Role and Vision of PMDA
~Promoting Global Public Health~

Taisuke Hojo

Senior Executive Director

Pharmaceutical and Medical Devices Agency (PMDA)

1st Malaysia-Japan Symposium
March 10th , 2015

Today's Topics

1. Introduction of PMDA
2. Our Major Services
   i. Review Services
   ii. Post-marketing Safety Measures
   iii. Relief Services for Adverse Health Effects
3. PMDA's International Activities
4. Conclusion

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Pharmaceuticals and Medical Devices Agency

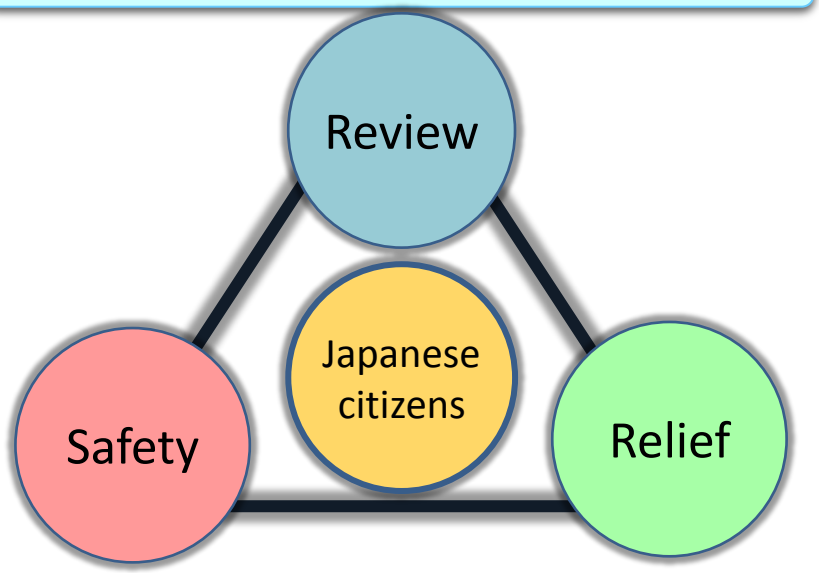
Date of Establishment : April 2004

Kansai Branch

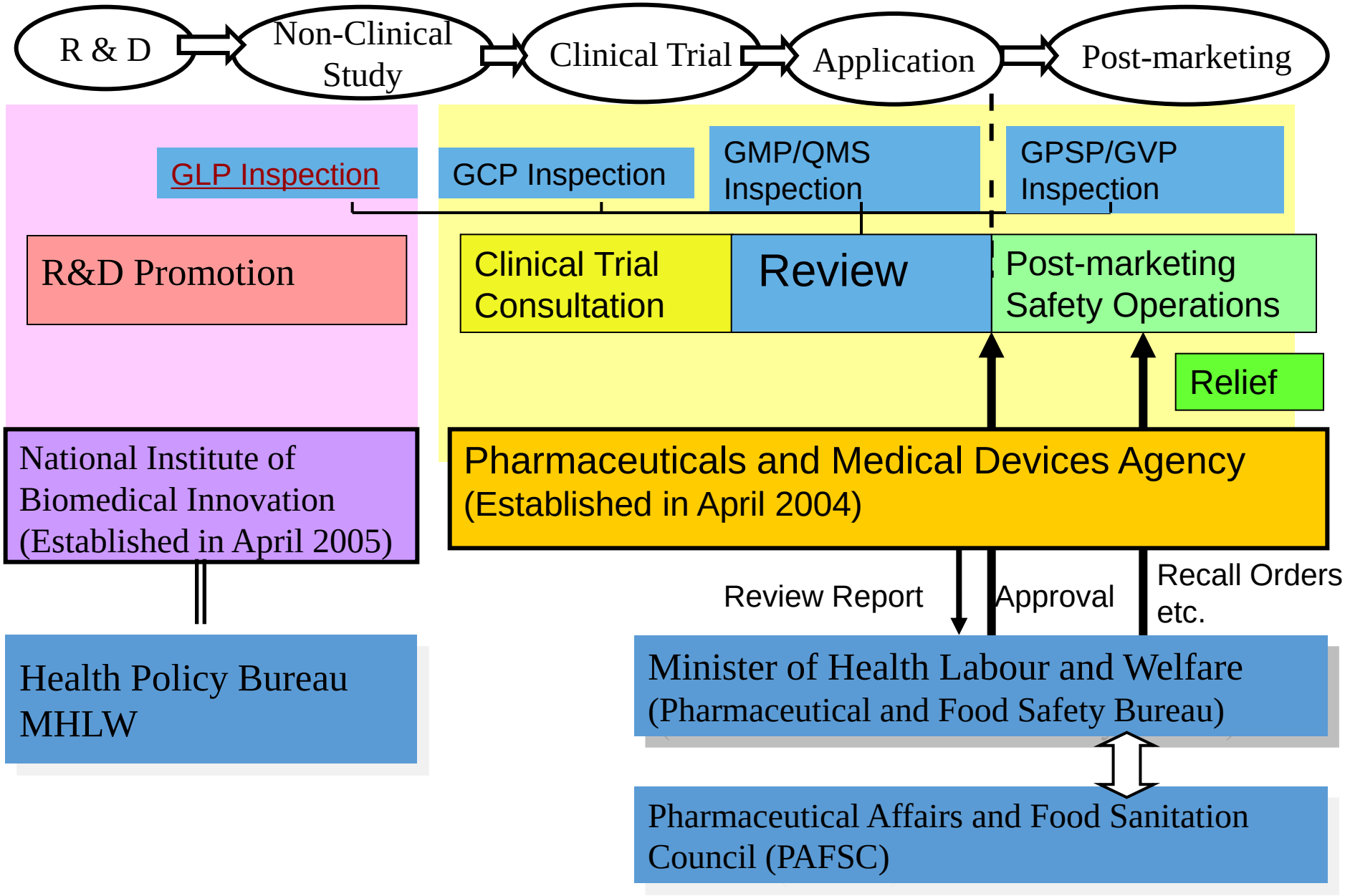
Major Services

- Scientific Review for Drugs & Medical Devices
- GCP, GMP Inspection
- Consultation on Clinical Trials
- Safety Measures
- Relief Services

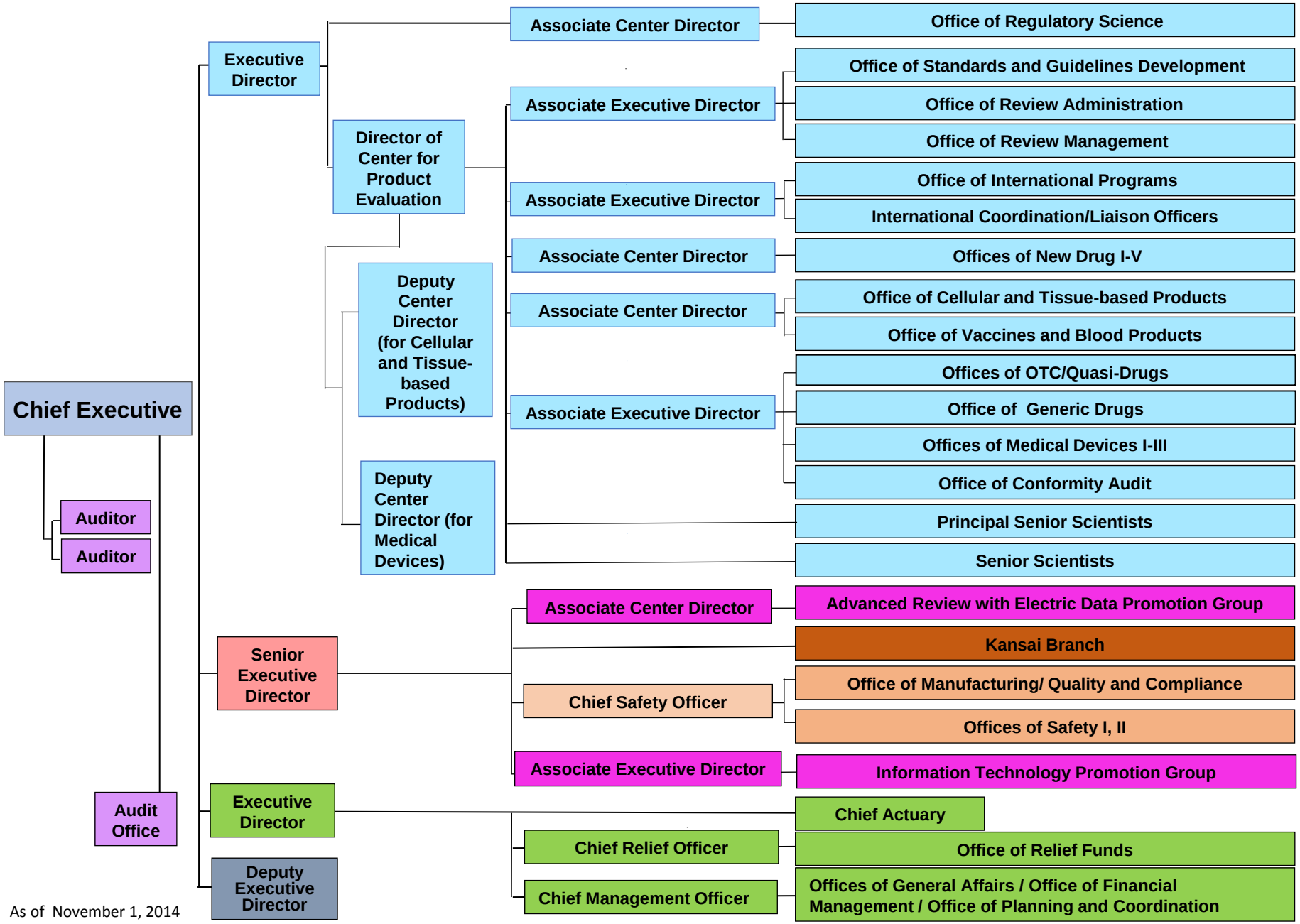
Unique Three-pillar System Securing Nation's Safety



