PMDA-ATC Quality Control (Herbal Medicine) Webinar 2020

Date: September 9-11, 2020　　Venue: Online

1. Pre-Live Self-learning

Date	Type	Session	Title	Duration
Sep. 2 - 7	E-learning	#3.1	Review Team	2 min
		#3.2	Application Dossier	3 min
		#3.3	Review Process	3 min
	Pre-recorded Lectures	Session 1.1	Overview of regulations on Herbal Medicines in Japan	20 min
		Session 2.1	Quality Evaluation of Crude Drugs (Herbal Drugs)	20 min
		Session 3.1	Evaluation process and GMP inspection by prefectural authorities	20 min
		Session 4.1	Regulation and Review Process of OTC Drugs	20 min
		Session 5.1	Japanese Pharmacopoeia (JP), Japanese Standards for Non-Pharmacopoeial Crude Drugs (Non-JP Crude Drug Standards)	30 min
		Session 6.1	Approval Standards for Over-the-Counter Kampo Medicines and Crude Drug Preparations	30 min
		Session 7.1	Quality Management and Manufacturing Management of Crude Drugs and Herbal Medicines	30 min
Sep.7 (9:00 JST)	Mini-test/ Evaluation Form/ Questionnaire Due			

2. Live Sessions (Webex Training)

JST (UTC)	**Day 1** Wednesday, Sep. 9	**Day 2** Thursday, Sep. 10	**Day 3** Friday, Sep. 11
14:00 (05:00)	14:00-14:15 Opening Remarks 14:15-14:30 (Q&A 15min) **Session 1.2** Overview of regulations on Herbal Medicines in Japan	14:00-14:15 (Q&A 15min) **Session 4.2** Regulation and Review Process of OTC Drugs	14:00-14:15 (Q&A 15min) **Session 7.2** Quality Management and Manufacturing Management of Crude Drugs and Herbal Medicines
14:30 (05:30)	14:30-14:45 (Q&A 15min) **Session 2.2** Quality Evaluation of Crude Drugs (Herbal Medicine)	14:30-14:45 (Q&A 15min) **Session 5.2** Japanese Pharmacopoeia (JP), Japanese Standards for Non-Pharmacopoeial Crude Drugs (Non-JP Crude Drug Standards)	14:30-15:00 (Facility's video 20min / Q&A 10min) **Session 8** Efforts of the Center for Medicinal Plant Resources
15:00 (06:00)	15:00-15:15 (Q&A 15min) **Session 3.2** Evaluation process and GMP inspection by prefectural authorities	15:00-15:15 (Q&A 15min) **Session 6.2** Approval Standards for Over-the-Counter Kampo Medicines and Crude Drug Preparations	15:00-15:30 (Facility's video 20min / Q&A 10min) **Session 9** Overview of the manufacturer (Storage of the raw materials crude drugs)
			15:30-15:45 Closing Remarks
17:00 (07:00)	Evaluation Form (Day 1)Due	Evaluation Form (Day 2) Due	Evaluation Form (Day 3) Due

as of July 27, 2020