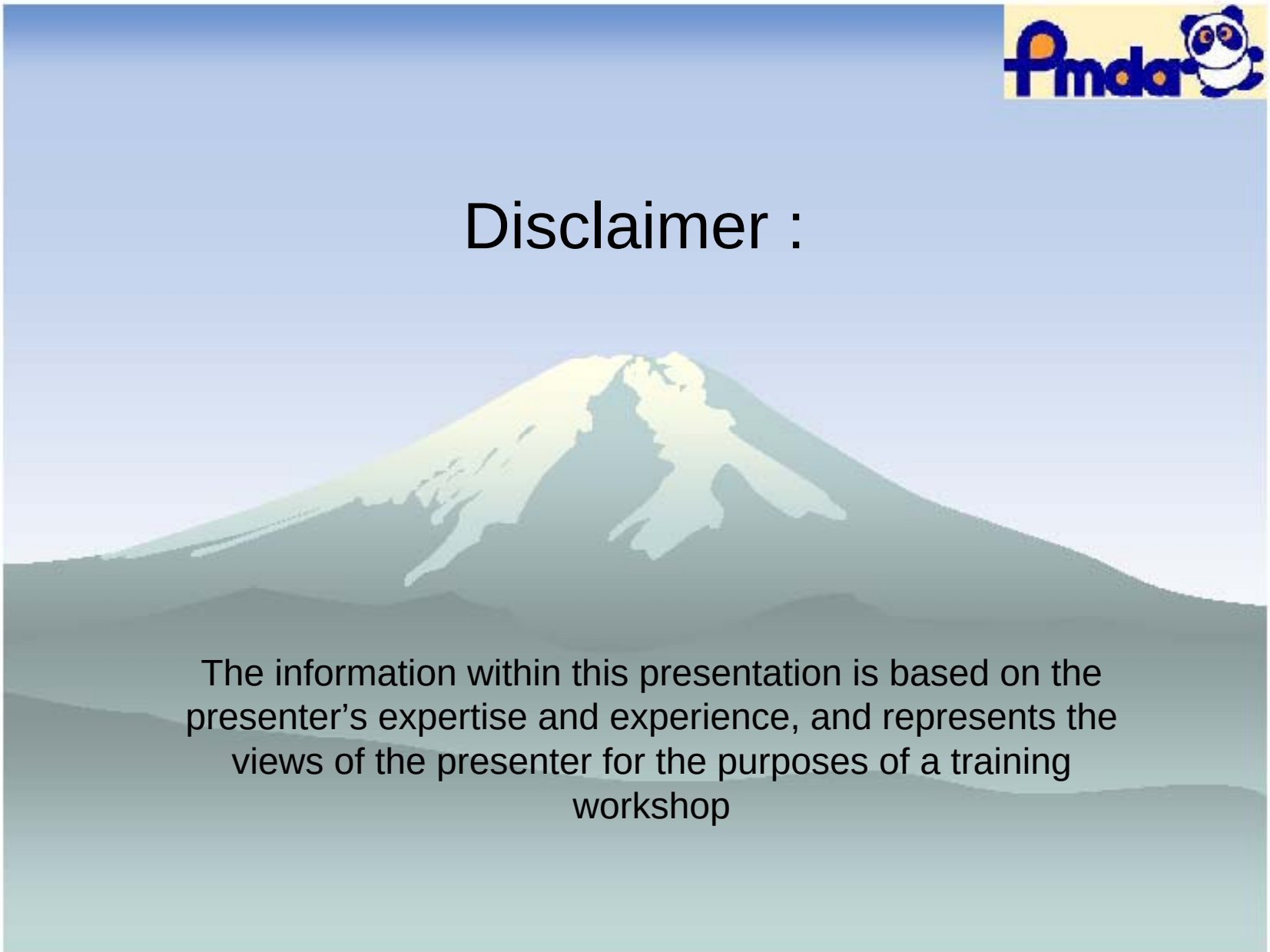
4.3 Qualification Expertise in Japan

