

## Farmabios, an Axplora company, granted cGMP approval from AIFA for extended production capacity in HPAPIs and Steroids

- In response to the growing demand for capabilities for increasingly complex and more potent Active Pharmaceutical Ingredients (APIs), this new cGMP (current Good Manufacturing Practices) production unit reinforces Axplora's position as the partner of choice in large scale manufacturing for Highly Potent Active Pharmaceutical Ingredients (HPAPIs) and Steroids, as well as for Generics and CDMO services.
- The versatile and modular facility is a vertical-designed building, composed of 4 floors with a 2,800 m<sup>2</sup> total area, including space for future cGMP capacity expansion.
- This multi-purpose facility produces batches up to 300 kg in size with state-of-the-art technologies and equipment.

**Raubling, 10 October 2023** – Axplora, a leading partner to Pharma companies and Biotechs for complex APIs, is pleased to announce the cGMP approval from AIFA (national public body regulating medicines for human use in Italy) for the first line of its new Farmabios' production unit, expanding large scale manufacturing capabilities for [HPAPIs](#) and [Steroids](#).

This is a key milestone for Farmabios (Gropello Cairoli, Italy), reinforcing its manufacturing services with a high containment system up to OEB 5 (Occupation Exposure Band), a cryogenic capacity up to -100°C and a fully automatized system with DCS (Distributed Control System). The new multipurpose workshop is designed to produce HPAPI and Steroid batches up to 300 kg thanks to a wide range of cutting-edge equipment including several reactors with a wide range capacity from 1,000 to 12,000 liters, vertically connected to filter driers, horizontal centrifuges, biconic dryer and ancillary tanks for temporary process storage. Fully-equipped isolators are also in place for loading and discharging starting materials, intermediates and final products.

*"This major project to expand the Gropello Cairoli site demonstrates Axplora's dynamism in our industrial investment strategy that we have been successfully deploying for several years",*

says **Paolo Perracino, Gropello Cairoli Site Director**. *“This is a significant and concrete answer for our pharmaceutical customers, who face growing challenges to find reliable, available capacities to manufacture HPAPIs and Steroids.”*

*“Complex chemistry is our core competence at Gropello Cairoli site, enabling us to meet our customers’ needs with the manufacturing of HPAPIs and Steroids”,* adds **Gianpietro Roncoletta, Project Engineer**. *“This new cGMP production unit strengthens our offering and supports our position as a reliable and agile partner in the drug products value chain. We are so proud of this achievement, resulting from years of working together closely in the project team. My warm thanks to each person involved in this exciting journey. We started in 2019 with the construction of the building and while being slowed down by the COVID pandemic, we did not give up. This is evidence of our resilience on this site.”*

Newly cGMP certified in June, this new production line aims to get additional approvals by the end the year to be fully operational and will welcome new customer projects. It is already producing first batches which will be delivered according to the initial plan agreed with customers to serve patients worldwide.

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## About Axplora

Coming from the merger between Farmabios, Novasep and PharmaZell, Axplora is the preferred API manufacturing partner to the world’s leading patient-centric pharmaceutical and biotechnology companies, delivering top quality active ingredients on time and at scale, to the highest industry standards. Axplora offers CDMO solutions to innovators for their small molecule and biomolecular active pharmaceutical ingredients, as well as products that address respiratory, inflammatory and liver diseases. Axplora is dedicated to serving pharmaceutical companies to make critical medicines faster, reliably, and sustainably benefitting patients worldwide. Explore more: [axplora.com](https://axplora.com)

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