ICPM2018
Symposium 1
Regulatory Sciences

Topics:

- **Translational research and regulatory implication**
- **Adaptive pathway and accelerated approval**
- **Orphan and non-orphan designated products**

Chairs:

- **Imoto, Masakatsu (AMED, Japan)**
- **Luria, Xavier (DDR, UK)**

Faculty:

- **Knöss, Werner (BfArM, Germany)**
- **Milne, Cristopher (Tufts University, US)**
- **Shibatsuji, Masayoshi (NCC, Japan)**

Objectives:

- **To elaborate on the various elements coming from precision medicine and other new methodologies to contribute to the translational research and therefore improve the drug development process.**
- **To discuss on how adaptive pathways on drug development may lead to accelerated regulatory review and approval.**
- **To identify specific characteristics of orphan drugs influencing their development and review process by regulators.**

Learning Outcomes:

- **Clarify the basics and trends of the latest pharmaceutical regulation related to the systems for accelerated regulatory approvals and the translational research in EU, Japan and US.**
- **The adaptive pathways in drug development and accelerating regulatory approvals.**
- **Orphan drugs as a paradigm of innovative development methodologies and future trends.**