An overview of The European Pharmaceutical Aerosol Group (EPAG)

A brief history of the formation of EPAG, its constitution, objectives, structure, influence, publications and input to regulatory guidance documents

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Background and formation

Prior to the transition from chlorofluorocarbon (CFC) to hydrofluoroalkane (HFA) propellants for the metered dose inhalers (MDIs), there was little collaboration among companies developing pharmaceutical products for administration to the human respiratory tract. However, by the 1990s, a realization was emerging among those involved in the development and manufacture of orally inhaled and nasal drug products (OINDPs) that significant scientific and technical benefits could accrue if a more collaborative approach was adopted across the industry to address the common problems. Such an outcome was already evident as the result of the following (not exhaustive) list of collaborative activities taking place during the late 1990s:

- To address the transition from CFC to HFA propellants, an industry-wide consortium, the International Pharmaceutical Aerosol Consortium (IPAC), collaborated on the development of a toxicological data package to assist in gaining regulatory approval of products formulated with the new propellants.
- The Inhalanda working party of the European Pharmacopeia (PhEur) coordinated a collaborative study on aerodynamic particle size methods.
- IPAC continued to collaborate and address new regulatory guidance documents concerning inhalers coming from both European and US regulatory agencies, eventually becoming IPAC-RS (International Pharmaceutical Aerosol Consortium on Regulation and Science) in 2001.
- A European-driven industrial consortium was established in 1998 to develop a cascade impactor designed specifically for testing inhaled products for the pharmaceutical industry, eventually overseeing the design, archival calibration and production of the first Next Generation (pharmaceutical) Impactors (NGIs).

During 1999, scientists representing various pharmaceutical companies involved at the time with OINDPs began collaborating and formed a European group focused on chemistry, manufacturing and control (CMC) aspects. The inaugural meeting of these experts from ten organizations, including representatives of Glaxo-Wellcome (now GSK), Boehringer Ingelheim, Astra, Rhone Poulenc Rorer (later Aventis Pharma, Sanofi-Aventis and then Aventis), Novartis and Innovata Biomed (now Vectura), was held at Loughborough, United Kingdom in December 1999. The name "European Pharmaceutical Aerosol Group (EPAG)" was agreed upon as the title to identify the new collaboration. By 2002, EPAG had expanded to 16 companies.

Constitution

A constitution was developed during the first year of operation that formally set out the detailed structure and organization, objectives, membership criteria and policies regarding published commentaries, reports, conference papers and archival journal articles. The constitution has undergone revision several times during the 22 years of the life of EPAG to reflect the evolving nature of the industry as well as the way the collaboration functions. Key highlights include the following:

- EPAG is set up as a voluntary, non-profit consortium.

- Each member company has a nominated person, selected by that company, to represent that organization on the organizing team (plenary committee/team). Costs of attendance are met by each member company.
- Additional staff from that company may attend EPAG meetings, workshops and sub-teams, as the need arises.
- The plenary committee has a chairperson, elected for a two-year term.
- Each plenary committee also has a two-year lifetime, after which members may be reelected to serve another term.
- Sub-teams may be set up to consider specific topics, and a sub-team leader will be elected from the EPAG company representatives serving on the plenary committee.
- Decision-making is normally made by consensus, but a majority vote will be held to come to a decision when is impossible to reach a consensus.
- Sub-group activities are also bound by the EPAG constitution.
- Members need to be aware of competition guidelines and anti-trust legislation that govern discussions and are cautioned against any reference to commercially sensitive information.

The constitution has been regularly reviewed, addressing the ways in which organization of the leadership of the group takes place, but its key aspects have remained largely unaltered since inception of the organization.

Goals and objectives

EPAG objectives were, from inception, linked to the sharing of non-confidential information among members and their companies. The overarching objectives were—and still are:

- To focus on pharmaceutical aspects relevant to pulmonary and nasal drug delivery products, including clinical aspects as appropriate
- To establish scientifically based best practices
- To provide consensus commentaries to industry and government agencies to improve standards and guidelines relating to inhaled product safety and quality control
- To recommend harmonized standards and methodology in relation to the testing and use of inhaled products

