

eCTD 2006: Harnessing Technology for Regulatory Advantage

"Lessons Learned"

Helen Teichman February 22, 2006

GLOBAL REGULATORY STRATEGY GLOBAL DOCUMENT MANAGEMENT GLOBAL SUBMISSIONS



My Experience

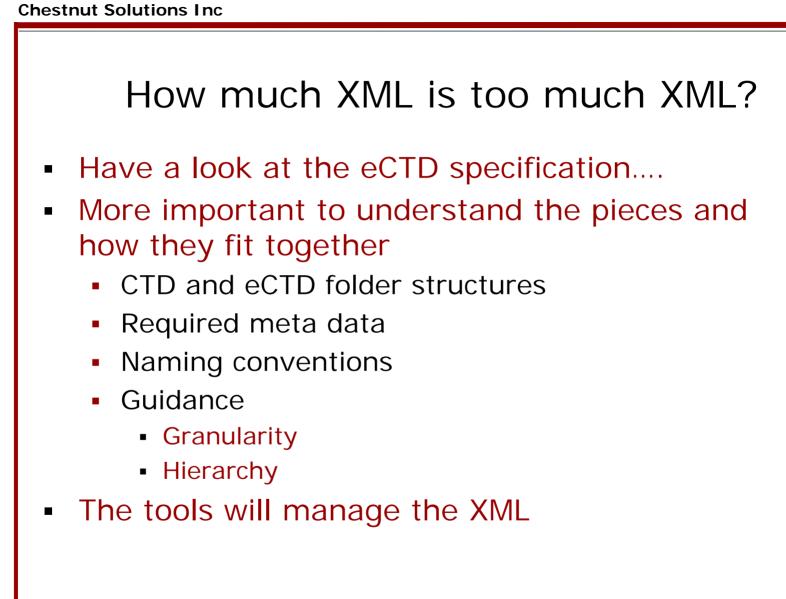
- Submission management support for several companies preparing eCTD
- Working with technology vendors
- Process consulting for companies on document management and eCTD readiness
 - Submission readiness
 - Templates





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







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.

		-		_		

□ 🚅 🖬 🚑 🐧 🖤 🐰 🛍 🛍 • ∽ · Σ • ᢓ↓ 60% • 😰 🐥 Arial 🛛 • 14 • Β Ι U 📑 ≡ Ξ 🖾 S 雪 ோ • 💁 • 🗛 • 🐥

🖄 🏜 📷 🖾 📴 🕍 😨 🎼 😥 🐄 Reply with Changes... End Review... 🖕

T 🖬 🗸

B220

→ f_{*} Study Report 001

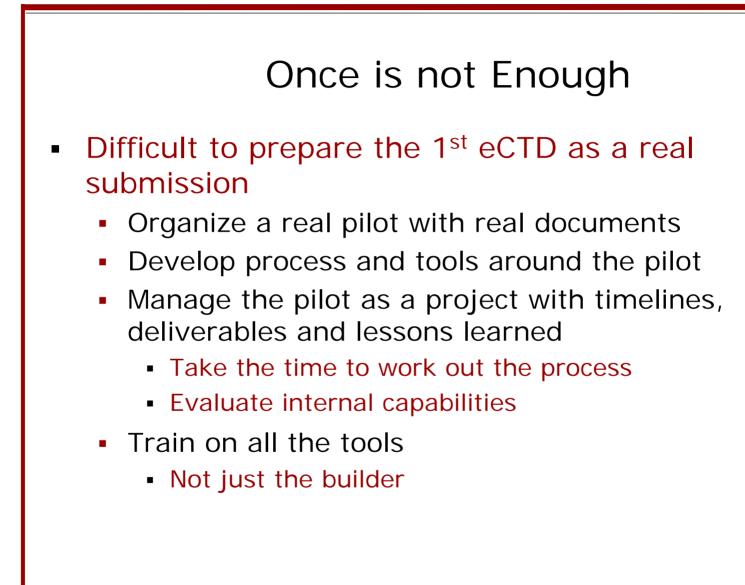
			-	-	-				
	A	B	С	D	E	F	G	н	
1 2	Section Number	Section Title	Prime Responsibility	Status (Draft, Review, Final, New, Revise, Reformat, Narrative)	Due Date to RA	NDA	Document Format (HC / Word / PDF)	Location	Notes
197	3.2.S.3	Characterization							
198	3.2.S.3.1	Elucidation of Structure and Other Characteristics		Narrative					
		Mana Sana Anakaia of reference standard	υт	Final		2	10	DD.	
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		?	нс	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			нс		
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	нс	QA	
203	3.2.5.4.2	Analytical Procedures	<u>.</u>	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	3.2.5.5.2	Characterization and Stability		Narrative					
216	3.2.5.6	Container Closure System		Narrative					
217	3.2.5.7	Stability							
218	3.2.5.7.1	Stability Summary and Conclusions		Narrative					
219		Summary of Drug Substance Stability Studies		Narrative				QC	
220		Study Report 001	НТ	Final		х	НС		•
H 4	🕨 🕨 🔪 Module 2 🖉 Rej	ports A Module 3			•				•

Ready





Chestnut Solutions Inc





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