



### 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. MVIC has expertise in all aspects of inhalation product development starting from pre-clinical via CMC to early clinical studies. We can do everything from smaller studies up to full development. With our broad and long experience, we will take your project forward efficiently focused on getting a product onto the market.

#### PRE-CLINICAL

In pre-clinical, we can perform various types of evaluations including animal studies. We have several different delivery systems and can perform e.g. PK and PD assessments. A key benefit of MVIC is the availability of formulation experts. Furthermore, we have medicinal chemistry experts that support as needed. Additional to pre-clinical studies, we can pursue inhalation toxicology evaluations and execute inhalation toxicology studies.

#### CMC

In CMC, MVIC can develop both dry powder and liquid formulations. We has run several formulation projects ranging from very low scale up to about 1 kg (GMP). We also perform analytical testing and has a range of test capabilities including particle sizing using impactors and a broad range of solid-state analysis equipment.

#### MVIC IS WORLD LEADING IN THREE KEY AREAS:

#### 1. In vivo prediction via in vitro models

Our test equipment, including anatomical throats and lung simulators, can assess all types of devices.

Combined with our unique modelling software for predicting lung deposition and PK, MVIC perfoms world leading in vivo predictions.

#### 2. Solid state aspects of dry powders

MVIC has access to all relevant equipment and experienced analysts to fully characterize powders in the inhalable particle size area.

#### 3. Dry powder formulation development

MVIC has both a broad theoretical competence as well as equipment and trained lab personnel to optimize dry powder formulations.

#### 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 inhouse, important both for study design as well as at evaluation.

#### **AUTOMATION & EQUIPMENT**

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









#### **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 multiple 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.

# MVIC OFFERS ITS SERVICES AS A SINGLE COMPANY

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

#### **SYMPOSIUM**

MVIC runs the MVIC symposium, annually in Lund. The symposium is at low cost and runs for 2 days with excellent podium presentations covering various areas of inhalation product development.

## FIRST-CLASS TRAINING AND EDUCATION IN INHALED DRUG DEVELOPMENT

MVIC offers customized courses based on our customers' specific needs. These courses can be held at Medicon Village in Lund, Sweden, or at your site. Please, contact us and we can allocate relevant staff and plan the details. Course material and training certificate will be available.



# MVIC – YOUR PARTNER AND CRO FOR INHALATION PRODUCT DEVELOPMENT

When heading major inhalation development projects, there are several key factors to reach success.

The first key factor is a very skilled project manager. Our experienced PMs work focussed with you and your team towards the common, well-defined goal. Additional key factors are a full-fledged span of competence and a vast experience in inhalation technology.

At MVIC we discuss strategic aspects of device and formulation development with our clients. Already at the first meeting, we give professional aspects on how ideas and early development should be developed into inhalation products.

Working with us, you will often get straightforward answers to complex questions. You will be amazed.

Our project managers and specialists have worked in the outmost frontline of the world when it comes to inhalation technology.

Most of us also have a very sharp business approach from years in top management and vast experience in working with a wide range of company sizes in pharmaceutical development projects.

We are a CRO and Partner with a large number of project managers and specialists in Discovery, Formulation, Regulatory, Device and Product Development.

We are located in Lund, a part of Southern Sweden with its cluster of universities, hospitals and pharmaceutical industries in Southern Scandinavia.

## **CONTACT**

For contact and more information

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