

AI-Powered CMC Authoring

A connected dossier for keeping Module 3 and the Module 2.3
Quality Overall Summary in sync throughout the product lifecycle

For CMC, Regulatory-CMC, Quality, and R&D Digital & AI leaders
Trusted by more than half of the world's top 20 pharmaceutical companies

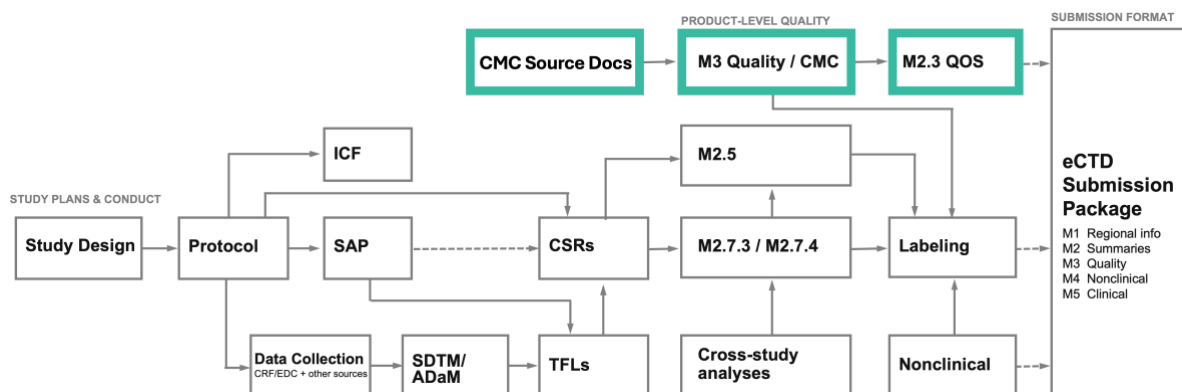
Executive Summary

One of the central operational challenges in CMC submissions is keeping an evolving, interdependent body of evidence and documentation coherent. Under M4Q(R1), Module 3 and the Module 2.3 Quality Overall Summary (QOS) must tell one traceable quality story across development reports, specifications, analytical methods, validation, and stability data, and keep telling it through every amendment, variation, and post-approval change.

The M4Q(R2) draft proposes a Quality Overview in Module 2.3, including 2.3.3 Core Quality Information. Regional adoption will determine transition timing. Earlier filing can have substantial value: McKinsey models approximately \$180 million in NPV for a \$1 billion peak-sales asset from roughly 12 weeks of acceleration between its 2020 median and 2024 top-quartile benchmarks.¹ That scenario is not a CMC-authoring ROI estimate or a product result. Faster writing matters only when net review effort falls and the filing critical path can move.

AuroraPrime is built for this environment. It connects controlled source evidence, CMC authoring, configurable regulatory and terminology checks, QC, and review in a human-governed workflow. The platform retrieves supporting evidence and produces CMC-structured drafts with source-level traceability; flags potential downstream impacts of changes across Module 3 and the QOS; and supports cross-document consistency review and inline QC. Qualified experts review, refine, and approve every output and every proposed change.

This paper is written for two readers who increasingly share one decision: the CMC and Regulatory-CMC leaders who own the dossier, and the digital and AI leaders who own the platform choice. It covers where the authoring burden sits, how a connected approach addresses it, and how to assess quality and traceability in an expert-led workflow.



AuroraPrime brings supported authoring workflows into a connected environment. Within configured CMC projects, source evidence, Module 3 content, and the QOS are linked to support review and coordinated updates. Confirm section coverage and any labeling, RIM, or publishing connections for the proposed implementation.

¹ McKinsey & Company, 'Rewiring pharma's regulatory submissions with AI and zero-based design,' August 2025, p.2 and footnote 1. The \$180 million scenario assumes roughly 12 weeks of acceleration from the 2020 median to the 2024 top quartile, at roughly \$60 million NPV per month.

1 Why CMC Authoring Is a Network Problem

CMC teams are judged on their science. Much of their time, however, goes into high-volume, highly structured writing—the Quality Overall Summary, Module 3 narratives, the rationale behind specifications, stability reporting—and into locating, transferring, and re-checking the evidence behind conclusions already reached. The role of AI here is not to substitute for expert judgment, but to shorten the distance between established scientific understanding and a well-drafted, internally consistent section that is ready for expert review.

