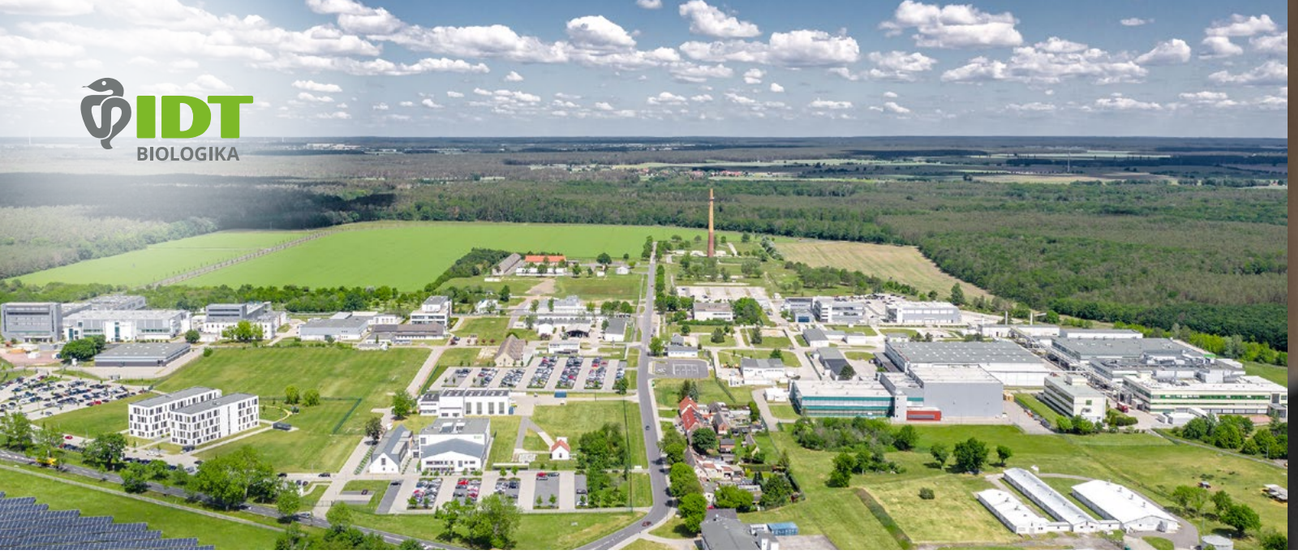
IDT BIOLOGIKA

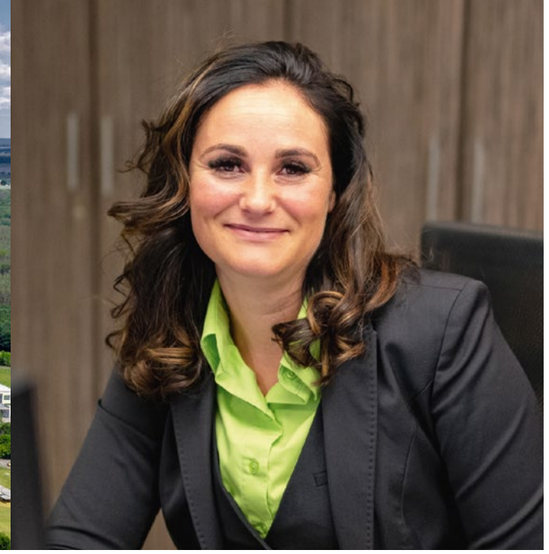
Advancing Biologics. Protecting Life.

End-to-End Services in Contract Development & Manufacturing of Vaccines and Gene & Immune Therapeutics

