Regulatory Matters

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Editorial

Artificial intelligence is in the initial stages of adoption for regulatory medical writing, with the prospects of shifting the field from manual drafting to an era of intelligent automation and strategic content management. Here, Jenni Pickett and Vanessa de Langsdorff illustrate how AI-driven tools enable writers to transcend routine tasks – such as formatting and repetitive drafting – allowing them to focus on developing clear, compliant, and well-structured key messages for regulatory authorities. The authors emphasise that standardisation and modular content are now essential for achieving quality, consistency, and efficiency across global submissions.

Pickett and Langsdorff also highlight the evolving skill sets required: today's medical writers must have a foundation in AI technology, apply document content and data in the context of AI tools, and collaborate with both project teams and technology specialists. Successful adoption, they argue, requires not only technological fluency, but strong change management and alignment with organisational content standards. Far from replacing writers, AI elevates the profession, turning writers into content architects who guide document strategy and ensure scientific integrity.

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The AI-enabled medical writer: A new era for regulatory writing

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Abstract

As artificial intelligence (AI) becomes increasingly integrated into the pharmaceutical industry, regulatory medical writers find themselves at a critical intersection of science, language, and technology. The traditional approach to document authoring – manual, time-consuming, and highly variable – is being augmented by intelligent automation systems. This article explores how medical writers are navigating this transition, what technological concepts they must grasp to succeed, and how their roles are evolving to collaborate effectively with cross-functional tech teams. The future of regulatory writing is here, and it is structured, standardised, and AI-enabled.

Regulatory medical writers have historically expended significant time and effort to transform complex clinical data into clear, compliant narratives for health authorities. However, the introduction of AI tools into medical writing is rapidly altering their workflow. No longer confined to laborious manual document development processes, today's writers are expected to work in dynamic, tech-driven environments where content must be modular, reusable, and aligned with digital workflows.

The integration of AI into the writing process requires scale and standardisation to achieve real time savings:

- **Standardisation** limits individual preferences in writing style and formatting.
- Medical writers focus on **what to say**, the key message, and the significance of the data.
- Technology manages **how it is said**, ensuring consistency in style and structure.
- **Consistent content** improves quality control, streamlines the review process, and supports dossier assembly and regulatory approval.

> Writers have the opportunity to embrace technology and step into a more strategic role, becoming content architects who help standardise information from source data through to final review.

With global submissions, multiple indications, and mounting pressure to reduce time-to-market, medical writing teams are exploring automation tools that can handle content generation and reuse with less tedious intervention. This means learning not only how to create fit-for-purpose regulatory content, but also how to configure it for automated workflows – structuring content so it can be parsed, analysed, and reused across the full regulatory dossier. Writers have the opportunity to embrace technology and step into a more strategic role, becoming content architects who help standardise information from source data through to final review.

Bridging the gap between writing and technology

For writers to collaborate effectively with tech teams, they must understand the language and logic of the tools they're being asked to use. This begins with foundational knowledge of how AI is implemented in regulatory writing tools.

Most medical writing software aligns with one or more of the following categories:

- Classic programming includes most software we have had up until 2019, like structured content authoring tools that store blocks of content to be reused between different documents.
- Symbolic AI, also called an expert system or deterministic AI, uses rule-based AI technology to generate accurate text and tables. Because symbolic AI requires an extensive knowledge base, it is typically found only in proprietary software designed for a specific task. Symbolic AI is able to perform Natural Language Generation (NLG) with 100% data accuracy.
- Generative AI creates text based on probabilities it has learned from huge datasets. Machine learning (ML) is used to identify patterns in human text, images, video, and audio. These patterns form a large language model, or LLM. Using a model to predict a response makes generative AI flexible to a variety of tasks, but its probabilistic nature means it can be challenging to get an exact reproducible result, and errors are a possibility.