A CMC dossier is written by many hands from many sources. The QOS synthesizes the detail and critically discusses key issues; it should not introduce information, data, or justification absent from Module 3 or other CTD sections. Ownership varies by organization and product; responsibility is divided, while consistency is not. Product type shapes the evidence: examples include structural characterization and synthesis-related impurities for small molecules, and cell-substrate history and process- and product-related variants for cell-derived biologics. Each product requires its own evidence and control strategy. The dependencies differ, but both face the same four structural challenges.

The dossier evolves throughout the lifecycle. ICH Q12 links established conditions, post-approval change management protocols, and the pharmaceutical quality system within regional reporting frameworks.² Reporting routes and timing depend on the change and jurisdiction; some changes need no regulatory reporting. Assess affected Module 3 and QOS content and record why other sections remain valid. Keep proposed, approved, and implemented states distinct. Revising a narrative does not authorize a manufacturing change.

Challenge 1 — Fragmented source content

A single Module 3 section may draw on development reports, specifications, analytical methods, stability data, batch records, certificates of analysis, and supplier documentation. These sources are often dispersed across systems and formats, making retrieval, data extraction, and source reconciliation time-intensive. Manual transfer between source records and the dossier also increases the risk of transcription errors and of using superseded content.

Challenge 2 — Sustaining scientific and regulatory precision

CMC content must be scientifically accurate, internally consistent, traceable to supporting evidence, and aligned with ICH M4Q and the applicable Q-series guidance. Authors must maintain this standard across detailed descriptions of manufacturing processes, controls, analytical procedures, specifications, validation, and stability—through each revision cycle, and often in a submission language that is not the author's first language.

Challenge 3 — Managing change impact across the dossier

CMC documentation is highly interconnected. A change to a process, control strategy, analytical method, specification, or stability protocol may affect multiple Module 3 sections, the QOS, and the regulatory reporting strategy. Identifying the full impact still depends heavily on expert recall, institutional knowledge, and manual assessment.

² ICH Q12, 'Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management,' November 2019, Chapters 2–4 and 6. Apply current regional rules, including 21 CFR 314.70/601.12 and the EU variations framework, as applicable; a single reporting route cannot be generalized globally. For QOS scope, see ICH M4Q(R1), Module 2.3 introduction, p.1 (12 September 2002).

Challenge 4 — Verifying consistency at scale

Key quality information—specifications, acceptance criteria, batch information, analytical methods, and stability conclusions—must remain aligned across source documentation, Module 3, and Module 2.3. Verifying these dependencies across a large and evolving document set is resource-intensive, while even minor discrepancies can trigger health-authority questions and review delays.

Why M4Q(R2) Sharpens the Problem

The M4Q(R2) draft proposes a Quality Overview in Module 2.3, with Core Quality Information central to assessment and lifecycle management.³ As regional implementation is defined, CMC teams may need to prepare for R2 filings while maintaining legacy R1 dossiers across active product lifecycles.

For material-related information, the draft uses Description, Manufacture, Control, and Storage (DMCS) across corresponding Module 2.3 and Module 3 sections; analytical procedures and facilities use different organizing logic. Depending on regional implementation, legacy content may need remapping and additional justification, not merely new headings. Teams should preserve provenance while assessing gaps and scientific sufficiency. The draft does not establish one universal deadline or retrofit rule for existing dossiers.

