

ICPM 2018

Workshop 5

Changing Environment in Pharmacovigilance

Topics:

- **Changing global safety environment (Dr. Luria)**
- **Advances and challenges in post marketing safety management (Dr. Geary)**
- **New initiatives and challenges in Japan: PMDA perspective (Dr. Moriguchi)**

Chairs:

- **Nishiuma, Shinichi (Celgene K.K., Japan)**
- **Stilting, Peter (IFAPP Academy, Netherlands)**

Speakers:

- **Luria, Xavier (DDR, UK)**
- **Geary, Stewart (Eisai, Japan)**
- **Moriguchi, Hiroshi (PMDA, Japan)**

Objectives :

With advancement of science, new medicines with new mode of action are developed and brought to patients, which requires more attention to patient safety. The purpose of the session is to understand various initiatives for improving post-marketing safety management in the world and discuss its challenges

Learning outcomes :

This workshop will provide an opportunity to catch up changing environment of safety management in the world and ongoing initiatives to

improve post-marketing safety management from both industry and regulatory perspective in major regions. Representatives from pharmaceutical company and regulatory agency will discuss current challenges and share their perspective in the future to improve patient safety. Participants can learn how far these new initiatives are in progress and translate into the daily practice of post-marketing safety management.