NUVISAN
Pharma Services

BRIDGING THE GAP BETWEEN CRO AND CMO

DRUG SUBSTANCE MANUFACTURING

>>> Now with GMP Grade at NUVISAN <<<

CHEMICAL DEVELOPMENT

NUVISAN DRUG SUBSTANCE MANUFACTURE

Producing Your API from mg to Kg

Developing, improving and Upscaling Drug Substances Manufacturing is a key step in **API Development.**

Yesterday

NUVISAN had the Capacity to support its Clients up to Non-Clinical Batches.

Today

With our **GMP** Certification we are today supporting you all the way to the first stages of Clinical Development. By doing so, we strengthen further the Extension of our Service Range, up to delivery of Tumkey Solutions for Phase I & II Batch Production.

At NUVISAN, Drug Substance Manufacture starts from Route Scouting through Safety and Scalability Evaluation, Process Development, Polymorph Screening and **GMP Manufacture.**

Our scientific Team has extensive Knowledge in the Development of Chemical Processes, with a strong focus on Solid Phase Characterization and Impurity Profiling.

NUVISAN then offers a full Range of Chemical Development Services for the Early-Phase Supply of your Drug Substances.

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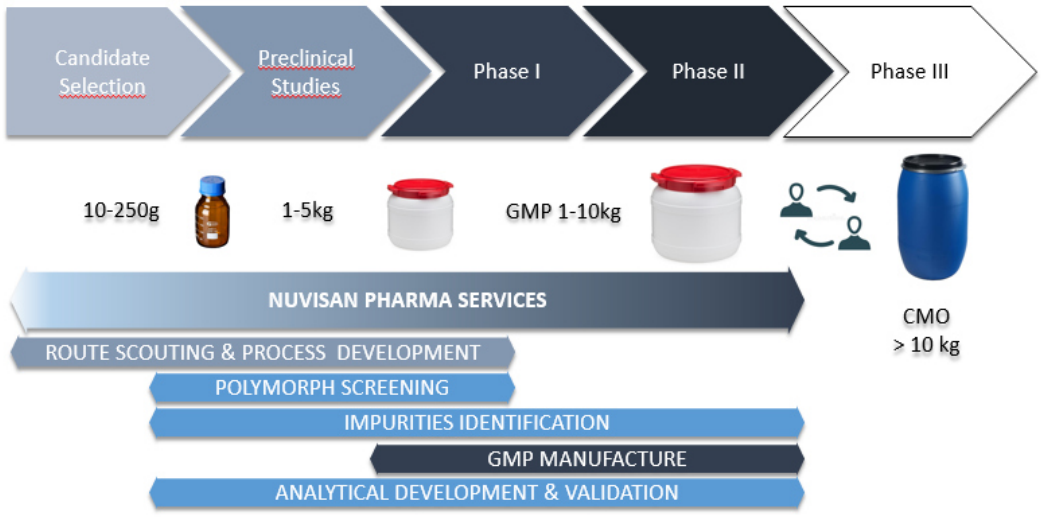
FULLY INTEGRATED CDMO SERVICE

Offering all of what is needed for API Manufacture



CHEMICAL DEVELOPMENT

GMP Batch Manufacturing

Our fully integrated offer of services from Process Development to Pre-Clinical Batches Manufacture ensures a fast and efficient delivery of your Drug Substance. Process Development and Kg Batch Manufacture are performed on the same site by our highly flexible and qualified Team of Scientists to ensure that Pre-Clinical Supplies can be delivered at the appropriate time, and to speed up and reduce the costs of your Clinical Supplies. Batches from 1 to 10 kg of your intermediate or **API** can be produced within our **GMP** Kilo-Lab with a specific control of impurity profile to ensure Clinical studies.

Solid Phase Investigation

NUVISAN´s Highly Experienced Scientists can readily help you to select and control the solid state of your API.

NUVISAN performs solid state Investigations of small organic Molecules to identify new solid forms such as Polymorphs, Salts, Co-Crystals or amorphous forms. These studies allow a deep understanding of the solid state of an intermediate or API.

Impurities Identification & Assessments

Identification and structural Elucidation of impurities represents a frequent task in Process Development. Our services comprise Isolation, Identification, Synthesis and Assesment unknown impurities present at levels allowed by ICH Legislation (0.1%). Our chemists can define degradation pathways, and potential Ingredient Interactions that will facilitate the examinations of the dossier by regulatory agencies.

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