2 How AuroraPrime Addresses Each Challenge

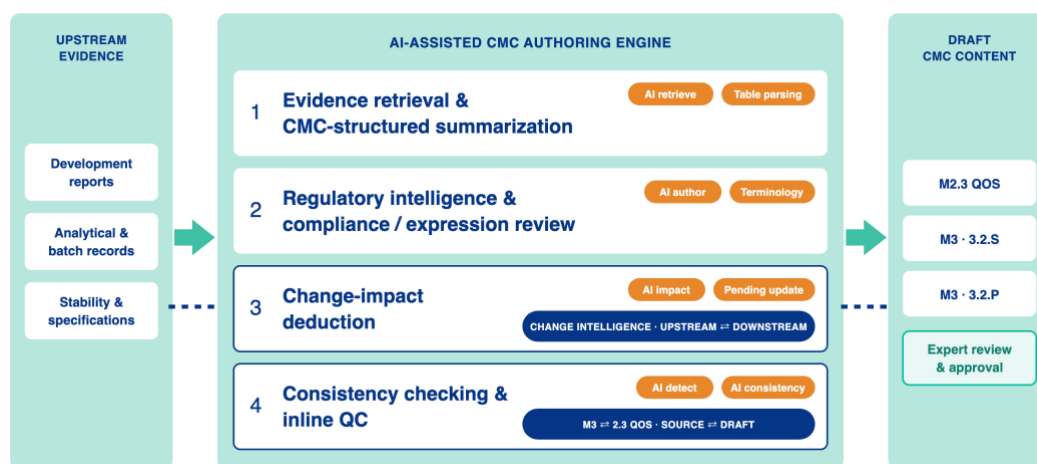


Figure 1. The four AuroraPrime capabilities described in this section sit between upstream evidence and draft CMC content. Experts review proposed outputs; supported sections and source relationships depend on the configured implementation.

³ FDA/ICH M4Q(R2), January 2026 draft, and ICH M4Q(R2) Mapping Document (12 January 2026). FDA status checked 18 September 2026: Draft / Not for implementation. Verify current ICH text, mapping version and regional transition rules before use.

1. Automated evidence retrieval and CMC-structured summarization

The platform retrieves evidence from supported source documents and prepares source-linked CMC drafts for expert review. Confirm handling of tables, figures, scanned files, and document versions for the selected workflow. Authors should inspect extracted values and the supporting passages: a citation that resolves does not necessarily support the conclusion. Missing or unreadable inputs should remain visible rather than becoming a fluent but unsupported draft.

2. Built-in regulatory intelligence and AI-powered compliance and expression review

Regulatory guidance, approved templates, controlled terminology, and organization-specific authoring rules are configured from project setup onward. As content is drafted, AuroraPrime checks it against configured rules and proposes wording for review. These checks support, but do not establish, scientific adequacy or regulatory compliance. Terms such as “approximately” or “should” require context, not automatic rejection. Review should preserve source qualifiers and request missing evidence, not convert an approximation into an invented statistic. For global CMC organizations, where many authors write in English as a second language, this in-draft review can also reduce language-editing friction later in the review cycle.

3. Intelligent change-impact deduction

For changes within the configured, associated content set, AuroraPrime helps identify potential downstream impacts for expert assessment. It flags potentially affected Module 3 content and QOS sections and surfaces them for expert review, with the relationship between source and target shown at the section level. Authors determine whether updates are needed and approve every change. Section 4 describes this human-governed loop.

Automated Version Comparison

2.3.5.7.2.1.3 Stability Acceptance Criteria

The analytical methods and acceptance criteria used to support the drug substance stability studies are a subset of the batch release methods for the ABC123 drug substance bulk solution. (Description of the analytical procedures are provided in Section 2.3.5.4.2 Analytical Procedures). The specification is provided in Section 2.3.5.4.1 Specifications).

Test	Stability Acceptance Criteria
Appearance	Clear liquid
pH	5.0-7.0
Protein concentration	5-10mg/mL
Identification	Form a specific precipitate line with diphtheria antitoxin
Purity	>95.0%
Molecular weight	50-100kDa
Residual endotoxins	Not more than 0.1 EU per mL
Stability	No evidence of microbial growth

2.3.5.7.2.2 Commitment

The Applicant commits to continue conducting stability studies in accordance with the established stability protocol for the ABC123 drug substance bulk solution.

2.3.5.7.3 Stability Data

2.3.5.7.3.1 Long-term (3-6°C)

Table 2.3.5.7.3.1-1 XXXXXXXX long-term stability study (3-6°C)

Test	Specification	Time points (Months)		
		Initial	3	6
Appearance	Clear liquid	Clear liquid	Clear liquid	Clear liquid
pH	5.0-7.0	5.10	5.9	5.9
Protein concentration	5-10mg/mL	8.2	7.9	7.9
Identification	Form a specific precipitate line with diphtheria antitoxin	Met	Met	Met
Purity	NLT 95%	100	98.92	97.81
Molecular weight	50-100kDa	57.90	56.06	57.74

Comparing...

Comparing Associated document versions, please wait.

1/100

Automated Impact Analysis

2.3.5.7.2.1.3 Stability Acceptance Criteria

Pending Update

Analyze & Summarize The analytical methods and acceptance criteria used to support the drug substance stability studies are a subset of the batch release methods for the ABC123 drug substance bulk solution. (Description of the analytical procedures are provided in Section 2.3.5.4.2 Analytical Procedures). The specification is provided in Section 2.3.5.4.1 Specifications).

