Biologics

Scaling biologics with confidence

Proven success from late-stage to commercial

Discover four real-world case studies highlighting how Thermo Fisher Scientific empowers biotech and pharma innovators to transfer, scale, and launch their biologics programs faster—without compromising on quality or regulatory excellence.

Bringing a biologic therapy from late-stage development to commercial supply is one of the most critical transitions a biotech drug developer will face—and one that demands both precision and partnership. At Thermo Fisher Scientific, we've helped innovators around the world navigate this stage successfully, helping to ensure smooth technology transfers, rapid scale-up, and reliable global supply.

In this brochure, you'll discover four real-world case studies that showcase how our flexible platforms, harmonized global sites, and deep regulatory expertise have helped to speed up commercialization timelines and reduce risk. Each story underscores our commitment to collaboration and operational excellence—from initial tech transfer through process validation and beyond.

Case study 1

Drug substance process development, optimization, and manufacturing for an Fc-fusion biologic

Background

The customer needed support with the tech transfer of an established Fc-fusion protein from Brisbane, Australia, to another biologics manufacturing facility, to redevelop the process for late-stage clinical supply and commercialization.

Requirements

- Consistent and reproducible seed train growth
- A 14-day process achieving 1–1.5 g/L titer

Risks

- Limited design space to improve titer without affecting critical quality attributes (CQAs)
- Tight timeline to execute process steps

Tech transfer strategy

Stage I

Ambr screening for media/feed optimization

- Seed train robustness tested in parallel
- Stage-gate post-Ambr to confirm results and direction
- Leverage existing data from prior Ambr experiments

Stage II

Ambr screening for media/feed optimization (Round 2)

Stage III

Optimization to increase titer

- 4×4 bench-scale reactors
- Analytical and formulation sciences (AFS)/downstream processing (DSP) support using current methods as needed to establish improvements

Stage IV

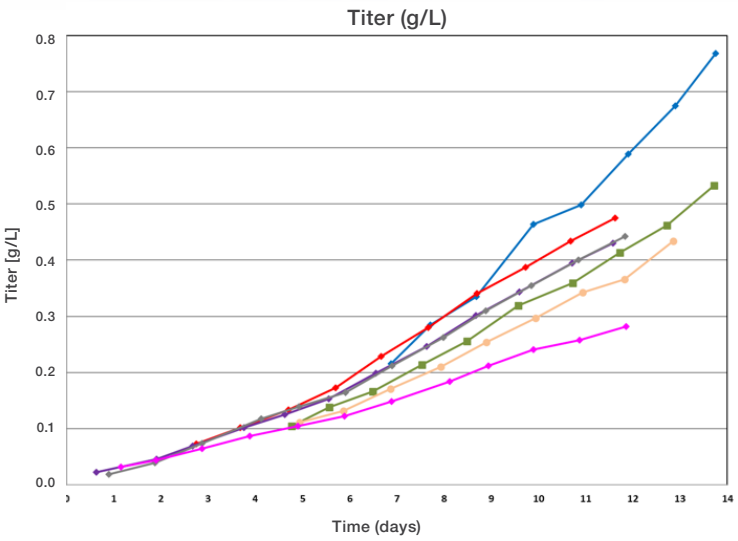
Confirmation, pilot, and engineering batch

- Establish scalability (12 L ➡ 250 L ➡ 2,000 L)
- Perform necessary confirmations for AFS/DSP
- Conduct bridging studies between processes

