Structured Product Labeling

Content Management

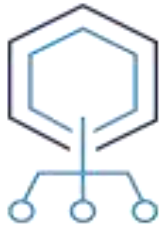
SPL PROCESS CAPABILITIES

SUBMISSIONS	COMPLIANCE AUTHOR	CONVERSION SERVICES
Drug Labeling, Listing and Drug Product Submission	☑	☑
Device Submission	☑	☑
Establishment	☑	☑
Registration	☑	☑
Labeler Code Requests	☑	☑
Self Identification Submission	☑	☑
Blanket No Change of Product Listing Data Submission	☑	☑
Risk Evaluation and Mitigation Strategy Submission		☑
Lot Distribution Reports		☑

GLOBAL LABELING FEATURES

Centralized Repository

Change Control



User-Friendly Workflow

E-Signatures

Business Rules Engine

Version Control

Content Reuse

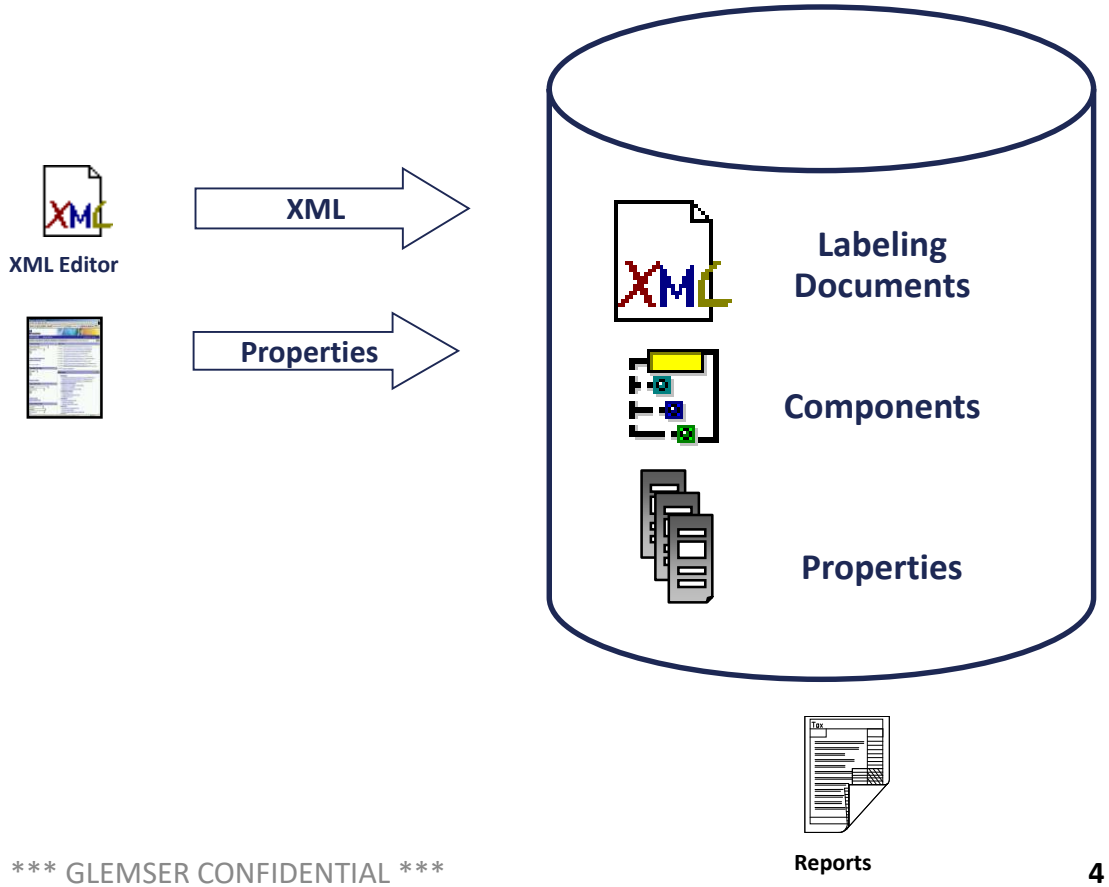
Translation Management

Data Integrity

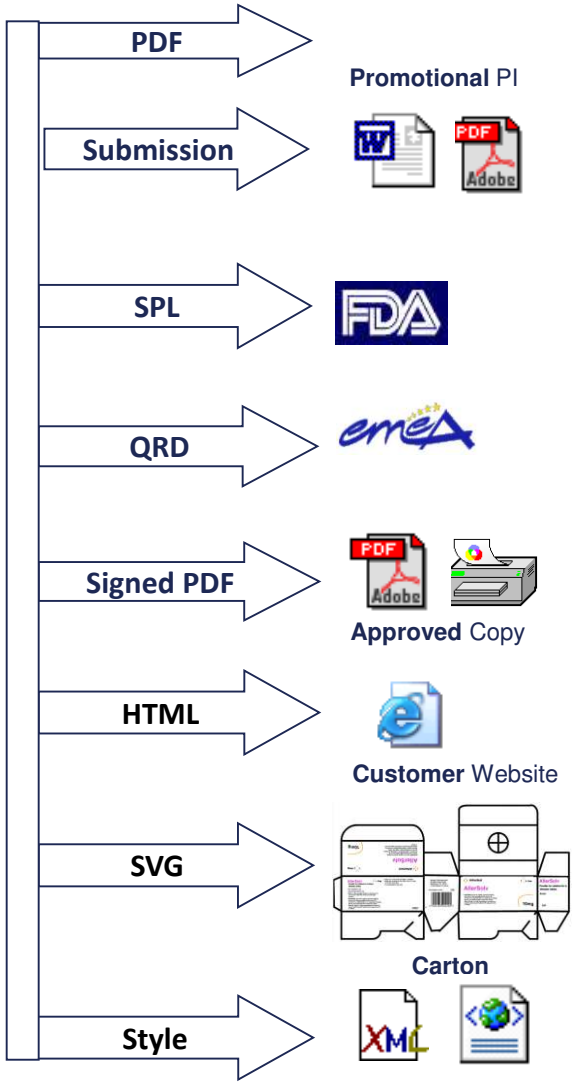
Glemser

CENTRAL REPOSITORY

All product labeling information is stored in one place

