

BIOLOGICS

Cell Banking

EXPERTISE

- Production of GMP-compliant cell banks in BSL2 cleanrooms
- Cell bank characterization meeting highest regulatory standards



SERVICES

Manufacturing

- Generation of research cell banks (RCB)
- Production of master cell banks (MCB), working cell banks (WCB), end of production cell banks (EoPC)
- Cell culture using serum-free and animal component free media
- Filling within certified laminar flow biosafety cabinets (Class A)

CELL LINES



- Microbial cell lines
 - Aerobic (e.g. E.coli) and anaerobic bacteria
 - Yeast

- Producer cell lines from mammalian and human origin (CHO, HEK293,...)

- Insect cell lines

Characterization

- Development and qualification of release/characterization assays
- Biosafety testing compliant with global pharmacopeial standards
- Stability testing

Documentation

- Manufacturing report and executed batch record documents
- Certificate of analysis for release and characterization assays
- BSE/TSE statement
- Certificate of GMP compliance



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CAPABILITIES

- Human IMP licenced manufacturing facility (FAHMP)
- Grade A/C suites, ISO 5/7 clean rooms
- Segregated BSL2 cell culture and fermentation rooms
- Qualified equipment
- Environmental monitoring program
- Storage of vials at -80°C or in vapor phase LN2

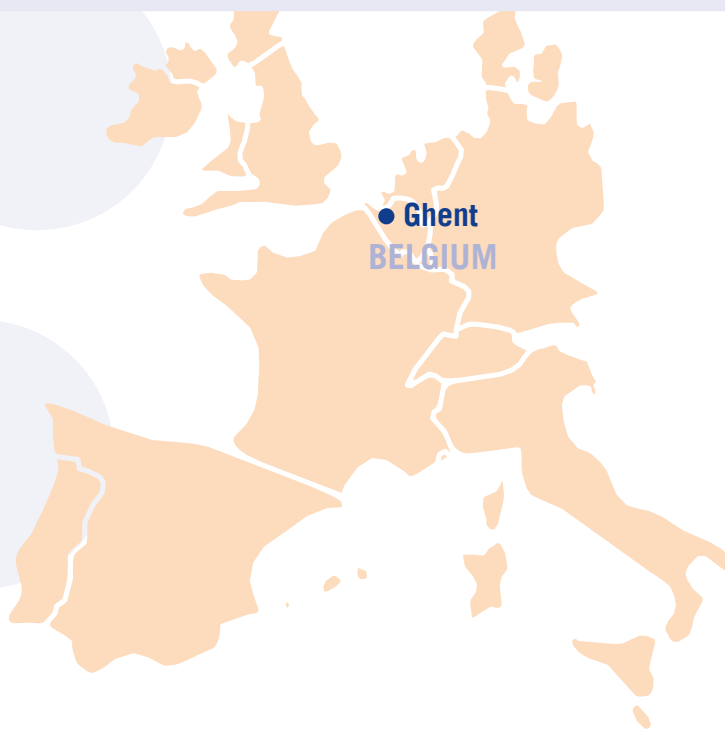


**Dedicated
Project Managers**



FACILITY

- Cell banking



ANSES

ANSM

AFMPS

FAGG

GMP



YOUR DRUG DEVELOPMENT PARTNER



Cell banking



Process
development



Clinical
manufacturing
(DS/DP)



Clinical supply
(packaging
& logistics)

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