Adobe structured product labeling solutions for pharmaceuticals

Simplify the creation, validation, and delivery of complex SPL documents

Use this solution to:

- **Rapidly create, validate, and publish SPL documents in XML**
- **Validate and test SPL content**
- **Convert existing product labels to SPL**
- **Provide customized package inserts**

Comply with new requirements for submission of product data

In October 2005, Structured Product Labeling (SPL) was mandated by the United States Food and Drug Administration (FDA) as the only accepted method for electronic submission of drug labeling content for original submissions, supplements, and annual reports. Also, SPL will soon be used to exchange information needed for other submissions, such as drug listings. In Europe, SPL is being implemented as a part of the emerging European Product Information Management (PIM) initiative, which aims to streamline electronic submission of product information within the European Union.

SPL is a schema-defined XML specification that has been developed as an open standard by Health Level Seven (HL7). SPL is a powerful, but relatively complex, specification based on HL7's Clinical Document Architecture (CDA). Replacing previous word processor-based requirements, SPL promises to eliminate redundant data collection and improve efficiency throughout the submission process, both within the regulatory authority and your organization.

Adobe solutions for SPL, based on Adobe® FrameMaker® and Acrobat® software, provide the trusted and powerful tools you need to make the transition to SPL a more manageable and successful process. With Adobe solutions for SPL, creating, commenting on validating, and submitting SPL content is faster and more accurate than existing unstructured methods.

Submit SPL documents with speed and accuracy

The electronic Common Technical Document (e-CTD) specification defines a standardized method for submission of regulatory documentation using XML. With Adobe's solution for electronic submissions, your organization can speed the delivery of SPL documents using an accurate and more secure e-CTD process.

Reduce development cycles with advanced SPL content creation and validation

One of the difficulties often associated with the creation or conversion of SPL content is the possibility of creating structurally correct data elements that have ambiguous meaning. Adobe's advanced SPL structure validation model will help you get it right. Adobe's SPL solution provides:

- ***Familiar, easy-to-use interface:*** Rather than struggling with raw code and unfamiliar formats, you can simplify development of SPL header, narrative content, and data elements using the familiar and intuitive interface consistent across Adobe products.
- ***Guided editing:*** Protect the structural integrity of the SPL document by providing unambiguous choices for content definition. The validation model in FrameMaker software prevents invalid SPL drug data element definition, while retaining full SPL XML validity.

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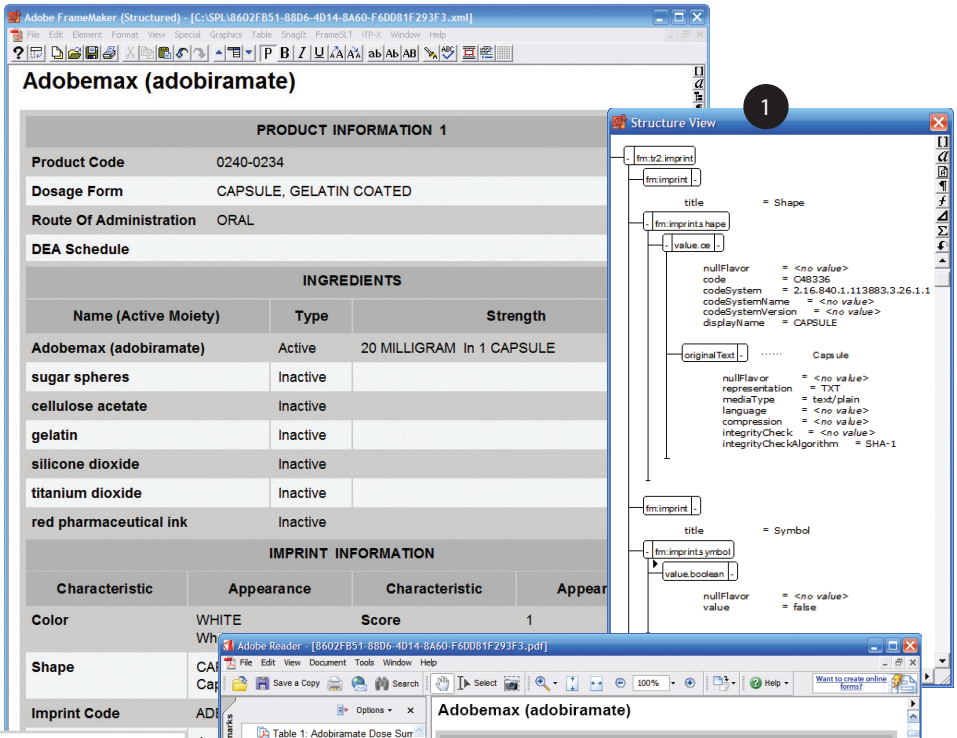
- ***Automatic generation of universally unique ID and LOINC codes:*** Remove the possibility of incorrect element and attribute coding. With Adobe's SPL solution, the SPL author need not worry about code assignment, because LOINC codes are created on output according to the validation model structure and element assignment.
- ***Built-in batch conversion tool:*** Convert existing unstructured product labels to SPL XML, either individually or in batch mode, using the batch conversion feature in FrameMaker.
- ***Internal validation:*** Ensure that your SPL document is valid not only against its schema, but also against your organization's internal business guidelines.
- ***Third-party validation:*** For collaborative projects, help ensure that your business partners and subcontractors supply valid SPL documents.
- ***Workflow, commenting, and updates:*** The Adobe SPL solution integrates the Acrobat commenting and incremental updates into a simple step-by-step workflow. Prior to submission, use the review and commenting tools in Acrobat software to help ensure the technical validity of the SPL document in accordance with your organization's business processes.
- ***Output to multiple formats:*** From the single XML source, Adobe's SPL solution can output to:
  - SPL-compliant XML for submission to the regulatory authority
  - Internet browser view using the SPL stylesheets
  - Adobe Portable Document Format (PDF) based on standard SPL formatting*
  - Adobe PDF fully formatted based on custom stylesheets*

