



Industry Panel eCTD Experience

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eCTD experience

- Choice of eCTD builder tools
 - Established business requirements for tool:
 - must fit logically within the current submission publishing process (doc mgmt, doc repositories)
 - must be able to function on pre-existing computing infrastructure
 - must be capable of delivering ICH compliant eCTDs and supporting electronic life cycle management of submissions
 - availability and breadth of functionality early version of tool must allow us to gain experience building
 - Interim tool selected for 2 yrs

eCTD experience

- Differences between the paper and eCTD
 - Content identical, with exception of TOC (not in eCTD)
 - Cross-references in paper appear as hyperlinks in eCTD; bookmarks are visible in eCTD but not in paper
- Main challenges in generating XML-based eCTDs
 - repairing broken hyperlinks; gathering of metadata
 - refining eCTD publishing steps continually as we gain experience (living document, new tool version/features)
 - fitting eCTD publishing steps into current submission preparation processes
 - when to gather metadata, meet with TPD

eCTD experience

- Suggestions for companies planning to transition from CTD to eCTD
 - Fully document your current paper submission preparation processes before beginning transition
 - Fully outline what future electronic process in as much detail as possible
 - content management/workflow - include all roles such as who is a valid author for each document, who determines/verifies metadata, who/what system determines a document is truly final, etc.
 - Refine/update electronic process as you gain eCTD submission experience