



# Your French Partner for Custom Development and Manufacturing

*Your  
chemistry  
differently*

## Company Overview

Since 2013, M2i Life Sciences develops and produces small complex molecules, Active Pharmaceutical Ingredients (APIs) and Key Starting Materials under current Good Manufacturing Practices.

Located in France, our R&D site and production facility integrate all development steps, from early process development to commercial production under regulatory clearance (ASMF).

Beyond a rewarded chemical expertise, we offer an original know-how on organic chemistry and polymers.

Our highly qualified, flexible and committed team makes us a privileged partner to support your projects with balanced tailored solutions.



4 locations

126 people



### R&D Lab in Lacq

*Innovation driven scientific team*

- Smart synthesis route development
- Specific knowledge in polymers synthesis
- ISO9001 certified
- Kilo-lab up to 20L
- Fully equipped in-house analytical lab

### cGMP manufacturing plant in Salin-de-Giraud

*Pharma plant with long history*

- Since 1896
- Multipurpose equipments
- 6 cGMP production lines
- 27 glass and stainless steel vessels from 160L to 3500L
- Class 10 000 finishing / packaging area
- Fully integrated analytical department
- On-site forced degradation and stability program according to ICH guidelines
- Regular inspections by customers and by the French Health authorities (ANSM) since 1998
- Proprietary portfolio: 8 APIs & 12 sensitive building blocks and starting materials



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## Our expertise

### Niche APIs and advanced intermediates production

- Clinical and commercial batch manufacture
- 16 patented technology since 2013

### Regulatory affairs

- Strong Chemistry, Manufacturing and Controls (CMC) expertise
- ASMF redaction and filing: 5 ASMF (Active Substance Master File) approved in more than 15 countries
- Customer regulatory support

### Renowned excellence regularly granted with famous French and European chemical awards

- Pierre Potier 2017 - Innovation in chemistry for sustainable development
- International Symposium on Green Chemistry Award 2015
- French Chemical Society Award 2015 - Industrial chemistry



Société Chimique de France



### Fully integrated CDMO offer from early process development to regulatory file filing:



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|--|---|---|
| <ul style="list-style-type: none"> <li>· Synthesis route design and scouting</li> <li>· Process engineering</li> <li>· Analytical development</li> <li>· Industrial cost evaluation</li> <li>· Industrial raw material sourcing</li> </ul> | <ul style="list-style-type: none"> <li>· Chemical process development &amp; optimisation</li> <li>· Key process parameters study</li> <li>· GMP clinical batches production</li> <li>· IMP dossier preparation</li> <li>· Validation of analytical methods</li> <li>· Forced degradation study</li> </ul> | <ul style="list-style-type: none"> <li>· Process validation</li> <li>· ICH stability program</li> <li>· ASMF preparation &amp; filing</li> <li>· Quality &amp; Regulatory support</li> <li>· Industrial scale cGMP production</li> <li>· Continuous improvement</li> <li>· APIs lifecycle management</li> </ul> |
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