

## PMDA-ATC Pharmaceuticals Review Seminar 2018 in Nay Pyi Taw, Myanmar

Date: October 15-16, 2018

Venue: Park Royal Hotel

### Program

#### Day 1 (Oct. 15)

New time	Theme
10:00-10:15	Opening Ceremony Speech by Dr. Nakashima, PMDA & Professor Dr. Khin Zaw, Myanmar FDA
10:15-11:45	<b>Introduction of PMDA</b>
11:45-13:00	Lunch
13:00-15:00	<ul style="list-style-type: none"> <li>• <b>Introduction of Myanmar FDA</b></li> <li>• <b>Drug Regulation of Myanmar FDA</b></li> <li>• <b>Regulation of Medical Device in Myanmar</b></li> <li>• <b>Post-marketing Activity</b></li> </ul>
15:00-15:15	Break
15:15-16:15	<b>From Clinical Trial to Drug Review / Approval in Japan</b>
16:15-16:30	Break
16:30-17:15	<b>Accelerating Novel Oncology Drug Development in Japan</b> – <b>Current Status and Future Perspectives</b> –
17:15-17:30	Closing of Day 1

#### Day 2 (Oct. 16)

Time	Theme
9:00-10:20	<b>New Drug Review</b> <ul style="list-style-type: none"> <li>• <b>Review Process and Importance of Each Milestone</b></li> <li>• <b>Strategy for Regenerative Products</b></li> <li>• <b>Benefit/Risk Evaluation</b></li> </ul>
10:20-10:40	Break
10:40-12:00	<b>Generic Drug Review</b> <ul style="list-style-type: none"> <li>• <b>BE Evaluation</b></li> <li>• <b>Biowaver</b></li> </ul>
12:00-13:00	Lunch
13:00-14:30	<b>Case Study (Clinical Review)</b>
14:30-14:50	Break
14:50-16:10	<b>Case Study (continued)</b>
16:10-16:30	Closing Ceremony