

Mandatory in 2026!

Why Attend Freyr's eCTD v4.0 workshop – Tokyo, Japan

Attending Freyr's eCTD v4.0 Workshop – It is important to prepare for ICH's Mandated Transition April 2026 and to ensure Submissions' Compliance & Efficiency

Why This Workshop is Non-negotiable

The ICH eCTD v4.0 standard will soon replace eCTD v3.2.2 with eCTD v4.0, introducing stricter technical requirements for global Regulatory submissions. Organizations that delay preparedness risk:

- Submission rejections due to noncompliance.
- Increased costs from rework and delayed approvals.
- Competitive disadvantage as early adopters streamline processes.

Freyr's workshop provides actionable, expert led training to mitigate these risks.

Key Workshop Benefits

Future-Proof Compliance

- Deep dive into eCTD v4.0 specifications and ICH guidelines.
- Avoid common pitfalls leading to validation failures.

Operational Efficiency

- Optimize submission workflows with structured data and automation.
- Reduce manual effort and accelerate timelines.

Strategic Readiness

- Align with IDMP/SPOR and other evolving standards.
- Network with industry peers and Regulatory experts.

Workshop Details

Date: August 28, 2025

Location: Tokyo, Japan (In-Person)

Audience: Regulatory Affairs, Submission Teams,

IT/Compliance, and QA Professionals





Agenda Highlights

- Explore the concepts, components and submission structure Gain deep insights into the evolving implications of eCTD v4.0 for submissions in Japan.
- Explore the eCTD v4.0 Submission Software
- Hands-On Certification
 Build a live PMDA eCTD v4.0 sample submission using Freya. Submit and earn your certification.
- Leadership Insight
 Hear from Freyr's CEO on the future of regulatory science and emerging
 global trends.
- In-Person Exclusive
 Choose one complimentary benefit—either a Free eCTD v4.0 Submission or
 Expert Advisory* (T&C apply).

Why Freyr?

- Trusted by 1800+ Life Sciences Companies for Regulatory solutions.
- · Led by Industry Experts with real-world eCTD migration experience.
- · Practical Focus: Less theory, more actionable strategies.

Approval Request

To ensure our organization remains compliant and competitive, we recommend sponsoring:

- Regulatory Submission Specialists
- IT/Data Managers
- Quality/Compliance Leads

Investment: [No Participation Fees] Early registration guarantees a seat.

Next Steps

- · Approve participation for critical team members.
- · Register early to secure seats.
- Postworkshop Knowledge Share: Internal briefing to align stakeholders.

