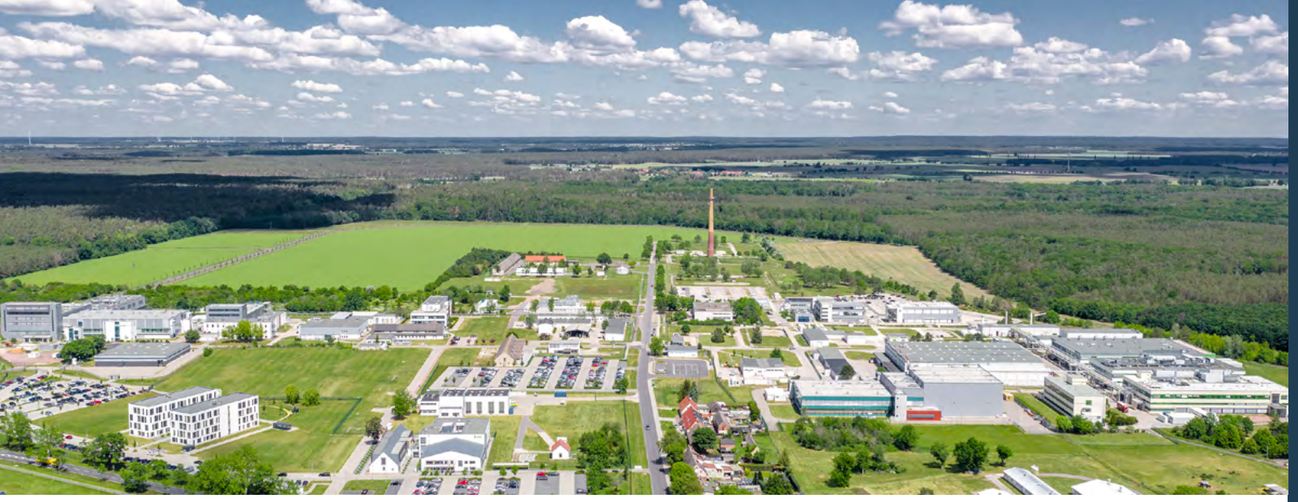
IDT BIOLOGIKA

End-to-End Services in Contract Manufacturing

Process & Analytical Development • Drug Substance • Aseptic Fill-Finish • Packaging

Cell Culture & Microbial Proteins, Enzymes, Viral Vectors, Vaccines, Gene & Immune Therapeutics, Oncolytic Viruses, Monoclonal Antibodies, Biosimilars

Read this brochure online
www.idt-biologika.com



Headquarter in Dessau-Rosslau, Germany

Over 100 Years of Expertise and Passion in Advancing Global Health

IDT Biologika, as part of SK bioscience, is a globally operating CDMO that specializes in end-to-end services in the development and manufacturing of biologics, biosimilars and other sterile injectable modalities.

Services
Process & analytical development, drug substance manufacturing from 200L to 2,000L, aseptic fill-finish and packaging with all related analytical services in-house.

Modalities
Cell-culture and microbial proteins, enzymes, viral vectors, vaccines, cell & gene therapeutics, oncolytic viruses, monoclonal antibodies, biosimilars.

We create solutions that empower our customers to enhance their products and address the evolving needs of global healthcare.

With our vision and mission, we reaffirm our unwavering committment to what truly matters – driving innovation, fostering strong partnerships with our customers, and delivering excellence and passion in manufacturing.

Our Vision: The trusted partner in shaping a healthier world

Our vision reflects our commitment as a CDMO to fostering strong, reliable partnerships. At IDT Biologika, we work hand in hand with our customers to create innovative solutions for their projects. Our dedication to trust and collaboration ensures that together, we can build a healthier world for all.

Our Mission: With passion we bring pharmaceutical solutions to life

Our mission is driven by excellence and passion to support our customers in delivering solutions that improve patient outcomes and contribute to global health advancements. We are deeply committed to innovation, quality, and making the difference.

