ThermoFisher SCIENTIFIC

MADE WITH

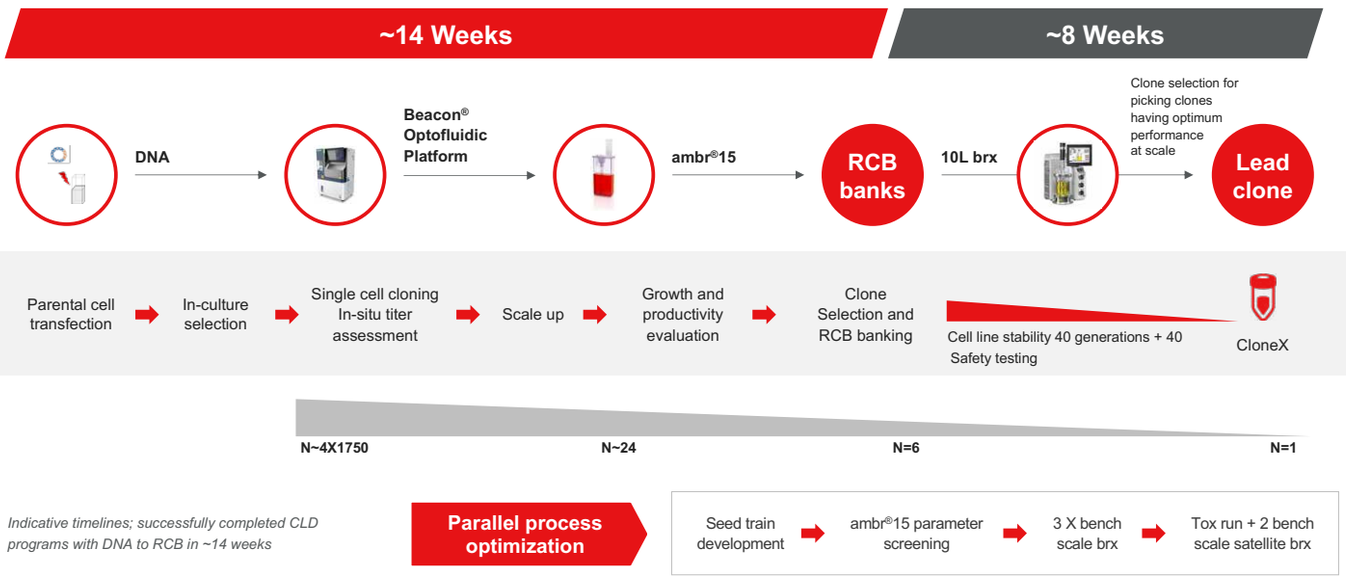
PROCESS & PURPOSE

Five Ways to Get to IND/IMPD Faster

The road to IND/IMPD isn't always easy. Balancing speed, risk, and future needs is a challenge. So how do you get to IND/IMPD faster without sacrificing quality and future commercialization goals? Our experts have shared a few things to consider when thinking about accelerating and optimizing your early development process.

1 Carefully design cell line development and process evaluation to balance speed and risk.

Work with your CDMO to ensure that the CLD and process evaluation steps are optimized for speed without taking significant risks or cutting corners. By starting upstream process evaluation in parallel to final clone selection, you can speed up the process establishment by 6-8 weeks.



