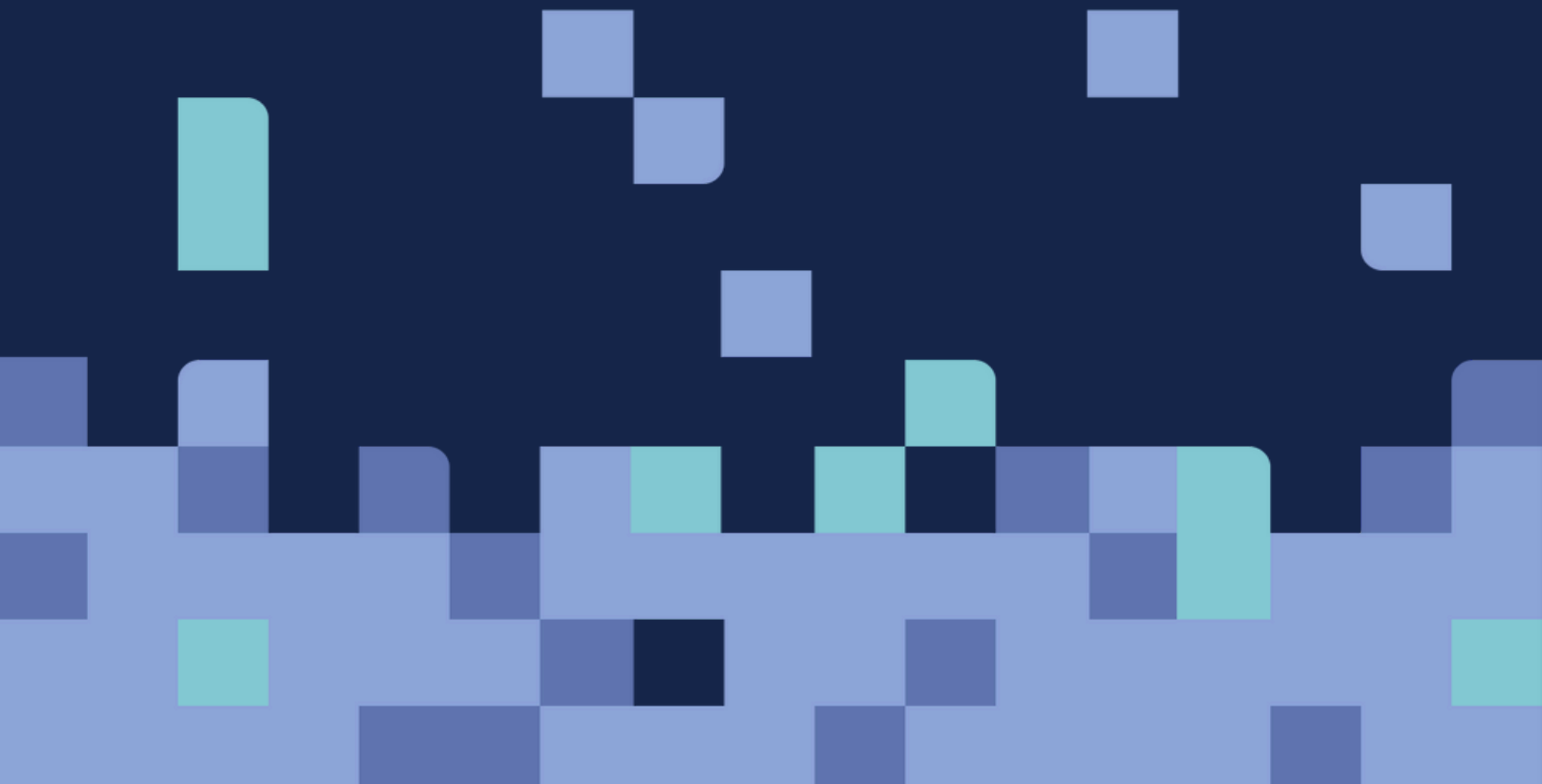
celegence

AI-Empowered Regulatory Services

for Pharmaceutical, Medical Device, and IVD Manufacturers



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As a consulting company, Celegence provides regulatory services and technology solutions for Pharmaceutical, Medical Device, and In-Vitro Diagnostics customers.

Our services are powered by advanced in-house AI technology and driven by an experienced global team of subject matter experts, enabling us to consistently deliver high-quality results more swiftly and cost-effectively than traditional consulting firms.

CERTIFIED: 14001:2015, 45001:2018, 9001:2015, 27001:2022

NMSDC Certified-MBE 2022

8+ CSAT score from 97% of customers

WBE Certified

TOPRA Awards for Regulatory Excellence 2024 INNOVATION

Innovation Award – TOPRA Awards for Regulatory Excellence 2024
for CAPTIS®, an AI-powered regulatory compliance platform

Our clients:

NOVARTIS · AstraZeneca · astellas · B|BRAUN · Gedeon Richter · REGENERON · Otsuka · Johnson&Johnson · kenvue · BAUSCH Health · COOK MEDICAL · Baxter · STALLERGENES GREER · BISCO · Pharming · PHILIPS Healthcare · MICROLINE SURGICAL · ARGON MEDICAL DEVICES

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Services

Pharmaceutical

- Regulatory publishing & eCTD submission
- CMC technical writing
- Medical writing
- RIMS management services
- Data governance & regulatory compliance
- Regulatory affairs consulting
- Regulatory intelligence
- eCTD viewer and manager
- eCTD templates
- Drug-led combination products

Medical Device & IVD

- MDR & IVDR consulting
- Clinical Evaluation Reports
- Post-market surveillance services
- Systematic literature reviews
- MDR maintenance services
- Post-market clinical follow-up
- US FDA medical device services
- Technical file remediation
- Complaints management
- Device-led combination products

+50%

Faster delivery with intact quality

>95%

Improved accuracy over manual processes

+30%

In savings against current operational cost

CAPTIS®

AI Platform for Medical & Technical Writing

CAPTIS® is our award-winning proprietary AI technology designed to streamline regulatory documentation processes. With powerful automation, machine learning, and intuitive workflows, CAPTIS® reduces users' manual effort significantly, freeing up hundreds of hours for both Celegence and customer project teams.

+62%
Average time savings

100%
Article deduplication

+60%
Faster literature reviews

+45%
Faster delivery of full-text PDF search & save

+30%
Faster clinical evaluation reports delivery

99%
First-time acceptance rate

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 transcript
Automated PRISMA and summary table generation for literature	Audit trail & reproducibility

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