

ASEAN-Japan Medical Devices Regulatory Training 2026

(PMDA-ATC Medical Devices Regulatory Seminar 2026 for AMDC in Jakarta, Indonesia)

(WIB)

Day 1 Wednesday, 1 July	Day 2 Thursday, 2 July
9:00-9:30 Registration	8:30-9:00 Registration
9:30-9:50 <u>Opening Ceremony / Photo Session</u>	9:00-9:50 (Lecture 30min+ QA 20min) <u>Session 5</u> (Industry (AdvaMed)) Post-market Safety Measures by Industry (Utilization of AI)
9:50-10:40 (Lecture 30min+ QA 20min) <u>Session 1</u> (PMDA) Overview of Post-Market Safety Measures for Medical Devices in Japan	Break
Break	10:00-10:40 (Lecture 20min+ QA 20min) <u>Session 6</u> (PMDA) Introduction to MDSAP
10:50-11:40 (Lecture 30min+ QA 20min) <u>Session 2</u> (IMDRF GRRP WG) Medical Device Regulatory Reliance Programs	10:40-11:00 Case Study Guidance
Lunch	11:00-11:30 <u>Session 7</u> (PMDA) Case study (210min) Post-market Safety Measures for Medical Devices - Introduction (30min)
13:00-15:30 (150min) <u>Session 3</u> Round Table Discussion Regulatory Updates of QMS and Post-Market Safety	Lunch
Break	12:30-15:40 <u>Session 7</u> (cont'd) -Group Discussion (90min) -Break (10min) -Group Presentation (60min) -Wrap up + QA (30min)
15:40-16:30 (Lecture 30min+ QA 20min) <u>Session 4</u> (PMDA) QMS Inspection for Medical Devices	15:40-15:50 Feedback of Day 2
16:30-16:40 Feedback of Day 1	15:50-16:00 <u>Closing Ceremony</u>