MVIC AB – Your Partner and CRO for Inhalation Product Development

www.mvic.se

MVIC – What We Can Offer

As a customer to MVIC, you will be safe and have a range of experts at hand in your development of inhalation products. We can do everything from smaller studies up to full development.

Pre-clinical

MVIC has expertise in all aspects of inhalation product development starting from pre-clinical via CMC to early clinical studies. In pre-clinical, we can perform various types of evaluations including animal studies. Our medicinal chemistry experts support as needed. Additional to pre-clinical studies, MVIC can pursue in-halation toxicology evaluations and execute inhalation toxicology studies.

CMC

In CMC, MVIC has a range of experts in dry powder and liquid formulations. MVIC has particularly within dry powder formulation development run several formulation projects ranging from very low scale up to about 1 kg (GMP). MVIC has also experts in analytical testing and has a range of analytical test capabilities including particle sizing using impactors and a broad range of solid state analysis equipment. In order to predict in vivo outcome, we have both human throat replicas as well as lung simulators. These methods together with in-house software to predict distribution within the lung makes MVIC world leading in the area.

Clinical

MVIC can also offer early clinical studies. To do this, we liaise with local clinics and collaborators for data management. We have statistical experts with long experience of inhalation studies in-house, important both for study design as well as at evaluation.

Equipment

One MVIC member company supports with equipment for inhaler testing and automation. These state-of-the-art systems have high capacity and are fully GMP compatible.

Interesting? Contact us and we can tell you more about us and what we can do to help you in your inhalation product development.

MVIC – EXPERTISE IN INHALATION PRODUCT DEVELOPMENT	Target discovery	Transla-tional science	Animal models	PK & PD	Invitro-cell-based assays biomarkers	Medicinal chemistry	ADME	Pharma-cology	Toxicology	Formulation science	Analytical chemistry	Solid state science	Device develop-ment	Computa-tional fluid dynamics	Statistical analysis & data processing	Lung deposition	Bio-pharma-ceutics	Regulatory affairs	Manu-facturing, tecnology transfer, specs.	Powder process development	Marketing & commu-nication & visual	GMP manu-facturing	Project Management, Documentation & Quality, Business Development	IP & trademarks	Phase I	Phase II	NDA, Phase III–IV Registration
AB FIA											●				●				●				●				
AB I LAMBERG CONSULTING													●					●									●
AB KAMSACO																									●	●	●
ADROIT SCIENCE										●	●	●						●	●	●			●	●	●	●	●
ASKING CONSULTING													●						●	●							
CISOLUTIONS																					●			●			
CR COMPETENCE										●	●	●					●			●					●	●	
DIGITAL CONTEXT																					●						
EMMACE CONSULTING											●		●			●				●					●	●	
GALENICA										●	●								●	●		●	●	●	●	●	●
GERIK MEDICAL CONSULTING													●			●	●	●			●		●	●	●	●	●
IMAGING RESOURCE										●	●	●	●							●	●						
LASTOW CONSULTING													●														
LIGATUM										●														●			
NORDICBIOCUBE				●			●																●		●	●	●
OM PROJEKT																							●				
RED GLEAD DISCOVERY	●				●	●	●	●			●																
ROCCIA																					●						
STATMIND				●											●										●	●	●
SÄRNSTRAND KARLSSON CLINICAL CONSULTING, SKCC		●		●				●																	●	●	●
TOXICOLOGY KNOWLEDGE TEAM, TKT									●																●	●	●
TRULY LABS	●	●	●	●	●			●								●	●										
TRULY TRANSLATIONAL	●	●		●				●									●				●		●		●	●	
VALIDUS ENGINEERING													●	●													
ZENIT DESIGN													●	●					●								

MVIC – 25 Member Companies

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. Develops specialized instruments and automatical systems for OINDP applications.
  www.fia.se

- **AB I LAMBERG CONSULTING**
  Expertise in regulatory strategic input at various levels and hands on work in compiling various applications. Expert advice in leadership and project management.

- **AB KAMSACO**
  Clinical development expertise.

- **ADROIT SCIENCE**
  Dedicated to novel post processing treatment and characterization of inhalation powder material (substances and formulations).
  www.adroitscience.com

- **ASKING CONSULTING**
  Expertise in pharmaceutical and medical device development; inhaled drug delivery and formulation development.

