www.dataconversionlaboratory.com -----



SPL & SPM RESOURCES

DCL is the industry leader in content structuring—XML content conversion, DITA conversion, SPL conversion services. Founded in 1981, DCL was named one of EContent's Top 100 Companies in the Digital Content Industry.



SPL Resources

We hope the following resources SPL resources and FDA contacts are useful. DCL is always happy to help, you can email DCL's subject matter experts at splfaq@dclab.com. Click the link in the left column.

DCL SPL Page	DCL offers comprehensive SPL conversion services to handle all product types.
Daily Med	NLM site for distributor listings.
FDA Global Substance Registration System search page	Use to find UNII and Preferred Substance Name.
FDA SPL Resources	Complete list of resources from the US FDA.
FDA Online Label Repository	FDA site for distributor listings.
Drug Establishments Current Registration Site	use to verify current registration, operations, and DUNS Number of Establishments.
Drug Nomenclature Monographs	Links to monographs that define FDA terms, some terms may not be allowed in SPL.

SPL Links & FDA Contacts

Status of OTC Rulemakings

Active Ingredient-Active Moiety Relationship/Basis of Strength (click on the link, open the zip file, open the spreadsheet)

CFR Title 21 on-line, Electronic Code of Federal Regulations

<u>Pragmatic Data Validator Lite</u> - Use to both Validate and View SPL

FDA SPL Group Email

<u>FDA Drug Registration and Listing System</u> – Contact them with regulatory questions and request setIds and version number





SPM Resources

We hope the following resources Health Canada resources are useful. DCL is always happy to help, you can email DCL's subject matter experts at splfaq@dclab.com.

Controlled Vocabulary List	<u>Preparation of Product Monographs in the Extensible</u> <u>Markup Language Format - Canada.ca</u>
GitHub - HealthCanada/HPFB	<u>Product Monograph master template - Canada.ca</u> (HTML)
Drug Product Database online query	Master Template PDF
Notice: Phase II of the XML PM Project (Product Monograph in the Extensible Markup Language Format) - Canada.ca	Validation rules for Product Monographs in the Extensible Markup Language (XML) format - Canada.ca