

**SMALL
MOLECULES**

BIG SERVICES



TAME THE BEAST IN YOUR PROJECT

A FULL RANGE OF CDMO SERVICES FOR APIs

- Outstanding quality assurance track record
- Strength of process chemistry
- Extensive validation experience
- Flexible and collaborative approach
- Multi-site API manufacturing capabilities
- Handling of complex and multi-step synthesis
- Broad toolbox of classical chemistry
- Expertise in specialized technologies



novasep
passion & smart processes

YOUR TRUSTED MANUFACTURING PARTNER

Novasep provides flexible development and manufacturing solutions for APIs & intermediates to innovators at a comprehensive range of production scales. We offer process development expertise, specialized technologies and an outstanding regulatory track record.

OUR SERVICES

More than 30 years of producing commercial APIs and delivering robust commercial processes, in full regulatory compliance



Process development services

- Technical transfer
- Process development & scale-up
- Analytical methods development, optimisation and validation
- Process validation
- Safety assessments
- Regulatory support
- ICH stability studies



Manufacturing services

- From kg-lab and pilot to full commercial scale
- Extensive validation experience
- Wide range of flexible reactor trains from 100L to 12.5m³
- Clean rooms class 100'000
- 5 API sites inspected by FDA & EU authorities
- >40 commercial APIs and advanced intermediates manufactured each year

1

Process development expertise

- Strong expertise in DoE to increase process robustness & accelerate timelines
- 50+ process steps transferred from R&D to manufacturing each year

2

Quality assured

- Outstanding regulatory track record
- Over 30 successful customer audits and regulatory inspections per year

3

Project management

- Communication, communication, communication!
- Over 40 projects successfully completed per year

4

Strength of chemistry

- Extensive toolbox of classical chemistry
- A world leader in:
 - ADC: payloads, conjugation
 - Hazardous chemistry
 - Industrial chromatography
 - Low temperature reactions

5

Flexibility

- Multiple-site strategy
- Over 500m³ cGMP reactor capacity with a wide range of equipment
- Reactive to changes in customer needs

6

Continuous improvement

- Ability to develop and implement innovative next generation processes to extend product lifecycle

7

Supply chain management

- Tight control of raw material supply
- Expertise and China-based team for low-cost sourcing

8

Corporate social responsibility

- Explicit and relevant sustainable development policy
- Alignment with customers' governance

8 REASONS WHY CUSTOMERS CHOOSE NOVASEP AS A CDMO PARTNER

OUR TECHNOLOGIES



Highly potent APIs

- Successful track record in the scale up, validation & commercial production of HPAPIs for oncology & other therapeutic areas
- The Le Mans (FR) facility is dedicated to the development & manufacture of HPAPIs and cytotoxics
 - Equipped to handle APIs and intermediates with an OEL below 30 ng/m³/8hrs
 - Flexible production capabilities under cGMP (30 g – 10 Kg per batch)
- The Chasse-sur-Rhône (FR) facility offers best-in-class CDMO services for APIs and Potent APIs
 - Equipped to handle APIs and intermediates with an OEL to 1 µg/m³/8hrs
 - Flexible production capabilities under cGMP (up to 350 Kg per batch)



Hazardous chemistry

- More than 35 years of experience in commercial manufacturing
- From R&D to industrial scale
- Expertise in explosive substances, shock & friction sensitive chemicals and self-igniting gases and liquids
- Hazardous reactions handled safely, for shorter and cost-effective syntheses
- Sophisticated chemical safety studies



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Antibody-Drug Conjugates (ADCs)

- Integrated services for conjugation and payloads
- From process development, fast-track to clinical supply and commercial cGMP manufacturing
- State-of-the art bioconjugation facility
- Demonstrated track record of success in the synthesis and the purification of ADC payloads (Maytansines (DMx), Auristatins, PBDs, Camptothecins (CPT), etc.)



