Technical leadership in contract development and manufacturing

FUJIFILM Diosynth Biotechnologies offers expertise across a range of CDMO services and is continuously innovating and developing new technologies.

What are the main outsourced services that your company provides?
We are a world-leading cGMP contract development and manufacturing organisation (CDMO) supporting our partners in the biopharmaceutical industry with the development and production of their biologics, vaccines and advanced therapies.

Our expertise includes working with products expressed in a wide range of expression platforms including: microbial fermentation (e.g., E coli, P pastoris), cell culture systems including CHO, HEK, Vero, MDCK, EB66 and insect cells, and transgenics. We also offer:

- In-house developed Microbial (pAVEway™) and mammalian (Apollo™) expression platforms
- Cell banking capabilities
- Saturn™ mAb Platform for the efficient and de-risked delivery of monoclonal antibodies
- Full lifecycle biological and viral products manufacturing from initial concept to commercial product
- High containment cGMP manufacturing capabilities (BSL2 and BSL3 capable)
- High potency biologics cGMP manufacturing capabilities
- Centre of excellence for process characterisation studies.

What differentiates your company from the competition?
Technical leadership differentiates FUJIFILM Diosynth Biotechnologies from its competitors. We are continuously innovating and developing new technologies. Our portfolio includes Apollo™, our mammalian cell culture platform, and pAVEway™, our advanced microbial protein expression platform. These are enhanced by our approach to experimental design and execution. Having access to the FUJIFILM Group’s experience to successfully combine its technology and manufacturing for over 80 years underpins our clients’ confidence in our organisation to deliver programmes.

What value-added services does your company provide?
We have a complete microbial production offering, spanning from strain development, process and analytical development, all the way to GMP production with a wide range of scales – from 100L to 15,000L. We also offer a high potency biologics production suite.

Our late-phase process characterisation (LPC) programmes are unrivalled in the industry. Through the experience we have gained in the execution of late-stage process development programmes we have developed a suite of Quality by Design (QbD) tools and documentation templates for the benefit of our customers. Our approach allows flexibility to construct a process characterisation study designed around your specific process and needs.

What are the main drivers affecting the supply and demand for outsourcing services across the pharmaceutical industry?
New therapeutic areas such as immuno-oncology, and gene and cell therapies, are driving supply and demand of access to manufacturing capacity and technical expertise.

COMPANY DETAILS
NAME: FUJIFILM Diosynth Biotechnologies
YEARS OF OPERATIONS: 25+
TOTAL EMPLOYEES: ~1,200
LOCATION: Billingham and Redcar, UK, Research Triangle Park, North Carolina, and College Station, Texas, US.
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Developers of cell culture-based therapies need reliable and proven partners with the development and manufacturing experience and resources to support the delivery of their therapies. FUJIFILM Diosynth Biotechnologies is a world leading cGMP Contract Development and Manufacturing organization with a mAb platform that has been carefully developed to reliably and flexibly provide early access to mAb research and cGMP with regulatory compliant processes, facilities and systems.

**Access to Cell Culture Capacity**

Our high-throughput manufacturing resources provide the built-in capacity access necessary to support critical customer deadlines. Our dedicated 10,000 sq ft cell culture Center of Excellence for Platform Establishment, features the latest high-throughput technologies, includes fully-automated bioreactor and chromatography systems and a cutting edge analytical mAb panel with extensive characterization capabilities.

**Platform with Built-in Options for Flexibility**

The Saturn™ platform can either take advantage of Fujifilm’s proven Apollo™ Mammalian Expression System or can easily support programs built around established customer cell lines. This built-in flexibility facilitates coping with molecules that have complex development needs and manufacturing challenges.

**Reliable/De-risked Manufacturing**

Robust and easily optimized programs, from Early Phase to Late Phase ready for validation, Fujifilm’s facilities are designed to support long-term commercial manufacturing by taking advantage of our state-of-the art 120,000 sq ft cGMP mAb facility with 3 x 2,000L of cell culture upstream capacity. All of our upstream and downstream units of operation feature best-in-class technologies and Saturn’s™ use of off-the-shelf raw materials and consumables de-risks supply chains.