

A Product Development Platform Approach For Structured Content & Data Management (SCDM) To Feed AI/ML, Technical Reports, And Dossier Granules

The Challenge

- >20% science and engineering time on data aggregation and transcription
- Multiple, disparate data sources with varying cleanliness
- Intensive, manual, time-consuming data table verification
- Need for rapid, accurate report generation
- Increasing requirements by health authorities



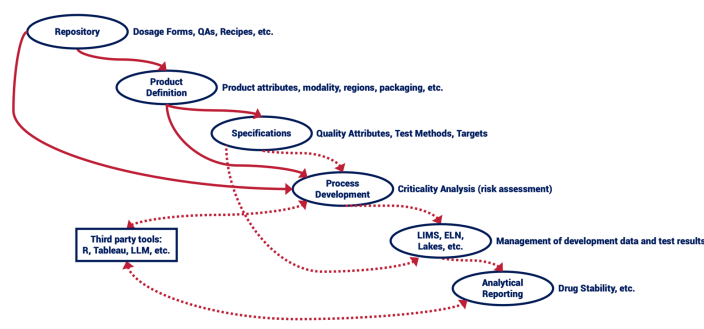
The Solution: Structured Content & Data Management (SCDM):

- Ontological and semantic mapping to organize data and connections
- Centralized repository of configurable report templates to meet regulations
- Automated data table and report generation
- Trusted source to feed LLM with clean data
- CMC data that is accurate, consistent, reusable, and reportable

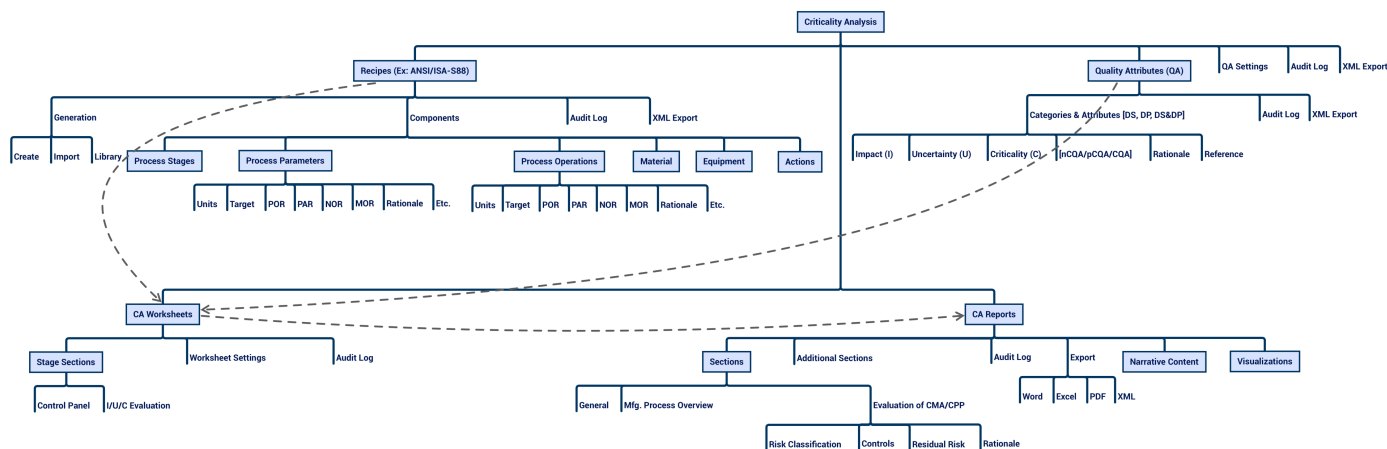
Internally structured data items are the foundation of SCDM. Data items are organized in multiple formats and used throughout reports for submission and internal use.



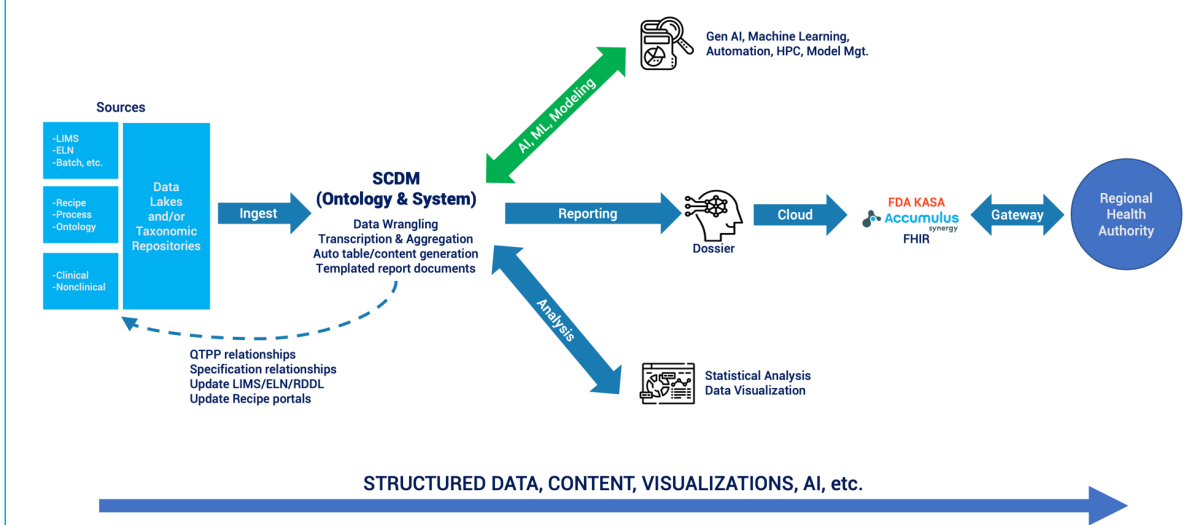
Example Structured Data Item Flow



Example: SCDM maps the interactions between internally structured data items and report sections for Criticality Analysis



Structured Content and Data Management (SCDM) Data Flow Strategy



STRUCTURED DATA, CONTENT, VISUALIZATIONS, AI, etc.