ThermoFisher SCIENTIFIC

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BIOLOGICS QUICK TO CLINIC™

patheon

QUICK TO CLINIC FACT SHEET

Get the best from Thermo Fisher Scientific, even faster.

Quick to Clinic™ is an integrated early development offering designed for biotech companies looking for a dependable solution to scale up recombinant antibodies from discovery to first-in-human (FIH) trials. With Quick to Clinic, you can:

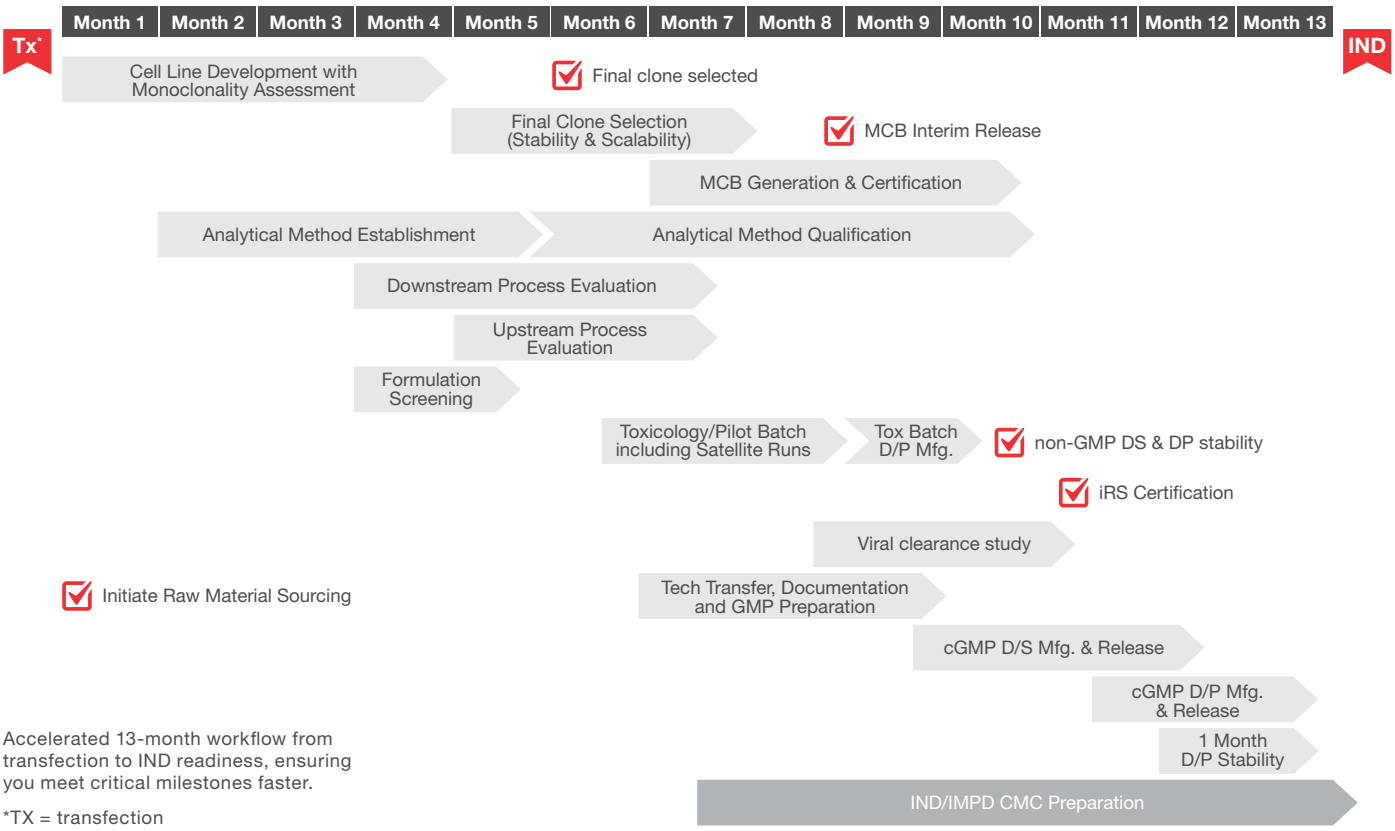
Speed up your early development to as little as 13 months from the start of transfection to IND with best-in-class technologies, allowing you to file faster and get to patients sooner.

Manage risk using a carefully constructed program that's backed by supply security from a company with a broad technology portfolio and deep scientific expertise leading to an assurance that you don't have to sacrifice quality for speed.

Focus on today's challenges and let us prepare you for the future. Getting your molecule from discovery to IND faster is just the first step. A royalty-free licensing option, high-yield expression system, and robust process platform help prepare you for long-term commercialization success.

A trusted cell line
A critical aspect of any early development work is the cell line that underpins the platform process. Quick to Clinic leverages Gibco™ Freedom™ ExpiCHO-S™, a commercial-ready cell line targeted to deliver antibody titers in the 3-5 g/L range. The Gibco Freedom ExpiCHO-S provides a 4-5 month cell line development timeline to final clone selection, cGMP host cells banked in chemically defined media free of any animal-derived components, and a licensing program with no royalty payments or exit fees to get you going quickly and set you up for long-term success.

An accelerated and optimized start-to-finish workflow



Accelerated 13-month workflow from transfection to IND readiness, ensuring you meet critical milestones faster.

*TX = transfection

Enhanced Quick to Clinic™

The enhanced Quick to Clinic has evolved to meet your growing needs. With innovations like a new expression platform with a two-vector system, use of high throughput automation technologies like the Beacon® Optofluidic System system for single cell cloning, and use of novel LC-MS based multi-attribute methodology for enhanced product quality attribute characterization, Quick to Clinic is designed to get you to clinic quickly while being thoughtful about risk and future scale-up.

WHAT YOU PROVIDE	WHAT WE USE	WHAT WE DO	WHAT YOU GET
Starting material: Gene • DNA sequence – genetic code	• Thermo Fisher Scientific Gibco™ Freedom™ ExpiCHO-S™ Platform • Patheon pharma services' platform process and Thermo Fisher media/ feeds with commercially available raw materials	• Cell Line Development using Berkeley Light Beacon® System • Evaluation of upstream and downstream platform process using high throughput automation technologies such as ambr® 15 microbioreactor & Tecan miniaturized purification platform • Formulation screening • Analytical method establishment & qualification • Toxicology batch • cGMP batch: 500L – 2000L • Viral clearance study • Stability testing	• Early toxicology material • Released drug substance • Released drug product • Minimum 1-month stability data for IND • Templated quality-reviewed reports • Clinical trial packaging and labeling (optional) • Regulatory CMC dossier for IND/IMPD filing

Pharma services global biologics and steriles network

Industry-leading, fully integrated network with five global Biologics sites and four global Steriles sites with 19 development and commercial lines as of 2020.

- Drug Product/Steriles
- Drug Substance/Biologics

*Quick to Clinic is not currently offered out of Lengnau and Hangzhou

Ready to talk about getting your large molecule to IND while balancing speed and quality? Contact us today.

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