Work Flow of Drugs Development

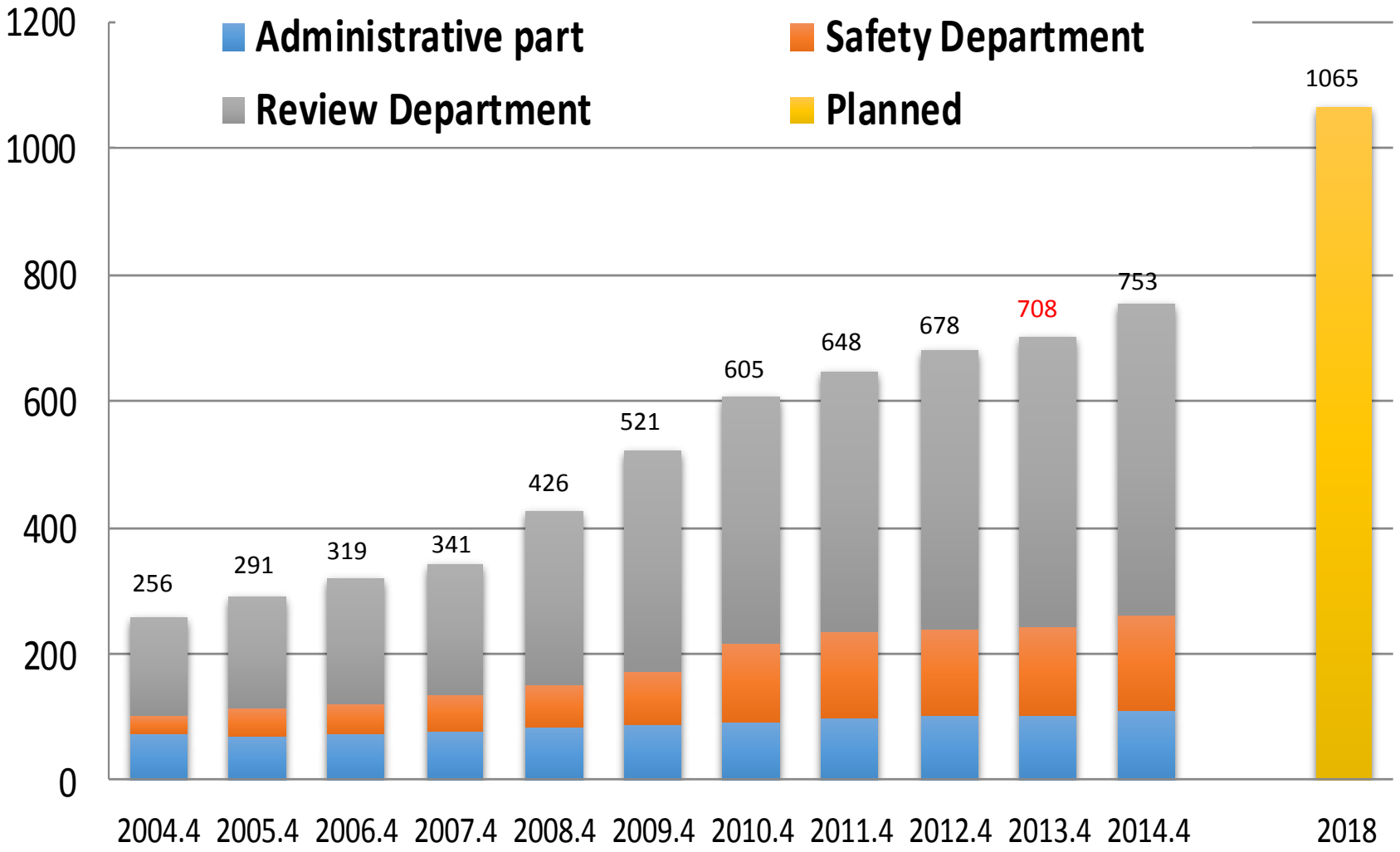


Organization of PMDA



As of November 1, 2014

PMDA Staff Size



Our Philosophy

(September, 2008)

PMDA continues to improve the public health and safety of our nation by reviewing applications for marketing approval of pharmaceuticals and medical devices, conducting safety measures, and providing relief to people who have suffered from adverse drug reactions.