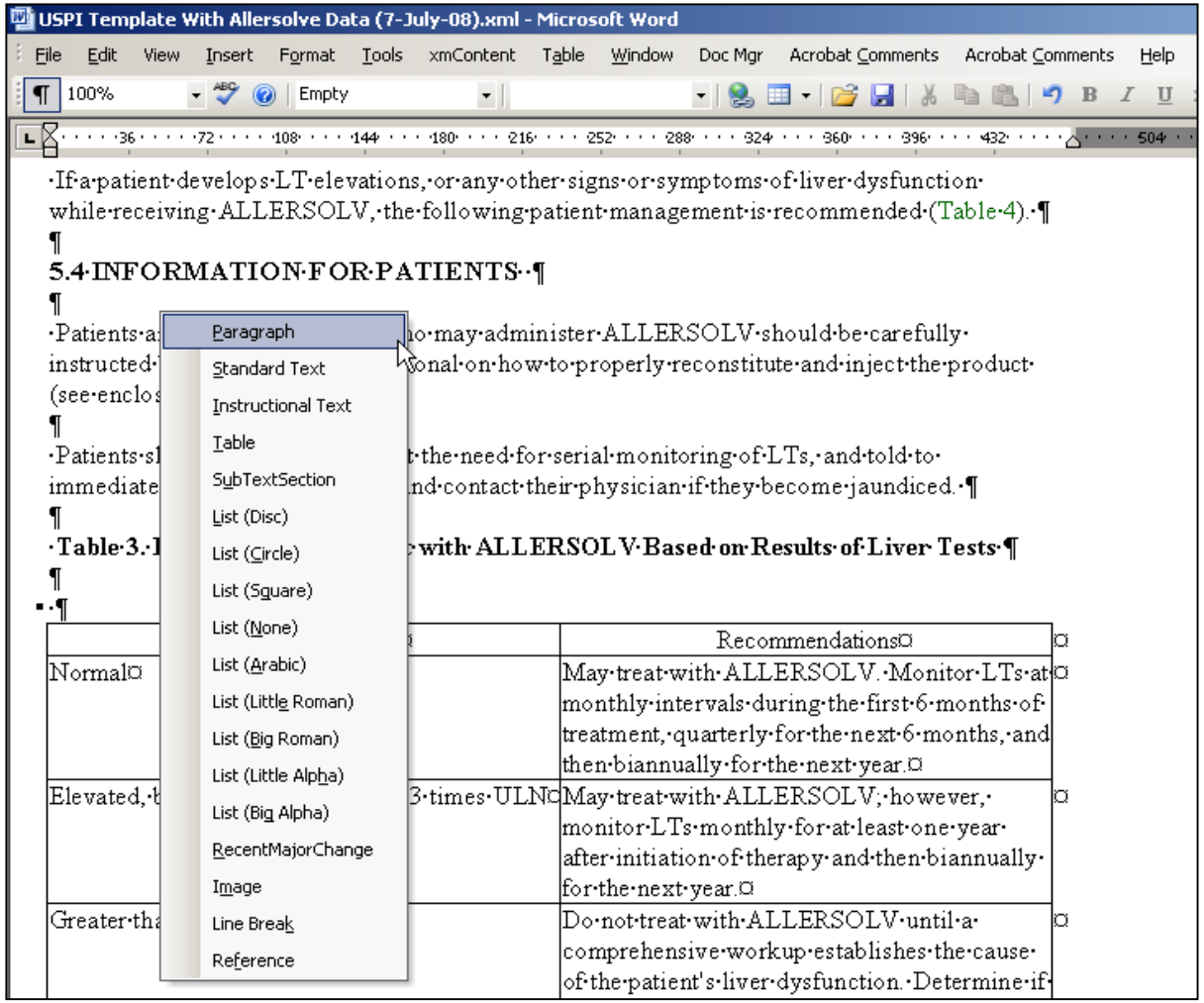


All product labeling outputs come from one place

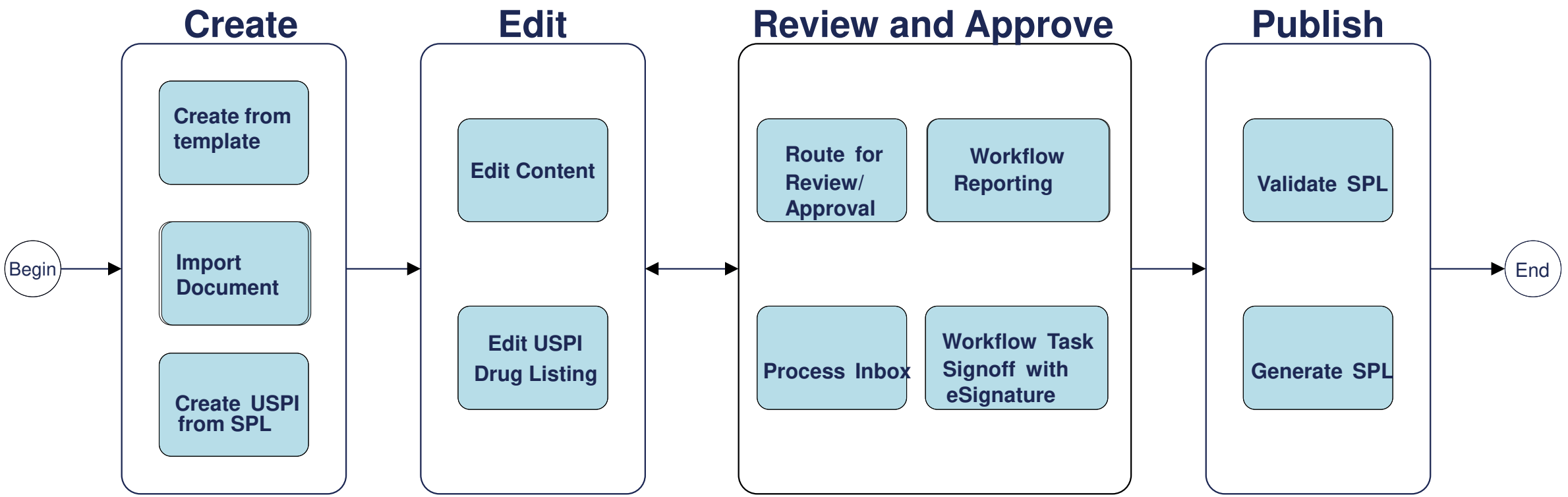


WORD INTERFACE FOR XML CONTENT

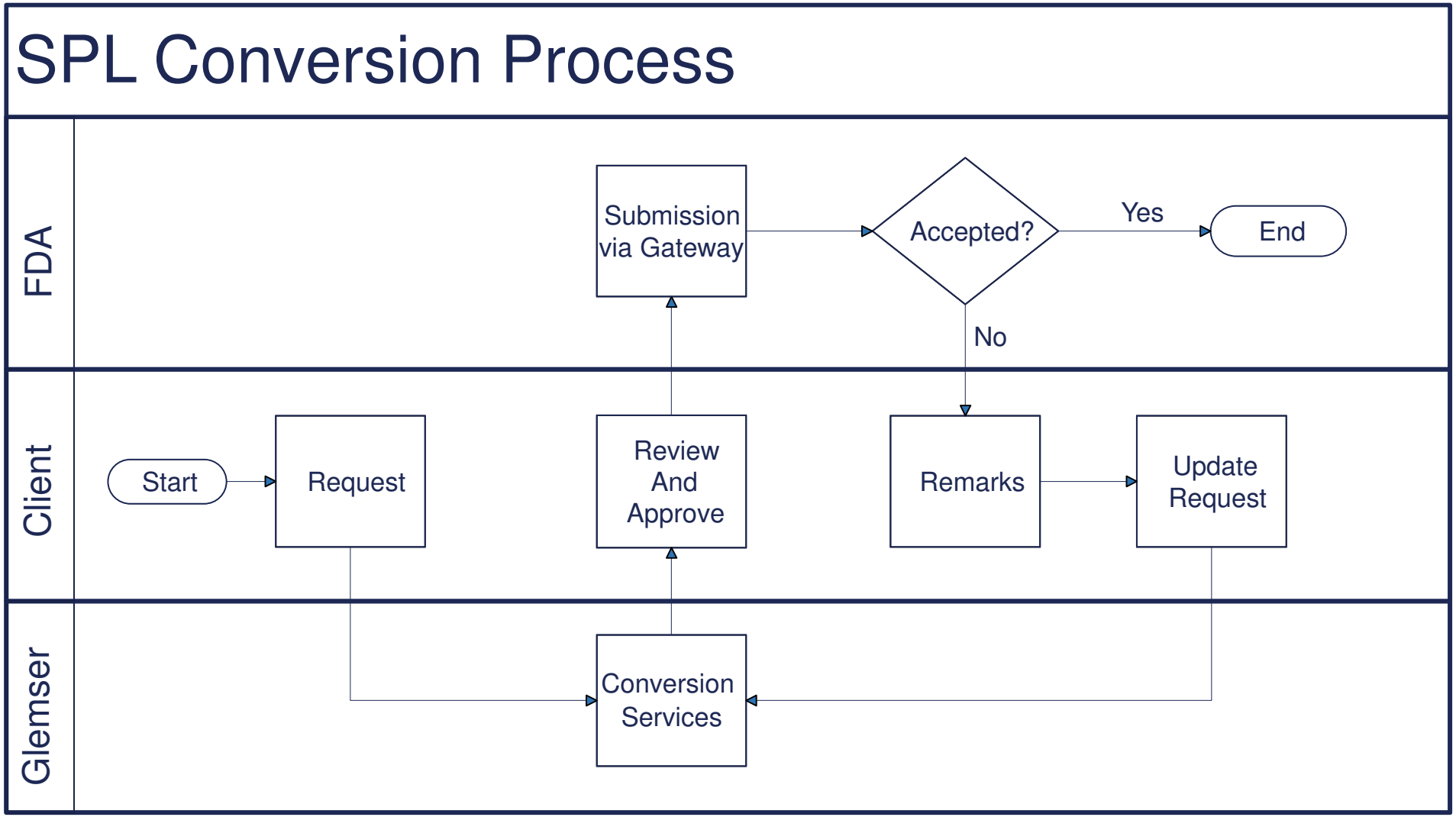
Microsoft Word styles hide complexity and enforce XML schema rules and validations



