Cross-industry organizations

The European Pharmaceutical Aerosol Group (EPAG): An update on recent activities

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On behalf of The European Pharmaceutical Aerosol Group (EPAG)

Introduction

The European Pharmaceutical Aerosol Group (EPAG) is an advocacy group comprised of pharmaceutical companies, support companies, academia and independent consultants. EPAG consists of a plenary group under which report a series of sub-groups, such as the Impactor, Nasal and Dissolution sub-groups. EPAG consists of more than 20 member companies, either in the plenary or the sub-groups.

EPAG aims to generate data, collect scientific information and work with other advocacy groups. This allows EPAG to provide recommendations via its plenary and/or sub-groups for a range of applications such as new technologies, new methodologies and responses to draft guidelines.

EPAG has a global reputation for being a key advocacy group, having world experts in their respective fields. Key successes in recent years include numerous scientific papers (with two published in 2020), poster presentations at the Drug Delivery to the Lungs Conference and collaborative work with Loughborough University. EPAG has also taken a prominent role in generation of data via its members and/or collaborations to evaluate new technologies or conduct fundamental research to prove and/or confirm principles within the pharmaceutical aerosol field.

Nasal Sub-Group

This sub-group's activity aims to develop European Pharmacopoeia (EP) methodology for nasal sprays to measure aerodynamic particle size analysis of two fractions (< 10 µm and > 10 µm), thereby proposing a standardized approach for measuring this parameter. The first work-phase (selection of a suitable nasal inlet port and analytical technique for % < 10 µm) and the second work-phase (assessment of the selected techniques using nasal spray pumps and nasal metered dose inhalers (MDIs)) have been completed. A publication titled, "Evaluation of nasal inlet ports having simplified geometry for the pharmacopeial assessment of mass fraction of dose likely to penetrate beyond the nasopharynx: A preliminary investigation" [1] summarizes this work effort. The third work-phase is ongoing and includes method validation and preparation of the EP monograph. Several discussions have been held with the European Medicines Agency (EMA) Inhalanda group in order to align the proposed methods from EPAG for measuring % < 10 µm in nasal sprays.

Dissolution Sub-Group

The desire and need to understand the dissolution behavior of inhaled products has increased over the last five years. There has been discussion around the principles of a pulmonary biopharmaceutical classification system [2] and the use of comparative dissolution data is now suggested in United States Food and Drug Administration (FDA) product-specific guidance [3] as evidence of *in vitro* bioequivalence. This increased regulatory interest in dissolution characteristics of inhaled products has opened questions and debate about the best way to carry out these measurements. Thus far, there is no standardized method of aerosol capture and subsequent dissolution testing. The Dissolution Sub-group within EPAG aims to collate and share member company experience in this area, with a view to developing sensitive, robust and easy-to-use methodology that can be placed into the public domain for the benefit of all.

Impactor Sub-Group

In recent times, the primary activity of the Impactor Sub-group has been to evaluate dry powder inhaler (DPI) method set-ups. The work is detailed in two publications [4, 5], which describe both experimental and computational modeling data characterizing the flow rate/rise time profiles of equipment used in these methods. This will be useful in facilitating harmonization within the impactor area—a critical objective of the group.

A further significant activity—in progress—is to address a request from the EDQM (European Directorate for the Quality of Medicines) for collaboration to provide an industry opinion regarding Abbreviated Impaction Methods (AIM). The sub-group is performing an analysis of the merits and shortcomings of the various AIM systems, highlighting potential advantages and disadvantages of each. This information is of potential importance as such

methods are being considered for possible future inclusion in the European Pharmacopoeia.

Looking to the future, the subgroup plans to develop understanding of DPI test method set-ups, in collaboration with Loughborough University. Work is also planned to characterize the mixing inlet typically used with a cascade impactor, to enable use of inhalation profiles for more clinically relevant testing.

Seeking new members

EPAG is always looking for new member organizations who can help us build on our success. Feel free to connect with us at https://epag.co.uk/ or https://www.linkedin.com/company/european-pharmaceutical-aerosol-group/ or Twitter: @EPAG_

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