eCTD 4.0:
A Brave New World

eCTD 4.0 marks the latest milestone in the ongoing quest to make the global submission and review process more efficient, harmonized, and seamless for both publishing teams and reviewers.

Initially defined as an interface to facilitate the transfer of regulatory information from the regulated industry to regulatory authorities, the eCTD aims to enhance the efficiency and effectiveness of the regulatory review process for medicinal products. As more countries adopt eCTD, it is becoming the standard format for submitting regulatory information worldwide.

Implementing eCTD 4.0 represents a significant step forward for both industry and authorities, entailing new software and processes that will require companies to invest time and resources.

Implementation

This upgraded version introduces **considerable improvements** in the **submission process** for sponsors and regulatory bodies alike. All major regulatory authorities are gradually transitioning to this standard. The timeline for implementation varies by region, with **mandatory implementation dates** ranging **from 2026 to 2030** for different health authorities.

The US FDA and Japan PMDA currently accept eCTD 4.0 on a voluntary basis, while other countries are in the process of implementation. Visit the ICH website for the latest updates on the eCTD v4.0 implementation schedule. eCTD v4.0 Implementation Dates

Services

At Asphalion, with our team of Regulatory Operations consultants, we are prepared to assist our clients in the timely adoption of eCTD 4.0 within their regulatory processes, offering a diverse range of services.

Our seasoned regulatory consultants leverage the latest software and self-developed, ISO-certified project management tools to ensure compliance with critical submission timelines. Many of our regulatory experts have decades of experience supporting all types of regulatory procedures and dossier types.

ASPHALION
Knowledge from experience

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1. Join our series of webinars
2. Receive Technical & Regulatory Consulting Advice
3. Rely on Asphalion for full lifecycle submission management
4. Participate in technical industry pilots with health authorities
5. Access tailored Training sessions
6. Schedule a meeting with our eCTD 4.0 EMA Subject Matter Expert

How to Prepare for eCTD v4.0

Proactive planning is crucial, as eCTD 4.0 introduces several new concepts that differ significantly from the previous version. Staying up-to-date with the latest changes is essential to ensure compliance with regulations.

Regulatory leaders will need to thoroughly review guidelines to adapt practices within their companies and teams in order to:

1. Provide team training
2. Update submission processes
3. Ensure publishing software compliance
4. Establish an implementation timeline
5. Review metadata and keywords
6. Monitor regulatory updates

Contact us!

Be Prepared! eCTD 4.0 is here, and it's time to capitalize on its benefits and position yourself to embrace this evolution.

Are you navigating complex regulations or challenges with compliance, quality systems, or regulatory submissions? Asphalion is here to help. Our expert team of consultants, with extensive experience across regulated industries, is ready to deliver tailored solutions designed to meet your unique needs.

Schedule a free meeting with our European Medicines Agency Subject Matter Expert for eCTD 4.0 and overcome your implementation challenges. Contact us to learn how we can help you achieve regulatory excellence.