

**Experience
Solutions.**



Leading the way in cGMP
contract biomanufacturing



Fujifilm Diosynth Biotechnologies is one of the world's leading cGMP Contract Manufacturing Organizations for the biopharmaceutical industry, operating from two sites in Research Triangle Park, North Carolina, USA and Billingham, UK. We offer an extensive breadth of process development and cGMP manufacturing experience to meet your needs at every stage of the product lifecycle, from efficient protein expression, process design and GMP manufacture through to process validation and commercial production.

Experts in the development and manufacture of biopharmaceuticals.

Proven track record

Our track record in delivering successful programs will provide manufacturing support as your product reaches its next clinical stage quickly, economically and on time. Our experience includes:

- Development and manufacture of >150 proteins
- Extensive clinical and commercial cGMP manufacturing experience, including four commercial products
- Expression in *Escherichia coli*, yeasts (including *Pichia pastoris* and *Saccharomyces cerevisiae*), *Pseudomonas*, CHO, baculovirus (BEVS), NSO, SP2/0
- Development, scale up, and validation of PEGylation unit operations, to include site specific PEGylation chemistry as well as linear and branched forms of PEG
- World class technical services and R&D teams on both sites for seamless technical transfer and scale-up to cGMP manufacturing
- Track record of on-time delivery through experienced and distinctive program management teams
- Routine commercial manufacture of drug substance to support drug supply in multiple markets

Proven development & scale-up

Our experience ensures process development is applied appropriately, dependent upon the development needs of customer products at different clinical stages.

- Over 180 process development scientists
- Wide range of constructs and expression options including development of a customer's existing system or creating *de novo* from our family of microbial and mammalian therapeutic protein production systems, including our award-winning pAVEway™ system

Microbial	Multiple 5L, 15L and 140L fermentors
Mammalian	Multiple 2L, 5L, 10L, 15L, 20L and 110L bioreactors Wave 20/50 200L Xcellerex systems
Pre-cGMP pilot	100L scale

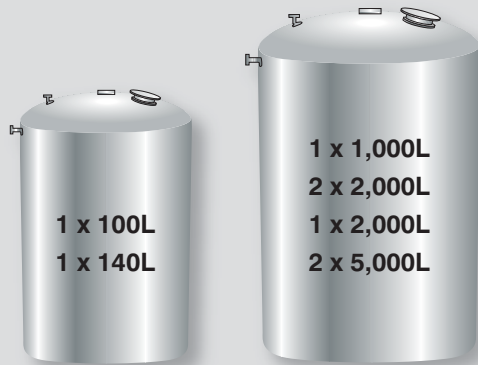
cGMP manufacturing

At our sites in Billingham, UK and Research Triangle Park, NC, we offer fully flexible clinical and commercial cGMP facilities for both microbial and mammalian cell culture production. We employ protocol-driven technology transfer processes to bring in projects from customers and seamlessly integrate them into our facilities. We are currently licensed to manufacture four commercial products.

Manufacturing Scales

Microbial Fermentation

- Various scales for rapid cGMP manufacture of material for Phase I-III clinical supply, process validation and commercial supply:



- Flexible plant configurations including disposables technology and refold volumes of up to 10,000L

Mammalian

- Rapid cGMP manufacture of material for Phase I-III clinical supply, process validation and commercial supply:



Manufacturing support services

The following additional services are offered to reduce complexity and risk of multiple suppliers:

- cGMP cell banking facilities for production of Master and Working Cell Banks
- Buffer screening studies to support downstream process development
- Development of stable product formulations
- Generation and characterization of reference material
- Full range of in-house analytical methods for in-process and drug substance and drug product analysis
- Full range of stability testing capabilities for drug substance and drug product

Quality and regulatory support

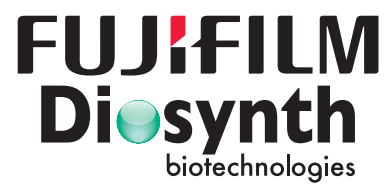
As you would expect of a world-class CMO, we provide all the necessary quality and regulatory support through an independent quality unit to ensure your product meets international regulatory requirements. Our regulatory inspection history includes FDA (CBER & CDER), MHRA, EMA, Health Canada, ANVISA, and certification by JMHLW.

- Regulatory support for IND/CTA submission, DMF and CMC as required
- QC analysis and release of raw materials, environmental and water in-process/final, sample retention
- Ownership and use of Qualified or Validated Methods
- Quality Agreement followed by routine interactions with customer throughout the program
- QP release

Program management

Our distinctive approach to Program Management enables a collaborative and trusting relationship, ensuring that we meet our customers' strategic, technical and quality goals in a timely and cost effective manner.

- Each program is supported by a dedicated, multi-disciplinary team led by an experienced and focused program manager
- Close customer interaction is promoted through regular teleconferences and face-to-face meetings
- Programs are milestone structured to ensure timely delivery



101 J. Morris Commons Lane, Morrisville NC 27560
Tel: +1 (866) 762 6259

Belasis Avenue, Billingham TS23 1LH, United Kingdom
Tel: +44 (0) 1642 363511

Email: enquiries@fujifilmdb.com
www.fujifilmdiosynth.com



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