (VCD), glucose consumption, lactate accumulation, and amino acid profiles
- Scale-up in 2 L bioreactors, ensuring proof of concept in pH-regulated cultivation systems

Using this approach, we applied multi-scale media benchmarking for CHO-DG44 cells, utilizing the Ambr® 15 mini-bioreactor platform for screening various clone | media combinations (Figure 1). The results suggest the Sartorius 4Cell® XtraCHO Media System delivered higher performance in terms of cell growth, viability, titer, and glycoprofile compared to reference media.

* Basal formulations, feeds, and transfection reagents when applicable

Figure 1: Product titers, integral cell concentrations, and culture duration in three cultivation systems, using four CHO DG44 cell clones and five sets of CHO culture media



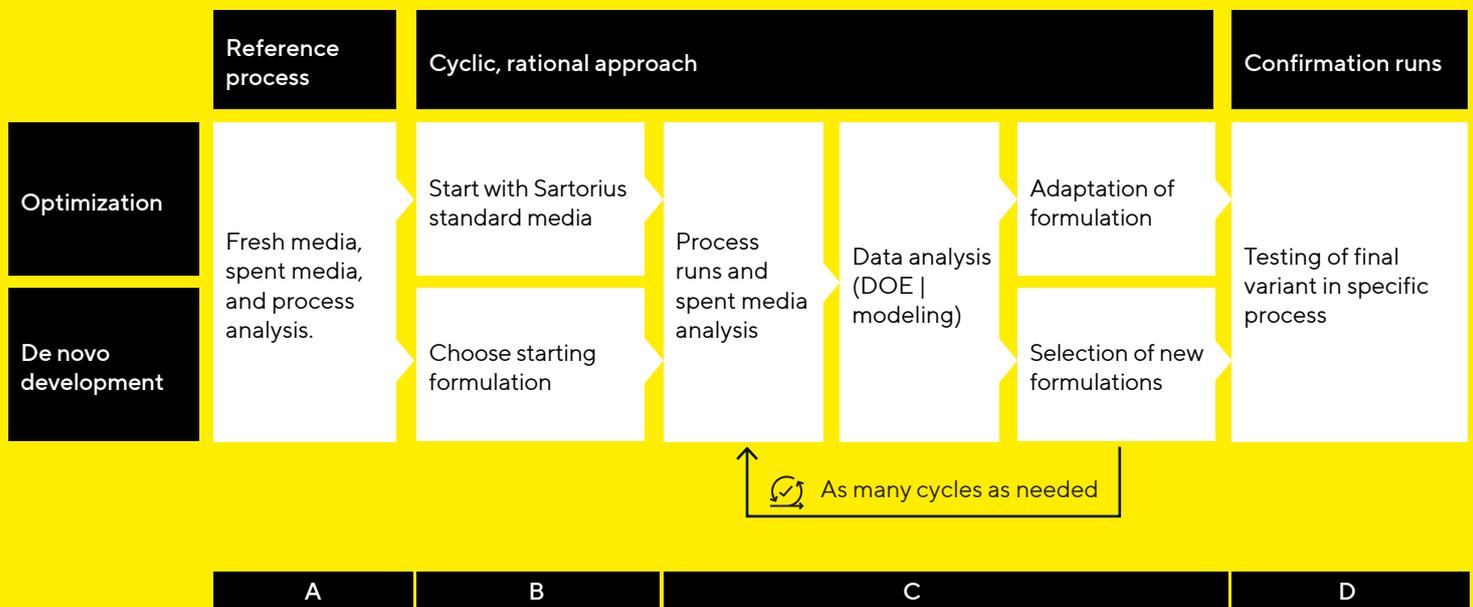
Note. IVCC = integral viable cell concentration.

Media optimization and development

Designing media to unlock process efficiency

Our in-house team works to design and deliver a unique media and feed combination tailored to your specific process needs. Working closely with your team, we share and evaluate interim data to determine the next steps. We confirm the optimized process in benchtop bioreactors to ensure a seamless process transfer and scale-up.

A cyclic approach to medium optimization and development



A

- Understand cellular metabolic demands
- Comparison to in-house processes
- Incorporation of empirical values
- Incorporation of tech batch data

B

- De novo development of first variant
- Use of existing basal development formulations
- Production of media

C

- Testing of media and variants (by supplementation)
- Inclusion of growth and process-specific testing (e.g., AAV production)
- Execution in shake flasks or Ambr®15 scale
- Possible upscaling, if in scope

D

- Verification of the final formulation's performance in the target process
- Potential upscaling to a 2 L benchtop bioreactor
- Potential comparison to the original process (tech transfer)

Fresh and spent media analytics

Improved process insights through comprehensive analytics

Provide us with your samples and receive all the necessary data to better understand your cell culture conditions.



