

## Regulatory Affairs Module 4

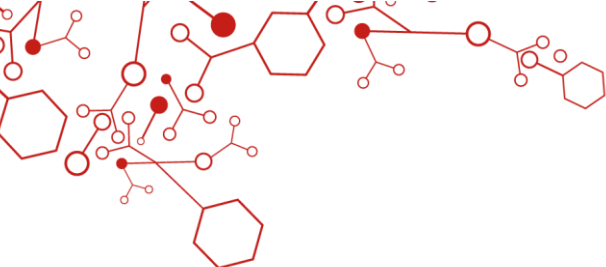
# The Regulatory Affairs Environment in Japan

**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)

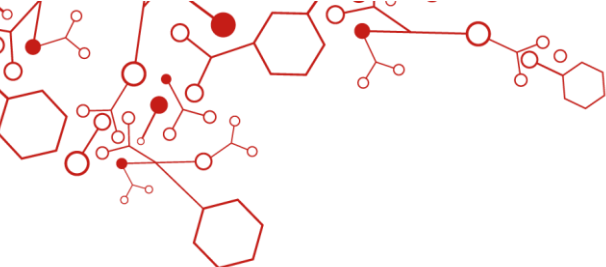
**Atrium:** Lone Rex, Head of the Scientific Team & Louise Hansen, Client Manager

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

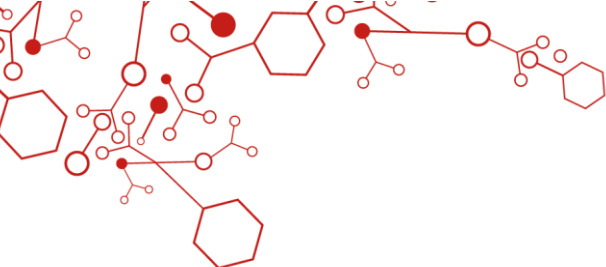
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| 08.45 – 09.00 |    | <b>Breakfast and registration</b>                                                                                                                                                                                                                                                                                                                                                                                     |
| 09.00 – 09.30 |  | <b>Welcome and setting the scene</b> <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 |  | <b>Japan's regulatory overview</b> <ul style="list-style-type: none"> <li>• Background information on Japan</li> <li>• Introduction to pharmaceutical regulatory systems</li> </ul> <p><i>Ms. Shohko Sekine, Deputy Division Director, Office of Asia Training Center and International Cooperation, PMDA</i></p>                                                                                                     |
| 10.15 – 10.30 |  | <b>Break // Coffee, Tea and a snack</b>                                                                                                                                                                                                                                                                                                                                                                               |
| 10.30 - 11.15 |  | <b>Review of new drugs in Japan</b> <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>Ms. Shohko Sekine, Deputy Division Director, Office of Asia Training Center and International Cooperation, PMDA</i></p> |



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| 11.15 – 11.25 |    | <b>Break</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 11.25 - 12.10 |    | <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>Mr. Yoshiaki Hattori, Senior Scientist, Research and Development Planning, CoreMed Corporation</i></p>                                                                                                                                                         |
| 12.10 – 13.00 |    | <b>Lunch</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 13.00 - 13.45 |    | <p><b>How to include Japan in Global Development - <i>continued</i></b></p> <p><i>Mr. Yoshiaki Hattori, Senior Scientist, Research and Development Planning, CoreMed Corporation</i></p>                                                                                                                                                                                                                                                                                                                                                                         |
| 13.45 – 13.55 |  | <b>Break</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 13.55 - 14.55 |  | <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>Ms. Fumi Sakai, Senior Specialist, Regulatory Affairs, CoreMed Corporation</i></p> |
| 14.55 – 15.10 |  | <b>Break // Coffee, Tea and a snack</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 15.10 - 16.10 |  | <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> <li>• Japan specific requirements (e.g. safety data presentation)</li> </ul> <p><i>Ms. Fumi Sakai, Senior Specialist, Regulatory Affairs, CoreMed Corporation</i></p>                                                                         |

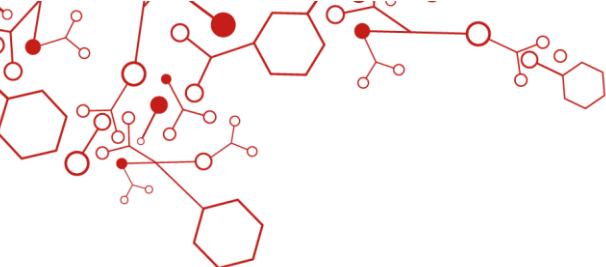


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| 16.10 - 16.20 |  | <b>Break</b>                                                                                                                                                                                                                                                                                       |
| 16.20 - 16.55 |  | <b>Pricing and Reimbursement</b> <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>Ms. Makiko Nahata, Director, Pricing &amp; External Affairs, Japan Access &amp; Value Pfizer Japan Inc.</i></p> |
| 16.55 - 17.00 |  | <b>Bio break</b>                                                                                                                                                                                                                                                                                   |
| 17.00 - 17.30 |  | <b>Case study - Success story in PMDA meeting</b> <p><i>Ms. Cheryl Madsen, President and CEO, RPM Strategic Solutions, LLC <b>(online)</b></i></p>                                                                                                                                                 |
| 17.30 - 18.30 |  | <b>Networking // Tapas</b>                                                                                                                                                                                                                                                                         |

