

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, 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 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 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

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

Phase III /Commercial Support

Taking the molecule to market

- Fate & purge studies
- Impurities marker synthesis & qualification
- 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

Research & Development

Equipment Description	Manufacture	Model
Process Development		
Jacketed Reactors	Chemglass	1 - 5 L
Parr Hydrogenators	Parr	0.06 - 2 L
Automated Chromatography with/Without MS Detector	Biotage	Isolera
Wiped Film Evaporator	Pope	2"
Parallel Reactors	HEL Mettler - Toledo	Polyblock 4 and 8 EasyMax 102 and 402
Mini Spray Dryer	Buchi	B290
Flow Chemistry Reactors	Vapourtec ChemTrix	-
Scale-Up		
Jacketed Reactors (20 & 30 L)	Chemglass	Various
Parr Hydrogenator	Parr	4 L
Rotary Evaporators	Buchi	2 x 20 L
Automated Purification	Biotage	Flash 150
Process Analytical		
300 MHz NMR	Bruker	AVI 300
LC/MS Systems with UV	Agilent	6330
UPLC & HPLC	Waters	Various
Process Safety		
Adiabatic Reaction Calorimeters	HEL	E1193
Thermal Screening Unit	HEL	E1256
Software		
Derek (Expert-Based)/Sarah (Statistical Based)	Lhasa Nexus	-
MNova	Mestrelab	-
Desgin Expert DoE Software	Stat-Ease	-
SciFinder	CAS	-

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