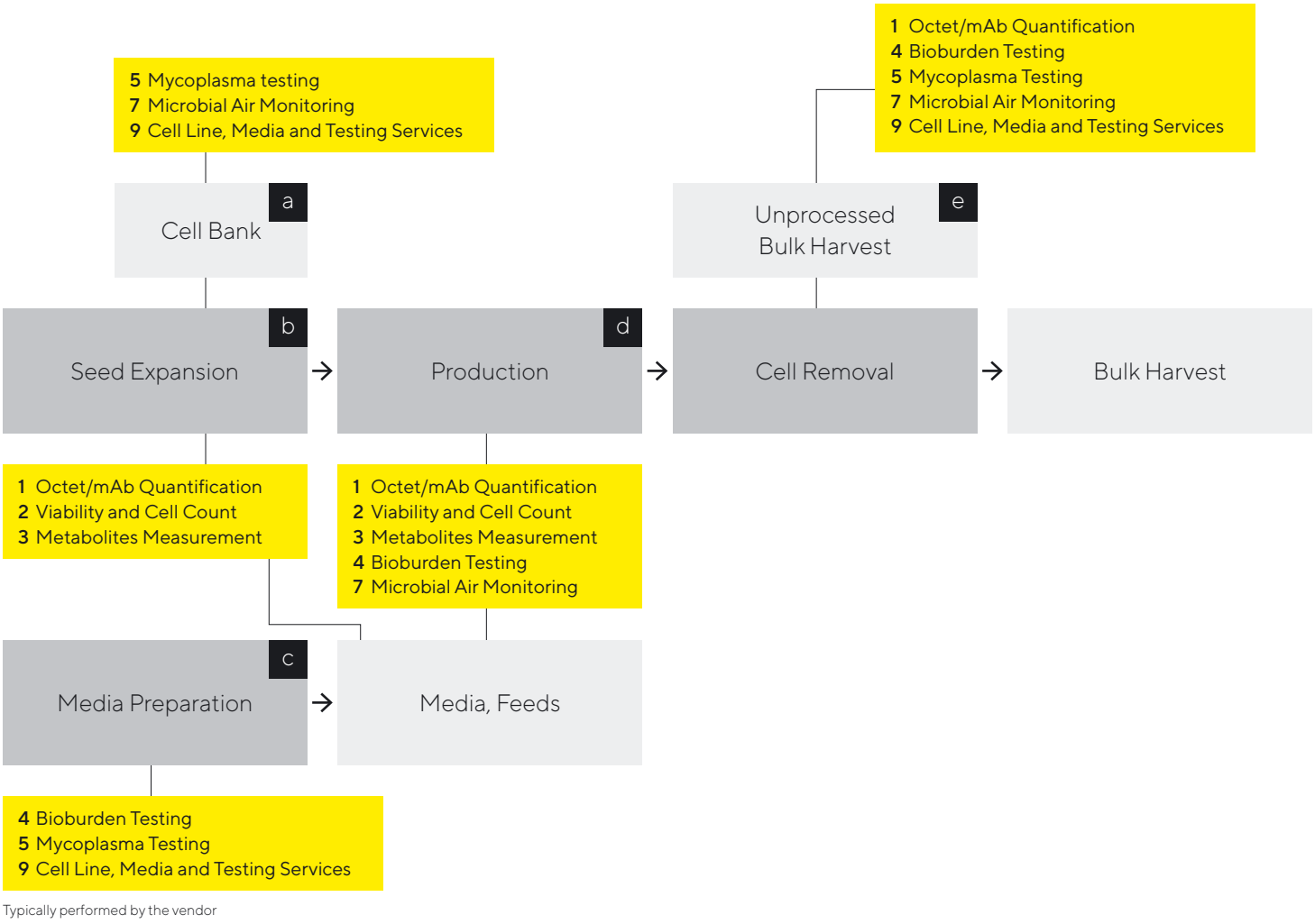
Quality Control of Monoclonal Antibody Production Process

Simplifying Progress

SARTORIUS

Sartorius QC Solutions

Upstream Process



Typically performed by the vendor

Your Application

1
OCTET GxP Solutions

GxP compliant solution for stability indicating and product lot release testing through ligand binding and potency assays as well as in-process testing including host cell protein (HCP) and residual protein A (RPA) detection.