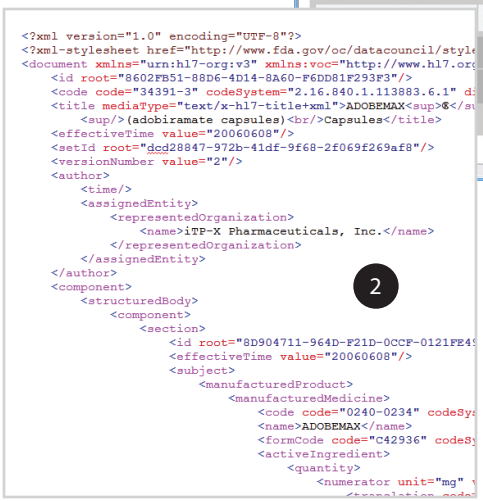
Get started today

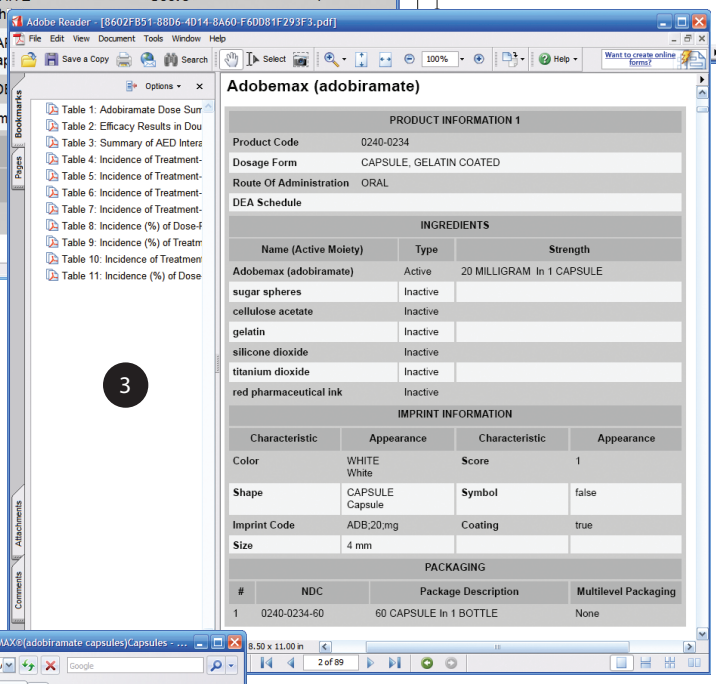
SPL provides many benefits to your organization, and Adobe's SPL solution can help you implement SPL quickly and successfully. To learn more about Adobe's SPL and e-CTD solutions for pharmaceuticals, call 888-649-2990 or send an e-mail to solutions@adobe.com.

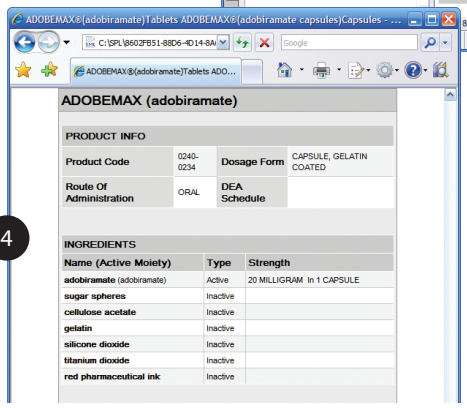
* SPL and PDF
• To comply with portions of the SPL submission regulations, some documents must still be submitted electronically in PDF or as printed paper documents.
• For patient information leaflet package inserts, you can output SPL to PDF and apply your organization's graphic design standards.

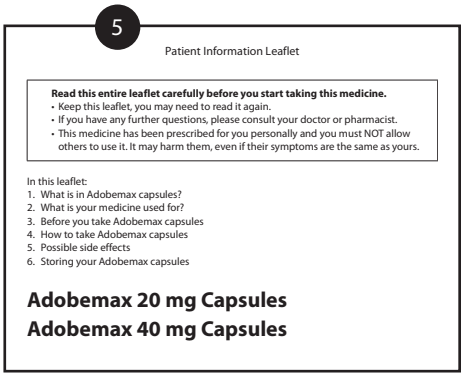
1. **Create SPL data elements and narrative content using the SPL solution in FrameMaker 7.2.**
2. **Save as XML, validated against the SPL schema.**
3. **Distribute as Adobe PDF for commenting, verification, and printing.**
4. **Display the output online using the official SPL browser stylesheet.**
5. **Create patient information leaflet package inserts using Adobe PDF.**











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