Case Study
Drug Substance

Investing in capacity – API commercial manufacturing

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Background

Cambrex was approached by a top 10 Asian pharmaceutical company looking to partner with a contract manufacturing organization (CMO) with commercial manufacturing capabilities and expertise, mid- to large-scale cGMP assets and exemplary quality systems and US FDA track record. The requirement was to find a cost effective process to produce the API for a new drug.

Cambrex had previously been working with the emerging company which initially developed the drug, so proactively approached the customer with innovative ideas for a new cost effective method. The original chemistry included a high number of chemical and purification steps and Cambrex believed a more efficient method was achievable. The customer felt that Cambrex had the necessary know-how, scale-up and commercial production expertise to meet its requirements.

The issue

In order to meet the project requirements, closed handling of dry material was required for the highly potent API. The project also required heavy analytical method development for genotoxic impurities, significant numbers of chromatographic methods and particle characteristics.

In order to achieve particle size via micronization, Cambrex needed to establish a narrow particle size distribution (PSD) range. Finally, the established supplier of the raw material could not be used so the qualification of key raw material suppliers was necessary.

Solution

In order to overcome the project's challenges and provide a cost effective process to produce the API, Cambrex made modifications to the production line, building containment for the safe drying of the product.

Significant efforts were also spent on the development and validation of new methods in both Cambrex's Karlskoga and Tallinn facilities. The Analytical Development package included several new genotoxic impurities (GTI) methods as well as particle characteristics such as PSD and Brunauer-Emmett-Teller (BET). Cambrex also worked on the qualification of a new supplier for regulatory starting material and was involved in writing the drug master file (DMF).

Outcomes

The outcome of the project was a new, cost effective process developed in two chemical steps. The new process was fully validated including significant numbers of new advanced analytical methods as well as stability programs.

Cambrex delivered the required volume of API in time at the customer's target cost whilst working in collaboration with the team to meet the safety requirements. Through dedication to the customer and the project, Cambrex was able to achieve project success. Collaboration and communication between the project team was critical.

Highlights

Development of new innovative cost effective method for API manufacturing to achieve:

- Higher yield and throughput
- Lower raw material and waste cost and environmental benefits versus original method
- Process optimization
- Full range of analytical and validation development including genotox impurities
- Scale-up of process and validated production
- Volume estimates of 1000-3000kg/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.