# Services in Upstream processing

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### LVA – A High Tech Upstream Pilot Plant in Kundl/ Austria

Piloting activities play an essential role in tech transfer and scale up of biotechnological products from Development to Manufacturing scale. The Novartis Upstream Processing (USP) pilot plant LVA is a high tech facility with fermentation scales ranging from small-scale (<1 mL) to pilot-scale (150 L). On more than 900 m<sup>2</sup> and grounded on our long lasting expertise with microbial and mammalian processing, we offer services regarding all aspects of technical or clinical development, tech-transfer and commercial support in all thinkable product categories: from enzymes to nucleic acids, small molecules to biopharmaceuticals.

### **Microbial Capabilities**

- Small- and lab-scale equipment for screening experiments (e.g. Shake flasks or Deep Well Plates)
- Pilot Plant with 24/7 coverage to realize a maximum of process oversight
- 50 bioreactors on over 900 m<sup>2</sup>
- Fermenter scale ranging from lab-scale glass bioreactors (1 L) to pilot-scale (50/ 150 L) stainless steel bioreactors
- Options for solvent based feeding strategies (e.g. methanol or ethanol), oxygen enriched processing or processing of toxic materials in place
- High degree of automation and digitalization (e.g. more than 80 ready to use controllers for process automation)

## **Mammalian Capabilities**

- Seed train in single use equipment
- Parallelized screening option in 250 mL-scale (12x fully automatized miniaturized single use bioreactors in fed-batch or perfusion mode with online, at-line and offline analytics for relevant process parameters)
- Lab-scale (15 L) glass-Fermenter for Fed-Batch or continuous operations

## **Additional Capabilities**

- Cell Line Development: Options for non-GMP cell line generation and strain screening available
- Analytics: Options for several internal or external analytical services in place (e.g. for analysis of substrates/ metabolites, products and biomass)
- Downstream Development: Options for non-GMP lab and piloting of Biopharmaceuticals / nucleic acid available

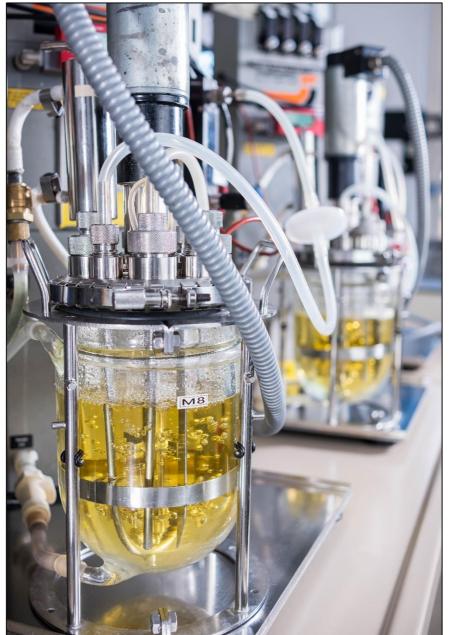




Fig. 1: Available microbial screening options in lab-scale



Fig. 2: Microbial pilot-scale (50 L) biorectors at LVA



Fig. 3: Parallelized mammalian process optimization at LVA