# Microbiological Quality Control Throughout the Biopharma Production Process

## Process Development

#### Bioburden Control

#### USP <61>, <62> & <1231>

Quantify microbial contamination with touch-free membrane transfer to agar.



Regulation-compliant methods for monitoring your bioproduction process for bacterial contamination.

**Microbial Enumeration Tests** USP <61> | <62> | <1231>

### Pharmaceutical Bioburden Testing

The following paper provides an overview on bioburden and microbial contamination testing, including a discussion of common procedures and newer, more rapid methods.

DOI: 10.1002/9780470054581.eib655

#### Microsart®@filter and Microsart®@media system

Membrane filtration is the method-ofchoice for detecting and quantifying microorganisms in liquid culture.

#### Microbiological Quality Control

Sartorius offers easy-to-use, smart solutions for your pharmaceutical QC process, including sampling, detecting, and counting microorganisms.

## **Upstream**

## Mycoplasma Detection

#### USP <63> | EP 2.6.7

Test for mycoplasma contamination in your bioreactor. Get your answer within 3 hrs (not 28 days).



Use our fully compliant qPCR-based test to detect even weak mycoplasma contamination, easily, rapidly, and reliably.

USP <61> | <62> | <1231>

#### A PCR Mycoplasma **Detection Method**

The following paper discusses a rapid method for detecting mycoplasma contamination. This method reduces the testing time by 2 weeks, and shows comparable sensitivity to the current agar-based detection methods.

DOI: 10.1002/9780470054581.eib655

#### Microsart® Mycoplasma qPCR detection kits

Mycoplasma qPCR detection assays offer gold standard performance for your pharmaceutical QC processes...

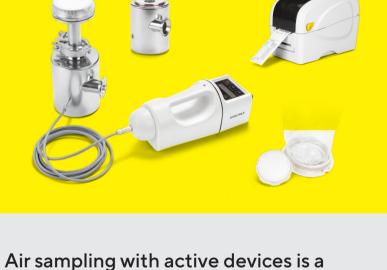
## Downstream

## Microbial Air Monitoring

## USP <1116>

#### **EU GMP Annex 1** Monitor your clean-room environment

for 8 hours non-stop.



commonly-used method for environmental monitoring USP <1116> | EU GMP Annex 1

Assessment of the MD8

## Microbiological Air Sampler The gelatine filters used in our MD8 Air

Sampler recovered monodispersed aerosols with 99.9995% efficiency. The flexible hose design makes the MD8 suitable for microbial monitoring in laminar flow hoods and isolators.

DOI: 10.1111/j.1365-2672.1996.tb03252.x

#### Gelatine filter disposables (membrane and holder) for use with the MD8 are

Gelatine Membrane Filters (GMF)

individually packed, pre-sterilized, and MD8 Airscan®

ready-to-use. Rule out false negative results with the MD8 Airscan®. The MD8 provides nonstop, active air monitoring over at least 8 hours with a single gelatine membrane.

The USP-approved filter retains the

allows monitoring of viability.

smallest airborne microorganisms, and

# Fill + Finish

## USP <71> | EP 2.6.1

Sterility Testing

## Sample your product aseptically

to ensure sterility.



with regulation-compliant sterility testing. USP <71> | EP 2.6.1

Get proof-of-sterility before batch-release

### Sterility Testing in Antibody Production Maintaining sterility between a perfusion

bioreactor and the capture step is critical. Read this study to see a good solution. DOI: 10.1002/bit.26069

Sterisart® Family Consumables

user software.

Ensure aseptic transfer of liquids with Sterisart® Septum technology. Your sample remains safely protected against contamination due to the septum's sterile barrier, while also minimizing the risk of puncture injuries during sample injection due to the simple piercing mechanism.

Sterisart® Universal Pumps Our peristaltic pump can be used in clean rooms, integrated into clean benches, or installed countersunk in the working surface of isolators. The pump is available

as an upgraded version with display and