Growing in Importance

While inactivated or live attenuated vaccines dominate the market today, a new generation of viral vaccines known as recombinant viral vectors or virus-like-particles (VLPs) are in the pre-clinical and clinical development phases. Viral vectors are also widely used for gene therapy and oncolytic applications.

Quality Control of the Viral Vaccine and Viral Vector Production Process — Ensuring That Your Product Is Safe, Effective, and Pure.

Take a look at the example production process map, with the most important QC applications, and see where our products and services can help you overcome some of your quality control challenges from master viral seed (MVS) and master cell bank (MCB) all the way to final product release testing.

Raw material testing  In-process control  Final release

Find out more
For more information, please visit sartorius.com
Sartorius QC Solutions

Upstream Process

1 **Viability and Cell Count**
   - Gives information about viable cell density in your cell culture; Allows automated cell bleed for perfusion processes or inoculation of seed trains.
   - Process Steps: a, b

2 **Metabolite Measurement**
   - Gives information about the productivity, biochemical status, and lifecycle of your cells; Allows automated feed control based on glucose measurements.
   - Process Steps: a, b

3 **Mycoplasma Detection**
   - Detect mycoplasma within three hours.
   - Process Steps: k, l, m, n, o, p, q

- **Seed Expansion**
- **Virus Propagation**
- **Optional:** Microcarrier Removal; Cell Lysis
- **Cell Removal**

Sartorius Solutions

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In-line monitoring and control of viable biomass in cell culture processes with BioPAT® ViaMass

On-line monitoring and control of glucose and lactate with BioPAT® Trace

Microsart® Mycoplasma AMP qPCR kit—a rapid, reliable, and easy-to-use solution in compliance with international guidelines

**Fully automated control of the cultivation process**

**Reduce time-to-result significantly**
Minimize risk of cross-contamination

Quantity a wide range of viruses and VLPs

Easy handling and reliable test results

Know results in just 3 hours

4 Microbial Contamination Control | Bioburden Testing

Biosafety and Characterization

Mycoplasma Testing

Bioburden

Virus Analytics

Downstream Process

Microbial Contamination Control | Bioburden Testing

Virus Analytics

Sterility Testing

Microbial Contamination Control | Bioburden Testing

Virus Analytics

Sterility Testing

Buffer Preparation

Clarification

Concentration

Inactivation (optional by vaccine production)

Buffer

Buffer Preparation

Clarification

Concentration

Inactivation (optional by vaccine production)
Formulation

Excipient Preparation

Buffer Preparation

Filling

Drug Substance

Formulation

Sterile Filtration

Buffer

Drug Product

Excipients

Buffer

9 Biosafety
3 Mycoplasma Testing
4 Bioburden

9 Biosafety and Characterization

Product and process related impurities, product purity
Potency, identity, quantity
Advanced physico-chemical characterization

* depending on the nature of the excipient

Microbial Air Monitoring

Quantitative detection of airborne microorganism.

Process Steps: specified rooms, clean rooms and filling lines

Data Analytics

Analysis and interpretation of complex data.

Process Steps: throughout the manufacturing process

Biosafety and Characterization Testing Service

Sartorius Cell Line and Media Testing Solutions (CL&MTS) is a leading Contract Testing and Research Organization specializing in biosafety, biological activity, physico-chemical and structural analyses.

Process Steps: i, j, k, l, m, n, o, p, q

7 Microbial Air Monitoring

Endotoxin:
Chromogenic LAL test, compliant to USP and EP requirements

Virus testing:
Endogenous viral particles, adventitious virus, retrovirus assays, virus and vector shedding

Product Impurities:
UPLC assays, SEC for aggregates stability studies

Process Impurities:
Residual Host Cell Proteins by ELISA, Residual DNA by qPCR

Ensure the most accurate data over an 8 hour period

Active air monitoring with MD8 Airscan®—agar-free, continuous air monitoring

Analyze and interpret complex data to efficiently develop new products, and control quality and costs

Identify efficiently critical process parameters

Release your final product safer and more cost-effectively
Planning for Quality Control Testing: Sample and Buffer Preparation

Contamination costs time and money. Improve the reliability of your analytical results and ensure speed-to-market by investing in appropriate contamination prevention products.

Sampling and Aseptic Fluid Transfer
TAKEONE® Aseptic Sampling System, MYCAP® Bottle Closures, and QUICK-SEAL® Aseptic Disconnect

Clarification and Filtration
Sartoclear Dynamics® Lab V50 kits: Virus harvesting in one step. Kits combine a vacuum filtration unit, Sartolab® RF 50 with a 0.45 µm PES membrane, and a filter aid for clarification.

Concentration and Purification of Viruses
Vivapure® Virus Purification and Concentration Kits. Adenovirus Purification with AdenoPACK kits and Lentivirus Purification with LentiSELECT kits

Pharma Compliant Weighing
Cubis® II Premium Lab Balances. Sartorius’s Cubis® II is designed to follow US FDA data integrity principles that require data to be accurate, legible, contemporaneous, original, and attributable (ALCOA). The Cubis® II balance, with pharma package, contains all the technical controls to support full compliance with common regulations.

See more Sample Preparation Solutions!
sartorius.com/en/applications/quality-control-testing/sample-preparation-qc

Service and Training
A comprehensive offering that includes qualified personnel, ensuring high-quality results and optimal operation.

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