Medical writing software may focus primarily on one underlying technology, or may be a blend of two or three. For example, the text could be generated by symbolic AI and then summarised or enhanced by generative AI. Classic programming provides you with buttons and menus to execute actions, for example.

Learning the tech lingo

To navigate AI tools confidently, medical writers must also become comfortable with some key technical terms:

- **Token**: The smallest unit of text processed by an LLM, often a word or part of a word. For example, according to the OpenAI Tokeniser, GPT-4o breaks "Learning the tech lingo" into 5 tokens: learning, the, tech, l, and ingo.
- **Context Window**: The total amount of text an LLM can "see" at once to generate accurate output. Regulatory documents can be too large to be processed by an LLM all at once because the context window may only be a few hundred pages.
- **Retrieval-Augmented Generation (RAG)**: A method that feeds relevant content into an LLM's prompt to improve factual accuracy. A RAG system breaks down long content into only the necessary chunks of information.
- **Multimodal Models**: AI systems that can interpret more than text – such as images, video, or audio. For regulatory writing, multimodal models are helpful to understand figures and schemas.
- **Hallucinations**: Content a large language model generates that is incorrect.
- **User acceptance testing**: A process where end users verify a system meets requirements before release. Testing typically includes predefined scenarios to validate accuracy, usability, and compliance.

This shared vocabulary enables smoother collaboration with product managers, developers, and data specialists – especially when evaluating or implementing software solutions.

Build versus buy: Choosing a software development strategy

Medical writers and their organisations face a critical decision in their AI adoption journey: whether to build a custom tool, buy a specialised platform, or adapt a general-purpose tool such as ChatGPT.

