

We have expertise in all aspects of inhalation product development starting from pre-clinical via CMC to early clinical studies.

► AB FIA

- An engineering company with a chemistry profile.
- 3D CAD design and workshop within mechanical and electrical production.
- Software (GAMP) development for Windows, PLC and embedded systems.
- Design and production of specialised laboratory instruments - unique experience within inhalation, nasal, solid dose and medicated chewing gums.
- Design and production of high throughput automated systems for performance and specification testing of pharmaceuticals within R&D and QC.
- Distributor and design of components for chemistry systems for lab and pilot scale.
- Adaptions, modifications and repairs.
- In-house skills; GMP, Part 11, ISO-13485 and method tech transfer.
- Number of employees: 9

www.fia.se | www.prototypverkstaden.com

► AB I LAMBERG CONSULTING

- Provide expert advice in leadership and project management at various levels.
- Advice in influencing skills such as various communication techniques and cross functional work can also be provided.
- Regulatory strategic input at various levels.
- Hands on work in compiling various applications.
- Number of employees: 1

► AB KAMSACO

- Clinical development expertise to development programs within the respiratory area both in early, late phase and in regulatory approval processes.
- Clinical experience and advice can be provided to projects in different formulations both nasal, oral or oral inhaled products delivered by nebulization, or in pMDIs or MDIs.
- Clinical support can be provided both in design, conduct and interpretation of studies.
- Number of employees: 1

► ADROIT SCIENCE

- Post-processing restoration of crystallinity, so called "conditioning".
- Amorphicity – detection and quantification.
- Evaluation of post-processing stability of inhalation powders and provision of tools to mitigate/eliminate stability issues.
- ID and API crystal modification on ordered mixtures using novel methodology based on a combination of impaction and XRPD.
- Formulation optimisation based on solid state characteristics.
- Salt and polymorph screening and general solid state characterisation work.
- Micronisation of API and excipients.
- Number of employees: 5

www.adroitscience.com

► ASKING CONSULTING

- Expertise in pharmaceutical and medical device development; inhaled drug delivery and formulation development.
- Number of employees: 1

► CISOLUTIONS

- Competitive intelligence comprising literature, patents, pipeline, clinical trials and market. Covering pre-idea to life cycle management.
- Competitive Intelligence, Patent Intelligence, Disease Intelligence Drug Intelligence.
- CISolutions are information experts in the specific life science areas Pharma, Med Tech, Diagnostics, Bio Tech and Functional Food.
- Number of employees: 2

www.cisolutions.se

► CR COMPETENCE

- Development and detailed physicochemical characterization of solutions and suspensions for pulmonary and nasal administration.
- Selection and characterization of excipients and container materials for liquid dosage forms.
- Surface modification and characterization as applied to products for inhalation.
- Micronization and characterization of micronized materials.
- Novel formulation concepts for poorly soluble compounds.
- Number of employees: 9

www.crcrom.se

► DIGITAL CONTEXT

- Visual communication, 3D graphics & animation, film, interactive design and rich media applications.
- 3D animations to describe and explain biological processes and medical devices.
- Developed and produced national interactive education program for asthma and allergy.
- For COPD we have 3D animation, films and interactive learning for doctors, health care personal and patient.
- Number of employees: 2

www.digitalcontext.se

► EMMACE CONSULTING

- Specialist competence within the inhalation pharmaceutical product arena especially in the area of analytical characterization of inhalers, pMDIs, DPIs, Nebulisers and soft mist inhalers and offers excellence in performance testing of pharmaceutical inhalation products on a CRO-basis.
- Traditional testing of inhalers using cascade impactors, laser diffraction and delivered dose uniformity characterisation according to US and EU Pharmacopoeias.
- Prediction of lung dose from inhalers by using a novel, front-edge, and validated in vivo realistic in vitro method including anatomically realistic mouth-throat models/inlets in combination with patient-like inhalation profiles.
- Plume geometry/Spray pattern measurements using the Envision system.
- Analytical laboratory facilities, designed and dedicated to inhaler performance testing, located at Medicon Village in Lund.
- Number of employees: 8

www.emmace.se

We have expertise in all aspects of inhalation product development starting from pre-clinical via CMC to early clinical studies.