Junko Sato, PhD

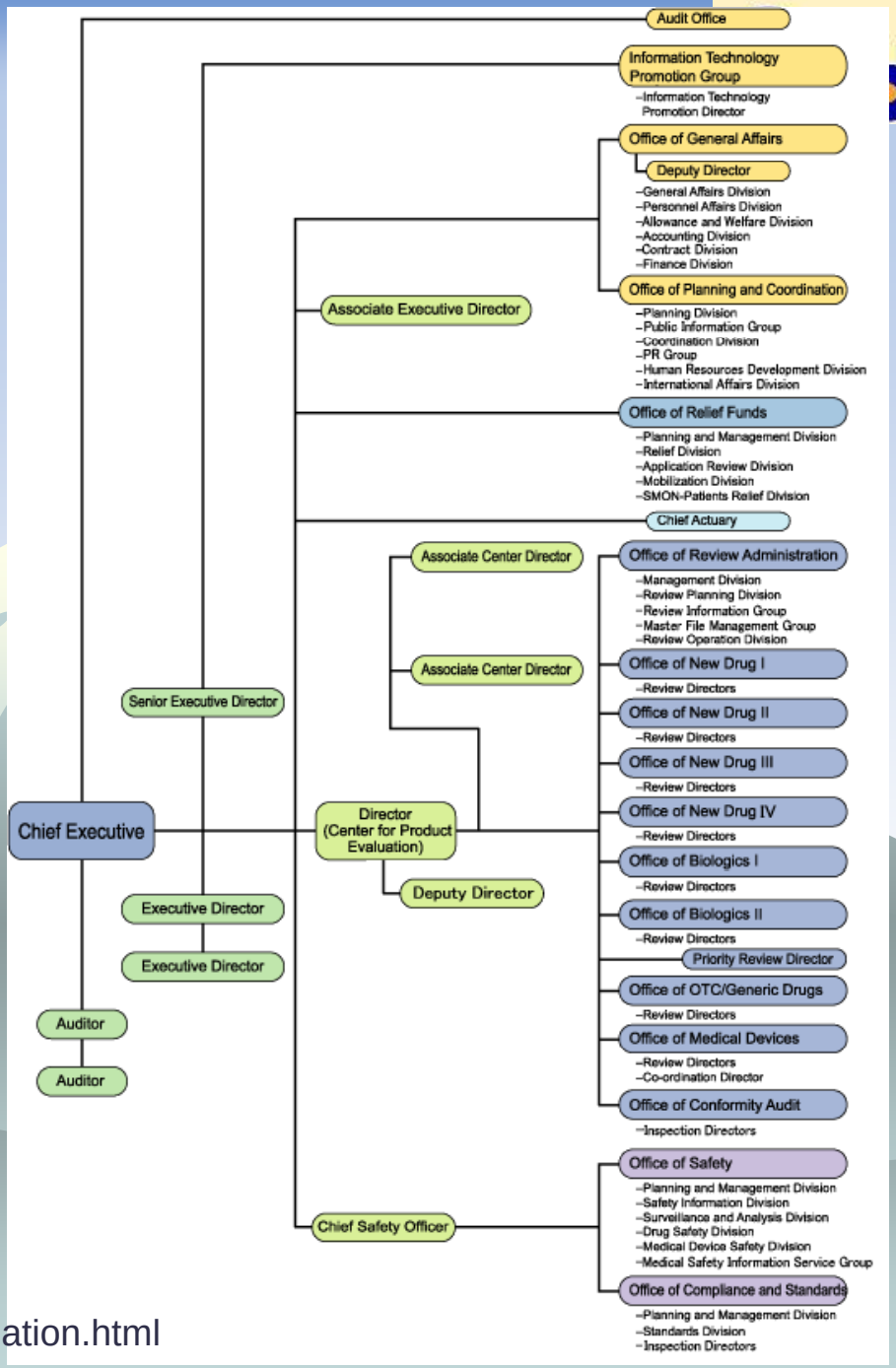
Review Director, Office