

## The Complete Web-based SPL Solution

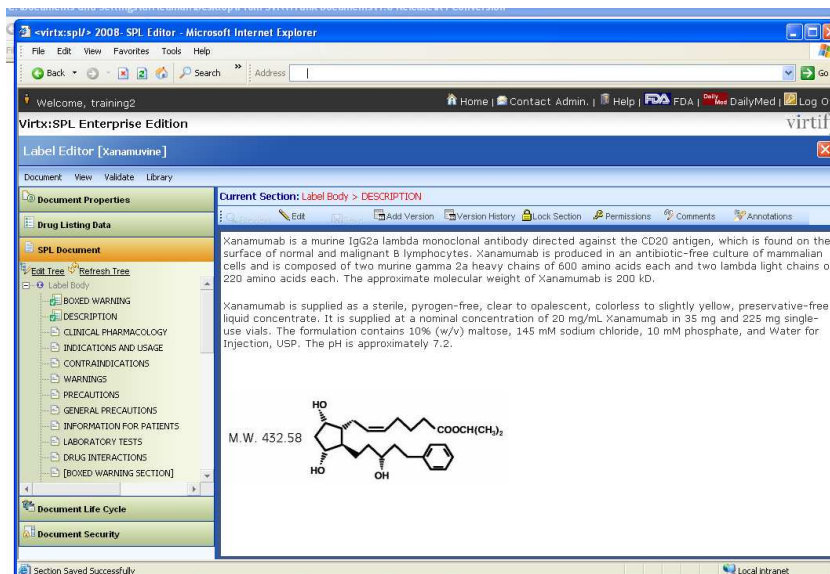
Virtify's **Virtix SPL** solution is designed to meet the FDA's Structured Product Labeling (SPL) standards and requirements. The solution enables biotechnology and pharmaceutical organizations to Author, Review, Publish and Transmit labeling information, within a collaborative, secure web-based environment.

## Compliance and Security

- 21 CFR Compliant Solution with Audit Trails
- Role-based Access Control
- eCTD Compliant labels
- Validated Solution

## Collaboration and Integration

- Integration with commercial document management systems
- Integration with eCTD and other Virtify Products
- Collaborative Review Environment
- Integrated Reporting Engine
- Submissions Lifecycle Management
- Drug Listing/Code Vocabulary lookup/Configuration

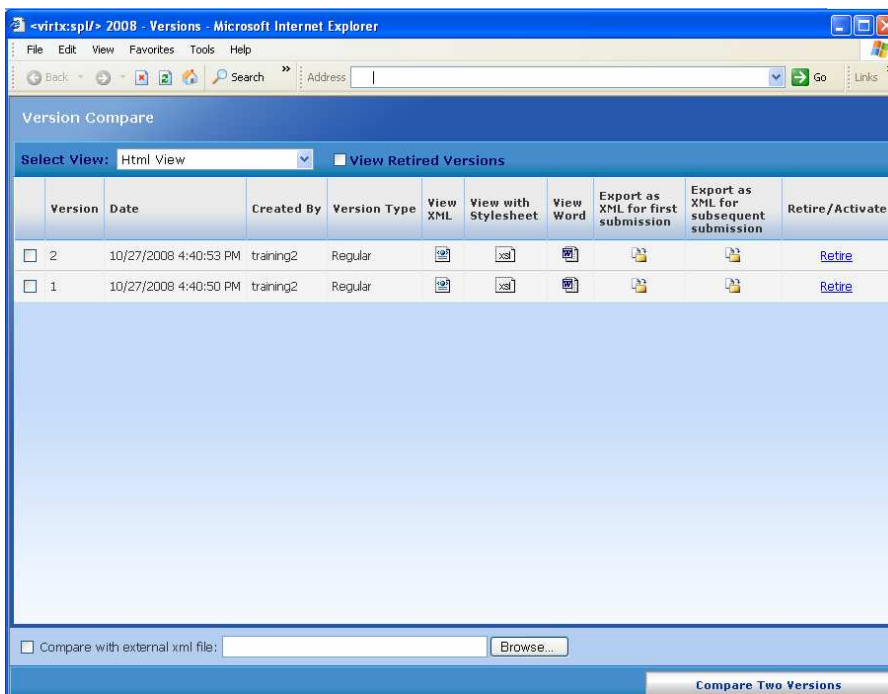
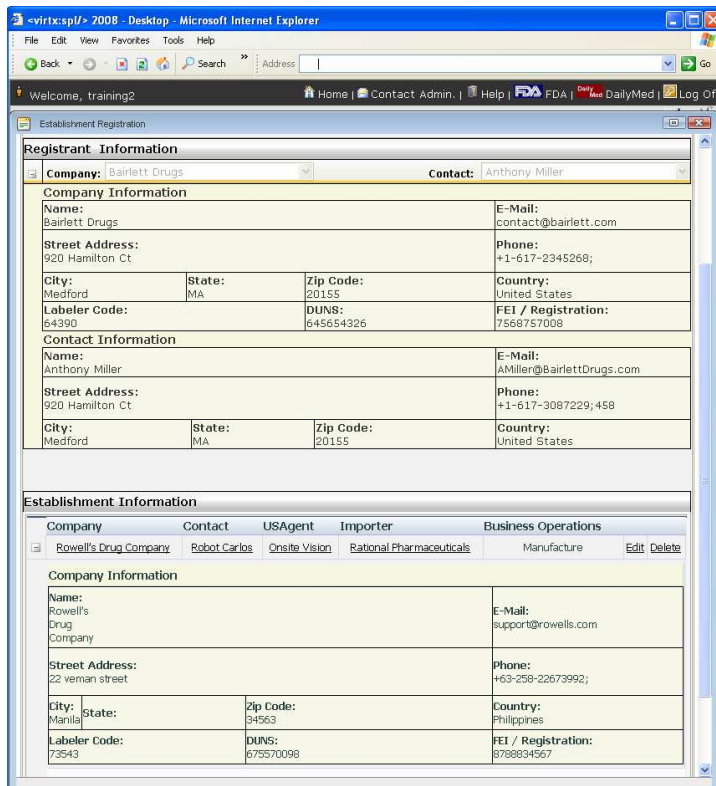


## SPL R4 FEATURES

- MANAGEMENT OF LABELER AND ESTABLISHMENT INFORMATION
- R4 COMPLIANT PRODUCT LISTING DATA
- TEMPLATES FOR LABEL TYPES NEW TO R4
- R4 COMPLIANT LABELS

## KEY FEATURES

- WEB-BASED COLLABORATIVE MULTI-USER ENVIRONMENT BUILT USING STATE OF THE ART WEB 2.0 TECHNOLOGY
- INTEGRATED VALIDATION ENGINE
- WORD-LIKE EDITING INTERFACE
- REUSABLE DOCUMENT AND CONTENT LIBRARY
- VERSION CONTROL
- LABELING REVISION HISTORY
- CONTENT LIBRARY
- LINK MANAGEMENT
- DEPENDENCY MANAGEMENT
- STATUS, NOTIFICATION AND ALERTS



## Labeler and Establishment Registration:

- NDC Labeler Code Requests
- Establishment Registration
- Labeler and Manufacturing Information in the Label

## Content Editing:

- Word-like editor interface
- Label Templates
- Image Management

## Submissions Workflow and Compliance:

- Versioned Content
- Export for Submission
- Integrated Validation Engine
- Audit Trails and Audit Reporting

## Product Listing:

- Intuitive interface
- Latest FDA vocabularies

## 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](http://www.virtify.com).