Product Quality Research Institute Reports

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The mission of the Product Quality Research Institute (PQRI) is to serve as a forum for academia, industry, and regulators to work cooperatively in conducting pharmaceutical product quality research and to support development of public standards and regulatory policy. PQRI was founded in 2001 under the guidance of the American Association of Pharmaceutical Scientists (AAPS). Within PQRI, scientists from FDA, industry, academia and USP come together to address urgent and challenging problems, and conduct research that would inform parties involved in the regulatory policy and decision-making processes. A PQRI Aerodynamic Particle Size Distribution (APSD) working group was established in 1999 to assess the chi-square ratio statistical test method for comparing particle size distribution profiles of pharmaceutical aerosols.

PQRI's Evaluation of Cascade Impactor Profiles of Pharmaceutical Aerosols: Parts 1 and 2 evolved from the work of the APSD working group and have undergone peer-review. These reports differ from the typical research article published by *AAPS PharmSciTech*, which are primarily hypothesis-driven. In this case, the PQRI working group focused on existing problems in the critical path of developing a product for commercial application and addressed those issues which impact regulatory policy and decision-making initiatives. The goal of the effort was to evaluate the properties of a statistical test that could be applied to a variety of pharmaceutical aerosols, which, as a result of different formulation and/or device characteristics, may have different aerodynamic particle size distributions. Careful attention to the perspectives of the various stakeholders and contributors was just as important an element of success as the statistical methodology.

Part 1 explains the philosophy of the statistical test as well as the process by which experts from different organizations could work collaboratively and productively. The article not only provides a glimpse into the challenges of applied regulatory science and the considerations behind regulatory recommendations, but also points to ways for finding solutions in the complex regulatory environment. Part 2 summarizes the thought process and approaches developed and pursued by the PQRI working group. The results obtained in this study led to the conclusion that the original proposed regulatory test may need to be supplemented with additional testing.

Together, the two reports present the relevant rationale, data, approaches, and results related to a statistical method of in vitro equivalence testing of orally inhaled and nasal drug products. These reports were published in *AAPS PharmSciTech* with the hope that they will enable and stimulate further scientific dialogue and potential improvement of the proposed requirements. Ultimately, these studies benefit the users of these drug products – the patients.

Respectfully Submitted,

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