Process Steps: b d e g h k

2
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: b d

3
Metabolite Measurement

Gives information about the productivity, biochemical status, and lifecycle of your cells. Allows automated feed control based on glucose measurements.

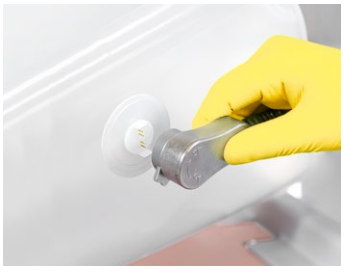
Process Steps: b d

Sartorius Solutions

GxP compliant Octet Systems; includes 21 CFR part 11 software, IQ | OQ and PQ kits. For mAb quantitation, potency and specificity to target analysis

Increase your analytical testing capacity

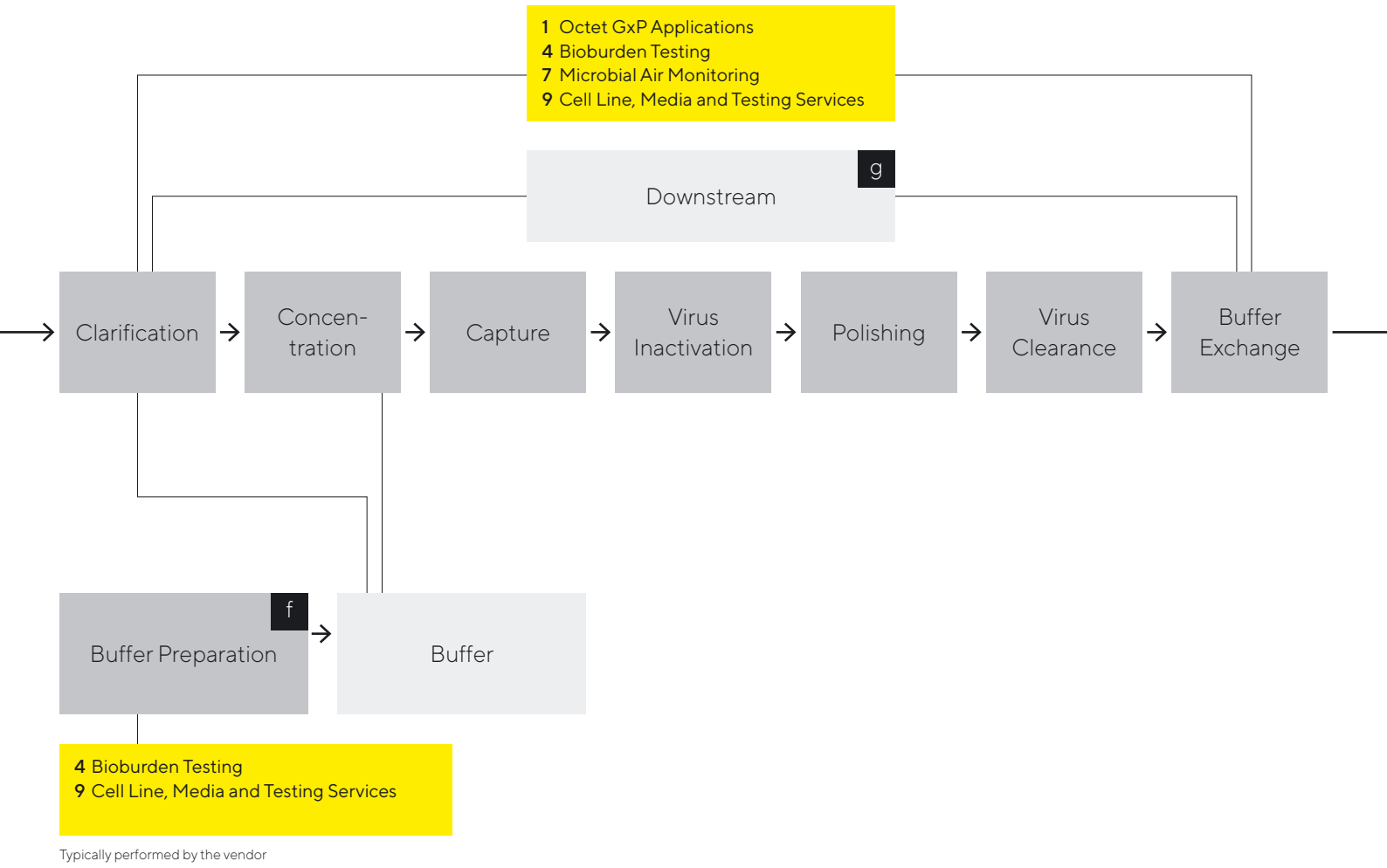
In-line monitoring and control of viable biomass in cell culture processes with BioPAT® ViaMass



Fully automated control of the cultivation process

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

Downstream Process



Typically performed by the vendor

4
Microbial Contamination Control
Bioburden Testing | Rapid Testing

Count the number of microbes in your sample using touchfree membrane transfer to agar or alternatively a rapid PCR-based total bacteria and fungi test.

