celegence

Medical Device Regulatory Experts for MDR Support & Global Compliance

Your Partner for Regulatory Affairs Operational & Strategic Consulting & Services

Our mission is to combine our expertise and innovation to enable the Life Sciences industry to achieve improved compliance and efficiency.

Some Of Our Clients

NOVARTIS · BAUSCH Health · Johnson & Johnson · TMRW · KAVO Kerr · Nobel Biocare · astellas GENE THERAPIES

List of **Service Offerings**

MDR & IVDR Gap Analysis SME Consulting	EU-UDI, EUDAMED, PMS etc... Consulting	Regulatory Intelligence Consulting	**Clinical Evaluation** CEP, Risk Management, PMS, PMCF Plans & Reports, Literature Search
CER Writing Remediation from Rev 3 to Rev 4 as well as new CERs & Maintenance Updates	PSUR, SSCP, FSCA, & PMSR Creation	**Medical Device Registration Support** for US, EU, APAC, LATAM Regions	Quality & Regulatory Audit Support, MDSAP, Notified Body Audits, etc.

MDR Technology

Our proprietary technology allows your team to streamline all aspects of your CERs and avoid constant revisions. This not only improves efficiency but allows for quality assurance and oversight from your RA project manager throughout the entire process.

Compliance

We leverage our technology to expand the compliance capabilities of your team by reducing the time spent on current activities while simultaneously amending your process to ensure compliance with the new MDR regulations. With live editing, project management, and alerts, our team will keep all contributors on track. This means your first submission will be fully compliant with a faster turnaround with your Notified Body.

Productivity

Significantly reduce the amount of time needed to complete literature research. Paired with our expert services, our technology allows our team to work cohesively to guarantee timelines are met, reduce your cost and improve overall efficiency.

Quality

Our technology assures the completeness of your documentation as per regulatory requirements, which will be accepted by your Notified Body. Features such as version control of your source documentation and the final report, alerts to writers as data analysis changes, and grammar improvement tools will ensure 100% quality for each submission.

Consultant Network

- Cumulative experience of 100+ years in the team related to Medical Devices Regulatory domain.
- Pool of clinicians, PhDs, Postgraduates, and Engineers.
- Global SME pool with experience in supporting regulatory strategy for 48+ countries including the US, Europe, and Asia Pacific.
- Experience in drafting new reports and addressing NB comments.

Notified Bodies where our consultant network has experience:

Lloyd's Register Marine · TÜV SÜD · bsi. · SGS

Therapeutic Areas

- OPHTHALMOLOGY
- RESPIRATORY
- COSMETIC SURGERY
- CARDIOVASCULAR
- NEUROVASCULAR
- FEMALE REPRODUCTIVE HEALTH
- GASTROENTEROLOGY
- RENAL DIALYSIS & NEPHROLOGY
- HAEMATOLOGY
- DIAGNOSTIC IMAGING
- ORTHOPAEDICS
- DENTAL SPECIALTIES
- ONCOLOGY
- UROLOGY
- INTERVENTIONAL
- RADIOLOGY
- GENERAL, ELECTROSURGICAL & LAPAR OSCOPIC SURGERY
- WOUND CARE

100+
Documents
Drafted & Approved Through
June 2020
(CEP/CER/LSR)

Excellent Feedback
from existing customers on deliverables

Referential Customers

Why **Celegence**

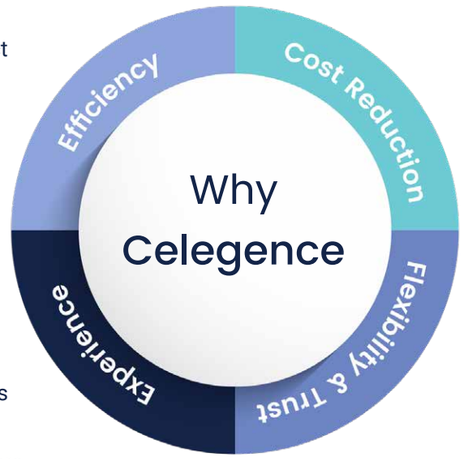
Entrusted by industry leaders, our expert team and business model guarantees the highest quality support while delivering exceptional value to our clients.

Efficiency

- Proprietary software platform to increase efficiency in medical writing and improve oversight.
- Minimal to no lead time in project ramp up.
- Effective Communication: Single point of contact project management model.

Experience

- 99% First Time CER acceptance by Notified Bodies.
- All Project Leads have a Masters or a phD.
- Consultation from Industry Leaders, many from Notified Bodies, with decades of experience.
- Vast experience in every major market - and nearly all emerging markets.



Cost Reduction

- Predictable Total Cost of Ownership (TCO) with cost effective services.
- Competitive pricing allowing you to reduce costs on average by ~20% for RA/QA support services.
- Dedicated resource pool, lowering the Total Cost of Ownership.

Flexibility & Trust

- Partnerships with 3 of the top 10 Life Science Companies Globally.
- SLA driven metrics- indemnification-insured performance and quality.
- ISO 9001:2008 & ISO 27001:2015 certified.

Testimonials

"I reached out to Celegence to help my company prepare for an upcoming MDR assessment for CE Certification in late April. The timeline was very short and the deliverables requested substantial. We needed a rewrite of our Clinical Evaluation Report (CER) as well as a Gap Analysis of our Technical Documentation to the new EU MDR within 2 months. The feedback was very detailed and actionable allowing us to quickly address all deficiencies within a week. Similarly, the CER prepared was top notch with all of the appropriate hooks in place to allow compliance with the new EU MDR. All in all I would highly recommend Celegence for any EU MDR compliance related projects."

Jim Talbot
Vice President, RA/QA
Zap Surgical

"The Celegence team has provided services to meet MDR compliance through high quality CERs in both a timely and cost-effective manner for our Medical Device portfolio. We look forward to a continued partnership in this compliance journey."

Dr. Carlos Munoz-Viveros
Director, Clinical Affairs,
Kavo Kerr Group

"I reached out to Celegence with an urgent project that we could not complete internally. Celegence immediately established a team of experts to strategize next steps. They started project execution nearly overnight and worked seamlessly with our internal team. I would strongly recommend Celegence and their team of experts to anyone facing resource challenges or regulatory hurdles."

Miriam Tenorio
Vice President, Marketing
Transonic Systems, Inc.

Leadership

Sonia Veluchamy is the CEO and co-founder of Celegence.

With nearly 15 years of industry experience, Sonia envisioned an opportunity to support Life Sciences companies in bridging the gap between regulatory intelligence and the operational activities associated with compliance.

Helping You With Your Medical Device Regulatory Challenges

Celegence has a wealth of knowledge to help you navigate through the complex challenges that Medical Device Regulation inherently brings.

We can assist you throughout the entire process to ensure that you and your business are compliant with all global device requirements.

For more information, reach out to us at

info@celegence.com

or contact us online at

celegence.com

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