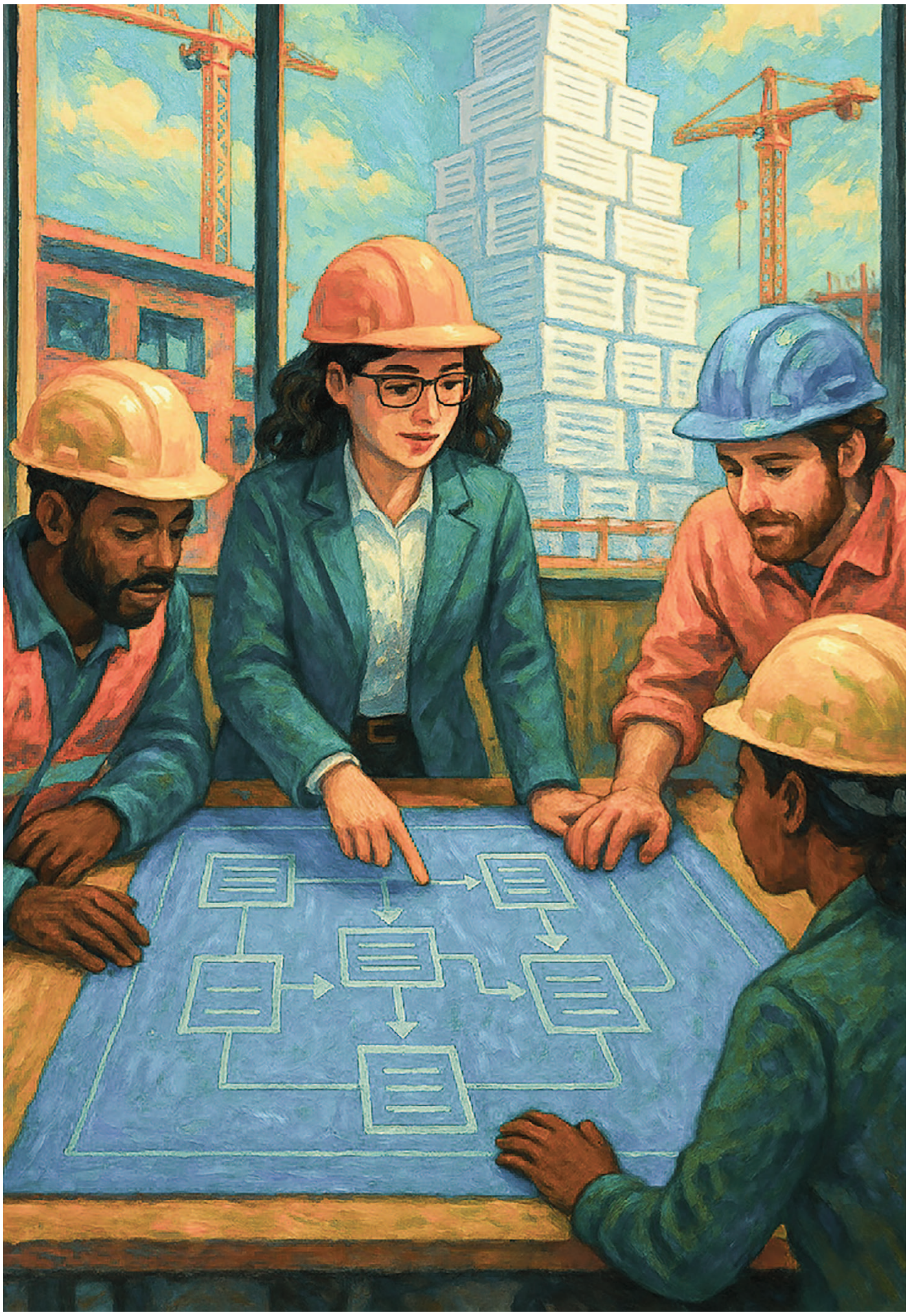
Illustration: ChatGTP

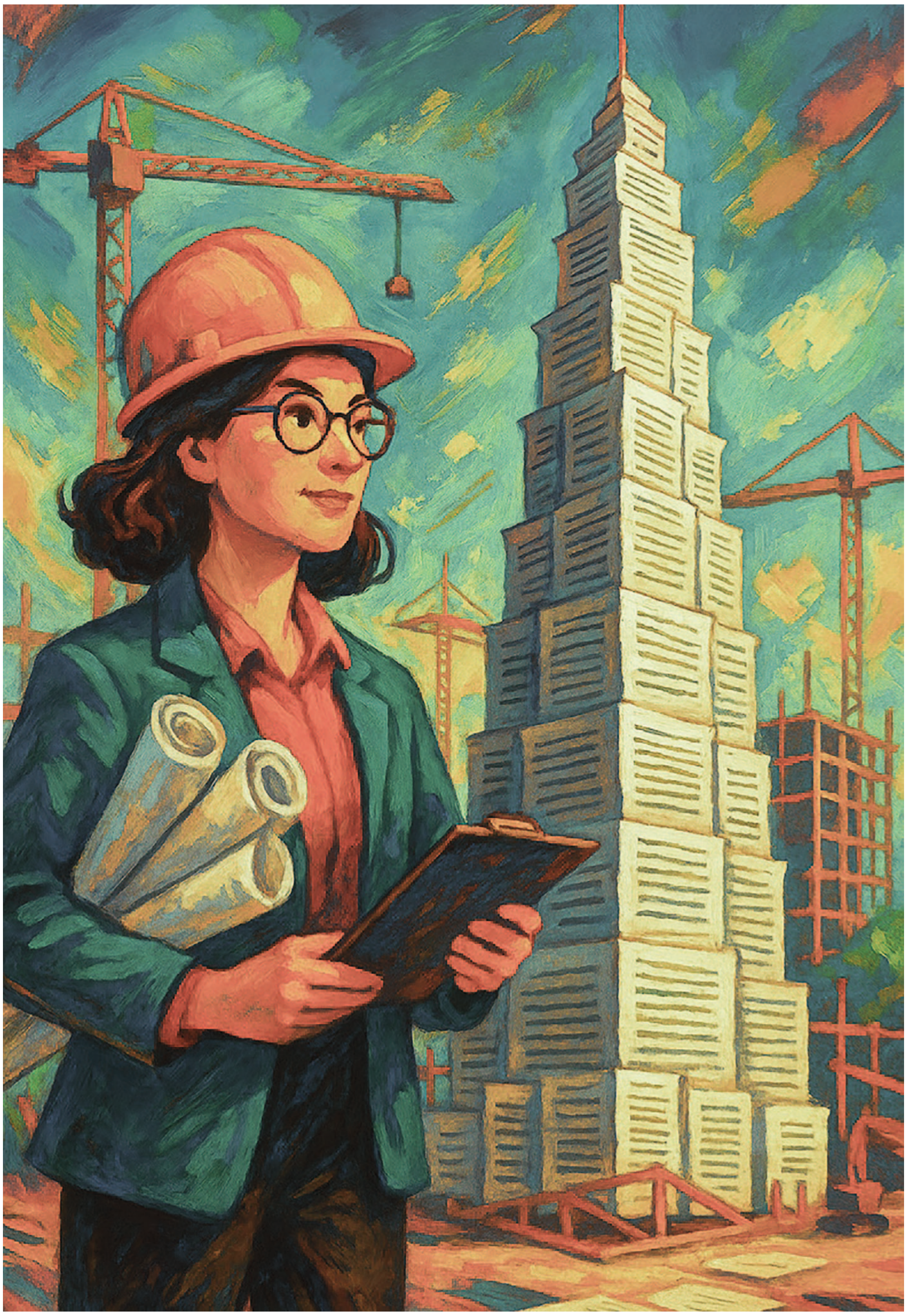

Illustration: ChatGTP

- **Custom tools (Build)** offer the highest level of control and integration but demand substantial investment, internal development resources, and ongoing maintenance for the life of the tool. The rapid evolution of AI technology adds further complexity to in-house development.
- **Specialised platforms (Buy)** are often designed specifically for medical writing and come with built-in security, compliance support, automation features, maintenance, and active user communities. These providers regularly enhance their tools, but adoption may require workflow changes and data-sharing agreements.
- **General-purpose AI tools (Adapt)** offer accessibility and flexibility making them appealing for experimentation. However, they pose challenges for regulatory writing, including data security risks, limited automation, lack of version control, and no safeguards against hallucinations. Prompting section-by-section may not yield major time savings, and lengthy regulatory documents often exceed these tools' context window.

Choosing the right approach depends on more than feature comparisons. It requires aligning with an organisation's goals, data security policies, and long-term scalability needs.

Working with tech vendors: what to expect

Successful implementation of AI writing tools depends on more than just choosing the right software. It also involves structured collaboration with technology vendors throughout evaluation, configuration, and deployment. The process typically begins with research and vendor outreach – understanding what's available, attending product demonstrations, and participating in hands-on evaluations.

Writers engaged in technology projects should expect to participate in pilot programmes, contribute to user acceptance testing, and provide real-world data and templates for evaluation. While sales and customer success teams usually lead these engagements, internal medical writing leads play a key role in reviewing content quality, assessing usability, and ensuring integration with existing workflows.

Participating in configuration and deployment also means adapting to software development processes. This might include working across different software environments – development, staging, and production – and providing structured feedback via tickets or feature requests.

Aligning content standards for AI readiness

One of the most important factors in successful AI adoption is the state of an organisation's content standards.[1] Many teams struggle with outdated templates, inconsistent formatting, or siloed writing styles. Without a shared approach to how key documents – such as Clinical Study Reports (CSRs) or summaries – present data and key messages, automation becomes significantly more difficult.

Content strategy

A clear, consistently implemented template supports automation and facilitates content reuse across the regulatory dossier. When content from study-level protocol and reports is structured for reuse, it can cascade into other documents such as summaries, investigator brochures, and briefing packages with minimal rework. This "intelligent content cascade" allows medical writers to shift their focus from redundant authoring to strategic messaging and scientific interpretation.