Fill-Finish of Biologics and Sterile Injectables

www.idt-biologika.com





IDT Biologika at a Glance

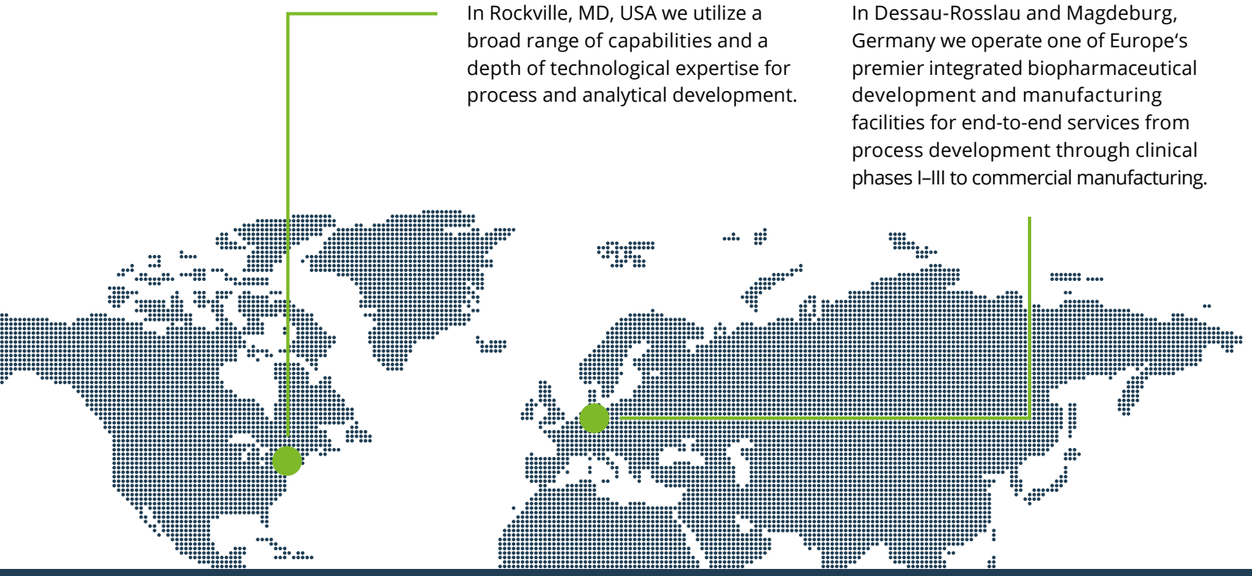
IDT Biologika is a globally operating biopharmaceutical CDMO that specializes in the **Contract Development and Manufacturing** of **Vaccines, Gene & Immune Therapeutics** and the **Fill-Finish of Biologics and other Sterile Injectables**. Our mission is to accelerate the development and flexible high-quality manufacturing of our client's therapeutic and prophylactic products, supporting our global healthcare partners to treat serious diseases that impact human health worldwide.

Our Sites in Germany and the USA

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

In Rockville, MD, USA we utilize a broad range of capabilities and a depth of technological expertise for process and analytical development.

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. Ulrich Valley, CEO

Employees
1,600 people in Germany and the USA

Regulatory Support
FDA, EMA and Anvisa approved

Recent Awards

- CDMO Leadership Awards (2023, 2024)
- CMO Leadership Awards (2022–2017, 2015, 2013)
- Vaccine Industry Excellence Awards (2021, 2019, 2018)

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.

End-To-End Services in GMP Manufacturing

From process development to manufacturing of clinical and commercial batches we ensure seamless integration at every step of the process, guaranteeing flexibility, the highest quality standards and regulatory compliance for your products.
We believe in the power of collaboration and we actively seek partnerships with biotech companies, leading academic institutions, healthcare organizations, and industry pioneers to foster knowledge exchange and accelerate discovery.

Did You Know?

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

Our Services

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

Key Differentiating Factors:

- **Broad spectrum of technologies for vaccines and C&GT**
- **Scale across entire lifecycle and end-to-end value chain**
- **Wide range of best-in-class analytical capabilities in-house**

Vaccines

Gene & Immune Therapeutics

Biologics

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

- Viral Vaccines
  Live-Attenuated, Recombinant Vectors, Inactivated
- Subunit Vaccines
  Proteins, Virus-Like Particles
- mRNA Vaccines (filling only)

Gene & Immune Therapeutics

- Oncolytic Viruses
- Adeno-Associated Virus Vectors
- Lentiviral Vectors
- Adenovirus Vectors
- Herpes Simplex Virus Vectors

Fill-Finish of Biologics and Sterile Injectables

- Innovative Biologics
- Biosimilars
- Large and Small Molecules

Our Expertise

Own Seed Cell Banks
GMP compliant own cell lines VERO and DF-1 available to accelerate process timelines and project starts

