



Intagras
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Package Insert Conversion Process

Document scrubbing

The first step in the conversion process is a document review and modification to ensure conformance to our client's formatting standard, use of tables, and proper formation of lists. This step is performed to ensure the highest level of conformance and mapping to SPL structures.

Data element identification and database population

Intagras uses the document text when possible to identify and populate the Drug Element Database (DED) with each drug's required data element structure. When necessary Intagras will discuss with our client's authors/experts to identify elements of the drug element and confirm assumptions.

Word to SPL conversion (Drug Conversion Application)

Intagras uses a proprietary tool (SPL Enabler) to convert Microsoft Word versions of package inserts into SPL format.

Post conversion quality assurance

Intagras

Intagras performs automated and manual conversion quality assurance checks to ensure the following:

- XML validity
- Schema validity
- FDA compliance (based on the FDA implementation guide)
- Content comparison (original document comparison)
- Image compliance (jpg or gif)
- Packaging compliance (based on the FDA implementation guide)

Client

Our clients are provided the opportunity to perform additional quality assurance checks to confirm the SPL document is acceptable.

Package Insert Version Management

Intagras retains and versions all of the following:

- Original MS Word package insert
- Post scrub MS Word package insert
- SPL / XML rendition
- Conversion version
- Images

SPL Package Insert Delivery Process

Intagras provides our clients with all files and images for each package insert to ensure electronic acceptance by the FDA.

Pre-Production FDA Test Submissions

Intagras works with our client's labeling department to submit test SPL labels to the FDA.