

iCELLis500: A versatile Manufacturing Platform for CGT and Oncolytic Virus Production



- Lessons Learned and Best Practices from Successful Programs -

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1. Introduction



IDT Biologika is a global biopharmaceutical **contract development and manufacturing organization** and part of SK Bioscience specializing in **cell culture** and microbial based proteins, **vaccines, gene & immune therapeutics**, biosimilars and other sterile injectables (Fig.1). Within this poster we present two phase III client projects. An AAV and an oncolytic virus (*Parvovirus*) project using the iCELLis500+ platform.

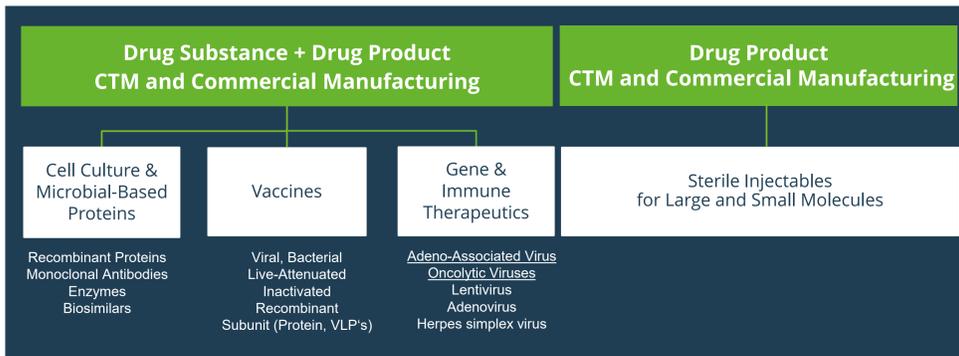


Fig.1: IDT Biologika's key strength in clinical and commercial services in DS & DP manufacturing.

2. Available drug substance technologies

IDT Biologika has implemented a wide range of scalable state of the art technologies in USP and DSP for end-to-end services. IDT provide all services beginning with process and analytical development, scale ups and ending in clinical trial or commercial manufacturing (Fig.2 & Fig.3).

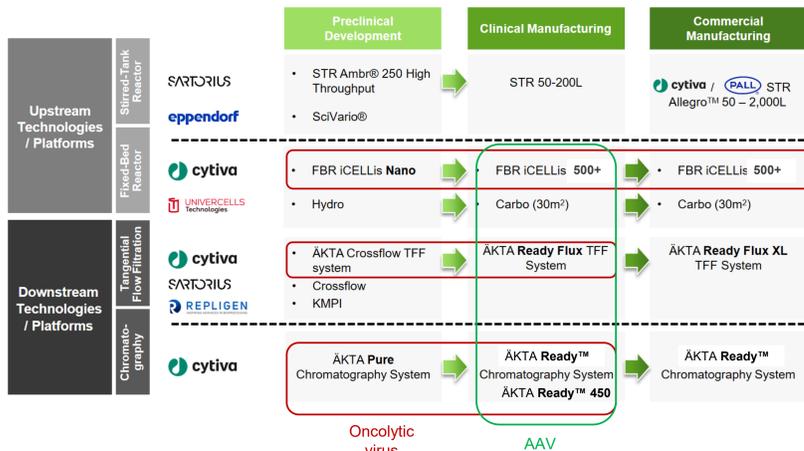


Fig.2: Overview of scalable USP and DSP technologies at IDT Biologika for process development and manufacturing.

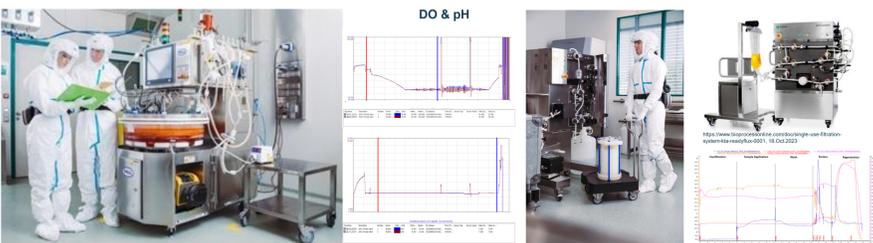
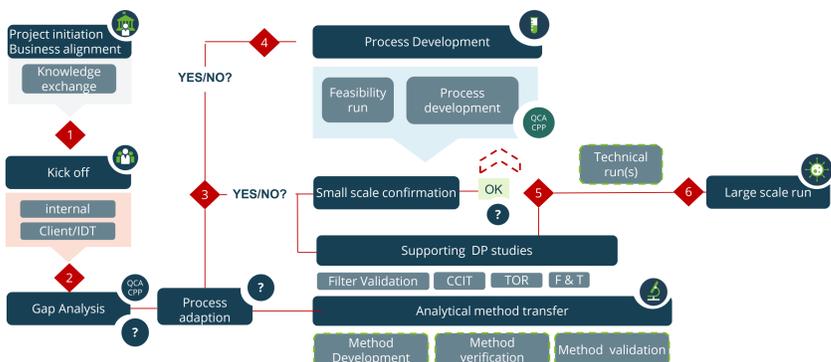


Fig.3: Insides in the manufacturing suites (BSL-3) and implemented technologies like the fixed bed bioreactor iCELLis 500+, chromatography system ÄKTA ready, tangential flow filtration (TFF) system ÄKTA readyflux and insights in the implemented software tools (Lucullus PIMS and Unicorn 7.11) for process automation and data collection.

