Regulatory Submissions, Information, and Document Management Forum

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#RSIDM23

eCTD v4 Update

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Agenda

- ICH Activities
- FDA Activities
- FDA Implementation Strategy
- Technical Pilot
- How to Prepare

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What is your readiness for eCTD v4.0?

ⓘ Start presenting to display the poll results on this slide.

eCTD v4.0 Update – ICH Activities

- ICH eCTD v4.0 Implementation Package
  - V1.5 May 2022
- Q&A Change Requests
  - V1.7 June 2022
- Regional Implementation Information posted on ICH eCTD v4.0 webpage
  - Regional planned Technical Pilots & Implementation Dates
  - Links to regional Implementation Documents

eCTD v4.0 Update – FDA Activities

- *eCTD v4.0 Technical Conformance Guide* and *FDA eCTD v4.0 Module 1 Implementation Package*
  - Posted February 2020 for public comment
  - Posted updates on September 2022
- *Specifications for eCTD v4.0 Validation Criteria (October 2022)*
- *eCTD v4.0 Comprehensive Table of Contents Headings and Hierarchy (June 2021)*
- Software updates and testing
  - Currently testing eCTD v4.0 vendor software
  - eCTD v4.0 Technical Pilot

eCTD v4.0 Update – FDA Implementation Strategy

- Initial release/acceptance for new applications in eCTD v4.0
  - Allows for development of eCTD v4.0 applications across regions
  - Perform testing with industry in 2023
  - Begin accepting new applications in eCTD v4.0 in FY24 Q1
- Future phases
  - Transition of current applications
  - Two-way communication

eCTD v4.0 Update – Technical Pilot

- The objective of this testing is to determine if the implementation satisfies the requirements in the technical specification and make any changes prior to accepting eCTD v4.0 submissions in the production environment.
- Identified companies to perform testing
- Testing started (June 2022)
- Testing ends (March 2023)
- Technical Pilot Scope
  - Submission Scope
    - Original eCTD v4.0 applications and subsequent submissions (e.g., amendments, supplements)
    - Grouped eCTD v4.0 submissions
  - Enhancement Scope
    - Life-cycle (one-to-one, one-to-many, many-to-one)
    - Document reuse
    - Document ordering
    - Keyword modifications
    - “Group Title” Keyword

eCTD v4.0 Update – How to Prepare

- Discuss eCTD v4.0 development plans with your vendor and/or IT organization
  - Understanding the specifications
  - Is there a plan for transitioning to eCTD v4.0?
  - Send questions to ICH or FDA
- Become familiar with eCTD v4.0 concepts and enhancements
  - ICH Supplemental Documents for eCTD v4.0
    - Support Documentation for eCTD v4.0 Implementation Package - Explains contents enclosed in the Implementation Package. The target audience is business and technical personnel who build and/or review the eCTD v4.0 XML Messages.
    - Orientation Material for eCTD v4.0 Implementation Package - Provides an outline of eCTD v4.0 concepts from business perspective. The target audience is business personnel and management involved in any aspect of eCTD submission design and preparation.
  - FDA eCTD v4.0 Technical Conformance Guide
- Know where to find the eCTD v4.0 information

eCTD V4.0 Websites

- ICH eCTD v4.0 Webpage (https://www.ich.org/page/ich-electronic-common-technical-document-ectd-v40)
  - ICH eCTD v4.0 Implementation Package
  - Supplemental Documents for eCTD v4.0 Implementation Package
  - Regional Implementation Information & Regional Links
  - Change Control
    - Process
    - Change Requests & Questions
    - Q&A document
- FDA eCTD v4.0 Webpage

  (https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/electronic-common-technical-document-ectd-v40)
  - FDA eCTD v4.0 M1 Implementation Package
  - eCTD v4.0 Technical Conformance Guide
  - Link to ICH eCTD v4.0 webpage

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