In large organisations, regulatory writing teams are often structured by function (e.g., clinical, safety) or therapeutic area, which can lead to a divergence in templates and inconsistent content standards. Readiness for automation requires realignment to common templates, style guides, and content standards.

An example of document readiness is the ICH M11 Clinical Electronic Structured Harmonised Protocol (CeSHARP) guideline and its accompanying Technical Specification document and Template.[2-4] These documents provide not only a common structure for all study protocols, but also a standard for electronic exchange of protocol metadata. At a minimum, consistent and descriptive document headings allow AI tools to easily find relevant content for intelligent reuse.

Data readiness

Typical clinical study output tables are designed to be human readable, with visual cues like merged column headers and indentations to indicate relationships that machines have difficulty understanding. Many AI tools work better with machine readable formats where the relationships of each data point to its descriptors or metadata are clearer.

A technology team may have questions about what format the data files come in, for example, SAS files, RTF tables in Word, or CSV tables in Excel. There are also other formats that structure data like JSON, HTML, and XML. Some medical writing AI tools can work with the raw individual-level Clinical Data Interchange Standards Consortium (CDISC) data that sponsors are already required to submit to health authorities. For example, individual patient data in Study Data Tabulation Model (SDTM) or Analysis Data Model (ADaM) formats can be used to write patient narratives.

In 2024, CDISC released a new data standard for analysed data called the Analysis Results Standard, in an effort to make the final analysed data, the summary statistics and endpoint analyses for example, more standardised and machine readable.[5] The push toward data standardisation is supporting this type of TLF output standard across sponsors.

At a minimum, a consistent format per type of study table (e.g., Overview of Adverse Events) across all studies allows for an AI tool to consistently and easily process tables into text.

Lean authoring: evolving to meet new demands

The advent of generative AI has wide implications on medical writing content standards. Lean authoring was originally developed with manual writing and human reading in mind. It was optimised at the individual document level, with an emphasis in saving writing, quality control, and reviewing time. Repetition of data from tables in the body text was intentionally minimised, as human readers could easily interpret patterns in tabular format, and creating and checking numbers in-text was resource-intensive to write and verify.

As the regulatory writing landscape shifts toward automation and global dossier strategies, lean authoring is adapting to meet new demands. Now, authoring long text with accurate data points is possible in seconds. However, enabling AI to write in a tightly controlled, concise format requires additional development effort.

To support an intelligent content cascade across the dossier, the goal shifts from minimalism to fit-for-purpose: the text must remain concise but also contain enough context to be understandable on its own. This is especially important as health authorities begin using AI systems to assist in their review. While human reviewers can easily interpret data in tables, large language models may struggle to determine which parts of a table are most relevant, how schemas should be interpreted, or how to follow contextual links. Including key data points and core messages directly in the text may improve the likelihood that AI systems summarise the information accurately.

Change management: preparing for a new role

It is tempting to apply new technology to existing ways of working, but embracing new approaches can accelerate the path toward AI-assisted submissions. A few practical steps can lay the groundwork for successful adoption:

- Revise document templates to guide standardisation, consistency, and fit-for-purpose lean writing
- Train teams on the benefits of automated text generation and standardised templates
- Update document preparation workflows, such as reviewing, locking, and quality checking data-independent content prior to database lock

For high-achieving professionals like medical writers, significant changes to long-standing work practices can be unsettling. Fears of becoming less valuable, of not being able to achieve career goals, or losing professional standing can lead to scepticism or resistance to new technology initiatives.

Successful technology initiatives prioritise change management to help dispel myths, empower users, and ease the workload strain during an impactful change. Thoughtful change management involves clear communication of how roles will change, affirmation of each contributor's value, small steps to meaningful and achievable goals, and a defined process for everyone to follow to success.

The role of the regulatory medical writer has evolved to suit the needs of the documents dramatically over time. We have progressed from circulating paper drafts to leading collaborative authoring and enforcing compliance with electronic Common Technical Document standards. The AI technology progression will guide us into the next evolution, that of becoming a configuration lead and editor.