Industrial chromatography

- More than 30 years of experience in the manufacture of APIs, HPAPIs & cGMP intermediates using industrial chromatography
- Wide range of industrial chromatography equipment
 - Batch or continuous operations
 - Chiral separation (SMB) or purification (HPLC)
 - Over 30 systems installed across 5 sites from grams to tons
- Chromatography for purification, from process development to commercial manufacturing



Flow chemistry

- >10 years of experience with flow chemistry at R&D scale
- Experience with continuous processes (SMB chromatography) including validation
- Strength of science & methodology (evaluation of potential batch to continuous switch)
- Pilot for cGMP production planned for 2022



Other technologies

- Palladium cross-coupling reactions
 - From development to validation and routine commercial manufacturing
 - Buchwald, Heck, Sonogashira, Suzuki, cyanation... reactions
 - Expertise in palladium recycling (heterogeneous and homogeneous catalysts)
- Hydrogenation and hydride reductions
 - Hydrogenation up to 20 bars
 - Large scale hydride reactions using a wide range of reducing agents
- Low temperature chemistry
 - Ability to handle low-temperature reactions down to -80°C
 - Seamless scale-up from pilot to commercial scale

OUR REGULATORY TRACK RECORD

SITE	2017	2018	2019	2020	2021
CHASSE-SUR-RHÔNE (FR)					
LE MANS (FR)					
LEVERKUSEN (DE)					
MOURENIX (FR)					
POMPEY (FR)					

FDA (USA)

Local authorities (France or Germany)
Note: Le Mans 2018 - mutual recognition of inspection between ANSM and FDA

PMDA accreditation (Japan)



Boothwyn, PA, USA
(USA headquarters)

R&D, Chromatography



Mourenx, FR

R&D, Manufacturing,
Chromatography

Chasse-sur-Rhône, FR

R&D, kg-Lab, Pilot, Manufacturing,
Low Temperature, Chromatography,
Potent APIs, Flow Chemistry

OUR MANUFACTURING SITES



Le Mans, FR

R&D, kg-Lab, Manufacturing,
Chromatography, HPAPIs & cytotoxics,
ADC conjugation & payloads



Pompey, FR

R&D, kg-Lab, Pilot,
Manufacturing, Chromatography,
APIs & Biomolecules purification



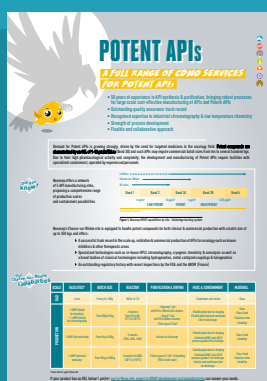
Leverkusen, DE

R&D, kg-Lab, Pilot, Manufacturing,
Hazardous Chemistry



**A STRONG, FLEXIBLE MANUFACTURING NETWORK FOR APIs
WITH COMPLEMENTARY TECHNOLOGIES AND A PROVEN TRACK RECORD**

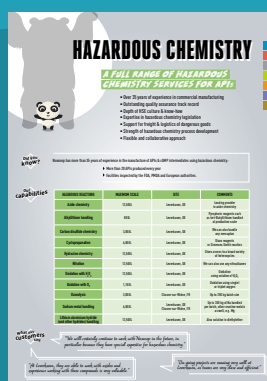
Learn more about our technologies in our dedicated publications including case studies!



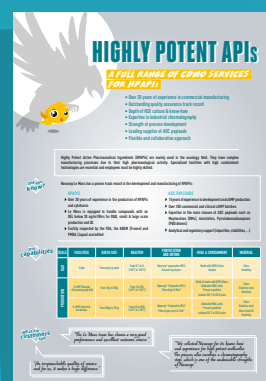
POTENT APIs
A full range of CDMO services
for potent APIs



INDUSTRIAL CHROMATOGRAPHY
A full range of industrial
chromatography services for APIs



HAZARDOUS CHEMISTRY
A full range of hazardous
chemistry services for APIs



HIGHLY POTENT APIs
A full range of CDMO services
for HPAPIs

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