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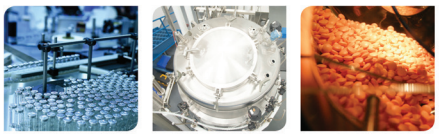

API commercialization support services

Eurofins Alphora is an FDA-approved CDMO focused on process chemistry, cGMP scale-up and analytical method development for complex, small molecule APIs, including highly potent molecules. We have taken molecules to market launch in numerous regions, including the USA, Europe, Japan, Canada, and Australia. Our facilities have undergone multiple successful PAI inspections since 2008. We will work with you and your current API CMO to optimize chemical processes, undertake CMC gap analysis, and perform other activities to support commercialization.

Strong development team focused on commercialization

The following commercialization support services can be provided as part of an existing program or stand-alone / one-off:

- CMC Gap Analysis and Risk Assessment
- Fate and Purge Studies
- Impurities Markers Synthesis
- Full Structure Characterization and Elucidation
- Process Optimization
- Design of Experiments
- Critical Process Parameters Studies
- Preparation for, and execution of process validation
- Tech transfer to client's API CMO, as applicable
- Continuing CMC support during and after market launch

As programs head towards commercialization, the process is mapped with direction provided by risk assessment and Design-of-Experiment methodology, leading to an understanding of the operational space and potential critical process parameters. The impurity profile is further examined, with targeted fate & purge studies, designed to ensure clearance of impurities and knowledge of carry-over and tolerable levels. Once the process has undergone successful validation, our CMC experts can support with registration with global Regulatory Authorities. The final objective is to achieve commercial approval with the client's chosen API CMO.

Eurofins Alphora

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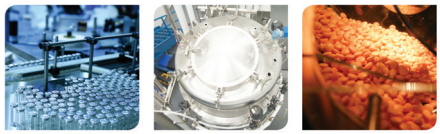

API commercialization support services

cGMP flexible facilities and breadth of experience

Eurofins Alphora operates multiple USFDA and Health Canada approved facilities with process volumes upwards of 500L. These facilities have undergone multiple PAI inspections and are routinely used for:

- Demonstration of the optimized process to confirm yields, control of impurities, and control of critical parameters
- Preparation and execution of process validation batches
- Commercial re-supply

The facilities have capabilities including:

- Scale-up reactor vessels of 20L, 50L, 60L, 200L and 500L
- Cryogenic conditions
- Hydrogenation
- Chromatography, including Biotage from bench to large scale
- Isolator containment for compounds with OEL's <30 ng/m^3

Beyond state-of-the-art facilities, we have a breadth of experience with a variety of chemical transformations including:

- Reductive amination
- Organometallics (RMgX, BuLi, LDA)
- Halogenations ($POCl_3$, $SOCl_2$, SO_2Cl_2)
- Reductions ($LiALH_4$, $NaBH_4$, DIBAL)
- Suzuki couplings
- Pauson-Khand cyclization
- Peptide chemistry
- Catalytic, hydrogen transfer

Project teams

Strong project management is an important component of our work. Every API Development & Commercialization project at Eurofins Alphora is carried out by a talented group of Process Research Scientists, Analytical Scientists, Technology Transfer Specialists, CMC and Regulatory Experts, all supported by a Project Manager. Project Managers act as a clear point of contact for all discussions with the customer. This proven structure has been designed to ensure effective communication and project management and is reflected in the high levels of customer satisfaction for which we have developed a reputation.

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