Session 2
Expectation to International Harmonization from Industry

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International Policy & Strategy Committee, JFMDA

Japanese Industry's Activities for International Harmonization

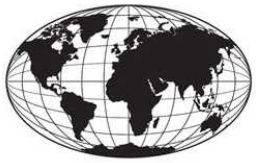
- GHTF
- IMDRF
- AHWP
- APEC
- ISO/IEC

GHTF

- GHTF Mirror Committee in JFMDA
- Committee Members

  MHLW, PMDA, Industry
- Periodical Meeting in Japan
- International WG Meeting
- GHTF Seminar in Japan
- Translation of Guidance Documents for Japanese Industry

IMDRF



IMDRF International Medical Device Regulators Forum

- International Regulatory Subcommittee in JFMDA
- Pre- and Post-Meeting with MHLW/PMDA
  Information sharing of Regulators Meeting
- International Meeting of IMDRF WG
- Regulatory Meeting of GMTA
- Meeting with MHLW/PMDA for Implementation of IMDRF Guidance on PMD Act

AHWP

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

- Send a member to AHWP meeting
- Presentation at AHWP Meeting
- Communication with AHWP at GHTF and IMDRF

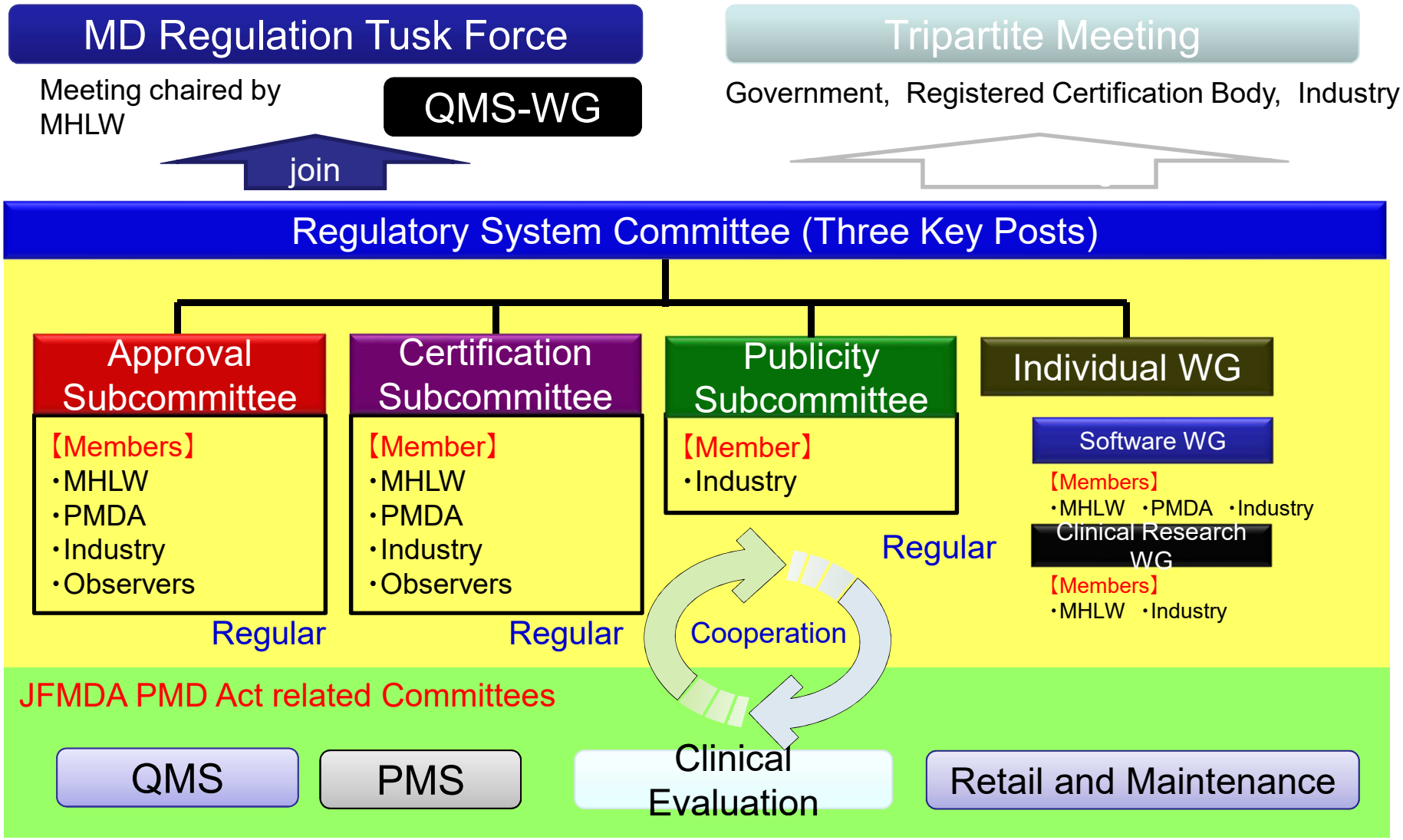
APEC

- Send a member to the Life Sciences Innovation Forum (LSIF) of APEC
- Meeting with MHLW/PMDA
- Meeting of related Committee in JFMDA
- Presentation at APEC

