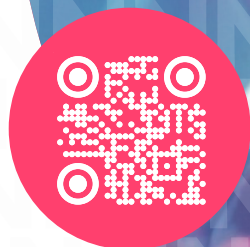
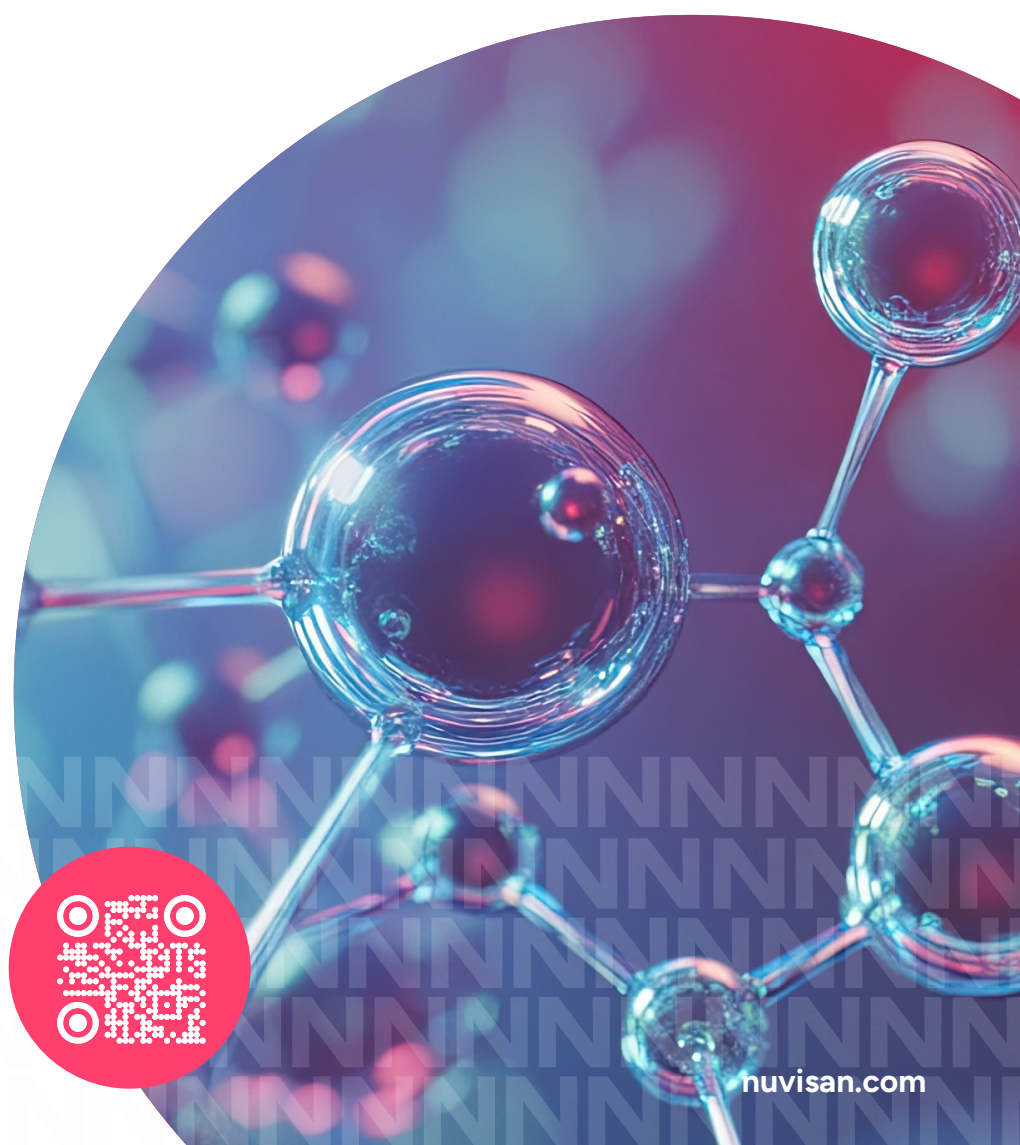


CMC SERVICES

Drug substance



Chemical development

Chemical process development includes several stages: from lab-scale process evaluation through safety and scalability analysis, process optimisation, purification development and solid-state analyses. Our scientific team has extensive knowledge in the development of chemical processes, with a strong focus on process mass intensity (PMI), solid-phase characterisation and impurity profiling.