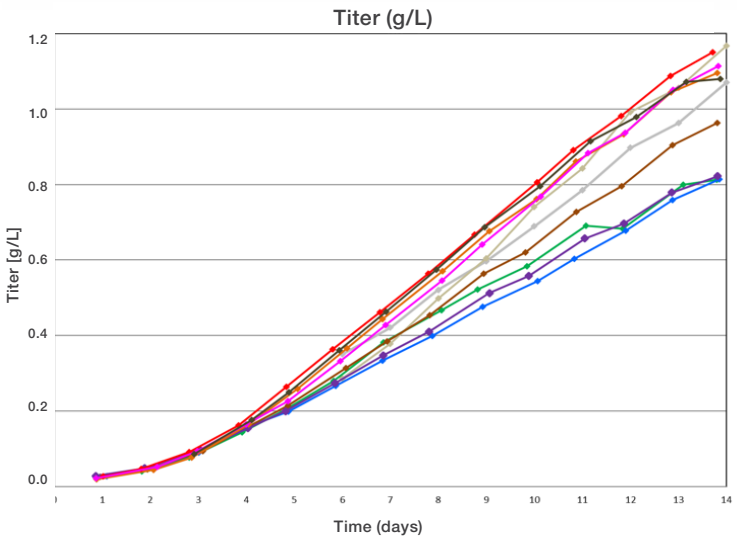
Stage V

Range finding and robustness

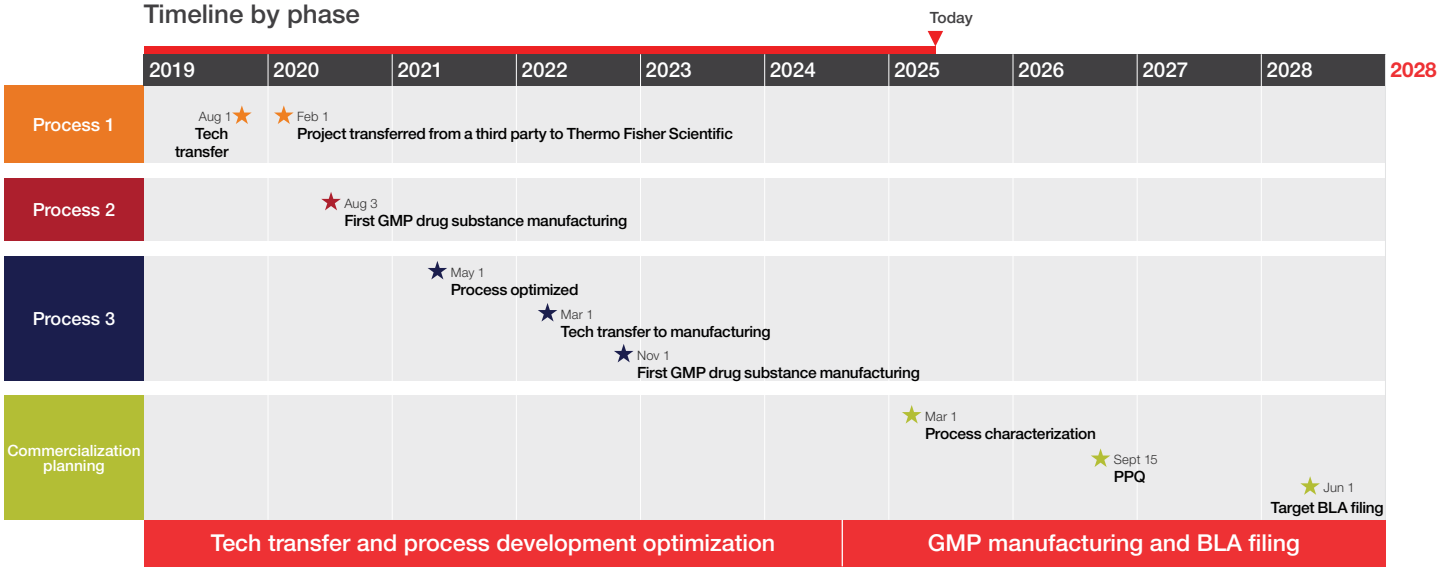
Pre-optimization



Post-optimization



Timeline by phase



Case study 2

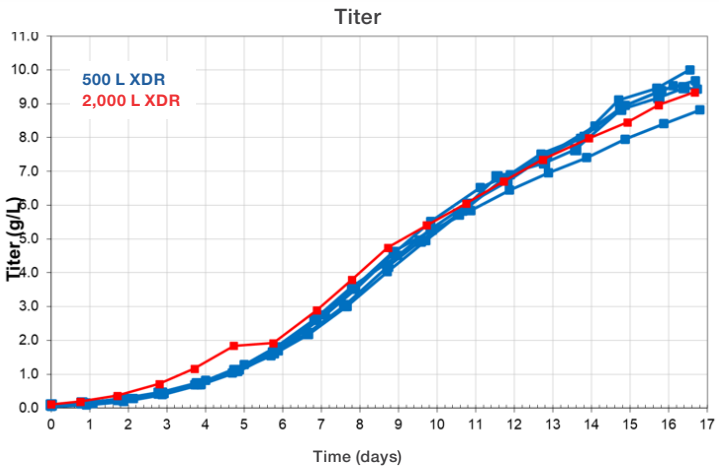
Phase I clinical trial drug substance process development, optimization, and scaled-up manufacturing for a bispecific biologic

