

PMDA-ATC Biosimilar Webinar for FDA Philippines

Agenda

Date: 14 December 2023

Time: 13:00-16:25 MST(14:00-17:25 JST)

Style: Virtual meeting

MST	JST	Sessions
13:00 – 13:05	14:00 –14:05	Opening Remarks (Office Director of ATC) Announcement by secretariat
13:05 – 14:05	14:05 –15:05	1. Overview of PMDA review process including biosimilars ◆ Q&A
14:05 – 15:05	15:05 –16:05	2. Biosimilar Regulation and Guidelines in Japan ◆ Q&A
15:05 – 15:20	16:05 –16:20	Break
15:20 – 16:20	16:20 –17:20	3. Case studies for Biosimilars ◆ Q&A
16:20 – 16:25	17:20 –17:25	Announcement by secretariat