



Experienced Reliable Scalable Customized Confidential Global Compliant

Diosynth Biotechnology

ACTIVE

PHARMACEUTICAL

INGREDIENTS



Active Pharmaceutical Ingredients: reliability is the issue

IN A NUTSHELL

Diosynth is a world leader in process development and cGMP production of recombinant protein biopharmaceuticals and has been supplying active pharmaceutical ingredients to the global pharmaceutical industry for more than 75 years.

From receipt of a customer cell line to release of commercial product, our aim is consistent: *to discover and develop the most effective and mutually advantageous ways to achieve our customers' goals.* From process to product, we understand that reliability is the key to lasting and successful relationships. By minimizing risks and ensuring maximum efficiency, we reduce development times, move products rapidly into the clinic and the market to optimize the profit-bearing lifespan of your product. Our customers benefit from our reliability, technical excellence and full compliance with both current Good Manufacturing Practices (cGMP) and with environmental, health and safety regulations.

Our state-of-the-art cGMP manufacturing facilities in the United States and Europe support mammalian cell culture and microbial fermentation including a full range of low and high pressure chromatographic techniques. Techniques such as ultra and nanofiltration and freeze drying enable us to offer truly optimal service. Our scientists provide a full service range of analytical and formulation development services and comprehensive support of stability studies. Through long experience, we offer unparalleled

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Frequently Asked

Q: What products does Diosynth Biotechnology manufacture?

A: We provide cGMP production for recombinant therapeutic proteins and peptides. (Diosynth also manufactures synthetic peptides.) We have expertise with a wide range of proteins including monoclonal antibodies, fusion proteins, hormones, anti-coagulants, cancer vaccines, glycosylated and non-glycosylated products.

Q: What cGMP biomanufacturing services does Diosynth Biotechnology offer?

A: We are a full service biopharmaceutical contract manufacturer. Our scale-up, cGMP manufacturing and validation services support preclinical, clinical and commercial production.

Q: What Process Development services does Diosynth Biotechnology offer?

A: We are experts in assembling robust, scalable unit operations and processes. We employ scientific excellence, our knowledge of global regulations and our experience in the efficient operation of biopharmaceutical production facilities to develop processes that are cGMP compatible and cost-effective. The range of process development services provided includes: fermentation/cell culture, recovery, purification and a comprehensive range of analytical development services. We also offer formulation development and stability studies.

Q: What expression systems does Diosynth have experience with?

A: We offer services supporting both cell culture and microbial production and have experience with all major expression systems including CHO, NSO, *E. coli* and *Pichia pastoris*. In addition, we offer production from *Baculovirus expression* systems.

Q: What scale and type of cGMP production does Diosynth Biotechnology provide?

A: We provide batch, fed-batch and perfusion technology. Our U.S. facilities offer a wide range of capacities for both cell culture and microbial fermentation up to 2,000-L scale and our European facilities

Customer-oriented dependability...



asked Questions

feature cell culture capacity up to 18,000-L and microbial fermentation to 10,000-L scale.

Q: Does Diosynth Biotechnology manufacture commercial products?

A: Yes. We manufacture products that are marketed in the US and Europe for a range of customers.

Q: Will Diosynth Biotechnology be able to meet my requirements in the future?

A: Yes. We are a highly experienced contract biomanufacturer and understand the essential need for a secure supply of product for both clinical and commercial supply. We will strive to be your supplier-of-choice by working closely with you to understand your long-term needs and to plan accordingly. Diosynth continues to invest in cGMP production infrastructure worldwide.

Q: How can I ensure that manufacturing capacity will be available?

A: It is never too early to contact us to discuss your requirements. Please contact us to discuss your technical and business requirements in detail.

Q: Have Diosynth Biotechnology's facilities been inspected by the FDA?

A: Yes. All of our cGMP production sites have been inspected by the FDA. We have also hosted inspections by other international regulatory authorities.

Q: What regulatory support does Diosynth Biotechnology provide?

A: We provide a full range of regulatory support services, including support of regulatory submissions via preparation of CMC sections and other necessary documentation, hosting regulatory inspections and customer audits and assisting clients in their interactions with global regulatory bodies.

Q: How much will my program cost and how long will it take?

A: Every product and program is unique. We customize our services for every program that we undertake. A Diosynth Business Development Director will be able to provide you with preliminary information based on your specific requirements.

Q: How would my program be managed?

A: An experienced program manager from within our Commercial Development department will manage your program to ensure on-time completion within the agreed budget. We place a great deal of importance on excellent communication and on building long-term and mutually beneficial relationships with our customers.



expertise in process validation and technology transfer. Diosynth Biotechnology is committed to quality in all aspects of its business practices. We operate under a Quality Management System that assures that all active pharmaceutical ingredients produced meet industry standards and all applicable regulatory requirements of the United States, Europe and Japan.

Diosynth develops customer-specific program design and execution on proven policies and procedures as well as long experience, technical expertise and know-how. Industry seasoned Program Managers will guide your program from inception to completion and ensure that we continue our tradition of maintaining excellent customer communication and building long-term, highly successful business relationships. •

...geared to trouble-free continuity.

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For more information, please contact:

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