CGMP Drug Substance Manufacturing

Clinical & Commercial Scale
2L-2000L Bioreactors

– Single-Use Platform
– Microbial
– Cell Culture
(mammalian, avian, insect)
– Virus
– Cell banking

Downstream Processing

– Single-Use Systems
– Aseptic Processing
– Depth Filtration
– Chromatography
– Ultrafiltration/Diafiltration
– 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

Platform Technologies

– Two Proprietary Platform Technologies:
  – MVAtor™
  (modified vaccinia virus
  Ankara vector)
  – ADAPTIR™
  (Mono and Multi-Specific
  Protein Therapeutic)
– Expression Systems Development
– Cell Line & Medium Optimization
– Assay Development

CGMP Drug Product Manufacturing

Sterile Fill/Finish Liquid
or Lyophilized Products
Prefilled Syringes (0.5cc - 20cc)

Vial Sizes

– 3cc - 125cc (2 filling lines)
– 2cc - 50cc (1 filling line)

Production Lyophilizers

– 216 ft²
– 240 ft²

Lyophilization Cycle Development

– Optimization of Critical
Cycle Parameters
– Material Characterization
– FDM/FTIR/DSC
– Supporting Stability

Laboratory Services

– Microbiology
– Method Development/Validation
– ICH Stability

Process Development & Validation
Labeling, Inspection & Packaging
Distribution

Experience with Complex
Formulation Types

– Proteins
– Plasmid DNA
– Liposomes
– Monoclonal Antibodies

Strong Regulatory History

– 20+ commercial products (products
distributed in 50 countries)
– 200 Clinical Candidates Supported
– e-CTD Filing
– Expertise with Government Contracts

PRECLINICAL DEVELOPMENT | TOX & CMC SUPPORT | PHASE I | PHASE II | PHASE III | COMMERCIAL

Emergent Headquarters

400 Professional Drive, Suite 400
Gaithersburg, MD 20879 USA
Tel: 301 795 1800
Fax: 301 795 1899

Emergent Contract Manufacturing Sites

Process Development
300 Professional Drive
Gaithersburg, MD 20879 USA

Bayview Campus
5901 East Lombard Street
Baltimore, MD 21224 USA

Camden Campus
1111 South Paca Street
Baltimore, MD 21230 USA

155 Innovation Drive
Winnipeg, MB R3T 5Y3 Canada

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

Emergent BioSolutions is Dedicated To One Simple Mission:
To Protect & Enhance Life

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