

## Regulatory Affairs Module 4

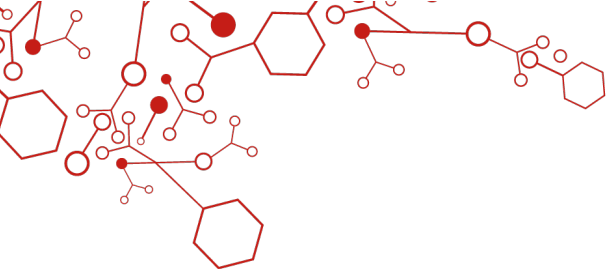
### The Regulatory Affairs Environment in Japan

**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)

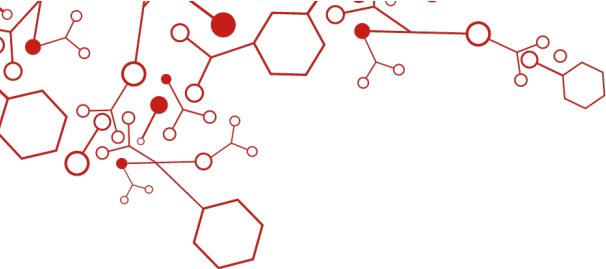
**Atrium:** Lone Rex, Educational Programme Leader &  
 Mette Ribergaard Rasmussen, Client Manager


#### DAY 1 – Wednesday, December 3, 2025

08.30 – 09.00		<b>Breakfast and registration</b>
09.00 – 09.30		<p><b>Welcome and setting the scene</b></p> <ul style="list-style-type: none"> <li>• Welcome to Atrium</li> <li>• Introduction to the Japanese regulatory affairs environment</li> <li>• Cultural awareness</li> </ul> <p><i>Atrium, Course leaders, Participants</i></p>
09.30 – 10.15		<p><b>Japan´s regulatory overview</b></p> <ul style="list-style-type: none"> <li>• Background information on Japan</li> <li>• Introduction to pharmaceutical regulatory systems</li> </ul> <p><i>Lecturer. Ms. Shohko Sekine, Deputy Division Director, Office of Asia Training Center and International Cooperation, PMDA</i></p>
10.15 – 10.45		<b>Break</b>
10.45 - 11.30		<p><b>Review of new drugs in Japan</b></p> <ul style="list-style-type: none"> <li>• Review process</li> <li>• Type of approval</li> <li>• Designation for orphan, SAKIGAKE and specific use drugs</li> <li>• Post-marketing (risk manager, risk management plan and re-examination.)</li> </ul> <p><i>Lecturer – Ms. Shohko Sekine, Deputy Division Director, Office of Asia Training Center and International Cooperation, PMDA</i></p>



