Antibody Manufacturing Powered by Proven Biomanufacturing Excellence

Leveraging Established Protein, Vaccine and Viral Platforms for High-Performance Antibody Production

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Why antibody programs fail at scale

1. **Process variability**
   Cell growth inconsistency, titer drift, shifting impurity profiles
2. **Downstream bottlenecks**
   Capture capacity limits, filtration constraints, polishing challenges
3. **Viral safety gaps**
   Not just clearance steps—but the strength of the supporting data
4. **DS–DP handoff risk**
   Timing misalignment, assay readiness, stability and aseptic readiness

A Strong Proven Foundation for Antibody Experience

Transferable core capabilities across biologics modalities

Shared bioprocessing principles:

- Mammalian upstream platforms
- Scalable and standardized purification technologies
- Validated, inspection-ready GMP operations
- Advanced analytics & quality systems

IDT Biologika applies validated experience across proteins, cell culture, microbial systems, and viral platforms to deliver scalable antibody manufacturing from development to clinical supply.

Structured progression from development to GMP supply

MS1	MS2	MS3	MS4
Manufacturability	**Foundation**	**Engineering**	**Supply**
>5 g/L	MCB released	Engineering runs	GMP batches

Established Platforms for Antibody Manufacturing

Upstream, Downstream and Scale-Up

Upstream Process Development

- Mammalian cell culture expertise (CHO, HEK293, Vero)
- Fed-batch process development and optimization
- Scale-up and scale-down models
- Suspension and fixed bed bioreactor technologies
- Seamless tech transfer into GMP manufacturing

Downstream Processing & Purification

- Platform chromatography systems (ÄKTA-based)
- Tangential flow filtration (TFF)
- Virus clearance strategies
- Single-use and multi-use purification trains
- Reliable impurity removal (host cell proteins, DNA)

Process Characterization & Validation

- Quality by Design (QbD) driven development approaches
- DoE based parameter definition and optimization
- Process characterization for Phase III and PPQ
- Continuous process validation
- Risk-based assessments (FMEA)

Process Development	Clinical Manufacturing	Commercial Manufacturing
• Process design	• GMP manufacturing	• GMP scale-up
• Scale down models	• Tech transfer	• PPQ / validation
• Analytical Development	• Process characterization	• Lifecycle management

Tech Transfer → GMP scale-up

GMP Manufacturing Excellence as a Key Enabler

- Fully integrated Drug Substance and Drug Product manufacturing on one campus
- Clinical and commercial scale operations within a single quality system
- 4,500+ GMP batches manufactured in recent years
- Regular, successful inspections by FDA, EMA and other global authorities
- Automated aseptic fill-finish for vials and prefilled syringes

This operational and regulatory infrastructure is purpose built to support high performing antibody programs.

CORE ANTIBODY MANUFACTURING PLATFORMS

Mammalian Expression Systems
CHO-based production platforms

Stirred Tank Reactors
Single-use & stainless-steel bioreactors

Scalable GMP Platforms
Clinical to commercial scale

SUPPORTING & COMPLEMENTARY PLATFORMS

- Fixed-bed & microcarrier systems
- Roller bottles (supportive use)
- Viral & microbial manufacturing platforms

Analytics and Quality Systems That Strengthen Antibody Manufacturing

Advanced analytics are integral to robust antibody process control and regulatory confidence.

- In-process testing (protein, DNA, impurities)
- Release & stability testing
- Protein characterization (purity, aggregation, potency)
- Fully integrated GMP quality control systems

Next Generation Sequencing → Differentiator
Next Generation Sequencing (NGS) is an advanced analytical tool enabling sensitive detection and characterization of genetic material to support viral safety and process understanding.

- Viral safety
- Adventitious agent detection

Why programs succeed

1. **Structured tech transfer**
2. **Parallel analytics development**
3. **Integrated QC execution**

This execution discipline prevents risk from compounding as programs scale.

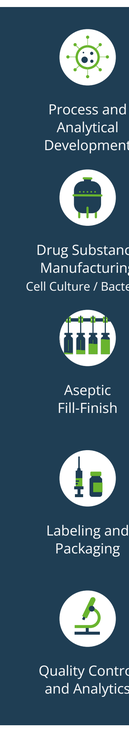
Take-Home Message

Proven biomanufacturing excellence is the foundation of successful antibody manufacturing.

IDT Biologika delivers antibody programs through:

- Established, scalable biomanufacturing platforms
- Deep GMP and regulatory experience
- Integrated development, drug substance, and drug product manufacturing
- Advanced analytics that support confident decision-making

IDT Biologika is a partner built for antibody execution.



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