eCTD 2006:
Harnessing Technology for Regulatory Advantage

"Lessons Learned"

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February 22, 2006

My Experience

- Submission management support for several companies preparing eCTD
- Working with technology vendors
- Process consulting for companies on document management and eCTD readiness
  - Submission readiness
  - Templates

4 Lessons

- About XML
- Table of Contents
- Pilots
- Vendors and consultants

How much XML is too much XML?

- Have a look at the eCTD specification….
- More important to understand the pieces and how they fit together
  - CTD and eCTD folder structures
  - Required meta data
  - Naming conventions
  - Guidance
    - Granularity
    - Hierarchy
- The tools will manage the XML

There is no Table of Contents!

- Manage content without a TOC
- Use a “document inventory” spreadsheet to identify documents, formats, naming conventions, meta data, life cycle plan etc.

B220 | Study Report 001

	A	B	C	D	E	F	G	H	
1									
2	**Section Number**	**Section Title**	Prime Responsibility	**Status (Draft, Review, Final, New, Revise, Reformat, Narrative)**	**Due Date to RA**	**NDA**	**Document Format (HC / Word / PDF)**	**Location**	**Notes**
197	**3.2.S.3**	**Characterization**							
198	**3.2.S.3.1**	**Elucidation of Structure and Other Characteristics**		Narrative					
199		Mass Spec Analysis of reference standard	HT	Final		?	HC	PD	
200		Sequence Analysis of reference standard	HT	Final		?	HC	PD	
201		Summary of Biophysical Studies	MS	Final		?	HC	PD	
202	**3.2.S.3.2**	**Impurities**							
203		Analytical Method for the Detection and Quantitation of Impurities	RP	**NEW**			W	An Dev	
204		Identification and Characterization of Impurities	RP	**DRAFT**	**1/4/2004**	**X**	W	An Dev	
205		Characterization of Impurities and Degration Products	RP	Final			HC		
206	3.2.S.3.2.3	Impurities from other sources (solvents, reagents, etc.)		NA					
207	**3.2.S.4.1**	**Specification**		Narrative					
208		Spec ABC Revision 04	GF	**REVISE**	**1/4/2004**	**X**	HC	**QA**	
209	**3.2.S.4.2**	**Analytical Procedures**		Narrative					
210	**3.2.S.4.3**	**Validation of Analytical Procedures**		Narrative					
211	**3.2.S.4.4**	**Batch Analyses**		Narrative					
212	**3.2.S.4.5**	**Justification of Specification**		Narrative					
213	**3.2.S.5**	**Reference Standards or Materials**		Narrative					
214	**3.2.S.5.1**	**Manufacture of Reference Standard**		Narrative					
215	**3.2.S.5.2**	**Characterization and Stability**		Narrative					
216	**3.2.S.6**	**Container Closure System**		Narrative					
217	**3.2.S.7**	**Stability**							
218	**3.2.S.7.1**	**Stability Summary and Conclusions**		Narrative					
219		Summary of Drug Substance Stability Studies		Narrative				QC	
220		Study Report 001	HT	Final		X	HC		

Module 2 | Reports | **Module 3**

Ready

Once is not Enough

- Difficult to prepare the 1st eCTD as a real submission
  - Organize a real pilot with real documents
  - Develop process and tools around the pilot
  - Manage the pilot as a project with timelines, deliverables and lessons learned
    - Take the time to work out the process
    - Evaluate internal capabilities
  - Train on all the tools
    - Not just the builder

The Vendors Know Best.....

- Consider partnering with a vendor to do the 1st eCTD
  - The vendor can manage and prepare the eCTD but train company along the way
  - Consultants and vendors have experience with multiple companies and multiple submissions
  - Transition submissions back in house
    - For life cycle management
    - New submissions