We conduct our mission in accordance with the following principles:

- We pursue the development of medical science while performing our duty with greater transparency based on our mission to protect public health and the lives of our citizens.
- We will be the bridge between the patients and their wishes for faster access to safer and more effective drugs and medical devices.
- We make science-based judgments on quality, safety, and efficacy of medical products by training personnel to have the latest technical knowledge and wisdom in their field of expertise.
- We play an active role within the international community by promoting international harmonization.
- We conduct services in a way that is trusted by the public based on our experiences from the past.

3rd 5-year mid-term plan of PMDA (FY201 2018)

4 Major challenges

- **Shortening the time from early development to approval**
  Measures: improvement in consultation system, accelerated review process , etc.
- **High quality review/consultation services**
  Measures: promotion of regulatory science research, etc.
- **Enhancing safety measures**
  Measures: utilization of medical information database
- **Globalization**
  Measures: information transfer with the world

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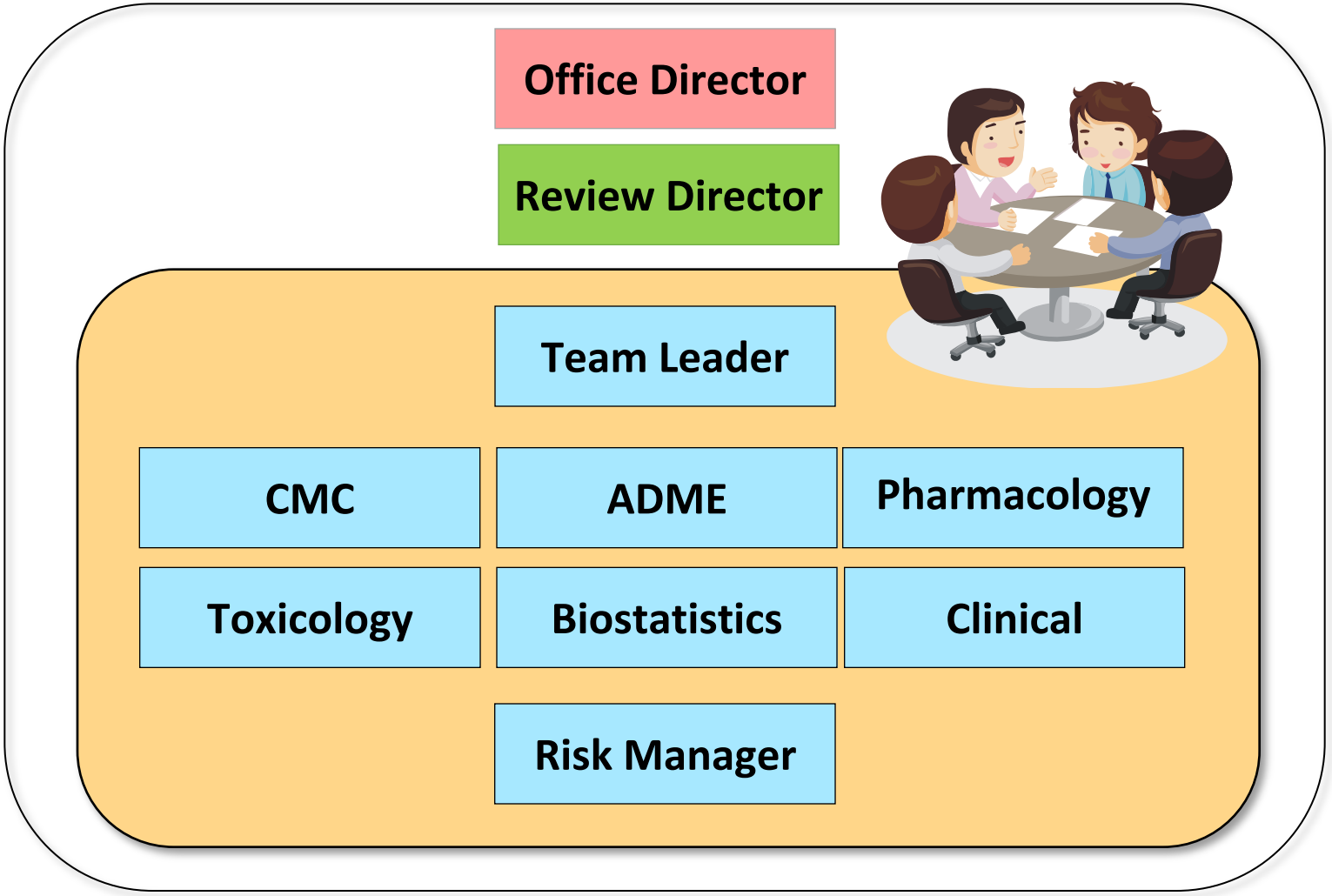
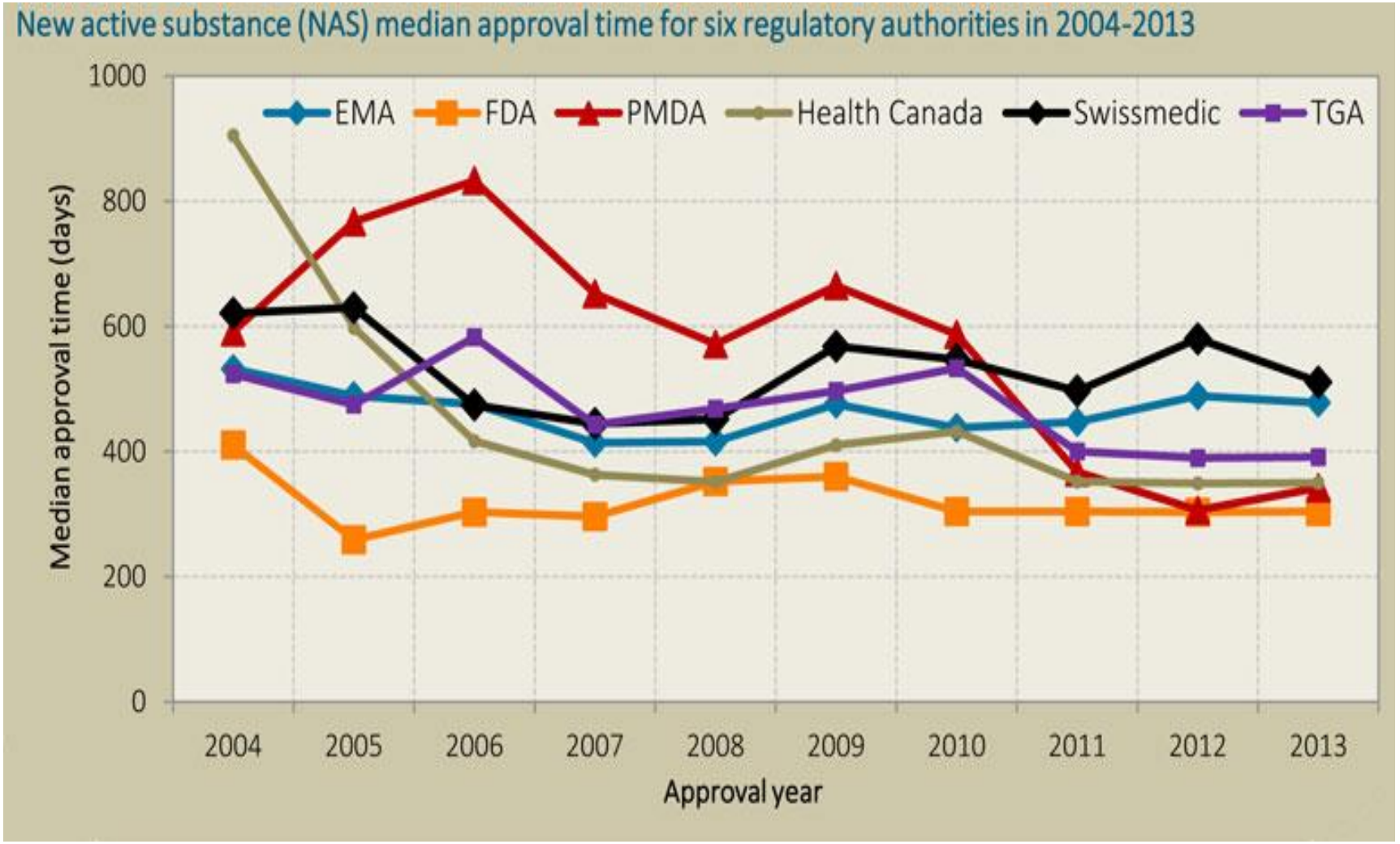
Team Reviewing at the PMDA

