Drug Discovery & Translational Science · Complete lead discovery and optimization projects · Medicinal chemistry – design & synthesis of smal molecules · Compound optimization for inhalation – lung retention and metabolic profile · Fragment-based screening for new chemical starting points · Peptide chemistry – design & synthesis · Radio isotope chemistry · NMR spectroscopy · Bioanalysis by LC-MS/MS · Physicochemical profiling and in vitro ADME · Assay development and screening (biochemical and cell-based assays – development & screening) · Transition from preclinical in vitro studies to concept testing in patients · Biomarkers · Pharmacology · Pharmacodynamics (PD) · Pharmacokinetics (PK) · Toxi cology support · Solid State Characterization · Salt and polymorph screening · Crystallinity determination · Conditioning development · Morphol ogy evaluation · Humidity interaction · Formulation Science · Formulations from preclinical phase through to market · Powder, aqueous, HFA

Carrier-based, micronized • Org • Composition, excipients • Elec nasal • Industrial design • User • typing & testing • Device optimi verification • Design control • M 13485, 14971, 20072, CFR 820 • and excipient characterization • optimization • Statistical Analysi ematical modelling of biological design, technology, dosing • In-1 • GMP, CGMP • Process validati powder • QC testing and release Logistics • Stability testing (ICH) • Pharmacopeias • Medical writi • Regulatory Affairs • Regulatory

MVIC AB – Your Partner and CRO for Inhalation Product Development

onditioning • Process equipmen wder inhalers, Nebulizers, pMD ion • Mechanical design • Protonbly and manufacturing • Design laterials • Work according to ISC • Chemical analysis, HPLC • AP ow visualization • Fluid dynamica • vitro to clinical settings • Math • acceutics • Inhalation toxicology d lung simulator • Manufacturing I • GMP formulations - liquid, dr gical samples (chain of custody) CH guidelines and ISO standard iological material • Risk handling • gy, Execution • Content provide

• 3D animation and film • Visualization • e-learning • Rich media application • Project Management • Pre-clinical project management • Pharma ceutical project management • Cross-functional coordination • Pharmaceutical product development • Redundancy Based Development, RBD Scale-up and supplier sourcing • Technology transfer • QbD • Clinical study outline • Clinical study protocols • Clinical development phase I to I' (EU, US, Japan) • Lean Sigma • Supply Chain Management/Process Optimisation • Intellectual Property & Due Diligence • IP strategy • Due diligence exercises and company evaluations in connection to company acquisitions, joint ventures and in-licensing • Competitor intelligence and experimeters • Drug Discovery & Translational Science • Complete lead discovery and optimization projects • Medicinal chemistry – design & synthesis of small molecules • Compound optimization for inhalation – lung retention and metabolic profile • Fragment-based screening for new chemica starting points • Peptide chemistry – design & synthesis • Radio isotope chemistry • NMR spectroscopy • Bioanalysis by LC-MS/MS • Physicochemical profiling and in vitro ADME • Assay development and screening (biochemical and cell-based assays – development & screening) • Transitio from preclinical in vitro studies to concept testing in patients • Biomarkers • Pharmacology • Pharmacodynamics (PD) • Pharmacokinetics (PK) Toxicology support • Solid State Characterization • Salt and polymorph screening • Crystallinity determination • Conditioning development • Morphology evaluation • Humidity interaction • Formulation Science • Formulations from preclinical phase through to market • Powder, aqueous, HF, • Carrier-based, micronized • Organic chemistry • Micronization and million • Crystallinity determination • Conditioning • Process equipment

• Composition, excipients • Electrostatics • Scalenasal • Industrial design • User centric design and typing & testing • Device optimization • Device – 1 verification • Design control • Manufacturing proce 13485, 14971, 20072, CFR 820 • Analytical Chemis and excipient characterization • Fluid Dynamics & optimization • Statistical Analysis & Data Processi ematical modelling of biological and PK/PD data • design, technology, dosing • In-vitro predicting me • GMP, CGMP • Process validation • Devices and f



www.mvic.se

elopment • Dry powder inhalers, Nebulizers, pMDI
• Concept generation • Mechanical design • Proto
• Design for assembly and manufacturing • Design
cost of goods • Materials • Work according to ISC
acopeias NGI, ACI • Chemical analysis, HPLC • AP
ol technology • Flow visualization • Fluid dynamics
rsis of data from in-vitro to clinical settings • Math
sition & Biopharmaceutics • Inhalation toxicology
tomical throats and lung simulator • Manufacturing
naterial Phase I-III • GMP formulations - liquid, dr

powder • QC testing and release testing • Test Equipment & Test methods • Customized Iab Kits • Labeling of biological samples (chain of custody) Logistics • Stability testing (ICH) • Documentation & Quality • CMC, GMP, GLP, GCP • FDA and EMEA regulations • ICH guidelines and ISO standard • Pharmacopeias • Medical writing & communications • Pharmaceutical information • Processes & services for biological material • Risk handling Regulatory Affairs • Regulatory strategies • IND, IMPD, NDA, MAA • Marketing Communication • Analysis, Strategy, Execution • Content provider 3D animation and film • Visualization • e-learning • Rich media application • Project Management • Pre-clinical project management • Pharmaceuti

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 preclinical, 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.

AB FIA											•				•				•				•				
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AB KAMSACO													-					-								•	•
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IMAGING RESOURCE										•	•	•	•							•	•						
LASTOW CONSULTING													•														
	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		NDA, Phase III–IV Registration
LIGATUM										•														•			
NORDICBIOCUBE				•			•																•		•	•	•
OM PROJEKT																							•				
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STATMIND SÄRNSTRAND KARLSSON CLINICAL CONSULTING, SKCC TOXICOLOGY KNOWLEDGE TEAM, TKT			•	•	•				•						•	•	•				•				•	•	-
STATMIND SÄRNSTRAND KARLSSON CLINICAL CONSULTING, SKCC TOXICOLOGY KNOWLEDGE TEAM, TKT TRULY LABS		•	•	•	•			•	•						•	•					•				•	•	-

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IMAGING RESOURCE										•	•	•	•							•	•						
LASTOW CONSULTING													•														
MVIC – EXPERTISE IN INHALATION PRODUCT DEVELOPMENT	Target discovery		Animal models	PK & PD	Invitro- cell-based assays biomarkers	Medicinal chemistry	ADME	Pharma- cology	IOXICOIOdV	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
LIGATUM										٠														•			
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.

ADBOIT 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 AB

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