

CELL & GENE THERAPY

IDT Biologika AAV & LV Platform Processes

With **more than 100 years of expertise** in viral vaccine manufacturing, we at IDT Biologika are proud to unveil our ground-breaking cell and gene therapy solutions, redefining the boundaries of innovation in **clinical and commercial** manufacturing for our clients.

Building upon our industry leading knowledge of virus and viral vectors, IDT Biologika's next generation **AAV and LVV platforms** expand on the company's success and partnerships with our clients. With our cutting-edge technology and unwavering commitment to improving lives, we are the sustainable partner in the field of CGT.

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.

IDT Biologika's AAV and LV platform processes are **scalable, cGMP-ready** and may accelerate the process development timeline. They are applicable **for all standard AAV serotypes and LVV variants**.

With sites in **Europe and the USA**, IDT Biologika offers both the flexibility and redundant capabilities that reduce manufacturing complexities often found in the market. Our expertise and capabilities allowed us to produce our **own HEK293 production cell lines** utilizing a wide variety of upstream platforms including iCellis, Cell Stacks, Univercells, and Stirred-Tank Reactors. Along with our own AAV and LVV platforms, we offer the flexibility to take on your project as a tech transfer for clinical or commercial supply. Our upstream and downstream suspension or adherent capabilities range **from 50 L – 2,000 L, and up to 2 x 500 sqm, respectively**. All Cell and Gene therapy specific **Quality Control Testing** can be done **in-house**.

Our End-to-end services include:



Process
Development



Drug Substance
Manufacturing



Drug Product
Manufacturing



Labeling
& Packaging



Quality Control
& Analytics

BROAD ANALYTICAL PORTFOLIO FOR PROCESS AND PRODUCT CHARACTERIZATION

HIGHLIGHTS:

- Adventitious viruses testing via NGS
- Method for hcDNA is developed and prevalidated in-house
- Mycoplasma method based on qPCR is completely developed, validated and operated in-house
- High experience in Endotoxin testing including LER and primary packaging material
- Genome titer is determined with dPCR, IDT Biologika is highly experienced in
- Viral proteins could be profoundly characterized by different MS technologies
- Comprehensive activity testing possible, due to long-term experiences in cell culture and potency assays

Our Overall Service Portfolio for Adeno-Associated Viruses and Lentiviruses

PLATFORM DEVELOPMENT	PROCESS DEVELOPMENT	CLINICAL TRIAL MATERIAL	COMMERCIAL MANUFACTURING
<ul style="list-style-type: none"> • Cell line development • Different serotypes • Strategic collaborations • Collaborative manufacturing strategy • In-house analytical portfolio 	<ul style="list-style-type: none"> • Small-scale feasibility testing • Process preparation for scale-up • Final parameter adjustments • Starting point for scale-up to GMP facility • Analytical development <p>STR 3 – 40 L FBR: 4 m²</p>	<ul style="list-style-type: none"> • CTM 1-3 manufacturing in GMP controlled environment • Suspension and fixed bed bioreactor technologies in place • Trained and experienced CTM staff • Automated filling capacities (DS/DP) • Assay prevalidation (APMP) <p>STR 50 – 200 L FBR: 30 – 500 m²</p>	<ul style="list-style-type: none"> • Commercial production scale-up and filling capabilities • High experience in commercial manufacturing systems • Risk assessment (FMEA) • Development of supportive process characterization and risk assessments • Process and assay validation <p>STR 2,000 L FBR: 500 m²</p>

DRUG SUBSTANCE MANUFACTURING	DRUG PRODUCT MANUFACTURING
<p>Cell Factories: CF 10 and CF 40 up to 32 x CF 40 / batch</p> <p>Roller Bottles: Up to 500 roller bottles per batch</p> <p>Fixed-Bed Reactors: Small and Large Scale • UNIVERCELLS • iCELLis®</p> <p>Stirred tank reactors: 50 L – 2,000 L</p>	<p>Small-Scale Filling Lines for Vials: Batch Sizes from 500 – 10,000 Vials (2R), Glass and CZ, different Formats available Lyophilization Capacity up to 3,000 / 4,000 Vials (2R)</p> <p>Other Filling Lines for Vials: Batch Sizes from 5,000 – 500,000 Vials (2R), Glass, different Formats available Lyophilization Capacity from 29,000 – 178,000 Vials (2R)</p> <p>Syringe Filling Lines: Batch sizes from 2,000 – 150,000 Syringes (1 ml), Glass, different Formats available</p> <p>Investments planned: Further Small and Large Scale Syringe Filling Lines</p>

Learn more about Partnering with IDT Biologika

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