NUVISAN

DISCOVERY | PRECLINICAL | CLINICAL

Dermatology & Topical development solutions

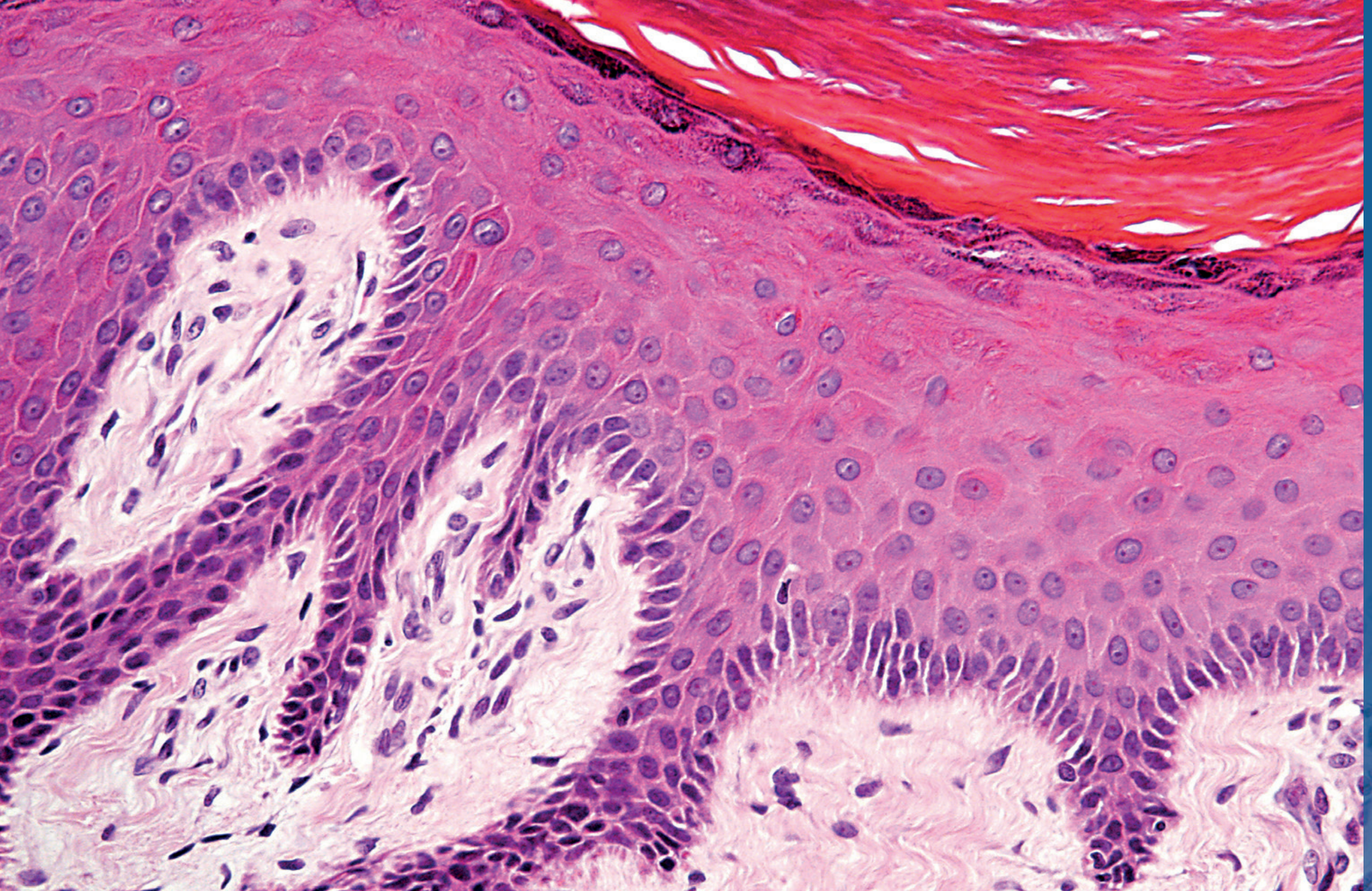
Integrated solutions for topical R&D

From molecule to market

To effectively support your project, NUVISAN offers a wide range of CRO / CDMO solutions spanning the full drug discovery and development cycle.

