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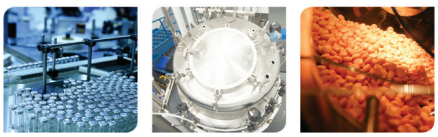


API developmental services

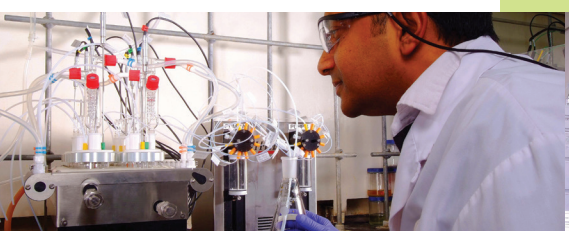
Eurofins Alphora is an FDA-approved CDMO focused on process chemistry, cGMP Scale-up and analytical method development for complex, small molecule APIs, including highly potent and cytotoxic molecules. Our talented team of Process Research, Analytical, Technology Transfer, CMC Specialists and Project Managers have supported clients from the pre-clinical phase through IND development, into late phase and commercial activities. Our work spans route selection to process and analytical development, and on to non-cGMP and cGMP scale-up; we also perform vital supporting activities such as criticality assessment and mitigation, CMC filing support, and supply chain management. We work closely with clients to provide phase-appropriate solutions to balance their immediate and long-term API development needs.

Early phase support

From the laboratory to the plant

After a Clinical Candidate is nominated, route selection and process development, leading to the establishment of a scalable, safe and GMP-friendly process is undertaken. API properties such as polymorphs, salts and other physicochemical properties are evaluated. Preliminary analytical methods are established and initial product understanding gained through stress and stability studies. To support early phase programs, including IND-enabling projects, our Development Team can execute the following:

- Development of new, scalable API route options
- Process safety and hazards assessment
- cGMP Starting Material assessment and establishment of regulatory concept
- Starting Material and other raw materials sourcing and development
- Polymorph screening and salt selection
- Analytical method screening and preliminary stability profile
- Pre-formulation and pre-clinical supply



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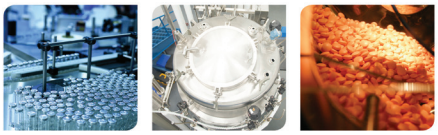


API developmental services

Phase II support

Setting the stage for the commercial process

At this Phase, the API development program moves to establish the potential commercial process.The chemistry is executed at increasing scale, targeting an efficient and robust process. Analytical development steps up to solidify and validate methods to support manufacture and long-term stability of the prospective API profile. The impurity profile is studied and challenged, from related substance and process impurities, to solvents and elemental impurities, as well as potential DNA-reactive impurities. Our scientists are keenly focused and examine the API and its physical forms at this stage, as the prototype for formulation is set. Eurofins Alphora's Development team performs Phase II support with the following services:

- Route or step rebuild
- Process optimization and demonstration
- Impurities assessment and synthesis
- Full Structure characterization and elucidation
- Analytical method development and qualification
- Stress studies and ICH stability studies
- CMC gap analysis for commercialization

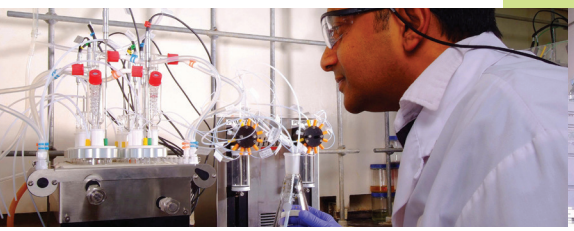
Phase III / commercial support

Taking the molecule to market

As programs head towards commercialization, a strong handle on process parameters is required to support validation studies. A deep understanding of the process, impurities, and final API are important aspects for regulatory approval. Eurofins Alphora has supported several regulatory approvals across the globe.

Our facilities have undergone multiple successful PAI inspections since 2008. Our team can provide support with:

- Fate and purge studies
- Impurities marker synthesis and qualification
- Design of Experiments
- Critical Process Parameters Studies
- Preparation for, and execution of process validation
- Continuing CMC support during and after market launch
- Technology transfer to Client's API CMO, as applicable



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