3. IDT Biologika's process implementation road map



Conclusion

- IDT is ready to implement/processes on iCELLis500 technology.
- IDTs flexible process transfer concept is able to implement manufacturing process on every stage of product lifecycle for DS & DP.
- At IDT automated process equipment's for all DSP-MUOs are available.
- Implementation of new equipment possible according to process needs and costumers' requirements.

4. AAV Project

Project starting point:

- GMP process performed at scale for CTM I&II at other CDMOs
- AAV & HEK293 cell line provided by client

Project Target:

- DS & DP manufacturing of CTM phase III with comparable BDS titer
- Implementation of new vial format at established filling line
- Process adaption for GMP compliant CTM Phase III & commercial manufacturing (including PPQ preparation)

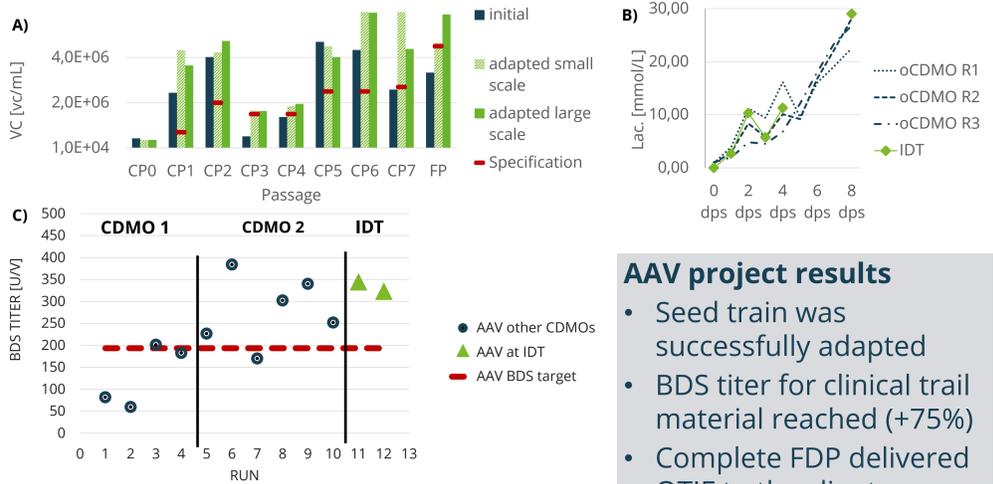


Fig.4: Results of A) adapted seed train, B) metabolic parameters during iCELLis cultivation and C) final BDS titer

AAV project results

- Seed train was successfully adapted
- BDS titer for clinical trail material reached (+75%)
- Complete FDP delivered OTIF to the client

5. Oncolytic Virus Project

Project starting point:

- Lab scale process was developed by customer
- Oncolytic Virus → MSV, WSV established at IDT Biologika
- Adherent human kidney cell line → MCB & WCB established at IDT

Project Target:

- >10x process scale up (final BDS volume) through substitution of CS40 technologies with iCELLis500+ with comparable BDS titer (>1.0E+09)
- Process development** for GMP compliant CTM Phase III and commercial manufacturing (including PPQ preparation) → substitution of density centrifugation with automated TFF and Chromatography

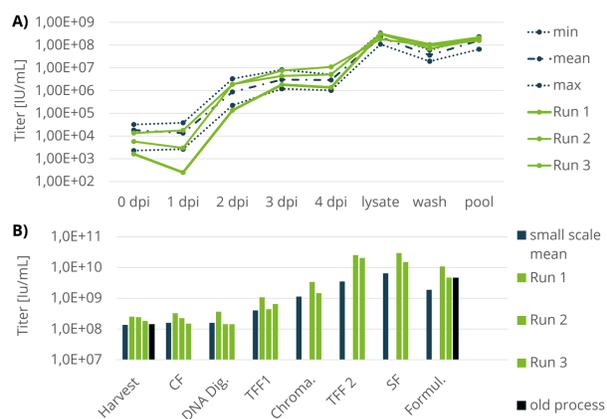


Fig.5: Titer results of A) USP and B) DSP process. Run 1: 1st. Scale up was only performed up to TFF1

Oncolytic Virus Project results

- Successful process development & scale up
- Successful implementation of simplified, scalable closed state of the art USP & DSP process with reduced contamination risk
- Complete FDP delivered OTIF to the client

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