Regulatory Affairs Module 4

The Regulatory Affairs Environment in Japan

Date:	December 3-5, 2025
Venue:	Atrium, Lersø Parkallé 101, DK-2100 Copenhagen
Course Leaders:	Ann Christine Korsgaard, CEO, Regulatory Executive, Ozack ApS, Maiken Kongstad, Head of Regulatory Affairs, LEO Pharma A/S Masami Tamura, President and CEO, CoreMed Corporation (Japan)
Atrium:	Lone Rex, Educational Programme Leader & Mette Ribergaard Rasmussen, Client Manager

DAY 1 – Wednesday, December 3, 2025		
08.30 – 09.00		**Breakfast and registration**
09.00 – 09.30		**Welcome and setting the scene** • Welcome to Atrium • Introduction to the Japanese regulatory affairs environment • Cultural awareness *Atrium, Course leaders, Participants*
09.30 – 10.15		**Japan´s regulatory overview** • Background information on Japan • Introduction to pharmaceutical regulatory systems *Lecturer. Ms. Shohko Sekine, Deputy Division Director, Office of Asia Training Center and International Cooperation, PMDA*
10.15 – 10.45		**Break**
10.45 - 11.30		**Review of new drugs in Japan** • Review process • Type of approval • Designation for orphan, SAKIGAKE and specific use drugs • Post-marketing (risk manager, risk management plan and re-examination.) *Lecturer – Ms. Shohko Sekine, Deputy Division Director, Office of Asia Training Center and International Cooperation, PMDA*

11:30 – 12:00		**Pricing and Reimbursement** • Summary of drug pricing in Japan • Brief overview of National Health Insurance *Lecturer – Ms. Makiko Nahata* *Director, Pricing & External Affairs, Japan Access & Value* *Pfizer Japan Inc.*
12.00 – 13.00		**Lunch**
13.00 – 14.30		**How to include Japan in Global Development** • Bridging strategy/Japanese P1 trials • Ethnic factors • Number of Japanese subjects • Early steps for the Regulatory Strategy showing opportunities *Lecturer –* *Mr. Yoshiaki Hattori, Senior Scientist, Research and Development Planning, CoreMed Corporation*
14.30 – 15.00		**Break**

15.00 - 16.00		**PMDA consultations**
		
		• Types (categories) of consultation
		• Procedures of consultation meetings (from request to official minutes)
		• Points to consider preparing meetings:
		  ○ Briefing documents
		  ○ Ethnic Factors
		  ○ Number of Japanese subjects in a global study
		  ○ Pediatric development
		  ○ Etc.
		
		Lecturer – Ms. Fumi Sakai, Senior Specialist, Regulatory Affairs, CoreMed Corporation

16:00 – 16:30		**Case study - Success story in PMDA meeting** *Lecturer – Ms. Cheryl Madsen, President and CEO, RPM Strategic Solutions, LLC*
16:30 – 17:30		**Japanese new drug application** • Types of applications and evaluation • Structure and content of J-CTD • Japan specific requirements (overview: reliability, standards, Evaluation data/Reference data) • NDA approval process

		• Japan specific requirements (e.g. safety data presentation) *Lecturer – Ms. Fumi Sakai, Senior Specialist, Regulatory Affairs, CoreMed Corporation*
17.30 - 18.30		**Networking // Tapas Lersø Parkallé**

DAY 2 – Thursday, December 4, 2025		
08.30 – 09.00		**Light breakfast**
09.00 - 09.15		**Short summary of day 1 and introduction to day 2** *Course leaders*
9.15-10.00		**GCP and Clinical trial notification in Japan** • Japanese GCP • In-Country Clinical Trial Caretaker / CRO • Format and contents of the CTN • CTN review process & timelines • Amendments to CTN *Lecturer – Satomi Kanayama, Deputy Director, Regulatory Affairs Department, A2 Healthcare Corporation*
10.00 -10.45		**Clinical studies in Japan** • Japanese guidelines of clinical studies • Requirements for IMP (labeling, GMP, import procedures) • Procedures/Requirements for each stage of clinical studies (clinical operations) *Lecturer – Hiroko Inoue, Director, Project Management Department, A2 Healthcare Corporation*
10.45 - 11.15		**Break**
11.15 - 12.15		**Non-clinical documentation and requirements** • Japan specific requirement • Frequently found gaps/issues *Lecturer –* *Mr. Yoshiaki Hattori, Senior Scientist, Research and Development Planning, CoreMed Corporation*
12.15 – 13.15		**Lunch**

13.15 – 15.15		**CMC for J-NDA – Highlights that global RA and CMC RA need to know** • Introduction • Key items (approval application form, GMP inspection, FMA, release testing, J-DMF, compliance review, GQP, JAN, standards for bio-derived raw materials etc.) • Relationship of key items in the J-NDA • Adherence of approved application form • Frequently found gaps/issues *Lecturer -* *Ms. Chiaki Nakanishi, Senior Specialist, CMC, CoreMed Corporation*
15.15 – 15.45		**Break**
15.45– 16.30		**Compliance Inspection** • What is Compliance Inspection • Documents required • How the Compliance Inspection conducted *Lecturer –* *Mr. Yoshiaki Hattori, Senior Scientist, Research and Development Planning, CoreMed Corporation*
16.30 - 17.30		**Group work** *Course leaders*

DAY 3 – Friday, December 5, 2025

08.30 – 09.00	**Light breakfast**
09.00 – 09.15	**Short summary of day 2 and introduction to day 3** *Course leaders*
09.15 – 10:00	**eData submission (CDISC)** • Japan specific requirements • Scope of eData submission • Points to consider *Lecturer to – Emi Nakamura, CDISC and eCTD Specialist, Datascience Solution Department, A2 Healthcare Corporation*
10:00 – 10.30	**eCTD** • eCTD V4.0 experience in Japan - Major Changes from 3.2.2 to 4.0 • Points to consider *Lecturer– Emi Nakamura, CDISC and eCTD Specialist, Datascience Solution Department, A2 Healthcare Corporation*
10.30 – 11.00	**Break**
11:00 – 11.30	**Labelling** • Japanese Package Insert (J-PI) • J-PI revision *Lecturer – Ms. Fumi Sakai, Senior Specialist, Regulatory Affairs, CoreMed Corporation*
11.30 – 12.00	**Pharmacovigilance in Japan** *Lecturer – Ms. Fumi Sakai, Senior Specialist, Regulatory Affairs, CoreMed Corporation*
12.00 - 13.00	**Lunch**
13:00 – 13.45	**Case study - Success story in JNDA** *Lecturer to be confirmed –*

13.45 - 14.45		**Group work** *Course leaders*
14.45 – 15.15		**Rounding up and goodbye** *Course leaders, Participants, Atrium*