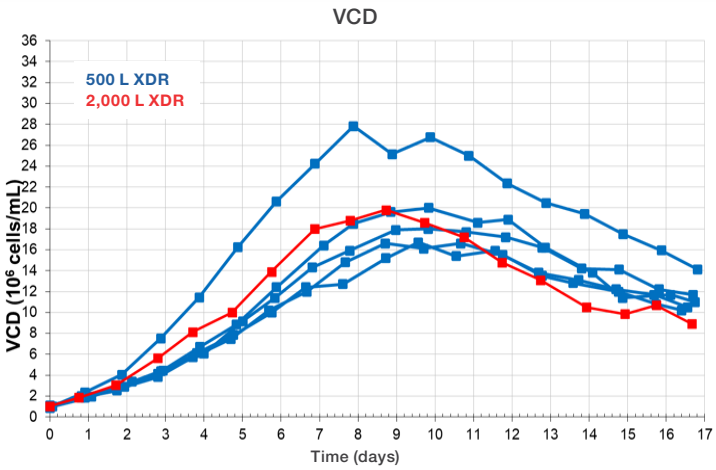
Background

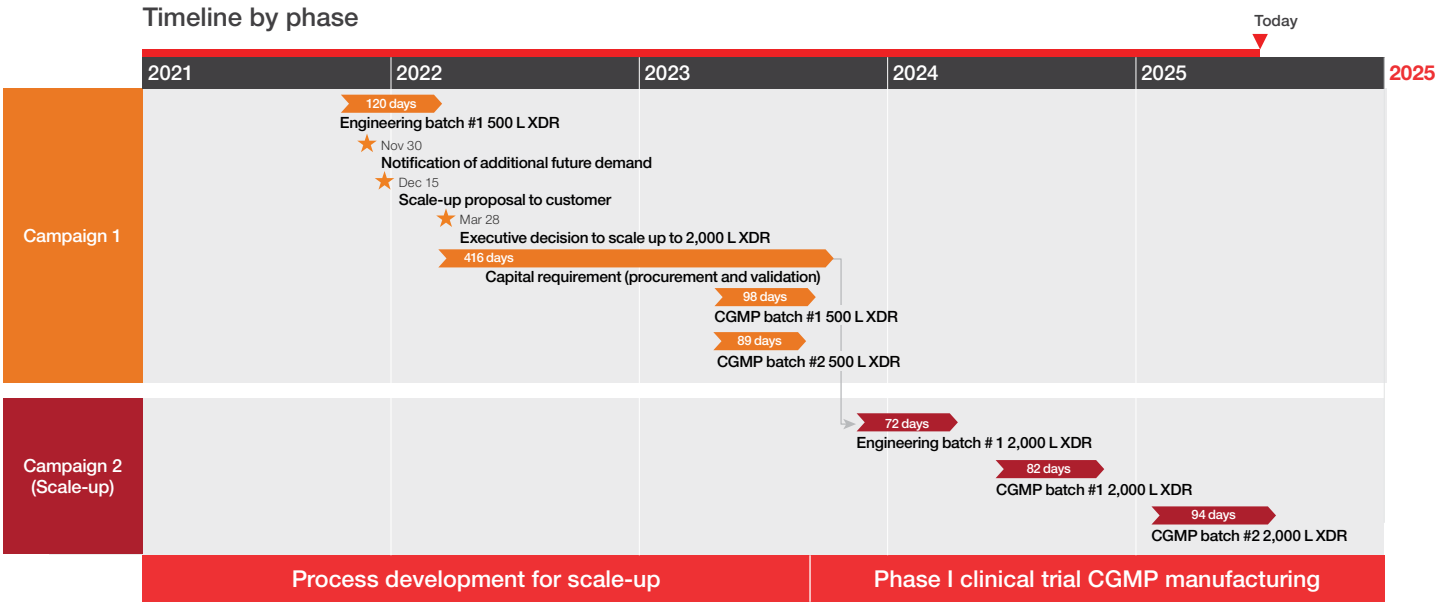
- The customer developed a manufacturing process for a bispecific antibody for a Phase 1a clinical trial.
- Clinical demand increased due to a high clinical dose.
- Additional batches in Brisbane were requested, but the production schedule was full. Brisbane offered to support the program's scale-up to 2,000 L to meet client demand.

