

The Complete Web-based eCTD Solution

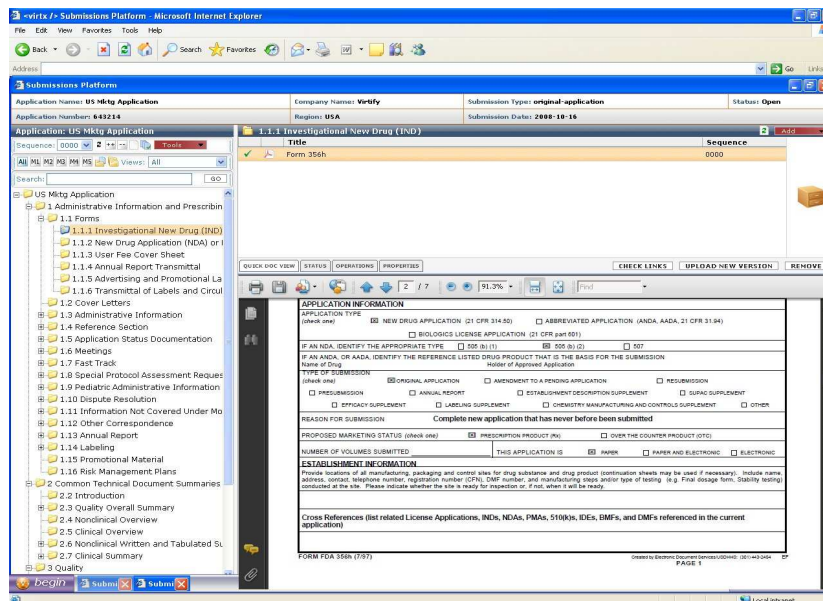
The Virtx eCTD Electronic Submissions Management solution offers a single environment to author, compile, review, QC, publish, and transmit Electronic Common Technical Document (eCTD) Submissions.

Submissions and Document Workflow

- Web-based solution to manage the life cycle of submissions
- Workflow management to support compilation, review, QC and delivery of submissions
- Integrated communication center for issue tracking, reporting and management
- Personalized workspace to suit individual user preferences
- State of the art utilities including drag and drop, one-click, and virtualized document linking

Publishing and Reporting

- Electronic publishing including creation of TOC, bookmarks, and hyperlinks
- Extensive paper based publishing features
- Personalized workspace to suit individual functional roles
- Built-in reporting provides invaluable metrics and statistics



BENEFITS

- WEB-BASED COLLABORATIVE ENVIRONMENT
- INTELLIGENT VALIDATION ENGINE
- FLEXIBLE DOCUMENT UPLOAD CAPABILITIES
- REUSABLE CONTENT LIBRARY

KEY FEATURES

- SUBMISSION WIZARDS CONSTRUCT CUSTOMIZED eCTD TEMPLATES
- SUPPORT FOR ALL DOCUMENT LIFE CYCLE ACTIVITIES
- FULL COMPLIANCE WITH eCTD SPECIFICATIONS
- BUILT-IN REPORTING CAPABILITY TO TRACK STATUS, METRICS, STATISTICS INFORMATION
- 21 CFR PART 11 COMPLIANT WITH REPORTABLE AUDIT TRAILS
- INTUITIVE USER INTERFACE FOR MANAGING ALL MODULES OF AN eCTD SUBMISSION
- VERSION CONTROL

