



News release

Three Novasep custom manufacturing sites renew FDA approval in 2016

Successful FDA inspections confirm Novasep's longstanding reputation in maintaining quality assurance systems fully compliant with the highest world standards

Lyon, France, December 19, 2016 – Novasep, a leading supplier of services and technologies for the life sciences industry, today announces that three of its custom manufacturing sites individually passed the general inspection process of the US Food and Drug Administration (FDA) free of any 483 form.

All three FDA general inspections have taken place at Novasep's manufacturing sites in France (Mourenx and Le Mans), and in Germany (Leverkusen) over the course of 2016.

Novasep's manufacturing site in Le Mans, produces highly potent cytotoxic active pharmaceutical ingredients (HPAPI) and registered advanced intermediates for commercial or clinical development use. The site also provides customers with regulatory and containment evaluation support. It produces paclitaxel, for which Novasep holds a valid Drug Master File and a European CEP (Certificate of Suitability). The site is also renowned for Antibody Drug Conjugate (ADC) payload production services that will soon be extended to ADC conjugation.

The manufacturing site in Mourenx, produces APIs and advanced intermediates.

Novasep's site in Leverkusen, amongst its set of technical expertise, can handle hazardous chemicals at industrial scale. This know-how is particularly suitable for designing shorter, cost-effective synthetic routes for producing APIs and advanced intermediates. The site also produces and sells pre-formulated Nitroglycerin products for the pharmaceutical market.

In each case, the FDA inspection confirmed that commercial APIs produced at each site are suitable for drugs marketed in the US.

"This success has been made possible by the day-to-day good practices adopted by every colleague involved in operations. They are supported by the robust system Novasep's quality assurance team implemented." said Jean-Claude Romain, VP quality at Novasep. "These three successful inspections reward this long-term teamwork and commitment."

Global professional juries have recognized Novasep several times for the quality of its services.

About Novasep

Novasep is a global provider of cost-effective and sustainable manufacturing solutions for life sciences molecules and fine chemicals. Novasep's unique offering includes process development services, purification equipment and turnkey processes, contract manufacturing services and complex active molecules to serve pharmaceutical, biopharmaceutical, fine



chemical, food and functional ingredients as well as fermentation and chemical commodities industries.

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