Considerations and outcomes

- A key challenge was that the high product titer entering the downstream processing (DSP) exceeded the capacity of the existing TFF skids, necessitating CAPEX.
- A new TFF skid was installed at the Brisbane facility, and IQ/OQ was successfully performed onsite.
- The process was executed right the first time, achieving high product recovery (>95%).


Titer
500 L XDR
2,000 L XDR
Titer (g/L)
Time (days)


VCD
500 L XDR
2,000 L XDR
VCD (10^6 cells/mL)
Time (days)


Timeline by phase
Today
2021
2022
2023
2024
2025
2025
Campaign 1
120 days
Engineering batch #1 500 L XDR
Nov 30
Notification of additional future demand
Dec 15
Scale-up proposal to customer
Mar 28
Executive decision to scale up to 2,000 L XDR
416 days
Capital requirement (procurement and validation)
98 days
CGMP batch #1 500 L XDR
89 days
CGMP batch #2 500 L XDR
Campaign 2 (Scale-up)
72 days
Engineering batch # 1 2,000 L XDR
82 days
CGMP batch #1 2,000 L XDR
94 days
CGMP batch #2 2,000 L XDR
Process development for scale-up
Phase I clinical trial CGMP manufacturing

Case study 3

Process development, optimization, and scale-up manufacturing

Background

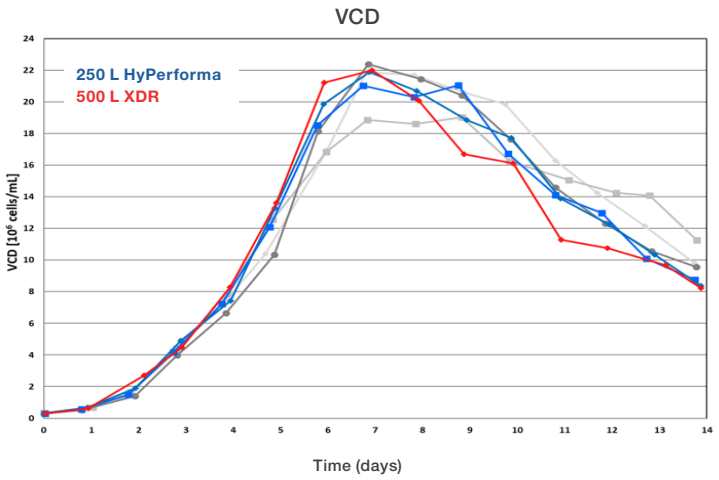
- The process was developed in St. Louis, MO, at our US biologics manufacturing facility, and then transferred to our Brisbane, Australia facility for CGMP manufacturing at 250 L scale in a HyPerforma S.U.B. for IgG1
- The 250 L and 500 L HyPerforma DynaDrive S.U.B.s were unavailable during the timeline requested by the customer
- Brisbane offered to scale up the program to a 500 L XDR bioreactor to meet the customer's timeline

