CROSS-INDUSTRY *Organizations*

An introduction to the International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS)

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On behalf of the International Pharmaceutical Aerosol Consortium on Regulation and Science

The International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS) advances scientifically-driven approaches to enhancing product quality of inhaled and intranasal drug products. The genesis of IPAC-RS lies in the International Pharmaceutical Aerosol Consortium (IPAC), formed in 1989 to address the effects of the Montreal Protocol on the inhaled drug industry. IPAC-RS was subsequently formed in 1999 when an IPAC working group, responding to the US FDA's Draft Guidance "Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products," decided to form an independent consortium to address a broader set of issues and needs of the orally inhaled and nasal drug products (OINDP) industry. Currently, IPAC-RS has four strategic objectives:

1. Provide information and services to enable member companies to achieve their current and future product development and regulatory goals.

2. Advance the science and regulation of inhalation products through discussion, research and publication.

3. Effectively collaborate with the broader OINDP industry, OINDP suppliers, regulatory authorities and other stakeholders.

4. Be a well-respected and effective advocate for the OINDP industry.

The work of IPAC-RS is global, with regard to industry, suppliers, regulatory authorities, and other stakeholders, including patients and healthcare professionals.

The nuts and bolts of IPAC-RS

IPAC-RS is currently comprised of twelve member companies (3M, AstraZeneca, Boehringer Ingelheim, Catalent, Chiesi, GlaxoSmithKline, MannKind Corporation, Merck & Co., Inc., Pfizer, Novartis, Teva and Vectura) that collaborate as a leading resource and voice of the OINDP industry. Representatives of member companies serve on the board of directors, which is a group of experienced industry specialists. Led by an elected chair and vice chair, the board provides leadership and direction to the consortium. The board is complemented by a planning committee, which provides strategic guidance and acts to progress decisions made by the board.

Currently, the IPAC-RS board of directors divides its efforts among 14 highly focused teams. These working groups are subdivided into four main categories by activity: 1) chemistry, manufacturing and controls (CMC) and product development tests, 2) regulatory affairs and outreach, 3) delivery systems, and 4) clinical and *in vivo/in vitro* correlation (Table 1). The law firm of Drinker Biddle & Reath acts as the secretariat, providing scientific and administrative support, project management and legal counsel to the Consortium.

Activities and initiatives

IPAC-RS has interacted with regulatory agencies across the world, including the US FDA, Health Canada and the European Medicines

Table 1

Currently active IPAC-RS working groups

CMC and product development tests	Delivery systems	Clinical and IVIVC
Cascade impaction	Devices	ISAM/IPAC-RS workshop
Delivered dose uniformity/PTIT	OINDP materials	Biomarkers
L&E development paradigms	Patient concordance	
Analytical methods		
Dissolution		

Regulatory affairs and outreach
Global regulatory review and outreach
Communications and technical committee

CMC = Chemistry, manufacturing and controls
PTIT = Parametric tolerance interval test
L&E = Leachables and extractables
OINDP = Orally inhaled and nasal drug products
ISAM = International Society for Aerosols in Medicine
IVIVC = *in vivo/in vitro* correlation

Agency (EMA), as well as pharmacopoeial bodies in the US, Europe and Japan and the International Organization for Standardization (ISO) and the Pharmaceutical Quality Group (PQG). Additionally, the Consortium has collaborated with trade and technical groups such as the Inhalation and Nasal Technology Focus Group (INTFG) of the American Association of Pharmaceutical Scientists (AAPS) and the European Pharmaceutical Aerosol Group (EPAG). IPAC-RS has been involved in the Product Quality Research Institute (PQRI) efforts on leachables and extractables, particle size distribution mass balance and particle size distribution profile comparisons. IPAC-RS activities and findings have also been featured in a range of journals.

IPAC-RS continues to be active on many scientific and regulatory fronts. Recently, the consortium coordinated a joint workshop with the International Society of Aerosols in Medicine (ISAM) in Frankfurt. This year, IPAC-RS working groups prepared several articles for RDD Europe 2011 and published articles in AAPS PharmaSciTech 2011. Publication of an L&E Handbook about leachables and extractables is anticipated in the near future. In addition, IPAC-RS is also conducting outreach efforts to emerging markets. In March, IPAC-RS held its third conference showcasing regulatory and scientific approaches for OINDP. The three-day event, which was open to the public, was attended by close to 200 participants from 14 countries.

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For more information on IPAC-RS, please refer to our website, www.ipacrs.com or contact Dede Godstrey at the secretariat, dede.godstrey@dbr.com.