FUJIFILM

Diosynth biotechnologies

CMC SUPPORT SERVICES

Your CDMO Partner Advancing Medicines Through Critical Milestones With Expert CMC Support Services

Pre-Clinical | **Phase I-III** | **PPQ, Approval & Launch**

- Cell Banking
- Cell Line Development
- Process Development & Optimization
- Formulation Development & Optimization
- Elucidation of Structure
- BLA Elucidation of Structure
- Process Characterization | Process Validation | Process Lifecycle Management
- Process Transfer & Comparability Testing
- Phase Appropriate Method Validation | ICH Validation | Method Trending
- Quality Attribute Identification and Process Monitoring
- Drug Substance/Drug Product QC Release and Stability Testing
- Manufacturing Control of Clinical and Commercial Processes
- Regulatory Services, Qualified Person Declaration to support IND/IMPD and BLA/MAA filings

Process Characterization

We understand the criticality of timely and successful process characterization to enable sustained delivery over the life cycle of your molecule. Our global network brings together leading-edge technologies, risk-based study design and efficient work-flows to deliver agile solutions for clients during their journey to commercialization.

Process Validation

Process Validation is a pivotal lifecycle activity that involves the collection and evaluation of process data and knowledge to establish a defendable control strategy and defines a capable manufacturing process that reliably meets product quality attributes.

Formulation Development

In the arena of formulation development, the roadmap is composed of molecular information that is collected using innovative, information-rich and scientifically-sound computational, biophysical and biochemical analysis. We provide approval-ready drug substance and drug product formulations with forethought to manufacturability, within rapid timelines.

Analytical and cGMP Quality Control

Our analytical and quality teams specialize in the development, transfer, and phase appropriate validation of methods to meet the chemistry, manufacturing and controls (CMC) required to assess the physical and chemical characteristics of each product, and to ensure their quality and consistency during manufacturing.

DS/DP Stability Studies and Testing

Across our entire network we execute both accelerated and long-term stability studies on both drug substance and drug product for mammalian, microbial and advanced therapies products. We offer study design and management coupled with comprehensive reporting to support your regulatory submission process.

Qualified Persons & Regulatory Support

IND drafting and CMC module writing including responses to information requests and post approval maintenance. We've worked with our clients to deliver >20 commercial products (6 since 2020), working with multiple regulatory bodies.

Contact us to discuss your science and get the latest updates on our network and capabilities.

20+
Years of experience in 65+ PC programs

2
Purpose built Lab & Analytical facilities / dedicated units

3000+
cGMP batches for biologics

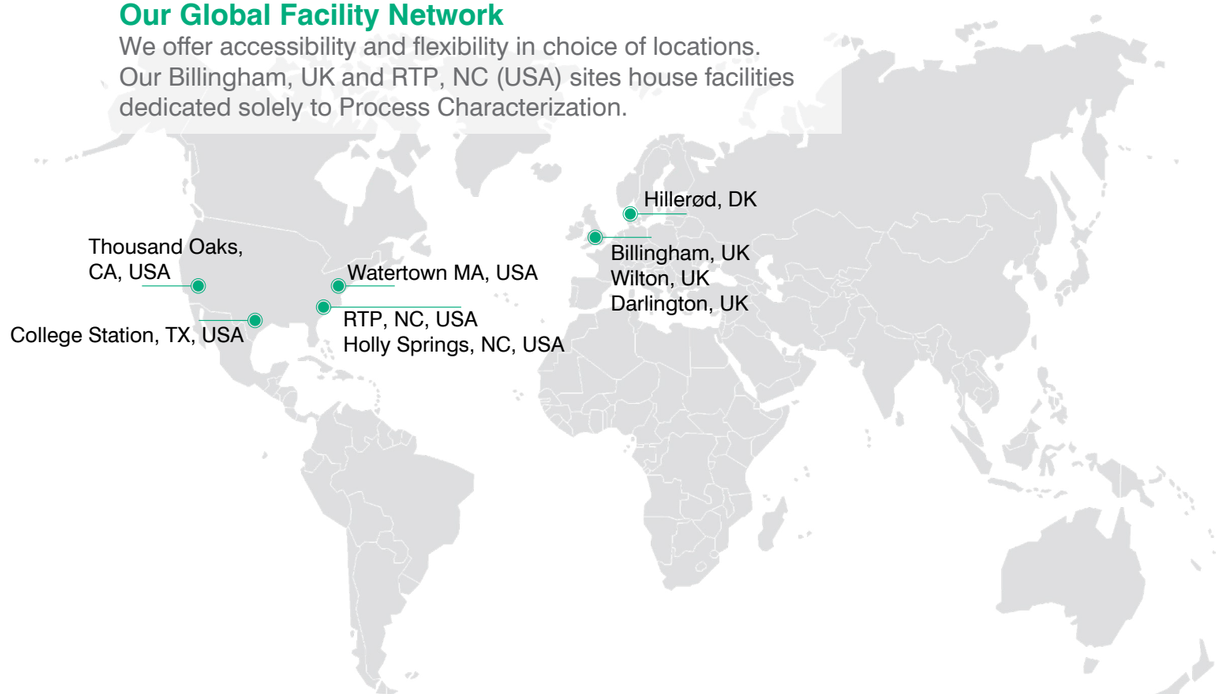
$7.4bn+
Invested in global facilities and advanced technologies

250+
Viral gene therapy clinical batches

500+
Scientists globally sharing expertise

Our Global Facility Network

We offer accessibility and flexibility in choice of locations. Our Billingham, UK and RTP, NC (USA) sites house facilities dedicated solely to Process Characterization.



CDMO LEADERSHIP AWARDS 2023

Contact us to discuss your science.

USA
College Station, Texas
3939 Fujifilm Way
College Station, TX 77845
+1 979 431 3500

USA
Research Triangle Park, North Carolina
101 J Morris Commons Lane
Morrisville, NC 27560
+1 919 337 4400

USA
Thousand Oaks, California
2430 Conejo Spectrum Street
Thousand Oaks, CA 91320
+1 805 699 5579

DENMARK
Hillerød
Biotek Allé 1
3400 Hillerød
+45 7741 6000

UNITED KINGDOM
Teesside
Belasis Avenue
Billingham, TS23 1LH
+44 1642 363511

USA
Watertown, Massachusetts
300 N. Beacon St.
Suite 100 Watertown, MA 02472

fujifilmdiosynth.com

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Advancing tomorrow's medicines

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