PMDA-ATC CMC/GMP Seminar 2019 in Hanoi, Vietnam

Date: 9th Oct 2019 Venue: Pullman Hanoi

Agenda:

8:40-9:10	Registration
9:10-9:30	Opening Ceremony, Group Photo
9:30-10:40	Review of Chemistry, Manufacturing and Control (CMC)
	• PMDA (40 min)
	• DAV (20 min)
	• Q&A (10min)
10:40-12:00	Overview of GMP
	• PMDA (50 min)
	• DAV (20 min)
	• Q&A (10 min)
12:00-13:30	Friendly get together
13:30-15:30	Case study –Risk based GMP inspection
	• Outline explanation (25 min)
	• Practice1 Inspection planning (40 min)
	• Practice2 Case study (40 min)
	• Wrap up (15 min)
15:30-16:00	Closing ceremony