NUVISAN

SPECIAL SOLUTIONS

Bioanalytical Solutions

Bioanalytical Solutions for your Drug Development

From Discovery to Clinic

To effectively support your drug development project and maximize your R&D productivity, NUVISAN offers a wide array of bioanalytical solutions for small and large molecules. Starting at the discovery phase, all the way through phase IV, we offer expertise in bioassays and high-sensitivity ligand-binding assays.

Our scientific teams have extensive experience with method transfer, development, validation, and analysis. Using client proprietary assays or NUVISAN in-house developed methods, we can analyze a wide range of biological matrices such as plasma, serum, blood, cerebrospinal fluid, saliva, bile, urine, feces as well as tissue specimens.

With operations performed at our four sites in Neu-Ulm (DE), Grafing (DE), Berlin (DE) and Sophia-Antipolis (FR), our unique know-how and state-of-the-art bioanalytical equipment can analyze a wide range of items, i.e small molecules, peptides, proteins, antibodies, hormones. We offer both stand-alone and integrated full-service packages across all phases of development.

Our bioanalytical scientific expertise at a glance

Over one hundred experienced bioanalytical scientists based in Germany and France

Integrated bioanalytical and regulatory solutions for seamless collaboration in discovery and GLP, GcLP bioanalysis

150 validated methods for most common concomitant mediations and DDI substrates readily available

1.500 m^2 facilities with a cell culture lab, a BSL2 Lab for infectious samples and a controlled area to handle radiolabeled samples (tritium and carbon-14)

Best-in-class equipment:
24 UPLC-MS systems
2 Tecan ELISA readers
2 MSD systems
2 Gyrolab systems

BIOANALYTICAL CONTINUUM AT **NUVISAN**

For your drug development and research, bioanalytical testing provides valuable information to assess the exposure, safety, and efficacy of therapeutic agents. From candidate selection through regulatory package development, our scientists guide fit-for-purpose assay development, transfer, and validation throughout the drug development continuum as well as bioanalysis of biological samples from in-house (non-clinical and clinical) and external studies.

With an in-depth knowledge of international regulatory agency requirements and a strong pharmaceutical industry background, we ensure that the data provided meets the quality demanded for each step of development, leading to successful submissions.

Highlights

More than 1.200 molecules analyzed in discovery and development since 2016

More than 250 projects reported on an annual basis (clinical / non-clinical)

Small and large molecules bioanalysis from a single source with a direct access to our clinical phase 1 unit

Our bioanalytical laboratories in Neu Ulm (DE), Grafing (DE) and Sophia-Antipolis (FR) are GLP accredited

METHOD DEVELOPMENT & VALIDATION

- Method development
- Method transfer and cross-validation
- Bioanalytical method validation
  - Bioanalysis in support of PK and/or immunogenicity (including cell-based assays)
  - Biomarkers (from exploratory to decision making)
  - Biosimilars (comparative assay validation)
- Sample analysis
  - Fit-for-purpose validation based on Context of Use
  - We have a wide range of techniques available for proof of exposure
    - LC/MS Bioanalysis
    - Immunoassays
  - We have a wide range of techniques available for proof of exposure
    - PK
    - Immunogenicity (incl. cell-based assays)
    - Biomarkers
- Capacity and throughput: from investigative studies with few samples to complete phase 3 supportive programs

PROJECT MANAGEMENT

A single project manager is assigned to the client as a key contact, responsible for project coordination with all technical experts and to liaise with the client through conduct of regular project meetings.

NUVISAN
YOUR SCIENTIFIC CRO 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.

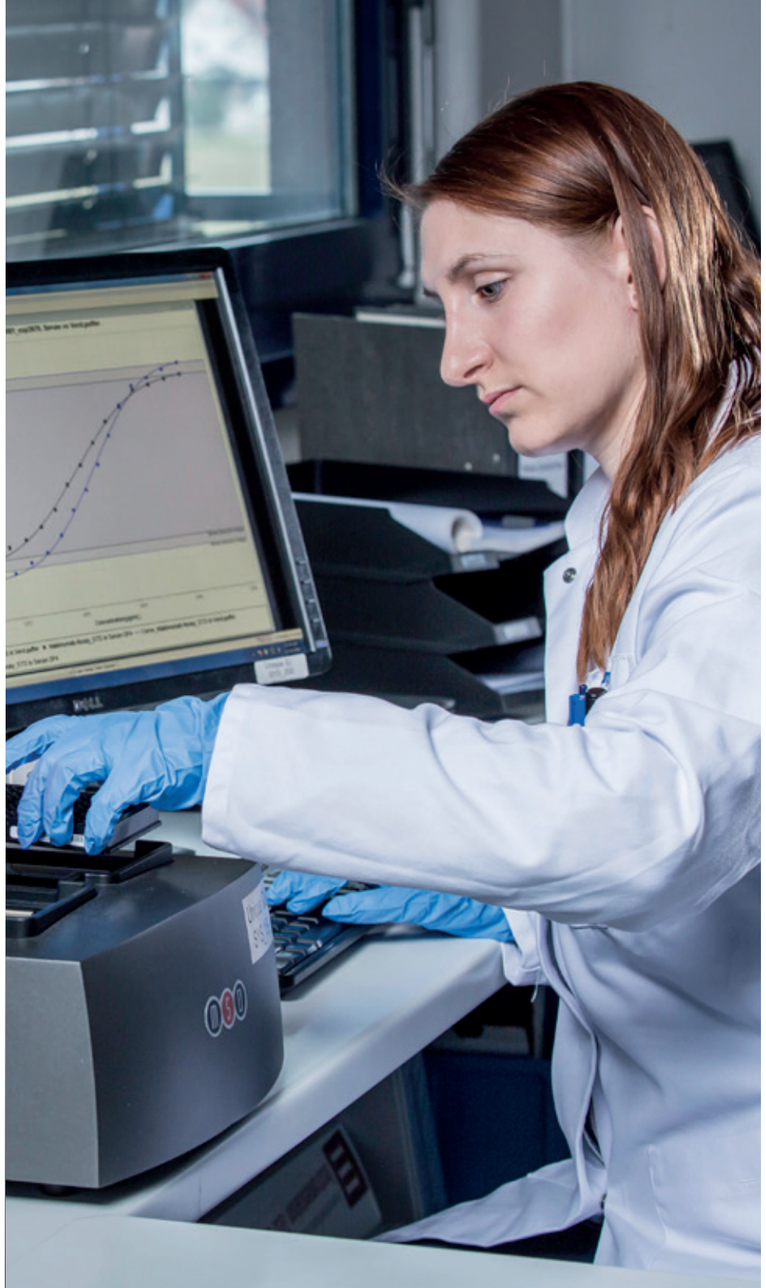
With capabilities distributed over 5 locations in Europe and with more than 40 years of experience, we deliver high-quality solutions certified by various accreditations and inspections (e.g. BfArM, EMA, FDA, ANVISA, ANSES, AAALAC, GLP, GMP).

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.

Any questions or need further information?

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