Process Steps: c d e f g h i j

Microsart @filter and @media membrane filtration method for forceps-free and effortless membrane transfer

Minimize risk of cross-contamination

Rapid microbial contamination control based on qPCR

Know results in just 3 hours

5
Mycoplasma Detection

Detect mycoplasma within hours.

Process Steps: a c e

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

Reduce time-to-result significantly

6
Sterility Testing

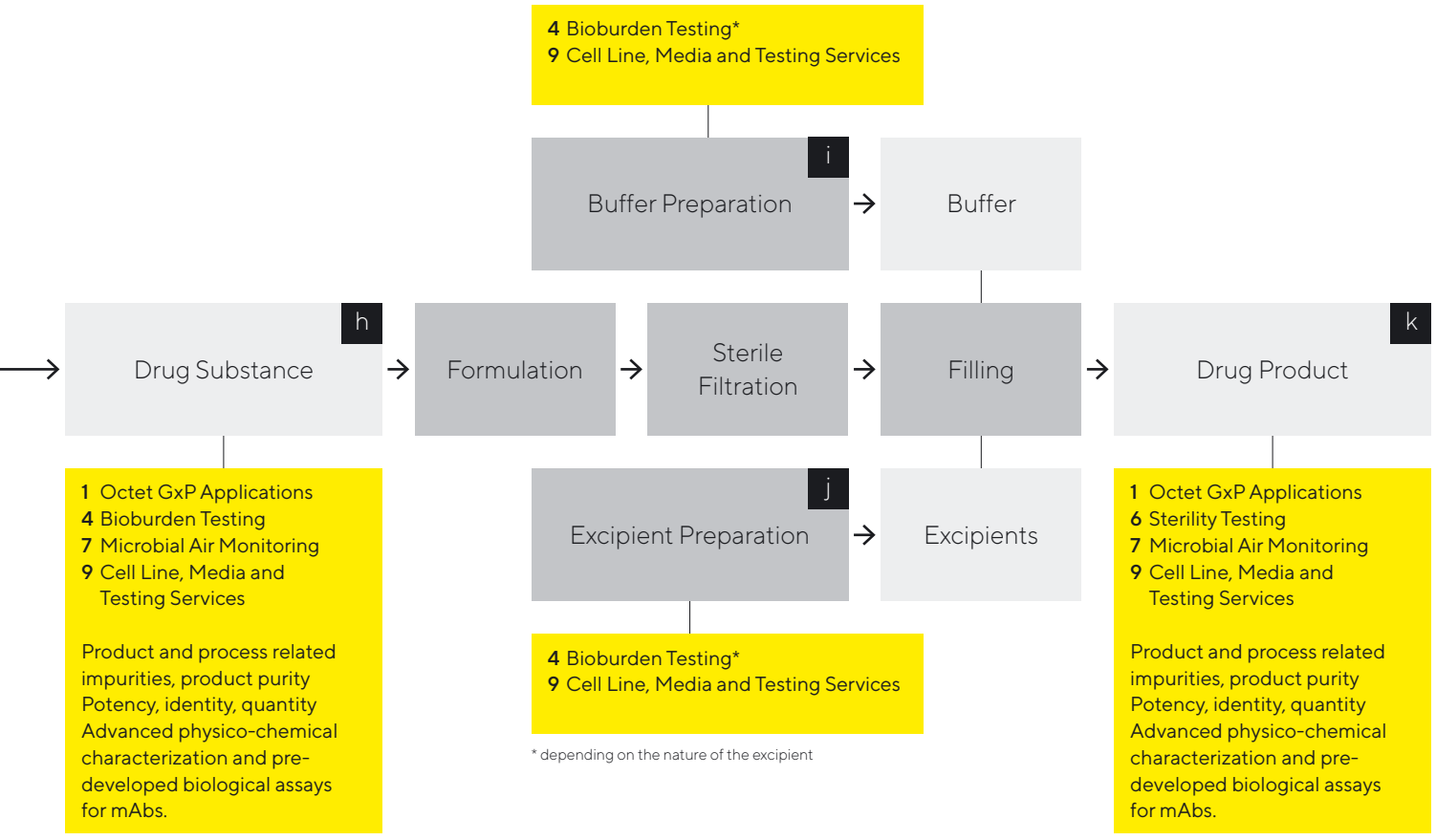
Confirm that your products are sterile and free of any microbial contamination using the closed-system membrane filtration method.

