12-13 October 2023 | Tivoli Hotel
Arni Magnussons Gade 2
Copenhagen

JAPAN IN YOUR REGULATORY STRATEGY

Learn how to implement Japan in your global drug development strategy

Moderated by
Ann Christine Korsgaard
CEO Ozack

KEY REPRESENTATIVES FROM JAPAN

Masami TAMURA
President and CEO
CoreMed

Hiroki MATSUSHIMA
Deputy Executive Director of Business Development, Head of Global Business Expansion
A2 Healthcare

About The Conference

What could be done early on to increase the future value of your asset for Japanese patients?

Join us on a 2-day conference to gain a well-rounded picture of opportunities on how to incorporate Japan into your global drug development. Examples through case studies will provide further insights into the possible paths you can take.

Start your Japanese journey by booking individual meetings with the speakers at the end of each day.

Relevant for pharmaceutical and biotech companies, involved in especially earlier phases of global drug development.

REGISTRATION

October 1st, 2023
Fee: 690 €*

*EARLY BIRD ON OR BEFORE JULY 31st, 2023

CoreMed | A2 Healthcare The Life First Company | OZACK

EVENT PROGRAM

DAY 1 – 12 OCTOBER

	08:00 – 09:00	**REGISTRATION**
Ann Christine KORSGAARD Ozack	**09:00 – 09:15**	**WELCOME** • Why Japan • Benefits from this conference
Masami TAMURA CoreMed Hiroki MATSUSHIMA A2H	**09:15 – 09:35**	**INTRODUCTION TO COREMED & A2H**
Masami TAMURA CoreMed	**09:35 – 09:55**	**OVERVIEW OF JAPAN** • Japanese market at a glance • Introduction to Japanese regulatory authorities (including PMDA's performance)
	09:55 – 10:15	**BREAK**
Yoshiaki HATTORI CoreMed	**10:15 – 12:00**	**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 • **Case study**
	12:00 – 13:15	**LUNCH**
Fumi SAKAI CoreMed	**13:15 – 14:00**	**PMDA CONSULTATION MEETING** • Earliest meaningful consultation from PMDA • Procedures of consultation meetings (from request to official minutes) • Points to consider for preparing meetings (i.e., briefing document) • **Case study**

EVENT PROGRAM

DAY 1 – 12 OCTOBER

Hiroko INOUE A2H	**14:00 – 15:00**	**CLINICAL STUDY IN JAPAN** • Local requirements (e.g. CTN, In-Country Clinical Trial Caretaker, IMP, site management) • Differences between EU/US and Japan • Issues when conducting a global study • **Case study**
	15:00 – 15:20	**BREAK**
Fumi SAKAI CoreMed	**15:20 – 16:00**	**EARLY ACCESS PROGRAM & INCENTIVES** • Orphan Drug • Sakigake • Conditional Approval • **Case study**
	16:00 – 17:00	**PERSONAL/INDIVIDUAL MEETINGS**

BOOK INDIVIDUAL MEETINGS WITH THE SPEAKERS AT THE VENUE THROUGH:

OR VIA LINK

EVENT PROGRAM

DAY 2 – 13 OCTOBER

Ann Christine KORSGAARD Ozack	**08:30 – 08:45**	**SUMMARY OF DAY 1**
Miyuki NANJO CoreMed	**08:45 – 09:45**	**CMC** • Japan specific requirements • Frequently found gaps/issues • Points to consider • **Case study**
Yoshiaki HATTORI CoreMed	**09:45 – 10:45**	**NONCLINICAL** • Japan specific requirements • Frequently found gaps/issues • Points to consider • **Case study**
	10:45 – 11:05	**BREAK**
Sunghwa YUN A2H Megumi SUZUKI A2H	**11:05 – 12:05**	**eDATA SUBMISSION (CDISC)** • Japan specific requirements • Points to consider • **Case study** **eCTD** • Japan specific requirements • Points to consider • eCTD V4.0 experience in Japan • **Case study**
	12:05 – 13:15	**LUNCH**
Masami TAMURA CoreMed	**13:15 – 14:15**	**CASE STUDY** • Success story in entering the Japanese market
Ann Christine KORSGAARD Ozack	**14:15 – 14:30**	**WRAP UP**
	14:30 – 16:00	**PERSONAL/INDIVIDUAL MEETINGS**

OUR SPEAKERS

CoreMed

Masami TAMURA

President and CEO

Masami TAMURA established CoreMed Corporation, a regulatory and strategy development consultancy based in Japan, with her colleagues in March 1998 and her career in regulatory affairs spans over more than thirty years. She was previously a manager of regulatory affairs in a Japanese CRO and responsible for all regulatory matters within the company. She managed projects from non-Japanese companies and organised J-NDA submissions as an In-Country Caretaker on behalf of overseas companies. Through her experiences, she gained wide range of Japanese regulatory knowledge and skills to help non-Japanese companies who wish to register their products in Japan. She has a Bachelor of Pharmaceutical Sciences from Kyoto University and is a registered pharmacist. In 2015, Regulatory Affairs Awards was granted by Osaka Prefecture Governor.