of New Drug I



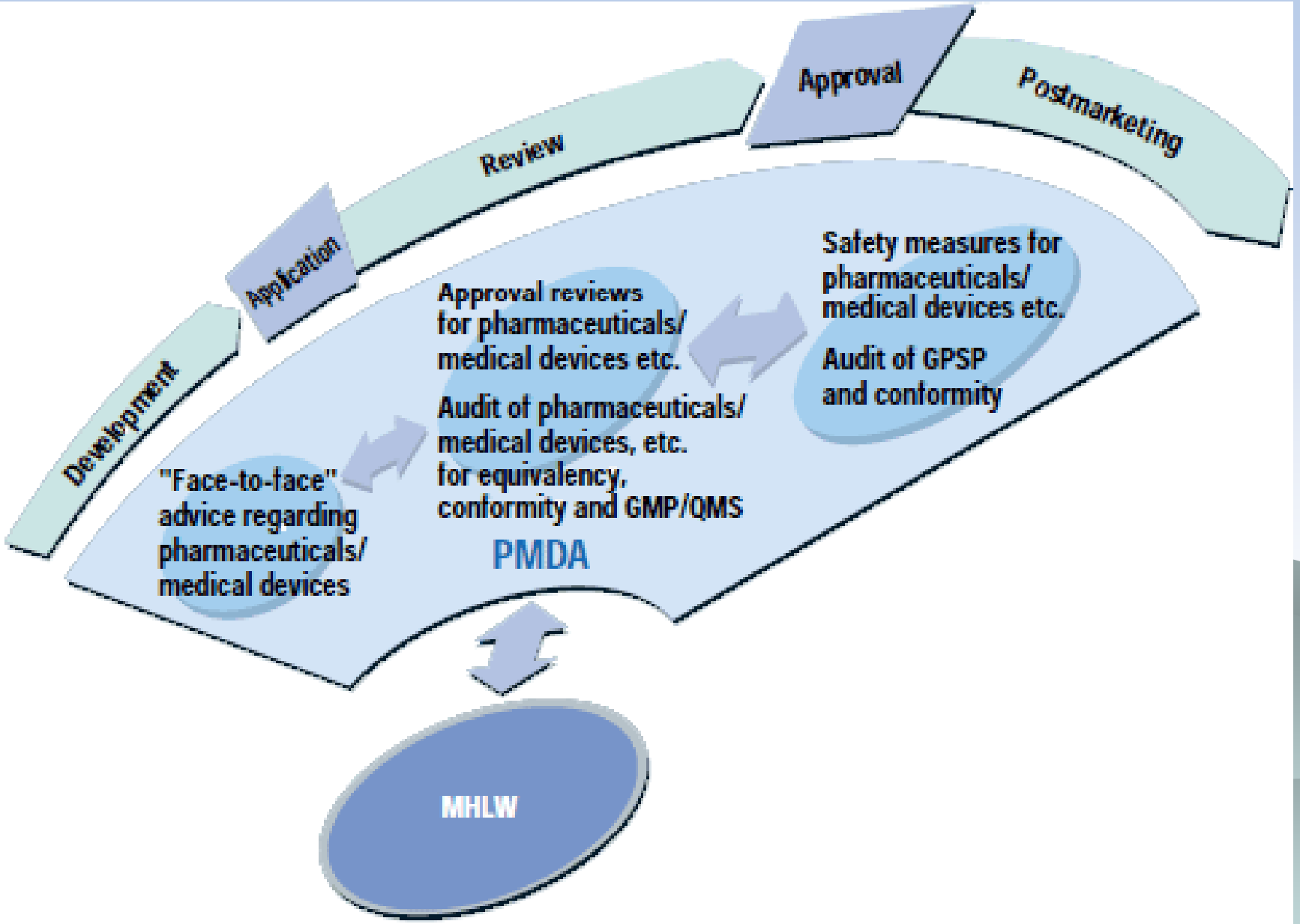
Disclaimer :