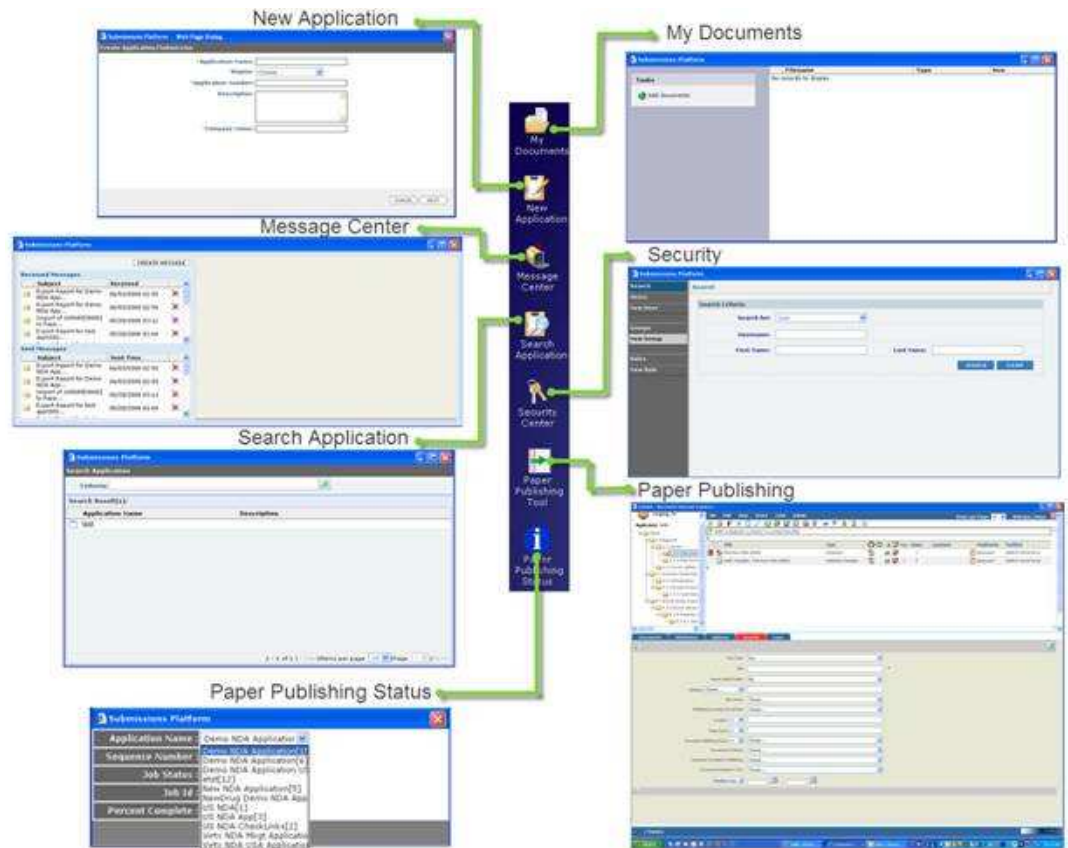
GLOBAL SUBMISSIONS SOLUTION

Compliance and Validation:

- Integrated validation engine ensures compliance with agency regulations
- One-touch compilation minimizes the work needed to prepare and publish submissions
- Automated validation seamlessly verifies content, structure, and metadata
- Support for all document life cycle activities
- Full compliance with eCTD specifications
- 21 CFR Part 11 Compliant with reportable Audit Trails

Flexible Architecture:

- Complete Web-based solution built using Web 2.0 architecture
- Support for both on-premise and SaaS deployment
- Flexible architecture to adapt to evolving global standards
- Advanced search and reporting capabilities
- Integrates and leverages existing desktop publishing tools (e.g. Adobe, Toolbox, etc.) and processes
- Compliant architecture allows for the simultaneous preparation of submissions for multiple jurisdictions
- Support for integration with existing internal systems (e.g. Active Directory, E-mail Systems, Publishing Tools,



About Virtify

Virtify is the market leader in Enterprise Content Compliance solutions for life sciences. Organizations rely on Virtify to reduce time-to-market, risk, and costs by managing and automating the complex regulatory compliance and content exchange requirements throughout the product life cycle. Virtify's easy-to-use Virtx software suite is the industry's only solution to provide a secure, collaborative web-based environment for managing regulated content throughout the entire continuum – from pre-clinical through product registration to commercialization.

Virtify, Inc. is headquartered in Cambridge, Massachusetts (USA), 55 Cambridge Parkway, Suite 410, Cambridge, MA 02142 and has additional facilities throughout North America, Europe and Asia. For sales or services information call 617-252-0770 or visit www.virtify.com