

# A leading manufacturer of active, life-saving pharmaceutical ingredients: **Axplora**



Dr. Ester Masllorens  
CTO

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*of exploration, collaborating closely with universities, research centers, and start-ups," said Dr. Ester Masllorens.*

*She further added, "Our Scientific Advisory Board, bringing together leading international experts with complementary areas of expertise spanning catalysis, flow chemistry, electrochemistry, and steroids to biotechnology and Antibody Drug Conjugates (ADCs), strengthens the deployment of innovative and sustainable technologies and modalities."*

*"As a company driven by an innovation mindset, we are constantly on the lookout for new elements in the value chain that could transform the way pharmaceutical players bring their drugs to market. The grant of a Pharmaceutical Establishment License in 2022 at our Le Mans site in France to offer enhanced quality control services*

that address lifestyle-induced respiratory, inflammatory, and liver diseases.

Dr. Ester Masllorens, CTO of Axplora, spoke exclusively to The Silicon Review about how the company is achieving best-in-class industry standards for delivery of high-quality APIs to make critical medicines better, faster, safely, reliably, and sustainably benefitting patients worldwide.

## **Axplora: A company driven by an innovation mindset**

Innovation is ingrained in Axplora's DNA and is central to its corporate mission. *"We embrace a culture*

**C**reated from the merger of Farmabios, Novasep, and PharmaZell, Axplora is a leading Active Pharmaceutical Ingredient (API) manufacturing partner, delivering high-quality active ingredients on time and at scale. Leveraging its combined expertise and manufacturing capabilities across nine industrial sites in Europe and India and an R&D facility in the USA, Axplora offers Contract Development and Manufacturing Organization (CDMO) solutions to innovators for their small molecule APIs and biomolecules, as well as products

*for ADC drug products embodies our commitment to strengthening our technology platform offering to support our customers in serving their patients worldwide.”*

## **Reflections on a legacy of over three decades in the API manufacturing sector**

Axplora benefits from a legacy of over 30 years' experience in process development and API manufacturing. One of Axplora's activities consists of providing best-in-class CDMO solutions to innovators for their small molecule APIs and biomolecules, from process development to clinical and commercial manufacturing, leveraging more than 15 differentiating technologies, ranging from ADCs, chromatography, continuous processes, electrochemistry, and biocatalysis.

Having an API network of seven cGMP manufacturing sites across Europe and two in India, as well as a development lab in the US, Axplora ensures quality manufacturing under US, EU, and other regulations.

*“With more than 120 R&D-dedicated scientists across 3 continents specializing in the design of innovative, competitive, and sustainable processes, and over 20 additional scientists being recruited, Axplora develops, optimizes, and implements innovative solutions to accelerate development, improve efficiency, and, in the end, better serve our customers and their patients worldwide. Our teams also develop second-generation processes to shorten complex synthetic routes and improve yields to reduce costs and environmental impacts.”*

*“Digitalization is key to our culture of innovation and is at the forefront of our strategy; it enables us to digitize our practices, such as the application of data mining to better characterize processes,” extols Dr. Masllorens.*

## **The go-to partner for reliable long-term supply of complex APIs**

Underpinned by innovation, Axplora has long been working on developing new technologies, such as flow chemistry, continuous processes, electrochemistry, or biocatalysis, to operate more efficiently and sustainably. *“Sustainability and greener technologies are integral to our innovation approach; we proactively offer multiple sustainable options and technologies to our customers.”*

As a responsible company, Axplora is investing to reduce its carbon footprint and its environmental impact through an ESG program.

*“ESG starts in R&D and is a key focus. All our sites have sustainability roadmaps, aiming to develop processes with reduced environmental impact and carbon footprints. For instance, we analyze metrics like Process Mass Intensity (PMI) in our efforts to minimize waste, and always consider the use of greener solvents and evaluate the recovery, reuse,*

*and valorization of solvents and reagents. We have broad experience in the removal, recycling, and evaluation of lower-loaded new generation metal catalysts.”*

*“Our capabilities, assets, and current investments are targeted to follow the needs and expectations of the pharma industry for increasingly complex, lower volume, and more potent APIs. For example, in the fast-growing oncology sector, we have responded to increased demand for targeted therapies such as ADCs by increasing capacity for HPAPIs in our network and expanding our services to include drug product release testing for ADCs. We aim to expand our capabilities to potential new conjugates, taking advantage of our existing technology, strong know-how, and more than 15 years' experience in this field.”*

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## **Improving the quality of life of patients through innovation**

Axlora is embracing Innovation 4.0 and is continuously looking for ways to optimize manufacturing operations, notably thanks to digitalization. Its dedicated team is focused on deploying digitization strategies, and concrete actions have already been launched, including:

- The implementation of electronic batch records that has enabled the company to reduce time to batch release and collect process data to improve the reactivity of investigations and identify room for improvement.
- The setup of a data lake system to retrieve data from production equipment and correlate it with other data,

for example, SAP, to be able to pilot, investigate, and analyze their data more efficiently to improve their manufacturing processes.

- The use of software to calculate Axlora's sites' carbon footprint.

## **Axlora's expert team**

*"People are the main asset of Axlora. We are harnessing the innovation, agility, passion, expertise, and commitment of our people to serve our customers and their patients."*

*"Axlora was recently recognized in the 2023 CDMO leadership awards in New York City as a global winner in the field of expertise; it's a fantastic recognition of our teams."*

Dr. Ester Masllorens appreciated her team for achieving this remarkable feat.

## **The Road Ahead**

Dr. Masllorens said that, *"cGMP flow chemistry pilot equipment has been commissioned on our Leverkusen site in Germany. It addresses the growing demand for sustainable chemistry, enables us to reinforce our capabilities in specialized technologies, and consolidates our*

*position as a leading CDMO for continuous processes."*

*"Axlora is continuously adding capacities to support growing customer demand. We invested in the capacity increase for commercial ADCs in Le Mans, France, and have also recently completed the construction of a new HPAPIs and steroids facility in Gropello, as well as increased our capacity in Vishakapatnam (Vizag)."*

*"We have also expanded our offerings related to innovative technologies (e.g., lipids, enzymatic chemistry, etc.). Our center of excellence for solid state in Gropello, Italy, is also a demonstration of our commitment to innovative solutions. Beyond capacities and equipment, we are also expanding our teams, especially on our Gropello and Vizag sites, to support further the needs of our clients."*

*"Our commitment to innovation is reflected in our continuous investment in greener technologies. We also think about innovation in all the activities we undertake for the benefit of our customers to bring innovative new medicines to their patients,"* concluded Dr. Ester Masllorens.

## **Dr. Ester Masllorens | CTO**

**Dr. Ester Masllorens** has a PhD in organic chemistry with specializations in organic and organometallic chemistry, electrochemistry and catalysis. She has been in the pharmaceutical sector for more than 17 years leading R&D and Pilot plant departments both in the API and FDF segments. She oversees multidisciplinary teams in all R&D & Innovation areas at Axlora.

Dr. Masllorens is a specialist in technologies & process safety with more than 14 years of experience in the field.