

AI in CMC From Data to Dossier

Automating CMC Dossier Creation WITH Structured Document Authoring AND Live Data Connections

CHALLENGES

Every change
requires
human data
verification

eCTD Regulatory Submission Module 3
Chemistry, Manufacturing and Controls (CMC)

CURRENT INDUSTRY CHALLENGE IN DELIVERING CMC

- Variety of data sources
- Inconsistent Ontology
- Assortment of tools – Word, Excel
- Multiple review cycles

50

Sections

>1000

Figures & Tables

1-4

Weeks / Section

100-200

FTE Weeks

Data Verification

3 Authoring, Review and Data Verification events **Per Table**

CHALLENGES IN CMC AUTHORIZING

Manual and error-prone
data transcription

Data duplication
in various places

Multiple data sources

Knowledge **locked**
in documents

Documents **deviation**
from standard layouts

**High regulatory
standards**

WHAT IS NEEDED?



AI

Using Deterministic AI for data and Generative AI for narratives accelerates CMC document creation



Data to Document

Moving from a document-centric to a data-driven approach, automates the generation of new CMC documents based on an immutable Data Lake



Collaborative Authoring

By automating the authoring of documents, human intervention is minimized; users don't waste their time with non-value adding activities



Content Lifecycle Management

Supporting the creation, versioning and approval of the documents reduces the complexity of managing CMC content

STRUCTURED DOCUMENT AUTHORIZING MAKES A DIFFERENCE



Quality and Compliance

- Reduce errors caused by manual activities
- Ensure data traceability and "data integrity by design"



Time & Costs

- Generate documents with AI and increase productivity
- Reduce manual data query of data in each application
- Eliminate repeated data verification approvals
- Reduce review cycles



Collaboration

- Collaborate simultaneously on documents
- Integrate new partners, suppliers and customers

THE VALUE



+\$2M cost savings*
per dossier



80%-time reduction* for creating
stability, batch analyses &
specifications sections



50% time saving*
across CMC content
authoring



Save 30 – 70% of time*
by omitting manual data
reverification



**Right-First-Time
submissions**

*Customer reported expectations

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