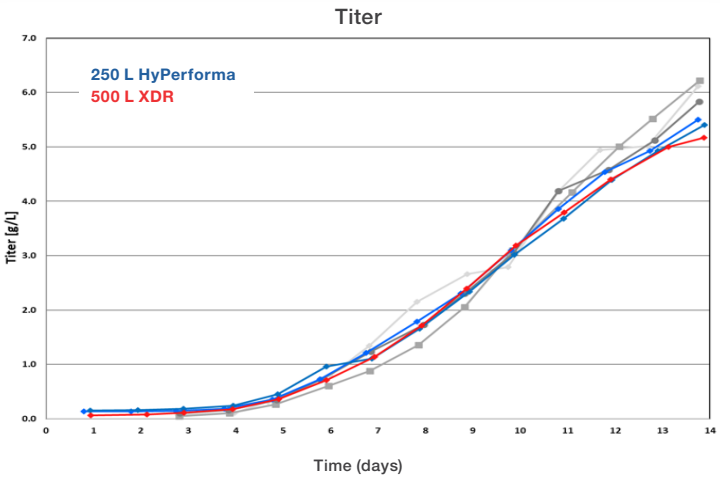
Requirements

- Maintain titer while scaling up and converting to XDR
- Manufacture a 500 L batch within the customer's specified timeline

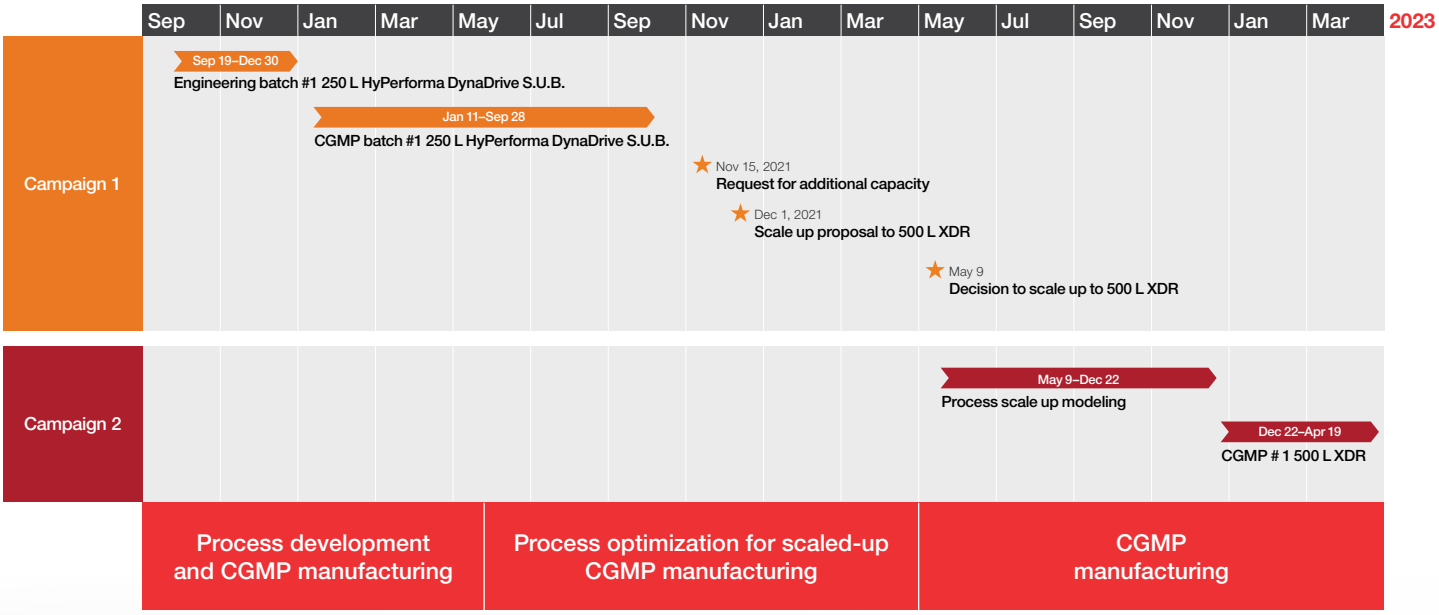
Considerations and outcomes

- A key challenge was that the process had never been run using XDR technology
- The scale change (250 L ➡ 500 L) and bioreactor system change (HyPerforma ➡ XDR) occurred within a single batch
- The batch was successfully scaled up in the new XDR bioreactor system
- Titer was maintained during the scale-up across the bioreactor systems





Timeline by phase



Case study 4

Process development, tech transfer, and scale-up

Background

- The molecule was a humanized IgG2/4 k monoclonal antibody intended for use as a biosimilar
- Direct technology transfer was performed from the customer's US facility to our Brisbane, Australia facility in the Asia-Pacific region
- A 15-day, 2,000 L fed-batch process was executed using customer-proprietary media formulations in a 2,000 L HyClone single-use bioreactor (S.U.B.)

