NUVISAN

SPECIAL SOLUTIONS

# Clinical Trial Supplies solutions

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## Clinical drug supply from Phase I to IV

NUVISAN's experts ensure a smooth clinical drug supply: From Phase I - IV as well as subsequent services for compassionate use/expanded access programs.

No matter if first-in-human expertise is needed or a large global oncology trial with an open-label-extension part has to be supported.

We are prepared to cope with your specific challenges, be it dry-ice-labelling of vaccines or global depot management.

NUVISAN is offering the full range of services to include non-sterile bulk manufacturing, over packaging, labelling, as well as sophisticated blinding solutions to include international supply chain management.

An extensive portfolio of supporting services, such as comparator sourcing, randomization, analytical testing, and regulatory affairs is also provided by NUVISAN.

Our facilities in Germany and France are complementary with regards to special technologies and on the other hand able to act as a mutual back-up for core technologies.

# OUR CORE ASSETS

More than 40 years' experience as a Clinical Trial Supplies service provider.

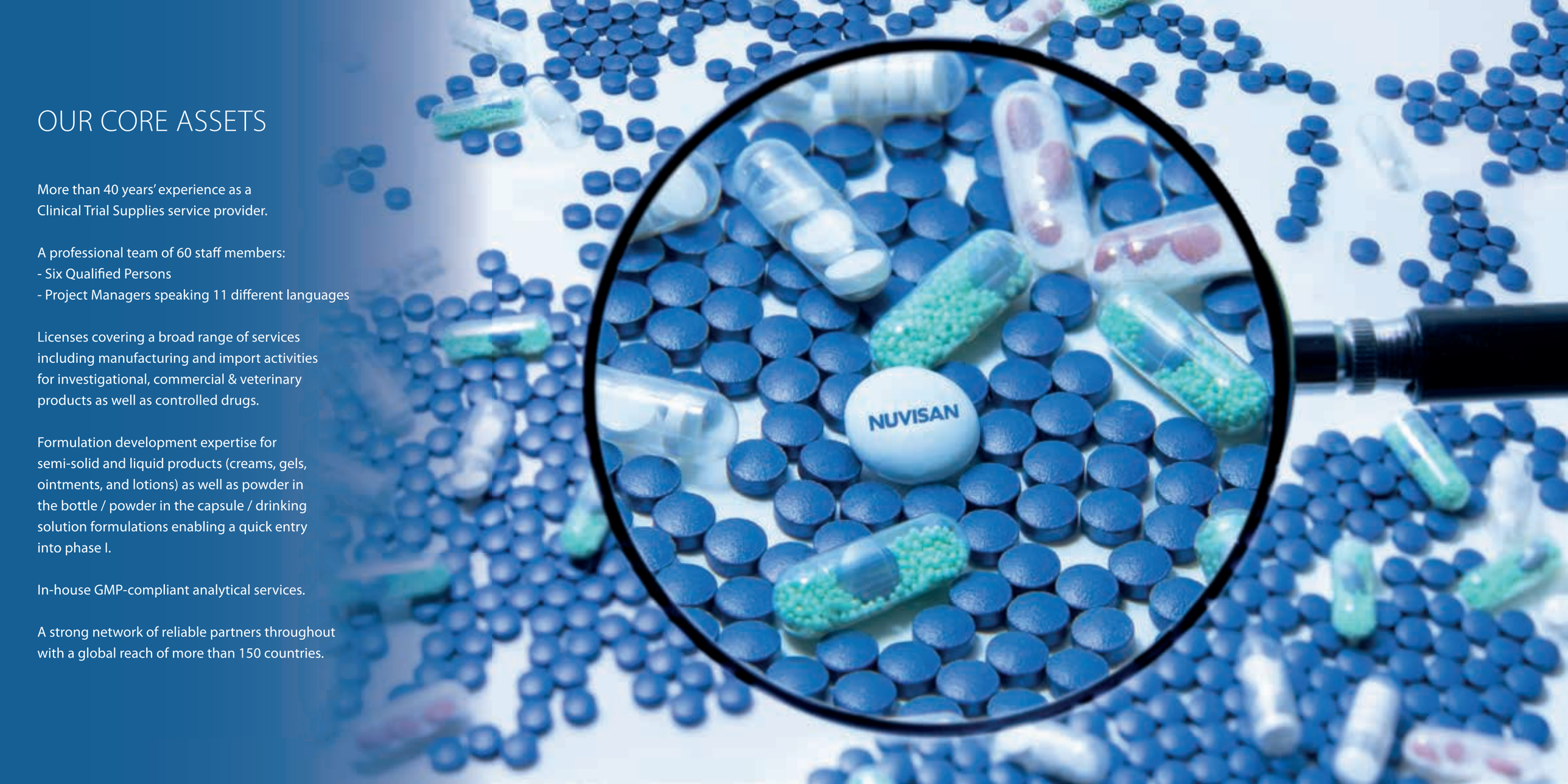
A professional team of 60 staff members:
- Six Qualified Persons
- Project Managers speaking 11 different languages

Licenses covering a broad range of services including manufacturing and import activities for investigational, commercial & veterinary products as well as controlled drugs.

