ThermoFisher SCIENTIFIC

CASE STUDY

UNITED WITH STRENGTH & PURPOSE

Delivering a large-scale product at a rapid pace

Challenge

When a pharmaceutical client needed to introduce, manufacture, and validate five stages of challenging chemistry to support a Phase III clinical development program, the Thermo Fisher Scientific pharma services team had to get to work. Speed, scale, and complexity immediately became the hallmarks of this project.

The team had to:

- Complete the tech transfer, clinical manufacture, validation, and commercial manufacture of API under **accelerated timelines**
- Manufacture at least 4.5MT of clinical API **within 7 months**
- Complete successful validation of a five-stage process with 12MT of API shipped **within 12 months**

Delivering an accelerated program to support the client's ambitious timelines for market authorization was no small feat for this team. Deploying 28 technical experts, the pharma services team developed a project plan to ensure rapid startup.

Solution

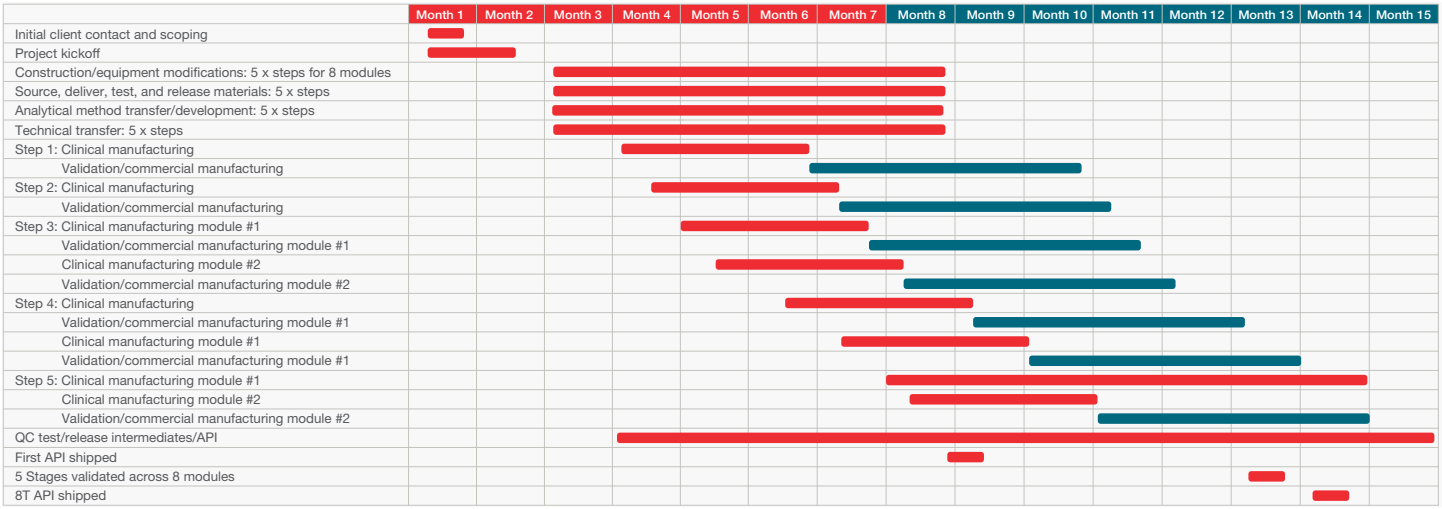
Upon mobilizing chemists, engineers, analysts, and a dedicated program manager, the technical teams adapted at speed to accommodate the numerous process and analytical changes required across the five stages of chemistry. To meet production startup dates, they completed significant site engineering and equipment modifications, along with recruitment and training to ensure adequate resources to support the project.

Mobilizing the right expertise, with detailed planning to act with agility

The supply chain team led a thorough and rigorous cross-functional planning program that included detailed end-to-end materials and tracking, batch production, intermediate and API testing, release, and shipment. In turn, a high volume of documentation supported production across multiple modules running simultaneously.

Phase-appropriate systems approach

Project timeline:



Results

Manufacture of the first stage of clinical API commenced 12 weeks from project kickoff and ramped up quickly, with 6 modules (~50% of site capacity) brought into production within 7 weeks.

Within 13 months, the pharma services team manufactured:

8.5MT of clinical-grade API

4.5MT of commercial API

Successful validation & execution of **five stages of chemistry** across **eight production modules**

Thermo Fisher's pharma services team met the client's timeline demands and delivered large-scale validated product rapidly and reliably.

Successful pre-PAI inspections to support accelerated regulatory timelines

"The team is very flexible and responsive to our requests, engages well, and shows great availability and good cooperation. We have access to an experienced and skilled Thermo Fisher Patheon team, and there is continuous learning from batch to batch. This is a good partnership. The team has the willingness and capability to change report templates to reflect our needs and to introduce additional controls in the lab for in-process methods. I'm also impressed with the thorough root cause analysis investigation and good track record on RFT."

—Pharmaceutical client

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