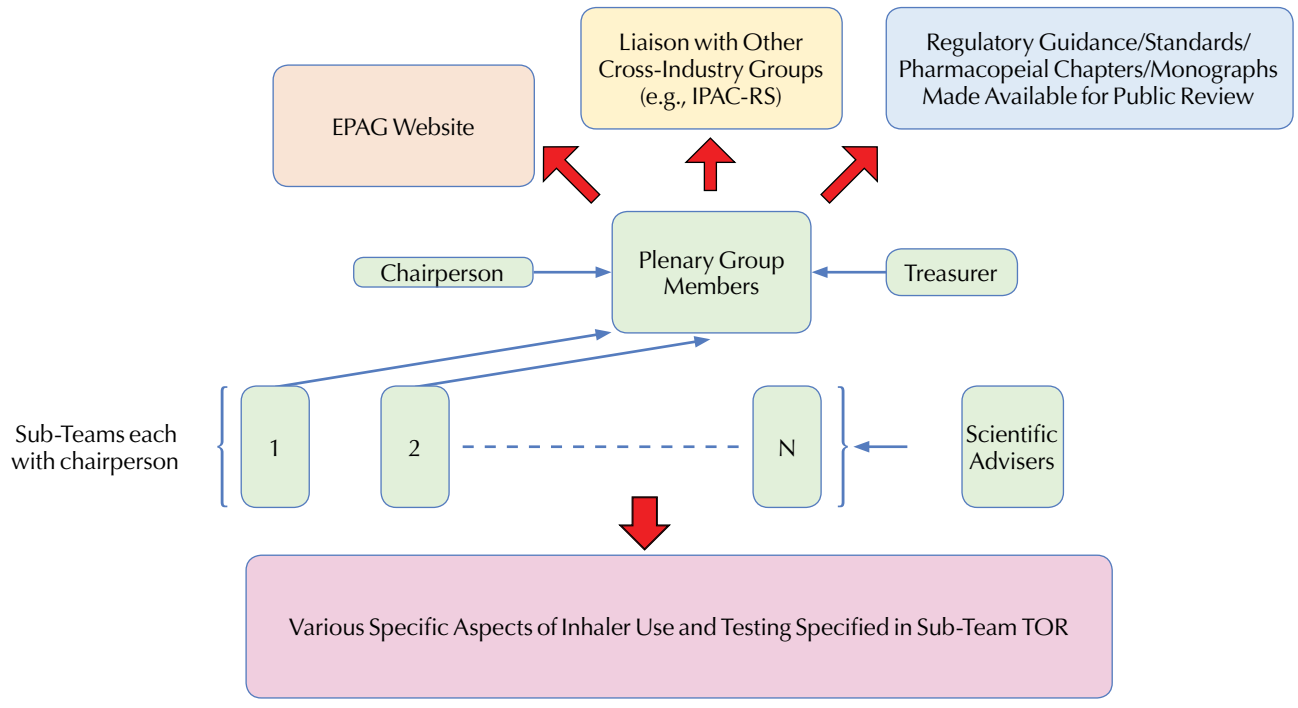
The first scientific publication was published at Drug Delivery to the Lungs-11 in December 2000, on the topic "Issues Related to Dose Content Uniformity Testing of Inhaled Products." Since then, more than 70 publications have been made available publicly via the EPAG website (see the list of publications and references section of this article).

Structure and evolution

The overall operational structure of EPAG is shown in Figure 1. Apart from oversight to sub-team activities described in the following section, the plenary group is responsible for coordinating responses to publicly available requests for scientific and technical comment relating to the continuously evolving area

Figure 1

Overall structure of EPAG



of standards, pharmacopoeial chapters/monographs and regulatory agency guidance to industry documents that are issued from time to time. In addition, a European-based draft regulatory guidance from any country that affects the work of the member companies would be considered for review and response.

A further important role for the plenary group is as liaison with other cross-industry groups, in particular IPAC-RS. EPAG has also worked with other scientific bodies on occasions when a topic of common interest has arisen. Examples are sessions organized in conjunction with the UK and Ireland Aerosol Society, which is responsible for the Drug Delivery to the Lungs (DDL) series of conferences held annually in December, and with the RDD organization that operates the Respiratory Drug Delivery (RDD) conference series that take place in North America, Europe and Asia, as each of these meetings relate to OINDP-based research.

Sub-teams/Scientific advisers

The core scientific work has been undertaken by a series of sub-teams (Figure 2), which are set up when a need is identified and disbanded on completion of the activities. The goals of each sub-team are approved by the plenary group and progress of each activity is monitored by a focused "Terms of Reference (TOR)." The TOR is normally updated on a quarterly basis by the sub-team leader to ensure that the work remains on track with EPAG objectives, as well as to keep up to date with developments within the scope of the sub-team. The lifetimes of these sub-teams therefore depend on a continued supply of tasks considered relevant to the interests of EPAG company members; the Impactor sub-team currently having the longest period of operation.

Influence

Regulatory agency guidance development

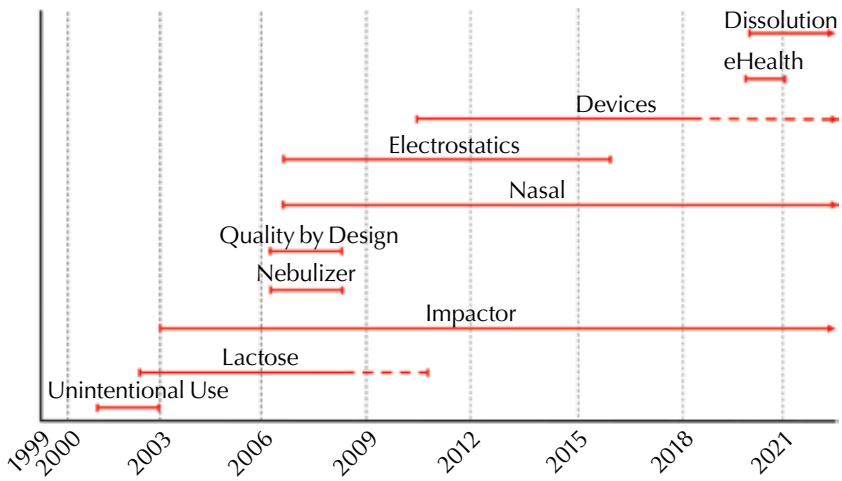
EPAG has had direct contact, primarily through the plenary group members, with representatives of several regulatory agencies, in particular the European Medicines Agency (EMA), the United States Food and Drug Administration (FDA) and Health Canada (HC). In addition, contact has been made from time to time with representatives of individual country-based regulatory agencies based in the UK, Sweden, Germany and the Netherlands. However, the normal channel by which technical advice has been provided has been in response to requests for public comment during the drafting stages of guidance for industry documents as well as when finalized guidances have been made available for public comment.

