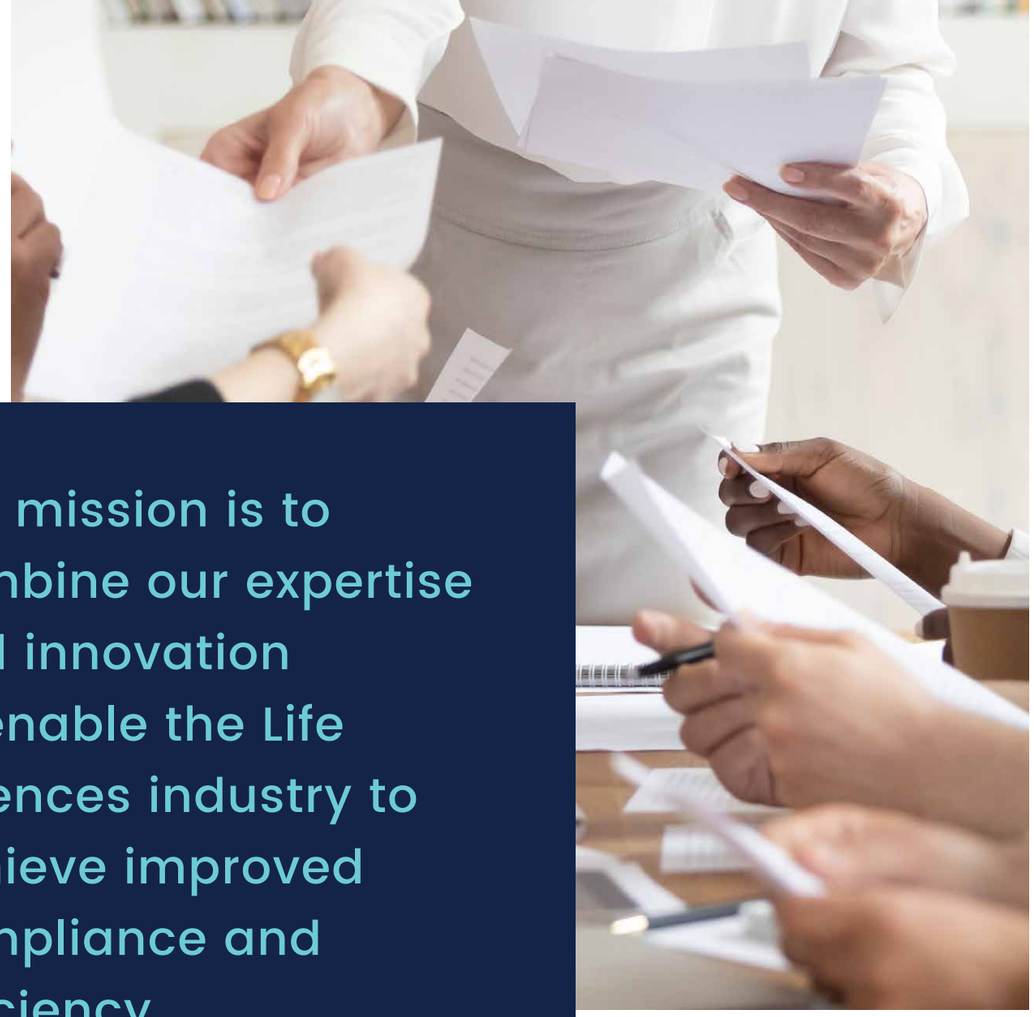
celegence

In Vitro Diagnostics Regulatory Experts for IVDR 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 · Gedeon Richter Ltd. · Envista · astellas GENE THERAPIES

IVD Service Offerings

Gap Assessments

- Device re-classification as per IVDR (Classes A, B, C, D)
- IVDR Readiness Assessments & Mock Audits
- Technical Documentation and PMS
- QMS development and implementation

Global Registrations & Documentation

- UDI and Labelling Requirements
- Technical File Creation
- Submission and Review
- CE-Marking and International Approvals

Medical Writing

- Performance Evaluation Plan (PEP)
- Performance Evaluation Report (PER)
- Scientific Validity Report (SVR)
- Analytical Performance Report (APR)
- Clinical Performance Report (CPR)
- Post-Market Performance Follow-Up Plan (PMPF)
- Post-Market Performance Follow-Up Report
- Post-Marketing Surveillance Documents (PMS)

IVDR Technology

Our proprietary technology allows your team to streamline all aspects of your PERs 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