Formulation development expertise for semi-solid and liquid products (creams, gels, ointments, and lotions) as well as powder in the bottle / powder in the capsule / drinking solution formulations enabling a quick entry into phase I.

In-house GMP-compliant analytical services.

A strong network of reliable partners throughout with a global reach of more than 150 countries.



# COLLABORATION AT **NUVISAN**

## NUVISAN's close collaboration with the client from the early beginning:

- Defining the best strategy for drug supply
- Continuous interaction with NUVISAN's project management to meet timelines
- High flexibility to address unexpected needs
- Corporate Project Managers organize cross-functional activities within NUVISAN

## Full drug supply services of a typical clinical trial:

- Importation of test product from third countries, including:
  - Auditing of manufacturing sites
  - QP declaration
  - Quality control
- Sourcing of comparators and ancillary materials
- Packaging & labelling activities, including:
  - Creation of randomization lists and code break envelopes
  - Blinding procedures
  - Label design & printing
  - Preparation of customized boxes, including inlays
  - Stability testing in final packaging containers
  - Final QP-release
- Regulatory support
- Global supply chain strategy, involving appropriate qualified courier services and depots

# OUR SERVICES IN DETAIL

## MANUFACTURING & FORMULATION DEVELOPMENT

- Oral powders for reconstitution
- Automatic capsule filling:
  - Sizes: 4, 3, 2, 1, 0, 00, C, B, AA, AAA, (including over encapsulation)
  - 100 % weight control
  - Capacity up to 75.000 conventional capsules / 15.000 over-encapsulations per shift
- Tablets as matching placebo
- Semi-solid and liquid formulation development and manufacturing (creams, gels, ointments, and lotions – handling of highly-potent APIs and botanicals), including a reliable strategy to reduce risks on scaling-up and strong support for the industrial transfer

## PRIMARY PACKAGING

- Glass or HDPE bottles
- Mono or mixed blisters:
  - e.g. PVC/Alu, PVC/PVDC
  - e.g. Triplex, COC (Amparis®), Aclar®
  - Alu / Alu
- Glass jars and aluminium or plastic tubes for topical formulations

## STABILITY TESTING IN SELECTED PACKAGING CONTAINER

- Chambers from -80°C to +60°C (zone I to zone IV)
- Cycling & compatibility studies, photostability, in-use stability, transportation stability, and stress testing

## RELIABLE BLINDING SOLUTIONS, FOR E.G.

- Different types of solid dosage forms by over-encapsulation
- Pre-filled syringes
- Inhalers | Tubes | Tablets | Capsules

## QUALIFIED STORAGE AND GLOBAL DISTRIBUTION SERVICES AT A VARIETY OF TEMPERATURES

- Ambient | 2-8°C | -20°C | -80°C including options of just-in-time labelling and direct-to-patient shipments

# NUVISAN

# YOUR SCIENTIFIC CRO / CDMO PARTNER

NUVISAN is a fully integrated CRO / CDMO offering all solutions from drug discovery to proof of concept in patients including: target identification, high-throughput screening, compound profiling, pre-clinical DMPK, toxicology, API synthesis, formulation development, pharmaceutical analysis, and clinical trials in healthy volunteers and patient populations.

With capabilities distributed over 6 locations in Europe, a presence in Latin America, and more than 40 years of experience, we deliver high-quality solutions certified by various accreditations and inspections (e.g. BfArM, EMA, FDA, ANVISA, ANSES, AAALAC, GLP, GMP, CIR).

40 **A trusted scientific partner**
With a 40-year track record of customer satisfaction

**A wide range of expertise**
A unique, comprehensive and, integrated offer from target identification to clinical trials

**A data-focused expert**
Our top priority is to ensure accurate, reliable, and consistent data quality

**A flexible service provider**
Fast turnaround ability and strong responsiveness to change

## Enquire now

Whether you need support in specific areas only or need a more comprehensive offer, NUVISAN can tailor a solution to fit your specific requirements.

If you have any questions or need more information, please reach out to us:

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