Our scientists and lab professionals cover a full range of chemical development and preclinical chemistry solutions for the supply of drug substances. Our clients benefit from our expertise at all points of the chemical development of an active pharmaceutical ingredient (API), from early project de-risking to late-stage route scouting.

State-of-the art laboratories for a fast and efficient route evaluation, selection and scale-up for a wide variety of chemistries.

Over 20 highly experienced chemists and analysts focused on the robustness, effectiveness, high-throughput, purity profile, scalability and safety of complex, multi-step chemical processes.

Ability to handle HPAPI up to OEL 0.1 µg/m³, cytotoxic, antibiotic and controlled substances.

Infrastructure optimised to support process development from mg to kg. GMP compliant.

Bridging the gap between CRO and CMO.



Process development



PROCESS RESEARCH AND DEVELOPMENT

Our state-of-the-art laboratories are fully equipped for a fast and efficient route evaluation, selection, and scale-up for a wide variety of chemistries.

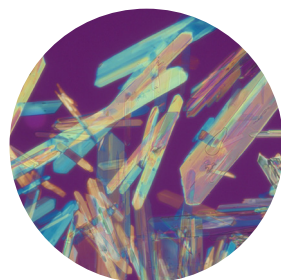
- Create a robust, safe and scalable process that allows control of API and intermediates for human/veterinary or cosmetic applications
- Help ensure preclinical supplies to be delivered at the appropriate time, speed and cost
- Able to develop reliable synthetic routes while offering a deep knowledge of the characterisation of your drug substance



SOLID-PHASE INVESTIGATIONS

Our highly experienced scientists can readily help you in selecting and controlling the solid state of your API.

- Polymorphism studies to optimise the solid-state properties of your APIs and formulations
- Tailored salt-screening studies to identify and optimise the most suitable salt form of your APIs. Our expertise helps ensure improved solubility, stability and manufacturability
- XRPD instruments that are qualified under good manufacturing practice (GMP) standards



Impurity profiling



IMPURITY IDENTIFICATION AND ASSESSMENT

Impurity identification and structural elucidation represents a frequent and often challenging task in process development. Nuvisan scientists can efficiently access impurity structures.

- Combining high-resolution mass spectroscopy (HRMS) and nuclear magnetic resonance (NMR) techniques for identification of impurities according to ICHQ3A/C/C-M7
- Analysis of degradation pathways
- In silico safety assessment



IMPURITIES ISOLATION/SYNTHESIS

We offer a wide range of isolation techniques to collect impurities even at low levels (<0.1%) and to synthesise them.

- Synthesis, from mg to hundreds of grams targeted impurity, and measured response factors to help ensure an accurate calculation of impurity content
- Generate impurity markers to support control strategies and analytical activities, including nitrosamines
- Prep-HPLC, as well as preparative SFC for efficient isolation



Manufacturing from mg to kg



GMP BATCH MANUFACTURING

Advance your candidate from preclinical through clinical studies by scaling up using Nuvisan's facilities.

- Flexible scale: From g scale to kg
- Fast development of analytical methods for intermediates and final API release
- Incorporate robust IPC to enhance efficiency, reliability and quality of your product
- Our batch records and technical package enable straightforward transfer to a CMO to produce larger batches

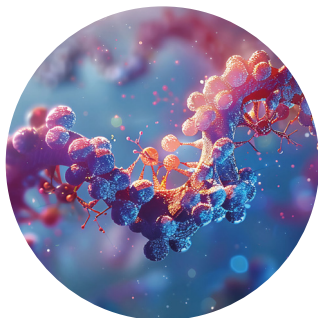


HIGH POTENT AND CONTROLLED SUBSTANCES

Nuvisan is specialised in high potency (hormones, cytotoxic, antibiotics, molecular glues and protac) and controlled substances (opioids, narcotics) development.

- Highly potent active pharmaceutical ingredients (HPAPI) up to an OEL 0.1µg/m³, from gram scale to multiKg
- Import, synthesis and analysis of controlled substances such as opioids, cannabinoids, narcotics and psycho-actives drugs
- Safe and compliant handling of controlled substances

FOLLOW US



THE SCIENCE CRO

YOUR PARTNER OF
CHOICE IN BRINGING
THERAPEUTICS TO LIFE

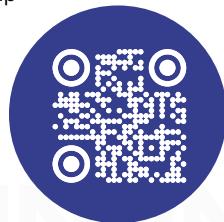
Nuvisan is a full-service contract research organisation (CRO) and development and manufacturing organisation (CDMO) with state-of-the-art laboratories in Germany and France.

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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