In 1998, the draft guidance issued by the US FDA to industry, on chemistry, manufacturing and controls for pMDI and DPI products, acted as a spur across the pharmaceutical industry to understand the more detailed requirements. As a result, EPAG produced a document addressing laboratory test methods for performance testing of inhalers in 2002 and in 2005, the results of a survey of EPAG companies regarding on-line leak testing of pMDIs under stress conditions. Also, in 2005, a position paper was presented at Respiratory Drug Delivery-Europe-2005 covering the responses of EPAG as an organization to current EU, US and Canadian regulatory requirements for assessing the quality of OINDPs at that time. These documents marked the first significant input by EPAG speaking as a single voice in the regulatory forum for inhaled products.

In 2003, the FDA issued a guidance for industry on the topic "Integration of dose-counting mechanisms into pMDI drug products" in response to concerns at that time that patients had no reliable means of ascer-

Figure 2

Sub-teams of EPAG and their operating periods



taining when their pMDI-delivered medication was exhausted. The plenary group developed a commentary that, although supportive of the guidance, raised concerns about its general applicability across the spectrum of therapies delivered by the pMDI route, the uncertain reliability of dose counting mechanisms at that time, and how such mechanisms can be adapted across the range of dose exhaustion profiles of existing products.

In 2004, members of the plenary group met with Fiona Mortimer of the United Kingdom Medicines and Healthcare Products Regulatory Agency (MHRA) to determine "hot topics of interest" in relation to inhaled product regulation in the EU from the UK perspective. The intent was to seek guidance and help steer activities of the group towards helping meet priority issues of concern, at that time being: dose content uniformity and fine particle dose (mass) specifications, incorporation of dose counters/indicators with pMDIs and stability bracketing and matrixing.

The EMA issued the first version of a reflection paper on the topic "Formulations of choice for the paediatric population" in the summer of 2005. EPAG provided commentary on this initial version of the reflection paper, which was revised the following year by the EMA, with feedback from EPAG and other stakeholders acknowledged by the EMA.

Later that year, a notable success was achieved by being a recognized party to the process of developing the current guidance to industry on the topic "Pharmaceutical quality of inhaled and nasal products," developed jointly by the EMA and HC. Several technical improvements were made to these documents based on feedback from experts within EPAG, particularly in relation to the assessment of mass balance and best practices for cascade impactor operation in relation to the quantification of inhaler aerosol aerodynamic particle size distribution (APSD).

In 2007, EPAG provided comments to the EMA on the paper "ICH topic Q8 annex, pharmaceutical development; Annex to note for guidance on pharmaceutical development." This annex appeared as part of the full note for guidance on pharmaceutical development published in June of 2009, revised in 2014.

In 2008, EPAG provided extensive comments to the EMA in relation to a new guidance document "Guideline on the Requirements for clinical documentation for orally inhaled products (OIP) including the requirements for demonstration of therapeutic equivalence between two inhaled products for use in the treatment of asthma and chronic obstructive pulmonary disease (COPD)." This input was recognized the following year by the EMA in their document summarizing the feedback that had been received.

In June 2011, EPAG presented the topic "The abbreviated impactor measurement (AIM) concept" to Joe Lim and a panel of reviewers at the MHRA. Although there is no formal link, this meeting may have resulted in a formal expression of interest regarding the AIM concept from the Inhalanda working party of the European Pharmacopoeia in August 2014. Since that time, members of the Impactor sub-team have been supporting this initiative by providing evidence and associated data in the form of peer-reviewed publications to the working party.

Also, in June 2011, EPAG provided comments to the German regulatory agency Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) on the topic "Lactose for inhalation, under development as a monograph for the European Pharmacopoeia," referring to a recently published paper by the Lactose sub-team.

In March 2014, EPAG provided commentary on a regulation on "Inhaled preparations" issued by the Turkish Medicines and Medical Devices Agency the previous June.

In September 2014, a meeting was held in Bonn with reviewer representatives (Janet Schriever, Cornelia Nopitsch-Ma and Jobst Limberg) of the German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)), at which the topic "Testing and requirements on Inhalanda in the medicinal product authorization approval procedure" was presented by the BfArM representatives. EPAG was able to provide a summary of activities including the AIM concept as well as an updated statement of vision and objectives (Figure 3) at this meeting to raise awareness of capability. The meeting continued efforts to establish face-to-face communication with regulatory agency experts in individual European countries as opposed to the EMA representing the whole of the European Union.

