IDT BIOLOGIKA

One-Stop-Shop for Contract Development and Manufacturing of Innovative Vaccines and Cell & Gene Therapeutics Fill-Finish of Biologics

Clinical and Commercial Supply

www.idt-biologika.com

Our Sites in Germany and the USA

Dessau-Rosslau, Germany
Magdeburg, Germany
Rockville, MD, USA

At IDT Biologika, we are committed to your development and manufacturing needs for innovative vaccines, cell & gene therapeutics from the early stages of process development to clinical trial materials and commercial manufacturing, and for fill-finish of other biologics.

In Rockville, MD, USA we utilize a broad range of capabilities and a depth of technological expertise for process development and manufacturing of clinical trial materials for phases I–II.

In Dessau-Rosslau and Magdeburg, 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 manufacturing.

Year Founded
1921

Management
Dr. Jürgen Betzing, CEO
Dr. Ulrich Valley, Managing Director, COO

Employees
More than 1,850 people
in Germany and the USA

Recent Awards
- CDMO Leadership Awards (2023)
- CMO Leadership Awards (2022–2017, 2015, 2013)
- Vaccine Industry Excellence Awards (2021, 2019, 2018)

IDT Biologika at a Glance

IDT Biologika is a globally operating biopharmaceutical CDMO that specializes in the Contract Development and Manufacturing of vaccines, cell & gene therapeutics, oncolytic viruses, viral vectors, recombinant proteins, and other biologics for sterile liquid and lyophilized products. Through the utilization of our innovative technologies, we help our clients to advance their prophylactic and therapeutic products to treat serious diseases that impact human health worldwide.

Headquartered in Dessau-Rosslau, Germany, with operations in the United States, IDT Biologika is a family-owned company that has achieved a well-earned reputation for deep know how and experience, innovative technology, and impeccable quality.

Working with World's Leading Biopharma Companies

With more than 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.

They trust us for our expertise, reliability and years of experience in the manufacturing of vaccines and other biological products. Many human vaccines developed by us, together with international partners, are already in use, fighting infectious diseases such as SARS-Cov2, smallpox, AIDS, malaria, dengue fever, ebola, chikungunya and pandemic influenza.

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

Did You Know?

IDT Biologika has more than 100 years of expertise in developing and manufacturing vaccines.

Innovative Vaccines

- Viral Vaccines
- Viral Vectors
- Recombinant Vaccines

Cell & Gene Therapeutics

- Oncolytic Viruses
- Viral Vectors
- Allogenic Cell Therapy

Fill-Finish of other Biologics

- Liquid Filling and Lyophilization
- Automated Visual Inspection
- Labeling, Packaging, Serialization

Our Services

IDT Biologika is a global contract development and manufacturing organization for innovative vaccines, cell & gene therapeutics, and fill-finish of other biologics.

Our end-to-end services include process development, drug substance manufacturing up to BSL-2, sterile liquid dosage filling and lyophilization, labeling and packaging, quality control and analytics.

We offer you a B2B single source CDMO partner at our sites in Germany and the USA, with seamless end-to-end solutions and the ability to nimbly scale projects from development through to commercialization. We handle every step in manufacturing and packaging of small clinical batches and large-scale commercial products.

Our fully integrated services are underscored by our commitment to quality and operational excellence that flows through our best-in-class process and cGMP (BSL-2) manufacturing capabilities meeting FDA, EMA and ANVISA standards.