AAV and AdV Platforms
Building upon our industry leading knowledge of virus and viral vectors, our next generation Adeno-Associated Virus and Adenovirus Vector Platforms expand on the successful partnerships with our clients

MVA Know-How
Globally leading in MVA (Modified Vaccinia Ankara) and recombinant and non-recombinant poxvirus technologies and aseptic processing

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

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

Development Services

Vaccines and Gene & Immune Therapeutics hold significant promise in addressing diseases such as cancer, neurological disorders, and genetic ailments, fueling a global demand for viral vectors. When considering a partnership with a Contract Development and Manufacturing Organization (CDMO) for viral vector production, IDT Biologika emerges as an ideal CDMO partner with its technical expertise, extensive manufacturing capabilities, experience across early and late-stage programs, secure supply chain, and a track record of successful global launches.

Process and Analytical Development

Our process development team of scientists and engineers is highly experienced in the development of cell cell culture technologies, virus production and accompanying analytical services. This includes 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 selecting the appropriate technologies and employing our experience to define a process that works best and can be scaled.

With our outstanding expertise and availability of most of the common state-of-the-art platform technologies, we ensure fast track supply for clinical and late stage phases, as well as for large scale commercial manufacturing.

Viral Vectors

We have been working on viral vectors for more than 30 years and are highly involved in the latest developments and use of recombinant and non-recombinant live viral vectors for immunotherapeutic use. Major viral platform vectors are:

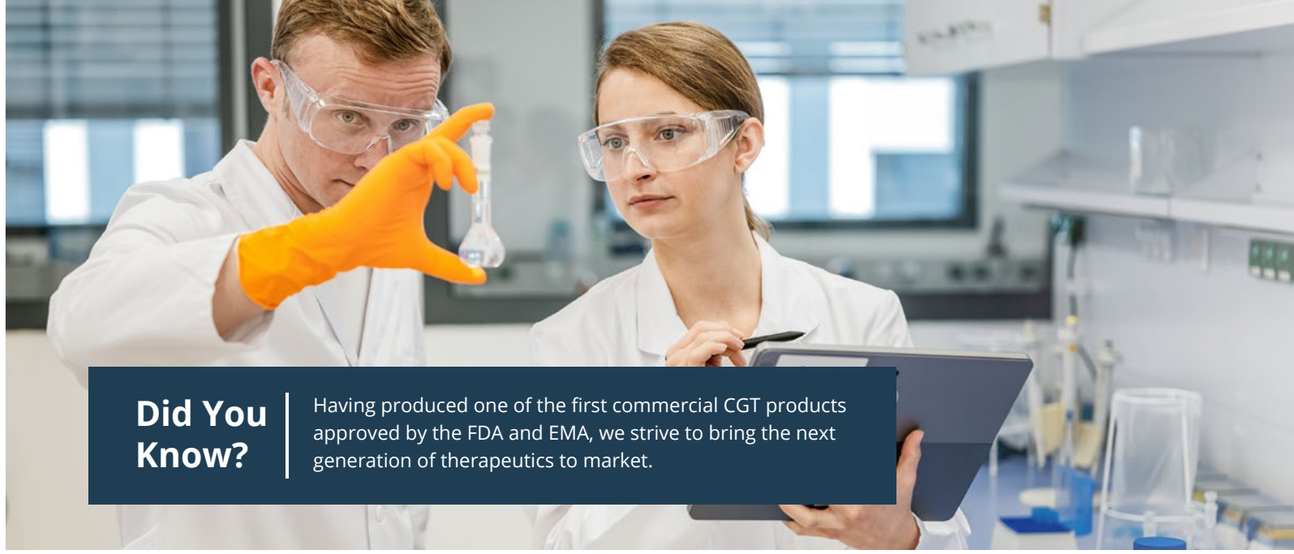
Viral Vectors for Vaccines

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

Viral Vectors for Gene & Immune Therapeutics

- Adeno-Associated Virus
- Adenovirus

Our platform processes are scalable, cGMP ready and may accelerate the process development timeline. They are applicable for all standard AAV serotypes and include platform and process development as well as clinical and commercial manufacturing.



Did You Know?
Having produced one of the first commercial CGT products approved by the FDA and EMA, we strive to bring the next generation of therapeutics to market.

