Regulatory Information Management System (RIMS)

Data Management & Business Process Training Support

When it comes to Regulatory Information Management Systems (RIMS)/ Regulatory Information Management, Celegence enable clients to optimize their processes, configure systems to maximize benefits, and reduce the operational inefficiencies of various software systems. With a strong knowledge of the unique challenges and client needs, our Regulatory consultants act as an extension of your team to create optimal processes that boost technological advantages while managing data in ways that are compliant and efficient.

These processes provide a comprehensive, first-time right approach for clients to navigate the regulatory solution landscape. Celegence contribute our deep knowledge of Regulatory data standards, such as xEVMPD and IDMP/SPOR when it comes to both assessing and implementing various solutions.

Why Celegence

Efficiency: Minimal lead time due to available trained resources & automation.

Experience: Industry Leaders with vast experience in all major markets and therapeutic areas.

Flexibility & Trust: Partnerships with small, mid-sized and top 20 Life Sciences companies.

Cost Reduction: At least 20% savings due to CAPTIS™ technology, automation, and blended resource model.

Selecting the Right Regulatory Solution

- Providing project management and subject matter expertise

- Analysis of 'As is' processes and gaps

- Driving and facilitating user requirements definition

- Providing recommendations on vendor selection that would best meet the needs of your organization

Manage RIM System Implementations

- Definition of 'To be' processes based on best practice

- Expert support and advice on system configuration

- Supporting data normalization, migration and import

- Supporting computer system validation according to 21 CFR Part and GAMP 5, for both the configuration and data migration

- Defining and implementing training strategy

- Change management and (post) Go-Live support

Operate & Improve Your Existing Regulatory Systems

- Offering operational data entry services, including xEVMPD, IDMP/SPOR, SPL

- Enhancing process and operational excellence, based on real world experience

- Ensuring data reconciliation and data quality measures

- Providing change request handling, release management & continuous testing/validation activities

- Providing audit and inspection support with appropriate queries and reports

Contact **Celegence** TODAY!

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