



IDT BIOLOGIKA, ROCKVILLE MD

**Contract Development and Manufacturing
of Vaccines, Gene & Immune Therapeutics
and Oncolytic Viruses**

www.idt-biologika.com



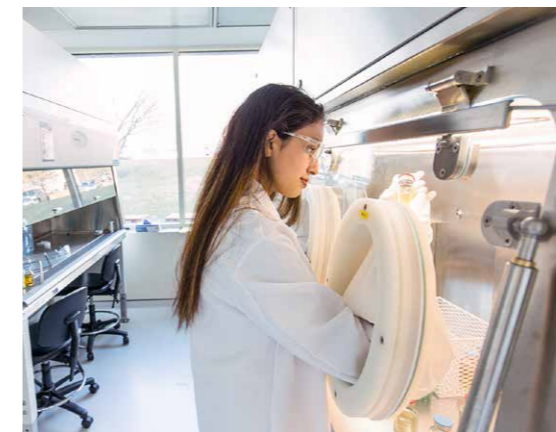
IDT Biologika at a Glance

IDT Biologika is a globally operating biopharmaceutical CDMO that specializes in the Contract Development and Manufacturing of Live Viral Vaccines, Viral Vectors for Gene and Immune Therapeutics, Oncolytic viruses and recombinant proteins including virus-like particles. Through the utilization of its innovative technologies, the company helps its clients to advance their prophylactic and therapeutic products to treat serious diseases that impact human health worldwide.

With 100 years of experience and access to cutting-edge technologies, the company has a long-standing history working with multinational, leading pharmaceutical and biotechnology companies, vaccine developers and government agencies.

DID YOU KNOW?

Rockville is closely integrated with our facility in Germany, so if needed, we can transfer a process after clinical trial material production to Dessau-Rosslau for Phase III and commercial production.



OUR cGMP MANUFACTURING SERVICES AND TECHNOLOGIES INCLUDE:

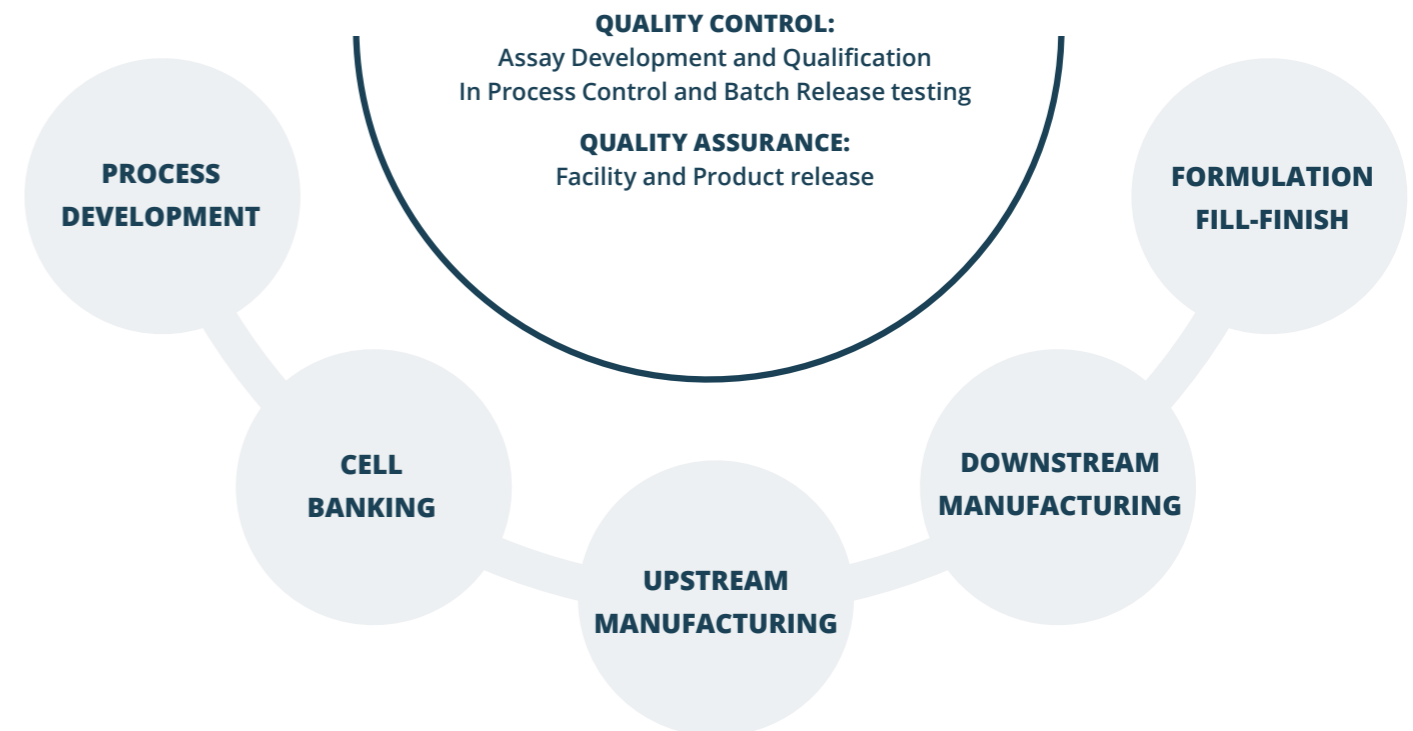
- Process Development
- Process Transfer
- Drug Substance Manufacturing
- Formulation Development
- Vial Filling (liquid)
- Lyophilization
- Adherent Technologies
- Suspension Technologies
- Aseptic Processing
- Release Testing
- Stability Testing

