

PMDA-ATC

Review of Cell therapy and Gene therapy products Webinar 2024 for PPWG member states

Agenda
Date: June 27 - 28, 2024
Style: On-line (Webex meeting)

Day 1 Thursday, June.27	Day 2 Friday, June.28
14:00 - 14:10 (JST, UTC+9) Opening Remarks	14:00 - 14:45 (JST, UTC+9) Session 5 Review of clinical data - Principle of review for gene and cell therapy products - Post-marketing plan
14:10 - 14:40 Session 1 Overview of review of cell therapy and gene therapy products	14:45 - 15:15 Session 6 Case study of CAR-T (Cell therapy product) - Sharing review points of CAR expressed T cell product for lymphoma
14:40 - 15:25 Session 2 Review of Quality - Features of cell and gene therapy products and its quality - Points to consider for quality assessment	15:15 - 15:45 Session 7 Case study of ocular disease - Sharing review points of several products for ocular disease
15:25 - 15:45 Break (20 min)	15:45 - 16:00 Break (15 min)
15:45 - 16:30 Session 3 Review of non-clinical data Part 1: gene therapy products	16:00 - 16:30 Session 8 Environment risk assessment - Japanese pharmaceutical regulation of genetically modified organisms (Cartagena Act)
16:35 - 17:15 Session 4 Review of non-clinical data Part 2: cell therapy products - Points to consider for non-clinical data assessment - Participants address presented questions	16:30 - 17:15 Session 9 Country Introduction
17:15 - 17:25 Evaluation of Day 1	17:15 - 17:30 Closing Remarks / Evaluation of Day 2 and Overall