2.3.5.7.2.2 Commitment

Analyze & Summarize The Applicant commits to continue conducting stability studies in accordance with the established stability protocol for the ABC123 drug substance bulk solution.

One-click M2.3 Updates

Document Name

2.3.5.1 General Information.docx

2.3.5.1 General Information v2.3.docx

Need Update Sections 1/2 References 0/2

2.3.5.2 Manufacture.docx

2.3.5.2 Production.docx

Need Update Sections 1/2 References 0/2

Figure 2. Illustrative version-comparison and impact-review screens. Update proposals require expert confirmation; availability depends on the configured workflow. Displayed values and criteria are examples, not recommended specifications.

4. Automated consistency checking and inline QC

Configurable consistency checks compare values, terminology, and conclusions within a document, between Module 3 and the QOS, and against rules derived from ICH M4Q and the Q-series, flagging potential mismatches in values and logic within the configured scope. Findings are collected in a central QC panel with supporting source evidence and can be resolved inline through reviewer comments. Not every difference is an error: drug-product release limits may be tighter than shelf-life limits where justified and permitted by regional requirements. A process set point and its justified operating range describe different aspects of process control and should be labeled accordingly, not treated as interchangeable values. The checks surface the difference; accountable experts decide whether it is a finding and how to resolve it.

Inline Automated CMC Consistency Check & QC

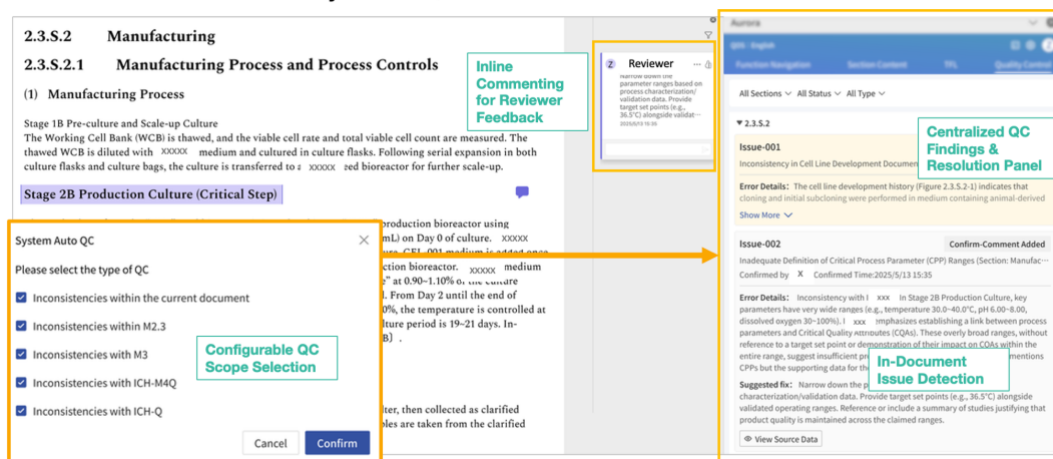


Figure 3. Illustrative QC interface. Flags and suggested wording require assessment against source evidence. Parameter ranges must be scientifically justified, not narrowed solely because AI flags them; sample values are not recommendations.

3 ICH M4Q(R2) Readiness: Structured R1 → R2 Transition

AuroraPrime is designed to support the M4Q R1→R2 transition through guided, human-reviewed content transformation, with targeted re-authoring where scientific or regulatory gaps remain. The approach includes:

- **Automated remapping:** Parsing existing Module 2.3 and Module 3 content, proposing its placement in the R2 structure, and flagging the exceptions that need author judgment.
- **Connected authoring:** Building Module 2.3 and Module 3 as linked, complementary content layers, reducing avoidable duplication and rework.
- **In-authoring structural checks:** Flagging potential structural misplacement and unnecessary duplication before content reaches formal review.
- **Mapping-document alignment:** Applying the 12 January 2026 ICH R1-to-R2 Mapping Document as configurable mapping checks while keeping expert review in control of complex or ambiguous mappings. ICH itself characterizes the mapping as conceptual rather than exhaustive; correct placement alone does not establish content completeness or submission readiness.

4 Change Intelligence: Keeping the CMC Dossier Coherent

CMC lifecycle changes require coordinated assessment and, where needed, coordinated revision across the connected dossier. AuroraPrime uses AI to identify potential downstream impacts, propose updates for Module 3 and the QOS, and maintain traceability, while experts retain control of every decision.

