



**STREAMLINED AND COST-EFFECTIVE
WET FORMULATION DEVELOPMENT
FOR NEBULIZERS, NASAL AND SMI**



MVIC

www.mvic.se

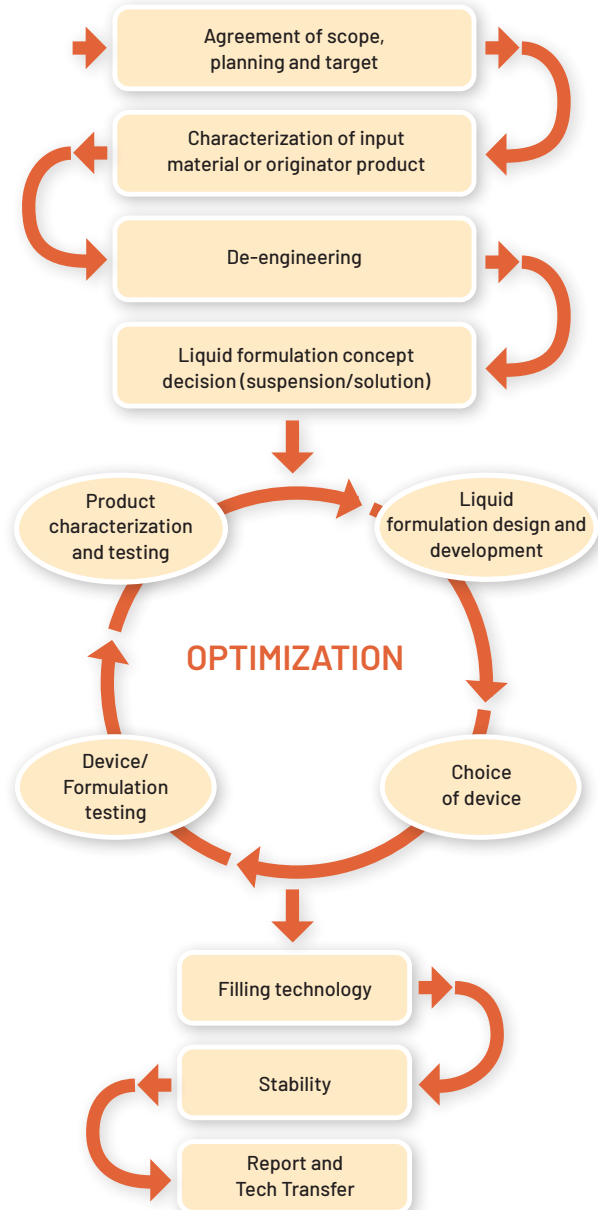
Formulation Development for Nebulizers, Nasal and Soft Mist Inhaler (SMI) Products

MVIC offers wet formulation development streamlined, cost-effective and high-quality performed liquid inhalation formulation/product development packages to customers. The development program can consist of formulation development for a nebulizer, or the development of a liquid inhalation product consisting of a formulation and device. The size and design of the development program is tailor-made together with the customer.

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

EXAMPLE OF PROJECT WORK FLOW



Specialised MVIC Skills that are Integrated in the Development Program

✓ ANALYTICAL METHOD DEVELOPMENT

- Analytical method development needed for de-engineering
- Analytical method development for material characterization and release specifications
- Specific analytical method development for aerosol instrument with chemical assays
- Method validation

✓ FORMULATION DEVELOPMENT

- Tailor made de-engineering of complex formulations and excipients
- Formulation concept design considering dose, solubility etc.
- Formulation design including selection of excipients, pH, tonicity etc.
- Formulation processing for suspensions considering stability, aggregation, agglomeration flocculation, sedimentation etc.
- Filling and stability recommendations

✓ PRODUCT TESTING

A genuine device performance testing through the development process is vital so that the impact of formulation changes is monitored. This enables fulfilment of the project end points and prediction of outcome in e.g. BE PK studies.

- Laser diffraction testing
- Spray pattern and Plume geometry testing
- Delivered dose testing
- Aerodynamic particle size distribution testing, with the NGI impactor
- In vivo relevant in vitro testing, such as different anatomical throat sizes in combination with different patient air flow profiles
- Stability testing of candidate packaging, formulation and device

✓ PROJECT MANAGEMENT

New prerequisites, project objectives or revised business cases require a smooth and swift interaction between customer and service provider.

- The dedicated MVIC project manager will engage in the initial design and scope of the program and will drive the project from start to finalisation. The project manager will coordinate the work within MVIC and will be the main contact between the customer and MVIC
- Knowledge transfer is key and a continuous dialogue is central to our project process
- Knowledge transfer between MVIC and third parties such as accredited analytical labs or production facilities of choice

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

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