



**Contract
Manufacturing
and Services**



CGMP DRUG SUBSTANCE MANUFACTURING

Clinical and Commercial Drug Substance Manufacturing

- ▶ Single-use Platform
- ▶ Manufacturing Capabilities
 - Viral, Mammalian, Avian, Insect
- ▶ Mammalian Cell Culture (200L–2000L)
- ▶ Viral Vector Vaccine Manufacturing (50L–2000L)
 - Suspension based, Microcarrier based
- ▶ Specializing in Protein Therapeutics and Emerging Infectious Diseases (EID) Vaccines

Downstream Processing

- ▶ Single-use Systems
- ▶ Aseptic Processing
- ▶ Depth Filtration
- ▶ Chromatography
- ▶ Ultrafiltration/Diafiltration

Customer Focus, Communication and Value

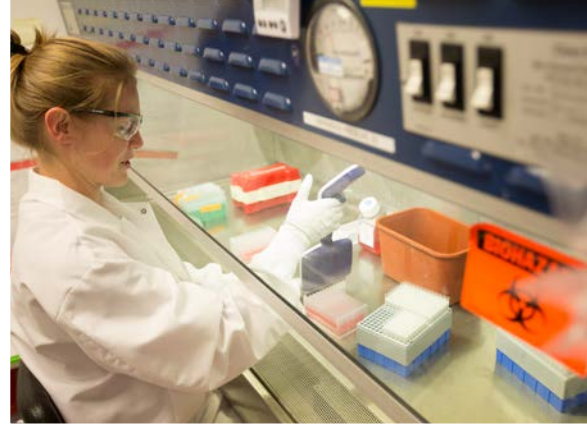
- ▶ Drug Substance Formulation
- ▶ Technology Transfer Plans (and Reports)
- ▶ Process Optimization and Scale-up
- ▶ Process Validation

Analytical

- ▶ Method Transfer
- ▶ Method Qualification and/or Validation
- ▶ Product In-process and Release Testing
- ▶ Stability Testing
- ▶ Raw Material Testing
- ▶ Assay Development

Platform Technologies

- ▶ Expression Systems Development
- ▶ Cell Line and Medium Optimization
- ▶ MVAator™ (modified vaccinia virus Ankara vector) cGMP bulk manufacturing
- ▶ Robust single-use manufacturing platform capable of rapid scale-up with flexibility to “scale out” as demand increases



PRECLINICAL
DEVELOPMENT

TOX & CMC
SUPPORT

PHASE I

PHASE II

PHASE III



CGMP DRUG PRODUCT MANUFACTURING

Sterile Fill Finish Liquid & Lyophilized Products

Vial Sizes

- ▶ 2cc - 125cc (2 filling lines)
- ▶ 2cc - 50cc (1 filling line)

Prefilled Syringes

Syringe Sizes

- ▶ 0.5cc - 20cc

Production Lyophilizers

- ▶ 216 ft²
- ▶ 240 ft²

Lyophilization Cycle Development

- ▶ Optimization of Critical Cycle Parameters
- ▶ Material Characterization
- ▶ FDM/FTIR/DSC
- ▶ Supporting Stability Studies

Laboratory Services

- ▶ Microbiology
- ▶ Method Development/Validation
- ▶ ICH Stability Testing
- ▶ Method Transfer
- ▶ In-process and Release Testing
- ▶ Raw Material Testing

Process Development & Validation

Inspection, Labeling, Packaging & Distribution

Experience with Complex Formulation Types

- ▶ Proteins
- ▶ Plasmid DNA
- ▶ Monoclonal Antibodies

Strong Regulatory History

- ▶ Support over 20 commercial products for our clients
- ▶ 200 Clinical Candidates Supported
- ▶ Expertise with Government Contracts



COMMERCIAL



Emergent Headquarters

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Emergent Contract Manufacturing Sites

Process Development

300 Professional Drive
Gaithersburg, MD 20879 USA

Drug Substance Manufacturing (Bayview Campus)

5901 East Lombard Street
Baltimore, MD 21224 USA

Drug Substance Manufacturing (Lansing Campus)

3500 N Martin Luther King Jr. Blvd.
Lansing, MI 48906 USA

Drug Product Manufacturing (Camden Campus)

1111 South Paca Street
Baltimore, MD 21230 USA

Process Development & Manufacturing

155 Innovation Drive
Winnipeg, MB R3T 5Y3 Canada

To learn more about Emergent's Contract Manufacturing Services contact us at CMO@ebsi.com or **800-441-4225**



PROTECTING & ENHANCING
50 MILLION LIVES BY 2025

Emergent BioSolutions is dedicated to one simple mission:
TO PROTECT & ENHANCE LIFE

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