Cell Lines

Cell Banking
For the process development of viral vaccines and vectors, we offer manufacturing services and provide characterized master cell banks (MCB) as well as 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
At IDT Biologika we are experienced in handling the most common permanent cell lines (adherent and suspension) for our clients. We also provide our own cell lines HEK293, VERO and DF-1, 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.

Own Cell Lines Available
HEK-293 · VERO · DF-1

Further Cell Lines in Use
HELA · NBK · MDCK · MRC-5

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.

DOWNLOAD
Whitepaper »Next Generation Sequencing«

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

Drug Substance Manufacturing

Clients come to IDT Biologika at both clinical and commercial stages, and in each case, we look at the process and the needs of the project and tailor our approach and, if still undefined, the technologies we employ to optimize the outcome. If you are ready to go straight into GMP manufacturing we directly move towards that.

We have been expanding our drug substance capacity dedicated to GMP production of live virus products to provide a greater level of volume and flexibility to suit the varied needs of our clients.

Ask us about our available Capacities

Upstream Technologies

- Cell expansion of adherent or suspension cells
- Fixed bed or stirred reactor technology for cell growth and viral replication
- Transfection
- Intracellular or extracellular virus harvest processes
- Incubator capacities and robot systems avaiable to support large scale tissue culture handling

Cell Stacks and Cell Factories
- up to 25 x CS10/CF10
- up to 16 x CS40/CF40

Hyper Stack Cell Factories
- 20 x HS12/HS36

Stirred Bioreactors
- 12 x 250 mL single-use STRs
- 6 x 200 L single-use STRs (50 L–200 L batch vol.)
- 2 x 2,000 L single-use STRs (also with Microcarrier Technology)

Fixed-Bed Bioreactors
- 9 x iCELLis® nano
- 2 x iCELLis® 500
- UNIVERCELLS Scale-X™ carbo (up to 30 m²)

Microcarrier Technology
Available

Roller Bottles
- up to 500 roller bottles per batch
- robot system

Downstream Technologies

- Enzymatic DNA degradation or precipitation
- Virus inactivation
- Automated TFF
- Automated chromatography
- Sterile filtration
- Controlled freezing

Tangential Flow Filtration (TFF)
- Automated and single-use systems for ultra filtration/dia filtration and micro filtration/dia filtration
  - 5x up to 18 L/min
  - 1x up to 60 L/min

Normal-Flow-Filtration (NFF)
- Controlled processing volume up to 500 L
- Pump units: automated, pressure/flow controlled filtration up to 18 L/min

Chromatography
- Automated and single-use systems (isocratic and gradient)
  - 5x up to 8.5 L/min
  - 1x up to 450 mL/min

Our Newest High-Speed Isolator Filling Line

Filling Volume
0.1–10 ml
2R–10R Vials
100 % In-Process
Filling Weight Control

up to
80–100 M 2R Vials
per year

up to
500,000 Vials (2R)
per batch

Aseptic Fill-Finish

For more than 3 decades we are working in the clinical and commercial fill-finish of vaccines, proteins and monoclonal antibodies, serving leading multinational companies to speed their products to market. With a combination of innovative technologies, world-class manufacturing solutions up to BSL 2, scientific expertise and process excellence we streamline the manufacture of your therapies and support you to bring your products flexible and with the highest quality to market.

