PMDA-ATC
Review of Cell therapy and Gene therapy products Seminar 2025 for South-East Asian countries

Agenda
Date: July 15 - 17, 2025
Venue: Tokyo

(JST) As of 2025.3.27

Day 1 Tuesday, July 15	Day 2 Wednesday, July 16	Day 3 Thursday, July 17
9:30-10:00 **Registration**	9:30-10:00 **Registration**	9:30-10:00 **Registration**
10:00-10:20 **Opening Ceremony**	10:00-11:00 **Session 4** **Review of non-clinical data** **Part 1: gene therapy products**	10:00-11:00 **Session 7** **Environment risk assessment** - Japanese pharmaceutical regulation of genetically modified organisms (Cartagena Act)
10:20-11:30 **Session 1** **Overview of review of cell therapy and gene therapy products** - Regulation of cell therapy and gene therapy products in Japan (Safety Act and PMD Act)		
Break (10m)	Break (10m)	Break (10m)
11:40-12:40 **Session 2** **Review of Quality data** - Features of cell and gene therapy products and its quality - Points to consider for quality assessment	11:10-12:10 **Session 5** **Review of non-clinical data** **Part 2: cell therapy products** - Points to consider for non-clinical data assessment - Participants address presented questions	11:10-12:10 **Session 8** **Development of CGT products by industry**
12:40-13:50 **Lunch break**	12:10-13:20 **Lunch break**	12:10-13:20 **Lunch break**
13:50-15:30 **Session 3 (Participants)** **Round table discussion**	13:20-16:00 **Session 6 Case study 1** **Quality data evaluation of the product** - Introduction - Group Discussion	13:20-15:20 **Session 9 Case study 2** **Clinical data evaluation of the product** - Introduction …Principle of review for gene and cell therapy products, Post-marketing plan, Review of clinical data - Group Discussion
Break (10m)	Break (10m)	Break (10m)
15:40-16:10 **Introduction of case studies**	- Group presentation - Q&A, Wrap up	- Group presentation - Q&A, Wrap up
16:10-16:20 **Feedback for Day 1**		15:20-15:30 **Closing ceremony**
16:45-18:00 **Friendly get together**	16:00-16:10 **Feedback for Day 2**	15:30-15:40 **Feedback for Day 3**