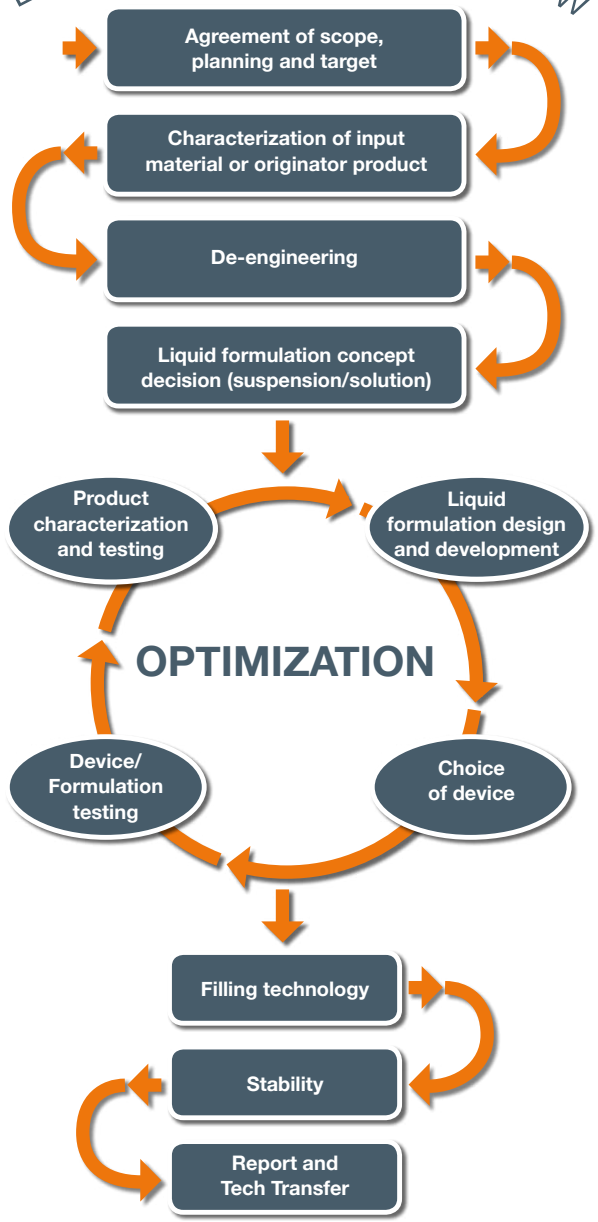
Wet Formulation Development (WFD) for Nebulizer, Nasal and Soft Mist Inhaler (SMI) Products

MVIC WFD offers streamlined, cost-effective and high-quality performed liquid oro-nasal inhalation formulation/product development packages to customers that either lack resources to perform a development program and/or require cutting edge input for e.g. problem solving. 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

Medicon Valley Inhalation Consortium, MVIC, 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.

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

Contact

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