



**MINAKEM** HIGH POTENT  
HIGHLY ACTIVE & CONTROLLED SUBSTANCES

**Louvain-la-Neuve, BEL**

Highly potent APIs  
Controlled substances  
Process Development /  
Verification / Scale-up  
Commercial manufacturing  
Services



**MINAKEM**  
FINE SERVICES FOR LIFE

**Beuvry-la-Forêt, FRA**

R&D Excellence Center  
Small scale manufacturing  
High Agility / Flexibility



**MINASCENT**  
CHALLENGING CHEMISTRY

**Leuna, DEU**

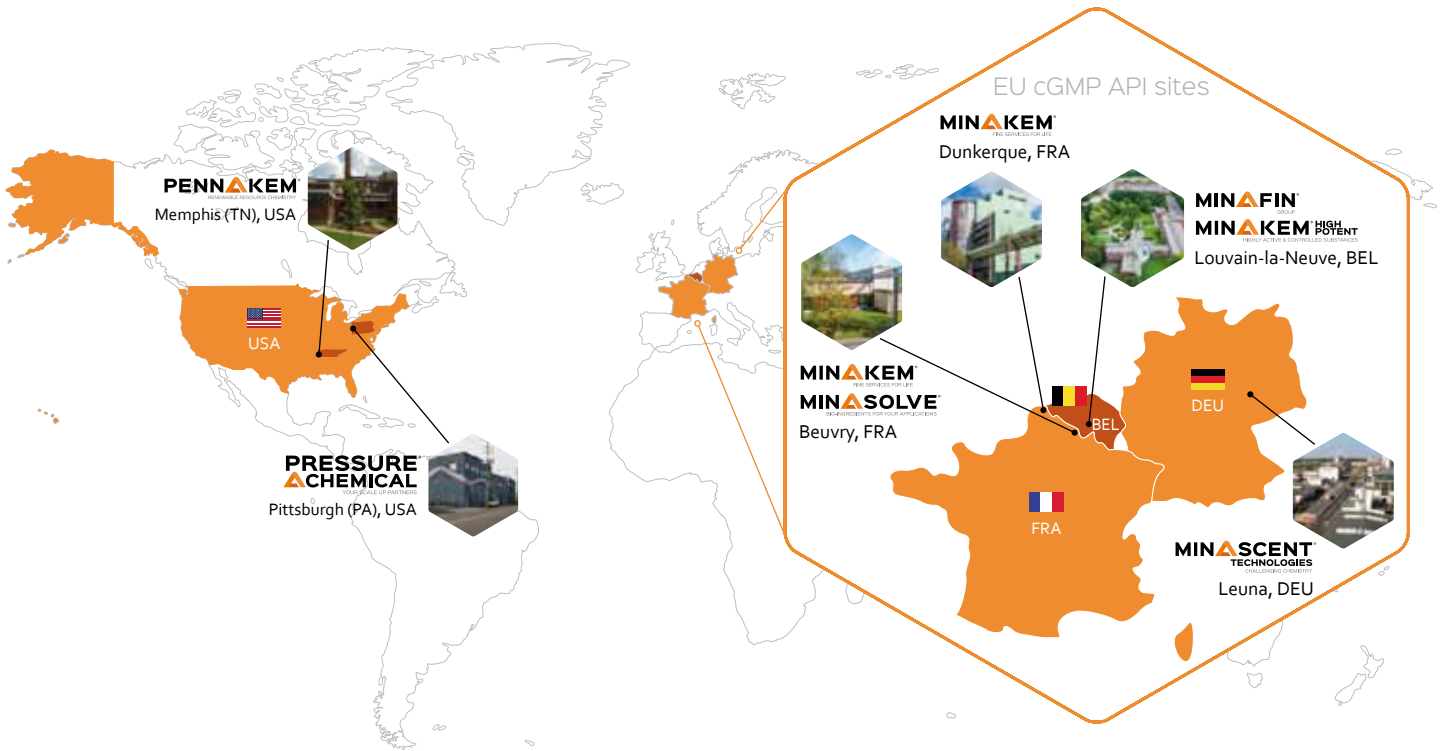
Challenging Chemistry  
Small & Large scale  
manufacturing



**MINAKEM**  
FINE SERVICES FOR LIFE

**Dunkerque, FRA**

State-of-the-art  
multi purpose API production  
Small & Large  
scale manufacturing  
API production > 250mt/y



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**MINAFIN**  
GROUP





# MINAKEM<sup>®</sup>

FINE SERVICES FOR LIFE

## MINAKEM your Partner of Choice For APIs & HAPIs

Minakem has leveraged on its external/organic growth and audacious ambitions to become a fully integrated and trusted development partner and commercial manufacturer for the global pharmaceutical companies.

