6th PMDA Training Seminar – Agenda

Day 1 (Monday, Oct. 19, 2015)

Time	Topic
13:00 - 14:00	Registration Open
14:00 - 14:30	Welcome and Introduction
14:30 - 15:00	Training Overview / Schedule Announcement
15:00 - 15:45	Overview of PMDA
15:45 - 16:15	Break
16:15 - 17:00	Revised Pharmaceutical Affairs Act
17:00 - 17:45	Review of Pharmaceuticals

Day 2 (Tuesday, Oct.20, 2015)

10:00 - 10:45	Clinical Trials and Consultation
10:45 - 11:30	GCP
11:30 - 12:15	GMP
12:15 - 13:15	Lunch on Your Own
13:15 - 14:00	Japanese Pharmacopoeia/Master File System
14:00 - 14:45	Overview of Post-marketing Safety Measures for Pharmaceuticals
14:45 - 15:15	Break
15:15 - 16:00	Safety Information (including Adverse Drug Reaction Reports and Risk Communication)
16:00 - 16:45	Risk Management Plan

Day 3 (Wednesday, Oct. 21, 2015)

10:00 - 10:45	Pharmacoepidemiology for Safety Measures
10:45 - 11:30	Evaluation of Adverse Drug Reaction Reports
11:30 - 13:15	Lunch on Your Own
13:15 - 17:00	Group Work 1
17:00 - 18:00	Wrap up: Group Work 1

Day 4 (Thursday, Oct. 22, 2015)

10:00 - 10:45	Early Post-marketing Phase Vigilance and The Yellow Letter / Blue Letter
10:45 - 11:30	PMDA'S Initiatives for Safety Evaluation (including Utilize Electronic Healthcare Data and MID-NET Project)
11:30 - 13:15	Lunch on Your Own
13:15 - 17:00	Group Work 2
17:00 - 18:00	Wrap up: Group Work 2

Day 5 (Friday, Oct. 23, 2015)

10:00 - 12:00	Relief Services
12:00 - 13:00	Lunch on Your own
13:00 - 15:00	Case Study of Relief Services
15:00 - 16:00	Wrap up of the Training Seminar