ISO/IEC

- ISO/TC 210 JFMDA
- IEC SC62A JEITA
- Joint Meeting of JFMDA & JEITA
- Debriefing of Japanese ISO/IEC TC's relating to Medical Device Standards
- Meeting with MHLW/PMDA and Regulatory Committees of JFMDA for Implementation of JIS(ISO/IEC) on PMD Act

Organization of Regulatory System Committee

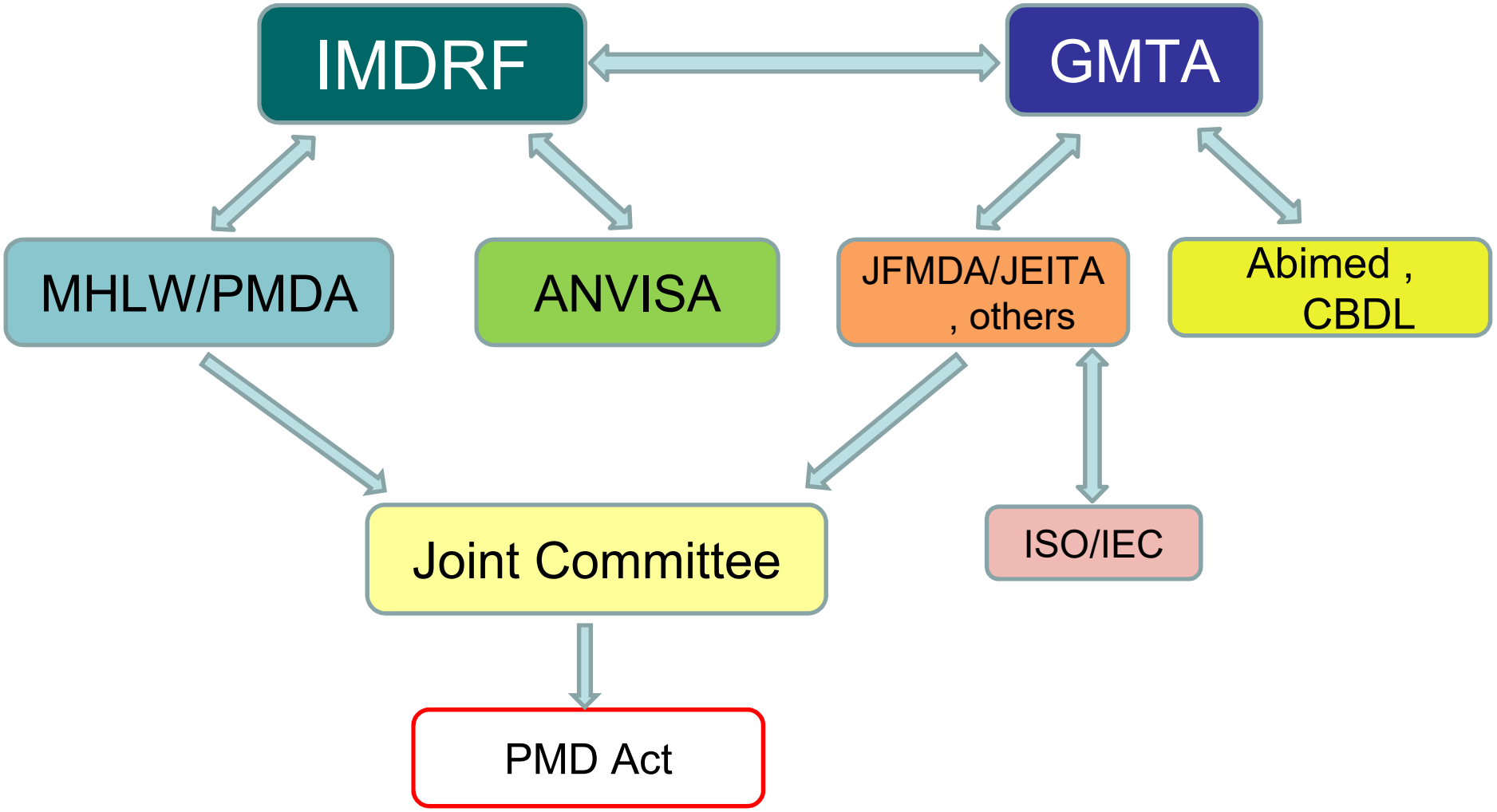


Participants of the regular meeting

Bimonthly

Three Key Posts
Chair (Proceedings), Vice-Chair, Secretary
Government (Honorary members)
MHLW Medical device Products Div. PMDA Office of Medical Device Review, and Standards
Industry members
Observers
JACRE, AMDD, EBC JFMDA: Chairs of QMS Committee, PMS Committee, Clinical Evaluation Committee and Retail and Maintenance Committee JFMDA Secretary

International Harmonization and Japanese Regulation
（Case of IMDRF）



Proposal

- Communication with Abimed and CBDL at GMTA
- Communication of MHLW/PMDA with ANVISA at IMDRF
- Promotion of Implementation of IMDRF Guidance Documents in all countries' regulations

Thank you for your attention.

JFMDA
The Japan Federation of
Medical Devices Associations