



See how Diosynth™ Biotechnology translates experience into a total CMC solution for all of your production needs.



How do you eliminate the risk factors associated with developing innovative medicines?

Partner with a world-class CMO: Diosynth Biotechnology.

What can we do for our customers other than manufacturing proteins?

- Meet the strategic, technical, and quality goals for customer programs in a timely manner through our customized approach to project management and execution.
- Employ protocol-driven technology transfer processes to bring in projects from customers and seamlessly integrate them into cGMP manufacturing facilities.
- Offer extensive upstream and downstream process development experience, world-class Quality Systems infrastructure, and comprehensive analytical capabilities.
- Work successfully with all types of protein expression systems (CHO, NSO, SP2/O, hybridoma, *Escherichia coli*, and *Pichia pastoris*) and upstream processes using fed-batch, continuous, and perfusion production technologies.
- Develop and qualify/validate assays for use in release and stability testing and in-process testing and for characterization of products, impurities, and reference standards.
- Facilitate the smooth and timely testing of new raw materials, process intermediates, bulk drug substance, and final bulk product while continuing to meet U.S. and international regulatory requirements.
- Integrate services in cell line development through cGMP manufacturing to fill/finish to simplify sourcing efforts.
- Apply cGMP experience gained in both clinical and commercial manufacturing projects.

FERMENTATION

Process Development	15 L to 140 L
cGMP Manufacturing	Multiple reactors (140 L and 2,000 L) 7,500 L and 14,000 L

CELL CULTURE

Process Development	15 L to 110 L
cGMP Manufacturing	Multiple reactors (110 L) 2,000-L train (20, 145, 650 L) 25,000-L train (7, 70, 750, 7,500 L)
Perfusion	Multiple reactors up to 500 L

To find out how you can take advantage of our CMC expertise, visit www.DiosynthBiotechnology.com

Whatever your stage of product development, whatever your goal, Diosynth™ Biotechnology Services has what it takes to help you get there.

Our breadth of experience with complex proteins and processes includes

- Commercial and clinical manufacturing
- Over 75 recombinant proteins developed and manufactured, including 4 commercial products
- Fusion proteins, cytokines, antibodies and fragments, growth factors, vaccines, hormones, and PEGylated proteins
- Flexibility of scale
 - Microbial fermentation from 15 L to 14,000 L
 - Mammalian cell culture from 15 L to 25,000 L
- Global manufacturing capabilities in Research Triangle Park, NC, U.S., and Oss, Netherlands

With facilities in the U.S. and Europe, Diosynth Biotechnology Services can make your idea fly. To find out how, call 1.866.762.6259 in the U.S.; outside the U.S., call +1.919.337.4477 or visit www.DiosynthBiotechnology.com



PROCESS TO PROTEIN
EXPERIENCE FULLY EXPRESSEDSM