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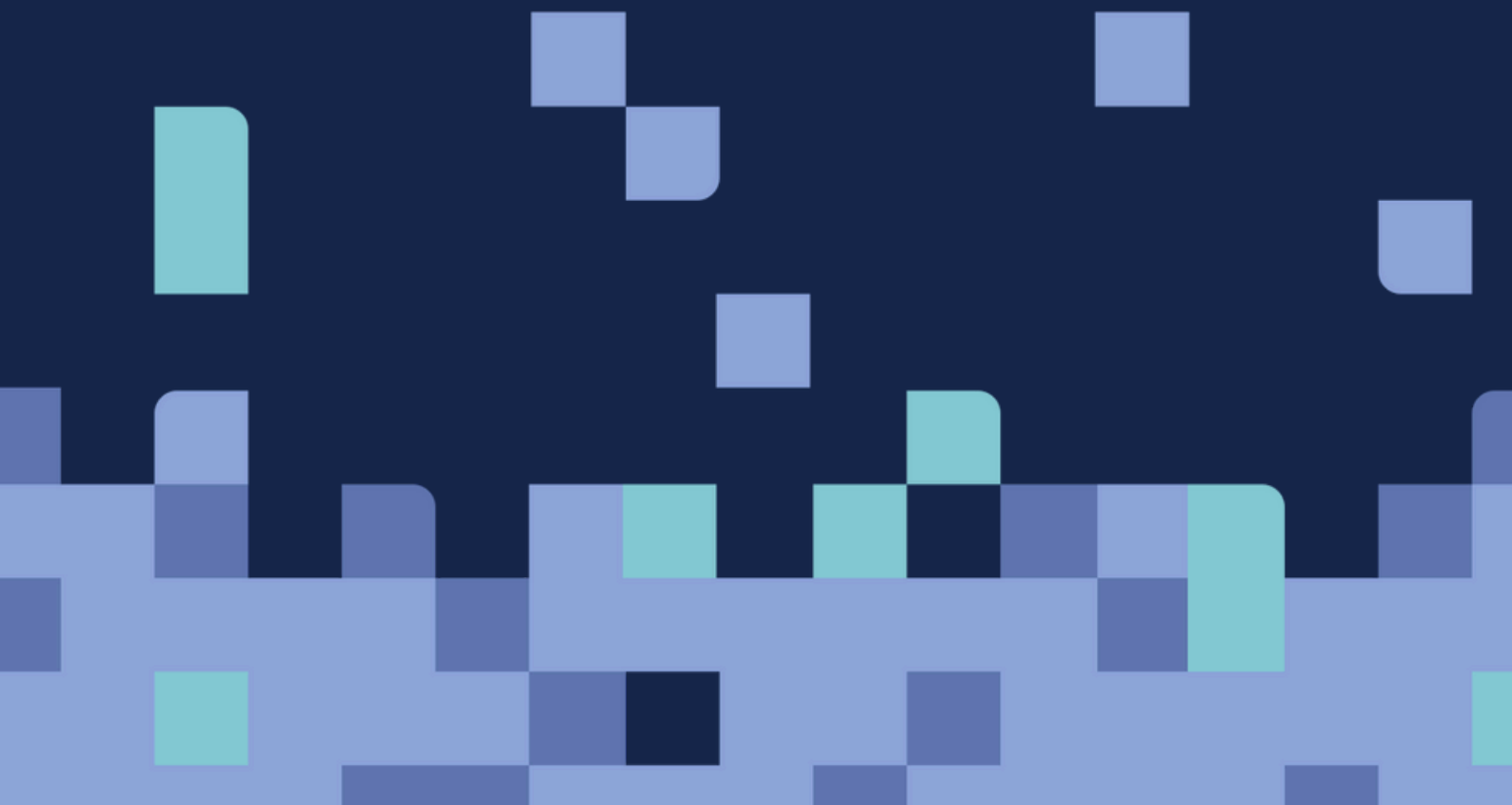
CAPTIS®

AI Platform
for Medical & Technical Writing



CAPTIS®

CAPTIS® is Celegence's proprietary AI-powered regulatory compliance technology, designed to streamline medical and technical writing, and documentation processes for medical device, IVD, and pharmaceutical manufacturers.

