THE EPAG WORKSHOP ON THE ABBREVIATED IMPACTOR CONCEPT IN DECEMBER, 2010: STATUS, KEY RESULTS AND FUTURE NEEDS IN ORAL INHALED PRODUCT TESTING

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BACKGROUND

• Last December, as part of Drug Delivery to the Lungs 21, the European Pharmaceutical Aerosol Group (EPAG) organized a half-day workshop covering experimental aspects of the Abbreviated Impactor Measurement (AIM) Concept
• Seven speakers presented examples of their own work with various designs of abbreviated impactors
• The data presented encompassed testing of most forms of Oral Inhaled Product (OIP), including pressurized Metered Dose Inhalers (pMDIs), Dry Powder Inhalers (DPIs) and nebulizing systems
• The workshop proved very popular with aerosol scientists, with about 80 delegates registered, demonstrating the high level of interest in AIM
• One key aspect of the workshop was to share across industry how others are developing AIM and the successes that are being had together with any issues that are being found
• By sharing information across the Industry the issues can be resolved and harmonized methodology developed

AIM WORKSHOP PRESENTATIONS

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<th>Presentation</th>
<th>OIP Type(s)</th>
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<td>Russell-Graham et al.</td>
<td>DPI</td>
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<td>Tervis-T hall et al.</td>
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<td>Sitapal et al.</td>
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<td>Goring and Mandant</td>
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A panel discussion followed, in which participants discussed future needs in support of robust method development for each OIP category, together with helping to define a roadmap towards regulatory/pharmacopeial acceptance for AIM
• The complete transcript of the Workshop, together with each presentation are available on the EPAG website: www.epag.co.uk
• Some information has been presented by one of the authors as a podium talk on AIM apparatus
• This poster summarizes the key findings that emerged from the panel discussion

PANEL DISCUSSION HIGHLIGHTS

• The evaluation of pMDIs appears to be a relatively straightforward process
• However, precautions need to be taken to mitigate particle bounce and re-entrainment for all pMDI-based work
• The internal bias space of the abbreviated system should ideally be close to that of the full resolution impactor when assessing pMDIs containing low volatile excipients such as ethanol
• Similarly, the evaluation of nebulizers by AIM-based techniques is also straightforward
• Nebulizers should ideally be tested at 15 L/min
• This practice is in accordance with recommendations in the new monograph 2.8.44 covering preparations for nebulizing systems in the European Pharmacopoeia
• Similar precautions to control evaporation are likely to be needed, as with full resolution impactors

FINDINGS

• The flow resistance of a given DPI as well as the de-aggregation behavior of the dry powder therefore become important factors
• These aspects will likely require evaluation on a protocol by product basis to determine the measure of agreement between abbreviated and full resolution impactors

FUTURE DIRECTIONS

• There is no clear leader in terms of AIM apparatus available for those new to the concept to evaluate for their OIP
• The Fast Screening Impactor (FSI; MSP Corp., St. Paul, MN, USA) is a popular choice because of its versatility in selection of cut-points and flow rates
• Andersen cascade impactor (ACI) based systems, such as the C-FSA (Copley Scientific Ltd), are also of interest, particularly with pMDI testing
• Configurations that convert the Next Generation Pharmaceutical Impactor into AIM-based systems have also been tested successfully for both pMDIs and DPIs

• There is a need for more research into apparatus start-up flow-time kinetics for DPI testing
• There is consensus that AIM-based measurements should always be verified by means of comparison of metrics such as fine particle fraction with equivalent data from the full resolution system
• For simplicity, the AIM and full resolution systems should share a necessary requirement (i.e. the FSI could be paired with an ACI)

EPAG will now take the information garnered from the workshop to define its work program for the Impactor Sub Team
• EPAG will also assist IPAC-RS in the process of developing compendial guidance for the IMPAC-RS Conference
  March 29 – 31, 2011
  Rockville, Maryland, USA