

Recycling an eCTD: The FDA, Health Canada and Beyond!

OPeNeCTD
Brussels 2006

canreg 
navigating regulatory affairs

Introduction:

- Market Priorities dictate submission order and allocation of resources.
- Common approaches to Global eCTD submission strategies include:
 - Simultaneous Builds;
 - Autonomous Builds;
 - Dossier Reuse.
- Variables and Dependencies include:
 - Centralized vs. decentralized organization;
 - integrated or stand-alone infrastructure;
 - In-house vs. outsource approach.

Accepting the Theory:

- Recognition that dossier reuse, the recycling of an eCTD, often mimics long established business processes, established in a paper-based environment.
- That the eCTD, being the electronic offspring of a harmonized CTD format, is interchangeable across all ICH regions (the FDA, Health Canada, and beyond).
- That compatibility is only going to get better.
- But how reusable is it really?

Technical Compatibility:

- XML as the great equalizer, is unforgiving to any deviation from its DTD.
- Dossiers are meant be portable from tool to tool.
- One region's dossier can be "saved as" another's, with rework of region specific content.
- Compatibility issues will exist before, during, and after build.
- That all file formats are not automatically accepted across all regions.

Regional Variation:

- Module 1 will always have to be built anew.
- That regional specific requirements will determine the need to add or subtract content.
- That any adjustments for specific markets, may have a cascading affect on the submission, requiring changes to eCTD attributes.
- That certain issues of formatting (both file and backbone), are not consistent between regions.

Validation:

- All agency validators are designed to work identically.
- Anecdotal evidence suggests that there are in fact differences.
- Different performance, raises concerns that rework of dossiers would be required to pass validation at different agencies.

Agency Capabilities:

- Important to know your agency
 - What types of submissions are being accepted?
 - Are all divisions/therapeutic areas operating equally?
 - Should you be submitting an eCTD at this time, or at all?
- Submission processes will vary, technically and procedurally.
- Different viewers are being used at different agencies

Lifecycle Management:

- Agencies vary on sequencing.
- Synchronization of submission sequences between regions is a losing battle.
- Good lifecycle management, organized to capture each region independently, is essential to the efficiency of submitting throughout a product's life.
- Sequence changes between regional dossiers, are not difficult to make, though are import to manage properly.

Supporting Document/Content Management:

- Preferred venue to capture lifecycle/sequence information.
- Ideally, all regional stakeholders should have access to an organization's EDMS.
- Ideal repository to capture and manage eCTD attribute information.
- Segregation of regional specific documents makes it easier to build/rebuild eCTD dossiers.

Conclusion:

- Important to have realistic expectations, and to take stock of all issues (technical compatibility, regional variations, etc.), when deciding on an ideal approach to global eCTD strategies.
- Realize that at present, all ICH regions are a work-in-progress and envisioned ideals of seamless technical harmonization are still to come.
- As with many things in life, the recycled eCTD is a glass either half-empty or half-full. Leaving you to determine whether to pour yourself a new one, or top-off what you've got.

Thank You!



Joe Zoric
Director, Regulatory Operations
CanReg Inc.
jzoric@canreginc.com