With our fully integrated value chain, we can effectively shorten time to proof-of-concept and market while establishing a sound foundation for clinical development and commercialization.

The NUVISAN portfolio supports dermatology and topical programs at every stage of development.



OUR SOLUTIONS AT A GLANCE

Patient-centric topical formulation development with comprehensive preformulation

API synthesis (GMP) & chemistry scale-up

Clinical trial supply (Phases 1-4) with specialty for semi-solid and liquid formulations (Phase 1-2, GMP)

Phase 1 clinical trials

Product analytical services including method development and validation, IVRT, container closure integrity testing, and microbiology

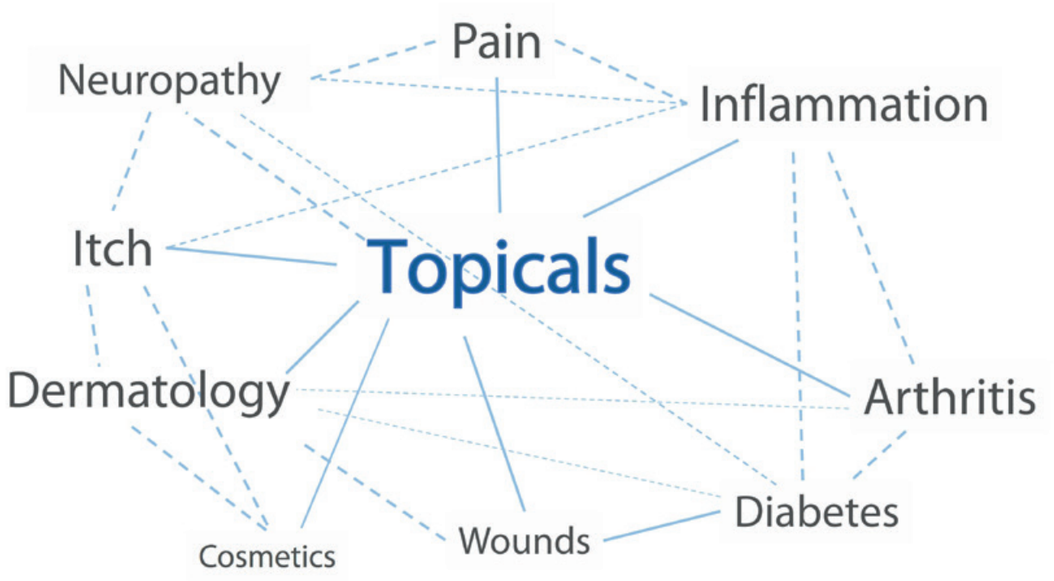
Bioanalysis, capable of low LLOQs to detect systemic exposure and in support of IVPT

Discovery & pre-clinical research:

- Target validation – diverse indication experience
- Lead identification & medicinal chemistry
- Pharmacology, inflammation platform, biomarker identification
- Toxicology
  - *In vitro* skin irritation, skin sensitization, skin corrosion
  - DMPK – ADME, QWBA

NCE, drug repurposing & life-cycle management

TOPICAL PRODUCT DEVELOPMENT SOLUTIONS AT **NUVISAN**



Begin with the end in mind

NUVISAN is passionate about topical product development. Our experience and pharmaceutical product development heritage support creation of innovative, stable, safe, and elegant topical formulas that maximize potential of clinical and market success.

Many of our scientists have contributed to successful pharmaceutical, over-the-counter, and consumer products, and thus we ensure efficient development and provide support throughout the entire product life cycle.

