June 2019

Eurofins CDMO: Highly Potent Drug Development from early stage

Elena Bejan, PhD, MBA, Vice President Research and Development, Eurofins Alphora, Elena.Bejan@alphoraresearch.com

Catherine Lacaze, Pharmacist, Technical Business Manager, Eurofins Amatsigroup, C.LACAZE@amatsigroup.com

High-potency drugs present numerous opportunities for improved drug selectivity, efficacy and safety profiles, and represent a growing area of global development focus, for applications such as oncology and hormone-based treatments. Although this class of molecules offers numerous benefits to patients, they require particular care and attention in ensuring the safety for those involved in their manufacture and handling.

Eurofins CDMO presents global offerings for the development and manufacture of high-potency drugs, from API production to formulation and manufacture of clinical and commercial materials.

Drug substance (API) Eurofins CDMO has significant experience in technology development of complex API molecules for scale up manufacture. High Potency APIs (HPAPIs) are frequently structurally-complex, requiring sophisticated process, manufacturing and analytical methodologies. Particular challenges associated with HPAPIs relate to safe containment and handling practices, and include:

- Engineering, environmental and cGMP controls in line with current guidance and best practices
- Dedicated equipment including isolators and auxiliaries
- Equipment and instrument cleaning procedures, analytical methods & criteria
- Institutional training and general & product-specific SOPs

In addition to establishing innovative synthetic routes, manufacturing processes and analytical controls, a Eurofins CDMO development program will evaluate and implement appropriate toxicity control strategies for HPAPIs.

Drug Product (Finished Product):

In parallel, Eurofins CDMO provides a wide range of drug product development services for HPAPIs, from early development to clinical, and further to commercial supply. We have successfully developed, transferred and supported the commercial manufacture and distribution of oral, liquid, semi-solid and parenteral finished products, for cytotoxics, hormones and other high-potency products.

In addition to their inherent toxicity, high-potency drugs frequently present formulation challenges requiring specific strategies, such as low aqueous solubility, poor bioavailability, food effects and high inter-subject variability. Thanks to containment facilities and specialized technologies, and with the benefit of more than 20 years of experience and a strong track record in the development, Eurofins CDMO has set up specific tools for the formulation of high potency and poorly-soluble entities based-upon their specific molecular characteristics, and according to multivariate, design-of-experiment (DoE) approaches.

For more information: Click here
To send us your request: Click here