Gen AI-powered Regulatory Submissions / Publishing

Challenges

Ever-Changing Regulations:
The life sciences industry faces constant regulatory changes, with approximately 2,500 annual updates globally in the pharmaceutical sector alone.

Global Variation:
Most life sciences companies struggle with the challenge of global regulatory divergence.

Data Integrity:
Many companies find it difficult to maintain accurate, consistent, and accessible records, which are crucial for compliance.

Product Lifecycle Compliance:
Ensuring compliance throughout a product's lifecycle demands continuous monitoring and assessment, as regulatory non-compliance accounts for a significant proportion of pharmaceutical product recalls.

Solutions

Dossier Management with Gen-AI:
Quantiphi offers a Gen-AI Dossier automation solution for better governance and operational control. It automates business notifications, query management, and provides insights, improving compliance.

Submission Quality Assurance:
Quantiphi's solution validates data to identify discrepancies, errors, or anomalies in datasets and can generate standard operating procedures (SOPs) and best practices to ensure the quality of submissions.

Regulatory Intelligence Management:
Quantiphi's solution monitors & analyzes changes in regional or global regulatory compliance, thereby helping pharma companies to adapt their strategies accordingly and ensuring regulatory submissions are tailored to comply with both global regulations, thus reducing the risk of non-compliance.

Business Impact

Operational Efficiency & Cost Savings:
Dossier Management streamlines compliance processes, reducing manual effort, speeding up workflows, and increasing operational efficiency. This results in lower operational costs.

Scalability and Competitive Advantage:
Gen AI's user-friendly adaptability provides scalability to handle a growing volume of regulatory submissions or adjust to fluctuations in demand, along with gaining a competitive edge by speeding up their time-to-market and reducing compliance-related obstacles.

Timely Alerts & Improved Compliance:
Quick responses to regulatory changes minimize disruptions and ensure adherence to regulatory compliance.