



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.

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.

Some Of Our Clients

STALLERGENES  GREER™

BAUSCH+Health

Johnson+Johnson

 **astellas**
GENE THERAPIES

 **NOVARTIS**

 Monopar Therapeutics

 **MENARINI**
group

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

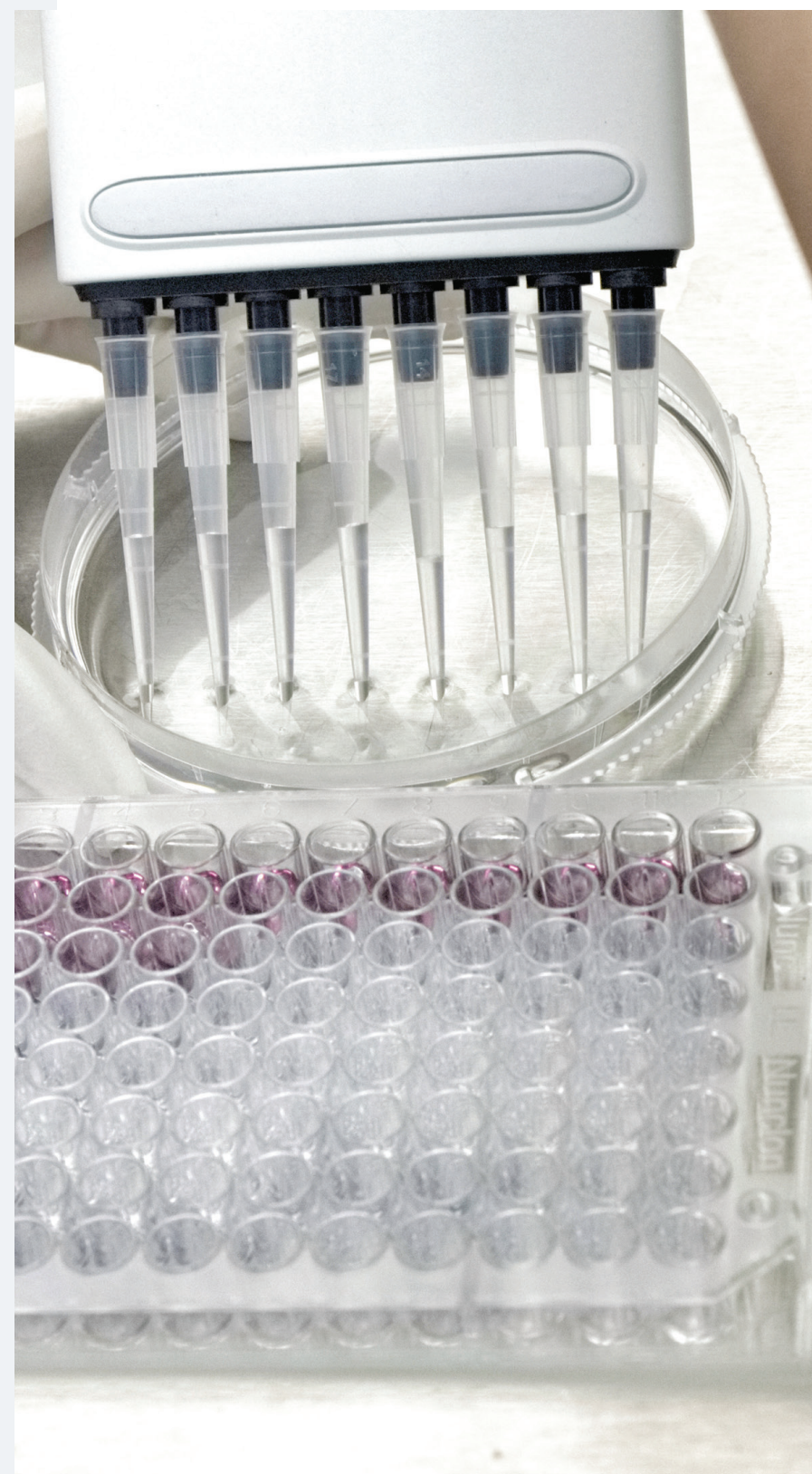
- Training on regulatory developments and optimizing business processes, including organizational standard operating procedures (SOPs).
- Curriculum training to cover regulatory processes.
- Improve internal return-on-investment (ROI) on technology usage (for example RIMS, document management, and publishing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

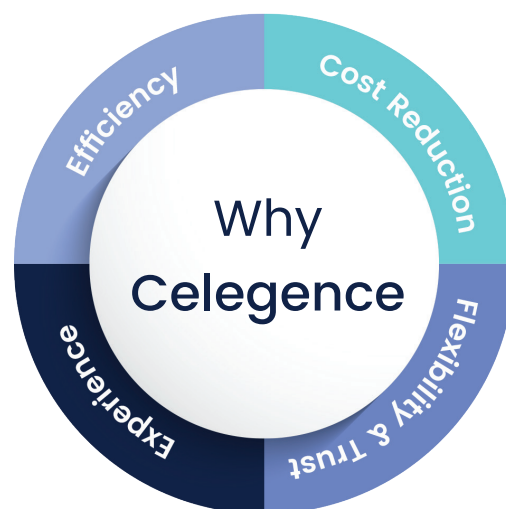


Efficiency

- 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.

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

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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