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

MINAFIN<sup>®</sup>  
GROUP



## DEVELOPMENT AND MANUFACTURING SERVICES

### TRACK RECORD PERFORMANCE

Scale-up from Lab  
to Launch

Process Safety  
Innovation

Lab Scale  
20 grams - 200 grams

Kilo-Lab  
200 grams - 2kg

Small Pilot  
2kg - 20kg

Large Pilot  
20kg - 200kg

Industrial Production  
200kg - 200MT

- 4 full cGMP manufacturing sites that are FDA approved sites with excellent inspection track record
- Multipurpose plants with broad technical capability and decades of experience in API manufacturing
- High containment capability down to OEB Class 6 (<0.1 µg/m<sup>3</sup>) for manufacturing facilities, process research and analytical laboratories
- Capacity from grams to hundreds of tons of RSM and API to support clients from early clinical phases to commercial launch
- Process development and scale-up
- State of the art technical centre, solid state lab, kilo lab & pilot plant
- Analytical laboratories are equipped with the latest instrumentation such as: HPLC, GC, HPLC/MS, GC/MS, IT, UV, DSC, XRD, NMR
- Regulatory affairs department for compilation and submission of registration files (CMCs, DMFs, CEPs)
- All our teams are highly trained to handle demanding custom manufacturing projects
- We offer dedicated project Management to ensure smooth and seamless progression of projects

- Open and transparent communication
- Reliable Process/analytical development
- Process optimization driven by Operational Excellence and cGMP compliance
- Safety First with our dedicated team to guarantee safe scale-ups
- Fast, flexible and responsive to customer requests
- Professional project management
- Continuous investment and facility upgrades
- Comprehensive catalog product portfolio available from stock
- EU/US manufacturing facilities
- Dedicated project teams

WHAT YOU CAN  
EXPECT FROM  
**MINAKEM**<sup>®</sup>  
YOUR PARTNER  
OF CHOICE



## OUR KEY TECHNOLOGIES

- **Reactions under extreme temperature conditions**

Cryochemistry	High temperature
-75°C	+300°C
(BuLi, Grignard reagents, Silyl derivatives...)	(Pyrolytic reactions, cyclisation...)
- **Hydrogenation and reactions under pressure in a dedicated workshop 12 bars (220 psi)**
- **Cyanidation in a safely equipped workshop**
- **Chiral chemistry**
  - chemical Resolution | Asymmetric synthesis | biocatalysis
- **Chemical reductions (hydrides) and oxydations**
- **Hazardous chemistry (nitration, hydrazine, DMS, epichlorohydrin...)**
- **Continuous reactions (up to 450°C)**
- **Multi-step synthesis (expertise in most other reactions)**
  - Halogenation (Bromination, Chlorination), Grignard reaction, Sulfochlorination, Heck and Suzuki coupling, Organometallics, Heterocyclic chemistry, Boronic acid synthesis, Corticosteroids.
- **Particle size management, micronization**
- **High containment capability down to OEB Class 6 ( $\leq 0.1 \mu\text{g}/\text{m}^3$ ) for manufacturing facilities, process and analytical laboratories**
- **Industrial preparative HPLC (300 mm)**
- **Continuous Flow Chemistry (Lab-scale & Industrial)**

## R&D SERVICES

Our process research and development team complemented by analytical development specialists and dedicated project managers consists of more than 60 industry professionals focusing on

- Route scouting
- Process development, optimization and scale-up
- Quality by Design (QBD) as stipulated by the ICH Q11 guidelines to perform impurity mapping and evaluate Normal Operating Ranges (NOR) and Proven Acceptable Ranges (PAR)
- Development, optimization and validation of analytical methods
- Process transfer to our full scale manufacturing units
- Ongoing continuous process improvement throughout the lifecycle of the product
- API stability studies according to ICH Q1A guidelines

As part of our ongoing continuous improvement process we identify alternative manufacturing routes with the goal of improving product quality and reducing product cost as well as waste and environmental impact.

We have R&D teams located on each site allowing for an efficient transfer of information on process and analytical details. Maintaining a close cooperation with affiliated sites within the Minafin group allows us to rapidly transfer large volume, early steps.

## PROJECT MANAGEMENT

We offer dedicated project management under full confidentiality focused on providing a positive experience to our customers throughout the project cycle. The project manager is responsible for arranging the project kick off meet, weekly updates and conference calls concerning technical and manufacturing status of the project.

Our structure facilitates quick decision making and we ensure the customer is involved in all key discussions. We provide development reports, pilot and industrial campaign reports and all necessary documentation for regulatory requirements.

We also ensure the all starting materials and intermediates meet the REACH regulations.