Here is an example of how AI-enabled regulatory medical writers are already generating documents in a fraction of the time:

- Ahead of database lock, the writer leads the creation of a first draft as follows:
  - Gathers all the source documents, dry run data outputs (or shells), and the appropriate Word template and connects them to the draft
  - If required, transforms the data into a machine-readable format by ensuring each data point is linked to key terms required for text generation (e.g, if the mean age in the placebo group is 65 years, the data point 65 is linked to years, age, mean age, and placebo)
  - Reviews the AI configuration template to confirm that the appropriate data and sources are linked to each section and that the content plan aligns with the document purpose, making adjustments as required
  - Populates the data-independent sections (e.g, introduction, study design) with a single click, then uses options within the tool to add additional context or enhance the text as needed
  - Reviews the data-independent sections with the team and locks the sections after review is complete
    - Quality control can be performed for data-independent sections using functions within the tool that allow the reviewer to view the source text and any changes that were made
  - Reviews the data-to-text plan with the team and adjusts the plan as needed (e.g., describe, compare groups, create an in-text table)
- After final data is available, the writer completes the document with these last few steps:
  - If required, converts final data into a machine-readable format
  - Populates most data sections (e.g., disposition, safety) with a single click, then uses options within the tool to enhance the text as needed

- Matches efficacy tables to predefined endpoints and generates interpretive and descriptive text using the SAP as context
- Reviews the data sections with the team and locks the sections after review is complete
  - Quality control can be performed for data sections using functions within the tool that allow the reviewer to view the source table and see if any edits were made to the AI-generated text

Future-proofing your career

AI is often associated with efficiency gains, cost reductions, and concerns about job displacement. However, within the pharmaceutical sector, AI's primary value lies in augmenting capabilities, industrialising complex domain knowledge, and accelerating drug delivery to patients.

This context fosters a growing demand for professionals with expertise in both life sciences and digital technologies like AI and data science, leading to new roles such as:

- Creating and implementing AI tools
- Medical writer AI leads or super-users, who integrate AI in their daily workflows and train other users

In software development, medical writing expertise ensures AI tools align with regulatory requirements and medical writer needs. For instance, validating an adverse event analysis prompt requires medical and scientific knowledge. Medical writers now have opportunities as product owners, product managers, prompt engineers, and business analysts, leveraging their expertise to work in AI implementation teams.

For AI users, the writer's role evolves from crafting every line of text to configuring AI settings, reviewing machine output, and aligning AI with team and project needs. Automation increases the expertise required to evaluate and control AI-generated content. This seemingly paradoxical shift elevates the seniority of medical writing roles, with junior writers utilising AI for repetitive tasks.

Valued skills now include data interpretation, prompt engineering, and structuring document creation. Modular thinking and cross-functional collaboration are essential for regulatory and medical writers.

On the other hand, manual formatting, repetitive drafting, and versioning tasks are becoming less critical, as generative AI and automation tools assume these functions. The core value shifts to shaping messages, interpreting data, and ensuring quality.

Pharmaceutical companies are also embracing blended teams or "squads", which pair domain experts with technology specialists. These collaborative models enhance adoption of AI tools and ensure solutions are grounded in regulatory reality. Medical writers who develop fluency in AI tools and understand their strengths and limitations are well-positioned to become AI-enabled subject matter experts in their field.

Conclusion

The role of the regulatory medical writer is evolving. Writers are no longer just authors; they are collaborators in software development, stewards of quality content, and architects of intelligent content ecosystems.

By embracing foundational tech knowledge and advocating for clarity and standardisation, medical writers can lead their organisations through a successful digital transformation.

The future of regulatory writing elevates the value of medical writers from "hands on the keyboard" to that of a strategic content designer. Writers who adapt to AI not only preserve their relevance but expand their influence across the regulatory lifecycle and future-proof their career.

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