► GALENICA

- One of the leading hi-tech pharmaceutical companies in Scandinavia, active in the development of new pharmaceutical products.
- Well established within formulation, manufacturing and quality control of all common dosage forms.
- Successful track record in pharmaceutical development, from early formulation concepts to products on the market.
- Pre-formulation and formulation, analytical services, stability studies, documentation, GMP production and packaging of clinical trial material (Phase I-III).
- Number of employees: 40

www.galenica.se

► GERIK MEDICAL CONSULTING

- Project management expertise in first time into man/patient projects as well as late phase projects including line extensions.
- Respiratory medicine expertise in asthma and COPD but also rhinitis and orphan diseases.
- Clinical development expertise from early clinical phases through registration into medical marketing for inhaled products delivered by pMDI, DPIs or nebulizers.
- Support provided to companies that need project or clinical leadership, and clinical development from strategy planning, designing programs or studies, evaluating and reporting studies and programs ready for registration and planning/initiating post-marketing activities.
- Number of employees: 1

www.GERik.se

► IMAGING RESOURCE

- Specialized imaging techniques, including scanning electron microscopy and High Speed Video Analysis, are used to create in-depth knowledge of particle and aerosol properties.
- Microanalysis of powders and device for particle properties and material compatibility.
- Aerosol characterization for plume geometry.
- Scientific imaging as a tool in product development and for marketing.
- Number of employees: 1

www.imagingresource.se

► LASTOW CONSULTING

- Inhalation Device development.
- Pharmaceutical project management.
- Product development methodology, technical due diligence.
- Advanced packaging.
- Electrostatics.
- Fluid dynamic and Computational Fluid Dynamics (CFD).
- Aerosol and spray technology.
- Number of employees: 1

► LIGATUM

- Intellectual property strategy.
- Broad scientific knowledge in medicinal chemistry, solid state chemistry and pharmaceutical sciences such as milling/micro-nization, agglomeration and mixing and not least in creating patent strategies by linking science and IP at an early stage in project development.
- Number of employees: 2

► NORDICBIOCUBE

- Expertise in optimizing global processes and services of biological material to meet chain of custody, Quality Assurance and legal demands.
- Clinical expertise (CPU, Safety, Clinical Operations) with thorough experience in respiratory studies from phase I to IV studies, including Japan and US, with both biomarkers, explorative samples and collaboration with external vendors.
- Unique experience in improvement project regarding global processes in clinical studies for biological samples.
- Number of employees: 2

www.nordicbiocube.com

► OM PROJECT

- Long experience in leading projects and people.
- In depth knowledge in Quality Systems for Pharmaceutical- and Med Tech industry.
- Specialist knowledge in business analysis and processes improvement using Lean Six Sigma tools.
- Assignment ranging from a short structured problem solving task or training event to extensive projects dealing with e.g. implementation of systems, routines or technologies.
- Track record of working with all from small start-up companies to large global enterprises.
- Number of employees: 2

www.omproject.se

► RED GLEAD DISCOVERY

- Delivery of high quality solutions with respect to preclinical services to support small molecule drug projects aimed at inhalation.
- In-house capabilities span across a large part of the drug discovery process chain from screening compounds for Hit identification to optimization of lead compounds towards candidate drugs.
- Capabilities: Organic synthesis, Medicinal chemistry, Peptide chemistry, Analytical chemistry, in vitro ADME, Assay Development & Screening, Bioanalysis, NMR.
- Key expertise: finding and developing chemical starting points into patentable lead compounds for inhalation.
- Number of employees: 18

www.redglead.com

► RESPIRON CONSULTING

- Advice when developing inhaler design to meet specification. Understanding device/formulation interaction, optimisation of drug delivery from device and delivery to patient.
- Setting specification for testing of inhalers, testing according to specification, follow up, documentation according to GLP/GMP.
- Advice in setting up aerosol test laboratories; specifications, equipment, documentation, guidelines/SOP's.
- Performing inhaler testing using laser diffraction methodology.
- Advice when technically designing, performing and evaluating inhalation toxicology studies. Optimisation of inhaled drug delivery to animals. (identifying equipment and delivery systems, conducting trials, evaluation and reporting).
- Identifying and connecting with CRO's for evaluation of inhaler/formulation options. Liaison in negotiations with pharma and device companies.
- Advice when scouting and identifying new inhalation systems (e. g. inhalers). • Number of employees: 1

www.respiroconsulting.com

We have expertise in all aspects of inhalation product development starting from pre-clinical via CMC to early clinical studies.

