

API DEVELOPMENTAL SERVICES

Eurofins CDMO is an FDA-approved contract development and manufacturing organization (CDMO) focused on process chemistry, cGMP scale-up and analytical method development for complex, small molecule APIs, including highly potent molecules. Our talented team of Process Research, Analytical Services, Technology Transfer, CMC Specialists and Project Managers have supported clients from the pre-clinical phase through IND submission, into late phase and commercial activities. Our work spans from route selection to process and analytical development, to non-cGMP and cGMP scale-up. Eurofins CDMO also supports 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.



OUR EXPERTISE

Early Phase Support: From the lab to the plant

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

Phase II Support: Setting the stage for the commercial process

- Redesign of the synthetic routes or steps
- Process optimization & demonstration
- Impurities assessment & synthesis
- Full structure characterization & elucidation
- Analytical method development & qualification
- Stress studies & ICH stability standards
- CMC gap analysis for commercialization



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Phase III / Commercial Support: Taking the molecule to market

- Impurities marker synthesis & qualification
- Spike, fate & purge studies
- Design of experiments
- Critical process parameters studies
- Preparation for, and execution of process validation
- Continuing CMC support during & after market launch
- Technology transfer to client's API CMO, as applicable



Project Teams

Strong project management is an important component of our work. Every API Development & Commercialization project at Eurofins CDMO is carried out by a talented group of Process Research Scientists, Analytical Scientists, Technology Transfer Specialists and cGMP Operators 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.

