Case Study
Drug Substance

Speed to market – API large scale commercial manufacturing

Background

Cambrex was approached by a top 20 US-based pharmaceutical company looking to partner with a contract manufacturing organization (CMO) with commercial manufacturing capabilities, large scale assets, multinational sites and exemplary quality systems/US FDA track record. The CMO would need to supply large volumes of an API in clinical phase III within a short timeline to pre-approval inspection (PAI). In order to meet the requirements of the project, the customer required more capacity to meet commercial supply needs.

With existing large scale assets, extensive commercial manufacturing expertise and excellent quality systems, Cambrex Charles City was chosen to build and validate a new facility following the customer's framework, which included a 12-month timeframe followed by a PAI. Cambrex was also required to validate the facility, processes and procedures, begin production, hire and train employees and secure and release new materials.

The issue

In order to build and validate a 7,000ft^2 facility following a specific framework, capital investment was required to construct the facility to the correct specification. Despite an original timeframe of 12 months followed by a PAI, the PAI timeline was compressed by two months with the overall project plan reduced to 10 months. This created an aggressive timeline for the completion of the building, including validation and approval. The customer also revised the initial requested volume, increasing it by 50% therefore creating a need for flexibility.

Solution

In order to supply large volumes of an API for phase III clinical trials whilst maintaining the highest levels of quality in a short period of time, Cambrex put a dedicated team in place to ensure project success. This included senior management, project managers, chemists, engineers, manufacturing specialists, QA/QC, validation, EH&S and regulatory affairs specialists.

Cambrex employees worked diligently to meet project milestones, including the installation of a new emissions containment system.

Outcomes

The project resulted in the creation of a new commercial manufacturing facility which was both customer and US FDA approved.

Cambrex completed the project within a reduced timeline, with the new facility built and in production within 10 months, while also achieving the increased volume demand. Cambrex also met the customer's technical requirements and delivered against raw material sourcing requirements.

Cambrex's customer focus and clear communication within the project team were key drivers in keeping goals aligned.

Highlights

- Supplied commercial volumes of an API in clinical phase III
- Creation of new facility for commercial manufacturing complete with three trains, controlled substance security, ISO 8 qualified and maintained cleanrooms and ECB 3 containment capability
- Reduced timeline from 12 to 10 months in response to customer need

About Cambrex

Cambrex is a leading global contract development and manufacturing organization (CDMO) that provides drug substance, drug product, and analytical services across the entire drug lifecycle.

With over 40 years of experience and a growing team of over 2,200 experts servicing global clients from North America and Europe, Cambrex is a trusted partner in branded and generic markets for API and finished dosage form development and manufacturing.