Tech transfer strategy

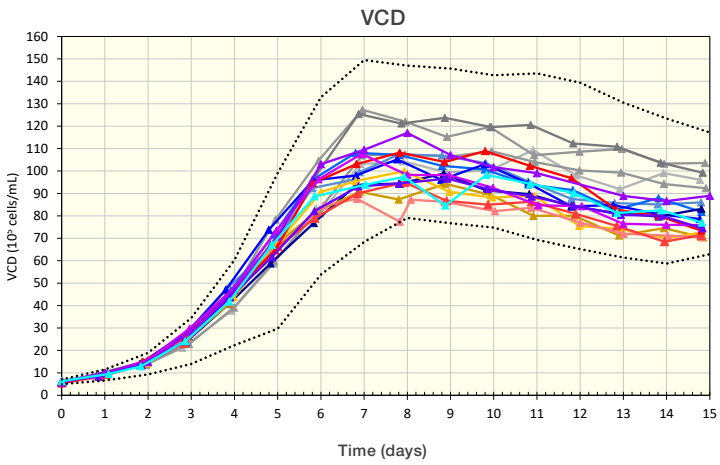
- Direct technology transfer from the customer's US facility
- At our facility in Brisbane, we executed 1 × 250 L engineering batch, followed by 4 × 2,000 L clinical batches
- Customer performed process characterization at their facility, followed by final process risk assessment and process control strategy formulation at our Brisbane facility
- At our facility in Brisbane, we executed 4 × 2,000 L batches for process performance qualification, and the process is now HA-approved and commercialized
- More than 30 commercial-scale batches have been successfully executed to data