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

Organization of PMDA



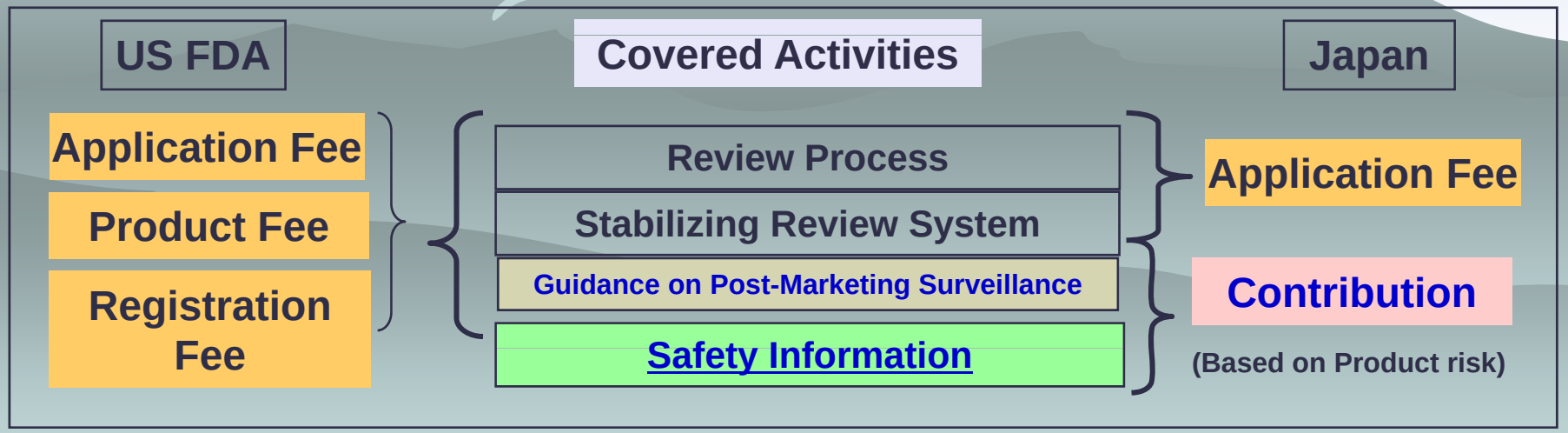
http://www.pmda.go.jp/english/about/organization.html


Development
Application
Review
Approval
Postmarketing
"Face-to-face" advice regarding pharmaceuticals/ medical devices
Approval reviews for pharmaceuticals/ medical devices etc.
Audit of pharmaceuticals/ medical devices, etc. for equivalency, conformity and GMP/QMS
PMDA
Safety measures for pharmaceuticals/ medical devices etc.
Audit of GPSP and conformity
MHLW

Comparison of Number of Reviewer, Fees

	Japan 2003	Japan 2008 (prospect)	US	UK (Drugs only)	France	EMEA
Number of reviewer	183	292 IAA inspection Safety operation	2,600	436	950	248
Application fee, etc	3.4 billion-yen	7.3** billion-yen	32 billion-yen	6.6 billion-yen	6.7 billion-yen	10.2 billion-yen

＊ Total of MHLW HQ, PMDA, ＊＊Total of Application fee and contribution



3 major Operations

Review and Audit for Drugs/ Medical Devices Efficacy and Safety

- Clinical Trial Consultation
- Review of Efficacy and Safety
- Conformity Audit for Application Materials of GLP,GCP and GMP