- **CISOLUTIONS**
  Competitive intelligence comprising literature, patents, pipeline, clinical trials and market. Covering pre-idea to life cycle management.
  www.cisolutions.se

- **CR COMPETENCE**
  As experts in formulation science, specially poorly solubles, process design and surface technology, we add novelty and competitive edge; Quality by Understanding®.
  www.colloidalresource.se

- **DIGITAL CONTEXT**
  Visual communication, 3D graphics & animation, film, interactive design and rich media applications.
  www.digitalcontext.se

- **EMMACE CONSULTING**
  Analyses and performance evaluations of inhalers and nebulizers.
  www.emmace.se

- **GALENICA**
  Formulation and manufacturing according to Good Manufacturing Practice (GMP).
  www.galenica.se

- **GERIK MEDICAL CONSULTING**
  Clinical development and project management expertise.
  www.GErik.se

- **IMAGING RESOURCE**
  Microanalysis of powders and device for particle properties and material compatibility. Aerosol characterization for plume geometry. Scientific imaging for marketing.
  www.imagingresource.se

- **LASTOW CONSULTING**
  Device development and project management.

- **LIGATUM**
  Intellectual property strategy.

- **NORDICBIOCUBE**
  Expertise in optimizing global processes and services of biological material to meet chain of custody, Quality Assurance and legal demands.
  www.nordicbiocube.com

- **OM PROJECT**
  Leadership in Improvement Projects, Quality Assurance, Project Management, Supply Chain Management and Lean Six Sigma.
  www.omproject.se

- **RED GLEAD DISCOVERY**
  Drug discovery services: Medicinal chemistry, peptide chemistry, ADME, in-vitro biology, bioanalysis and NMR.
  www.redglead.com

- **ROCCIA**
  Marketing communication within legal framework.
  www.roccia.se

- **STATMIND**
  Statistical analysis and modelling. Design and interpretation. Pharmacokinetics.

- **SÄRNSTRAND/KARLSSON CLINICAL CONSULTING AB – SKCC**
  Provide clinical and strategic support in design of pre-clinical and clinical studies and programs, as well as study conduct and interpretation of studies.

- **TOXICOLOGY KNOWLEDGE TEAM – TKT**
  Provides toxixology and risk assessment services within the pharmaceutical industry, from discovery phase to product launch.
  www.tktsweden.com

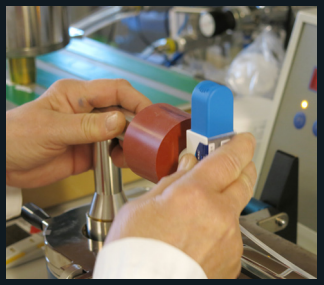
- **TRULY LABS**
  High quality customized in vitro and in vivo services: Cell-based assays, biomarker analysis, PK, PD, dose prediction, and state of the art inhalation services.
  www.trulylabs.com

  TRULY TRANSLATIONAL
  Drug development and business development consultancy services: Translational science & pharmacology, strategic & project planning, project leadership, documentation, and business development.
  www.trulytranslational.com

- **VALIDUS ENGINEERING**
  Computational modeling. Device development through FEA and CFD including the simulation of structure, fluid flow, thermal and moisture transport.
  www.valeng.com

- **ZENIT DESIGN**
  Device development, industrial design, packaging design and service design.
  www.zenitdesign.se




MVIC is Your Full Service CRO and Partner Specializing in Inhaled Drug Delivery

MVIC, Medicon Valley Inhalation Consortium, is a full service CRO specialized in inhalation product development and is located in Skåne in the Medicon Valley area. MVIC offers world class expertise within the field of inhalation, covering the whole value chain from drug discovery, development to Phase I/II. MVIC has facilities approved according to Good Manufacturing Practice, GMP, well equipped labs, advanced instrumentation and highly skilled staff.

Business Model

MVIC AB is a company registered in Sweden and is owned by member companies. MVIC is responsible for marketing and business development for the consortium.

Working with MVIC is like working with one company but using the competence and resources of 25 companies. For each project, MVIC forms a project team and appoints a project manager who is responsible for all work and deliverables. The project team members are allocated from the member companies as appropriate. This is fully seamless to the client.

One company

- One CDA
- One proposal
- One supplier agreement
- One invoice
- One contact person
- One project manager
- One accountable supplier

Symposium

MVIC runs a symposium, MVIS, anually in Lund. The symposium is at low cost and runs for 1.5 days with excellent podium presentations covering various areas of inhalation product development.

Training

MVIC runs various types of dedicated training sessions within inhaled drug delivery. Particularly, we run a 1.5-days inhalation overview course, Workshop, in connection to the MVIC symposium, MVIS. Read more and register at: www.mvic.se

MVIC AB has more than 70 inhalation experts and represents over 1000 years of inhalation experience!

MVIC
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INHALATION CONSORTIUM

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