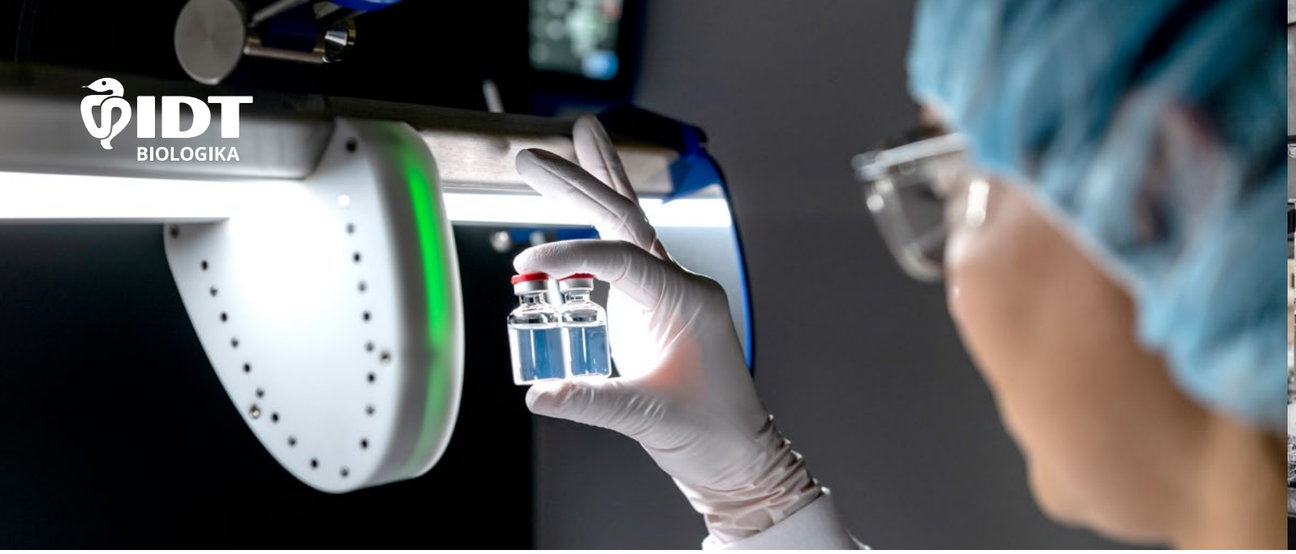
Filling
- Clinical and commercial use
- 2R–20R vials
- Glass, plastic, CZ vials
- From small batches with 500 vials to late stage-commercial batches with 500,000 vials
- 0.5–3 ml pre-filled syringes

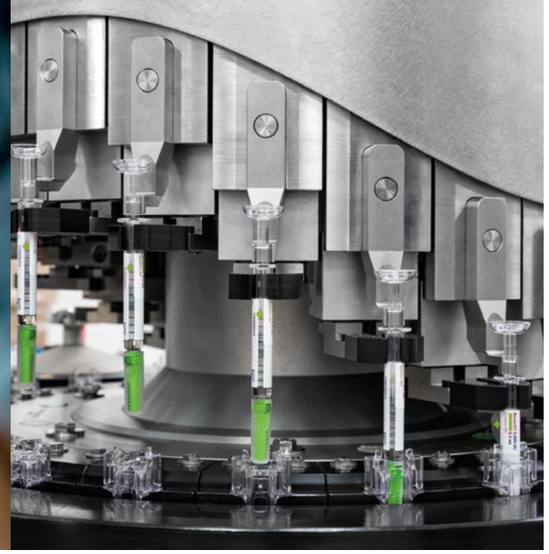
Lyophilization
- Vials for clinical and commercial use
- Freeze-dryer capacity up to 430 sq.ft.

The expansion of our fill-finish manufacturing capacity for large and small molecules by another **state-of-the-art isolator high-speed filling line** will ensure us to deliver industry-leading contract manufacturing services that will support our client's needs in the medium and long term.

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.

DOWNLOAD
»Introducing our new High-Speed Filling Line«





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 gene & immune therapeutics, vaccines and other biologics.

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 and 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

A high-performance automated visual inspection line complement our manual and semi-automated visual inspection services. Especially for large batch sizes and commercial supply we use our new high-performance automated visual inspection line with a capacitiy of up to 36,000 2R vials per hour.

Sustainability

Our commitment to ethical practices and sustainability is embedded in everything we do. We adhere to the highest ethical standards in research and patient care, ensuring that our therapies are safe, reliable, and accessible to those who need them most.

SILVER 2023 ecovadis Sustainability Rating

We are also committed to ensuring the safety and health of our employees and to preserving natural resources, but also go beyond and set our own standards that exceed applicable laws and regulations.

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 teams are well experienced and highly-trained with a wide array of analytical technologies and all vaccine and gene & immune therapy specific testing can be done in-house:

- 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

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 client audits annually
- 12 US-FDA inspections in Dessau since 2006
- Last FDA inspection in September 2023

Take Home Message

- Contract Development and Manufacturing of Innovative Vaccines, Gene & Immune Therapeutics and Fill-Finish of Sterile Injectables
- Process and Analytical 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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