celegence

Regulatory Affairs Experts Offering a Full Suite of Compliance Services for the **Pharmaceutical Industry**

Your Partner for Regulatory Affairs Operational and Strategic Consulting & Services

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

Our **Clients**

NOVARTIS · BAUSCH Health · Johnson & Johnson · astellas · AUDENTES THERAPEUTICS · STALLERGENES GREER · Monopar Therapeutics · MENARINI group

List of **Service Offerings**

- Publishing Services
- Labeling Services
- Regulatory Information Management System (RIMS)
- IDMP & Compliance Consulting
- Learning Management
- Medical, Scientific & Regulatory Writing
- Regulatory Strategy Consulting

Publishing Services

- Document processing and dossier submissions to various health authorities.
- Planning, dossier development, tracking, publishing, submissions, and delivery confirmation.
- Paper and NeeS conversion to eCTD format.

Labeling Services

- Compliance analysis and labeling document reviews.
- Streamlined writing of your global Company Core Data Sheets (CCDS).
- Management and harmonization of the following:
  - HQ and local affiliate activities.
  - Lifecycle management of CCDS, artwork, and labeling variations.

Regulatory Information Management System (RIMS) Data Management

- Proactive end-to-end data processing related to RIMS with an outsourced model reducing total cost of ownership.
- Improvements to submission quality, regulatory compliance, and adoptions of new data standards.
- Management of operational challenges such as cost, resources, and quality via clear SLAs and OLAs.

IDMP & Compliance Consulting

- Addressing regulatory compliance for – IDMP, xEVMPD, etc. including data collection and management to develop a compliance readiness strategy for your company.
- Collecting, converting, and reporting relevant data.
- Allocation of regulatory consultants to implement efficient regulatory data management strategies.

Learning Management

- Training on regulatory developments and optimizing business processes, including organizational standard operating procedures (SOPs).
- Curriculum training to cover regulatory processes.
- Improve internal return-on-investment (ROI) on technology usage (for example RIMS, document management, and publishing tools) including pre-existing set of RIMS business process training curricula.

Medical, Scientific and Regulatory Writing

- High quality outputs of the following documents: investigator brochures, clinical study reports, contributor reports, clinical and non-clinical summaries, etc.
- Documents related to preclinical, clinical, marketing authorization, and post-marketing activities.
- Regulatory documents including: Risk Management Plans (RMP), Proposed Prescribing Information (PPI), Package Inserts/Medication Guides, United States Product Insert (USPI), Summary of Product Characteristics (SmPCs), INDs, NDAs, MAAs, other international drug submissions, and briefing documents for agency meetings.
- Analytical reports, SOPs related to GLP, and other non-clinical report writing.

Regulatory Strategy Consulting

- Intelligence on regulatory requirements – including the following areas:
  - Submissions for clinical trials
  - Marketing authorizations
  - Post-marketing maintenance
  - Global and regional requirements
- Reports on industry trends – including regulatory operations and interpretation of regulatory information to improve processes and KPIs.
- Regulatory submission strategy — specific to product types, therapeutic areas, and geographical regions.

100+
Years
combined experience in the Pharmaceutical Regulatory domain

Master
Degree
All of our project leads have a Masters degree in a relevant field

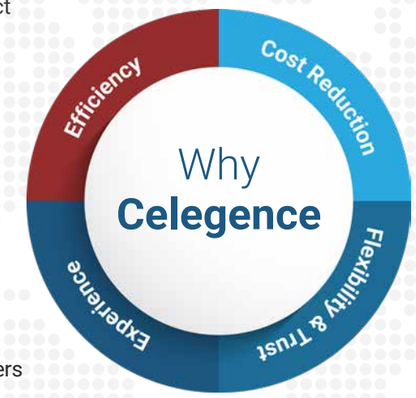
Global
SME
pool with experience in supporting regulatory strategy for
50+ Countries

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.



Cost Reduction

- 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.

Experience

- All Project Leads have a Masters or a phD.
- Consultation from Industry Leaders with decades of experience.
- Vast experience in every major market - and nearly all emerging markets.

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.

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.

Testimonials

"Celegence's team serves as an extension of our internal publishing and compliance team and has allowed us to achieve significant time and cost savings in comparison to our previous regulatory partners."

Hervé Rique
Director of Safety & Regulatory Information Management
Stallergenes-Greer

STALLERGENES GREER™

"Celegence's expert publishing team allowed us to submit our briefing book and other documents to the US FDA in eCTD format, thereby reducing dependencies on our core team and allowing them to focus on more strategic initiatives."

Frederick Cope
Executive
Physis International

PHYSIS INTERNATIONAL
BUILDING GLOBAL HEALTH ACCESS

Helping You With Your **Pharmaceutical Regulatory** Challenges

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