MINAKEM®
FINE SERVICES FOR LIFE

Your European CDMO partner: Excellence in custom APIs and HPAPIs

Minakem has successfully completed a number of acquisitions & internal investments in recent years. We have diversified and perfected our CDMO services and capabilities to efficiently handle your projects from early clinical Phase to launch & commercial supply.

From small biotech to the big pharmaceutical companies, **our premium services are tailored to the needs of our customers.** We take pride in working on custom small molecule API projects for each customer with the same passion and commitment to help you achieve your goals.

The key factor of our excellence is a regular and transparent communication by our dedicated project teams that are focused on innovation and open to new challenges.

Beyond Minakem's recognized expertise in process development, scale-up, commercial cGMP production and HPAPI capability, **we offer a full range of services** from route scouting to regulatory dossier approvals.

HP CAPABILITIES

SECURITY OF SUPPLY

DEDICATED PROJECT TEAM

FROM LAB TO LAUNCH

INNOVATION

OPERATIONAL EXCELLENCE

Minakem ensures the security of supply with our well-established network of 3 full cGMP sites in France and Belgium. We work on synergies with other business units within the Minafin Group in Europe and the US. We seek to backward integrate starting materials, intermediates, or specific steps and also have the knowledge and input from a broad range of experts within the Minafin Group.

Our process optimization and technical transfer approach is driven by Operational Excellence, with a focus on quality every step of the way. We have R&D, QA, QC, Regulatory support and project management on our manufacturing sites. Our goal is to provide our customers **the assurance that their products will successfully launch** and change the lives of the patients globally.

Our comprehensive offer

CHEMICAL DEVELOPMENT	CLINICAL SUPPLY	SCALE-UP TO LAUNCH	COMMERCIAL
Process Development-Optimization-Transfer – From an existing route or from scratch for alternative route development – On one specific step or multiple, or entire synthesis – Adapted to future scale-up			**Continuous Improvement** **Adaptation to scale/ demand change**
Analytical Development-Optimization* – Methods development/transfer/validation – Impurities management (HRMS) – Nitrosamines studies *see Minalytics brochure for more details			
Procurement strategies to ensure sustainable supply of starting materials			**Life-cycle management**
Process safety study			**Risk analysis**
Toxicology expertise – Analysis of customer data – Non cross-contamination management			
Route scouting	**IPC and process controls**	**Process validation**	
	Critical parameters study		
Synthesis for proof of concept	**Scale-up (pilot) campaign**		
	Use of inter-site synergy to optimize manufacturing and reduce costs		
	Stability studies	**Annual and long-term Stability studies**	
		CMC and regulatory support for drug filling	**Compilation and submission of Regulatory dossier**
One Dedicated project manager: organizes regular update meetings, main contact and coordinator for customer and sales representative			

R&D Services/Expertise

- **60 chemists** on two research centers
- **Strong interactions between the teams** through common management
- **Agnostic about the chemistry we do**
- **Broad expertise on modern and old reactions** at various scales
- **Solid state studies** (XRPD, DSC, PSD etc…)
- **Innovation driven / focused**
- Green metrics to **optimize processes**
- Solid network with **top-tier academic researchers**

Key technologies

- **Preparative HPLC** (50, 110 and 300 mm)
- **High containment laboratory down to OEB 6** (< 0.1 mg/m3.shift)
- **Pressure reactions up to 12 bar**
- **Flow chemistry**
- **Electrochemistry & Photochemistry**

Operating range

LAB SCALE	KILO-LAB	SMALL PILOT	LARGE PILOT	INDUSTRIAL PRODUCTION
20 g > 200 g	200 g > 2 kg	2 kg > 20 kg	20 kg > 200 kg	200 kg > 200 MT

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Minakem is an affiliate of Minafin