Yoshiaki HATTORI

MSc. Pharmacist, Senior Scientist, Research and Development Planning

Yoshiaki HATTORI has been working with CoreMed for nine years. He, as an expert of non-clinical pharmacokinetics and clinical pharmacology, supports pharma/biopharma companies for various types of projects including but not limited to gap analyses, PMDA consultation meetings, and J-NDA submissions. He previously worked as a research scientist in Pharmacokinetics and Safety Research Department of a Japanese pharmaceutical company. He has a Master of pharmaceutical sciences from Osaka University Graduate School and is a registered pharmacist.

Fumi SAKAI

Senior Specialist, Regulatory Affairs

Fumi SAKAI has been working with CoreMed for seven years. She supports pharma/biopharma companies for various types of projects including but not limited to regulatory development strategies, PMDA consultation meetings, ODD and J-NDA submissions. She has previously worked as a CRA and project manager in R&D division of a Japanese pharmaceutical company. She has a Bachelor of Agriculture from the University of Tokyo. She is a member of the Regulatory Affairs Committee of the Kansai Pharmaceutical Industry Association and is actively involved in the activities of the Association.

Miyuki NANJO

MSc., Senior Specialist, CMC

Miyuki NANJO joined CoreMed Corporation in 2016 and specializes in regulatory CMC. With extensive experience working with domestic/foreign pharmaceutical companies, she is responsible for coordinating CMC documentation for Japanese filling, supporting of foreign manufacturer accreditation and GMP inspection. Prior to joining CoreMed Corporation, she worked in the analytical division of a global pharmaceutical company. She has a Master of Science from the University of Kobe.

OUR SPEAKERS

Hiroki MATSUSHIMA

Deputy Executive Director of Business Development

Hiroki Matsushima is Deputy Executive Director of Business Development, Head of Global Business Expansion in A2 Healthcare. He has joined A2 Healthcare in 2012 and ever since has been dedicated to support oversea sponsors to develop in Japan. Today, A2 Healthcare has become one of the top tier CROs in Japan with 1,200 employees and more than half of the projects is either from oversea sponsors or being a part of a global study. Hiroki also takes part as a senior governing member of partnerships, which A2 Healthcare has with oversea sponsors and partners. He has been a part of this industry for 20 years, also having work experience in Japanese biotech and global CRO.

Hiroko INOUE

Director of Project Management

Hiroko Inoue is a Director of Project Management Department of A2Healthcare, Pharmacist and holder of PMP. She has over 15 years of experience, including clinical operational experience. She has experience managing more than ten global studies (including studies which A2 Healthcare functioned as sponsors' local representative – In Country Clinical Care-taker role in Japan) with global sponsors and is the expert on supporting global sponsor to develop in Japan. She was the manager of the project that implemented Japan's first "Sakigake" as fast track program and succeeded in obtaining approval for the first time.

Sunghwa YUN

CDISC Specialist

Sunghwa Yun is CDISC Specialist in A2 Healthcare, which has been a member of CDISC organization since 2009 and has strength in CDISC-related tasks including SDTM, ADaM and e-data submission. A2's e-data submission support has been highly recognized by global sponsors who do not have data science staff in Japan or who are not familiar with e-data submission to PMDA. Sunghwa is one of the most experienced staff in A2 in supporting global sponsors for their success in PMDA e-data submission.

Megumi SUZUKI

eCTD Specialist

Megumi Suzuki is eCTD specialist in A2 Healthcare. She has over 10 years of experience in CROs, including clinical system development such as EDC and medical writing of CSR and CTD, and is currently engaged in compiling eCTD. A2 is focusing on compilation work with eCTD v4.0. In 2021, A2 Healthcare participated in the v4.0 pilot test conducted by PMDA and achieved great results, and in 2022 achieved the first eCTD v4.0 submission in Japan proving to be the leader in this industry. A2 is now ready to implement all operations from monitoring to submission in one stop.

REGISTRATION

REGISTRATION DEADLINE: OCTOBER 1ST, 2023

AVAILABLE ONLINE:

OR VIA LINK

TERMS AND CONDITIONS
***REGISTRATION FEE**
Early Bird: **690 €** on or before 31 July 2023
Regular Fee: **990 €** from 1 August 2023

The conference fee includes two-day conference programme, refreshments and coffee during breaks, lunch on Thursday and Friday, and opportunity to book consultation meetings with Japanese experts. Seats are limited and allocated on a first come, first serve basis. You registration will be confirmed by email.

CANCELLATION POLICY
Full refund on or before October 1, 2023
Cancellations must be done through the registration page by the cancellation date above. You may transfer your registration to a colleague at any time. Please notify us of any such substitution as soon as possible.

We reserve the right to alter the venue and the program/speakers, if necessary. If the event is cancelled, the organizer is not responsible for any airfare, hotel or other costs incurred by registrants.

EVENT RECORDING
Photographs and/or videos of the event will be made that may include your participation in the event.

PRIVACY STATEMENT
The organizer respects the privacy of all attendees. No personal data will be transferred out of the EU by the organizers. The personal information provided when you register will be used only for conference related tasks, as is invoicing or sharing of conference materials. By submitting information in your registration form, you are regarded as having agreed to this handling of information.