Sharing Information Across the Globe: IPAC-RS Global Regulatory Review and Outreach (GRRO)

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GRRO North America

Monitors and shares information on regulatory and standards activities in US and Canada. Conducts outreach to regulatory agencies and standards bodies.

- Supports IPAC-RS joint commenting on FDA guidance, USP chapters, and stimulus articles
- Led engagement with FDA on IPAC-RS comments to the 2018 Draft Guidance for MDIs and DPIs
  - Held knowledge exchange meeting with FDA to discuss aspects of the Draft Guidance in February 2020
  - Will hold follow-up discussions with FDA statisticians on PTIT and provide examples of risk management and QbD concepts applied to MDI or DPI development

GRRO Brazil

Monitors and shares information on ANVISA regulatory activities. Conducts outreach to ANVISA and local industry associations.

- Held joint 2018 workshop with Anvisa on OINDP therapeutic equivalence
- Met with ANVISA in 2019 to discuss the Resolution (RDC 278) and Normative Instruction (IN 33) on OINDP therapeutic equivalence
- Worked with ANVISA to organize an IPAC-RS/ANVISA Population Bioequivalence (PBE) webinar held in March 2020
- Co-authored with ANVISA the article, Overview of Brazilian Requirements for Therapeutic Equivalence of Orally Inhaled and Nasal Drug Products *(AAPS PharmSciTech, June 2019)*

Objectives

IPAC-RS established the GRRO work-streams to:

Stay abreast of regulatory developments in regions relevant to the membership

Understand requirements in new markets

Initiate outreach to regulatory agencies, pharmacopeias and other standard-setting bodies worldwide

Collaborate with other trade groups

IPAC-RS currently has 4 GRRO workstreams: North America, Europe, Brazil, and China

Looking into the Future...

What will be key developments and issues for the industry?

Implementation of the MDR – impacts on the OIP industry

Finalization of the EMA drug-device guideline – linking to MDR and current FDA drug device combination product guidance

New drafts of EMA guidelines on OINDP quality and on demonstration of OIP therapeutic equivalence

Finalization of the FDA MDI DPI guidance – application of PTIT; clarity on device requirements versus QbD approaches

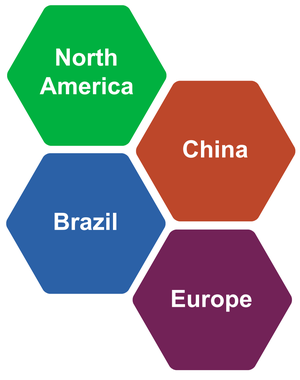
Alignment on global requirements for biocompatibility

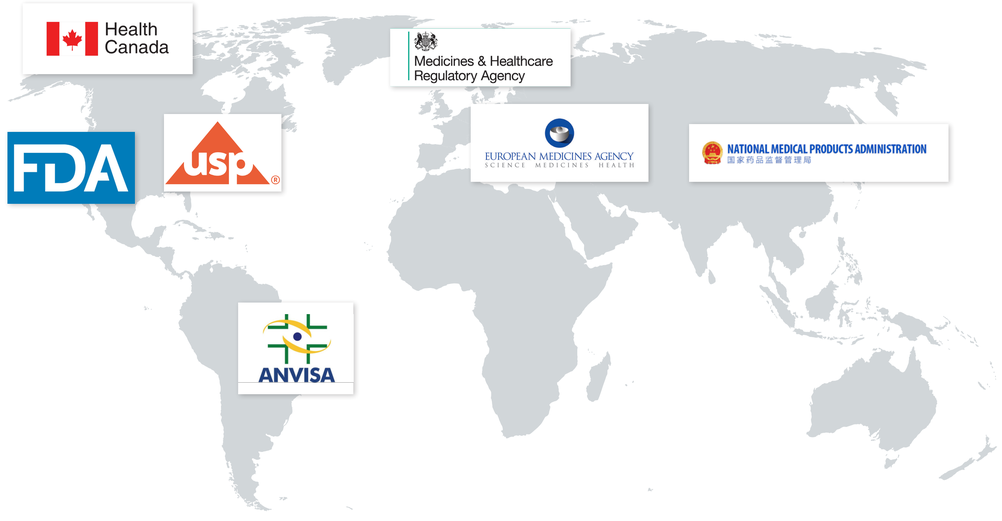
Need for clarity on submission and inspection requirements in China; development of the NMPA BE guideline for inhalation products

Working with Anvisa on the implementation of recent regulations on Therapeutic Equivalence (TE) and PBE; Anvisa approaches on variations

GRRO Work-streams

Leverage Technical Group Experts and Output





GRRO China

Monitors and shares regulatory activities of the China National Medical Products Agency (NMPA) and its sub-agencies, e.g., National Institutes for Food and Drug Control (NIFDC), Chinese Pharmacopoeia (ChP), and Center for Drug Evaluation (CDE). Conducts outreach to these agencies and local industry associations.

- Led submission of IPAC-RS comments to
  - CDE draft guideline on bioequivalence for inhalation products
  - ChP inhalation and nasal-related chapters: 0111 Inhalation Preparations; 0112 Sprays; 0113 Aerosols
  - China Pharmaceutical Packaging Association (CNPPA) draft
- Partnering with the Chinese Pharmaceutical Industry Association and Aptar on a joint drug delivery workshop; and with NIFDC on a regulatory roundtable discussion

GRRO Europe

Monitors and shares information on EMA, EC and MHRA activities relevant to OINDP.

- Collaborated with IPAC-RS Device Working Group to
  - Comment on the EMA Drug-Device Combinations guideline
  - Submit a joint letter to the EC on MDR Annex VIII Rule 20 requirements
- Provide feedback on an MHRA concept paper *Consultation on the application of Analytical Quality by Design concepts to pharmacopoeial standards for medicines*

† For more information on IPAC-RS please contact the IPAC-RS Secretariat: info@ipacrs.org