
ComplianceAuthor Product Line

ComplianceAuthor

- Structured Content Authoring content management solution
- Comprised of two components:
 - A Document Management System (DMS) component that manages document translations, relationships, version control, lifecycles, review and approval workflows, system notifications, tracking and reporting, audit trail, security, etc.
 - An XML authoring component that integrates with Arbortext Epic Editor and Quark XML Author which enables the user to author regulated content in a generic XML format
- Configured OTB for SOP, Forms, Annual Reports, Supporting Documents, and Change Requests
- Foundational product for Glemser's product line

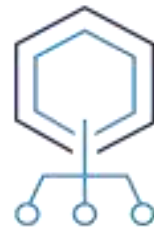
ComplianceAuthor – Core Features



Centralized Repository



Change Control



User-Friendly Workflow



E-Signatures



Content reuse



Version Control



Review & Approval



Translation Management



Data Integrity

ComplianceAuthor Rendition Engine

- Lightweight rendition engine focus on transformation of:
 - XML to Word and/or PDF
 - Word to PDF
- Integrates with all ComplianceAuthor products
- Utilizes Adlib limited OEM license for Word to PDF renditions

ComplianceAuthor for Product Labeling

- Global Labeling Solution built on ComplianceAuthor
- Configured OTB to support Label types including:
 - Core Data Sheets
 - US Prescribing Information Documents
 - EU Labeling Documents (including SmPCs, Leaflets, Annex II, Immediate Labeling, Inner Labeling, and Outer Labeling)
- Capable of generating SPL for US Submissions and QRD compliant output for EU submissions
- Tracks changes to Core Data Sheets and ensures downstream compliance in labels
- Tracks Submission activities

ComplianceAuthor for Test Specifications

- Test Specifications and Analytical Procedures Management System
- Enables users to manage complex specifications in a structured way
- Provides a global view of tests
- Configured OTB to manage
 - Test Specifications (XML)
 - Analytical Procedures (XML)
 - History Sheets (Word)
 - Validation Reports (PDF)
- Integrates with Quark's XML Author editor

ComplianceAuthor for Clinical Labeling

- Clinical Labeling solution
- Released August 2016
- Manages the Phrase library, Study Data, and Business Rules in XML format
- Configured OTB to manage: Phrase Groups containing Phrases, Study Data, Panels, Published Labels, Master Labels, Shelf Life Extensions, and Business Rules
- Supports the creation of Study Data from approved Business Rules and Phrase Groups based on Country/Label Type/Pack Type
- Utilizes a user-friendly custom editor to edit Phrase Group and Business Rules content
- Produces XML output of completed booklets compatible with InDesign