

INITS
474 Allée Henri II de Montmorency,
34000 Montpellier
France

FyoniBio GmbH
Robert-Roessle-Str. 10
13125 Berlin
Germany

INITS and FyoniBio Join Forces to Deliver a Fully-Integrated Offer from R&D to GMP

Press Release

Montpellier, France / Berlin, Germany — October 2025

INITS, an innovative French biopharmaceutical service company, and **FyoniBio**, a German expert in cell line and process development, are pleased to announce a strategic collaboration aimed at offering biotech companies a fully integrated path from R&D to GMP-compliant clinical production.

Through this partnership, clients will benefit from the combined expertise of FyoniBio's broad technology platform for cell line and process development and INITS' state-of-the-art GMP facility. Together, they ensure efficient and reliable biologics production — from early development through to clinical supply.

Bridging the gap between R&D and GMP – the challenge addressed by INITS

Today, biotech companies often invest in their own R&D capabilities or contract process development platforms. For preclinical or clinical batches, they typically either build in-house production capacity or outsource to a contract development and manufacturing organization (CDMO).

With its **Shared Manufacturing Organization (SMO)** – a disruptive concept set to become operational in **Q2 2026** – INITS will enable biotech companies to implement their processes and produce their own clinical batches. Clients will retain full control over their manufacturing processes while ensuring complete GMP compliance, supported by INITS' comprehensive guidance.

Combining Strengths with FyoniBio

FyoniBio, backed by over 15 years of CDMO expertise, offers robust and broad cell line development capabilities to produce not only monoclonal antibodies and biosimilars with unparalleled productivity and quality using its CHOnamite® and CHOFlow® platforms, but also hormones, blood factors, fusion proteins, and other complex recombinant proteins through its GlycoExpress® technology.

Through this partnership, FyoniBio will collaborate with INITS' SMO site in Montpellier to produce drug substance (DS) clinical batches of up to 400 L, supported by INITS in project

management, quality assurance, quality control, regulatory affairs, training, and supply. INITS will then take over drug product (DP) manufacturing, packaging, product release, and supply to clinical centers.

The combined expertise will provide biotech companies with bespoke solutions at every stage — from early R&D to GMP clinical production. The partnership reflects both companies' shared commitment to reliability, scientific quality, and long-term collaboration in the biopharmaceutical field.

"Our partnership with INITS brings together two complementary strengths. FyoniBio's broad capabilities in cell line and process development align seamlessly with INITS' new GMP facility," said **Lars Stöckl**, Managing Director and Founder of FyoniBio.

"This collaboration with FyoniBio is a major step forward for INITS. By combining our regulatory and GMP expertise with their world-class cell line and process development capabilities, we can offer biotech innovators a truly integrated path from lab to clinic." said **Amel Hadri**, CEO and Founder of INITS.

Key Highlights:

- **FyoniBio** will provide cell line and process development services, including master cell bank generation for biologics manufacturing.
- **INITS** will provide its GMP production facilities and expertise to FyoniBio's team, ensuring seamless project continuity under GMP conditions.
- Together, the two companies will offer biotech innovators an **end-to-end solution** — from early R&D to GMP batch production for clinical trials.

About INITS

Founded in 2013 and headquartered in Montpellier, France, INITS is a service company supporting biotech companies throughout their pharmaceutical development journey.

INITS has over 12 years of experience and has supported more than 250 clients in France and internationally. With a strong expertise in biologics (C>, EVs, mAbs, proteins) and a team of more than 40 experts, INITS covers all pharmaceutical development challenges, including CMC, regulatory, clinical supply, quality assurance, and audits.

For several years, INITS has been developing a disruptive project: INITS SMO, a shared bioproduction unit that is expected to be operational in Q2 2026. This unit will allow biotech companies to maintain control over their process by producing themselves their DS batches while benefiting from INITS' support (regulatory, QA, QC, training, supply, fill & finish, packaging, product release and clinical supply).

Learn more at: <https://inits.fr/>

About FyoniBio

FyoniBio is a biologics service provider with over 15 years of scientific expertise and a proven track record of supporting more than 100 biologics projects for biotech and pharma companies worldwide. Trusted by partners whose products have reached clinical development in both FDA and EMA regions, FyoniBio offers a broad service portfolio covering the entire development chain — from cell line and process development to analytical characterization and clinical bioanalysis under GCLP.

Our team combines deep scientific understanding with flexibility and transparent communication to deliver tailored solutions that meet each project's specific needs. All services are performed under our ISO 9001–certified quality management system, ensuring full compliance with international ISO and ICH standards.

Learn more at: <https://www.fyonibio.com/>

Press Contacts

Tanguy URENA
Business Development Officer, INITS
t.urena@inits.fr

Abdullah KARACORLUOGLU
Business Development Manager, FyoniBio
abdullah.karacorluoglu@fyonibio.com