

PMDA-ATC Medical Devices Webinar 2025 for AMDC

DRAFT Agenda

Date: February 5 2025

Style: On-line (Webex meeting)

Time (JST)	Sessions
14:00 - 14:05	<u>Opening Remarks</u>
14:05 - 15:05	<u>Session 1</u> (Lecture 30m.+Q&A 30m.) Utilization of international standards in Japanese regulation
15:05 - 15:15	Break
15:15 - 16:15	<u>Session 2</u> (Lecture 30m.+Q&A 30m.) Software as a medical device (SaMD)
16:15 - 16:20	<u>Closing Remarks</u>

PMDA: Pharmaceuticals and Medical Devices Agency
AMDC: ASEAN Medical Device Committee