

# FTI Consulting Health Solutions Regulatory Risk, Quality and Compliance Services

As we advance towards a post COVID-19 “New Normal”, forward-thinking life sciences companies recognize that Quality is a driver of business and supply chain resiliency, top-line growth, improved profitability, and sustained regulatory compliance while, most importantly, providing higher quality and safe medical products.

## DELIVERING VALUE

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



Improve Agility and Resiliency in Supply Chains and Businesses



Enhance the Patient and Customer Experience



Accelerate Time to Market



Improve Alignment with Strategic Growth



Drive Harmonization and Standardization



Promote Transparency and Communication



Increase Effectiveness at Lower Cost



Evolve from a “Culture of Compliance” to a “Culture of Quality”



Enhance Business Partnering Across Value Chain



Sustain Regulatory Compliance

## Quality and Compliance Services

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

**Quality Process Excellence** — We help clients with the simplification and harmonization of quality processes (including enterprise level) to reduce complexity, increase efficiencies/effectiveness, and improved margins while sustaining compliance.

**Intelligent Automation** — As the workforce is adjusted due to the impact of COVID-19, new ways of working will be explored. 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, time-consuming tasks and enhance quality processes.

**Quality Management System (QMS) Optimization** — We help our clients enhance and strengthen their QMS globally across key components including strategy, capabilities, governance, processes and technology. We help operationalize new and emerging regulations and enable adoption of new technologies.

**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 that monitor performance, mitigate risk, and prevent quality problems. We help organizations to move “quality beyond compliance” and demonstrably enhance product quality and patient safety.

**Culture of Quality/Change Management** — We assist clients with developing and executing 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 assist clients with enhancement of their assessment, control, communication, and review of risks concerning product quality and its integration across the product lifecycle, functions, and stakeholders.

**Data Integrity** — We assist clients with the enhancement of their IT quality and compliance management processes across the enterprise (and extended to suppliers and partners) to reduce complexity, improve data integrity and increase efficiencies and effectiveness while sustaining compliance.

The significant 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 will need to focus on improving data sharing and communication and enhance the integration between regulatory, clinical, manufacturing, and commercial functions to successfully operate.

#### DELIVERING VALUE

We collaborate with our clients to assess their regulatory strategy and operating model, streamline their regulatory processes and strengthen the integration between regulatory affairs and the business.



Increase Agility to Plan and Respond to Changes



Enhance Integration Between Regulatory Affairs and the Business



Reduce Direct and Indirect Costs



Accelerate Time to Market



Improve Product Quality and Patient Outcomes



Sustain Regulatory Compliance

#### REGULATORY SERVICES

**Regulatory Strategy**—We assist our clients with the development and execution of global and regional strategies that provide clarity and effective communication throughout the organization while also proving adaptable to both internal and external changes.

**Capability Maturity Assessments**— We assist our clients with performing rapid assessments that enable organizations to compare themselves against leading industry practices, quickly identify key risk areas, and prioritize opportunities for improvement.

**Operating Model Enhancement**—We help our clients enhance their global and regional operating models to improve alignment with strategic objectives, better integrate and communicate within the organization, increase process efficiencies and agility to address complex, changing regulatory requirements.

**Intelligent Automation**— As the workforce is adjusted due to the impact of COVID-19, we assist clients with automating manual, repetitive and time-consuming tasks leveraging various technologies including robotic process automation (RPA), machine learning (ML), natural language processing (NLP), and advanced analytics that reduce costs and errors while also boosting morale for employees to engage in higher-impact work.

**Business Integration**—We assist our clients in strengthening communication and data sharing 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 to more effectively plan and manage changes in a highly dynamic environment.

**Regulatory Information Management**—We assist companies with vendor evaluation of RIM technologies as well as the design and implementation of RIM solutions that reduce the cost of compliance, planning and executing of new regulations, as well as positively impacting time to market, product quality and patient outcomes.

**Submission Optimization**—We assist clients with the end-to-end simplification and harmonization of regulatory processes and data to reduce complexity, increase efficiencies, and improve submission quality.

#### George Serafin

Senior Managing Director  
212.841.9352  
George.serafin@fticonsulting.com

#### Brett Barlag

Senior Managing Director  
202.312.9183  
Brett.barlag@fticonsulting.com

#### Tim Renjilian

Senior Managing Director  
404.460.6222  
Tim.renjilian@fticonsulting.com