

PMDA-ATC/AMDC Medical Devices Webinar

Date: 25th - 26th August, 2021

Target Participants: all AMDC member countries

Day 1 (Wednesday, 25th August, 2021)

JST	Sessions
14:00-14:10	Opening Remarks
14:10-14:40	Recent topic (e.g. COVID-19 test kits) Lecture (15 min.) Q&A (15 min.)
14:40-15:50	Review of High-Risk Medical Device (Contact Lenses) Lecture (40 min.) I. Essential Principles II. “Approval standard” for high-risk medical devices review III. Medical device review using “approval standard” in Japan Q&A: (30 min.)
15:50-16:50	Review of High-Risk Medical Devices Case study (30 min.) Q&A: (30 min.)
16:50-17:00	Closing of Day 1

Day 2 (Thursday, 26th August, 2021)

JST	Sessions
14:00-15:00	Post market safety measures Lecture (30 min.) I. Overview II. Adverse Event Reporting System Q&A: (30 min.)
15:00-16:00	Lecture (30 min.) III. Examples of post market safety measures in Japan Q&A: (30 min.)
16:00-16:50	International Activities Lecture (25 min.) Q&A (25 min.)
16:50-17:00	Closing Ceremony