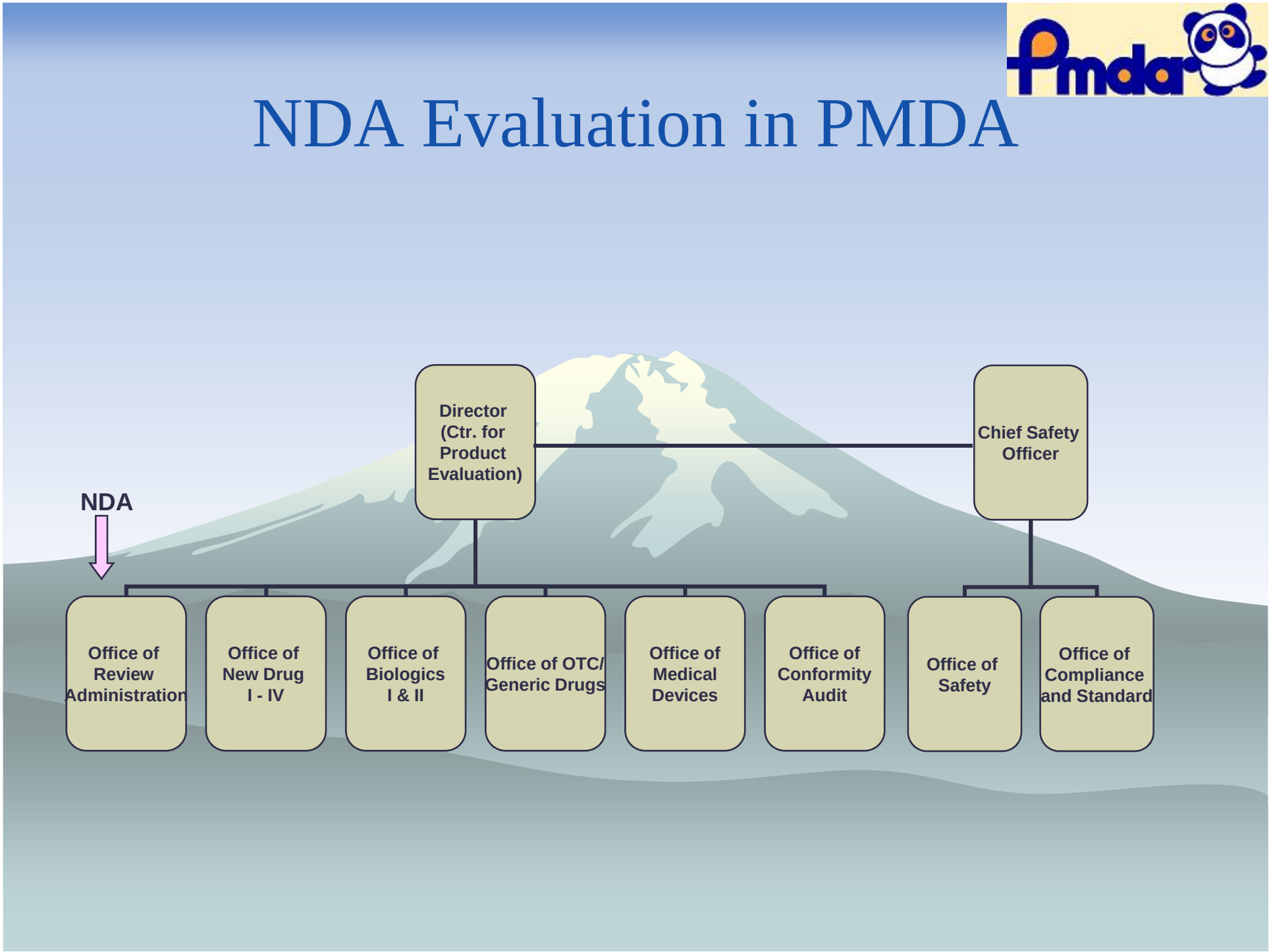
Post-marketing **Safety** Operations for Drugs/ Medical Devices

- Reinforced Safety Information (Database)
- Scientific Review and Research for Safety Information
- Information Provision (via the Internet), Pharmaceutical Consultation for Consumers

Relief Service for ADR and Other Infectious Disease

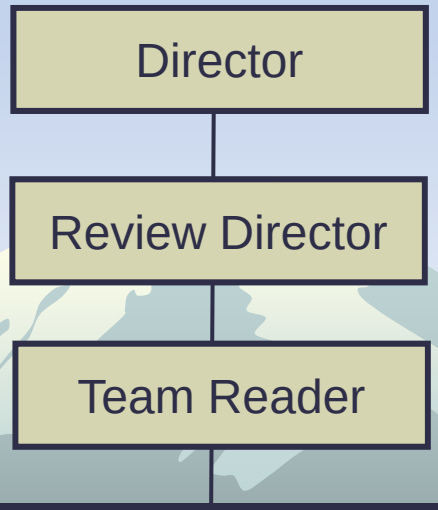
- Provision of Medical Expenses, Disability Pensions etc.
- Relief Service for SMON, HIV-positive and AIDS patients

