



# IMDRF

International Medical  
Device Regulators Forum

## Japan Update

IMDRF Open Stakeholder Forum  
September 2018



厚生労働省

Ministry of Health, Labour and Welfare





# IMDRF

International Medical  
Device Regulators Forum

## - Regulatory Authorities in Japan -

### MHLW

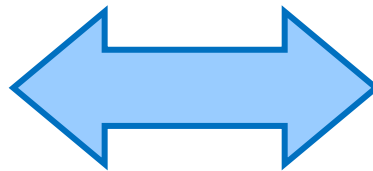
Ministry of Health, Labor and Welfare

- Final Authorization of applications
- Publishing Guidelines
- Advisory committee
- Supervising PMDA Activities

### PMDA






Pharmaceuticals and Medical Devices Agency

- Scientific Review for Drugs & MD
- GCP, GMP Inspection
- Consultation on Clinical Trials etc.





## Medical Device Regulations in Japan

| Classification                              | Class I   | Class II  | Class III  | Class IV  |
|---|---|---|--|---|
| Category                                    | General MDs   | Controlled MDs  | Specially controlled MDs   |   |
| Premarket regulation                        | Self-declaration  | Third party certification   | MHLW approval (PMDA review)  |   |
| Example                                     |  |  |  | <br> |
| Post market safety (vigilance/surveillance) | PMDA and MHLW   |   |  |   |



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# JAPAN UPDATE

1. Discussing Need of Revision
2. Revision of GPSP (utilizing RWD)
3. AI
4. Cyber Security Guidance
5. Others



## 1. Discussing Need of Revision

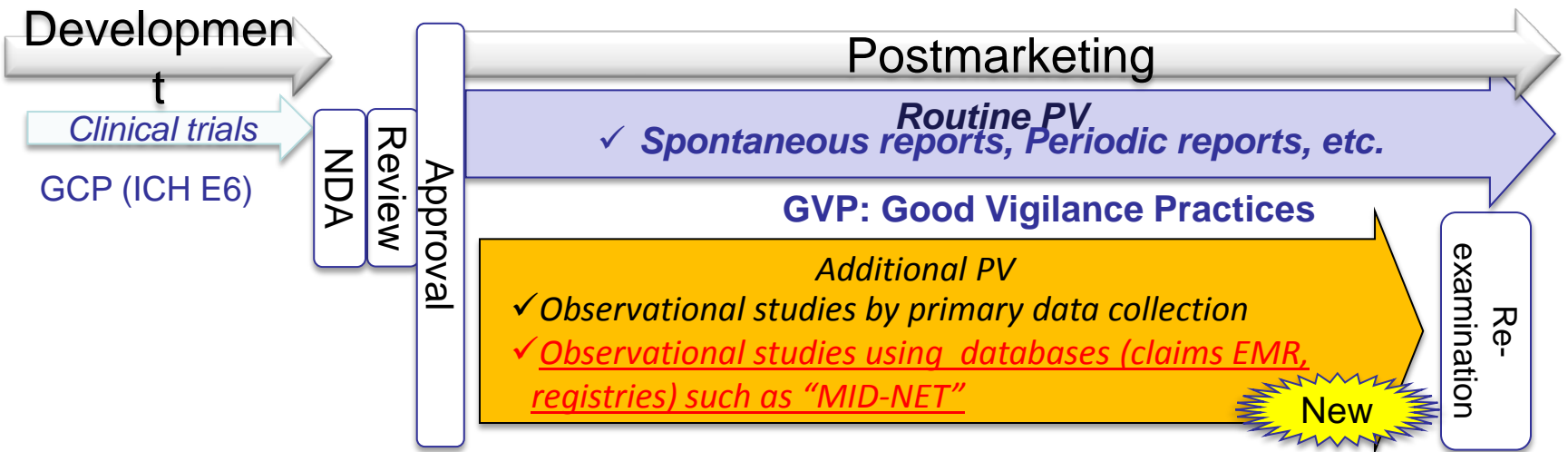
- 5 years will have passed since a big amendment of the Pharmaceutical affairs Act in 2014
- A committee are now reviewing the results of the amendment and discussing points which needs to be revised
- The topics are...
  - Sakigake designation system
  - Approval framework for medical devices
  - QMS audit etc.



