

International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS)

Summary of 2011-2013 Strategic Plan

Vision

IPAC-RS is and will remain the leading resource and advocate of the Orally Inhaled and Nasal Drug Products (OINDP) industry.

Mission

The mission of IPAC-RS is to advance scientifically driven approaches to enhancing product quality of inhaled and intranasal drug products.

Current Members

3M
AstraZeneca
Boehringer Ingelheim
Chiesi
GlaxoSmithKline
MannKind Corporation
Merck & Co., Inc.
Pfizer
Novartis
Teva
Vectura

Associate Members

Aptar
Rexam
SHL Group
West

Interested in learning about IPAC-RS initiatives? Interested in IPAC-RS membership?

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Strategic Objectives

IPAC-RS focuses on four strategic objectives:

1. Provide information and services to enable member companies to achieve their current and future product development and regulatory goals.
 - Serve as a resource for sound analyses of OINDP regulatory requirements.
 - Engage in initiatives to facilitate current and future OINDP product development processes.
2. Advance the science and regulation of inhalation products through discussion, research, and publication.
 - Identify and address key questions for OINDP through IPAC-RS initiatives.
 - Develop and publish IPAC-RS best practices for OINDP.
3. Effectively collaborate with the broader OINDP industry, OINDP suppliers, regulatory authorities, and other stakeholders.
 - Expand relationships with decision-makers at regulatory agencies worldwide and standard-setting bodies.
 - Provide educational and scientific workshops and conferences for the OINDP industry, suppliers, and regulators on current and emerging scientific and regulatory topics relevant to OINDP.
 - Contribute actively to scientific and regulatory discussions among industry, government, and standard-setting bodies.
4. Be a well-respected and effective advocate for the OINDP industry.
 - Actively comment on regulations and guidances that impact OINDP and promote clear and harmonized international regulatory expectations for OINDP.
 - Engage regulatory authorities in constructive discussion and sharing of ideas on OINDP best practices.



Implementation of 2011 – 2013 Plan

IPAC-RS leads a range of scientific and regulatory projects and, through workshops, publications, discussions and collaborations, seeks to advance scientifically driven approaches to enhancing product quality of OINDP. Some of the activities for IPAC-RS in 2011-2013 include:

- undertake collaborative efforts with other groups as a means to more effectively and efficiently focus resources on core priorities and activities;
- broaden focus beyond the US and EU by monitoring and reporting on relevant regulatory developments in emerging markets and advancing a unified industry position regarding sound and harmonized international regulations for OINDP;
- develop concrete goals relating to the organization's plans for addressing the relationships between quality, and safety and efficacy, particularly in locally acting drugs. These goals should specify how IPAC-RS will address this topic over time and with greater engagement by clinical colleagues, as well as liaisons with associations of clinicians;
- promote internal tools that will increase contacts and knowledge sharing between members; and
- grow the membership base to include a more diverse group of companies that share the goal of advancing scientifically driven approaches to enhancing product quality of OINDP.

Work Streams and Initiatives

IPAC-RS initiatives are grouped into work streams, which combine activities with a similar focus and regularly discuss their progress.

1. CMC and Product Development Tests

Cascade Impaction: Examine application of Quality-by-Design (QbD) concepts to Aerodynamic Particle Size Distribution (APSD) testing .

Delivered Dose Uniformity (DDU)/Parametric Tolerance Interval Testing (PTIT): Promote common understanding of the DDU PTI-TOST proposed by FDA; equip companies for successful discussion of appropriate DDU acceptance criteria with regulators.

Dissolution Rate Testing: Review available techniques, prepare and publish a summary of their advantages and limitations in the context of OINDP development, optimization and control.

Leachables and Extractables: Develop and share best scientific approaches and best industry practices for management of leachables and extractables in OINDP for product development and registration. Additionally, explore and create a new development paradigm for extractables and leachables in OINDP.

Analytical Methods: Explore how QbD principles can be applied to analytical method development and understand how analytical method variability impacts the design space and control of critical quality attributes (CQA).

Stability Shelf Life: Propose best practices with respect to stability indicating quality attributes.

2. Regulatory Affairs and Outreach

Global Regulatory Affairs and Outreach

Committee: Monitor and assess worldwide regulatory developments that may be applicable to OINDP. Facilitate outreach to regulatory agencies worldwide and collaborate with other industry groups in relevant efforts.

IPAC-RS 2011 Conference Organizing Committee: Prepare and conduct IPAC-RS 2011 Conference.

Communications Technology Committee: Enhance internal collaboration within IPAC-RS and increase the public presence of IPAC-RS.

3. Delivery Systems

Devices: Identify and promote best practices for development of OINDP devices.

OINDP Materials: Seek to improve OINDP materials quality and integrity while reducing supply chain problems and reducing or eliminating unnecessary testing.

Patient Concordance: Conduct a workshop (March 2011) for discussion of key issues in patient adherence with stakeholders and consider a white paper to capture lessons learned from the workshop.

4. Clinical, IVIVC

ISAM/IPAC-RS European Equivalence Workshop: Prepare and publish a report on the 2010 ISAM/IPAC-RS Workshop.

Additional Conferences/Workshops: Plan additional conferences and workshops to closer link CMC characterization and clinical aspects of OINDP.