In September 2015, a similar meeting was held with representatives of the Swedish Medical Products Agency (MPA) during the plenary group meeting held in Mölndahl, Sweden.

In February 2017, the EMA published a concept paper on revision of the guideline on the pharmaceutical quality of inhalation and nasal products, originally approved in 2006. EPAG provided comments and suggestions before the deadline for receipt of public comments in June 2017. Claudia Vincenzi of the EMA also presented an update on the proposed revision at DDL-2017, at which it was evident that some of the EPAG suggestions had been incorporated.

In March 2018, the plenary group agreed to focus on the two concept papers regarding existing EMA guidelines relating to inhalation products which were—and still are—under consideration for revision and released for a 6-month public consultation in 2018, with a view to develop and provide EPAG consolidated comments. However, the move of the EMA from London to Amsterdam in the wake of the

UK leaving the European Union (Brexit) combined with the impact of the current COVID-19 pandemic since March 2020 has postponed the process of revising guidelines by the regulatory agencies.

In 2019, after a deadline to comment on several pertinent draft chapter revisions in the United States Pharmacopeia (USP) had passed without the opportunity to submit organized feedback from EPAG, the plenary group decided to improve coordination of future comments on regulatory guidance documents. A member was appointed on a 6-month rotating basis to coordinate this activity. Accordingly, in August 2019, Beatrix Fyrnys coordinated submission of comments from EPAG in connection with a draft guideline on quality requirements for drug/device combinations, now published in finalized form. Some of the feedback from EPAG was adopted in the final guidance document. In 2019, EPAG also provided input to an MHRA draft consultation on the topic of application of analytical quality by design concepts to pharmacopoeial standards for medicines. The response to the consultation document was subsequently published in August 2020.

Development of standards relating to inhaled products

Support to the development of industry standards has represented a significant effort from EPAG member organizations and participating individuals. This situation was especially true during the first half of the lifetime of the organization, when both national and international standards relating to inhaled product development were undergoing a spurt of improvement to make them more relevant to the needs of stakeholders.

From 1997 until publication of the first version of the Canadian standard for spacers and valved holding chambers in 2002, a committee of the Canadian Standards Association (CSA) led by Myrna B. Dolovich (McMaster University, Hamilton, Canada), was involved in creating a new standard that covered the design, development and performance testing of these add-on devices for pMDIs. At that time, there was little interest in these devices from the pharmacopoeial authorities, as they were regarded as purely passive conveyers of the aerosol containing the drug product(s) from the inhaler mouthpiece to the patient. As early as 2000, EPAG was involved in the informal provision of feedback to the CSA committee to help overcome some of the significant technical issues pioneering a passive device-based standard. More formal feedback was provided in 2001 when a draft text of the 2002 version of the standard was released for public comment, much of which was incorporated into the standard that received minor revision in 2008 and has been reaffirmed twice since. At the time of writing of this article, the standard is currently undergoing a further reaffirmation. In particular, the patient-age specific tidal breathing patterns contained therein, have become incorporated either partially or fully into an ISO standard for nebulizers, informally harmonized pharmacopoeial chapters for preparations/products for nebulization and chapter <1602> of the USP, devoted specifically to these add-on devices.

In the 2000s, EPAG was also a contributor to the development of two ISO standards through individual membership of the relevant organizing committees and by provision of comments to draft versions

Figure 3

EPAG 2014 vision and objective summary

EPAG
European Pharmaceutical Aerosol Group

Vision

- EPAG will remain the principal industry-based opinion leading and influencing group for the pharmaceutical development and regulation of products for pulmonary and nasal delivery in Europe.
- EPAG will continue to be recognized internationally as a valued contributor to the worldwide pulmonary and nasal product development and regulation arena.

Objectives

- Focus on pharmaceutical issues relevant to aerosol products for pulmonary and nasal drug delivery, including product development and patient use including related clinical aspects as appropriate.
- Establish best practice. Propose common approaches to be adopted by the industry or common formats for submitting data.
- Provide consensus comments to industry and government agencies to promote safety and quality standards.
- Recommend harmonized standards and methodology.

- Achieved by sharing of non-confidential information and generating own data through cooperative studies.

(not available publicly). The first (ISO 20072) was published in 2009 and revised in 2013 and is concerned with aerosol drug delivery design verification. The second standard (ISO 27427) was published in 2010, revised in 2013, and is concerned specifically with nebulizing systems, including their laboratory-based performance testing. EPAG members made significant contributions towards the design verification process that was adopted at the core of ISO 20072 (Figure 4), and to the performance testing methodologies that feature as normative annexes C and D of ISO 27427.

