



Diosynth Biotechnology
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Vital Statistics

Year Founded: 1995

Number of Employees: Approximately 500

Key Personnel: George Koch, Ph.D., Chief Scientific Officer
 Jenifer Wheat, Senior Director, Commercial Development

Who We Are

DIOSYNTH BIOTECHNOLOGY has a proven record in Process Development and Clinical & Commercial cGMP Contract Manufacturing of complex recombinant proteins, vaccines, antibody derivatives, enzymes and fusion proteins.

We ensure our customers' success by rapidly and cost effectively developing scalable, robust processes, together with our in-house talent in analyzing complex molecules. Our demonstrated experience with a broad range of expression systems (*E. coli*, *Pichia*, Pf ϵ nex Expression Technology™, *Saccharomyces*, CHO, NS0, SP2/0, Baculovirus, etc.) is combined with applied expertise in recovery, PEGylation & purification process technologies.

We apply our global regulatory experience (EMEA, FDA [CBER/CDER], Health Canada, JMHLW) with over 80 different products and processes to assist you in determining what is relevant for your stage of product development. Whether your product is in early stage development or you are preparing for BLA/MAA filing, Diosynth Biotechnology is committed to exceeding your expectations.

Major Markets

WE SERVE BIOPHARMACEUTICAL customers of all sizes, worldwide, including virtual, big and small biotechnology companies and large pharmaceutical companies with clients in the US, Europe, Australia, Canada, Japan, etc.

Diosynth Biotechnology is a part of Schering-Plough Corporation.



Services Offered

DIOSYNTH BIOTECHNOLOGY offers the following the services:

- Technology Transfer
- Fermentation & Cell Culture Process Development (DOE, QbD)
- Purification Process Development (DOE, QbD)
- Analytical Method Transfer, Development, Qualification and Validation
- Formulation Development
- Protein & Impurity Characterization
- Reference Standards
- cGMP Manufacturing (Clinical and Commercial)
- Drug Substance and Drug Product testing
- cGMP Stability (ICH guidelines)
- Process Validation (Master Plans, protocols, etc.)
- Quality and Regulatory Services (CMC preparation, Inspection readiness)
- Collaborative Program Management

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