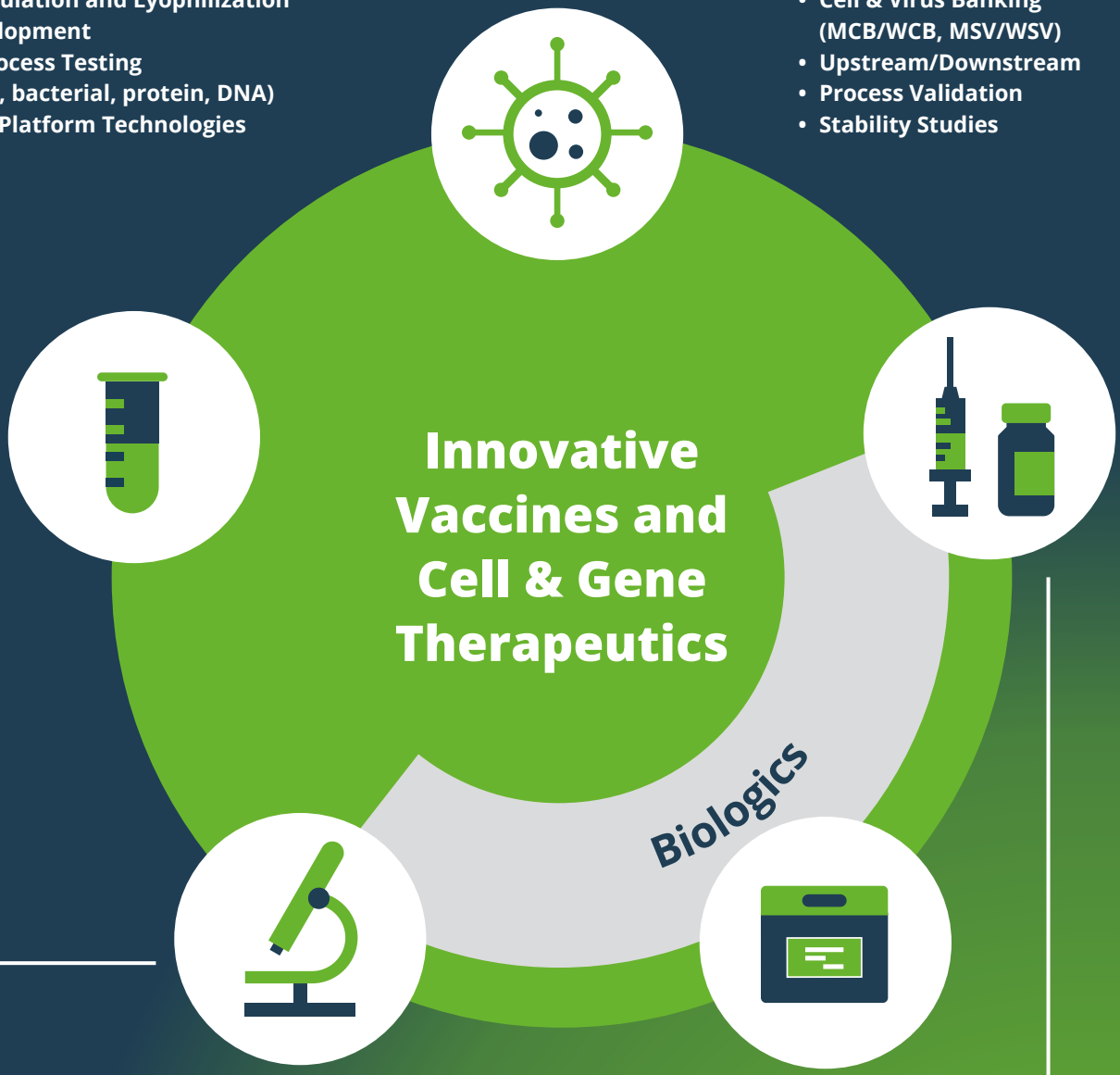
At IDT Biologika we have the quality and supply mindset to provide reliable high quality services on your products and your needs to speed them to the market.

Process Development

- Process Transfer, Development, Verification, Qualification and Validation
- Formulation and Lyophilization Development
- In-Process Testing (viral, bacterial, protein, DNA)
- New Platform Technologies

Drug Substance Manufacturing

- Transfer of Customer Technologies
- Cell Line Development
- Cell & Virus Banking (MCB/WCB, MSV/WSV)
- Upstream/Downstream
- Process Validation
- Stability Studies



Quality Control and Analytics

- Method Transfer, Development, Verification, Qualification and Validation
- Raw Material Testing and Release
- In-Process Testing
- Batch Release Testing
- Stability Studies
- Environmental Monitoring
- Utility Monitoring
- Cleaning Validation & Analytics

Labeling and Packaging

- Technology Development
- Labeling, Blistering, Packaging of Vials and Pre-filled Syringes
- Safety Device Assembly Labeling, Packaging
- Pen/auto injector Assembly and Packaging
- Combination Products
- Serialization (Track and Trace)
- Code Reading Systems
- Storage between -65 and 25 °C (-85 and 77 F)

Aseptic Fill-Finish

- Process Transfer
- Bulk Formulation
- Aseptic Filling
- Lyophilization
- Visual Inspection (automated, semi-automated and manual)

Development Services

Process Development

Our process development team of scientists and engineers is highly experienced in the development of cell culture technologies and virus production, including complex upstream, downstream and formulation processes, to speed up clinical development and time to market. We help you to overcome challenges with your products by defining the appropriate technologies and employing our experience to define a process that works best and can be scaled. For this, we can choose between different analytical methods and a broad range of different upstream and downstream technologies as well as formulation strategies to really design the process according to its overall project needs.