Year Founded
1921

Shareholders
SK bioscience 60%
Klocke Holding 40%

Management
Dr. Sally Choe, CEO
Dr. Ulrich Valley, CEO

GMP Manufacturing
More than 4,500 batches since 2020

Regulatory Support
FDA, EMA and Anvisa approved

Employees
1,600 individuals

Recent Awards
CDMO Leadership Awards (2025-2023)
CMO Leadership Awards (2022–2017, 2015, 2013)

End-To-End Services in GMP Manufacturing

At IDT Biologika, we combine more than 100 years of expertise in the manufacturing of vaccines and sterile injectables with innovations in advanced therapies.
From process development to clinical and commercial manufacturing, we ensure seamless integration for our customer's projects at every step of the process, guaranteeing flexibility, the highest quality standards and regulatory compliance for your products.

Driving Innovation for our global customers

By leveraging our experience and forward-thinking mindset in working with the world's leading biopharma companies, we ensure impactful partnerships that drive progress and deliver meaningful results for patients worldwide.

Did You Know?

Our newest filling line is one of the fastest in the world with a speed of more than 32,000 vials (2R) per hour.

Reliable partnership throughout the entire process

From Process Development through Clinical Phases I–III to Commercial Manufacturing

Seamless integration of customers projects at every step of the process possible

Key Differentiating Factors:

Broad spectrum of technologies for vaccines and CGT

Scale across entire lifecycle and end-to-end value chain

Wide range of best-in-class analytical capabilities in-house

Process and Analytical Development

Services and Capabilities

- Tech transfer
- Up- and downstream development
- Formulation development
- Process characterization
- Process optimization
- Development of analytical methods

Technologies

- Fixed bed & stirred bioreactors
- Automated filling capacities
- Assay pre-validation
- Particle characterization
- Spectrometric tools
- Nanophotometer

Drug Substance Manufacturing

Services and Capabilities

- BSL 1, 2
- Viral and mammalian seed materials (MCB/WCB, MVB/WVB)
- Clinical trial material (phases I–III)
- Commercial manufacturing
- Process validation
- Analytical validation

Technologies

- Fixed bed & stirred bioreactors
- Cell factories, roller bottles
- Aseptic manufacturing of DS
- Tangential flow filtration and chromatography

Aseptic Fill-Finish

Services and Capabilities

- BSL 1, 2
- Bulk formulation
- Aseptic filling (vials, syringes)
- Lyophilization
- Clinical trial material (phases I–III)
- Commercial manufacturing
- Process validation

Technologies

- Automated large scale and pilot scale filling of vials and pre-filled syringes
- Large-scale lyophilizers (178,000 vials max capacity)
- Automated, semi-automated and manual visual inspection

Labeling and Packaging

Services and Capabilities

- Technology development
- Labeling, blistering, packaging
- Safety device assembly
- Combination products
- Serialization (track and trace)
- Code reading systems

Technologies

- Track & trace, serialization, tamper evidence and aggregation
- Level-5 interfaces
- SAP Pharma Network & Tracelink
- Manufacturing execution system (MES)
- Advanced cold storage logistics (chambers, pallets storage down to -65 °C)

Quality Control and Analytics

Services and Capabilities

- Method transfer and development
- Implementation and validation
- Raw material testing and release
- In-process testing
- Batch release testing
- Stability studies
- Environmental monitoring
- Utility monitoring
- Cleaning validation analytics

Technologies

- Fast track analytical methods (e.g. Adventitious Agents Testing via NGS, Fluorescent Activated Cell Sorter, Mycoplasma Testing by qPCR)
- Full range of Pharmacopeia assays established
- Labor information management system (LIMS)

Innovative Vaccines

- Recombinant
- Live-attenuated
- Inactivated
- Subunit Vaccines
  Proteins, Virus-Like Particles
- mRNA (filling)

Sterile Injectables

- Cell-culture and microbial-based proteins
- Enzymes
- Monoclonal antibodies
- Biosimilars

Gene & Immune Therapeutics

- Adeno-Associated Virus
- Lentivirus
- Adenovirus
- Herpes Simplex Virus
- Oncolytic Viruses

Process Development

Vaccines and Gene & Immune Therapeutics offer great potential in combating infectious diseases, as well as addressing other major health challenges worldwide such as cancer, neurological disorders, and genetic diseases, fueling a global demand for viral vectors.

