

# PMDA-ATC Quality Control (Herbal Medicine) Webinar 2021

Live Sessions: Jun. 22 to 24

May 26, 2021

JST (UTC)	Day 1 Tuesday, Jun. 22	Day 2 Wednesday, Jun. 23	Day 3 Thursday, Jun. 24
14:00 - ( 5:00 - )	14:00 - 14:10 Opening Remarks	14:00 - 14:50 (Lecture 30min / Q&A 20min)	14:00 - 16:20
	14:10 - 14:35 (Lecture 15min / Q&A 10min) <u>Session 1</u> Overview of regulations on Herbal Medicines in Japan	<u>Session 4</u> Quality Management and Manufacturing Management of Crude Drugs and Herbal Medicines	<u>Session 7</u> Case study - Approval of herbal medicines based on the approval standards -  14:00 - 14:10 (Lecture 10min) Overview of Japanese Pharmacopoeia and Approval Standards for Over-the-Counter Kampo Medicines and Crude Drug Preparations
15:00 - ( 6:00 - )	14:35-15:25 (Lecture 30min / Q&A 20min) <u>Session 2</u> Quality Evaluation of Crude Drugs (Herbal Medicine)	14:50-15:10 (Facility's video 20min) <u>Session 5</u> Overview of the manufacturer (Storage of the raw materials crude drugs)	14:10 - 14:20 - Case Study Introduction
	15:25-16:00 (Facility's video 20min / Q&A 15min) <u>Session 3</u> Efforts of the Center for Medicinal Plant Resources	15:10 - 16:40 <u>Session 6</u> Case study - GMP Inspection for Herbal Medicines	14:20 -15:20 - Group Discussion  15:20 -15:50 - Group Presentation
16:00 - ( 7:00 - )		15:10 - 15:20 - Introduction  15:20 -16:20 - Group Discussion  16:20 -16:40 - Q&A and Wrap up	15:50 - 16:20 - Q&A and Wrap up
			16:20 - 16:30 Closing Remarks
	Evaluation Form (Day 1) Due	Evaluation Form (Day 2) Due	Evaluation Form (Day 3) Due