Viral Vectors

We are highly involved in the latest developments and use of recombinant and non-recombinant prophylactic live viral vectors for immunotherapeutic use. Major viral platform vectors are:

Viral Vectors Vaccines

- MVA / Vaccinia Virus
- Orthopoxvirus
- Adenovirus
- Avipoxvirus
- Vesiculovirus
- Measles Virus
- Lyssavirus
- Herpes Simplex Virus
- Baculovirus
- Cytomegalovirus
- Morbillivirus
- Retrovirus
- Arenavirus

Viral Vectors Cell & Gene Therapeutics

- Adeno Associated Virus
- Lentivirus
- Lentiviral Vectors

Our Expertise

MVA Know-How
IDT Biologika is globally leading in MVA (Modified Vaccinia Ankara) and recombinant and non-recombinant poxvirus technologies and aseptic processing.

Fluorescent Activated Cell Sorter (FACS)
Fluorescence based flow cytometer for cell based potency determination and characterization of viral vaccines:

- More rapid and more objective analysis than conventional plaque forming cells and dilution techniques

Adventitious Agents Testing (AVT)
Based on Next Generation Sequencing (NGS) technology using a self-developed bioinformatics analysis pipeline. Advantages:

- Generic assay with lower matrix effects
- Highly sensitive test
- More rapid testing at lower costs than conventional testing using in-vitro tests, cell culture tests and animal experiments

Cell Lines

Cell Banking
During process development for viral vaccines and vectors, we offer manufacturing and, for selected cell lines, provide characterized master cell banks (MCB) and working cell banks (WCB) for GMP production. MCBs and WCBs are characterized according to current regulations and used throughout the lifecycle of the product.

Use of Our Cell Lines
We provide own cell lines which are already characterized and accepted by regulatory authorities. When you decide on using our cell lines, we can get started quickly with a GMP process for your product, taking advantage of the investments IDT Biologika has already made. Especially if you are at a very early stage in preclinical development, it is a faster and more advantageous approach to use one of these cell lines.

Cell Lines in Use

VERO | DF-1 | AGE1.CR | MRC-5 | HEK-293 | SF9 | CHO | MDCK | PER.C6

Analytical Development

Our analytical services cover early process development through scale-up to commercial manufacture, ensuring end-to-end consistency and comparability of data throughout the lifecycle of your product. These include method development, transfer, optimization, qualification and validation according to ICH Q2R1 / VICH/ EP/ USP, raw material testing and release, in-process testing (viral, bacterial, protein and DNA), release testing, stability testing, as well as cleaning and validation analytics.

Special know how and capabilities in Adventigious Agents Testing (AVT) based on Next Generation Sequencing (NGS), and Fluorescent Activated Cell Sorting (FACS) are one of our outstanding expertises.

Process Design

Process Validation

Upstream Process Development

Downstream Process Development

Formulation and Lyophilization Development

Assay Development

Production Technologies

At IDT Biologika, we have the capability to manufacture live vaccines as recombinant vector vaccines or as live attenuated virus vaccines. For cell & gene therapeutics we provide viral vectors and oncolytic viruses. For other biologics, we are well known for reliable and high-quality fill-finish and packaging.
We utilize the latest, most advanced technologies in the safe handling and production in comply with GMP requirements and handle every step in manufacturing and quality control processes.
The demands of avoiding any contamination are higher than usual with live agents, especially during changeovers. That is why we prefer to use single-use equipment including disposable mixing systems in areas with product contact.

Aseptic Fill-Finish Technologies

Aseptic filling of vials, including lyophilization, and of pre-filled syringes are our core competencies. We integrate them when we are manufacturing drug substance. We also offer fill-finish as a standalone service for a range of biologics.

Fill/Finish	• Vials 2R–20R for clinical and commercial use, glass or plastic vials • Syringes 0.5–3 mL for clinical and commercial use
Lyophilization	• Vials for clinical and commercial use • Freeze-dryer capacity up to 430 sq.ft. • Syringes 0.5–5 mL for clinical and commercial use

INCREASED CAPACITIES

We respond to the strong growth in demand for high quality manufacturing services and continuously invest in new manufacturing capacities and in the development of innovative technologies.

Available Now
NEW DRUG SUBSTANCE CAPACITIES
NEW HIGH-SPEED FILLING LINE

Drug Substance Technologies

In Drug Substance Manufacturing, we provide master/working cell banks, master/working virus seeds, manufacture of bulk drug substance, and multiple manufacturing platforms. Working with our clients, we have been involved in the GMP manufacture of many of the world's most notable vaccines developed over the last two decades.