Reviewers are required to have a high level of expertise



Japan's Performance on NDA Review



Reference: The impact of the changing regulatory environment on the approval of new medicines across six major authorities 2004-2013. CIRS (Centre for Innovation in Regulatory Science) R&D 55

http://cirsci.org/node/73

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Adverse Drug Reaction (ADR) Reporting System in Japan

Investigation

Health Care Providers

Pharmacies

Reporting

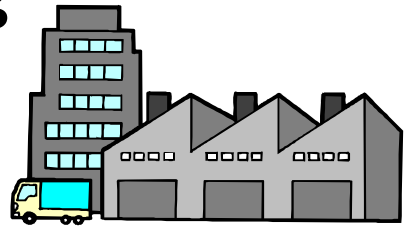
FAX
Postal Mail
Electronic reporting

Pmda

Analyze and evaluate collected data

Reporting

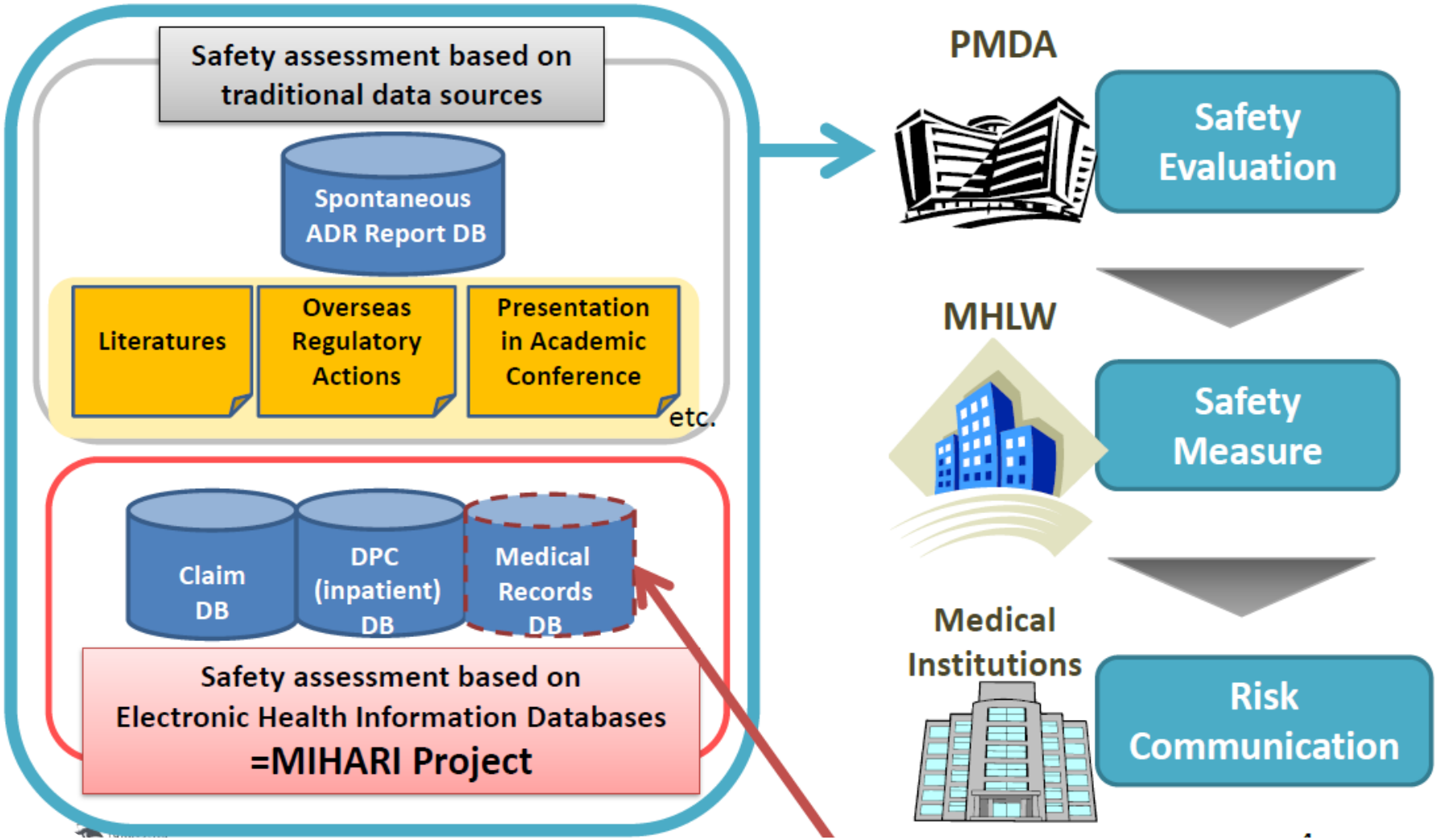
Feedback



Marketing Authorization Holders (MAH)

