axplora
Reliable partner. Agile explorer.

# CDMO services for Pharmaceuticals

- A reliable partner to the world's leading pharma & biotech companies
- Outstanding regulatory track-record with extensive validation experience
- Multi-site capacity offering flexible solutions & specialized technologies
- Agile & responsive experts offering a proactive, transparent & collaborative approach

# Axplora: your trusted manufacturing partner

**Axplora provides flexible development and manufacturing solutions for APIs, cGMP intermediates & RSMs to innovators at a comprehensive range of production scales.**

**We offer process development expertise, specialized technologies and an outstanding regulatory track record.**

## Our services

### Process development

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

### Manufacturing

- From kg-lab and pilot to full commercial scale
- Wide range of flexible reactor trains from 30L to 12.5m³
- Clean rooms class 100'000
- 10 API sites inspected by FDA & EU authorities
- 40+ commercial APIs and advanced intermediates manufactured each year
- Continuous improvement

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

- Successful track record
- Extensive validation experience
- Flexible capacities
- Multi site approach

## Our technologies

### Hazardous chemistry

- Expertise in explosive substances, shock & friction
- Sensitive chemicals and self-igniting gases and liquids
- Leverkusen site: center of expertise in azide chemistry & manufacturing of nitrogen-rich heterocycles
- Hazardous reactions handled safely, for shorter and cost-effective syntheses
- Sophisticated chemical safety studies

### 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
- Chromatography for purification, from process development to commercial manufacturing

### Steroids

- Our Gropello site has more than 50 years of experience in cGMP manufacturing of steroids
- Multi-purpose facilities with more than 80m³ reactor capacities
- R&D center with high expertise in steroid process development

### Electrochemistry

- A world leader in electrochemistry for pharmaceutical manufacturing
- More than 30 years' experience in commercial cGMP manufacturing using this technology
- More than 1000t of intermediates & APIs produced per year
- 3 sites with capabilities to perform electrochemistry at industrial scale

### Antibody-Drug Conjugates (ADCs)

- Integrated services for conjugation and payloads
- From process development, fast-track to clinical supply and commercial cGMP manufacturing
- 15 years clinical & commercial track-record
- 200+ cGMP batches
- Demonstrated track record of success in the synthesis and the purification of ADC Payloads becomes first line

### Highly potent APIs (HPAPIs)

- Successful track record in the scale up, validation & commercial production of HPAPIs for oncology & other therapeutic areas
- Facilities dedicated to the development & manufacture of HPAPIs and cytotoxics

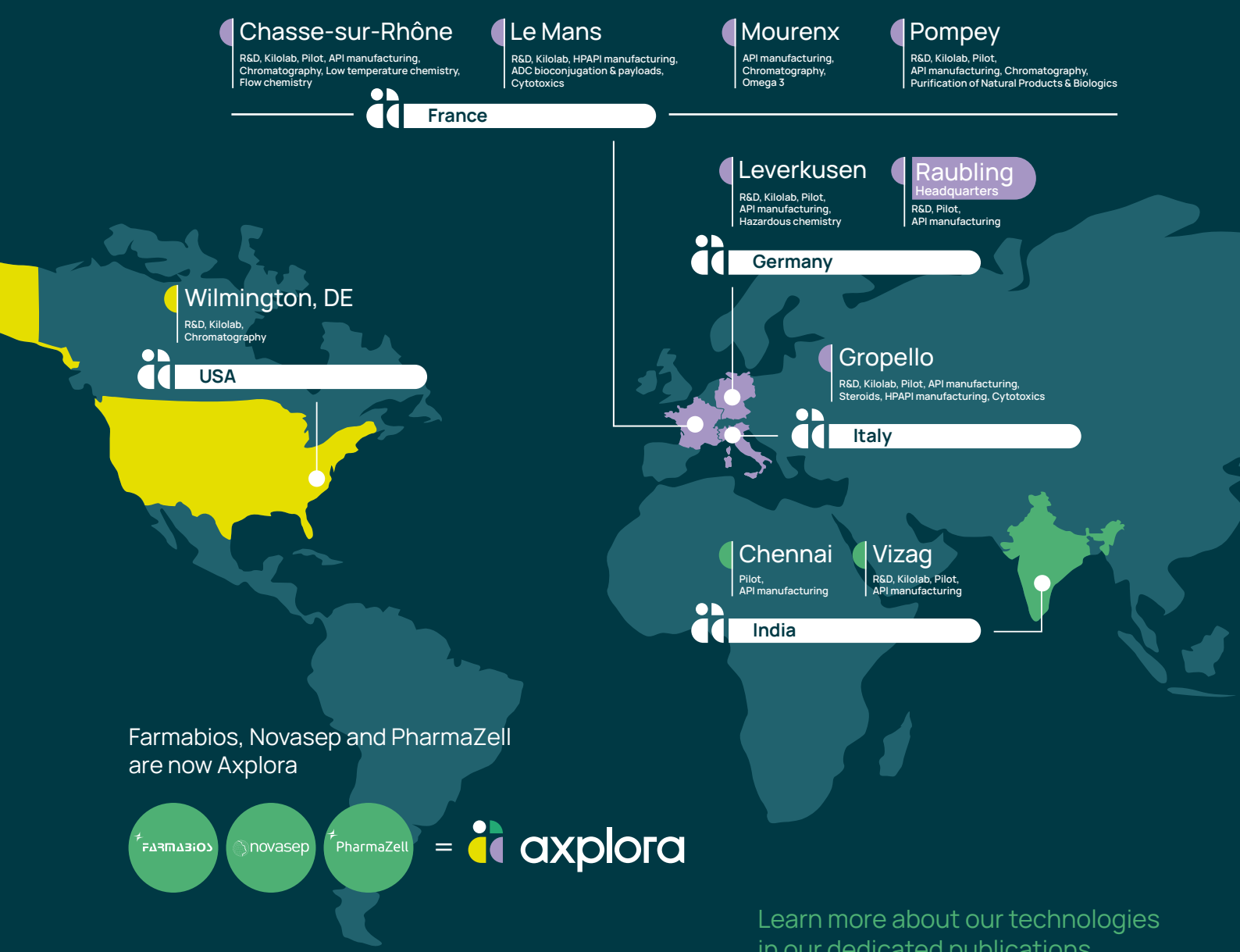
### Flow chemistry

- 10+ years of experience with flow chemistry at R&D scale
- 30 years of experience with continuous processes (SMB chromatography) including validation
- Strength of science & methodology (evaluation of potential batch to continuous switch)
- Pilot for cGMP production commissioned in 2023

### Other technologies

- Palladium cross-coupling reactions
- Hydrogenation and hydride reductions
- Low temperature chemistry
- Lipid Purification

# Our manufacturing footprint




Farmabios, Novasep and PharmaZell are now Axplora

FARMABIOS novasep PharmaZell = axplora

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

- Hazardous chemistry
- Industrial chromatography
- Highly potent APIs
- ADC Payloads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