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, VP, Head of Regulatory Affairs, Antag Pharmaceuticals & Masami Tamura, President and CEO, CoreMed Corporation (Japan)
Atrium:	Lone Rex, Head of the Scientific Team & Louise Hansen, Client Manager

DAY 1 – Wednesday, December 3, 2025		
08.45 – 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 *Ms. Shohko Sekine, Deputy Division Director, Office of Asia Training Center and International Cooperation, PMDA*
10.15 – 10.30		**Break // Coffee, Tea and a snack**
10.30 - 11.15		**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) *Ms. Shohko Sekine, Deputy Division Director, Office of Asia Training Center and International Cooperation, PMDA*

11.15 – 11.25		**Break**
11.25 - 12.10		**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 *Mr. Yoshiaki Hattori, Senior Scientist, Research and Development Planning, CoreMed Corporation*
12.10 – 13.00		**Lunch**
13.00 - 13.45		**How to include Japan in Global Development - *continued*** *Mr. Yoshiaki Hattori, Senior Scientist, Research and Development Planning, CoreMed Corporation*
13.45 – 13.55		**Break**

13.55 - 14.55		**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.
		
		Ms. Fumi Sakai, Senior Specialist, Regulatory Affairs, CoreMed Corporation

14.55 – 15.10		**Break // Coffee, Tea and a snack**
15.10 - 16.10		**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) *Ms. Fumi Sakai, Senior Specialist, Regulatory Affairs, CoreMed Corporation*

16.10 - 16.20		**Break**
16.20 - 16.55		**Pricing and Reimbursement** • Summary of drug pricing in Japan • Brief overview of National Health Insurance *Ms. Makiko Nahata, Director, Pricing & External Affairs, Japan Access & Value Pfizer Japan Inc.*
16.55 - 17.00		**Bio break**
17.00 - 17.30		**Case study - Success story in PMDA meeting** *Ms. Cheryl Madsen, President and CEO, RPM Strategic Solutions, LLC* ***(online)***
17.30 - 18.30		**Networking // Tapas**

DAY 2 – Thursday, December 4, 2025

08.45 – 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 *Ms. Minori Kuto, Regulatory Affairs Staff, Regulatory Affairs Department, A2 Healthcare Corporation* ***(online)***
10.00 – 10.10		**Break // Coffee, Tea and a snack**
10.10 -10.55		**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) *Ms. Hiroko Inoue, Director, Project Management Department, A2 Healthcare Corporation* ***(online)***
10.55 - 11.10		**Break**
11.00 - 12.00		**Non-clinical documentation and requirements** • Japan specific requirement • Frequently found gaps/issues *Mr. Yoshiaki Hattori, Senior Scientist, Research and Development Planning, CoreMed Corporation*
12.00 – 12.45		**Lunch**

12.45 – 13.45		**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 *Ms. Chiaki Nakanishi, Senior Specialist, CMC, CoreMed Corporation*
13.45 – 13.55		**Break**
13.55 – 14.55		**CMC for J-NDA – Highlights that global RA and CMC RA need to know - *continued*** *Ms. Chiaki Nakanishi, Senior Specialist, CMC, CoreMed Corporation*
14.55 – 15.15		**Break // Coffee, Tea and a snack**
15.15 – 16.00		**Compliance Inspection** • What is Compliance Inspection • Documents required • How the Compliance Inspection conducted *Mr. Yoshiaki Hattori, Senior Scientist, Research and Development Planning, CoreMed Corporation*
16.00 - 17.00		**Group work** *Course leaders*

DAY 3 – Friday, December 5, 2025

08.45 – 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 *Ms. Emi Nakamura, CDISC and eCTD Specialist, Datascience Solution Department, A2 Healthcare Corporation* ***(online)***
10.00 – 10.10		**Break**
10.10 – 10.40		**eCTD** • eCTD V4.0 experience in Japan - Major Changes from 3.2.2 to 4.0 • Points to consider *Ms. Emi Nakamura, CDISC and eCTD Specialist, Datascience Solution Department, A2 Healthcare Corporation* ***(online)***
10.40 – 11.00		**Break // Coffee, Tea and a snack**
11.00 – 11.30		**Labelling** • Japanese Package Insert (J-PI) • J-PI revision *Ms. Fumi Sakai, Senior Specialist, Regulatory Affairs, CoreMed Corporation*
11.30 – 11.40		**Break**
11.40 – 12.10		**Pharmacovigilance in Japan** *Ms. Fumi Sakai, Senior Specialist, Regulatory Affairs, CoreMed Corporation*
12.10 – 13.00		**Lunch**

13.00 – 13.45		**Case study - Success story in JNDA** *Ms. Camilla Benjnou, Head of Regulatory Affairs Projects, Leo-Pharma*
13.45 - 14.45		**Group work** *Course leaders*
14.45 – 15.00		**Break // Coffee, Tea and a snack**
15.00 – 15.30		**Rounding up and goodbye** *Course leaders, Participants, Atrium*