KPMG

Regulatory Affairs

Services for Life Sciences Companies

Our goal is to help our clients improve efficiency within their Regulatory Affairs function by implementing process and technology changes. These transformational changes help Life Sciences companies bring products to market more quickly, while reducing compliance risk and enabling a sustainable approach to regulatory activities.

Business and operations consulting

- Operating model and process re-design
- Support preparing for regulatory mandates
- Support for compliance remediation activities
- Regulatory strategy enablement
- M&A and divestitures – pre & post deal support
- Data quality programs
- Program management
- Change management

Technology/digital enablement

- Technology roadmap and solution selection
- Business requirements definition
- Design of supporting processes, including data entry model and governance
- Global data collection/harmonization
- Cross-functional integration design
- Business scenario testing and UAT support
- Development of digital/automation tools for specific Regulatory use cases

Regulatory Affairs Focus Areas

Submission planning & tracking	Dossier management	Submission document management	Product registration tracking	Product information management	Health Authority interactions	Regulatory archiving	Change control/ variation management	Labeling operations	Regulatory intelligence

Example client engagements

1. **Helped lead a global RIM transformation program for a Top 10 Pharma company**
   - Provided strategic direction and project management across several implementations
   - Helped facilitate key process and technology decisions, strategic planning and end user enablement
   - Provided change management and communications

2. **Led an org and process redesign assessment for a Reg Affairs function of a top 10 Pharma company**
   - Captured current state and made recommendations on future state design
   - Scope included process mapping workshops, organizational cost baseline, analysis of IT systems, leadership workshops and development of future state design recommendations

3. **Supported a three-part transformation program for the RA function of a top 10 Med Device company**
   - Led all business-facing activities for the global RIM project (solution design, data collection, and training)
   - Supported eIFU solution implementation, including process design, solution design, and training
   - Facilitated process design and business adoption of system to be used for global UDI and Eudamed

4. **Led operating model assessment and design for the Reg Affairs function of a top 25 Pharma company**
   - Defined opportunity areas for centralizing or externally sourcing certain Regulatory activities
   - Led effort to create business case and detailed design for prioritized opportunity areas

Why KPMG

Proven experience on complex projects – we can provide client references upon request

Deep industry expertise, comparators and accelerators – we have tailored approaches specific to Reg Affairs

Highly trained team members – our team has Regulatory Affairs professional and software certifications

Unique combination of business and technical expertise – we can help you solve a wide variety of challenges

Contact us

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