

CROSS-INDUSTRY Organizations

At 15th anniversary, EPAG expands membership, sets new goals

Yorick Kamlag
On behalf of the European Pharmaceutical Aerosol Group

EPAG's history and new approaches

EPAG was established in 1999 by a group of ten companies to have a collaborating European Chemistry, Manufacturing and Controls (CMC) group. In December 2014, EPAG will celebrate in its fifteenth anniversary.

EPAG now consists of 23 companies: 3M, Actavis, AstraZeneca, Almirall Sofotec, Aptar Pharma, Bespak Europe Ltd., Boehringer Ingelheim, Chiesi, GlaxoSmithKline, Hovione, McNeil AB, MundiPharma, Mylan, Novartis, Pari, Philips-Respironics, Prosonix Ltd., Sanofi, SkyePharma, Teva, Trudell Medical International, Vectura and Zentiva Inhalationsprodukte GmbH. This fast increase shows that EPAG is highly respected as a consortium and that companies value their input on EPAG activities.

When EPAG was established, the goal was focusing on the European market, which at that time meant that mainly companies located in Europe were active in the market. Today, EPAG recognizes that the market has evolved and that many non-European companies develop products for the market. Therefore, as of this year, EPAG has changed its membership criteria so the voluntary, non-profit consortium will include member companies that develop new products for human use via the pulmonary or nasal route that are intended for use in the European market.

In addition, while aiming to be the principal, industry-based, opinion-leading, influencing group for pharmaceutical development and regulation of products for pulmonary and nasal delivery in Europe, EPAG will continue making efforts to be further recognized internationally as a valued contributor and partner in the worldwide pulmonary and nasal product development and regulation arena.

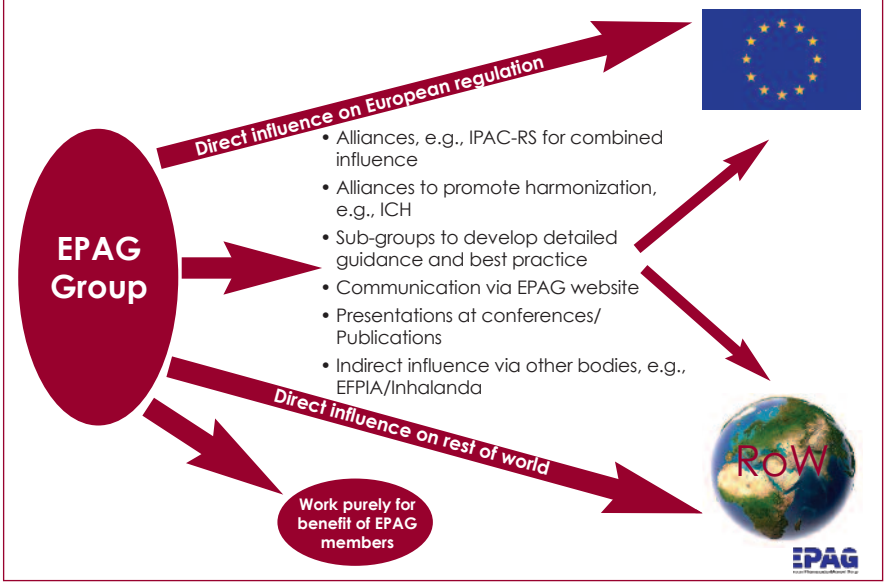
Figure 1 shows the mechanism for delivering the EPAG vision and providing guidance on regulatory and CMC issues in Europe and worldwide.

Regulatory issues

EPAG has a number of direct contacts with regulatory agencies throughout the world. Exchanges often occur between EPAG and the agencies as regulations are being drafted. A recurring theme of these exchanges finds EPAG trying to harmonize regulations from the various agencies. An example of its efforts is a poster EPAG will present at RDD 2014. In it, EPAG proves the terms for the same "quality attributes" used within international pharmacopeias and other regulatory guidances (i.e., FDA, Health Canada and EMA, ICH guidelines and ISO standards) are currently very different. EPAG is presenting a survey of most commonly used terms for quality attributes by the member companies and is proposing that harmonization of terminology in regulatory guidance and communications should be strived for because current differences in terminology create a burden for international companies and confusion for regulators. EPAG is more than willing to support all attempts of harmonization.

Figure 1

Mechanisms for delivering the EPAG vision



EPAG's subteams and 5-year plan

Within EPAG, four subteams are currently active: impactor, nasal, electrostatic and device. They support EPAG's vision and objectives through defined work packages. They also act as a focal point for channeling expertise associated within these topics.

EPAG includes relevant experts who can contribute to the defined topics, and to achieve this, the subteams are open to non-EPAG member companies, suppliers, service suppliers, regulatory representatives, academics and others.

EPAG has defined its latest 5-year plan and the following tasks and topics are to be addressed:

- Continue the process of disseminating best practices for the evaluation of OINDPs, including the development of methods that are more clinically pertinent
- All objectives should comply to harmonization, best practices or influence criteria
- Provide consensus positions to developments in the OINDPs regulatory environment
- Identify, influence, promote and recommend harmonization of testing standards and guidance of OINDPs across regions by consensus
- Encourage sharing of information and data to identify common issues
- Develop better understanding in non-CMC areas, e.g., clinical, toxicology (to foster better understanding of patient needs)
- Good communication/alliance with other influencing groups

Examples of specific tasks for the subteams are listed below and are expected to be completed in the coming years:

- AIM initial experiments – alternative inlets and validated AIM data for Inhalanda WG
- Development of a Ph. Eur. methodology for nasal sprays for aerodynamic particle size analysis of two fractions (<10 μm>), thereby proposing a standardized approach for measuring this parameter
- Develop understanding of issues relating to adverse electrostatic phenomena as they affect inhaler and add-on products
- Support recommendations for effective control/minimization of electrostatic effects in manufacturing process, test methods, standards and guidances
- Develop a best practice roadmap on device development for OINDPs

For more information please visit our website: www.EPAG.co.uk.

Yorick Kamlag is the Chair of EPAG and Head of Pharmaceutical Development, Zentiva Inhalationsprodukte GmbH, Staffelseestrasse 4, 81477 Munich, Germany, Tel: +49 89 710 502 160, yorick.kamlag@zentiva.de.