Inhaler Testing Methods for Orally Inhaled Products (OIPs): How they are adjusting to support clinician needs towards the improvement of in vitro/in vivo relationships (IVIVRs)

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Existing pharmacopeial methods for the *in vitro* testing of orally inhaled products (OIPs) are simplified representations of clinical reality, primarily because the goal is to provide robust metrics that can be used to assess product quality. Imaging-based techniques that quantify particle deposition in terms of location in the human respiratory tract may be helpful to link *in vitro* to *in vivo* data as surrogates for clinical responses. However, attempts to correlate laboratory-determined measures, such as fine particle fraction < 5 µm aerodynamic diameter, using pharmacopeial methods with clinical response factors have been notoriously difficult to achieve. A reappraisal of the purposes for laboratory-based testing of OIPs is therefore required if this problem is to be resolved satisfactorily.

This webinar provided guidance on approaches that may be helpful to develop more clinically-appropriate methods to assess OIP performance in the laboratory, with the ultimate objective of developing robust *in vitro/in vivo* relationships (IVIVRs) for the major inhaled drug classes.

**Bibliography of peer-reviewed articles discussed:**

**Clinically-Appropriate Testing:**


**Cascade Impactor Method:**


**Other Aerosol-Sizing Methods for Orally Inhaled Products:**


