

## An introduction to the European Pharmaceutical Aerosol Group (EPAG)



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### Background

Before the early 1990s, there was little if any industry cooperation among companies developing respiratory products. Gradually, a number of collaborations showed that significant benefits could arise to companies working together. For example, the EP Inhalanda working group conducted a collaborative study on aerodynamic particle size methods. The transition from chlorofluorocarbon (CFC) propellants to hydrofluoroalkane (HFA) propellants resulted in formation of IPAC, the International Pharmaceutical Aerosol Consortium, which principally collaborated on a toxicological data package. In 1998, a European driven industry consortium was established to develop a Next Generation (pharmaceutical) Impactor. During 1999, the idea of a collaborating European Chemistry, Manufacturing and Controls (CMC) group was voiced and the level of interest established. An inaugural meeting of ten companies was held and the European Pharmaceutical Aerosol Group (EPAG) was established. From that first meeting, EPAG has grown and now includes representatives from all the major European pharmaceutical inhalation businesses.

### EPAG's function and structure

EPAG is open to "European Pharmaceutical Companies that develop

new drug products for human use utilizing the pulmonary or nasal route of delivery." EPAG is a voluntary, non-profit organization and has developed a constitution to describe its working practices and membership requirements. A pharmaceutical company is described as "a company responsible for the development of the drug product; it would normally have its own research and/or development capability and the capability to submit applications for product licenses."

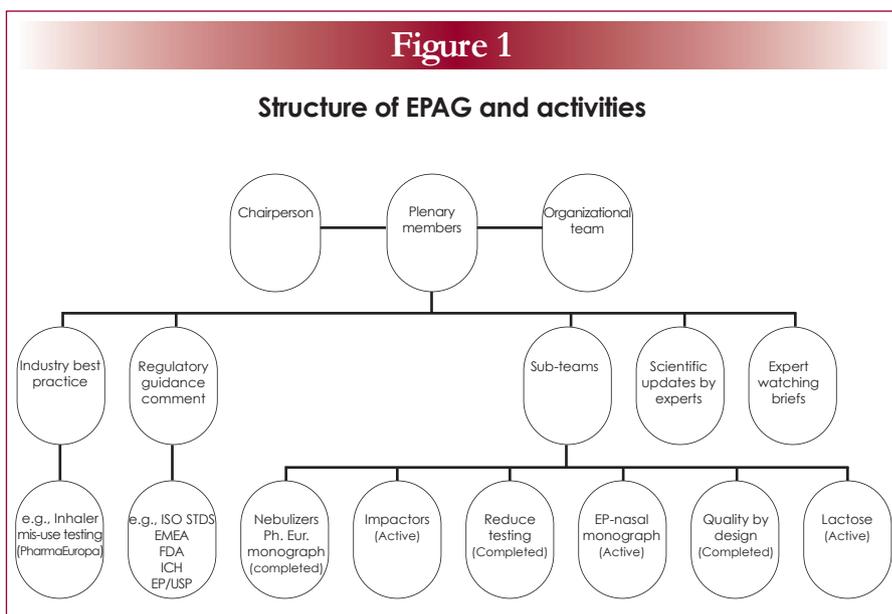
EPAG has recognized that product development can take place in collaboration, and includes efforts with non-pharmaceutical companies, for instance active pharmaceutical ingredient (API) suppliers, device designers, component manufacturers, etc. These companies can be invited to attend meetings, or be a sub-team member, when a particular need is identified. In addition, companies including non-European companies, may be admitted to EPAG where they provide specific

expertise that supports and enhances the organization's objectives. By using these criteria, EPAG intends to keep focus on delivery of good science and professional conduct to aid respiratory product development. Each member company would ordinarily have one representative at each plenary meeting.

Specific EPAG objectives are shown below and are achieved by sharing of non-confidential information:

- To focus on pharmaceutical issues relevant to pulmonary and nasal delivery products, including clinical aspects as appropriate.
- Establish scientifically-based best practices.
- Provide consensus comment to industry and government agencies to promote safety and quality standards.
- To recommend harmonized standards and methodology.

The structure and activities of EPAG are summarized in Figure 1. EPAG has an organizational team, a member who acts as a chairperson



and one as treasurer. All other administration and business is performed by members. There is a five-year plan to capture both short and long term projects. However, it is important that EPAG can also respond rapidly to changes and new events as they occur.

Apart from plenary meetings EPAG has established sub-teams to work on specific needs and topics. A sub-team is led by a plenary member and is composed from those companies who feel it is relevant for them to participate in that activity. A new “electrostatics” sub-team has recently been approved and one dedicated to “inhalation device issues” is under consideration.

### **Collaborative activities**

EPAG is aware of other organizations in Europe and globally that have similar interests and participates with them whenever possible. EPAG successfully organized an Abbreviated

Impactor Measurement (AIM) workshop at Drug Delivery to the Lungs 21. The presentations of this workshop can be accessed via the EPAG website. Furthermore, EPAG annually sponsors the best poster prize at DDL. EPAG has committed to a presentation on AIM for the Medicines and Healthcare Products Regulatory Agency (MHRA) in June 2011. It is also planning workshops for European regulatory agencies about CMC issues and is currently seeking opinions from these agencies on topics that would be most useful to them.

EPAG has also published in the science literature, to ensure quality documents are produced a publications review process has been established and EPAG is keen to continue this.

### **EPAG and regulatory agency guidance**

EPAG has a number of direct contacts within several regulatory agencies. It has provided comment to

agencies during the drafting stages of some guidances and the time at which a guidance is available for public comment. It has achieved considerable success in providing comment that has eventually been considered worthwhile to include in issued guidance. It was instrumental in encouraging and participating in the European Medicines Agency (EMA) meeting of “interested parties” on the now-issued inhalation and nasal product guidance.

### **Future activities**

EPAG will continue to develop relationships with regulatory agencies, propose best practices and conduct studies that are relevant to inhaled product development. Currently, the majority of European inhalation pharmaceutical companies are members, which is a very strong endorsement of the success EPAG has had. For more information and publications, please visit [www.EPAG.co.uk](http://www.EPAG.co.uk).