



IDT Biologika

Contract Development and
Manufacturing of Live Viral Vaccines,
Viral Vectors for Gene and Immune Therapeutics,
and Fill/Finish of Biologics



Single Source
CDMO Partner
for Clinical Test
Material and
Commercial
Products

Dedicated
to Contract
Development
and Manufacturing

IDT Biologika is a global biopharmaceutical contract development and manufacturing organization (CDMO) that specializes in the production of breakthrough live viral vaccines, viral vectors for gene and immune therapeutics as well as fill/finish of sterile liquid and lyophilized biologics to improve human health worldwide. We offer clients a single source CDMO partner with seamless end-to-end solutions and the ability to nimbly scale projects from development through clinical phases I-III to commercialization.

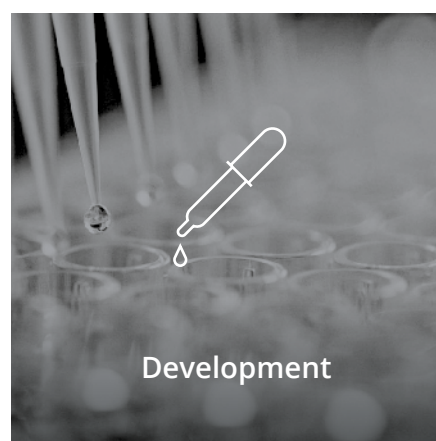
Our fully integrated services are underscored by our commitment to quality and operational excellence that flows through our best-in-class process and cGMP (up to BSL2) manufacturing capabilities meeting EMA and FDA standards (ANVISA ready). On request of our clients we supply their products in vials, pre-filled syringes (with and without safety devices), autoinjectors or as combination products.

Innovative Vaccines & Gene and Immune Therapeutics

Process Development • Drug Substance • Drug Product • Packaging • Quality Control

Biologics

Drug Product • Packaging • Quality Control



Development

- Process Development
- Formulation Development
- New Platform Technologies



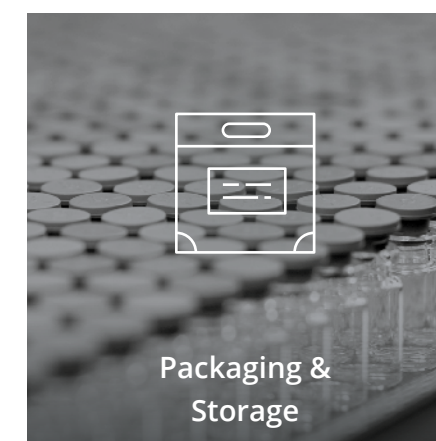
Drug Substance
Manufacturing

- Manufacturing for Preclinical, Clinical and Commercial Supply
- Transfer of Customer Technologies
- Cell Line Development
- Cell & Virus Banking (MCB/WCB, MVB/WVB)
- Upstream/Downstream
- Process Validation
- Stability Evaluation



Drug Product
Manufacturing

- Manufacturing for Clinical and Commercial Supply
- Process Transfer
- Bulk Formulation
- Aseptic Filling
- Lyophilization
- Visual Inspection (automated, semi-automated and manual)



Packaging &
Storage

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



Quality Control &
Analytics

- Method Transfer, Development, Implementation and Validation
- Raw Material Testing and Release
- In-Process Testing
- Batch Release Testing
- Stability Studies
- Environmental Monitoring
- Utility Monitoring
- Cleaning Validation Analytics
- Methods: Microbiological, Biological, Molecular-Biological, Virological, Physico-Chemical Testing



Our Sites in Germany and the USA



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 and on to commercial manufacturing in its sites in Germany and the USA.



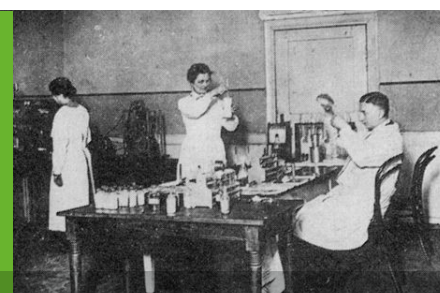
In Dessau-Rosslau, Germany we operate one of Europe's premier integrated biopharmaceutical development and manufacturing facilities for end-to-end services from process development through clinical phases I–III to commercial manufacturing.



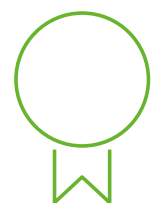
In Rockville, MA, USA we utilize broad capabilities and a depth of technologies for process development and manufacturing of clinical trial material for phases I–II.

Did You Know?

IDT Biologika can also look back on many years of experience in bacterial vaccine production and celebrates its 100-year anniversary in 2021.



Award winning Expertise and Innovation



With great know-how, commercial excellence and investment in capabilities, IDT Biologika has received international accolades for the development and manufacturing of innovative vaccines on behalf of our clients. This commitment to excellence has resulted in the company receiving several international awards, including the CMO Leadership Award six times over the last eight years.

Many human vaccines developed by IDT Biologika, together with international partners, are already in use, fighting infectious diseases such as tuberculosis, AIDS, malaria, cancer, dengue and ebola.