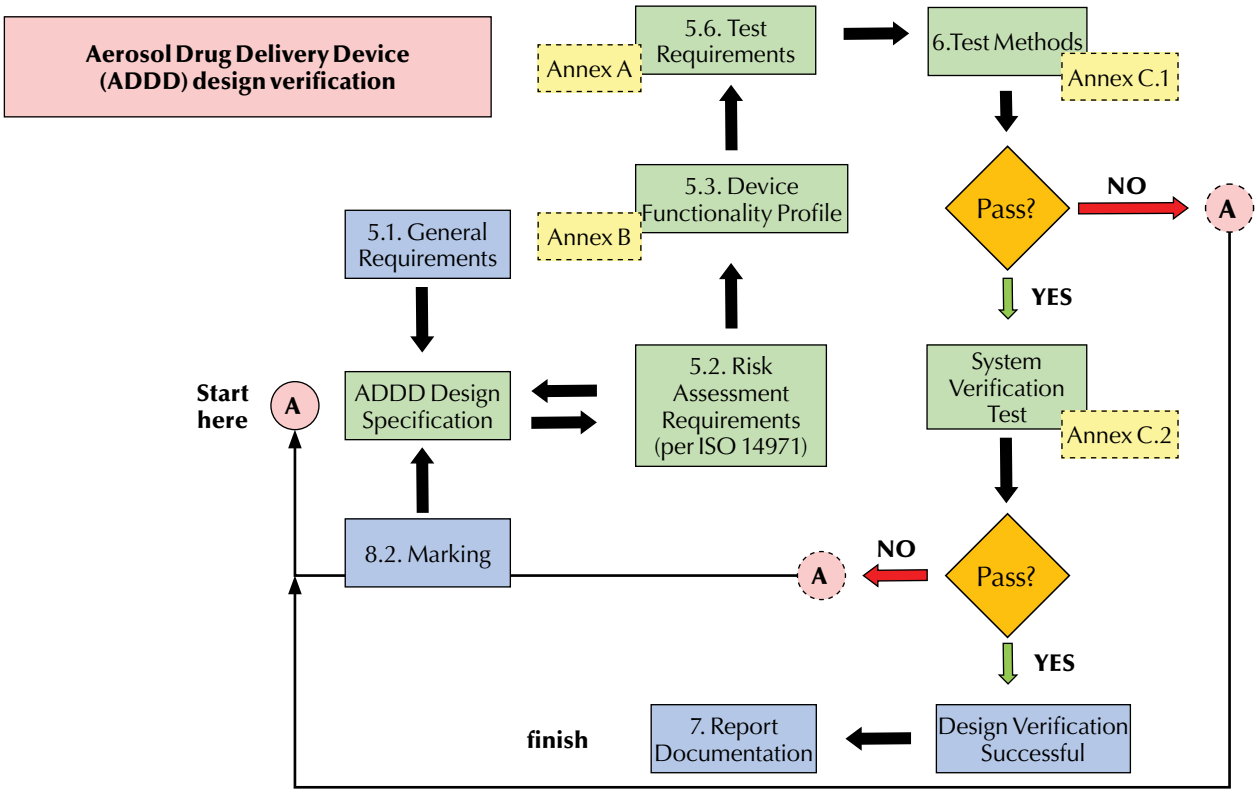
In 2014, in response to the start of developments to update the Medical Devices Directive (MDD) in the EU, EPAG, primarily through the Devices sub-team, developed a document titled "Best practices in device design for OIP/OINDP products," containing a hierarchy of pertinent ISO/International Electrotechnical Commission (IEC) standards related to the inhaler device development process (Figure 5).

Pharmacopoeial methodology development

The European Pharmacopoeia (PhEur) and the USP are the primary pharmacopoeial compendia to which EPAG has provided input. Almost from its inception, EPAG has been involved with the revision processes associated with the PhEur monographs 0671 (Preparations for Inhalation), 0676 (Nasal preparations), 2.9.18 (Aerodynamic Assessment of Fine Particles), 2.9.40 (Uniformity of Dosage Units) and 2.9.44 (Preparations for Nebulisation). For example, in 2008, the Inhalanda working party of the PhEur provided feedback to the EPAG plenary group on the development of monograph 2.9.44, following earlier commentary from EPAG members. Likewise, in 2011, this working party provided feedback to EPAG concerning prior commentary relating to the AIM concept. This feedback was the result of an initial request from the Inhalanda working party in connection with acquiring data for the different oral inhaler classes to support the AIM concept. These discussions led to the undertaking of a multi-participant study in 2012-2013 on the topic "Comparison of Ph. Eur. fine particle dose methodology to that using abbreviated impactor measurement (AIM) methodology," which was published at Drug Delivery to the Lungs-25 in 2014 and in fuller form in the archival journal *AAPS PharmSciTech*. A formal enquiry was also issued in 2014 in the EDQM journal, *Pharmeuropa*, by the Inhalanda working party, on the topic "Abbreviated impactor measurements and efficient data analysis (EDA)—A reliable tool for the quality control of inhaled drug products?" However, since that time, focus of the Inhalanda working party has moved away from EDA towards consideration of the applicability of the AIM concept. Since 2017, the Impactor sub-team has informally collaborated with the Inhalanda working party to develop a fuller understanding of the outstanding needs in connection with the possible introduction of the latter into the PhEur. In

Figure 4

Design verification process adopted in ISO 20072:2009 rev.2013



November 2019, Erika Stippler (Inhalanda working party liaison officer) made a request to the EPAG plenary group for collaboration to provide an industry opinion regarding abbreviated impaction methods. The response to this request has focused on gathering published data and is ongoing.

