

BIOLOGICS Clinical Manufacturing

EXPERTISE

- **Tailored solutions for manufacturing of diverse range of biologics**

Proteins (antibodies, fusion proteins, enzymes, virus like particles and vaccines)
Prokaryotic and eukaryotic expression systems
Live/inactivated bacteria



- **From cell banking to fill & finish**

- **Clinical trial supply including secondary packaging & logistics**

- **Focus on quality and fluent technology transfer**



SERVICES

DRUG SUBSTANCE

Manufacturing

- Cell banking services (MCB, WCB, EoPC)
- Buffer preparation, upstream processing (cell culture and microbial), downstream processing
- Technical batches and scale-up
- GMP manufacturing
- Storage (2-8°C, -20°C, -80°C, vapour phase of liquid nitrogen)

CAPABILITIES

- Human IMP licensed manufacturing facility (FAHMP)
- Grade C suites, ISO 5/7 cleanrooms
- Fermentation and cell culture activities in segregated suites (BSL2)
- State of the art, single-use equipment

 Mammalian production line: 10L/50L/200L

 Microbial production line: 50L

- Qualified equipment
- Environmental monitoring program

Testing & Characterization

- Extensive analytical toolbox for IPC, release and characterization testing
- Analytical method qualification/validation
- GMP MCB/DS/DP stability studies



BIOLOGICS Clinical Manufacturing

DRUG PRODUCT

ROUTES



Injectable



Oral



Topical



Nasal

Sterile manufacturing

- Liquids
- Freeze dried products



Non sterile manufacturing

- Live biotherapeutic products
- (coated) Tablets or capsules
- Spray-dried powder



Type of packaging	Volume/Units per batch
Bulk	From < 0.5 L & up to 20 L
Vials	Up to 5,000 units (e.g. 2R vials)
Syringes	Up to 5,000 units (e.g. syringes 1 mL long)

Other packaging upon request

Form	Batch size
Solutions, suspensions, emulsions	5 mL up to 50 L
Semi-solids	5 g up to 50 kg
Tablets	100 up to 200,000 units
Capsules	100 up to 200,000 units

QP confirmation & release

FACILITIES

- Cell banking
- Sterile manufacturing
- Non sterile manufacturing

YOUR DRUG DEVELOPMENT PARTNER



Cell banking



Process development



Clinical manufacturing (DS/DP)



Clinical supply (packaging & logistics)



ANSES
ANSM
AFMPS
FAGG
FDA
PMDA

GMP



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