

## Generative AI for Medical Writing & Faster Regulatory Submissions

Flyer



Medical writing lies at the core of pharmaceutical R&D and regulatory processes. From clinical study reports to submission documents, producing accurate, compliant content is essential—but it's often time-consuming, resource-intensive, and prone to delays.

Hexaware's Medical Writing as a Service (MWaaS) changes that. It combines the power of Generative AI with the precision and domain expertise of experienced medical writers. The result? Faster, smarter, and fully compliant automated regulatory documents.

If you're drafting CSRs, IBs, protocols, or regulatory meeting packages, Hexaware's medical writing services help you get there quicker—without compromising on quality.

### What Is Medical Writing as a Service?

Medical Writing as a Service (MWaaS) is an AI-powered, cloud-enabled service designed to automate and optimize the medical writing process. It enables you to:

- Automatically generate structured, high-quality drafts
- Ensure traceability and regulatory alignment
- Collaborate in real time across teams
- Deliver submission-ready documents in significantly less time

Ideal for sponsors, CROs, and regulatory teams looking to scale documentation efforts without increasing overhead.

### Key Capabilities and Features of MWaaS

#### Built-in Regulatory Compliance

- Aligned with ICH E3, FDA, EMA, and other global standards
- Integrated audit trails, version control, and compliance checkpoints
- Structured templates to reduce variability and risk

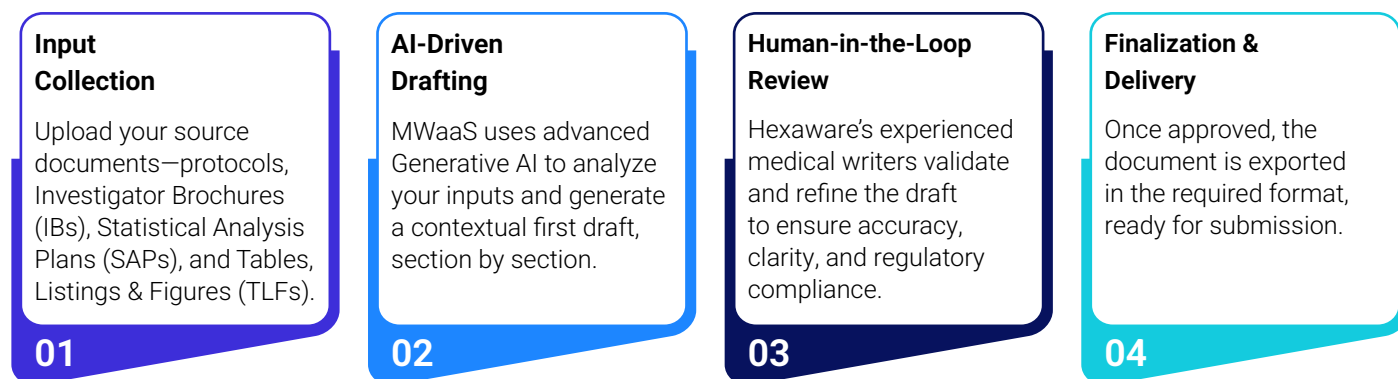
#### Full Traceability & Validation

- Every section of the draft is linked to its original source (protocol, SAP, TLFs, etc.)
- Enhances document transparency and supports audit readiness

#### Workflow & Collaboration Automation

- Real-time collaboration between writers, reviewers, and statisticians
- Integrated comments, approval workflows, and version tracking
- Reduces back-and-forth and shortens review cycles

## How It Works



## Human-in-the-Loop Medical Writers

MWaaS is not a black-box automation tool. It’s a collaborative solution where AI in medical writing handles repetitive tasks, and expert medical writers ensure scientific and regulatory precision.

- Global Coverage: 16x5 support with teams across India and the US
- End-to-End Support: Assigned writers partner across the full asset lifecycle
- Strategic Focus: Writers focus on interpretation, validation, and alignment with submission strategy

## Why MWaaS?

| Benefit                   | Impact                                                 |
|---------------------------|--------------------------------------------------------|
| Faster Time to Submission | Reduce authoring timelines by 30–40%                   |
| Built-in Compliance       | Meet global regulatory standards effortlessly          |
| Enhanced Collaboration    | Real-time, multi-user workflows                        |
| Audit-Ready               | Full traceability and version control                  |
| Scalable Support          | Handle growing document volume without added headcount |

## Built by Experts, Backed by AI

- Proven success with leading pharma and biotech clients
- Flexible onboarding and pricing models
- Templates tailored to your standards
- White-glove support throughout your engagement

## Accelerate Your Regulatory Journey

With Hexaware’s MWaaS, you can streamline documentation, improve accuracy, and reduce manual effort—so your teams can focus on what matters most: bringing life-changing treatments to market, faster.

Ready for a demo? Contact us at [marketing@hexaware.com](mailto:marketing@hexaware.com).

## About Hexaware

Hexaware is a global technology and business process services company. Every day, Hexawarians wake up with a singular purpose: to create smiles through great people and technology. With this purpose gaining momentum, we are well on our way to realizing our vision of being the most loved digital transformation partner in the world. We also seek to protect the planet and build a better tomorrow for our customers, employees, partners, investors, and the communities in which we operate.

With offices across the world, we empower enterprises to realize digital transformation at scale and speed by partnering with them to build, transform, run, and optimize their technology and business processes.