

PMDA-ATC Pharmaceuticals Review Seminar 2016 in Bangkok, Thailand  
 Date: September 26 - 29, 2016.      Venue: Crowne Plaza Hotel, Bangkok, Thailand

	Day 1 9/26 (Mon)	Day 2 9/27 (Tues)	Day 3 9/28 (Wed)	Day 4 9/29 (Thurs)
AM-1	9:00-9:20 Opening ceremony, group photo	9:00-9:10 Opening	9:00-9:10 Opening	9:00-9:10 Opening
	9:20-10:00 Seminar outline, Self-introduction			9:10-12:00 New drug development Utilization of Asian multi-regional clinical trial for new drug development
Break	10:00-10:20 Break	9:10-12:20 Group discussion (1)	9:10-12:20 Group discussion (2)	<ul style="list-style-type: none"> <li>• 9:10-10:00 Industry's perspective</li> <li>• 10:00-10:50 PMDA's perspective</li> <li>• 11:00-12:00 Discussion</li> </ul>
AM-2	10:20-12:00 Outline of PMDA	* Break during session	* Break during session	* Break during session (10:50-11:00)
Lunch	12:00-13:30 Lunch	12:20-13:50 Lunch	12:20-13:50 Lunch	12:00-13:30 Lunch
PM-1	13:30-16:00 From clinical trial notification to drug review / approval in Japan  * Break during session	13:50-15:00 How to develop an innovative product: <ul style="list-style-type: none"> <li>• Pharmaceutical Affairs Consultation on R&amp;D Strategy</li> <li>• Priority review</li> <li>• Collaboration with AMED</li> </ul>	13:50-14:50 International activity	13:30-15:10 Safety Measures <ul style="list-style-type: none"> <li>• 13:30-14:20 Package insert, RMP</li> <li>• 14:20-15:10 MID-NET</li> </ul>
Break		15:00-15:20 Break	14:50-15:10 Break	15:10-15:30 Break
PM-2	16:00-16:30 Wrap-up	15:20-16:20 Advanced review	15:10-16:30 Introduction of regulations by participants	15:30-16:30 Relief services
		16:20-16:40 Wrap-up	16:30-16:50 Wrap-up	16:30-17:20 Closing ceremony
Evening	17:00- Friendly Get-together			