With powerful automation, machine learning, and intuitive workflows, CAPTIS® performs tasks that can take hundreds of hours for regulatory teams in minutes.

CAPTIS® AI platform reduces manual effort, enhances regulatory accuracy, and creates effortless experiences for Celegence project teams and our customers.

CAPTIS® supports your teams with:

- Time and cost-effective report development and maintenance
- Consistency and quality in compliance
- Enhancing collaboration & project oversight

+62%

Average Time Savings

Compared to manual processes

+45%

Faster delivery of full-text PDF search & save

Proprietary technique for data retrieval combined with PubMed & Google Scholar integrations

+60%

Faster Literature Reviews

Average savings of 13 hours and 16 minutes with AI-powered systematic literature review module with automated data extraction

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CAPTIS® Functionality & Features

AI content generation, including first-draft CER and Pharma Module 3 CMC documents	Built-in writing support, content linking, and regulatory intelligence
AI-Powered literature reviews with automated dynamic report tables	US FDA MAUDE/TPLC adverse event database integration
PubMed, Google Scholar, and Europe PMC direct integrations	Disparate yet intertwined device and state of the art workflows
Multi-reviewer collaboration and project dashboards	Source document management and AI chat
Automated PRISMA and summary table generation for literature	Audit trail & reproducibility

+30%

Faster clinical evaluation reports delivery

Time and cost savings against manual efforts

+99%

First-time acceptance rate

Pre-built compliance with Notified Body requirements

+100%

Article deduplication

Users saved 100% of time because duplicates are detected automatically

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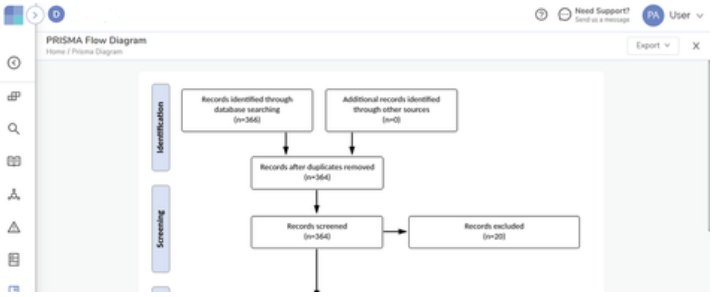

Systematic Literature Review

- Search or import results from multiple scientific databases sources into a single, consolidated workspace
- Multi-stage, customizable screening workflows with duplicate detection, reviewer questions, and keyword highlighting
- Separate review tracks for device-under-evaluation and state-of-the-art searches
- AI-assisted data extraction & summarization: capture demographics, outcomes, and metrics with smart suggestions you can validate
- Automated literature updates until your review end date, with weekly or monthly new-article alerts
- Generate and insert auto-updating review outputs such as PRISMA Diagrams directly into your project documents

Adverse Event Data Analysis

- Integration with major adverse event databases such as US FDA MAUDE and TPLC
- Enhanced interface allowing users to search quickly and simultaneously for multiple product codes and brand names
- Flexibility to review events on the platform or easily export all events on a single click to an Excel sheet

Automated Report Generation

- Built-in report generation to automatically create complex reports required for final submissions
- Integrate an up-to-date Literature Report with the click of a button to save significant time and reduce the chance of human error

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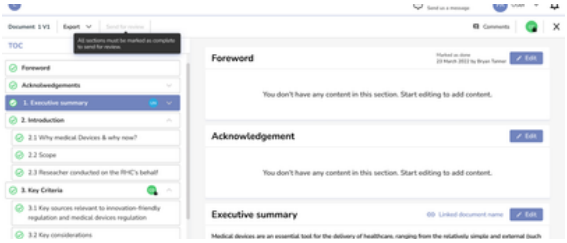