Safety Measures

Goal of MIHARI Project & MID-NET



Create new DB = MID-NET

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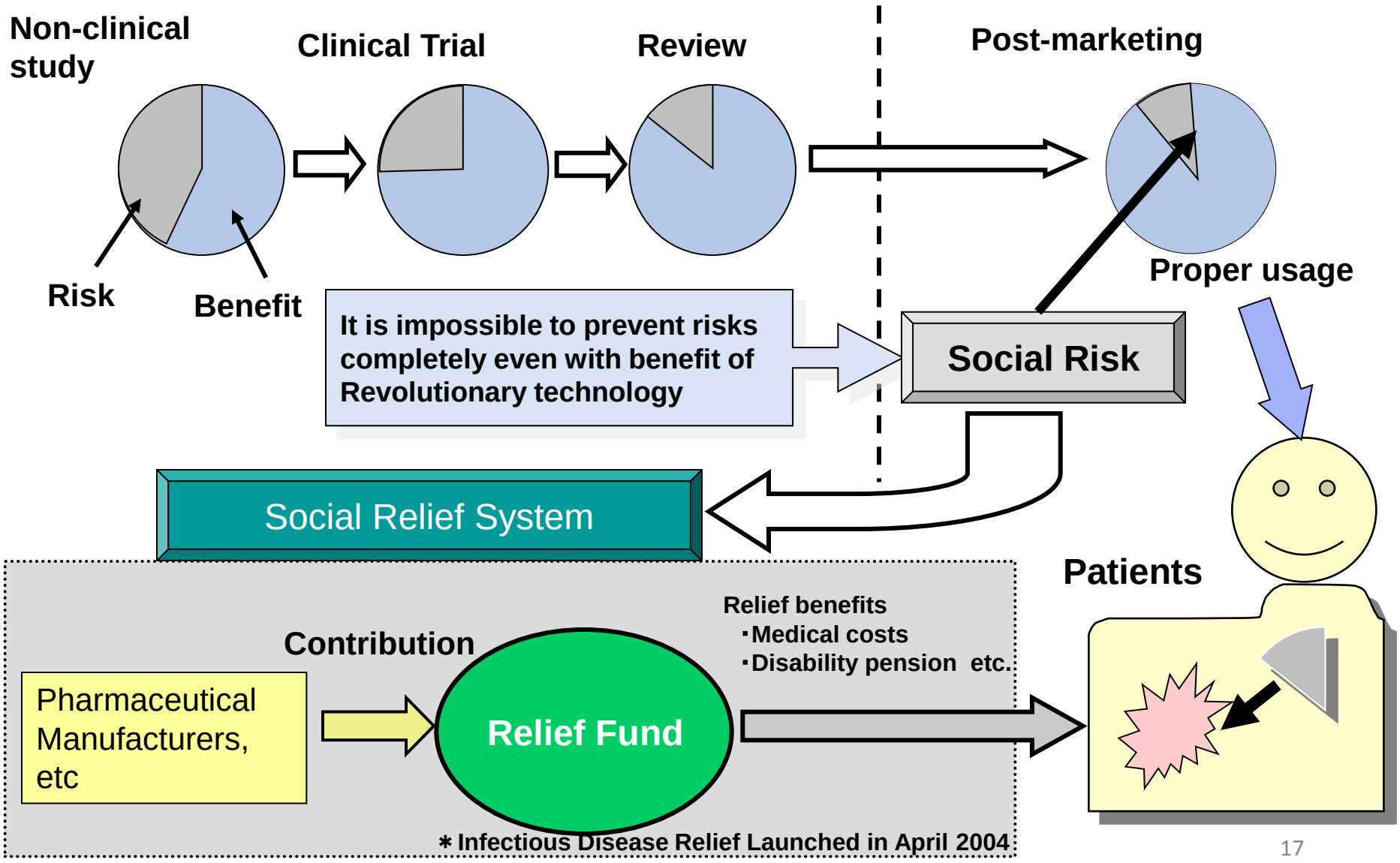
Drug Risk & Relief



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Global Activities

Summit	ICH	IMDRF	PIC/S	HBD	ICDRA
APEC LSIF RHSC	OECD	PDG	IDGRP	ICMRA	

and more…

Abbreviation	Official Name
Summit	International Summit of Heads of Medicines Regulatory Agencies
ICH	International Conference on Harmonization
IMDRF	International Medical Device Regulators Forum
PIC/S	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
HBD	Harmonization By Doing
ICDRA	International Conference of Drug Regulatory Authorities
APEC LSIF RHSC	APEC Life Science Innovation Forum Regulatory Harmonization Steering Committee
OECD MAD	OECD Mutual Acceptance of Data
PDG	Pharmacopoeial Discussion Group
IGDRP	International Generic Drug Regulators Pilot
ICMRA	International Coalition of Medicines Regulatory Authorities