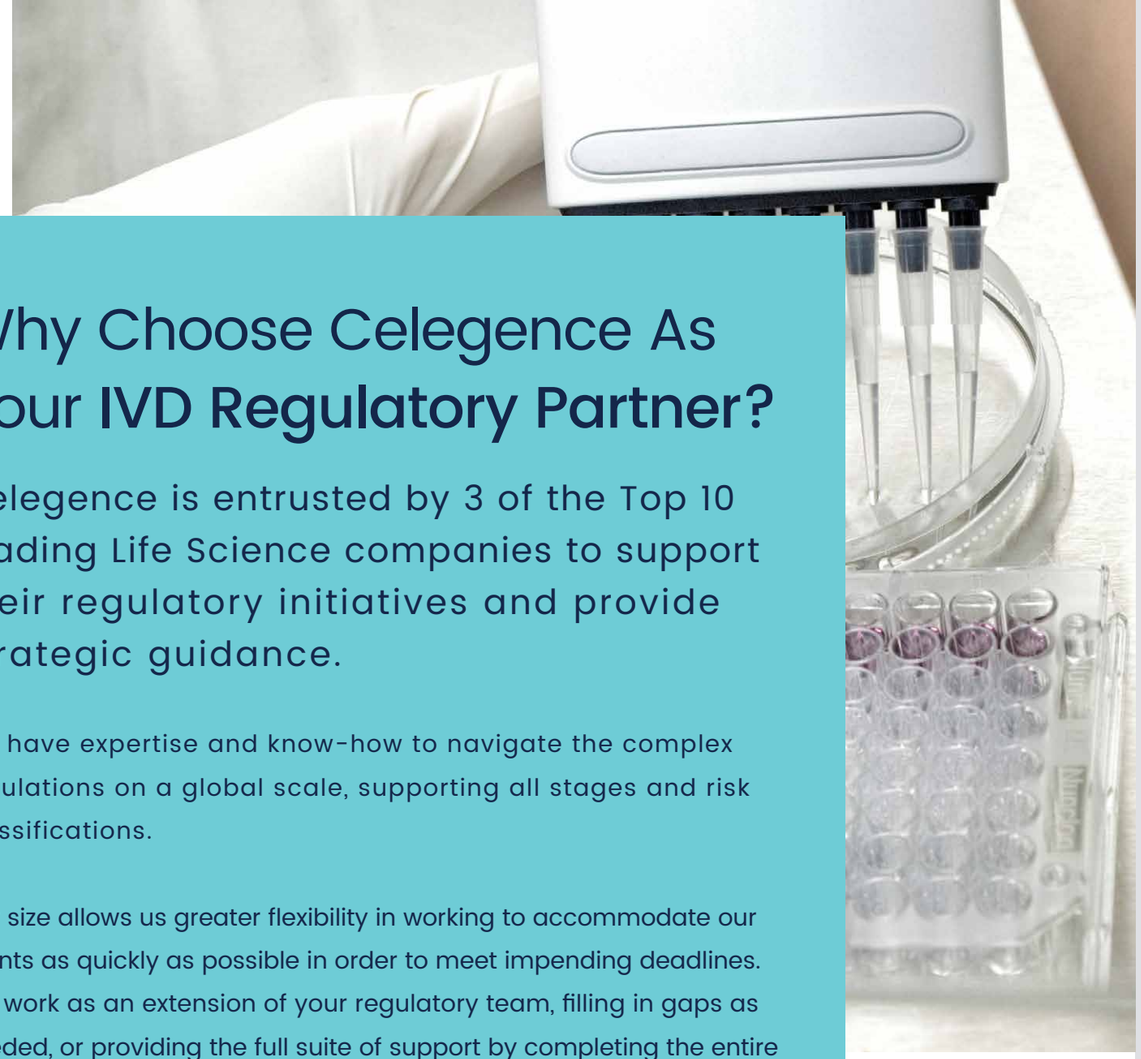
We leverage our technology to expand the compliance capabilities of your team by reducing the time spent on current activities while simultaneously amending your process to ensure compliance with the new MDR regulations. With live editing, project management, and alerts, our team will keep all contributors 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.



Why Choose Celegence As Your **IVD Regulatory Partner?**

Celegence is entrusted by 3 of the Top 10 leading Life Science companies to support their regulatory initiatives and provide strategic guidance.

We have expertise and know-how to navigate the complex regulations on a global scale, supporting all stages and risk classifications.

Our size allows us greater flexibility in working to accommodate our clients as quickly as possible in order to meet impending deadlines.

We work as an extension of your regulatory team, filling in gaps as needed, or providing the full suite of support by completing the entire scope of work required for market approval.

Team Expertise

- IVDD TO IVDR GAP ANALYSIS, REMEDIATION AND IMPLEMENTATION
- IVDR END-TO-ENDIMPLEMENTATION INCLUDING CREATION OF TECHNICAL FILES
- NOTIFIED BODY IVD EXPERTISE
- MHRA'S COVID-19 UPSCALING PROGRAM
- AUTHORING PEP AND PER, PMPF AND PMPR

Testimonials

"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.

"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, California

"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

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 IVD Regulatory Challenges

Celegence has a wealth of knowledge to help you navigate through the complex challenges that IVD 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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