CMC Strategy Forum Japan 2018
Welcome and Introductory Comments

Takao Yamori
Executive Director / Director of Center for Product Evaluation
Pharmaceuticals and Medical Devices Agency (PMDA)
Regulatory Science Center established in PMDA

- PMDA has promoted regulatory science for evaluation/judgment of quality/efficacy/safety of medical products
- Regulatory Science Center was established in April 1, 2018, centralizing PMDA’s RS-related activities to achieve followings:
  - Addressing and streamlining resolution of scientific issues
  - Improving quality of review and safety measures
  - Activating discussions with each stakeholder by providing RS information
Main services of the Regulatory Science Center

1. Providing services/information on cutting-edge technology

• Collecting information on cutting-edge technology expected to be used for medical products to get ideas for evaluation and regulations through discussions with stakeholders
  ⇒ Science Board, Horizon scanning

Outcomes of the Science Board related to biologics (in English)
• Proposal on Basic Principle to Quality Assurance of Cell Therapy (CT) Products (June 14, 2015)

• Current Perspective on Evaluation of Tumorigenicity of Cellular and Tissue-based Products Derived from induced Pluripotent Stem Cells (iPSCs)* and iPSCs as Their Starting Materials (August 20, 2013)
Main services of the Regulatory Science Center

2. Promoting use of submission data/real-world data

• Wide use of submission data
• Wide use of real-world data such as medical records, etc.
⇒ Maximize the use of submission data/real-world data for optimal use throughout product lifecycle and development of innovative products

3. Human resource development

• Supporting staffs to deal with scientific issues and release its results
• Promoting RS and developing human resources through partnership with academia (e.g., cross appointment program)
⇒ Exchange of expertise between academia and PMDA staff
Collaborative Functions of Regulatory Science Center with other offices

Office of Advanced Evaluation with Electronic Data

Support advanced analysis, Create disease model for data evaluation etc.

Coordination Officer for Evaluation of Advanced Science and Technology

Better regulatory decision making with advanced technology and science

Office of New Drugs
For drug approval

Support epidemiological data evaluation and study planning

Office of Safety
For safety measures

Safety measures based on cross products analysis etc.

Safety measures based on epidemiological analysis etc.

Medical Informatics and Epidemiology

For safety measures
CMC Strategy Forum Japan
Enjoy !

http://www.pmda.go.jp/

PMDA