PMDA-ATC Pharmacovigilance Webinar 2024

Agenda
Date: February 26 - 29 2024
Style: Live Sessions (Webex meeting)

Time (JST)	Day 1 Monday, Feb. 26	Day 2 Tuesday, Feb.27	Day 3 Wednesday, Feb. 28	Day 4 Thursday, Feb. 29
14:00	14:00-14:10 **Opening Remarks**	14:00-16:20 **Session 4** (Group Work 1) ADR Case Evaluation/Identification of safety specification - Brief Introduction (10min) - Group Discussion (60min) - Break (10min) - Group Presentation (30min) - Q&A / Wrap up (30min)	14:00-16:20 **Session 5** (Group Work 2) Risk Management Plan - Brief Introduction (10min) - Group Discussion (60min) - Break (10min) - Group Presentation (30min) - Q&A / Wrap up (30min)	14:00-15:30 **Session 6** (Case study) Pharmacovigilance Methods (signal detection) - Introductory Lecture (40min) - Brief Introduction (5min) - Group Discussion (30min) - Q&A / Wrap up (15min)
	14:10-15:00 **Session 1** (Lecture 30m.+Q&A 20m.) Evaluation of Benefit/Risk Balance throughout Product Lifecycle, Assessment of Effectiveness of Risk Minimization Activities			
	15:00-15:50 **Session 2** (Lecture 30m.+Q&A 20m.) End-to-End Labeling process: CCDS/CCSI Labeling System, Electronic Labeling Initiatives, patient centric labeling/health literacy			15:30-15:40 Break
	15:50-16:00 Break			15:40-16:50 **Session 7** Utilizing Real world Data - Real world Data and Real world Evidence (Lecture 20min) - Q&A (15min) - Quality Assurance of Real world Data (Lecture 20min) - Q&A (15min)
	16:00-16:30 **Session 3** (Lecture 10m) Group Work Introduction			
	16:30-16:40 Evaluation Form (Day 1) Due	16:20-16:30 Evaluation Form (Day 2) Due	16:20-16:30 Evaluation Form (Day 3) Due	16:50-17:00 **Closing Remarks**
	16:40-17:10 Startup meeting for Group Work	16:30-17:00 (optional) Free Study Room for Group Work 2	16:30-17:00 (optional) Free Study Room for Case Study	17:00-17:10 Evaluation Form (Day 4) Due