



**Diosynth Biotechnology offers cGMP contract manufacturing services for recombinant vaccines, proteins, and monoclonal antibodies.**



### cGMP Manufacturing

- Extensive clinical and commercial cGMP manufacturing experience
- Over 80 recombinant proteins, including cytokines, growth factors, transcription factors, hormones, enzymes, anticoagulants, recombinant vaccines, antibodies and fragments, fusion proteins, and PEGylated proteins
- Currently licensed to manufacture multiple commercial products
- Expression System experience including, *Escherichia coli*, *Pichia pastoris*, Pfenex Expression Technology™, CHO, baculovirus (BEVS), NS0, SP2/O

### Facilities

- Inspected by FDA (CBER & CDER), EMEA, Health Canada; certified by JMHLW
- Flexibility of scale
  - Microbial fermentation from 15L to 14,000L
  - Mammalian cell culture from 15L to 25,000L

It is about **delivering on expectations**. Our **Program Management** approach ensures open communications and performance of programs on time and within budget.

- Demonstrated track record of on-time delivery
- Most collaborative project leadership per an independent marketing study
- Open and transparent communication style
- Highly experienced Customer Project Leaders

You think it up . . .  
. . . We'll work it out.



## Services

- Technology Transfer
  - Transfer of customer developed processes
  - Scale-up to final cGMP manufacturing scale
- Process Development
  - Streamlined early and comprehensive late programs
  - Preparation for commercial manufacturing
  - Design of Experiments (DOE)
  - Quality by Design (QbD)
- Preparation for Commercial Filing
  - Process characterization and validation
  - Studies using small scale models
  - Validation Master Plan
- Formulation Development
  - High concentration
  - Stable formulation
  - Vaccine formulations
  - Lyophilized, liquid and frozen formulations
- Full ***In-house*** Analytical Capabilities
  - Method development, qualification, and validation
  - Protein and impurity characterization
  - cGMP testing: Drug Substance and Drug Product
  - cGMP stability programs
  - Reference standard characterization
- cGMP Manufacturing
  - Preclinical, clinical, commercial

## Quality and Regulatory

Quality systems support projects from clinical trials through conformance manufacture and commercial launch

- Submission-ready reports/documentation
- CMC strategy and CMC preparation
- Support in regulatory authority meetings, including FDA
- World-class Quality systems
- Successful track record with regulatory filings/inspections, including CBER/CDER, EMEA, Health Canada and JMHLW certification

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