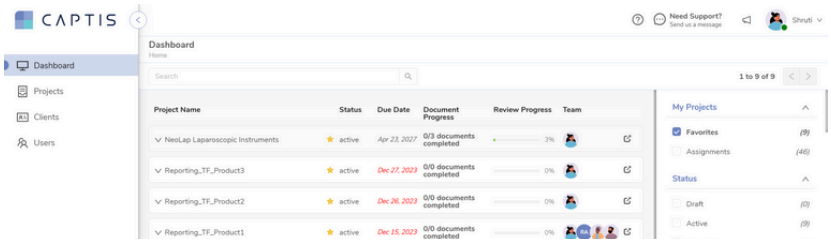

Collaboration & Review

- Communicate with your team and update project status
- Designated roles and responsibilities with customizable review workflows
- Work concurrently on various projects so that no time is wasted

Source Document Management

- Upload source documentation, such as IFUs, to ensure the final report reflects accurate information
- Tag information from source documents directly into final reports for traceability
- Receive notifications when collaborators upload new versions.
- Easily categorize, track, and highlight each data source
- AI-powered document chat: interact with source files to ask questions, extract insights, or generate summaries of non-clinical and clinical study reports

Report Writing & Maintenance

- Link data from source documentation directly into your report for accuracy
- Maintain alignment across PMS documentation with centralized updates
- Record frequently used terms in the a Data Dictionary as a “Single Source of Truth” — with placeholders that auto-populate templates
- Configurable styles and formatting applied automatically for consistency
- Smart templates with built-in guidance, example text, and instant reference management
- Auto-generate tables of abbreviations, reference lists, and submission-ready PDF folders
- Custom review workflows with visibility, progress tracking, and automated review notifications
- Streamlined collaboration with commenting and project tracking

Streamline Regulatory Submissions with CAPTIS®

Pharmaceutical companies face growing complexity in preparing and managing global regulatory submissions.

From CMC submissions to lifecycle updates across multiple regions, teams spend valuable time on repetitive tasks, version control, and compliance checks.

CAPTIS® helps reduce that burden with intelligent automation, collaboration, and quality-driven publishing.

CMC Authoring & Lifecycle Management

- Automates repetitive authoring tasks
- Ensures data consistency across Module 3
- Tracks changes for variations and supplements

Collaboration Across Global Teams

- Real-time visibility into document status
- Centralized workspace for regulatory, CMC, and quality functions

Efficiency in Submissions

- Reduces manual formatting and QC time
- Supports simultaneous regional requirements

Compliance Confidence

- Built-in validation checks
- Alignment with evolving standards (e.g., eCTD 4.0, IDMP readiness)

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Pharmaceutical Submissions from CMC Authoring to Lifecycle Management

Why Pharma Chooses CAPTIS®

- CAPTIS drafts CMC documents in minutes — not days
- 65-80%+ accuracy on initial drafts with AI
- Proven in collaboration with a Top 20 pharma companies
- 2,500+ submissions supported globally
- Proven in small molecules, biologics, ATMPs, generics, and more
- Built by regulatory experts who understand CMC challenges

Results from our pilot with Kenvue

1. Drafted 5 high-volume CMC documents in minutes instead of days
2. Achieved +80% accuracy after minor refinements
3. Validated the feasibility of AI-enabled CMC authoring
4. Enabled teams to focus on high-priority tasks

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Celegence Partnership Models

Balance Technology & Services

Introduction of AI into your regulatory operations brings significant efficiencies and cost savings, however, it's important to find the right fit for it. From AI-powered turnkey deliverables to innovative transformation of compliance, we help companies leverage technology according to their needs.
Use this guide identify which model best matches your operational goals.

What is the level of tech engagement you're looking for?

I want turnkey deliverables

Our internal teams should be engaged

I want technology embedded into the backend of the service for high-quality and cost-efficient delivery

I want to collaborate, review, and have visibility into the project and some degree of tech onboarding for me or my team

I want a trusted digital transformation partner to build out our internal capabilities long-term

TRANSACTIONAL MODEL	**COLLABORATIVE** MODEL	**INNOVATOR** MODEL
Quick turnaround out-of-the-box projects such as: • Medical Device: **CERs, SLRs** • Pharmaceutical: **IND, NDA, DMF**	Hybrid outsourcing – internal tech enablement, plus on-demand services: • Medical Device: MDR Maintenance • Pharmaceutical: Module 3 maintenance	Client-driven innovation built with Celegence tech, such as: • Medical Device: Internal client; Full product lifecycle management • Pharmaceutical: Modules 4 & 5

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