PMDA and Application Procedures

Pharmaceuticals and Medical Devices Agency (PMDA)

Junko Sato
Disclaimer:

The information within this presentation is based on the presenter’s expertise and experience, and represents the views of the presenter for the purposes of a training workshop.
WHAT’S
Our Agency

PMDA Office

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Shin-Kasumigaseki Bldg.
3-3-2, Kasumigaseki, Chiyodaku,
Tokyo 100-0013 JAPAN
History of Drug Review System in Japan

1994
- Commissioned new activities to OPSR

1995
- Commissioned new activities to JAAME

1997
- Establishment of PMDEC at NIH

1999
  - Doubled resource by 3 year plan from 1997

2001

2004
- Establishment of PMDA

Development of Human Resources

  - (incl. PMDEC, OPSR, JAAME)

Note: Numbers indicated here stand for sum of the officials of Drug and Device Review and Vigilance (including administrators & reviewers)

- MHW
- PMDEC
- OPSR (KIKO)
- JAAME
- MHLW
- PMDA
Drug Development in Japan

Non-Clinical
(Synthesis) (Preparation) (Pharmacology) (Toxicology) etc

Clinical
Phase I
Phase II
Phase III
Phase IV

Review
NDA

Post-Market

Many chances to discuss with PMDA
Numbers of PMDA consultations

- **Application**
- **Conducted**
- **Withdrawal**

<table>
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<th>Year</th>
<th>Application</th>
<th>Conducted</th>
<th>Withdrawal</th>
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<tr>
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● From this April, **New IND Scientific Consultation Process** will be started
  – Increase numbers of meeting to meet a demand by sponsors
  – Meeting in more timely manner
NDA Review Process

- NDA
- Primary Meeting (Applicant & PMDA)
  - Inquiry & Answer
  - Review Report (1)
- Expert Discussion (External Expert & PMDA)
  - Inquiry & Answer
- If necessary
  - Interview Review Meeting (PMDA, External Experts & Applicant ± specialists)
- Submit final PMDA review report
- Approval

MHLW

MHLW Council
(Pharmaceutical Affair and Food Sanitation Council)
Thank you for your attention.

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