NDA Evaluation in PMDA



Organization of Office

Team Member



CMC	Pharmacol.	ADME	Tox.	Clin.	Statistician
1	1	1	2	2-3	1-2
Pharmacist			Veterinary	MD	Bio Statistician

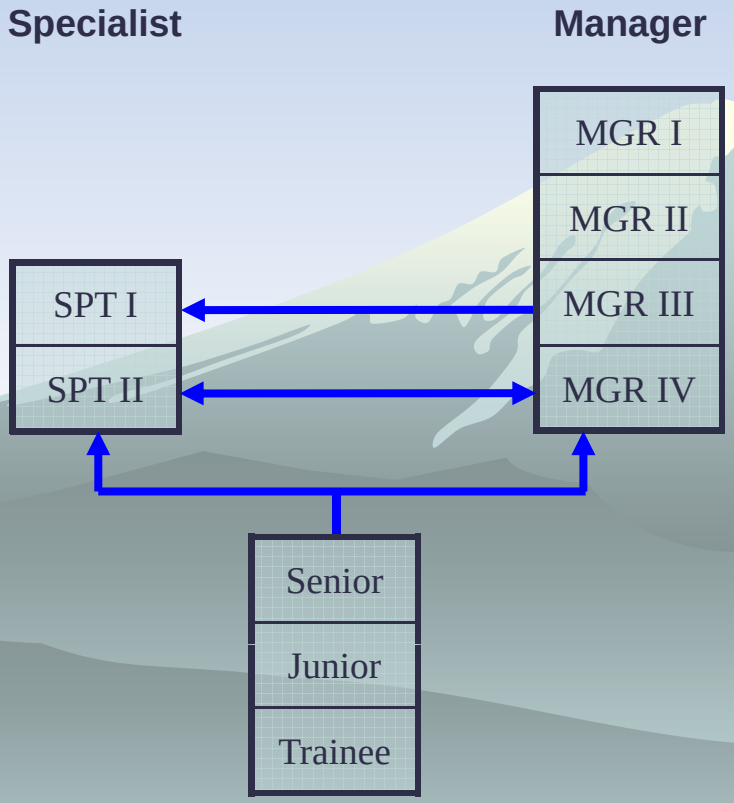
Reviewers

- **Education :** PhD, MS or MD(Dent.D) is required.
- **Knowledge :** Current science, regulations, review process, etc.
- **Abilities :** Communication, make recommendation to consultation & review, English

Previous post

- Academia
  - Research, teach etc.
- Pharmaceutical Industries
  - Research, clinical development etc.
- Students

‘Career Path’ in PMDA (in developing)



Grade	Requirements
MGR Ⅰ	Executive Director, Executive Director, Chief Safety Officer etc.
MGR Ⅱ	Associate Center Director
MGR Ⅲ	Office Director
MGR Ⅳ	Manage review team and resolve problems between teams, Make decisions as a review team, Advises to team and reviewers, manages communication between team and sponsors, contribute to develop guidelines and policies (Review Director, Associate Director etc.)
SPT Ⅰ	Advises from extremely advanced expertise, and bears improvement of judgment, personnel training, knowledge, and technical level, supervise SPT II
SPT Ⅱ	Contributes to teams by knowledge and improvement of technical level based on advanced expertise
Senior	Recommend to review and Consultation with high level acknowledgements, analyze and judge review process
Junior	Contributes to typical and atypical review and consultation with intermediate level acknowledgements
Trainee	Contributes to typical review and consultation under supervise

Manager ? Specialist ?

- What are difference ?
  - Manager
    - Contribute to all job by general consideration
  - Specialist
    - Contribute to job by specialty (cf. CMC, ADME, etc.)

Recruitment and Retention

- To increase reviewers,
  - Introduce our job in universities
  - Advertisement on Science Journal
  - Presentation on our job in scientific conference
- For retention,
  - Make path of reviewers clear
  - Keep incentive

Training for reviewers in PMDA

- Training
  - Review Skills
    - Basic process/Legislation
    - Case studies
    - Scientific Seminar
  - IT skills
    - Review Database
    - Word etc.
  - Writing Skills
  - Communication skills etc.

Thank you for your attention !