## 2. Revised GPSP: Good Post-marketing Study Practices

(Ministerial Ordinance, October 23, 2017)

- GPSP indicates the reliability of required post-marketing studies that MAHs are required to conduct to later apply for approval re-examination.
- GPSP were revised to incorporate a reliability standard for conducting observational studies using **databases such as MID-NET**, effective as of this April.



New GPSP: Good Post-Marketing Study Practices



## 3. AI

- PMDA Science Board AI subcommittee published a paper regarding consideration on reviewing/consultations for medical devices incorporating AI technologies

Regulatory Science on AI-based Medical Devices and Systems K. Chinzei, et. al.  
Advanced Biomedical Engineering 7:118-123, 2018

[https://www.jstage.jst.go.jp/article/abe/7/0/7\\_7\\_118/article/-char/en](https://www.jstage.jst.go.jp/article/abe/7/0/7_7_118/article/-char/en)

- MHLW Expert Consultative group reports consideration of evaluation points for diagnostic imaging products incorporating AI technologies



## 3. AI

- MHLW interests in application of AI in field of Public Health and Medical Service
  - AI conference reported important six fields (Genomic medicine, Diagnostic Imaging, Clinical Decision Support, Drug Development, Dementia Care, and Surgery Support)
  - Succeeding “AI Consortium” are now discussing how to accelerate development and use of AI technologies in field of Public Health and Medical Service





## 4. Cybersecurity

- MHLW has issued Guidance for Cybersecurity of Medical Devices

“Guidance for ensuring cybersecurity in medical devices”

PSEHB/MDED Notification No.0724-1/PSEHB/PSD Notification No.0724-1

July 24, 2018

- Japanese Government is now highly interested in Cybersecurity.



## 5. Others

### PMDA-ATC Medical Devices Seminar 2018, November 12 to 16, 2018

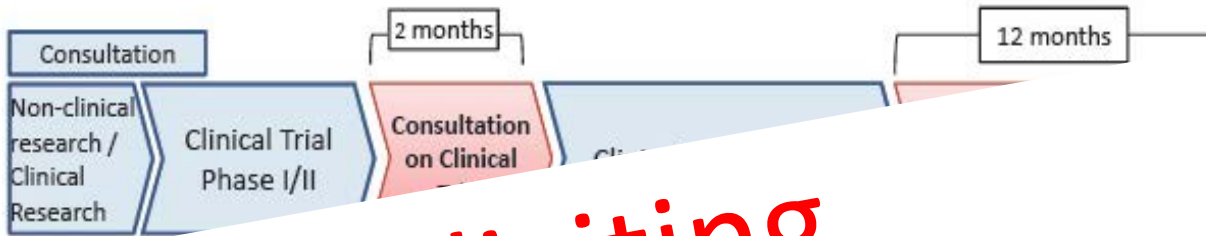
#### Key Seminar Objectives:

1. To learn basics of medical device regulations and regulatory organization
2. To learn the key regulatory flow of the review of medical devices, especially on the following points.
  - Product classifications based on risk
  - Scientific reviews
  - GCP/GLP/QMS/standards
  - Safety measures
3. To have discussions among participants using cases to experience the details of the learnings from lectures
4. To obtain updated information about international medical device activities (utilization of international standards, IMDRF, etc)
5. To observe the efforts at the manufacturing site to comply with the regulation
6. To make use of the learnings / findings from the seminar for the betterment of the regulatory system in the participant's organization.



## SAKIGAKE Designation System

【Ordinal Review】



We are soliciting applications for 4<sup>th</sup> designation from Oct. 1<sup>st</sup> to Nov. 30<sup>th</sup>



※Accept the data of Phase III after the application depending on conditions

⑤ Strengthening post-marketing safety measures (re-evaluation period)



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# Thank you!



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