

# PMDA-ATC/AMDC Medical Device Webinar 2021

Proposed Date: 25<sup>th</sup> - 26<sup>th</sup> August, 2021

Target Participants: all AMDC member states

(Draft Agenda)

## Day 1 (Wednesday, 25<sup>th</sup> August, 2021)

JST	Sessions
14:00-14:10	Opening Remarks
14:10-14:40	1. Recent topic (e.g. COVID-19 test kits) Lecture (15 min.) Q&A (15 min.)
14:40-15:50	2. Review of High-Risk Medical Devices (e.g. contact lens) 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	3. Case study (30 min.) Q&A: (30 min.)
16:50-17:00	Closing of Day 1

## Day 2 (Thursday, 26<sup>th</sup> August, 2021)

JST	Sessions
14:00-15:00	4. 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	5. International Activities Lecture (25 min.) Q&A (25 min.)
16:50-17:00	Closing Ceremony