Legacy in Biologics Contract Manufacturing

CDMO PARTNER FOR PRECLINICAL DEVELOPMENT AND CLINICAL TRIAL MATERIALS PHASES I-II

The IDT Biologika US site in Rockville, MD has a long history of biologics contract manufacturing using state-of-the-art technologies to develop and manufacture clinical trial materials for viral vaccines, gene & immune therapeutics, oncolytic viruses and recombinant proteins. We provide clinical phase I-II manufacturing, which is convenient for customers located in North America.

Core Capabilities Phases I & II





Our Sites in the USA and Germany

IDT Biologika is a global CDMO offering extensive contract services for Viral Vaccines, Gene and Immune Therapeutics and Biologics from process development through clinical phases I-III, as well as commercial manufacturing in its sites in the US and in Germany.



In Rockville, MD, USA we utilize broad capabilities and a depth of technologies for process development and manufacturing of clinical trial material for phases I-II manufacturing.



In Dessau-Rosslau, Germany we operate one of Europe's premier integrated biopharmaceutical development and manufacturing facilities for end-to-end services from process development through clinical phases I-III to commercial.

Cell Lines & Virus Experience

IDT Biologika Rockville has experience with a wide range of different cell lines and viruses.

CELL LINES	VACCINES AND VIRAL VECTORS	
• Vero	• Adenovirus	• Orthopoxvirus
• DF-1	• Vesiculovirus	• Morbillivirus
• MRC-5	• Lyssavirus	• Arenavirus
• HEK-293	• Baculovirus	• Retrovirus
• CHO	• Cytomegalovirus	• Avipoxvirus
• MDCK	• Simian Adenovirus	
• AGE.1CR		
• SF9		
• PER.C6		
NEW TECHNOLOGIES		
<ul style="list-style-type: none"> • The site is developing a pilot process for Lentivirus manufacturing and analysis. • Viral and cell line potency, content, and expression by flow cytometry and HPLC-(FLD/RI) 		



Process Development Technologies

UPSTREAM

- Cell Line & Media Development
- Cell & Virus Banking
- Transfections & Infections
- Cell / Virus Production
 - Sartorius 50L/200L STR, Eppendorf 310 & 320
 - Rocking Bioreactor (≤ 25L) – Sartorius Wave
 - Fixed-bed Bioreactors (≤ 8m²) iCELLis Nano

DOWNSTREAM

- Cell Lysis / Homogenization
- Resin and Buffer Screening
 - ÄKTA Chromatography Systems
- Filter/Membrane Screening
 - Forward Flow Filtration (depth filtration, sterile filtration & nano filtration)
 - Tangential Flow Filtration (hollow fibers & flat sheets)
 - Single-use Cross Flow TFF System
 - Manual TFF set ups

FORMULATION

- Excipient and Buffer Screening for liquid and heat-stable Formulations
 - Analytical Characterization (DSF, DSC, DLS, HIAC, FDM)
- Lyo-Cycle Development
 - Pilot scale Lyo up to 900 vials (DIN2R)
- Force Degradation
 - Stress Studies and in-use Stability

Thanks to the strong growth in demand for high quality manufacturing services for biotechnological products, especially in the area of therapeutic and prophylactic vaccines, IDT Biologika will continue to invest in additional manufacturing capacities as well as in the development of innovative manufacturing technologies.

WE STRIVE FOR STRONG, TRUSTING AND ENDURING CLIENT PARTNERSHIPS

Working with World's Leading Biopharma Companies and the US government

International companies in the biopharmaceutical industry trust IDT Biologika for its expertise, reliability and years of experience in the manufacturing of vaccines and other biological products. IDT Biologika is unique in its ability to accommodate the development, testing and manufacture of viral vaccines, gene and immune therapeutics and other biological products for the world's leading biopharmaceutical companies. Our track record of success is evident in our longstanding 100 year+ history – working with multi-national pharmaceutical and biotechnology companies, vaccine developers and governments.

Our most important assets are our employees, whose expertise and collaborative nature complement our innovative technologies, resulting in high quality customer service and satisfaction.