► ROCCIA

- A strategic, creative and knowledge driven communication partner.
 - Specialist competence in pharma and health, provides the best foundation for the client's.
 - Extensive knowledge of the market, large network of specialists including scientists, key opinion leaders, medical writers, creators and behavioral experts – offer expert communication and knowledge in life science.
 - Businessmodel: Analyse, Strategy, Content providing, Production and Follow-up.
 - The company is proud to ensure that it always can match the project needs, budget, timeline and with the best suitable competence.
 - Number of employees: 5
- www.roccia.se

► STATMIND

- Statistical analysis and modelling.
- Design and interpretation.
- Pharmacokinetics and pharmacodynamics. Input to Clinical Development Programs, early and late phase.
- Experience from all phases of clinical development, from first-time-into-man to marketing aspects. Specific inhalation issues including in-vitro experiments, lung deposition studies, switching programs for inhalation devices, therapeutic equivalence and biomarker evaluation.
- Number of employees: 3

► SÄRNSTRAND/KARLSSON CLINICAL CONSULTING AB

- Provide clinical and strategic support in design of pre-clinical and clinical studies and programs, as well as study conduct and interpretation of studies.
- Clinical development expertise in the translational phase between pre-clinical and clinical, "first time into human", pharmacokinetic/ pharmacodynamic, dose-finding studies in patients.
- Number of employees: 2

► TOXICOLOGY KNOWLEDGE TEAM SWEDEN – TKT

- Provides toxicology support and risk assessment services to pharmaceutical companies, from discovery phase to product launch.
 - Full toxicology project support.
 - Extensive experience in safety assessment of potential drug targets, an important component of early stage drug discovery projects.
 - In-house in silico QSAR availability and expertise, for drug candidates, intermediates and impurities.
 - Procurement, planning and monitoring of toxicology and safety pharmacology studies.
 - Regulatory documentation including IMPD/IND submissions.
 - Risk assessments for fine chemical production (OELs, PDEs).
 - Expertise in inhalation toxicology.
 - Number of employees: 6
- www.tktsweden.com

► TRULY LABS

- High quality, tailor-made preclinical in vitro and in vivo services.
- State of the art preclinical inhalation services.
- Extensive experience and expertise of designing, performing, evaluating, and reporting preclinical studies in an efficient and flexible way.
- Customized efficacy (PD) models and pharmacokinetic (PK) studies.

- PK/PD relationships and dose predictions.
 - A wide range of cell-based assays, incl. mode-of-action and efficacy assays, and biomarker analysis.
 - Services performed by experienced personnel in dedicated, fully equipped facilities.
 - Number of employees: 6
- www.trulylabs.com

► TRULY TRANSLATIONAL

- Experienced team of drug development consultants providing services with emphasis on pharmacology, translational science, and business development.
 - Experts in preclinical inhalation.
 - Preclinical study design; in vitro and in vivo study protocols.
 - Coordination of biomarker activities; Analytical and clinical validation and implementation in clinical studies.
 - Strategic planning – Project and Business Plans, Target Product Profile (TPP), and Translational Medicine Plans.
 - Market research and evaluation.
 - Evaluation of project ideas and projects – Is there a business case for an inhalation approach?
 - Regulatory preclinical development plans and documentation.
 - Number of employees: 4
- www.trulytranslational.com

► VALIDUS ENGINEERING

- Device development using numerical simulations, e.g. FEA and CFD.
 - Device general flow simulations such as flow patterns, distribution, pressure drop and turbulence.
 - Dry particle modelling including tracking, impaction, deaggregation, retention and deposition.
 - Spray modelling with evaporation, tracking and deposition.
 - Cavity emptying simulations.
 - Simulation of vapour-based inhalation devices.
 - Moisture ingress simulations.
 - Heat sealing thermal simulations.
 - Structural integrity simulations of inhalation devices; including general integrity as well as drop testing.
 - Vast experience within the simulation of pMDI, MDI and DPI devices as well as blister packs.
 - Number of employees: 35
- www.valeng.com

► ZENIT DESIGN

- Device development and industrial design.
 - Hands-on experience from all aspects of development of inhalation devices and medical devices.
 - Thorough understanding of the intricate interaction between device, formulation and performance.
 - Long pharmaceutical product development background.
 - Unique combination of in-house skills: Mechanical design, industrial design, inhalation technology, physics, aerosol science, electrostatics, fluid dynamics and pharmaceuticals.
 - Combine innovative industrial design with state of the art product development and a strong pharmaceutical expertise.
 - Number of employees: 25
- www.zenitdesign.se