We have been working on **viral vectors** for more than 30 years and our experts are highly experienced in the development of cell culture technologies, virus production and accompanying analytical services. This includes complex upstream, downstream and formulation processes.

We specialize in the most common permanent **cell lines** (adherent and suspension) and offer our own cell lines, which are already characterized and approved by regulatory authorities. Using our cell lines ensures a fast GMP start, leveraging our existing investments.

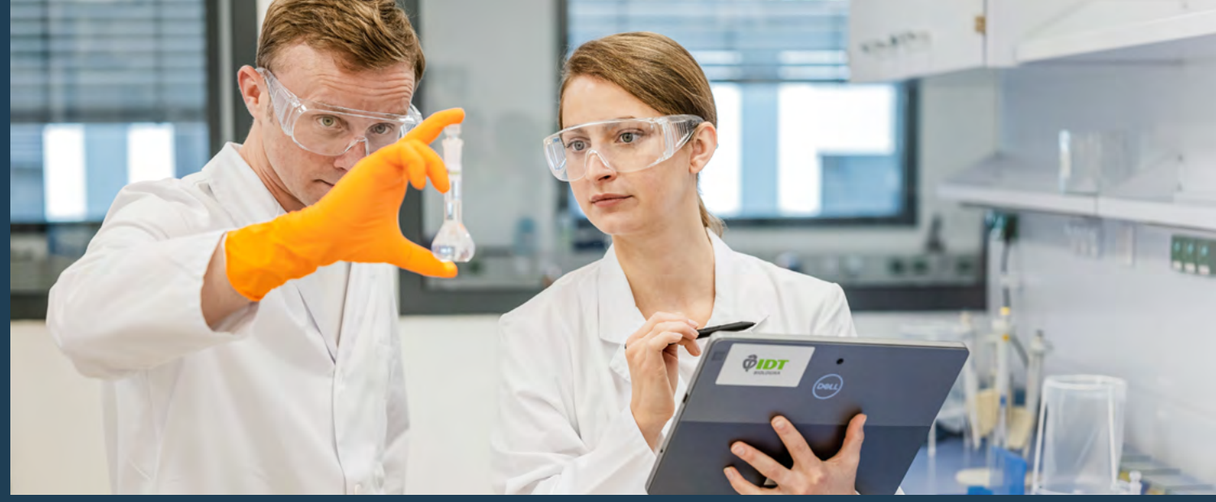
Our **in-house analytics services** cover early process development through scale-up to commercial manufacture, ensuring end-to-end consistency and comparability of data throughout the lifecycle of your product.

By selecting the appropriate state-of-the-art technologies and employing our outstanding expertise, we create scalable, efficient processes tailored to your needs.

Our Expertise

- **Own Seed Cell Banks**
- **AAV, LV and AdV Platforms**
- **MVA Know-How**
- **Fluorescent Activated Cell Sorter (FACS)**
- **Adventitious Virus Testing (AVT) by Next Generation Sequencing (NGS)**

DOWNLOAD
Whitepaper »Next Generation Sequencing«



Our state-of-the-art technology portfolio, combined with our long-term expertise, enables the fast track supply of vaccines and gene & immune therapeutics.