Drug Substance GMP Manufacturing

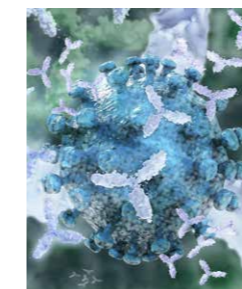
UPSTREAM TECHNOLOGY		
Rocking Motion Bioreactors <ul style="list-style-type: none"> 50L/100L wave bag 	Single-Use Bioreactors <ul style="list-style-type: none"> 50 /200L twin 200L STR 	Stationary – Flatware <ul style="list-style-type: none"> HS-12 HS-36 CS-10
DOWNSTREAM TECHNOLOGY		
Chromatography <ul style="list-style-type: none"> Äkta Process ÄktaReady 	Tangential Flow Filtration <ul style="list-style-type: none"> Sartorius FlexAct ÄktaReady – Flux 	BDS Production <ul style="list-style-type: none"> Standard Processing Aseptic Processing (closed system)

Drug Product GMP Manufacturing

ASEPTIC – LIQUID & SUSPENSIONS	CLINICAL SCALE	LYOPHILIZATION
<ul style="list-style-type: none"> Formulation Development Vials – 2R, CZ vials, other vial sizes (5,10, 20R feasible) 	<ul style="list-style-type: none"> Semi-Automated fill (up to 2,000 2R vials) <ul style="list-style-type: none"> Flexicon pump with single use filling assembly Fully-automated fill (up to 8,000 2R vials) <ul style="list-style-type: none"> M&O Perry FSC (filling, stoppering, capping machine) Integrated Flexicon pump utilizing single use filling assembly 	<ul style="list-style-type: none"> GMP Millrock Lyophilizer – SIP/CIP <ul style="list-style-type: none"> Lyophilization (up to 4,000 2R vials) 1.5 sqm

Analytical Testing Capabilities

ACTIVITY AND PURITY	POTENCY AND IDENTITY	CONTENT AND SAFETY
<ul style="list-style-type: none"> HPLC Assays <ul style="list-style-type: none"> Agilent DAD, FLD, RID SE, IEX, RP/HILIC, Mixed-mode Viral Particle Quantitation Plasmid Purity Product and Process Impurities Cell-based Bioassays <ul style="list-style-type: none"> Agilent Penteon Flow cytometry ELISA / Competitive ELISA Western Blotting Transgene Expression Cell Killing / Proliferation assays Metabolic assays Enzyme Kinetics Vi-Cell Enumeration Particle Characterization <ul style="list-style-type: none"> ZetaSizer / DLS HIAC Light Obscuration 	<ul style="list-style-type: none"> Viral Titration Assays <ul style="list-style-type: none"> Infectivity: Plaque, FFA/IFA, TCID₅₀ Genomes: qPCR / qRT-PCR Particles: SDS-A260, AEX, ELISA Cell and Viral Characterization <ul style="list-style-type: none"> Identity by PCR, qPCR, RFLP, RAPD Vector Copy Number Transformation Efficiency Vector / Genetic Stability Replication Competency testing Empty Capsid assays (E:F ratio) Flow-based expression assays Host-cell contaminants (HCP, HCD) Electrophoretics and Imaging <ul style="list-style-type: none"> SDS-PAGE, AGE, IEF, 2D Western and Southern Blots 	<ul style="list-style-type: none"> Spectroscopy <ul style="list-style-type: none"> Beckman UV-Vis/NIR Shimadzu FT-IR NanoDrop Chemistry <ul style="list-style-type: none"> USP/EP Appearance testing pH, Conductivity, and Osmolality TOC and RI USP/EP Identity testing Water and air / gas quality testing Microbiological Safety <ul style="list-style-type: none"> USP <71> Sterility/B&F testing Mycobacteria / Mycoplasma PCR Bioburden, Coliform, and Gram assays Kinetic Chromogenic LAL-Endotoxin



END-TO-END PARTNER

Expert project teams at IDT Biologika work closely and collaboratively with partner companies to provide customized support and guidance every step of the way. The IDT team is dedicated to providing solutions that cover client's diverse needs. Our project teams have the technical acumen to leverage multiple complex platforms addressing development and manufacturing of the most complex vaccines and biologics. As an end-to-end partner, IDT Biologika offers comprehensive support services, including project management and regulatory affairs.

IDT BIOLOGIKA TAKE HOME MESSAGE

- CDMO Partner for Preclinical Development and Clinical Trial Materials Phases I-II
- Process Transfer for Phase III and Commercial Manufacturing to IDT Biologika Germany
- GMP-compliant (FDA/EMA) BSL-2 Facility
- Expertise with live viral agents and recombinant proteins
- Extensive range of manufacturing platforms
- Cross-trained, flexible workforce

Learn more about partnering with IDT Biologika

INQUIRIES ARE WELCOME

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