celegence

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

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 · gsk · astellas GENE THERAPIES · B|BRAUN · SANDOZ · Gedeon Richter

List of **Service Offerings**

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

Publishing and Submission Support Services

- Create consistent, transparent and reusable documents for global submissions with our eCTD document templates.
- We enable companies to author right first time documents using the full set of Dosscriber™ eCTD document templates (other formats also available, e.g. ASEAN). The document templates optimize lifecycle management, consistency and avoid duplication of work.
- 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 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.

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.

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.

Regulatory Strategy Consulting

- Intelligence on regulatory requirements – including the following areas:
  - Submissions for clinical trials
  - Marketing authorizations
  - Post-marketing maintenance
  - Global and regional requirements
  - Organize and support scientific advice meetings
  - Pre-submission meetings and RMS selection
  - Act as the EU SME agent on behalf of non-EU SMEs
  - Selection of documents to include per submission type
  - Guidance on the content of briefing packages
  - Nonclinical and clinical overviews and Module 3
  - How to optimise repurposing of documents
- 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.

Dossplorer
Viewing Matters!

eCTD Viewer

Dossplorer™ allows you to share, view and review eCTD, NeeS and other dossier formats from any region and access them from any location.

Unlock and explore the true value of your regulatory dossiers in a safe and secure, web-based eCTD viewer. The hybrid cloud / on-premise solution offers you cloud-based software as a service whilst keeping your data privately stored on-premise or in a virtual private cloud. Alternatively, Dossplorer™ can be installed as a full on-premise solution.

Key features of Dossplorer™ eCTD viewer include:

- Automated import of dossiers and sequences
- Hybrid-cloud, full cloud or on-premise architecture
- Explore holistic views across dossiers worldwide
- Personalized navigation tree utilizing metadata already present in dossiers
- Multiple dossier formats supported
- Advanced restrictions
- Integrated eCTD viewer with Single Sign-on solutions

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

10+
Years
combined experience in the Pharmaceutical Regulatory domain

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

Why Celegence

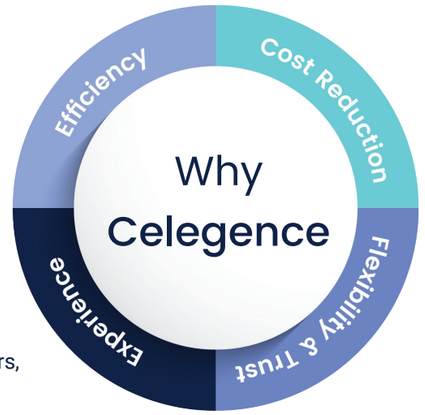
Entrusted by industry leaders, our expert team and business model guarantees the highest quality support while delivering exceptional value to our clients.

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.

Experience

- 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

"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™

"I am incredibly satisfied with the work Celegence has done thus far. They communicate well and receive feedback well. I find the team I have been assigned incredibly easy to work with, friendly, and people I genuinely look forward to speaking with once a week."

JULIANA PHERAROLIS
Project Management and Operations
Astellas Gene Therapies

astellas GENE THERAPIES

"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

The Qdossier team – and I explicitly mean the entire team – are experts in nearly everything you need to run your regulatory business successfully: it goes without saying that the regulatory expertise (e.g. XEVMPD, ISO-IDMP, Submission, etc.) is excellent, but it's the knowledge and result-based approaches that make the "wow" effect: troubleshooting, extinguishing fires, development of new (and successful) ideas, excel-magic. Just state your problem and get options of solutions that work. They are great!"

CHRISTIAN KLEWITZ
Head of Data Management
B Braun

B BRAUN

Leadership

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 **Pharmaceutical Regulatory** Challenges

Celegence has a wealth of knowledge to help you navigate through the most complex challenges that pharmaceutical regulations can pose.

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

For more information, reach out to us at

info@celegence.com

or contact us online at

celegence.com

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