

Development and production of NCE amid pandemic lockdowns and supply chain interruptions

Case Study

About the client

Esperion Therapeutics is a pharmaceutical company that focuses on the development and commercialisation of oral therapies aimed at treating patients with elevated low-density lipoprotein cholesterol (LDL-C). Their flagship products, NEXLETOL® and NEXLIZET®, which are first-in-class medication for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease, target cardiovascular diseases by lowering LDL-C levels.

Project objectives

Following FDA approval in February 2020, Esperion needed to expand the supply of Bempedoic Acid, the active ingredient in NEXLETOL® and NEXLIZET®. The goal was to do a successful technology transfer and be able to supply commercial quantities of Bempedoic Acid API in a challenging pandemic environment.

The challenges

1. Overcoming the pandemic environment – The emergence of COVID-19 created a challenging manufacturing environment, with strict lockdowns and safety protocols.

2. Managing through an operational slowdown – Workforce capacity was reduced to 50% of pre-pandemic levels due to health and safety regulations. Facilities and equipment readiness also posed a challenge during lockdown.

3. Managing difficult supply chains – Global supply chain interruptions caused delays and uncertainties in importing and exporting critical materials.

Neuland's approach

Neuland employed a multi-faceted approach to overcome these challenges -

- **Technology transfer and pilot batch production** – Collaborated closely with Esperion to conduct a seamless technology transfer, which included pilot batches of Bempedoic Acid.
- **Remote monitoring and virtual guidance** – Implemented remote monitoring capabilities, allowing analytical, engineering, and supply chain teams to provide real-time virtual support and guidance.
- **Process validation and scale-up studies** – Conducted thorough scale-up studies and process validation (PPQ) to ensure production process met all required standards.
- **Regular collaborative reviews** – Held twice-weekly technical meetings with Esperion to review project progress, focusing on scaling up both intermediate and final API production.
- **Manpower management** – Prioritised the team working on Bempedoic acid, ensuring continuity despite reduced workforce capacity.
- **Facility readiness** – Prepared and bought online idled systems during the lockdown, ensuring all facilities were operational.
- **Alternative supplier readiness** – Proactively ensured alternative suppliers were ready to mitigate any potential supply chain delays and disruptions.
- **Commercial production** – Transitioned from R&D to full-scale commercial production at Neuland's manufacturing unit in Hyderabad, India.

Outcome

Neuland Labs successfully completed the technology transfer, process validation, and received approval for the global regulatory filings on-time. The collaboration not only met immediate project goals but also established a foundation for continued commercial production and support.

Conclusion




Neuland Labs played a crucial role in supporting Esperion Therapeutics during the unprecedented challenges of the COVID-19 pandemic. Through innovative problem-solving, effective remote collaboration, and strategic supply chain management, Neuland ensured the successful expansion and continuous supply of Bempedoic Acid. This partnership highlights Neuland's capability to deliver critical pharmaceutical solutions even under the most challenging circumstances and its ability to adapt to rapidly changing global conditions.



About Neuland

Neuland Labs is a leading global Contract Development and Manufacturing Organization (CDMO) providing an end-to-end continuum of customised chemistry services. Our services include process development, process optimization, analytical testing, and regulatory support. Right from early-stage drug development through to commercial manufacturing of Complex APIs, we offer both small- scale clinical trial quantities and full commercial- scale supply with minimal tech transfer timelines. We are a project-oriented company that fosters collaborative customer relationships with a culture of agility, transparency, and quality at its core. We work with over 500 pharma and biotech organizations, advancing healthcare solutions, to help create a healthier world.

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