Opening Remarks

1st India-Japan Medical Products Regulation Symposium

18th May 2016

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Executive Director,

Pharmaceuticals and Medical Devices Agency (PMDA)

JAPAN

What is Pharmaceuticals and Medical Devices Agency

Headquarter

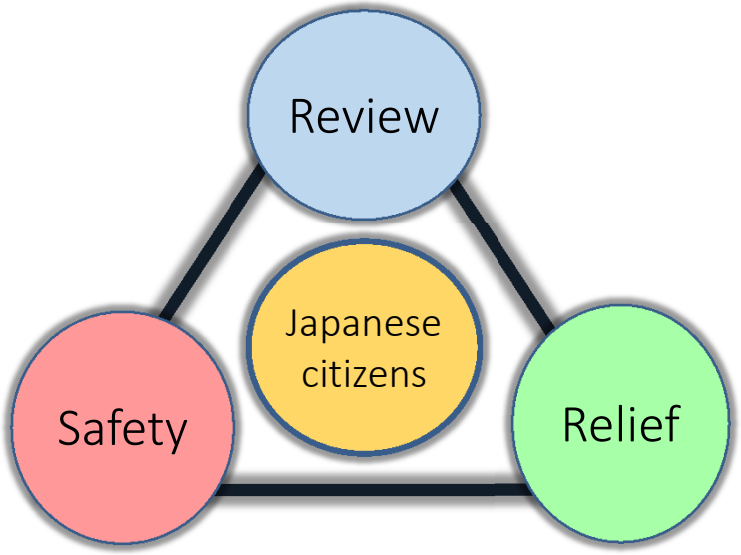
Kansai Branch

Established in 2004

Major Services

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

Unique Three-pillar System Securing Nation's Safety



Staff Size of PMDA and Average Review Period of Drugs

- Staff size

  256 as of 2004.4 → → → 1,065 as of 2018.4

- Review Period

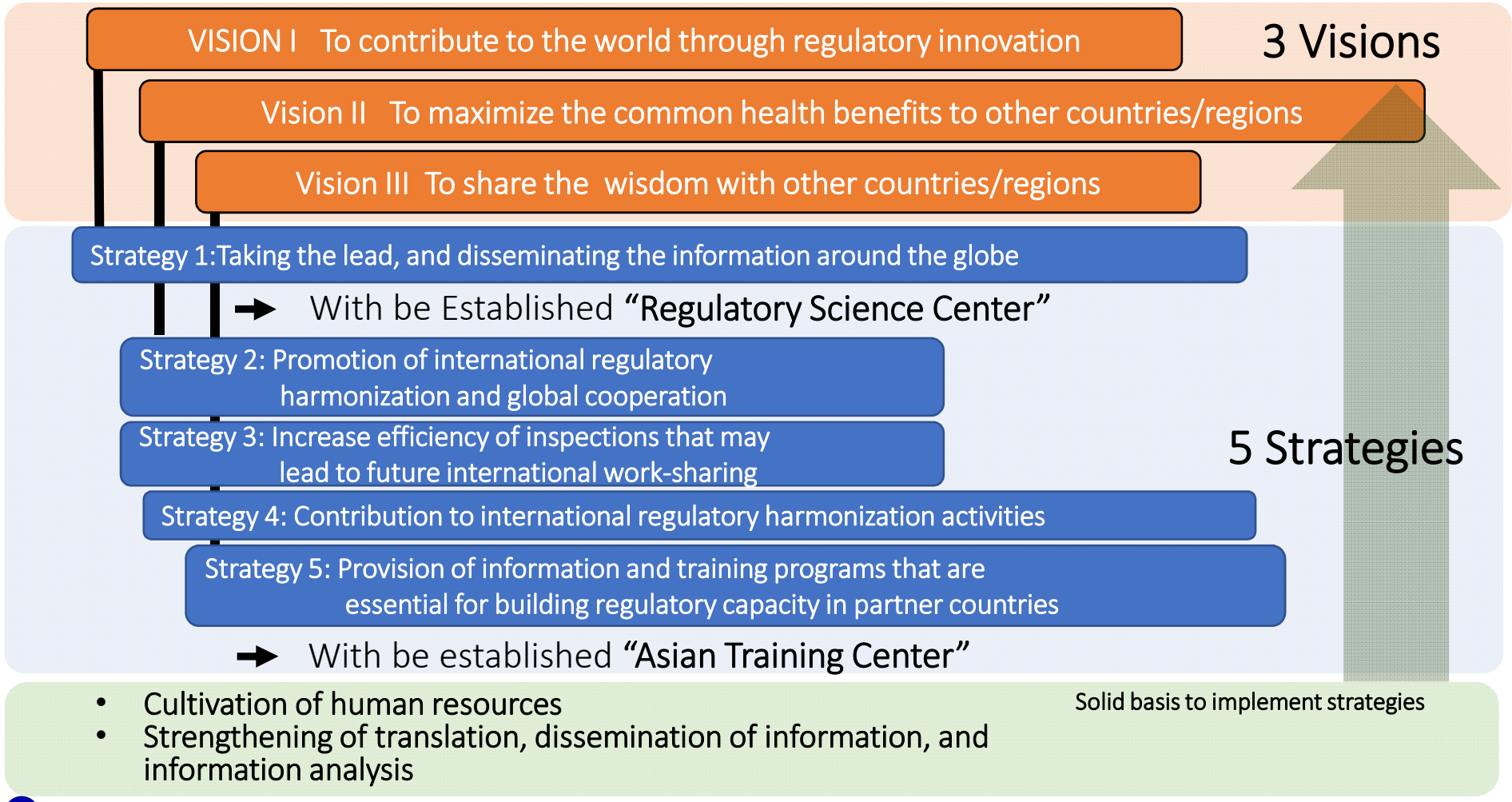
  apprx. 800 days as of 2005

  → → → 306 days as of 2014*

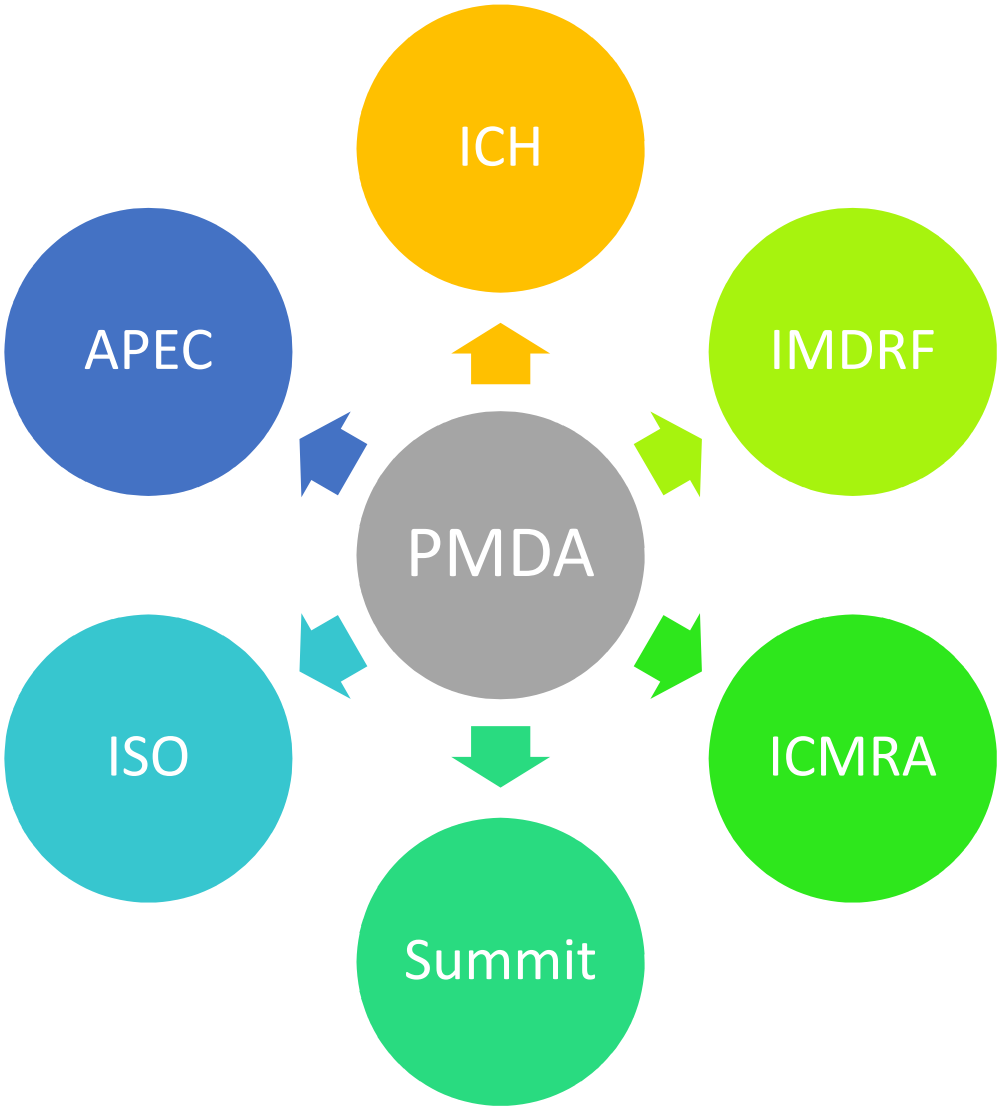
  * 418 days in EMA, 343 days in FDA

PMDA International Strategic Plan 2015

- **PMDA's primary responsibility:** Providing a reliable environment which affords quicker access to more effective and safer medical products
- **Change of environment surrounding PMDA**: Globalization of research, development, manufacture, and distribution of the products, Expectation to PMDA for International Contribution



Global actions and the importance



We believe global actions to harmonize regulations are beneficial because…

- Those actions could reduce redundancy of procedures or required documents between countries or areas.
- That would be benefit of both regulatory authorities and applicants.

Thank you for the attention.