AI-Assisted Change Workflow

A human-governed change workflow should make six steps visible. AuroraPrime supports source-linked review and update proposals; confirm which steps and associations are supported in the offered configuration:

1. **Detect changes** — flags new or revised content when configured source documents or records are updated within the associated content set, for example from a connected RIM system.
2. **Interpret meaning** — analyzes what changed and where it is referenced, not only the text difference.
3. **Assess impact** — traces documented dependencies across underlying evidence, Module 3 content, and the QOS, and presents likely and conditional impacts for the reviewer to confirm.
4. **Propose revisions** — generates concept-level update proposals for impacted sections, where appropriate.
5. **Expert review** — delivers proposals to authors in Word, alongside the upstream content and a side-by-side impact panel.
6. **Retain rationale** — records each accepted, refined, or rejected proposal together with the reviewer's comments, so that the record captures the decision, not only the text delta.

Treating the dossier and its source evidence as one connected network, rather than a collection of independent documents, is what makes this loop possible.

"A human may miss one or two changes. This connected, AI-powered document network helps trace their downstream impact and records every decision in the audit trail."

— Sharon Chen, Founder & CEO, AlphaLife Sciences

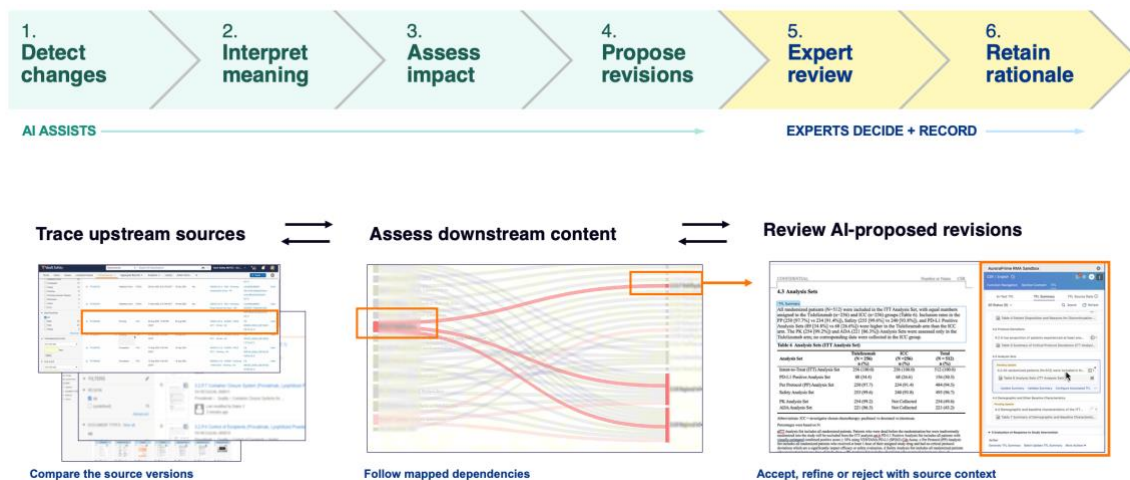


Figure 4. A human-governed change workflow, illustrated with cross-document interface examples. Clinical screens do not establish CMC-specific functionality.

5 Trustworthy by Design: The Quality Framework

Drafting is only the beginning. AuroraPrime is designed to help submission content withstand health-authority review and to make quality evidence visible to the people accountable for it. Buyers should evaluate outputs against five core quality dimensions:

Dimension	Definition
Accuracy	Numeric values, data, and terminology faithfully reflect controlled sources and approved vocabularies.
Completeness	Required content is present for the intended use; missing evidence and unresolved questions are visible.
Consistency	Related statements agree where context is the same; legitimate differences are preserved.
Factuality	Evidence supports factual statements; interpretations, calculations and assumptions are identified for review.
Traceability	Source identity/version and review decisions can be inspected and reconstructed.

Ask the supplier to demonstrate the controls supporting these dimensions:

- **Grounded generation:** Show the source passages and versions behind a draft, and test what happens when evidence is missing, contradictory, or does not support the proposed conclusion.
- **Independent assessment:** Evaluate deterministic checks and model suggestions separately against expert-adjudicated evidence. A second pass by the same model is not independent validation.
- **Audit-supporting traceability:** Verify retention and export of source versions, configuration, reviewer actions and decisions. Supplier evidence supports, but does not replace, customer validation, access control and records management for the intended use.
- **Human expertise remains decisive:** Qualified writers and CMC experts define the quality standard and approve every output; automated metrics are signals, not a substitute for judgment.