Cell Lines

Own Cell Lines
- HEK293
- Vero
- DF-1

Expertise with:
- MRC-5
- SF9
- CHO
- MDCK
- AGE-1

Viral Vectors

- MVA / Vaccinia Virus
- Adeno-Associated Virus
- Adenovirus
- Avipoxvirus
- Vesiculovirus
- Measles Virus
- Lyssavirus
- Herpes Simplex Virus
- Lentivirus

Manufacturing Platforms

- Cell Factories
- Microcarrier Technology
- iCELLIS®
- UNIVERCELLS Technologies
- Stirred Bioreactors
- Roller Bottles
- Stainless Steel Fermenters

Own Seed Cell Banks

- Development and qualification of own seed cell banks for GMP manufacturing

Did You Know?

Having produced one of the first commercial CGT products approved by FDA and EMA.
More than 75 GMP batches produced since 2020.

Process Design

Process Validation

Upstream Process Development

Downstream Process Development

Formulation and Lyophilization Development

Assay Development

Drug Substance Manufacturing

At IDT Biologika we bring together technical expertise, advanced manufacturing across early and late-stage programs, secure supply chain, and proven global launch success.
Wether at clinical or commercial stages, we tailor our approach to your project's needs, optimizing outcomes with the right technologies. If you are ready to go straight into GMP manufacturing we directly move towards that.

Upstream Technologies

Small to Large-Scale Upstream Technologies

Cell Factory™/Cell Stacks

- Up to 25 x CS10/CF10
- Up to 16 x CS40/CF40
- Hyper Stack Cell Factories
  20 x HS12/HS36

Fixed-Bed Bioreactors

Cytiva iCELLis
- 9 x Cytiva iCELLis™ nano
- 2 x Cytiva iCELLis™ 500+
- 1 x Cytiva iCELLis™ 500

UNIVERCELLS Technologies
- scale-X™ carbo (up to 30 m²)

Stirred Tank Reactors

- 6 x 200 L cell culture, single-use
- 2 x 2,000 L cell culture, single-use
- Microcarrier Technology
- 2 x 100 L microbial, stainless steel
- 2 x 800 L microbial, stainless steel

Roller Bottles

- Up to 500 roller bottles/batch
- Robot system

Downstream Technologies

Combination of all Downstream Technologies possible

Centrifugation

- Clarification and concentration of up to 12 L per run

Depth Filtration

- Up to 30" filter capsules
- Controlled filtration up to 200 L
- Integrated in single use systems

Continuous Flow Centrifugation

- Concentration
- Separation
- Centrifugation with single use systems

Tangential Flow Filtration (TFF)

- Concentration or buffer exchange
- Ultra filtration and dia filtration (UF/DF) single use system

Chromatography

- Äkta systems, scalable from development to commercial
- Chromatography with single use systems

Drug Product Manufacturing

For over three decades we have been working with leading multinational companies in the fill-finish of **sterile injectables**. Combining innovative technologies, world-class manufacturing up to BSL 2, and process excellence we deliver flexible, high-quality solutions for filling of vials and pre-filled syringes. The demand for contamination prevention is especially high with live agents, particularly during changeovers. Therefore, we prefer using single-use equipment.

Filling Lines for Vials and Prefilled Syringes

From Small to Large-Scale

Line No.	Scale	Formats	Batch Sizes (min. – max.) pieces	Lyo Batch Size (2R)
(1) Vials incl. Lyophilization	Commercial	**2R**, 4R, 6R, 10R	25,000 – 250,000 (2R)	3 x 178,000
(2) Vials	Commercial	**2R**, 6R, **10R**	80,000 – 500,000 (2R)	(Lyo Option)
(3) Vials	Clinical	**2R**, **10R**, 25R	5,000 – 55,000 (2R)	29,000 & 55,000
(4) Vials (Glass/CZ) incl. Lyophilization	Clinical & Commercial	2R, 4R, 6R, 10R, 25R	500 – 10,000 (2R)	Up to 3,000
(5) Vials	Commercial	**2R, 3R, 6R**	10,000 – 100,000 (2R)	48,960
(6) Vials	Commercial	**2R, 3R, 6R, 10R, 20R, 25R**	10,000 – 150,000 (2R)	–
(9) Vials	Clinical	**10R, 20R, 25R**	5,000 – 45,000 (10R)	–
(7) Syringes	Commercial	**0.5 ml, 1 ml, 1 ml long, 3 ml**	30,000 – 150,000 (1 ml)	–
(11) Syringes	Clinical	**0.5 ml, 1 ml, 1 ml long, 3 ml**	2,000 – 30,000 (1 ml)	–

