eCTD Guidance Overview

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Overview

- eCTD Guidance and Specifications
  - eCTD Guidance Document
  - eCTD Specifications
- eCTD Guidance
  - Changes from eNDA Guidance
  - Continuation of eNDA Guidance
- Submissions 101 References

eCTD Guidance

- Providing Regulatory Submissions in Electronic Format - Human Pharmaceutical Product Applications and Related Submissions
  - All submission types
    - NDA, ANDA, BLA, IND, DMF, Annual Reports, Periodic Safety Reports, Advertising and Promotional Labeling
  - Last Published as Final April 2006
- Preferred Format for Submissions

eCTD Specifications

- eCTD Specifications
  - FDA Module 1 Specification
  - FDA Modules 2 to 5 Specification
  - Study Tagging File Specification
- FDA eCTD Table of Contents Headings and Hierarchy
- Documentation Available On-Line

http://www.fda.gov/cder/regulatory/ersr/default.htm

Be on the lookout for

- Updated Specifications from ICH
  - eCTD Version 3.2.1
  - STF Version 2.2
- FDA Validation Criteria
- Beginning discussions on updating Module 1

eCTD Changes

- XML-based eCTD Backbone replaces PDF Tables of Content
- Increased document granularity in accordance with ICH eCTD agreements
- No requirement to submit technical sections or study reports in paper

eCTD Changes

- GSValidate processor performs rigid validation of backbone against DTD
  - Requires adherence to specifications
  - Do not add or modify leafs within the backbone
- Once a submission is sent in eCTD format all future submissions for the application should be in eCTD format
- Opportunity to use Part 11 Compliant Electronic Signatures

What doesn't change

- Data files submitted in SAS XPORT format
- Documents submitted in PDF Format
- Draft labeling submitted in MS Word

Implementing the Guidance

- Initial Pilot Phase
  - Contact CDER prior to generating pilot submission
  - Review process and make adjustments
- Pilot submission evaluated for technical compliance only unless directed otherwise
- Accepting all submission types, e.g., IND, NDA, Amendments, Master Files, Annual Reports…

Submissions 101

Please Remember…

- Your application number is 6 numeric characters
  - 99-909 is bad
  - 099909 is good
- Your sequence number is 4 numeric digits
  - 909 is bad
  - 0909 is good
- Your sequence number must be unique

Urban Legend

- “I had to send in that material outside of the eCTD because I can’t put it in the backbone”

Reality

- "I had to send in that material outside of the eCTD because I can't put it in the backbone"
  - Everything that you need to send us can be included in the backbone
  - Go back to your tool vendor; they need to update their tool!

Just say no…

- No paper, except briefing packages
- No Word files or file formats not specified in the guidance
- No electronic submissions or records sent directly to a reviewer or project manager
- No electronic desk copies

Just don't do it…

- Do follow the Guidance & Specifications
  - Don't use node extensions in preparing eCTD
  - Don't send customized style sheets
- Do take advantage of granularity
  - Don't combine multiple documents into single PDF
  - Think of the future

References

- CDER Contact for information on eCTD submissions

  esub@cder.fda.gov
- CDER Contact for information on SDTM submissions

  cder-edata@cder.fda.gov
- Electronic Regulatory Submissions and Review website

  http://www.fda.gov/cder/regulatory/ersr/default.htm
- International Conference on Harmonization

  http://www.ich.org