

eCTD v4.0

Freyr Regulatory Solutions

Position Your Organization at the Forefront of
eCTD v4.0 Regulatory Innovation



August 28th, 2025



9:00 AM – 2:30 PM (Japan Time)



Edogrand, 22F, 2 Chome-2-1 Kyobashi,
Chuo City, Tokyo 104-0031

Agenda at a Glance

09:00 – 09:30

Tea & Networking

- Participant Check-in & Registration
- Tea & Networking
- A Special Freyr Exclusive: Reserved for Workshop Participants

09:30 – 09:35

Welcome & Introduction

Speakers ➤



Yooya Matsumura

Japan Business Head, Freyr Solutions

- About Freyr - Global Presence & Japan Capabilities
- Introduction to Freya Fusion Platform & Innovations

09:35 – 11:30

PMDA eCTD v4.0 Concepts & Industry Impact

Speakers ➤



Akira Toyama

Publishing Lead, Freyr Solutions,



Chandra Louis

Publishing Lead, Freyr Solutions



Ragavendra Babu

Global Publishing and Submissions
Head, Freyr Solutions

PMDA eCTD v4.0: Strategic Overview

- Japan's Evolving Regulatory Landscape
- Industry Impact of eCTD v4.0
- PMDA Application Types & Submission Considerations

eCTD v4.0 Key Concepts

- ICH and PMDA key concepts and requirements
- Regional Requirements by Application Type
- Key Features Across Modules 1-5

11:30 – 12:00

CEO Insights eCTD v4.0: Evolution and the Future

Speakers ➤



Suren Dheenadayalan

Founder and CEO, Freyr Solutions

12:00 – 13:00

Networking Lunch

Connect with industry peers and Freyr leadership over
an informal networking lunch

13:00 – 14:00

Practical Training: eCTD v4.0 Submission Using Freya.Fusion

Speakers ➤



Akira Toyama

Publishing Lead, Freyr Solutions,



Chandra Louis

Publishing Lead, Freyr Solutions



Ragavendra Babu

Global Publishing and Submissions
Head, Freyr Solutions

- Step-by-step work instructions for Real PMDA eCTD v4.0 submission
- Overview of the eCTD v4.0 submission tracker
- Application creation and document upload in Freya.Fusion
- Tagging keywords, priority numbers, filenames, and leaf titles
- Module-specific guidance, including CDISC (Module 5) and M4/M5 structuring
- QC checklist, final review, and output preview in the Viewer
- Live Q&A session with Freyr experts

14:00 – 15:00

Certificate Distribution, Closing Conversations & Workshop Conclusion

- eCTD v4.0 Certification Distribution
- Final Remarks & Key Takeaways
- Tea & Networking

What You'll Gain

- Deep understanding of PMDA's eCTD v4.0 standards
- Real- PMDA eCTD v4.0 submission
- Strategic guidance on organizational readiness
- Free certificate of participation
- Preview of Freya.Fusion – built for global compliance

Reserve Your Spot Today!

[Register Now](#)



Scan



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