

CDMO services for ADCs



15 years clinical
& commercial track-record.
> 200 cGMP batches



Excellent regulatory
history



Multi-scale bioconjugation
manufacturing capacity
with short term availability



One stop-shop for Drug
Substance and Drug Product
analytical services



Robust processes & analytics
for complex molecules



Phase-adapted, scientifically
sound development throughout
the drug lifecycle



Cross-functional collaborative
approach between
ADC experts



Fast-track bioconjugation
services with seamless
transition to clinical supply

Axplora: a reliable partner for ADCs

ADCs are complex molecules where manufacture requires both biological and chemical know-how.

Recognized for our expertise in this field for more than 15 years, we offer reliable and flexible CDMO services from process and analytical development to cGMP manufacture.

Working with our FDA-inspected Le Mans site dedicated to ADC manufacturing, you will benefit from in-house purification expertise, built on our Novasep heritage, HPAPI culture and state-of-the-art cGMP bioconjugation facilities.

ADC packages by phase

From early phase to commercial

Fast track offer for Preclinical Studies* •
One ADC sample with RoA

- 1 - 100 mg ADC sample
- Platform analytical methods
- 6 weeks turnaround time

Phase I-II Package •
First in human clinical trials

- Process and analytical development
- Phase-adapted validation
- cGMP manufacturing
- Methods validation

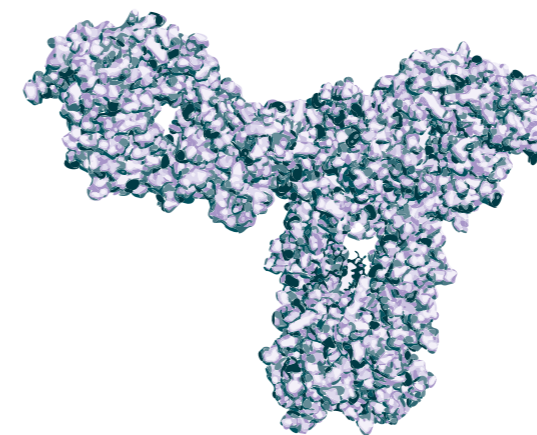
Phase III Package •
Support to validation

- Process characterization
- ICH analytical validation
- Process validation
- BLA regulatory support

Commercial phase Package •
Lifecycle support

- Continuous Process Verification
- Continuous process improvements
- Dedicated Product Owner
- Performance indicators monitoring

- > 15 years ADC experience
- Handling of highly potent compounds with an OEL < 30ng/m³/8h
- A proven track-record in the main classes of ADC payloads:
 - Maytansines (DMx)
 - Auristatins
 - Tecans
 - Pyrrolobenzodiazepines (PBD dimers)
- A recognized expertise in the main ADC bioconjugation technologies:
 - Stochastic cysteine & lysine
 - Site-specific
 - Enzymatic
- Complex molecules purification
- Successful ANSM & FDA inspections
- Dedicated project management team



“Axplora, and more specifically the people at Axplora, are great to work with. Knowledgeable and flexible and results oriented.”
US Biotech

“I really respect Axplora because they are strongly committed to the success of our projects.”
Japanese Big Pharma

“Le Mans is really state of the art for ADC and Axplora is probably one of the best companies out there.”
EU Big Pharma

“The technical reports were comprehensive and the project leads explained how they optimized all the conjugation and analytical conditions.”
US Biotech

Bioconjugation & Payload services

A full and flexible range of development, analytical & manufacturing services, conveniently located on the same site.

Process development

- Process transfer
- Process development
- Process characterization

Analytical development

- Analytical development
- Analytical validation & transfer
- Reference standard characterization

Manufacturing

- Multi-scale manufacturing suites
- Clinical & commercial manufacturing
- Process validation

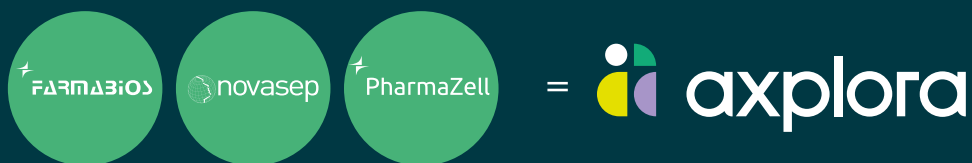
DS & DP testing

- IPC and Drug substance (DS) release testing
- Drug product (DP) release testing
- DS & DP stability studies

An integrated range of ADC capabilities

| | Service | Batch size | Reactor | Purification | Containment |
|-------------|---|----------------|--|---|---|
| Payload | R&D | Up to 10 g | Up to 2 L (-60°C to +130°C) Glass | Preparative HPLC Tray dryers | 14 bench hoods with HEPA filters Stainless steel isolator |
| | cGMP Production (multiple workshops) | Up to 500 g | Up to 60 L (-60°C to +130°C) Glass or Stainless steel | Preparative HPLC Tray dryers Filter dryer | Dedicated HVAC unit with HEPA filters Pressure gradients airlocks Stainless steel isolator class 10,000 |
| | | Kilogram scale | Up to 150L (200L in 2024) (-60°C to +130°C) Glass lined or Hastelloy | Preparative HPLC Filter dryer | Dedicated HVAC unit with HEPA filters Pressure gradients airlocks Stainless steel isolator class 10,000 |
| Conjugation | R&D | Up to 10 g | mL-2L Glass | Preparative FPLC Single use TFF | 10 bench hoods with HEPA filters Stainless steel isolator Biological safety cabinet |
| | Proof of Concept | Up to 100 g | 10-20L Glass or Single use | Preparative FPLC Single use TFF | Dedicated lab Stainless steel isolator Biological safety cabinet |
| | cGMP Production | Kilogram scale | 20-200L Glass, Single use or Stainless steel | Preparative FPLC Single use TFF | Dedicated HVAC unit with HEPA filters Pressure gradients airlocks Stainless steel isolator class 10,000 Class B biosafety cabinets |

Farmabios, Novasep and PharmaZell now form Axplora



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