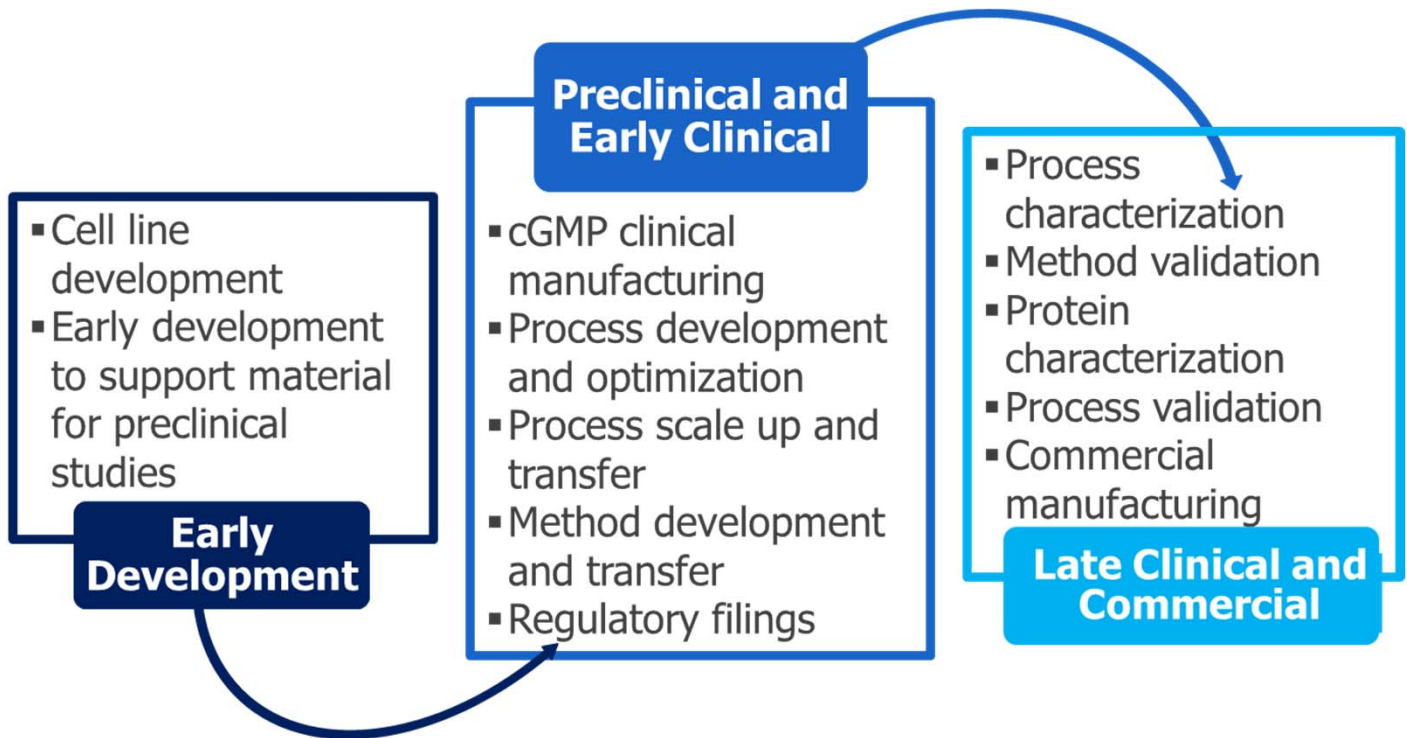


Full Lifecycle Capabilities-From Concept to Commercial Supply



Proven Regulatory Track Record



We are compliant with worldwide requirements for commercial production regulated by US FDA, EU, ANVISA & Health Canada.

- Successful PAIs In 2005, 2012, 2014, 2015 & 2017
- 2017 FDA Inspection Resulting In Zero 483 Observations
- Over 14 Years Of Inspection History With No Significant Impact to Business Operations



Our regulatory team has extensive experience in developing a regulatory strategy and approach, drafting responses and assisting in formulating strategies for interactions with regulatory authorities. We offer a range of services, including:

- Comparability Assessments
- Amendments & Supplements
- CMC Gap Analysis
- IND/BLA/IMPD Submissions
- Assistance With Response To FDA Questions

STATE-OF-THE-ART MYFORD FACILITY

Designed for Fully Disposable Manufacturing Processes

- Commissioned in 2016
- 42,000 ft² facility
- Equipped with 200L, 1,000L & 2,000L Single-use bioreactors
- Uni-directional process flows for personnel & materials
- Integrated QC labs for in-process samples, final release, & environmental monitoring
- Controlled raw material warehouse
- Modular clean room design
- MCB & WCB storage

FRANKLIN COMMERCIAL FACILITY

Commercial Manufacturing Facility Since 2005

- cGMP manufacturing since 1993
- 12,000 ft² facility
- Stainless steel bioreactors (100L, 300L & 1,000L)
- WFI, RODI, clean steam
- Raw material storage
- Single-use bioreactors (200L & 1,000L)

BIOREACTOR CAPACITY

Stainless Steel



Single-Use



EXCELLENCE IN PROCESS SCIENCE

- Demonstrated expertise in cell culture development, with proven ability to maximize productivity and guide glycosylation
- World-class purification experience, with knowledge to provide the chromatography media and methods that will give you the highest productivity and product quality
- Full spectrum analytical capability, with extensive experience and technical knowledge required to develop difficult assays, including live-cell assays
- Highly Experienced in Rapid Technology Transfer and Process Validation
- More than a decade of experience developing processes for smooth scale-up and transfer to cGMP manufacturing

