

## **ABSTRACT:**

# **Measurements: Particle Size Measurements for OINDP Quality – 2: New Concepts**

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The multi-stage cascade impactor (CI) is well known to be a relatively complex method in use for the laboratory assessment of inhalers-generated aerosol aerodynamic particle size distribution (APSD). As a result, there has been increasing interest in developing a comprehensive collection of guidance that assists both the novice and experienced practitioner in the correct set-up, use and data analysis from a CI-based determination. The concept of Good Cascade Impactor Practice (GCIP) for (a) operation and (b) apparatus maintenance is introduced. Under part (a), flow rate setting (assertion) as well as verifying the elimination of leakages and a cleaning regimen are key aspects to consider. Under part (b), stage mensuration; and the management of damaged stages and collection surfaces are important. The recently introduced Abbreviated Impactor Measurement (AIM) concept and related Effective Data Analysis (EDA) methodology for handling CI-generated data are then discussed in detail, since both approaches have the potential for large time savings in early stage product development as well as in quality control.

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