EPAG has also taken a keen interest in developments associated with the USP, given the importance of this compendium as the primary pharmacopeia in North America as well as in many other countries worldwide. As early as 2001, the plenary group, in an internal review of priorities, took the position that harmonization of chapters in the USP with the appropriate monographs in the PhEur was highly important. However, the existing harmonization between chapter <601> and monograph 2.9.44 (both defining quality tests for dose content uniformity (DCU) and emitted aerosol APSD) was broken in 2016 because of the need, expressed by USP officials, for significant local text in the former document to meet US FDA requirements.

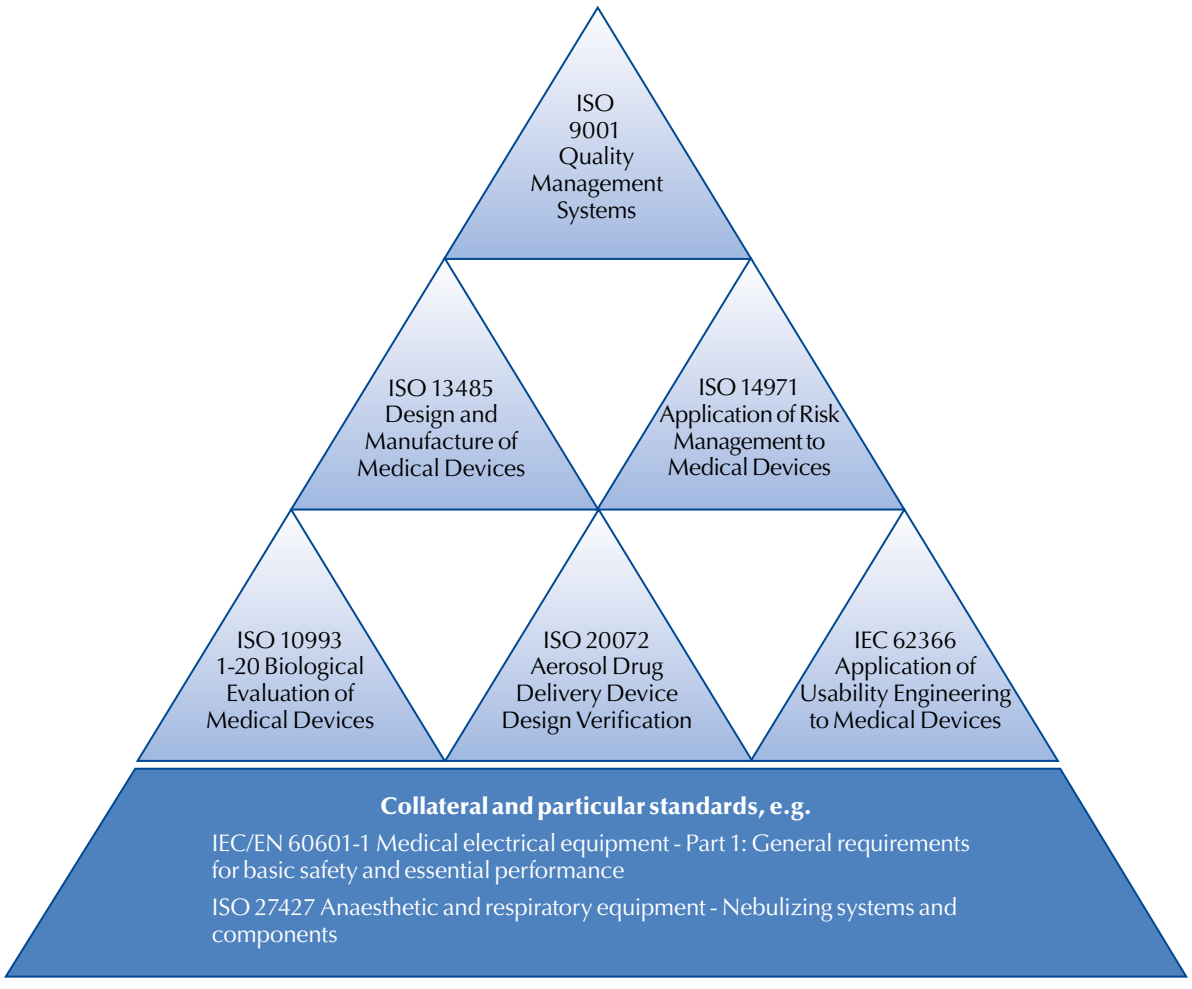
In February 2002, a set of comments was submitted to the USP in response to a proposed revision to chapter <61> "Microbiological examination of nonsterile products: microbial enumeration tests" and chapter <62> "Microbiological examination of nonsterile products: Tests for specified microorganisms."

In 2005, the plenary group provided extensive comments on the proposed revision to normative chapter <429> "Laser diffraction measurement of particle size." The EPAG comments covered topics such as the use of calibration reticules for laser diffractometers, preference for the more rigorous Lorenz-Mie theory rather than the Fraunhofer approximation for accuracy in the size range of particles associated with orally inhaled products, appropriate limits for method validation and traceability of laser diffraction measurements. Many of these suggestions were incorporated into the (now harmonized) chapter <429>.