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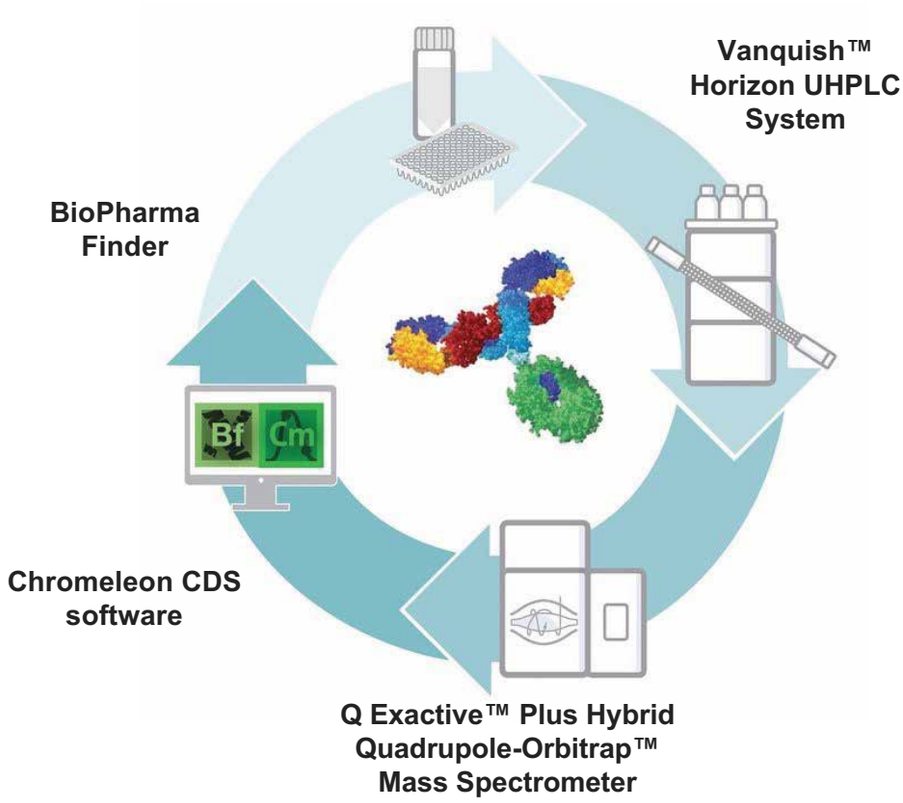
2 Use formulation screening vs. full formulation development.

Formulation development is typically required for complex molecules, but for more common monoclonal antibody types, an abridged approach can be taken by simply screening a panel of known formulations based on prior knowledge and successful experience with similar molecules. This approach can significantly shorten development timelines, especially for the manufacturing of toxicology and first-in-human material.

Pre-formulation				
Identify optimal pH, degradation pathways and stability indicating methods	Customized approach based on phase of development and molecule	Formulation development recommended for Fc-fusion, IgM, Fab, enzyme, or recombinant proteins	Formulation selection approach for IgG and bi-specific molecules to accelerate timelines	Short term stability study (6+ mos) to evaluate final formulation using long term, accelerated and stressed storage conditions

3 Incorporate MAM (multi-attribute analysis) for larger data set around product quality, creating a solid foundation for Phase II and III production.

A multi-attribute analysis uses highly sensitive mass spectrometry for low-artifact reduced peptide mapping, to accurately quantitate product quality attributes and to directly monitor post-translational modifications at the amino acid level. This allows for data-driven decision making around process evaluation and scale-up, as well as detailed analysis on the product quality changes during DS/DP stability studies, and a more shortened analytical method lifecycle.



4 Use a trusted expression system.

For example, the enhanced Quick to Clinic™ solution from Thermo Fisher Scientific delivers target titers in 3–5 g/L range using the new Gibco™ Freedom™ ExpiCHO™-S expression system. Plus, there are no clinical milestone or royalty payments.

5 Have your CMC regulatory dossier prepared and ready to meet filing requirements.

A best practice is to align your dossier preparation timeline with your development and manufacturing stages, enabling timely information flow from the CMC source data directly to M3 IND/IMPD dossier content in CTD format.

- **Adapted for high-density culture (2 x 10^7 cells/mL)**
- **Short doubling time**
- **High specific productivity**
- **Stable growth and expression profiles over many passages, compared to parental CHO-S cells**
- **High-quality, biologically active protein**

Ready to talk about how you can accelerate your biologics early development timeline with solutions like Quick to Clinic™? We're prepared to help.

Connect with us today.

About us

Thermo Fisher Scientific provides industry-leading pharma services solutions including end-to-end drug development, clinical trial services and commercial manufacturing solutions to customers of all sizes through our Patheon brand. With more than 65 locations around the world, the company has extensive capabilities including small and large molecule drug substance and drug product development, viral vector and cGMP plasmid development and manufacturing to support cell and gene therapy and vaccines, clinical trial services and commercial-scale manufacturing and packaging.

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