Highlights

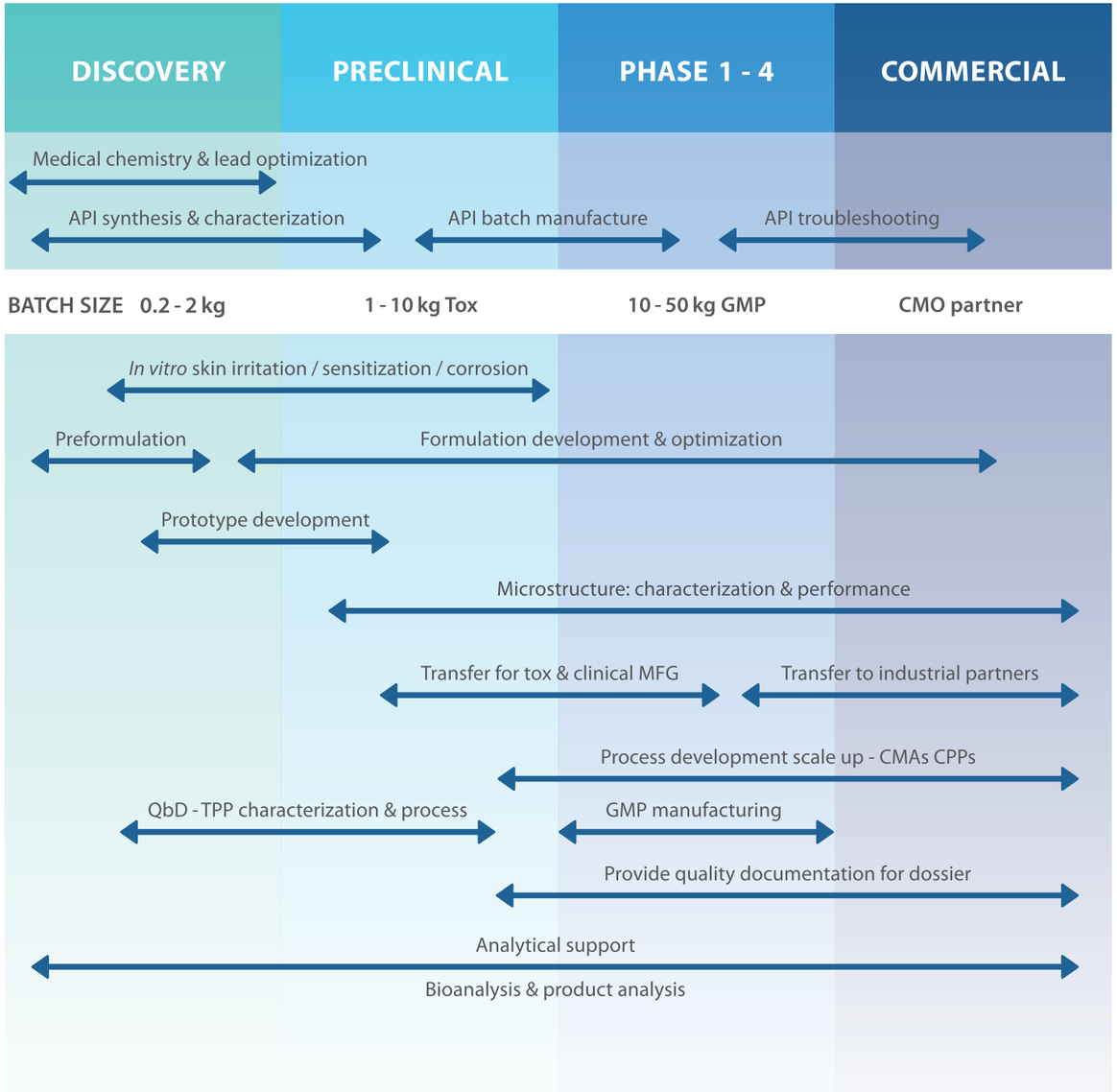
Multidisciplinary teams with more than 20 years of experience in successfully working on the development and manufacturing of topical products

Ability to develop API and finished semi-solid and liquid products including creams, gels, ointments and lotions

State-of-the-art topical product development facilities including a site that was formerly the world's largest skin-focused R&D center

