FTI Consulting Health Solutions
Regulatory, Quality and Compliance Services

Forward-thinking life sciences companies recognize that Quality is a driver of top-line growth, improved profitability, and sustained regulatory compliance while, most importantly, providing higher quality, safer medical products.

DELIVERING VALUE

FTI Consulting has the global presence and breadth and depth of experience across the life sciences value chain to assist clients with addressing their most complex challenges and opportunities.

- Improve supply chain and businesses agility and resiliency
- Enhance the patient and customer experience
- Accelerate speed to market
- Improve alignment with strategic growth
- Drive harmonization and standardization
- Promote transparency and communication
- Increase effectiveness, at lower cost
- Enhance business partnering across the value chain
- Sustain regulatory compliance
- Evolve from a "culture of compliance" to a "culture of quality"

QUALITY AND COMPLIANCE SERVICES

Product Quality Strategy — We assist with the development and execution of strategies that shift focus from compliance to continuous improvement, fueling innovation and growth, operational effectiveness, profitability, and a culture of quality.

Quality Management System (QMS) Optimization — We perform capability maturity and risk assessments and work with clients to enhance and strengthen their QMS globally across key components including strategy, capabilities, governance, processes and technology. We help operationalize emerging regulations and enable adoption of new technologies.

Quality Process Excellence — We facilitate simplification, harmonization and automation of quality processes to reduce complexity, increase efficiency and effectiveness, and improve margins while sustaining compliance.

Intelligent Automation — We assist clients with leveraging new technologies including robotic process automation (RPA), machine learning (ML), natural language processing (NLP), and advanced analytics to automate repetitive tasks as well as accelerate continuous improvement.

Regulatory Compliance Remediation — We assist our clients in responding to regulatory enforcement including the development and execution of corrective action plans. We improve processes, not only to address identified problems but to enable operational efficiency and sustained compliance.

Quality and Risk Analytics — Utilizing cutting-edge analytical techniques, we help companies develop capabilities and dashboards that monitor performance, mitigate risk, and prevent quality problems. We help organizations to achieve "quality beyond compliance" and demonstrably enhance product quality and patient safety.

Culture of Quality/Change Management — We develop and execute change management plans to transform companies from a Culture of Compliance (Doing things right) to a Culture of Quality (Doing the right things).

Quality Risk Management — We assess and build control and communication capabilities related to product quality and their integration across the product lifecycle, functions, and stakeholders, as well as support pre-deal due dilligence and post-merger integration.

Data Integrity — We enhance IT quality and compliance management processes across the enterprise (and extended to suppliers and partners) to manage complexity, improve data integrity and increase efficiencies and effectiveness while sustaining compliance.

EXPERTS WITH IMPACT™

FTI CONSULTING™

The delays, waste, and rework that exist in today's global regulatory ecosystem will be exacerbated in a post COVID-19 world. Now more than ever, organizations need to focus on improving data and information management and enhancing the integration among regulatory, clinical, manufacturing, and commercial functions to successfully operate.

DELIVERING VALUE

We collaborate with our clients to assess their regulatory capabilities, streamline their regulatory processes and strengthen the integration among regulatory affairs, the business, and the broader ecosystem.

Increase agility to plan and respond to changes

Accelerate time to market

Enhance interaction among regulatory affairs, the business and the global ecosystem

Drive successful implemetation, integration and adoption of RIM technology

Reduce direct and indirect costs

Getting the right products to the right people at the right time

Optimize regulatory and trade compliance

REGULATORY SERVICES

Regulatory Strategy — We assist with the development and execution of global and regional regulatory and product registration strategies that provide a framework for effective decision-making.

Operating Model Enhancement — We build effective global regulatory operating models through effective organizational design and development of governance frameworks for effective communication and collaboration across the extended enterprise (economic operators). This includes charters, processes, SOPs, roles and responsibilities, operating agreements and performance dashboards.

Regulatory Information Management (RIM) — We support RIM vendor evaluation as well as the design, implementation, integration and adoption of RIM solutions that support effective planning and tracking, optimized submission and lifecycle processes, commitment management and advanced regulatory performance and risk management.

Capability Maturity Assessments — We perform rapid assessments for mature, top global biopharma and medtech as well as emerging, pre-revenue life sciences companies to enable comparison against leading industry practices, quickly identify key risk areas, and prioritize opportunities for improvement.

Intelligent Automation — We assist clients with automating repetitive tasks leveraging technologies such as robotic process automation (RPA) that reduce costs and errors while also boosting morale for employees to engage in higher-impact work. We apply more advanced automation such as machine learning (ML), natural language processing (NLP), and advanced analytics to derive new levels of understanding, innovation and control, enabling concepts such as Minimum Viable Submission (MVS) and right-first-time performance.

Regulatory Intelligence — We apply solid processes, RPA and machine learning technologies to achieve improved compliance and higher quality submissions, improving speed-to-market and increasing the probability of regulatory success.

Business Integration — We help strengthen communication and data sharing, through process alignment and technical systems integration, between regulatory affairs and key functions including quality, supply chain, health economics, and commercial operations to improve process efficiencies, accelerate time to market, and increase agility.

Submission Optimization — We facilitate end-to-end simplification and harmonization of regulatory processes and data to manage complexity, increase efficiencies, and improve submission quality.

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