Upstream Technologies

Rocking Motion Bioreactors	50 L/100 L wave bag
Single-Use Bioreactors	• 50 /200 L twin • 200 L STR
Cell Factories	• CF 10 and CF 40 • up to 32 x CF 40 / batch • compatible robot
Hyper Stack Cell Factories	• HS-12 • HS-36 • CS-10
Stirred Tank Reactor	• 1 x 50 L single-use STR (10 L–50 L batch vol.) • 6 x 200 L single-use STRs (50 L–200 L batch vol.) • 2–6 x 2,000 L single- use STRs (also with Microcarrier Technology)
Fixed-Bed Bioreactors	• iCELLis® • 9 x iCELLis® nano • 5 x iCELLis® 500 • UNIVERCELLS Technologies • Scale-X™ carbo (up to 30 m²) • NevoLine™ (up to 600 m²)
Stainless Steel Bioreactors	up to 800 L
Single-use Stirred Bioreactors	PD: The Ambr® 250 HT, SciVario® GMP: Biostat STR® up to 200 L, Allegro™ up to 2,000 L
Microcarrier Technology	Available
Roller Bottles	• up to 500 roller bottles per batch • robot system

Downstream Technologies

Chromatography	• Äkta systems, scalable from development to commercial • Chromatography with single use systems
Tangential Flow Filtration (TFF)	• Concentration or buffer exchange • Ultra filtration and dia filtration (UFDF) single use system
Centrifugation	Clarification and concentration of up to 12 L per run
Depth Filtration	• Up to 30" filter capsules • Controlled filtration of up to 200 L • Integrated in single use systems
Continuous Flow Centrifugation	• Concentration • Separation • Centrifugation with single use systems

Labeling and Packaging for Clinical and Commercial Supply

At IDT Biologika, our dedicated team is supported by an in-house technology development team to meet best the requirements for your products. Our services for the complete packaging process include:

- Full-, semi-automated and manual capabilities for labeling, blistering and packaging of vials and pre-filled syringes
- High speed multi packaging
- Single and multi-component packages (Kit Packaging)
- Code-reading systems for labels and folding boxes
- Auto injector and safety device assembly and packaging
- Track and Trace systems (Serialization)

We maximize safety through robust GMP processes and dedicated production rooms and provide short holding time at ambient temperature through a one-room solution for visual inspections and clinical packaging.

Visual Inspection

Our fill-finish services include automated, semi-automated and manual inspection of vials (liquid and lyophilized), pre-filled syringes and auto-injectors. Especially for large batch sizes and commercial supply we use a high-performance automated visual inspection line with a capacity of up to 36,000 2R vials per hour.

Quality Control and Analytics

Our quality oversight system is based on the constant monitoring of all relevant GMP guidelines. New developments are integrated into the quality systems to keep all manufacturing activities compliant with regulatory requirements.

Our quality control and analytical development teams support a wide array of analytical technologies needed to develop novel assays for the characterization, release, and stability testing of vaccines and cell & gene therapeutics:

- Method Transfer, Development, Verification, Qualification and Validation
- Raw Material Testing and Release
- In-Process Testing
- Batch Release Testing
- Stability Studies
- Environmental Monitoring
- Utility Monitoring
- Cleaning Validation and Analytics
- Methods: viral, microbiological, molecular-biological, biological, chemico-physical testing

Comprehensive Support Services to Meet Your Needs

Expert project teams at IDT Biologika work closely and collaboratively with you to provide customized support and guidance every step of the way. Our project teams have the technical acumen to leverage multiple complex platforms addressing development and manufacturing of even the most complex cell & gene therapeutics, vaccines and other biologics.

Audits and Client Inspections

Transparent collaboration with our clients is a key aspect in ensuring compliance to regulatory filings. Regular inspections prove that our services are underscored by our commitment to quality and operational excellence that flows through our best-in-class process and cGMP manufacturing capabilities meeting FDA, EMA and ANVISA standards.

- 10 to 15 official inspections annually
- 15 to 20 customer audits annually
- 11 US-FDA inspections in Dessau since 2006
- Last FDA inspection in March 2021

Sustainability

We are committed not only to ensuring the safety and health of our employees and to preserving natural resources but also to go beyond and set our own standards that exceed applicable laws and regulations.
Sustainability is a major goal for IDT Biologika. Our engagement and approach in reaching these targets are underscored by the annual Ecovadis certification.

ecovadis

IDT BIOLOGIKA

Take Home Message

- Contract Development and Manufacturing of Innovative Vaccines, Cell & Gene Therapeutics and Fill-Finish of other sterile liquid and lyophilized Products
- Process Development, Drug Substance Manufacturing up to BSL-2, Aseptic Fill-Finish and Lyophilization, Labeling and Packaging, Quality Control and Analytics
- GMP compliant Manufacturing, meeting FDA, EMA and ANVISA standards
- Clinical Trial Materials and Commercial Presentations
- Vials, Pre-filled Syringes, Pens/Auto Injectors, Combination Products
- Company Sites in Germany and the USA

Learn more about partnering with IDT Biologika

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