Amino acids
(20+)



Trace metals
(30+)



Vitamins
(10+)

 **Fast and reliable methods** validated according to ICH guidelines for data-based decision making

 **Small volume required:** 0.5 mL sample per method (1 mL for trace elements, and 2 mL for bundles)

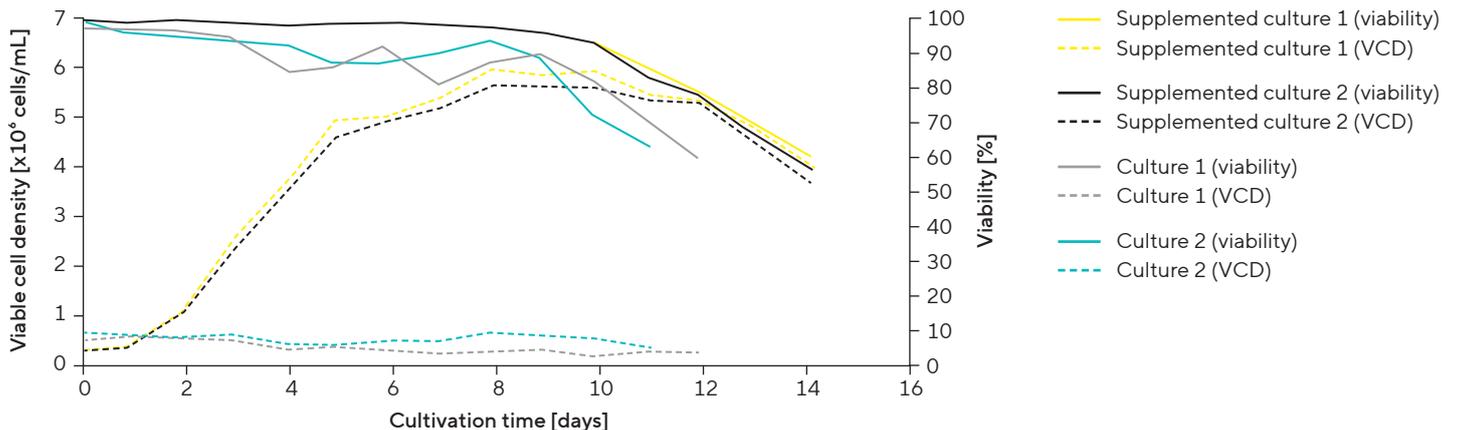
 **Included in all our media services** to monitor cultures, track developments and report improvements

Targeted analytics include conventional methods for amino acids, vitamins, and trace elements, providing valuable insights for process understanding and routine monitoring.

Untargeted analytics are innovative and holistic methods for root cause analysis, which our service users can use for exploration or investigating batch-to-batch variability. This supports data-driven decision-making through statistical models and multivariate data analysis (MVDA) using principal component analysis (PCA). Results are visualized and interpreted in collaboration with Sartorius experts.

In the example shown in Figure 2, copper was not part of the defined medium formulation and was inadvertently introduced, for example, by raw materials at the original site. However, this copper impurity was important for cellular performance. As such, the medium formulation was changed, and copper concentration was actively controlled to ensure its levels did not inhibit growth.

Figure 2: Results of targeted analytics comparing cell cultures run in duplicate using a new copper-supplemented medium vs. the existing formulation





Media manufacturing services

Reliability through scale-up

Accelerate supplier qualification and trial batches with our rapid media prototyping service. Your specifications are confirmed at pilot scale and scaled up to larger volumes for further manufacturing applications.

Benefit from a wide range of primary packaging for liquids from bottles to 2D and 3D Flexsafe® bags, as well as buckets and single-use bags for powders. Shipping validations have been conducted for secondary packaging in accordance with ASTM standards.

Shelf-life studies

If further stability data are required for the liquid or powder formulations produced for you, a dedicated project manager will coordinate a study tailored to your needs.

- Broad range of validated tests available: physical, analytical, microbiological, and biological
- Storage under various conditions with controlled humidity and temperature
- Real-time or accelerated studies under severe conditions
- Extensive range of representative packaging options

Prototyping	Pilot	Large-scale
<ul style="list-style-type: none"> ▪ Shortest lead times ▪ No quality claim ▪ ACF raw materials only ▪ Limited to one order per formulation ▪ Up to 3 kg 100 L per batch ▪ Same equipment as larger scales ▪ Fee for service 	<ul style="list-style-type: none"> ▪ RUO claim ▪ Qualified raw materials (including new qualification if needed) ▪ Validation processes ▪ Limited QA QC documentation ▪ Exactly the same process as large-scale production 	<ul style="list-style-type: none"> ▪ Full batch sizes available ▪ FFM claim ▪ Full QA QC documentation ▪ Possibility to establish an MSA ▪ Scheduled deliveries
Supplier selection	Process validation	Long-term commercial supply

Note. ACF: animal-component free, RUO: research use only, FFM: for further manufacturing, MSA: master supply agreement



Beyond cell culture media services

Benefit from dedicated products and services for your CHO- or HEK-based process, simplifying and accelerating 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, supported by a proven track record.



Testing Services
Our assay lifecycle management and GMP-qualified | validated, ready-to-use assay packages and platforms from our GMP testing facility help you meet regulatory requirements and free up in-house resources.



Cell Banking Services
Our dedicated GMP cell banking facility and expert support team specialize in delivering tested master cell banks in four months. Closed-system manufacturing allows our partners to achieve high cell quality with sufficient cell densities and viabilities to transition smoothly to the production phase without delay.

 For more information, visit
sartorius.com/en/services/cell-culture-media-services

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