PMDA and the World

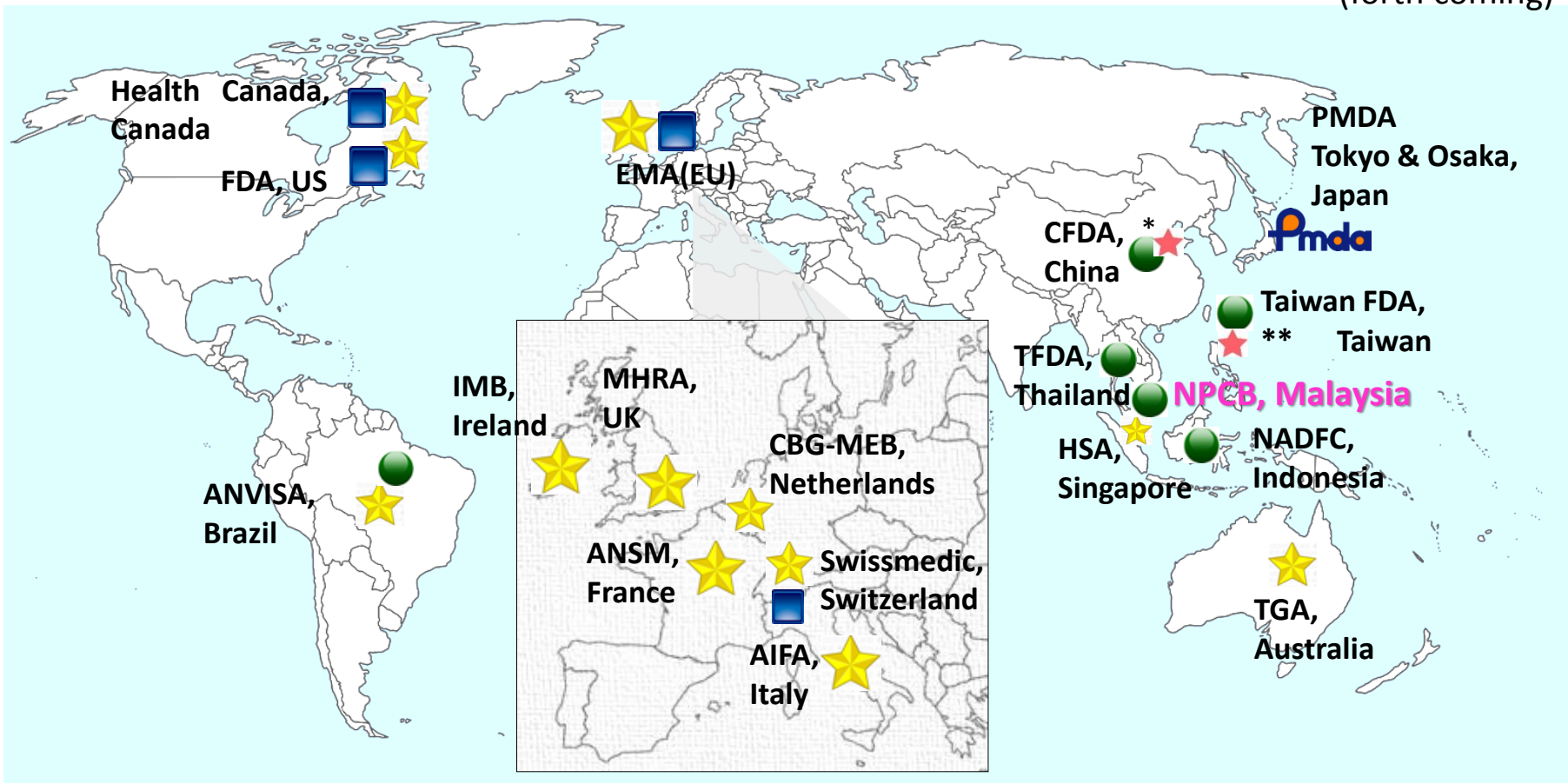
Confidentiality Arrangement

Memorandum of Understanding (MOU)

Resident Staff

Joint Symposium

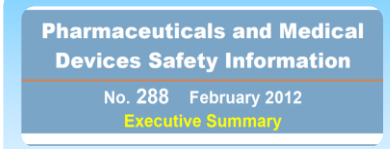
(forth coming)



- *MOU between the Chinese SFDA (present CFDA) and the Japanese MHLW, under which PMDA supports cooperative activities*
- *** MOU concluded between Interchange Association and East Asia Relations Commission, but is being implemented through cooperation of related organizations.*

Dissemination of Information

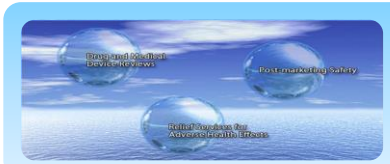
Review Report



Safety Information

PMDA Updates

News Release



And more…

Training for Foreign Regulatory Officers

PMDA Training Seminar

Pharmaceuticals:

1st (Nov. 2010) Reviewing of New Drugs
2nd (Dec. 2011) GMP inspection
3rd (Jan. 2013) Post-Marketing Safety & Relief Services
4th (Feb. 2014) Reviewing of Generic Drugs

Medical Devices:

1st (Mar. 2014) Medical Device Regulation
2nd (Feb. 2015)

Individual Training (including OJT)

- ✓ NADFC (Indonesia) officials: 5 days, 2013
- ✓ FDA (US) analyst: 6 months, 2014-2014
- ✓ NPBC (Malaysia) officials: 1 month, 2014
- ✓ Thai FDA (Thailand) officials: 5 days, 2014 2014 etc.

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Toward Global PMDA

Approve innovative products first in the world!

Spread technology of Japanese origin world-wide

Collaborate with review organizations globally

Review

Strengthen post marketing safety measures

Timely relief for acknowledged damage

Japanese citizens

Safety

Health damage relief

Contribute to global healthcare

The society where people can receive necessary healthcare services at the most advanced level

➡ Extend healthy life expectancy for Japanese citizens

Thank you very much for your attention.

Terima Kasih !!

http://www.pmda.go.jp/english/index.html