Best-in-class equipment including Liquid Chromatographs (HPLC, UPLC), LC-MS/MS, Q-TOF, qNMR, Biolumix, LUMISizer, RapidOxy, and AP/MALDI-MS

Integrated chemistry and topical formulation – Capabilities & analysis



CHEMISTRY

- Medicinal chemistry & lead optimization
- API synthesis and characterization
- Polymorph and salt screening
- Preliminary solubility studies
- Trouble shooting for excipient compatibility and stabilizer assessments
- Isolation and structural elucidation of impurities
- API batch manufacture (GMP)
- API trouble shooting and degradation pathways
- Scale-up
- Route scouting
- Process development

FORMULATION DEVELOPMENT

- Preformulation studies
  - Saturated solubility in individual excipients and mixtures (solvents and key components for formulation development)
  - Compatibility studies
  - Screening of stabilizers (pH adjusters, antioxidants and chelating agents)
- Analytical methodologies: UPLC-UV and accelerated screening tools
- Synergistic collaboration with chemistry
- Prototyping, R&D stability studies

PRE-CLINICAL & CLINICAL SUPPORT STUDIES

- Batch manufacturing and clinical trial supplies (including patient kits preparation)
- Analytical support to manufacturing process development, scale-up and Quality by Design
- Methods validation / transfer
- Batch release / Pre- and post study analysis
- Cleaning verification method development and validation
- Non sterile microbiological testing
- *In vitro* Release Testing (IVRT)
- *In vitro* Permeation Testing (IVPT)
- TPP analysis for Quality by Design process and critical process parameters
- ICH stability study (Zone 1 to 4)

FORMULATION SCALE-UP & GMP MANUFACTURING

- Process scale-up (1-50 kg)
- GMP manufacturing
- Critical process parameters definition
- Filling & packing (50 kg batch - GMP)
- QP release of GMP batches
- Stability studies trouble shooting
- Structural elucidation for unknown impurities

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.

SEMI-SOLID ANALYTICAL CHARACTERIZATION & MICROBIOLOGY

IVRT TESTING

- Support to agency requirements in terms of scale-up and post-approval
- Change for semi-solids (SUPAC-SS) guidance
  - Method development: IVRT conditions and specific HPLC assay
  - Method validation in accordance with ICH
  - GMP studies for comparative test (reference and test)
- Formulation screening

RHEOLOGY

- Rheometers
  - Flow behavior, viscosity and flow curves (dynamic and static yield stress study)
  - Determination of viscoelastic behavior
- Viscosimeter
- Texturometer
- Colorimeters

MICROBIOLOGY

- Preservative Efficacy Test (PET)
- Microbial limit test
- Biolumix (PET screening)

OTHER TECHNIQUES

- Differential Scanning Calorimetry (DSC)
- Dissolution
- Particle size
- Solid-phase investigation (chemical development)
- Structure elucidation (HRMS, RMN, IR)

SEMI-SOLID PERFORMANCE EVALUATION

IN VITRO PERMEATION TESTING (IVPT)

Enables evaluation of drug delivery into the various layers of skin and receptor fluid.

- Established methodology to support API and formulation selection
- Provides relevant and crucial insights into dermal deposition and uptake
- Employed as part of our holistic approach to topical product development
- Human skin used and obtained from elective surgery
- Clinically relevant dose applied

AP / MALDI-MS IMAGING DISTRIBUTION

Label-free *ex vivo* technique(s), to visualize the spatial distribution of molecules at cellular level in tissues by their molecular mass.

- Use of mass spectrometry allows the simultaneous visualization and analysis of multiple molecules from one measurement
- Complementary to other analytical (i.e. LC-MS) and visualization techniques (i.e. QWBA, immunostaining, etc.)
- Quantitative, if used with calibration standards

OTHER STUDIES

- Efficacy – *in vitro* & *in vivo*
- PK / PD – *in vitro* & *in vivo*
- Toxicology – *in vitro* & *in vivo*
- Early clinical studies – FIH to POC

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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