

# PMDA-ATC Pharmaceuticals Review Seminar 2020 in Jakarta, Indonesia

Date: February 13 - 14, 2020

Venue: Hotel Gran Melia Jakarta, Jakarta, Indonesia

## Draft

|       | Day 1 (February 13)  | Day 2 (February 14)  |
|-------|--|--|
| AM    | 9:30-9:45<br>Opening ceremony  | 9:00-10:20<br>7_ Review of New Drugs<br>-from NA-DFC<br>-from PMDA |
|       | 9:45-10:25<br>1_ Introduction of PMDA                                  |  |
|       | 10:25-11:10<br>2_ Introduction of NA-DFC                               |  |
|       | 11:10-11:30 Break  | 10:20-10:40 Break  |
|       | 11:30-12:00<br>3_ Innovative review pathways in Japan                  | 10:40-12:00<br>8_ Review of Generic Drug                           |
| Lunch | 12:00-13:15  | 12:00-13:15  |
| PM    | 13:15-13:45<br>4_ Review of Chemistry, Manufacturing and Control (CMC) | 13:15-14:30<br>9_ Case Study (Clinical Review)                     |
|       | 13:45-14:15<br>5_ Current Effort on CMC from industries' point of view |  |
|       | 14:15-14:30 Q&A  |  |
|       | 14:30-14:50 Break  | 14:30-14:50 Break  |
|       | 14:50-16:40<br>6_ Case Study (CMC)                                     | 14:50-16:00<br>9_ Case Study (Clinical Review, continued)          |
|       |  | 16:00-16:20 Break  |
|       | 16:40-16:50 Closing of Day 1   | 16:20-16:50 Closing Ceremony                                       |