About AlphaLife Sciences

AlphaLife Sciences is an AI-native platform company transforming how therapies move from lab to market. AuroraPrime supports nonclinical, clinical, CMC, safety, labeling, and post-market documentation across the drug lifecycle, helping pharmaceutical companies, biotech firms, and CROs prepare, review, and maintain content for IND, NDA, BLA, and MAA submissions.

Defensible leadership is built on depth, workflow, and eCTD connectivity. AlphaLife delivers the document intelligence infrastructure that enables life sciences teams to author, control, review, and maintain high-stakes regulatory content with greater rigor across the R&D lifecycle. Three pillars set the platform apart: **depth by document type**—each workflow purpose-built for the scientific, regulatory, and operational requirements of its document type, with performance proven in complex, high-stakes deliverables such as CSRs; **one connected lifecycle workflow**—authoring, evidence, reasoning, quality control, and review unified in a single workflow, with end-to-end integration into existing systems; and **connected eCTD intelligence**—an interconnected submission environment in which documents, content, and evidence remain aligned across the dossier, enabling intelligent management of cross-document relationships and change impact.

The team includes talent from Google, Microsoft, Veeva, Medidata, and McKinsey, with guidance from former FDA officials and senior pharmaceutical executives. Strategic partners include NVIDIA, Veeva, and Johnson & Johnson Innovation JLABS. Validated as Microsoft’s strategic AI content-authoring partner for life sciences, AuroraPrime is trusted by more than half of the world’s top 20 pharmaceutical companies.

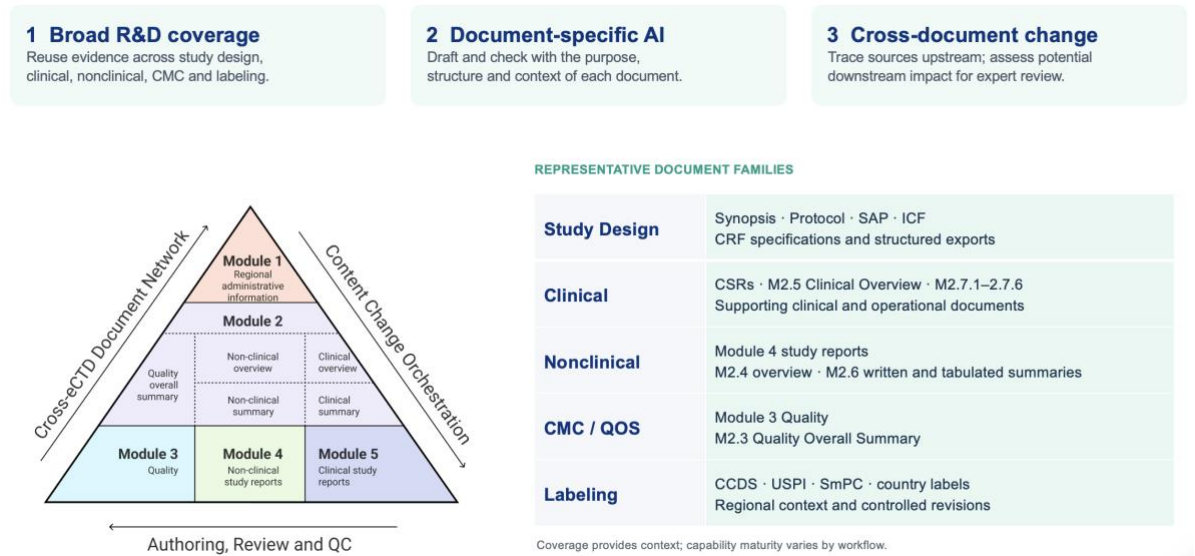


Figure 5. CTD content structure (M4Q(R1) quality terminology): linking supported document workflows, source evidence, review and QC. Confirm coverage and change-management capability by document type and implementation.

AN ALPHALIFE SCIENCES CMC WHITE PAPER

***Know every connection.
Change with confidence.
Automate with control.***

Bring an approved or de-identified Module 3 section, its QOS text, and a source change, or use our demonstration dataset. Agree the scope, then inspect source evidence, proposed impacts and updates, and expert review in AuroraPrime.

Visit us: AlphaLifeSci.com

Book a CMC workflow demo: AlphaLifeSci.com/book-a-demo