Apotex eCTD Experience

Agenda

- About Apotex
- Implementing eCTD
- Current eCTD Process
- Managing eCTDs
- eCTD Experience
- Looking Ahead

About Apotex

- Largest Canadian owned pharmaceutical company
- Produces more than 260 medicines to 115 countries
- R&D expenditures for Apotex over $153 million in 2005

About Apotex

- Apotex initiated the Electronic Regulatory Submission Project in late 2001, and completed in April 2004
- The driving force of this project
  - Optimizing productivity, efficiency and decreasing cost
  - Sharing submission information
  - Most of all, reducing cycle time

Implementing eCTD

- Project preparation
  - Support from the Executives
  - Project team from all areas of business
- Business process evaluation
  - Understanding the new workflow and identifying the gaps
- Evaluating vendors
  - Tools fit the business process
- Validating all processes

Current eCTD Process

- Tools for e-information management, exchange and submissions
  - Waters Nugenesis
    - » Electronic scientific data management system for lab information
    - » “Cut and paste” into MS Word template for submission
  - BroadVision – One-to-One Content
    - » Electronic document management system for submission information
    - » Electronic workflow, Approved PDF on Web for submission

Current eCTD Process

- Lorenz docuBridge
  - » Electronic submissions management system
  - » “Drag and drop” PDF or MS Word files into docuBridge from Web to compile the eCTD
  - » Printout where required
- LabelBridge
  - » SPL
- Access to eCTD building tool through Intranet via citrix

Managing eCTDs

- Regulatory Operations managed eCTD pilots to transition business to the electronic world
  - Initiated e-submission plan
  - Trained and supported business
  - Managed pilots for all regions
  - Communicated with TPD to verify Sample eCTD
- As of February 2006
  - Compiled 31 ANDS for Canada
  - Submitted 15 (0000) and 4 (0001) to TPD

Managing eCTDs

- Support from the Executives
  - All new submissions and their PLCM will be eCTD
  - All submissions will be created in eCTD building tool
- Continue to manage the uniqueness of each regulator's process
  - Paper burden from CAN and EU regulators
  - Electronic only for US
  - STF, SPL & PIM requirements

eCTD Experience

- Establishing open communication
  - Starting early
  - transparency
- Training
  - Business may require ongoing refresh training after initial implementation
- Establishing a permanent support structure for the business

eCTD Experience

- Our approaches and learning
  - Open communication with TPD
  - Assist the business to transform the pCTD to eCTD world
  - Table of content not required for eCTD
  - Delete the empty nodes where not applicable
  - Avoid scanned PDFs (images) if possible
  - pCTD includes “N/A” documents but not required for eCTD
  - Submission documents contain bookmarks at template level
  - Content Management as important as eCTD
  - Large monitors for ease of hyper-linking and reviewing
  - Sharp leaning curve required with US eCTD only submissions

eCTD Experience

- Feedback from TPD
  - Apotex is one of the sponsors who submitted many submissions in eCTD format
  - File eCTD samples in advance of real eCTD
  - IT report from TPD
  - No node extensions accepted in M3 and M5
  - Unable to read bookmarks which are included in the backbone (TOC)
  - Several corrupted PDF files and dead hyperlink were submitted
  - A top folder with an e-Identifier is required
  - Proper orientation of electronic files and preset landscape document

eCTD Experience

- Challenges
  - Difficulties to manage the pCTD and eCTD at the same time
  - Associates will need to keep on top of the eCTD LCM
  - Continuing to improve the quality of eCTD both internally and externally
  - More hyperlinks required
  - pCTD is modular, eCTD is very granular, develop submission in pieces and approve pieces separately

Looking Ahead

- Working together with TPD
  - Taking the advantage of Co-Submissions and moving towards hybrid submissions for PLCM
  - Participating hybrid submissions (July/06)
- Comply with Revised/Draft Guidelines
  - More detailed than previous versions
  - Guide the business with “Best Practices” to comply with requirements
- Integration of documentation and submission management system to increase performance and efficiency

THANK YOU!