Press release

As a unique initiative in France, INITS-SMO, an innovative shared manufacturing facility for biotech companies, is currently under construction close to Montpellier.

- 27 million euros deal to meet the needs of biotech companies seeking to produce their own batches of innovative drugs for clinical trials.
- INITS SMO will be one of the very few players in France to offer a comprehensive biomanufacturing solution, and the only one to offer a shared solution.
- First production runs are scheduled for early 2026.
- This Eurobiomed and MedVallée label project, supported by the Occitanie region, the Pays de l'Or agglomeration and the Montpellier metropolis, will boost the attractiveness of the Montpellier region as a center of excellence in healthcare, while boosting training in biomanufacturing professions.

Montpellier, February 5, 2024 - INITS, a consulting company with more than 10 years of experience in the pharmaceutical development of biotech products and quality assurance, has reached a major milestone with the creation of the INITS SMO biomanufacturing unit - an acronym for Shared Manufacturing Organization. This dedicated unit focuses on the development and production of innovative drug candidates by and for biotech companies, uniquely tailored for use in their preclinical and clinical trials.

This fully modular unit allows for seamless adaptation to various technologies and the unique requirements of each client. Equipped with state-of-the-art technology, it provides a platform for biotech companies to transfer and execute even the most complex manufacturing processes, particularly in the areas of gene and cell therapy, while ensuring compliance with regulatory standards.

Amel Hadri, CEO of INITS, explains: *"In the context of global biomanufacturing capacity fluctuations, increasing biotech companies' requirements, and major technological and regulatory challenges, INITS-SMO aims to add a new dimension to the support it provides to biotech companies. This includes enabling them to produce their own preclinical and clinical batches autonomously, allowing greater control over their operations, preserving and protecting their proprietary knowledge, while ensuring the level of quality required for drugs to be administered in clinical trials.".*

Vincent Bounes, Vice-President of the Occitanie Region in charge of Health, commented: *"This facility will play a key role in strengthening the biomanufacturing sector in France. It will provide biotech companies with the necessary tools to demonstrate the efficacy of their products, paving the way for future treatments. It's not just a health issue; it's a sovereignty issue, contributing to the increased production and industrialization of innovative therapies in France. In addition, the project will enhance the attractiveness of the Montpellier region, positioning it as a globally recognized center of excellence in healthcare, while improving training programs for biomanufacturing professions".*

With a newly constructed area of nearly 3200 m2, the INITS SMO pharmaceutical facility will provide biotech clients with shared production areas tailored to their needs, covering the entire spectrum from development phases to batch production and final certification[1]. These companies will benefit from a state-of-the-art infrastructure that will ensure the production of their APIs in compliance [2] with Good Manufacturing Practice (GMP[3]) standards. INITS SMO will apply its expertise throughout the process, covering all aspects essential for compliant drug production, including regulatory compliance, quality assurance, quality control, supply management and project management.

Another major advantage of this project is the fact that INITS SMO will be able to handle fill & finish, packaging, control, batch release and delivery to clinical centers, making INITS SMO one of the only players in France to offer a global solution and the only one to offer a collaborative solution. Groundbreaking for this facility is scheduled for the first quarter of 2024, with construction expected to be completed by the end of 2025 and operations beginning in early 2026. The facility will include research and development laboratories, GMP-equipped manufacturing suites, a GMP fill and finish suite with robotic aseptic filling under isolator, and a packaging suite. Together, these facilities will have the capacity to handle up to 9 projects simultaneously.

This major initiative involves an investment of 27 million euros, divided into two parts: one for the real estate facilities and the other for the operation of INITS SMO. Major investors such as Altex, ARIS, IRDI Capital Investissement and Sofilaro have participated in the financing. The project also enjoys the support of prestigious banking partners such as Banque Populaire du Sud, Caisse d'Épargne du Languedoc, BPI Languedoc-Roussillon and Crédit Agricole Languedoc. In addition to INITS, the Occitanie region, the Pays de l'Or conurbation, the City of Montpellier, and Eurobiomed, the South of France competitiveness cluster, are major contributors to the project.

While such biomanufacturing units already exist, notably in the United Kingdom, INITS SMO will be

1 Certification: Certification of batch quality prior to release for sale or distribution to clinical trial sites.

2 Active ingredient: A substance used in the composition of a drug product that has therapeutic or prophylactic properties.

3 GMP (Good Manufacturing Practices): A set of procedures and guidelines designed to ensure the high quality of medicinal products manufactured for human or veterinary use.

the first of its kind in France, reinforcing the country's sovereignty in the biomanufacturing of innovative therapies.

The production unit will be located at the Parc Industries Or Méditerranée in Mauguio and will create approximately 60 skilled jobs over the next four years.

Bastien Caumes, director of the INITS-SMO project, concludes: *" The location selected for this new facility, in the vibrant environment of Montpellier and close to the train stations and the airport, offers numerous advantages to streamline access for our customers. It is also a key element in the development of the biomanufacturing sector in the Occitanie region. Building on this positive momentum, we are committed to actively engaging with students. This includes initiatives such as organizing visits and hands-on experiences on our premises to promote this industry and inspire future talent to join our ranks".*

Key numbers:

- 27 million euros investment
- Almost 3200 m2 new building
- Groundbreaking in Q1 2024
- First production in Q1 2026
- Over 60 new skilled jobs

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About INITS-SMO (https://www.inits-group.com/shared-manufacturing-organization/)

"Who could be more skilled at applying a manufacturing process than the biotech company that meticulously developed it?"

INITS-SMO's answer is simple: the customer produces its API in a GMP-compliant pharmaceutical environment, with subsequent steps such as fill & finish, packaging and certification managed by SMO. Throughout the process, companies benefit from training and guidance, supported by an experienced CMC[4] project manager and a dedicated quality assurance team.

The benefits of using SMO for biotechs are many. First, it allows biotechs to retain their technological edge and intellectual property, ensuring greater value creation. Second, it reduces the risk of production failure and the potential loss of control associated with transferring know-how to subcontractors. Finally, it streamlines and secures the biomanufacturing process for biotechs by minimizing reliance on a single partner to perform all tasks essential to compliant drug production.

About INITS (inits-group.com)

Founded in 2013 by Amel HADRI, INITS is a specialized consulting company focused on Pharmaceutical Development and Quality Management. With a team of 24 professionals currently, including engineers, pharmacists and PhDs, the company provides customized consulting services. Its mission is to advise and support biotech companies throughout the pharmaceutical development process, including development strategy, partner selection, biomanufacturing, drug substance considerations, finished products, investigational products, CDMO (Contracts Development Manufacturing Organization) audits, CMC project management, regulatory strategy and quality assurance. Over the past few years, INITS has experienced a remarkable 30% growth in revenues.

In terms of achievements, INITS has conducted more than 200 audits at pharmaceutical sites worldwide, designed more than 40 manufacturing processes, and successfully established 4 manufacturing units in both Europe and China.

[4] CMC (Chemistry, Manufacturing and Controls) : set of manufacturing practices and specifications that must be followed and respected to ensure product safety and batch-to-batch consistency.

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