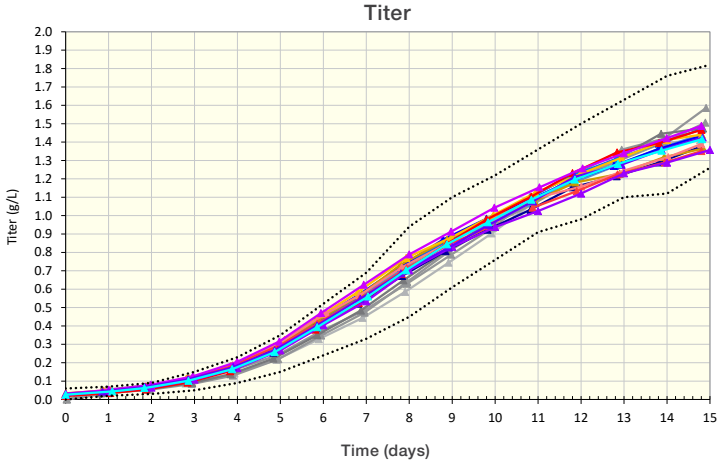
Requirements

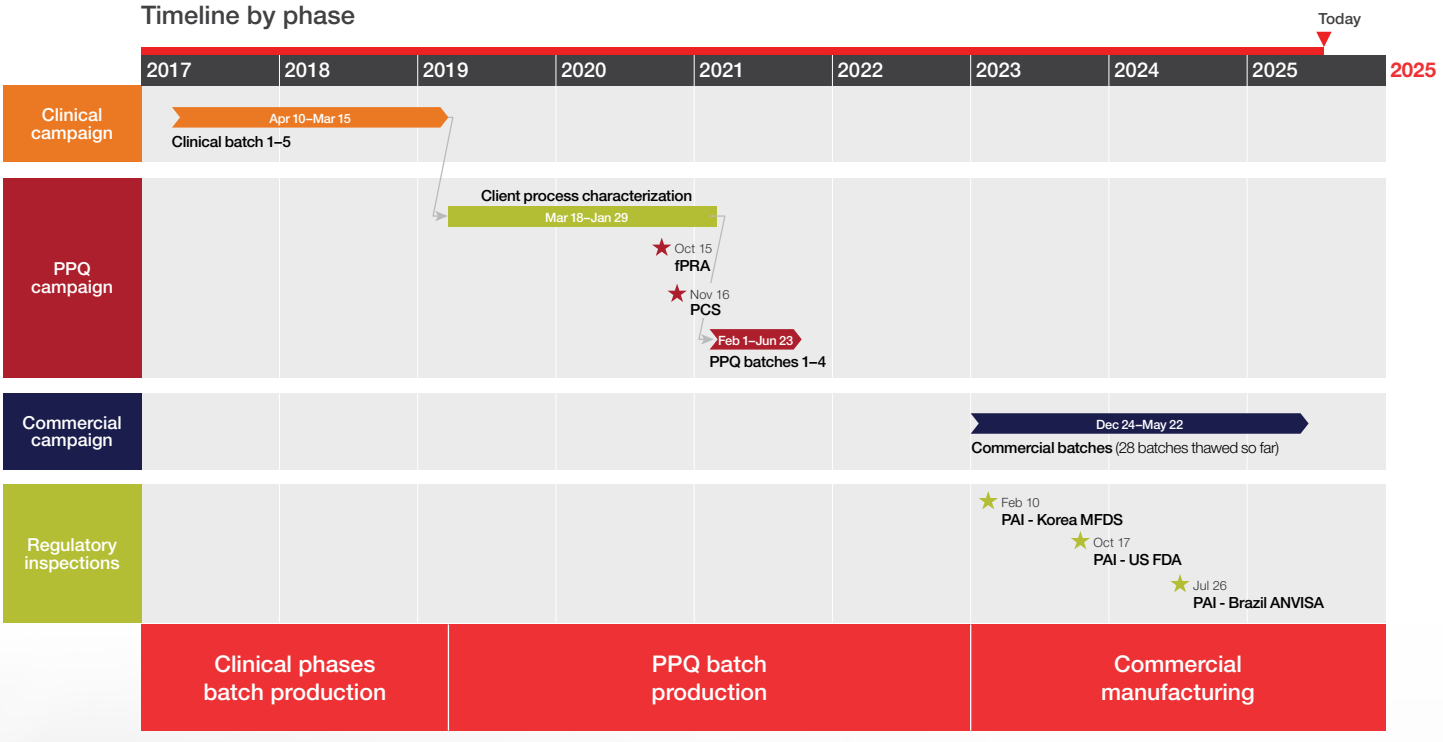
- Accelerated timelines from clinical supply to PPQ and BLA filing
- Asia-Pacific support for the FDA's information request (IR) and requested process changes, including updates to process ranges and criticality rankings following PPQ
- Introduction of a replenishment WCB

Execution plan/risk mitigation

- Duplicate 2,000 L S.U.B.s
- Duplicate cell counters and metabolite analyzers
- Original working cell bank (WCB) had a 9% likelihood of failing thaw viability criteria. As mitigation, up to 3 thaws are allowed (if required) to set up passage 1 per PCS (failed thaws discarded)
- Replenishment WCB has demonstrated improved thaw consistency to date


VCD
VCD (10⁵ cells/mL)
Time (days)


Titer
Titer (g/L)
Time (days)


Timeline by phase
Today
2017
2018
2019
2020
2021
2022
2023
2024
2025
2025
Clinical campaign
Apr 10–Mar 15
Clinical batch 1–5
PPQ campaign
Client process characterization
Mar 18–Jan 29
Oct 15
fPRA
Nov 16
PCS
Feb 1–Jun 23
PPQ batches 1–4
Commercial campaign
Dec 24–May 22
Commercial batches (28 batches thawed so far)
Regulatory inspections
Feb 10
PAI - Korea MFDS
Oct 17
PAI - US FDA
Jul 26
PAI - Brazil ANVISA
Clinical phases batch production
PPQ batch production
Commercial manufacturing

From late-stage development to full-scale commercial production

Ready to scale your biologic with confidence?

Connect with your local Thermo Fisher Scientific representative today.

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Learn more at **thermofisher.com/patheon**
or email us at **pharmaservices@thermofisher.com**