celegence

CAPTIS®

AI Platform for Medical & Technical Writing

celegence.com

CAPTIS® is Celegence's proprietary AI-powered regulatory compliance technology

Designed to streamline literature reviews, regulatory authoring, collaboration, and document maintenance for medical device, IVD, and pharmaceutical teams.

Platform value

Used by Celegence writing teams and customers worldwide, CAPTIS® combines regulatory expertise, AI-assisted workflows, and purpose-built technology to improve efficiency, consistency, and regulatory quality.

CAPTIS® supports your teams with:

- **Faster, smarter literature reviews**
- **Time and cost-effective report development and maintenance**
- **Consistency and quality in compliance**
- **Enhancing collaboration & project oversight**

CAPTIS®

1,000+

Regulatory documents delivered by Celegence writing teams, supported by CAPTIS®

40-50% Faster

CER drafting and review when compared to traditional manual processes

25-30% Faster

Annual updates and maintenance when previous projects were completed in CAPTIS®

Up to 60% Faster

Literature review through smart workflows and AI-assisted data extraction

100% Traceable

Evidence connected from source to final deliverable

Literature Review & Evidence Management Capabilities

Scientific Literature Review

- PubMed, Google Scholar, and Europe PMC integrations with search auto-updates
- Multi-stage screening workflows with PDF management
- Device Under Evaluation (DUE) and State of the Art (SOTA) review tracks
- Multi-database literature import
- Duplicate detection and reviewer collaboration
- Automated literature review tables and PRISMA diagrams
- AI-powered article extraction, automated evidence table generation, and cross-study insights across your reviewed literature

Adverse Event Search and Analysis

- FDA MAUDE and TPLC integration
- Retrieve and export complete datasets without FDA website 500 record limitations
- Compare brand-specific adverse event counts against overall product code totals
- Export filtered TPLC and patient problem datasets for further analysis and reporting
- Search multiple product codes, brand names, and manufacturers simultaneously
- Download TPLC reports directly without manual data extraction
- Analyze patient problem trends through CAPTIS-generated reports derived from MAUDE data

Outcome: Faster evidence collection, review, analysis, and reporting.

CAPTIS®

Regulatory Authoring & Content Development
Capabilities

Source Document Intelligence

- Centralized project source document repository
- AI-powered document chat, summarization and insights
- Source document categorization and tagging
- Source-backed AI responses with traceability

Regulatory & Scientific Authoring

- Configurable document templates with reusable content and guidance
- AI-generated first drafts for select CER sections (coming soon)
- Automated abbreviation tables
- Automated formatting workflows
- AI-assisted content generation from source documents
- AI-generated first drafts for select CTD Module 3 CMC sections (coming soon)
- Integrated reference management with submission ready outputs
- Reusable content across multiple documents

Outcome: Faster content development with greater consistency.

Collaboration & Project Delivery Capabilities

- Multi-reviewer collaboration
- Configurable review workflows
- Automated notifications and reminders
- Commenting and discussion tracking
- Project dashboards
- Review visibility and oversight

Outcome: Keep writers, reviewers, SMEs, and stakeholders aligned throughout the project lifecycle.

Traceability, Compliance & Lifecycle Management Capabilities

- Source-to-report traceability with content links
- Evidence linked directly to final content
- Review history, decision tracking and audit trails
- Centralized maintenance workflows
- Cross-document consistency management
- Submission-ready outputs

Outcome: Improve compliance, maintain consistency, and accelerate future updates.

Technology + Expertise

Combine AI-enabled technology with experienced regulatory and scientific writing professionals.

Regulatory Expertise

- Medical device, IVD, and pharmaceutical SMEs and regulatory writing specialists
- Flexible engagement models ranging from advisory support to full document authoring

An Extension of Your Team

- Scale resources based on project demands
- Support literature reviews, CERs, PMS documentation, CMC authoring, and maintenance activities
- Leverage expert SMEs and writers working within CAPTIS® workflows

Benefits

Access specialized expertise without expanding headcount

Accelerate delivery with proven workflows and AI-enabled technology

Maintain consistency, quality, and compliance across submissions

One partner for both technology and regulatory writing support

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We Deliver The Outcome

Regulatory Expertise • AI Accelerated

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