

BIOLOGICS DIVISION

Company Overview

Eurogentec provides products and services in two main areas, a therapeutics manufacturing unit (Biologics) for microbial GMP production of proteins, vaccines, plasmids and a research products and a services division (Genomics & Proteomics) for custom oligos, Real-Time PCR kits, peptides and antibodies.

Biologics Division

A GMP certified manufacturer of biologics from bacterial and yeast sources, Eurogentec offers 10+ years of GMP know how in technology transfer, process development, scale up and manufacturing of proteins, plasmids and vaccines for pre-clinical, clinical and commercial phases.

Company Services

- Design of experiments (DoE)
- Risk analysis
- Construct and optimization of producer strain
- Technology transfer and process development
- Fermentation and downstream processing (DSP)
- Analytical transfer and development
- Process scale up and validation
- Validation of analytical procedures
- Cell banking and storage
- GMP manufacturing of API drug substances and drug products
- Quality control
- Master Batch Record
- Quality Assurance and Regulatory Compliance
- Batch release
- Stability studies (ICH, accelerated, stress etc)
- Dedicated project management
- Protein modifications by chemical means

Product Experience

- Plasmid DNA
- Recombinant subunits, cytokines, enzymes, antibody fragments, etc
- Live / attenuated vaccines
- Commercial API manufacturing in various scales (g to kg)
- >400 GMP batches completed
- >80 biopharmaceuticals produced

Resources

- Biosafety Level 2
- 600 m² Process development
- 600 m² GMP production
- 200 m² Quality Control
- Fermenters include 50, 100, and 350 l (working volume)
- Qualified equipment
- Class A - D production environments
- 6 production units in 3 suites
- On-site WFI system
- Dedicated Project Managers
- On-site Qualified Person
- GMP accreditation (1994)

Summary

- One-stop-shop for GMP biopharmaceuticals



Company
Eurogentec s.a.

Address
Biologics Division
LIEGE Science Park
Rue du Bois Saint-Jean 14
B-4102 Seraing, Belgium

Telephone
+ 32 4 366 61 11

Fax
+ 32 4 365 1604

E-mail
biologics@eurogentec.com

Web
<http://biologics.eurogentec.com>

Established
1987

Form
Privately held

Employees
Company wide - 290
Biologics Division - 70

GMP Experience
>400 GMP batches
>80 different biopharmaceuticals
Contact Persons

Sales and Marketing
Pascal Bolon, Ph.D.
p.bolon@eurogentec.com
Tel.: + 32 4 366 61 16

