

Formulation Considerations for Inhaled and Nasal Product Development

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Inhaled and nasal dosage forms offer unique and advantageous routes for delivering medicines for both local and systemic treatment. The growing patient population and unmet patient needs along with the new drug development and therapeutic applications have driven the advance of the medical aerosol science in multiple disciplines. This includes development of new devices, formulation/particle and process technologies, along with the research for more advanced product characterization techniques and a better understanding of correlation between the *in vitro* performance and *in vivo* efficacy to support regulatory justification.

As a combination product, development of inhaled dosage form can be complicated as the finished product performance is determined by the combination effect from both formulation and device. In addition, the overall performance of the inhaled products is dominated by the cumulative behaviors of the individual aerosol particles which makes it even more challenging in the formulation development.

This presentation discusses the brief history of the inhaled and nasal drug delivery systems, basic functions of the devices such as examples from the metered dose inhaler, dry power inhaler, nebulizer, Softmist inhaler, liquid and dry powder nasal spray, and the key considerations in designing and developing the inhalation and nasal formulations.