

**3rd PMDA Medical Devices Training Seminar Program
(February 15-19, 2016)**

	Monday, Feb. 15 Day 1	Tuesday, Feb. 16 Day 2	Wednesday, Feb. 17 Day 3	Thursday, Feb. 18 Day 4	Friday, Feb. 19 Day 5
10:00 - 12:00	10:00 - 10:15 Welcome Speech Chief Executive	10:00 - 11:00 ⑦ Quality Management System for Medical Devices Office of Manufacturing/ Quality and Compliance	⑫ Academia-Industry-Government Collaboration (Strategic Consultation, Collaboration, etc) Academia, Industry (JFMDA ^{*2}), Office of Review Management, Office of International Programs	⑯ Medical Device Training Facility Tour Office of International Cooperation	⑰ Group Work on Review of Medical Devices #2 Office of Medical Devices
	10:15 - 10:30 ① Overview of Training Program/Schedule Office of International Cooperation				
	10:30 - 11:00 ② Overview of PMDA Office of International Programs				
	11:00 - 12:00 ③ Medical Device/IVD Regulations in Japan Pharmaceutical and Food Safety Bureau, MHLW ^{*1}	11:00 - 12:00 ⑧ Post-marketing Safety Measures for Medical Devices Office of Safety			
Lunch					
13:00 - 15:00	④ Review and Approval of Medical Devices (classification, review process, scientific advices, etc) Office of Medical Devices	13:00 - 14:00 ⑨ Standards for Medical Devices (utilization of international standards, etc) Office of Standards and Guidelines Development	13:00 - 14:00 ⑬ Review and Approval of Medical Devices (combination products, etc) Office of Medical Devices	⑱ Wrap-up Office of International Cooperation	⑱ International Activities on Medical Device Regulations (IMDRF guidelines, etc) Office of International Programs
		14:00 - 15:00 ⑩ Third-party Certification Certification Body	14:00 - 15:00 ⑭ Review of IVD Office of In Vitro Diagnosis		
Break					
15:30 - 17:30	15:30 - 16:00 ⑤ GCP/GLP Inspections Office of Non-clinical and Clinical	15:30 - 18:00 ⑪ Introduction of Medical Device Regulations of Participant's Own Country (15 min. each) Office of International Programs - 15:45 Bahrain - 16:00 Ghana - 16:15 Hong Kong - 16:30 Indonesia - 16:45 Iran - 17:00 Malaysia - 17:15 Myanmar - 17:30 Saudi Arabia - 17:45 Singapore - 18:00 Taiwan - 18:15 India	⑮ Group Work on Review of Medical Devices #1 Office of Medical Devices	⑲ Wrap-up Office of International Cooperation	⑲ Closing Remarks, Presentation of Certificates Chief Executive, Associate Executive Director
	16:00 - 17:30 ⑥ Clinical Trials for Medical Devices Office of Medical Devices				
18:00 - 19:30	Friendly Get-together				

*1 MHLW: Ministry of Health Labour and Welfare

*2 JFMDA: The Japan Federation of Medical Devices Associations