# INHALATION PRODUCT TESTING AND CHARACTERISATION



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## Inhalation Product Testing and Characterisation to Customer Requirements and High Level of Quality

Inhalation product testing and characterisation requires product understanding as well as capabilities for performing the tests. MVIC has the experience to do the right tests with procedures that are standardised or matched to customer requirements with high level of quality. MVIC are proud to provide individualized aerosol characterisation according to our clients' precise needs and specifications.

Aerodynamic particle size distribution (APSD) is along with delivered dose crucial to fully understand the impact of a candidate aerosol. MVIC is a full-service partner with a unique ability to assist in product characterisation of inhaled pharmaceuticals. We are utilizing a silico modelling of lung deposition and determine PK outcomes based on in vitro data.

# **AEROSOL CHARACTERISATION METHODS** SP / PG IMPACTOR DD PSD

### 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

## $\checkmark$

#### IMPACTOR BASED TESTS (APSD):

- Next Generation Impactor (NGI), Andersen Impactor (ACI), Multi-stage Liquid Impinger (MLI)
- Standard USP throat or anatomically realistic mouth throat model of different sizes
- Lung Simulator for generation of tidal breathing (nebulizers) or replay of inhalation profiles by using the mixing inlet method
- Mechanical hand for fire off pMDI inhalers at certain and different time points at inhalation profiles
- By adapting a suitable AIM set-up, the fine particle dose uniformity can be assessed

#### DD: DELIVERED DOSE

- Standard DUSA as specified in Pharmacopeia, but also faster and less laborious methods
- Bespoke dose collection system, adapted to clients need
- Semi- and full automation systems designed together with client and installed at client site

#### SP: SPRAY PATTERN / PG: PLUME GEOMETRY (ENVISION SYSTEM FROM OXFORD LASERS)

- Open system up to 500Hz sampling rate
- At variable distances
- Pneumatic actuation unit
- SP and PG can be used with inhaler specific housing for "push through" air flow for triggering





- Laser diffraction (Malvern Spraytec, Mastersizer S, Malvern 3000 + Aero S)
- Aerodynamic Particle Sizer (APS 3321) combined with Impactor inlet for screening tests
- Open and closed Inhalation cells so that a bolus inhalation can be generated when using a lung simulator
- PSD of liquid and powder products
- PSD powder formulations alone without device
- Investigations of dose release and PSD over time
- Characterisation of the emptying process of the dose out of a device
- Pneumatic actuation unit

#### MISC:

- Characterization of dissolution rate of the lung dose/fine particle dose
- Stability testing in any kind of T/RH settings
- Possibility to perform dose withdrawal in different temperatures and relative humidities
- Anatomical models of the nasal cavity available for deposition testing
- In silico modelling of lung deposition and subsequent PK outcome based on in vitro data
- Determination of the air volume required to empty the powder dose from a DPI
- Pressure drop testing
- Manufacturing of silicone-based adapters (e.g. inhaler vs USP throat)



#### pMDI fire action vs. IP



#### Anatomical throat models



Plume Geometry



Spray Pattern

## MVIC AB – YOUR PARTNER AND CRO FOR INHALATION PRODUCT DEVELOPMENT

When heading major inhalation development projects, there are three things that will qualify you for success.

The first is a very skilled project manager, i.e. yourself. The second and third are a full-fledged span of competence and a vast experience in inhalation technology. That's us.

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 small to large pharma clients in pharmaceutical development projects.

We are a CRO and Partner with more than 70 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

MSC. LARS ASKING CEO lars.asking@mvic.se Phone: +46 702 26 62 40



MVIC AB | Medicon Village | Scheeletorget 1 | SE-223 81 Lund | Sweden Phone: +46 702 26 62 40 | info@mvic.se | www.mvic.se