Additionally in 2005, EPAG provided a commentary relating to a stimulus-to-revision article on the topic of microbial testing for oral and nasal inhaled products that had appeared in the July-August issue of the USP journal *Pharmacopeial Forum.* Here the focus was on allowing larger sample sizes and testing of bulk formulation for high content products.

Figure 5

EPAG-developed hierarchy of ISO/IEC standards pertinent to the design of orally inhaled and nasal drug products



In 2011, the Inhalation Dosage Forms "Aerosols" sub-committee (formerly the Aerosols Expert Committee) of the USP issued a stimulus article on the topic "*In vitro* assessment of spacers and valved holding chambers used with pressurized metered-dose inhalers: The need for a USP chapter with clinically relevant test methods." EPAG provided suggestions relating to the proposed testing methodology that eventually resulted in the development of chapter <1602> "Spacers and valved holding chambers" that became official text in 2017. In the same issue of *Pharmacopeial Forum*, the Aerosols sub-committee introduced the new general chapter <5> "Inhalation and nasal drug products—General information and product quality tests," in which the tests for properties other than dose content uniformity (DCU) and APSD are contained. EPAG provided extensive commentary. This feedback was generally supportive of the proposed changes, but suggested improvements with respect to the presentation of the various test parameters. It also highlighted inconsistencies in chapter <5> and a request for a reconsideration of the proposed specifications for DDU as well as the provision of rationales for the changes proposed in chapter <601>. Some of these suggestions were subsequently incorporated into the final versions of both chapters.

In 2013, members of the Impactor sub-team contributed an industry guidance paper on the topic "Good cascade impactor practice (GCIP) and considerations for "in-use" specifications" that was published in the archival journal, *AAPS PharmSciTech*. The content of this article was based on the collective experience with cascade impactors within this sub-team. As a result, much of the content was adopted into a USP stimulus to revision article on the same topic that appeared in *Pharmacopeial Forum* the following year. Subsequent discussion of the merit of the GCIP approach to cascade impactor maintenance and use within the Aerosols sub-committee of the USP led to publication in 2016 of a new informative chapter <1603> as a stimulus article for public comment format in 2016, followed by initial issuance of the draft chapter as an in-process revision, and finally publication as official text in December 2017.

Likewise, EPAG members, primarily through the Impactor sub-team, made significant contributions, via feedback at public comment stages, to a proposed new informative general chapter <1604> "Data interpretation of aerodynamic particle size distribution measurements for orally inhaled products," published in 2019 in *Pharmacopeial Forum*. The purpose of this chapter is to complete the translocation of the data analysis section removed several years ago from <601> into an informative chapter, allowing greater user flexibility in interpretation, subject to local regulatory requirements. The significantly revised version was republished in *Pharmacopeial Forum* in 2020 following further feedback from stakeholders including EPAG Impactor sub-team members.

Development of future aerosol scientists

In 2014, EPAG accepted a 5-year commitment to sponsor the "Best Poster" prize at the Drug Delivery to the Lungs conference in December of each year. At the first award ceremony, there was significant appreciation expressed by members of the DDL organizing committee for this expression of support from EPAG as a cross-industry organization.

Invited speakers

Since the mid-2000s, at the plenary group level, there has been an interest in having a visiting speaker at quarterly meetings to focus on a topic of immediate interest and importance, in addition to any presentations that may be given by representatives of the host organization. The main purpose of these visiting speaker presentations has been to educate members on current issues where EPAG might have a part to play.

In 2007, Wamadeva Balachandran (Brunel University of London) was invited to the March meeting to present on the topic "Electrostatic Charge on Pharmaceutical Aerosols."

In March 2008, Ian Anderson introduced the consulting company, Sagentia, at the meeting while Ross Jones and Simon Shohet presented work on mathematical modeling applied to the development of healthcare products including inhalers and in opportunity discovery respectively. In December of the same year, Tim Noakes (Ineos Fluor, now Koura), presented on the topic "Electrostatic effects on inhaled medications."

At the December 2009 meeting, Monica Fletcher (CEO, UK for Health, Warwick, UK) gave a talk on the topic, "It's easy, just take two puffs…," focusing on patient interactions with inhalers and issues surrounding non-compliance with clinician instructions and the user instructions.

There was a gap of nine years during which time there was frequent discussion regarding prospective external speakers, before Tom Oakley (director of drug delivery device development, Springboard, Cambridge, UK) presented at the March 2018 plenary group meeting on the topic "Connected devices—Inhalers and beyond," relating to the rapidly developing issue of e-health. In December of the same year, Tim Noakes returned to give a presentation "MDI propellants: Time for a change," this time focusing on the further transition from existing HFA propellants to the new "greenhouse gas-friendly" propellants, such as hydrofluoroalkane 152 (HFA-152).

