

# ACCSQ PPWG - PMDA-ATC Pharmaceutical Review Seminar 2025

## Agenda Dates: October 7 - 10, 2025 Venue: Tokyo

(JST)

As of August 13, 2025

| Day 1<br>Tuesday, October 7                                                        | Day 2<br>Wednesday, October 8                 | Day 3<br>Thursday, October 9                   | Day 4<br>Friday, October 10                        |
|------------------------------------------------------------------------------------|-----------------------------------------------|------------------------------------------------|----------------------------------------------------|
|                                                                                    | 9:00-9:30 <b>Registration</b>                 | 9:00-9:30 <b>Registration</b>                  | 9:00-9:30 <b>Registration</b>                      |
| 9:30-10:00 <b>Registration</b>                                                     | 9:30-10:00 (30m)                              | 9:30-10:20 (50m)                               | 9:30-11:50                                         |
| 10:00-10:20                                                                        | <b><u>Guidance for case studies</u></b>       | <b><u>Session 7</u></b>                        | <b><u>Session 10</u></b>                           |
| <b>Opening Ceremony</b>                                                            |                                               | <b>Structure of Risk Management Plan (RMP)</b> | <b><u>Case study 5: Clinical part 1</u></b>        |
| 10:20-11:10 (50m)                                                                  | 10:00-12:50                                   | 10:20-11:50                                    | Efficacy and safety data evaluation of the product |
| <b><u>Session 1</u></b>                                                            | <b><u>Session 5</u></b>                       | <b><u>Session 8</u></b>                        | - Introduction (50m)                               |
| <b>Overview of new drug review in Japan</b>                                        | <b><u>Case study 1: Quality part</u></b>      | <b><u>Case study 3: Toxicology part</u></b>    | - Group Discussion (90m)                           |
| - Regulations, review process, review system                                       | - Introduction (30m)                          | Toxicology data evaluation of the product      |                                                    |
|                                                                                    | - Group discussion (70m)                      | - Introduction (30m)                           |                                                    |
|                                                                                    | - Group presentations (40m)                   | - Group Discussion(60m)                        |                                                    |
| 11:10-12:00 (50m)                                                                  | - Q&A, Wrap up (30m)                          |                                                |                                                    |
| <b><u>Session 2</u></b>                                                            |                                               |                                                |                                                    |
| <b>Points to consider in evaluation of new drugs</b>                               |                                               |                                                |                                                    |
| 12:00-13:10 <b>Lunch break</b>                                                     |                                               | 11:50-13:00 <b>Lunch break</b>                 | 11:50-13:00 <b>Lunch break</b>                     |
| 13:10-14:00 (50m)                                                                  | 12:50-14:00 <b>Lunch break</b>                | 13:00-14:10                                    | 13:00-15:00                                        |
| <b><u>Session 3</u></b>                                                            | 14:00-15:30                                   | <b><u>Session 8 (Cont'd)</u></b>               | <b><u>Session 10</u></b>                           |
| <b>Structure of PMDA Review Report</b>                                             | <b><u>Session 6</u></b>                       | - Group presentations (40m)                    | <b><u>Case study 5: Clinical part 2</u></b>        |
|                                                                                    | <b><u>Case study 2: Pharmacology part</u></b> | - Q&A, Wrap up (30m)                           | - Group presentations (80m)                        |
| Break (20m)                                                                        | - Introduction (30m)                          | Break (10m)                                    | - Q&A, Wrap up (40m)                               |
| 14:20-16:20 (120m)                                                                 | - Group Discussion(60m)                       | 14:20-15:50                                    | Break (10m)                                        |
| <b><u>Session 4</u></b> (participants)                                             |                                               | <b><u>Session 9</u></b>                        | 15:10-15:20                                        |
| <b>Round table discussion on review issues in ASEAN JA and national assessment</b> |                                               | <b><u>Case study 4: ADME part</u></b>          | <b>Closing ceremony</b>                            |
|                                                                                    |                                               | ADME data evaluation of the product            | 15:20-15:30 Feedback - Day 4, seminar overall      |
|                                                                                    |                                               | - Introduction (30m)                           |                                                    |
|                                                                                    |                                               | - Group Discussion(60m)                        |                                                    |
|                                                                                    | Break (10m)                                   | Break (10m)                                    |                                                    |
|                                                                                    | 15:40-16:50                                   | 16:00-17:10                                    |                                                    |
|                                                                                    | <b><u>Session 6 (cont'd)</u></b>              | <b><u>Session 9 (cont'd)</u></b>               |                                                    |
|                                                                                    | - Group presentations (40m)                   | - Group presentations (40m)                    |                                                    |
|                                                                                    | - Q&A, Wrap up (30m)                          | - Q&A, Wrap up (30m)                           |                                                    |
| 16:20-16:30 Feedback - Day 1                                                       | 16:50-17:00 Feedback - Day 2                  | 17:10-17:20 Feedback - Day 3                   |                                                    |
| 16:45-18:00 <b>Get-together</b>                                                    |                                               |                                                |                                                    |