The Parenteral Drug Association presents:

Pharmacopoeia Conference

Convergence, Harmonization &
The Future Direction of Pharmacopoeias

CALL FOR PAPERS & POSTERS

29-30 May 2018
Vienna | Austria
Conference Overview

A pharmaceutical product submitted and marketed in different countries or economic regions has to comply with the respective pharmacopoeias legally binding in those countries and regions. Typically, however, international pharmacopoeias differ in the quality requirements for the same product. Compliance, therefore, becomes a major challenge for pharmaceutical companies, resulting in the need to develop and maintain labor-intensive and costly processes. Please join us for this inaugural PDA conference where representatives from the most relevant pharmacopoeias will share approaches to international convergence, harmonization & the future direction of pharmacopoeias with respect to the overall framework of regulations and guidelines. Pharmaceutical industry will provide insights into their best-practices to effectively and efficiently implement international pharmacopoeial requirements.

TUESDAY, 29 MAY 2018

Session 1
Pharmacopoeias & Their Respective Regulatory Framework

The role of pharmacopoeias is defined by their respective regulatory framework. We will focus on:

Ph. Eur. - European Pharmacopoeia
USP - United States Pharmacopoeia
JP - Japanese Pharmacopoeia
ChP - Chinese Pharmacopoeia
RP - Russian Pharmacopoeia
IP - Indian Pharmacopoeia

Panel discussions will include additional international representation for current and emerging pharmacopoeial activities in their regions.

Session 2
Procedures of Pharmacopoeias

This session will focus on industry stakeholder perspectives for communication and collaboration with pharmacopoeial entities. It will highlight where interactions have been successful, areas where challenges exist, and potential future directions. Issues of discussion will include:

- Need for stakeholder involvement
- Industry perspective on collaboration with pharmacopoeias
- Industry participation in public notice and commenting procedures
- Transparency of working pharmacopoeial principles
- Industry’s experiences with current analytical methods for existing products
- Case studies

WEDNESDAY, 30 MAY 2018

Session 3
Harmonization & Convergence

This session will cover current international harmonization and convergence initiatives, including the Pharmacopoeial Discussion Group, WHO Good Pharmacopoeial Practices and regional authority agreements of mutual recognition. Issues to be addressed include:

- Role of the Pharmacopoeial Discussion Group
- Interaction of the three Pharmacopoeias:
  - Ph. Eur. - European Pharmacopoeia
  - USP - United States Pharmacopoeia

Panel discussions will include additional international representation for current and emerging pharmacopoeial activities in their regions.

Session 4
Involving Pharmacopoeias in Scientific and Technological Innovations

In this session, we will focus on how innovative developments are incorporated into the core pharmacopoeial activities such as monographs, standard setting, etc.

- Monographs for biologics
- New products & new technologies: how best to incorporate into pharmacopoeia
- How to identify pharmacopoeial standards that best serve the industry
- ICH Q 12 - post approval changes
- Physical reference standards for biologics

All submitted abstracts will be reviewed by the Program Committee for acceptance. Upon review by the Program Committee, PDA Europe will advise each submitter of the status of the paper for presentation in writing.

Submissions received must include the following information:

- Title
- Presenter
- Presenter’s biography (approx. 100 words)
- Additional authors
- Full mailing address
- Phone number
- E-mail address of the presenter
- Key objectives of your topic
- 2-3 paragraph abstract, summarizing your topic

Please submit your abstract online: https://www.surveymonkey.de/r/2018Pharmacopoeia

If you have any questions, please do not hesitate to contact us.

Deadlines

Abstracts of papers for presentation: 31 October 2017
Poster abstracts: 28 February 2018