独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

CMC Strategy Forum Japan 2023
Welcome and Introductory Comments

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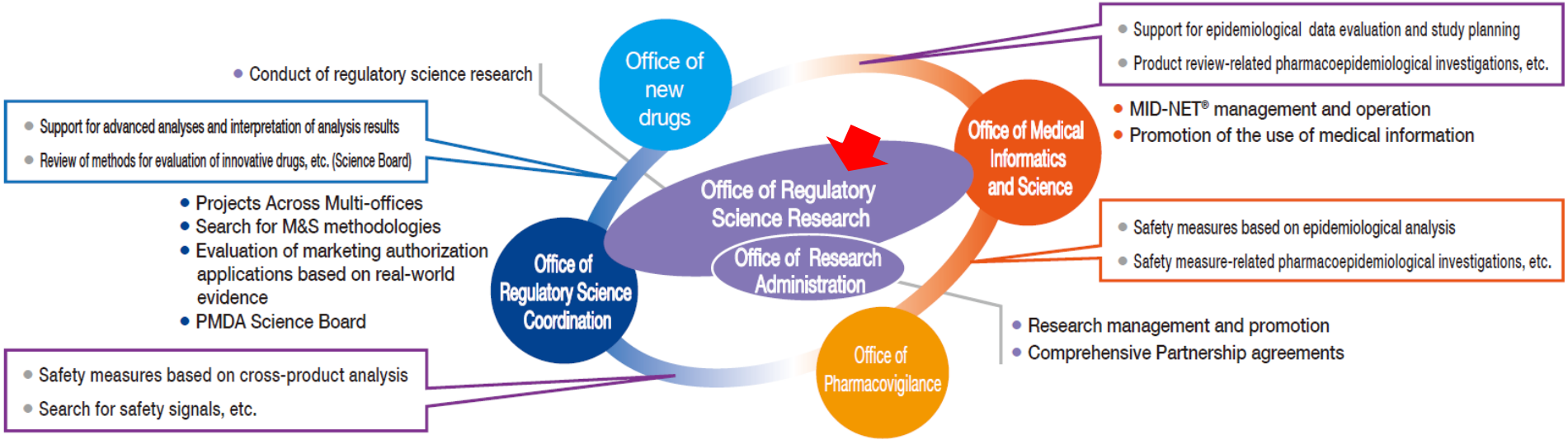
Pharmaceuticals and Medical Devices Agency

Scientific Program

- Recent Trends in the Regulation of Biopharmaceutical Products
- Stability of Biopharmaceutical Products: Topics about ICH Guideline Q1/Q5C Revision
- Cell and Gene Therapy Products
- A Strategy for the Quality Control of Antibody-Drug Conjugates (ADCs) Throughout the Entire Life Cycle of the Product

Office of Regulatory Science Research as of July 2023



Establishment of PMDA overseas office in Asia (FY2024)

- facilitate the development of/access to innovative medicines & medical devices in Japan and Asian countries

Asian Office

- Location: Bangkok
- Mission:
  - Establish a regulatory infrastructure with regulatory authorities in Asian countries
    - PMDA-ATC
    - Facilitated review pathway
  - Information exchange with industries to grasp key issue in countries and region
  - Support Asian clinical research networks*
    *facilitated by National Cancer Center and National Institute Global Medicine

Establishment of PMDA overseas office in US (FY2024)

- facilitate the development of/access to innovative medicines & medical devices in Japan and Asian countries

US Office

- Location: Washington DC
- Mission:
  - Facilitate information exchange with Industries in US
    - Disseminate information on Japanese regulation and PMDA services to SMEs and ventures*

      *conducting R&D of orphans drugs and other innovative medicines
  - Stimulate communication between FDA and PMDA

(Draft) Direction of PMDA Mid-term Plan (FY2024-FY2028)

https://www.pmda.go.jp/files/000265089.pdf

Review Services

- Prompt and appropriate implementation of pharmaceutical review

<New drug Evaluation>

① Maintain the world's fastest level of review time and conduct efficient and high-quality review

② Provide consultations/reviews that accurately respond to innovation, including dissemination of **"Early consideration"** and formulate clinical evaluation guidelines based on the latest scientific knowledge

③ Actively support the development of orphan and pediatric drugs with high patient needs

④ Create an environment that foster earlier development/introduction of innovative drugs developed overseas in Japan and enhance information dissemination

⑤ Establish an emergency consultation/review system capable of responding to pandemics, etc.

Enjoy!

https://www.pmda.go.jp/