Process Steps: k

Batch release sterility testing with the Sterisart® NF canisters and Universal pump in compliance with international pharmacopeia

Easy handling and reliable test results

Fill and Finish



7
Microbial Air Monitoring

Quantitative detection of airborne microorganism.

Process Steps: a d e g h k

specified rooms, clean rooms and filling lines

Active air monitoring with MD8 Airscan® – agar-free, continuous air monitoring with gelatine membrane filter

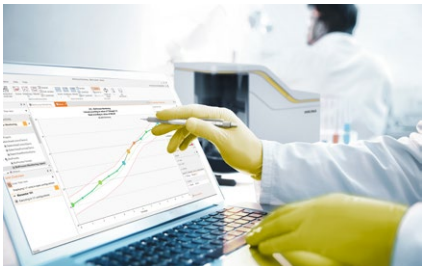
Ensure the most accurate data over an 8 hour period

8
Data Analytics

Analysis and interpretation of complex data.

Process Steps:
throughout the manufacturing process

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



Identify efficiently critical process parameters

9
Cell Line, Media, and Testing Service

Sartorius Cell Line and Media Testing Solutions (CMTS) combines Cell Line Development with Media provision, Cell Bank Manufacture and Testing, and Biosafety Testing and Characterisation of your mAb product. Our testing team specialise in ready to use solutions in biosafety, biological activity, physico-chemical and structural analyses of mAbs.

Process Steps: a c e f g h i j k

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

Product Characterization: PhysChem, ADCC, CDC, ADCP, Binding kinetics, cell based potency assays.

Release your final product safer and more cost-effectively

Growing in Importance

As the significance of biopharmaceuticals continues to rise, so does the need for analytical testing. Due to their complexity, QC testing of biopharmaceuticals is often even more challenging than for classical pharmaceutical drugs. Within the biopharmaceutical market, monoclonal antibodies have been widely adopted due to their ability to offer specifically targeted treatment and fewer side effects.

Quality Control Testing in the Production of Monoclonal Antibodies (mAbs)

Ensuring That Your Product Is Safe, Effective and Pure.

Are you looking for more confidence in your quality testing? Compliance is the basis for this. To support your daily routine work we offer you

- simplified workflows
- accelerated time to results
- reduced risk of contaminations

The following figure shows a generic workflow for monoclonal antibody (mAb) production with analysis points for quality control applications.

Take a look at the workflow-application map and see where our products and services can help you overcome your quality control challenges.

Raw material testing | In-process control | Final release

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.

Buffer and Standard Preparation
Semi-automatic preparation and documentation of highly reproducible HPLC calibration standards with the Cubis® MSA high capacity micro balance.

Arium® Type 1 Ultrapure Water Systems
The Arium® UV and Arium® Pro ultrapure lab water systems provide high quality Type 1 water for analytic and life science application.

Clarification and Sterile Filtration with Sartoclear Dynamics® Lab V50 kits: harvesting in one step.
Kits combine a vacuum filtration unit, Sartolab® RF 50 with either a 0.2 µm or a 0.45 µm PES membrane, and a filter aid for clarification.

Clarification or Sterile Filtration of media and aqueous solution up to 5 Liters with pressure filtration units
Sartolab® P20 & Sartolab® P20 Plus units.

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!
www.sartorius.com

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

Germany
Sartorius Lab Instruments GmbH & Co. KG
Otto-Brenner-Strasse 20
37079 Goettingen
Phone +49 551 308 0

USA
Sartorius Corporation
565 Johnson Avenue
Bohemia, NY 11716
Phone +1 631 254 4249
Toll-free +1 800 635 2906

For further contacts, visit
www.sartorius.com