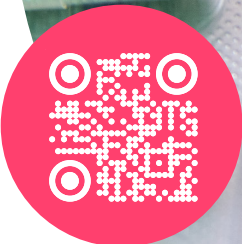


CMC SERVICES

Clinical trial supplies solutions



Clinical trial supplies expertise

Nuvisan experts ensure smooth clinical drug supply from phase I–IV. From supporting first-in-human to global clinical trials, we are prepared to help meet your specific challenges.

Nuvisan offers a full range of services including non-sterile IMP bulk manufacturing, primary and secondary packaging/labelling, international supply chain management, and sophisticated blinding solutions.

Our facilities are equipped with complementary special technologies and can provide mutual back-up allowing us to offer an extensive range of services. This provides the utmost flexibility and reactivity for the services provided.

Importation of test products including auditing of manufacturing sites, quality control and QP declaration.

Manufacturing of investigational medicinal product (IMP) with capability to handle highly potent and controlled drug substances.

Analytical testing including stability studies.

Packaging & labelling including randomisation list creation.

Global supply-chain strategy, involving appropriate qualified courier services and depots.



Manufacturing & Packaging



MANUFACTURING OF IMP

Nuvisan offers formulation development and manufacturing services for a quick entry into phase I.

- Oral powders for reconstitution (1 or 2 bottles systems)
- Oral liquid formulations
- Semi-solid formulations (creams, gels, ointments)
- Capsule filling.



PACKAGING AND LABELLING

Nuvisan offers primary packaging such as bottles, blisters, wallets and customised patient kits combining different products needed for the application and/or take-home medication.

- Creation of randomisation lists, labels design and printing
- Blistering (PVC / Alu, Alu / Alu, Aclar) and wallet packs
- Primary packaging of non-sterile products in bottles and tubes
- Packaging of light-sensitive products
- Secondary packaging and labelling at ambient/2-8°C/-20°C/on dry ice.



On-request services



BLINDING SOLUTIONS

Our experts provide reliable solutions for blinding your investigational medicinal products.

- Blinding solutions for PFS, inhalers, tubes
- Pre-filled syringes – over-encapsulation
- Patient kit assembly.



ANALYTICAL SUPPORT

To complete your needs for clinical trials, we offer a wide range of analytical and stability testing in the selected packaging.

- Chambers from -80°C to $+60^{\circ}\text{C}$ (zone I to zone IV)
- Cycling and compatibility studies, photostability, in-use stability, transportation stability and stress testing
- Shelf-life determination based on analytical data generated in-house.



QP release and supply



QP RELEASE

All GMP activities are done under the supervision of EU qualified persons (QPs) located at our two GMP facilities.

- Release of various types of finished products: oral, topical, injectable, and biological drugs as well as vaccines and blood products
- Importation of test products from third countries
- Audit and qualification of manufacturing and testing sites.

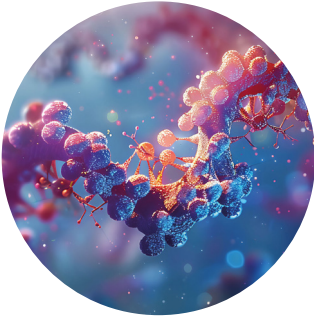


LOGISTICS AND DEPOT SOLUTIONS

Our overall GMP area consists of 2.850 m² access controlled, qualified, and temperature-monitored rooms.

- Qualified storage capacities for ambient, 2-8°C, -20°C, and -80°C are available. Secured storage for controlled drugs
- Worldwide distribution with qualified partners
- Drug returns from clinical sites, performing drug accountability according to your specific level of detail.

FOLLOW US



THE SCIENCE CRO

YOUR PARTNER OF
CHOICE IN BRINGING
THERAPEUTICS TO LIFE

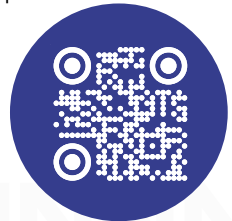
Nuvisan is a full-service contract research organisation (CRO) and development and manufacturing organisation (CDMO) with state-of-the-art laboratories in Germany and France.

Our pharmaceutical, biotechnology, venture capital and non-profit clients partner with us because our high-quality end-to-end solutions and scientific expertise enable us to streamline and accelerate drug discovery and development – from ensuring target understanding to helping bring therapeutics to life.

Founded over 40 years ago by a team of pharma industry innovators, Nuvisan has established a reputation for expertise and professionalism.

Our team leaders have extensive experience in the biopharma industry, and our unique centres of excellence – for drug discovery in Berlin, formulation and GMP manufacturing in Sophia Antipolis, and our bioanalysis hub in Neu-Ulm – enable our experienced scientists to help guide and advance projects.

We know how to discover, develop and bring the next generation of medicines to market. At the same time, we are committed to flexibility, transparency and collaboration in our approach, working closely with you to adapt to your individual needs, minimise risks and help deliver your project.



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