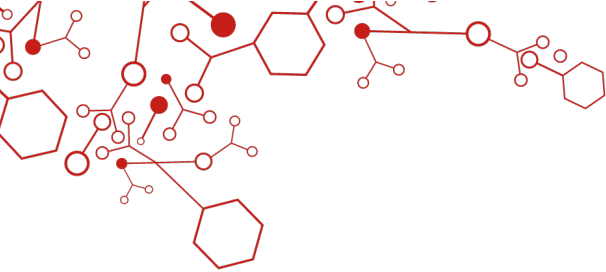
<p>11:30 – 12:00</p>	<p><b>Pricing and Reimbursement</b></p> <ul style="list-style-type: none"> <li>• Summary of drug pricing in Japan</li> <li>• Brief overview of National Health Insurance</li> </ul> <p><i>Lecturer – Ms. Makiko Nahata Director, Pricing &amp; External Affairs, Japan Access &amp; Value Pfizer Japan Inc.</i></p>
<p>12.00 – 13.00</p>	<p> <b>Lunch</b></p>
<p>13.00 – 14.30</p>	<p><b>How to include Japan in Global Development</b></p> <ul style="list-style-type: none"> <li>• Bridging strategy/Japanese P1 trials</li> <li>• Ethnic factors</li> <li>• Number of Japanese subjects</li> <li>• Early steps for the Regulatory Strategy showing opportunities</li> </ul> <p><i>Lecturer – Mr. Yoshiaki Hattori, Senior Scientist, Research and Development Planning, CoreMed Corporation</i></p>
<p>14.30 – 15.00</p>	<p> <b>Break</b></p>
<p>15.00 - 16.00</p>	<p><b>PMDA consultations</b></p> <ul style="list-style-type: none"> <li>• Types (categories) of consultation</li> <li>• Procedures of consultation meetings (from request to official minutes)</li> <li>• Points to consider preparing meetings:             <ul style="list-style-type: none"> <li>○ Briefing documents</li> <li>○ Ethnic Factors</li> <li>○ Number of Japanese subjects in a global study</li> <li>○ Pediatric development</li> <li>○ Etc.</li> </ul> </li> </ul> <p><i>Lecturer – Ms. Fumi Sakai, Senior Specialist, Regulatory Affairs, CoreMed Corporation</i></p>
<p>16:00 – 16:30</p>	<p><b>Case study - Success story in PMDA meeting</b></p> <p><i>Lecturer – Ms. Cheryl Madsen, President and CEO, RPM Strategic Solutions, LLC</i></p>
<p>16:30 – 17:30</p>	<p><b>Japanese new drug application</b></p> <ul style="list-style-type: none"> <li>• Types of applications and evaluation</li> <li>• Structure and content of J-CTD</li> <li>• Japan specific requirements (overview: reliability, standards, Evaluation data/Reference data)</li> <li>• NDA approval process</li> </ul>







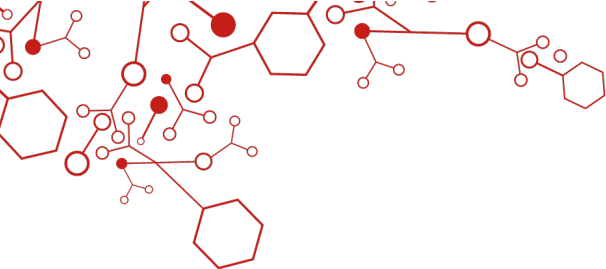
	<ul style="list-style-type: none"> <li>• Japan specific requirements (e.g. safety data presentation)</li> </ul> <p><i>Lecturer – Ms. Fumi Sakai, Senior Specialist, Regulatory Affairs, CoreMed Corporation</i></p>
17.30 - 18.30	 <b>Networking // Tapas Lersø Parkallé</b>

## DAY 2 – Thursday, December 4, 2025

08.30 – 09.00	 <b>Light breakfast</b>
09.00 - 09.15	 <b>Short summary of day 1 and introduction to day 2</b>  <i>Course leaders</i>
9.15-10.00	 <b>GCP and Clinical trial notification in Japan</b> <ul style="list-style-type: none"> <li>• Japanese GCP</li> <li>• In-Country Clinical Trial Caretaker / CRO</li> <li>• Format and contents of the CTN</li> <li>• CTN review process &amp; timelines</li> <li>• Amendments to CTN</li> </ul> <p><i>Lecturer – Satomi Kanayama, Deputy Director, Regulatory Affairs Department, A2 Healthcare Corporation</i></p>
10.00 -10.45	 <b>Clinical studies in Japan</b> <ul style="list-style-type: none"> <li>• Japanese guidelines of clinical studies</li> <li>• Requirements for IMP (labeling, GMP, import procedures)</li> <li>• Procedures/Requirements for each stage of clinical studies (clinical operations)</li> </ul> <p><i>Lecturer – Hiroko Inoue, Director, Project Management Department, A2 Healthcare Corporation</i></p>
10.45 - 11.15	 <b>Break</b>
11.15 - 12.15	 <b>Non-clinical documentation and requirements</b> <ul style="list-style-type: none"> <li>• Japan specific requirement</li> <li>• Frequently found gaps/issues</li> </ul> <p><i>Lecturer – Mr. Yoshiaki Hattori, Senior Scientist, Research and Development Planning, CoreMed Corporation</i></p>
12.15 – 13.15	 <b>Lunch</b>

