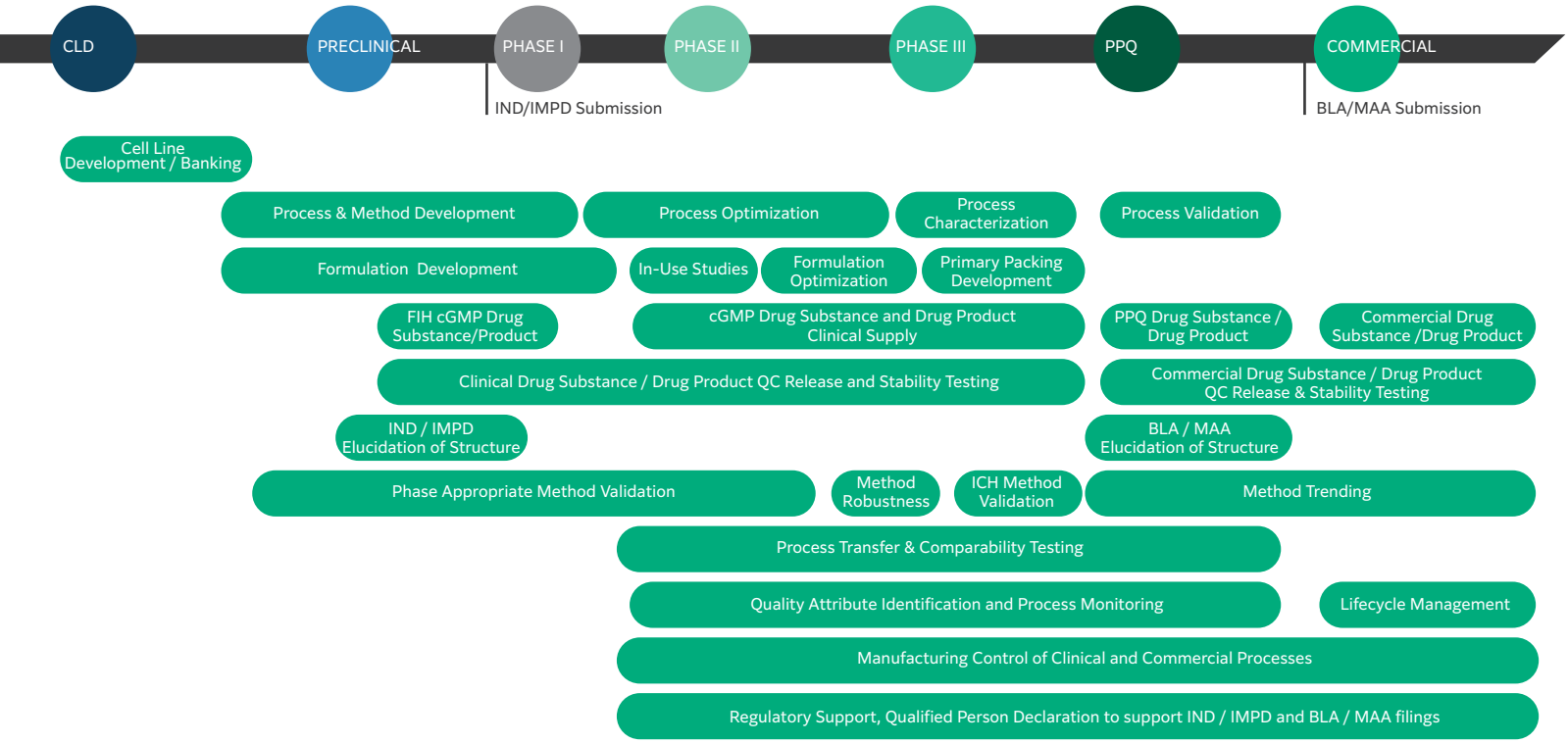
FUJIFILM

Diosynth biotechnologies

CMC SUPPORT SERVICES

Your CDMO Partner For Life With Expert CMC Support Services



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

Our services include 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

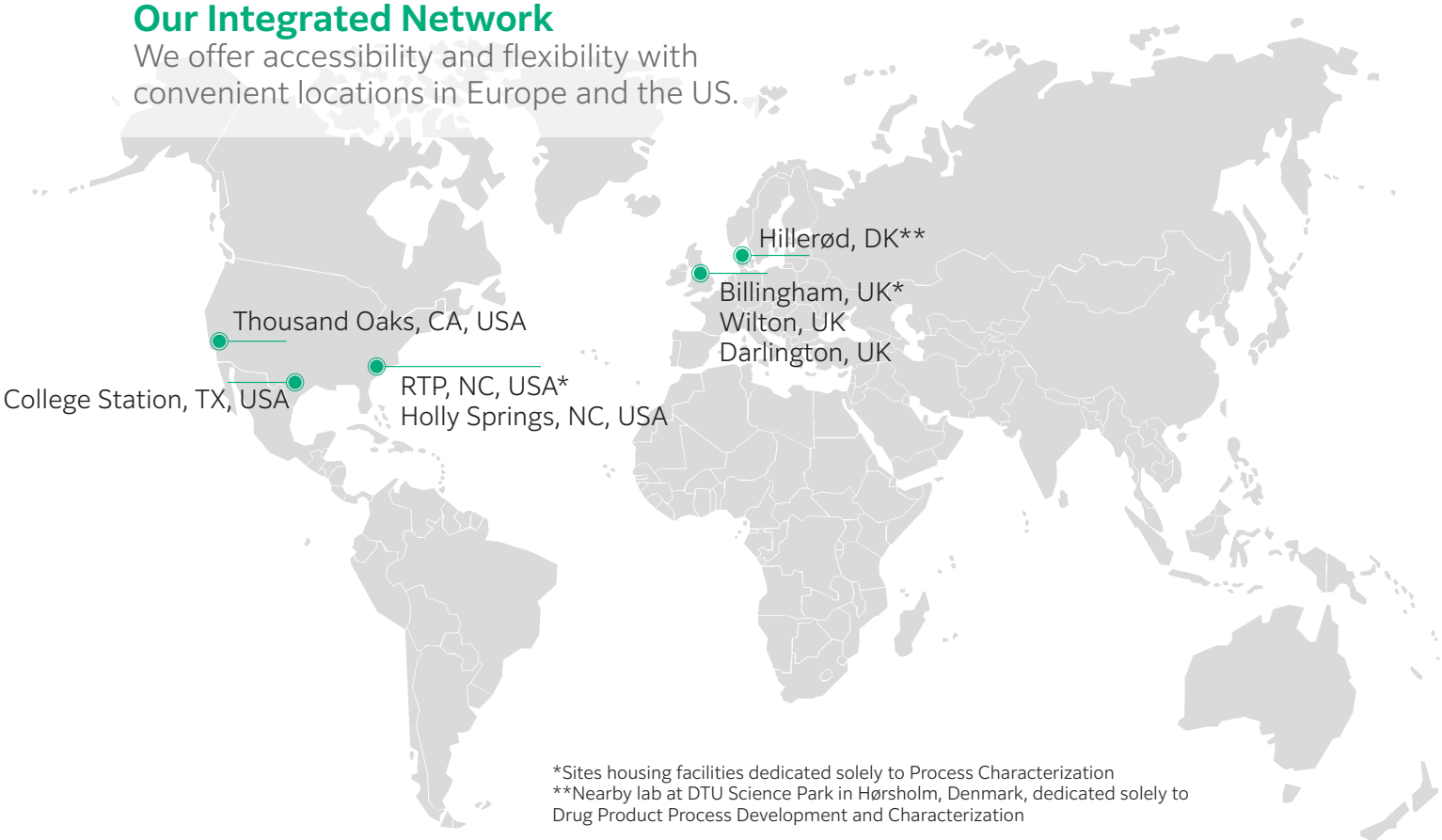
$8.6bn+
Invested in global facilities and advanced technologies

250+
Viral gene therapy clinical batches

500+
Scientists globally sharing expertise

Our Integrated Network

We offer accessibility and flexibility with convenient locations in Europe and the US.



*Sites housing facilities dedicated solely to Process Characterization
**Nearby lab at DTU Science Park in Hørsholm, Denmark, dedicated solely to Drug Product Process Development and Characterization

CDMO LEADERSHIP AWARDS 2024

Contact us to discuss your science.

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Partners for *Life*

FSC