Cambrex

Case Study
Drug Substance

Adapting to change - API custom development and manufacturing


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Raw Material Handling

Background

Cambrex was approached by a top 100 European-based pharmaceutical company looking for a development and manufacturing partner to assist with an in-licensed product originating from an emerging pharma company. The molecule was in clinical Phase II / III trials and the customer required development work and scale-up to commercial manufacturing. The chemistry required was particularly challenging and Cambrex needed to upgrade its commercial manufacturing assets prior to project initiation.

Cambrex Karlskoga, Sweden, was selected to assist with the project as the company had an existing relationship with the originator company and extensive experience with the chemistry and process. The customer also felt that Cambrex had the necessary scale-up and commercial production expertise.

The issue

In order to safely manufacture the high potency API, Cambrex Karlskoga upgraded to containment assets capable of manufacturing at a 1-10 µg/m^3 occupational exposure limit (OEL). Capital investment was also needed for the processing area. Following a market assessment, the customer also revised the initial requested volume down by 50 per cent, creating a need for flexibility.

Solution

In order to meet the agreed project start date, Cambrex was required to build containment assets to safely manufacture within four months. This included validating the area, process and procedures. Following the build, the processing area for APIs to 1-10 µg/m^3 OEL was inspected and approved, including the flexible isolators and contained charging.

Working in collaboration with the customer on the safety requirements, a toxicology consultant was also engaged to assist in evaluation where necessary.

Outcomes

The project resulted in a new manufacturing area being installed into an existing validated and approved cGMP manufacturing site. Training was also performed on procedures, equipment, the facility and PPE resulting in 10 FTEs trained. Procedures were also developed/revised for manufacturing the highly potent compound.

The project is an example of scale-up to production within one year, with the plant upgraded to include a flexible high potency containment area that is able to meet volume change requirements without impacting the project timeline.

Cambrex's customer focus, dedication to the project and customer irrespective of project changes and collaboration and communication kept the project on track.

After the handover of the project from the originator, the customer evaluated Cambrex during the relationship. This resulted in high scores in HSE and excellent QA.

Highlights

- Complex chemistry and process with several chemical steps
- Compound re-classified as highly potent (1-10 µg/m^3 OEL) during project campaign
- Full range of analytical and validation development services
- Product registration
- Validated production
- Volume estimates of 10s of kg / year

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.