# PMDA-ATC Pharmaceuticals Review Seminar 2018

Date: June 18-22, 2018

Venue: PMDA office in Tokyo and Manufacturing site in Toyama

Offered by Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC)

| | Day 1 | Day 2 | Day 3 | Day 4 | Day 5 |
|---|---|---|---|---|---|
| AM-1 | 10:00-10:15<br>Opening Ceremony,<br>Seminar Outline | 9:00-9:10 Opening | Manufacturing Site Visit and Lecture by Toyama Prefecture | 9:00-9:10 Opening | 9:00-9:10 Opening |
| | | 9:10-10:00<br>Toxicology Studies,<br>Good Laboratory Practice (GLP),<br>First in Human (FIH) Studies | | 9:10-10:10<br>Review of Generic Drugs | 9:10-10:10<br>Relief Sevices for Adverse Health Effects |
| Break | | 10:00-10:20 Break | | 10:10-10:30 Break | 10:10-10:30 Break |
| AM-2 | 10:15-11:45<br>Outline of PMDA | 10:20-12:00<br>Clinical Trials,<br>Good Clinical Practice (GCP)<br>Inspections | | 10:30-12:30<br>Case Study (Review of Generic Drugs)<br>Explanation, Group Discussion, Presentation and PMDA comment | 10:30-12:00<br>Current Effort by PMDA |
| Lunch | 11:45-13:15 Lunch | 12:00-13:30 Lunch | | 12:30-14:00 Lunch | 12:00-13:30 Lunch |
| PM-1 | 13:15-14:15<br>Start of Clinical Trial to NDA/MAA | 13:30-15:00<br>Review of New Drugs | | 14:00-15:00<br>Review of Biosimilars | 13:30-15:20<br>Current Effort on Chemistry, Manufacturing and Control (CMC) |
| Break | 14:15-14:35 Break | 15:00-15:20 Closing | | 15:00-15:20 Break | 15:20-15:30 Break |
| PM-2 | 14:35-17:35<br>Introduction of Pharmaceutical Regulations by Participants | | | 15:20-16:50<br>Post-marketing Pharmacovigilance | 15:30-16:00<br>Closing Ceremony |
| | 17:35-17:40 Closing | | | 16:50-17:10 Closing | |
| | 18:00-18:30 Group Photo | | | | |
| | 18:30- Friendly Get Together | | | | |