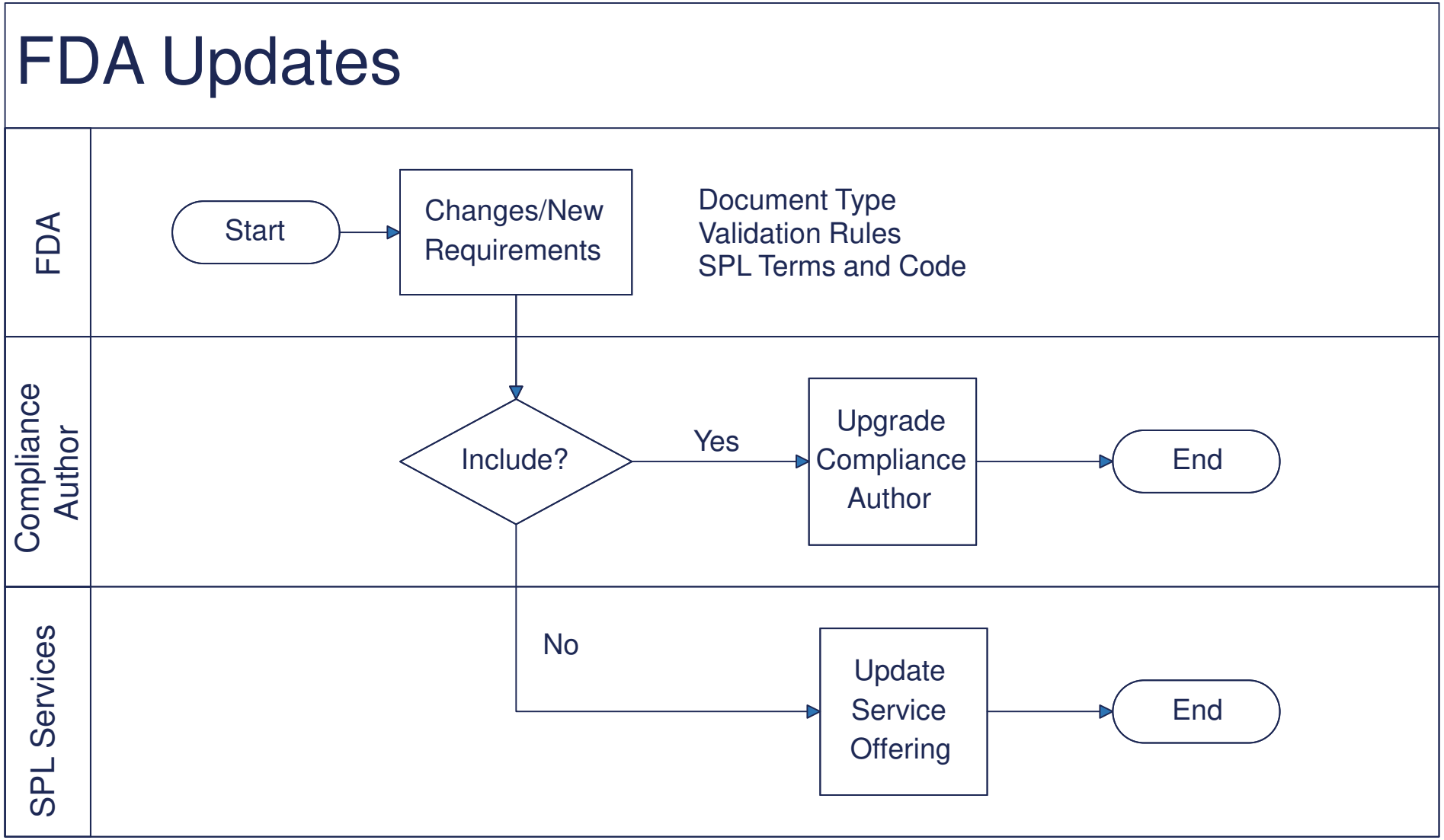
CREATE SPL: COMPLIANCE AUTHOR



SPL CONVERSION SERVICES



KEEPING UP WITH THE FDA



Blanket No Change

Lot Distribution Report

Glemser

LABELING AND IDMP STRATEGY

Defining solutions to leverage IDMP's master data management tools to supplement content management