



LYOFAL GIVEN THE GO-AHEAD TO PRODUCE CYTOTOXIC MEDICINAL PRODUCTS

An extension to the scope of authorisation to produce cytotoxic medicinal products for human use granted by the ANSM (French National Agency for the Safety of Medicines and Health Products) to the pharmaceutical subcontractor LYOFAL for products in small batches, in freeze-dried or other forms, including investigational medicinal products

ENTZHEIM, 10 January 2019: Groupe SYNERLAB is proud to announce that its LYOFAL plant, which specialises in freeze-drying, has been given the go-ahead by the ANSM for the extension of its scope of authorisation to produce cytotoxics in injectable sterile freeze-dried form intended for medicinal products for human and investigational use.

Backed up by various certifications, LYOFAL embarked on this extension procedure as the result of its wish to open up to this new market. *"The success of this project is all the more important in that the handling of these hazardous products involves specific plants, protection of the technicians handling the substances and flawless management of the contaminated area"*, says Charles Duval, General Director of LYOFAL, while praising the work of his team.

This extension provides LYOFAL with new opportunities and it will thus be able to offer its clients the benefit of its experience with this type of production and, more broadly, the processing of high potent products, which requires a specific environment and know-how.

"This extension of the scope of authorisation to cytotoxic medicinal products is an important step in LYOFAL's development into high added value products", affirmed Pierre Banzet, CEO of Groupe SYNERLAB.

Let's reach success together!

ABOUT LYOFAL

- Approx. 35 employees
- 1 200 m² of clean rooms, nearly 200 m² of which in containment areas for grade A aseptic processing
- Expertise in the use of disposable isolators
- Automated system deployed on the entire site
- R&D laboratory with pilot scale freeze dryers

ABOUT GROUPE SYNERLAB

As a CDMO, Groupe SYNERLAB has six production plants in France and Spain and employs more than 1,000 people.

Assisting highly reputed pharmaceutical laboratories in the development and manufacture of their medicinal products, it produces a wide range of pharmaceuticals in dry forms (tablets, gelatin capsules, soft capsules, stick packs, stick pouches), liquid forms (syrups, oral and nasal drops, stick packs, stick pouches), sterile liquid forms with or without preservatives (nasal sprays, eye drops, ear drops), pasty forms (ointments, creams) and injectable sterile forms.

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