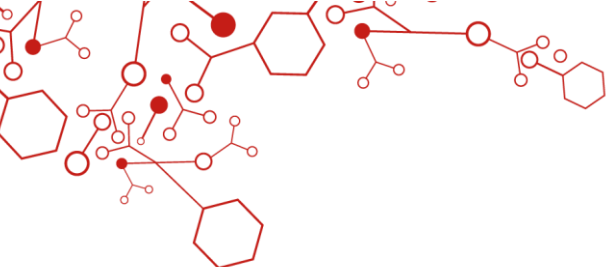


**DAY 2 – Thursday, December 4, 2025**

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| 08.45 – 09.00 |    | <b>Light breakfast</b>                                                                                                                                                                                                                                                                                                                                                                                                           |
| 09.00 - 09.15 |    | <b>Short summary of day 1 and introduction to day 2</b><br><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>Ms. Minori Kuto, Regulatory Affairs Staff, Regulatory Affairs Department, A2 Healthcare Corporation (<b>online</b>)</i></p> |
| 10.00 – 10.10 |  | <b>Break // Coffee, Tea and a snack</b>                                                                                                                                                                                                                                                                                                                                                                                          |
| 10.10 -10.55  |  | <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>Ms. Hiroko Inoue, Director, Project Management Department, A2 Healthcare Corporation (<b>online</b>)</i></p>                   |
| 10.55 - 11.10 |  | <b>Break</b>                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 11.00 - 12.00 |  | <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>Mr. Yoshiaki Hattori, Senior Scientist, Research and Development Planning, CoreMed Corporation</i></p>                                                                                                                                           |
| 12.00 – 12.45 |  | <b>Lunch</b>                                                                                                                                                                                                                                                                                                                                                                                                                     |

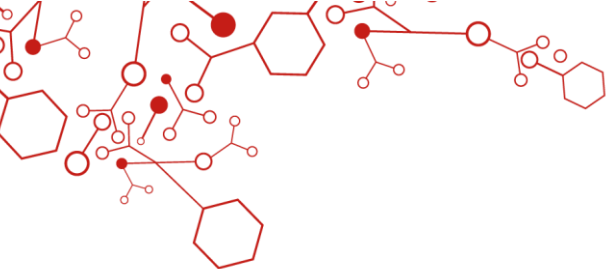


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| 12.45 – 13.45 |  <p><b>CMC for J-NDA – Highlights that global RA and CMC RA need to know</b></p> <ul style="list-style-type: none"> <li>• Introduction</li> <li>• Key items (approval application form, GMP inspection, FMA, release testing, J-DMF, compliance 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>Ms. Chiaki Nakanishi, Senior Specialist, CMC, CoreMed Corporation</i></p> |
| 13.45 – 13.55 |  <p><b>Break</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 13.55 – 14.55 |  <p><b>CMC for J-NDA – Highlights that global RA and CMC RA need to know - <i>continued</i></b></p> <p><i>Ms. Chiaki Nakanishi, Senior Specialist, CMC, CoreMed Corporation</i></p>                                                                                                                                                                                                                                                                                                                                                                    |
| 14.55 – 15.15 |  <p><b>Break // Coffee, Tea and a snack</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 15.15 – 16.00 |  <p><b>Compliance Inspection</b></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>Mr. Yoshiaki Hattori, Senior Scientist, Research and Development Planning, CoreMed Corporation</i></p>                                                                                                                                                                                                                                 |
| 16.00 - 17.00 |  <p><b>Group work</b></p> <p><i>Course leaders</i></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |



**DAY 3 – Friday, December 5, 2025**

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| 08.45 – 09.00 |    | <b>Light breakfast</b>                                                                                                                                                                                                                                                                                            |
| 09.00 – 09.15 |    | <b>Short summary of day 2 and introduction to day 3</b><br><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>Ms. Emi Nakamura, CDISC and eCTD Specialist, Datascience Solution Department, A2 Healthcare Corporation (<b>online</b>)</i> |
| 10.00 – 10.10 |   | <b>Break</b>                                                                                                                                                                                                                                                                                                      |
| 10.10 – 10.40 |  | <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>Ms. Emi Nakamura, CDISC and eCTD Specialist, Datascience Solution Department, A2 Healthcare Corporation (<b>online</b>)</i>                      |
| 10.40 – 11.00 |  | <b>Break // Coffee, Tea and a snack</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>Ms. Fumi Sakai, Senior Specialist, Regulatory Affairs, CoreMed Corporation</i>                                                                                                    |
| 11.30 – 11.40 |  | <b>Break</b>                                                                                                                                                                                                                                                                                                      |
| 11.40 – 12.10 |  | <b>Pharmacovigilance in Japan</b><br><i>Ms. Fumi Sakai, Senior Specialist, Regulatory Affairs, CoreMed Corporation</i>                                                                                                                                                                                            |
| 12.10 – 13.00 |  | <b>Lunch</b>                                                                                                                                                                                                                                                                                                      |



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