Four presentations were given at the March 2019 meeting. The first, given by Frank Chambers (Inhalytic Consulting) was on the topic "Ultrafast analysis of pressurized metered dose inhaler (pMDI) by

direct spray mass spectrometry." Precious Akhuemokhan of the Institute of Pharmaceutical Sciences, King's College London, who was winner of the EPAG-sponsored best poster award at DDL-2018, gave the next talk, on the topic "Models for investigating the effect of excipients on drug transport in the lungs." Debbie Huck-Jones of Malvern Panalytical followed on the topic "Application of Morphologi 4-ID for inhaled and nasal products" and Per Bäckman (Emmace Consulting) presented "Respiratory drug delivery—Future directions, challenges and opportunities." In September 2021, Jonathan Reid (University of Bristol and Director of the EPSRC Centre for Doctoral Training in Aerosol Science) gave a virtual presentation on the topic "A new postgraduate training and research paradigm for aerosol science and drug delivery."

Concluding remarks

The large body of published articles coming from EPAG, together with the influence exerted externally in the community of stakeholders associated with OINDPs, are strong evidence that the organization has met and continues to meet its goals and objectives defined at the outset and revised regularly in the 5-year plan for the group. The organization has also managed the issues associated with increasing difficulties for the plenary members and the sub-teams to attend face-to-face meetings, since the beginning of the COVID-19 pandemic. However, much of the work was already being conducted at individual organization laboratories with most sub-group meetings being held by teleconference. The current pattern is a mixture of virtual meetings and face-to-face meetings, with the December meeting being face-to-face each year around the time of the Drug Delivery to the Lungs conference, when many members are already gathered in Edinburgh, UK where the DDL conferences have taken place since 2005. The continued existence of EPAG confirms the original concept from 1999 that industry is able and stronger when it works together to deliver much-needed OINDPs.

EPAG publications and references

The following list of publications represents output from EPAG that has appeared in the public domain. Most of these articles are available in the public area of the EPAG website: https://epag.co.uk/library/.

Year 2000

1. Olsson B, Sandell D. Issues related to dose content uniformity testing of inhaled products. Drug Delivery to the Lungs-11, The Aerosol Society, London, UK, 2000, pp. 117-122.

Year 2002

2. Purewal TS. Test methods for inhalers to check performance under normal use and unintentional misuse conditions. PharmEuropaSciNotes, EDQM, Strasbourg, France. 2002;14(3):470-474.

Year 2003

3. Asking L, Nichols S. Next generation pharmaceutical impactor (NGI): EPAG collaborative study. Drug Delivery to the Lungs-14, The Aerosol Society, London, UK, 2003, pp. 33-36.

4. Marple VA, Olson BA, Santhanakrishnan K, Roberts DL, Mitchell JP, Hudson-Curtis BL. Calibration of the archival next generation pharmaceutical impactor (NGI) at 15 L/min. Drug Delivery to the Lungs-14, The Aerosol Society, London, UK, 2003, pp. 37-41.

5. Mitchell JP. Practices of coating collection surfaces of cascade impactors: A survey of members of the European Pharmaceutical Aerosol Group (EPAG). Drug Delivery to the Lungs-14, The Aerosol Society, London, UK, 2003, pp. 75-78.

Year 2004

6. Nichols S. Particle size distribution parameters using the next generation pharmaceutical impactor. Respiratory Drug Delivery IX, Eds., RN Dalby, PR Byron, J Peart, JD Suman and SJ Farr, Davis Healthcare International Publishing LLC, River Grove, Illinois, USA, 2004, pp. 485-487.

Year 2005

7. Nichols SC. EPAG's response to EU, US, and Canadian regulator requirements for inhaled drug products. Respiratory Drug Delivery-Europe 2005, Eds., RN Dalby, PR Byron, J. Peart and JD Suman, Davis Healthcare International Publishing LLC, River Grove, Illinois, USA, 2005, pp. 145-150.

8. Colthorpe P. Stress testing of pMDIs: A survey of practices adopted by members of the European Pharmaceutical Aerosol Group (EPAG). Drug Delivery to the Lungs-16, The Aerosol Society, Edinburgh, UK, 2005, pp. 111-114.

9. Mitchell JP. Good practices of qualifying cascade impactors (CIs): A survey of members of the European Pharmaceutical Aerosol Group (EPAG). Drug Delivery to the Lungs-16, The Aerosol Society, Edinburgh, UK, 2005, pp. 189-192.

Year 2006

10. Mitchell JP, Tservistas M. Laser diffractometry and cascade impaction for nebulizer product characterization. PharmEuropaSciNotes, 2006; 2: 49-52.

11. Mitchell JP. Methods for cascade impactor (CI) cleaning: A survey of members of the European Pharmaceutical Aerosol Group (EPAG). Drug Delivery to the Lungs-17, The Aerosol Society, Edinburgh, UK, 2006, pp. 197-199.

12. Dennis J, Berg E, Sandell, Kreher C, Karlsson M, Lamb P, Jauernig J, Nichols S, Tservistas M, Mitchell J. European Pharmaceutical Aerosol Group (EPAG)

Nebulizer sub-team: Assessment of proposed European Pharmacopeial (Ph. Eur.) monograph "Preparations for Nebulization." Drug Delivery to the Lungs-17, The Aerosol Society, Edinburgh, UK, 2006, pp. 146-149.

Year 2007

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