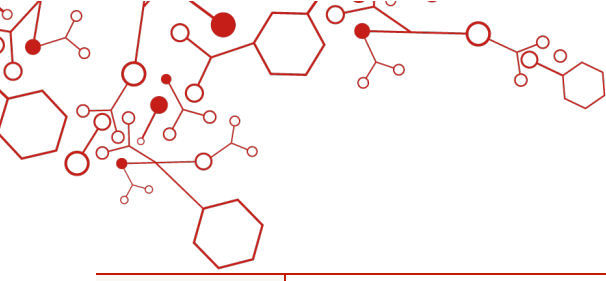




<p>13.15 – 15.15</p>	<p><b>CMC for J-NDA – Highlights that global RA and CMC RA need to know</b></p> <p></p> <ul style="list-style-type: none"> <li>• Introduction</li> <li>• Key items (approval application form, GMP inspection, FMA, release testing, J-DMF, compliance review, GQP, JAN, standards for bio-derived raw materials etc.)</li> <li>• Relationship of key items in the J-NDA</li> <li>• Adherence of approved application form</li> <li>• Frequently found gaps/issues</li> </ul> <p><i>Lecturer - Ms. Chiaki Nakanishi, Senior Specialist, CMC, CoreMed Corporation</i></p>
<p>15.15 – 15.45</p>	<p> <b>Break</b></p>
<p>15.45– 16.30</p>	<p><b>Compliance Inspection</b></p> <p></p> <ul style="list-style-type: none"> <li>• What is Compliance Inspection</li> <li>• Documents required</li> <li>• How the Compliance Inspection conducted</li> </ul> <p><i>Lecturer – Mr. Yoshiaki Hattori, Senior Scientist, Research and Development Planning, CoreMed Corporation</i></p>
<p>16.30 - 17.30</p>	<p> <b>Group work</b></p> <p><i>Course leaders</i></p>



## DAY 3 – Friday, December 5, 2025

08.30 – 09.00		<b>Light breakfast</b>
09.00 – 09.15		<b>Short summary of day 2 and introduction to day 3</b> <i>Course leaders</i>
09.15 – 10:00		<b>eData submission (CDISC)</b> <ul style="list-style-type: none"> <li>• Japan specific requirements</li> <li>• Scope of eData submission</li> <li>• Points to consider</li> </ul> <i>Lecturer to – Emi Nakamura, CDISC and eCTD Specialist, Datascience Solution Department, A2 Healthcare Corporation</i>
10:00 – 10.30		<b>eCTD</b> <ul style="list-style-type: none"> <li>• eCTD V4.0 experience in Japan - Major Changes from 3.2.2 to 4.0</li> <li>• Points to consider</li> </ul> <i>Lecturer– Emi Nakamura, CDISC and eCTD Specialist, Datascience Solution Department, A2 Healthcare Corporation</i>
10.30 – 11.00		<b>Break</b>
11:00 – 11.30		<b>Labelling</b> <ul style="list-style-type: none"> <li>• Japanese Package Insert (J-PI)</li> <li>• J-PI revision</li> </ul> <i>Lecturer – Ms. Fumi Sakai, Senior Specialist, Regulatory Affairs, CoreMed Corporation</i>
11.30 – 12.00		<b>Pharmacovigilance in Japan</b> <i>Lecturer – Ms. Fumi Sakai, Senior Specialist, Regulatory Affairs, CoreMed Corporation</i>
12.00 - 13.00		<b>Lunch</b>
13:00 – 13.45		<b>Case study - Success story in JNDA</b> <i>Lecturer to be confirmed –</i>



13.45 - 14.45	 <b>Group work</b> <i>Course leaders</i>
14.45 – 15.15	 <b>Rounding up and goodbye</b> <i>Course leaders, Participants, Atrium</i>