Particularly noteworthy recent collaborations include with the Biomedical Advanced Research and Development Authority (BARDA), an office of the U.S. Department of Health and Human Services, the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH), an agency of the United States Department of Health and Human Services, and the Coalition for Epidemic Preparedness Innovations (CEPI).



Production Technologies

IDT Biologika has the capability to manufacture live vaccines as recombinant vector vaccines or as live attenuated virus vaccines. Oncolytic, Vaccinia, HSV, Adeno, Orthopox, Avipox, Vesiculo, Lyssa, Baculo, Cytomegalo, Lenti Viruses are used as viral vectors. IDT Biologika utilizes the latest, most advanced technologies in the safe handling and production of vaccines. The company handles every step in manufacturing and quality control processes: bulk active substances, sterile filling, efficient packaging systems, cold chains, early development, production of small clinical batches and large-scale production under GMP.

► Drug Substance Technologies

| | |
|---|--|
| Cell factories/Cell stacks | CF /CS10 and CF/CS 40, up to CF/CS60 |
| iCELLIS® fixed bioreactors | iCELLIS® Nano / iCELLIS® 500, 10L–200L |
| Wave® bioreactors | 10L–200L wave fermenters |
| Roller bottles | up to 800 roller bottles/batch, robot system |
| Stainless steel and single use bioreactors | up to 800L, BIOSTAT STR® 50–200L |
| Microcarrier technology | |
| Temperature-controlled, double-jacket mixing systems | 10L, 25–50L, 50–500L |
| Downstream technologies | chromatography, TFF, single-use filtration systems, centrifugation, separation |

► Drug Product Technologies

| | |
|-----------------------|--|
| Fill/Finish | vials 2R–20R for clinical and commercial use, glass or plastic vials syringes 0.5–5mL for clinical and commercial use |
| Lyophilization | vials for clinical and commercial use, freeze-dryer capacity up to 430 sq.ft. |

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

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, and Fill/Finish of Biologics. 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.

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 knowhow and experience, innovative technology, and impeccable quality.

With nearly 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.

Year Founded
1921

Employees
More than 1,500 people
in Germany and the USA

Management
Dr Jürgen Betzing,
CEO

Locations
Dessau-Rosslau,
Germany (Headquarters)
Rockville, MA, USA
Magdeburg, Germany

**20% Reinvestment
Initiative**
Continuous facility
improvement

Recent Awards

- CMO Leadership Awards (2020, 2019, 2018, 2017, 2015, 2013)
- Vaccine Industry Excellence Awards (2019)
- Facility of the Year Award for Facility Integration (2015)

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 history – nearly a century – working with multinational 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.

► Excellence in Collaboration

| Smallpox vaccines | Ebola, Sudan, Marburg, Lassa Fever Vaccines | MERS Vaccine | Respiratory Syncytial Virus Vaccine |
|---|--|--|--|
| Development of a scalable technology for manufacturing of smallpox vaccines. Transferred to Bavarian Nordic and used for manufacturing more than 20 m doses of stockpiled smallpox vaccine (Elstree and MVA BN) | Thomas Jefferson University received a \$30 m contract from the National Institute of Allergy and Infectious Diseases (NIAID) to prepare and test a vaccine formulation that was designed to protect against the deadly Ebola, Sudan, Marburg, and Lassa fever viruses. Development of the manufacturing process and vaccine production (2017) | CEPI Awards contract worth up to \$36 m to a consortium led by IDT Biologika to develop a Middle East Respiratory Syndrome (MERS) vaccine (2018) | NIAID has awarded IDT Biologika a new Task Order within the 10-year Indefinite Delivery, Indefinite Quantity (IDIQ) contract no. HHSN272201800011I to provide process development activities and production of a vaccine against the Respiratory Syncytial Virus (RSV), 2019 |

Comprehensive Support Services to Meet Client Needs

Expert project teams at IDT Biologika work closely and collaboratively with partner companies to provide customized support and guidance every step of the way. They are 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 even the most complex vaccines and biologics.

As an end-to-end partner, IDT Biologika offers comprehensive supportive services, including project management and regulatory support.



Did You Know?

IDT Biologika is a global leader in MVA (Modified Vaccinia Ankara) and poxvirus technologies (offering proprietary cell line and CEF cells). Contact us to learn more.

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.

Achieving sustainability is a major global goal for IDT Biologika. Our engagement and approach in reaching this target was rewarded with the Ecovadis Silver Medal in 2019 and 2017.





IDT Biologika Take Home Message

- ▶ Contract Development and Manufacturing of Live Viral Vaccines, Viral Vectors for Gene and Immune Therapeutics, Fill/Finish of Biologics
- ▶ Development and Manufacturing of Clinical Trial Materials for Phases I-III and of Commercial Products, Quality Control/Analytics, Packaging, Cold Storage
- ▶ Vials, Pre-filled Syringes with and without safety devices, autoinjectors, combination products
- ▶ Company located in Germany and the USA

Learn more about partnering
with IDT Biologika

Inquiries are welcome
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