Regulatory use of innovative tools in drug development

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Innovation & Regulatory Experiences

Applicable for regulatory use

More scientific data

More regulatory experience

Immature

Science

Mature

Many

Regulatory experience

Less
PMDA’s approaches to promote scientific innovation in drug development

- Encouraging an exploratory use in drug development
  - Formal/informal scientific discussion
    - Scientific consultation
    - Scientific conference/workshop

- More cooperation with academia
  - Science Board
  - Human resource exchange program
  - Collaborative graduate school program
Recent PMDA’s initiatives to advance “Regulatory Science”
PMDA Science Board

Basic Research
Seeds of medical products discovered in Japan
Discovery in Basic research e.g; iPS

Practical Use
Innovative Medical Products
e.g.; HAL
iPS-derived products

Office of Review Innovation

Science Board

Board Member

Academia

Office of Review; Drugs, Biologics, Medical Devices
Review
Scientific Consultation
Non-Clinical
Clinical
Quality
NDA
Approval
Post Market
PMDA
Pharmaceutical Affair Consultation

Pharmaceuticals & Medical Devices Agency

PRS Workshop, Boston, May 23th 2013
Collaborative Graduate School Program

PMDA

Collaboration

Joint Graduate School agreement

Graduate School

- PMDA Staff
  - Visiting Professor (Lecture in regulatory science)
  - Graduate student (Ph.D. program); Research in University

- University student
  - Graduate student (Ph.D. program); Research in PMDA

The agreement with 17 Universities (as of March 2013)
Regulatory Science Research &
Human Resource Exchange Program
(for developing innovative drug, device, cell & tissue products for practical use)

- Proactive establishment of the guideline and standards
- Promoting development using innovative techniques

Outcome of research:
- Improving a quality of review and other services in PMDA
- Learning a state-of-the-art technology
- Effective research & development for regulatory approval
- Training in regulatory science
Research funds for developing innovative drug, device, cell & tissue products for practical use
Regulatory Science Bridge

Stronger & More Complete Regulatory Science Bridge will help us in the future drug developments

Information

- HOMEPAGE (English)

- Regulatory Science Page
  http://www.pmda.go.jp/regulatory/index.html

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Thank you for your attention