Mid & Large-Scale Filling

Vial Formats: 2R – 10R
Filling Speed (2R vials):
22,000 – 32,000 vials/hour
Batch Sizes
10,000 – 500,000 vials 2R

Large-Scale Lyophilization
Capacity: Up to 3 x 178,000 vials

Small-Scale Filling

Vial Formats: 2R – 100H
Filling Speed (2R vials):
6,000 vials/day
Batch Sizes
1,000 – 10,000 vials 2R

Small-Scale Lyophilization
Capacity: Up to 3,000 vials

Did You Know?

More than 3,500 Drug Product GMP batches produced in the last four years.

Visual Inspection

All visual inspection services are handled in-house, ensuring every batch meets all GMP guidelines.
We provide high-performance automated visual inspection alongside manual and semi-automated inspection options.

Fully-automated visual inspection
- High-performance automated visual inspection unit
- Up to 36,000 vials 2R per hour
- Especially for large batch sizes and commercial supply

Semi-automated visual inspection
- Vials (lyophilized)
- Vials (liquid), possible but not yet established

Manual visual inspection
- Vials (liquid and lyophilized)
- Prefilled Syringes (liquid)
- Pens (medical devices)
- Blisters

Quality Control and Analytical Services

Quality is at the heart of our manufacturing process, with advanced in-house analytical services ensuring each batch meets stringent regulatory and GMP standards.
By managing these services internally, we guarantee your products are of the highest quality, fully traceable, and compliant with international regulations.

- Testing methods:
  - Molecular-biological
  - Chemical / Physical
  - Virological / Biochemical
  - Microbiological

- Method transfer, implementation and validation
- Development of specific methods
- Raw material testing and release
- In-process testing: viral, bacterial, protein, DNA
- Batch release testing
- Stability studies
- Environmental monitoring
- Utility monitoring
- Cleaning validation and analytics

Audits and Client Inspections

Transparent collaboration with our clients is a key aspect in ensuring regulatory compliance.
Regular inspections confirm our commitment to quality and operational excellence meeting FDA, EMA and ANVISA standards.

- 10 to 15 official inspections annually
- 15 to 20 client audits annually
- 12 US-FDA inspections in Dessau since 2006
- Last FDA inspection in September 2023

Labeling and Packaging

Our dedicated team, supported by an in-house technology group, ensures your product requirements are fully met. We prioritize safety through robust processed and dedicated production rooms, offering short holding times. Our packaging expertise includes the following:

- Fully automated, semi-automated and manual capabilities for
  - Labeling, blistering and packaging of vials and prefilled syringes
  - 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 and serialization
- Packaging of clinical trial materials

Environmental, Social, Governance

Our dedication to ESG principles are integral to everything we do and guide our decision making, fostering trust and long-term value creation.

This commitment has been recognized with the Ecovadis Gold medal in 2024.

IDT Biologika is also member of UN Global Compact.

IDT BIOLOGIKA

Take Home Message

- IDT Biologika is Part of SK bioscience
- Contract Development and Manufacturing of Biologics, Biosimilars, Sterile Injectables
- GMP compliant End-to-End Manufacturing
- Clinical and Commercial Presentations
- FDA, EMA and ANVISA approved
- Vials, Pre-filled Syringes, Pens/Auto Injectors, Combination Products
- Cost-efficient and risk-managed manufacturing of your products

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Contact us

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