

LIFE SCIENCES

REGULATORY COMPLIANCE, INVESTIGATIONS, AND DISPUTES

Service Highlights

FTI Consulting's life science clients come to us for practical, immediate, and sustainable solutions. Below is a sample of these services:

Regulatory Compliance

- Compliance Program Assessment and Improvement
- Compliance Policy and Platform Optimization
- Compliance Auditing and Monitoring
- Compliance Training
- Anti-Bribery/Anti-Corruption
- Fair Market Value Services
- Transparency Reporting and Analytics
- Grants Program Design and Management
- Interactions with HCPs and Payers
- Clinical Research Compliance
- Independent Review Organization Services
- Compliance Expert and Board Advisory Services

Investigations and Disputes

- Sales and Marketing Investigations
- Off-Label Promotion Inquiries
- Drug Pricing Litigation and Investigations
- Regulatory Price Reporting
- Risk Assessments for Medical Affairs and Research & Development
- Corporate Integrity Agreement Readiness
- Electronic Evidence, Document Collection, and Production Services
- Litigation Presentation Services

The life sciences industry is one of the largest and fastest growing segments of the global economy. It is also one of the most competitive and heavily regulated. The operational and regulatory demands on the industry are already substantial, and they are growing as competitive pressures increase and governments impose tighter regulations in an attempt to balance access to life sustaining and enhancing treatments with economic constraints.

For many years industry regulatory enforcement was focused on: (i) improper remuneration to healthcare professionals (HCPs) and institutions; (ii) unapproved marketing of drugs and devices; and (iii) improper pricing of products to governmental payers. In recent years the U.S. government has also focused on the use of the Foreign Corrupt Practices Act to police activities of life sciences companies outside the U.S. Other governments have also tightened laws and enforcement, with a particular focus on anti-bribery and anti-corruption efforts that target payments and other economic incentives provided to healthcare providers and government officials. These governmental initiatives have been matched by a corresponding growth in U.S. federal and state-level whistleblower cases, which have resulted in a steady stream of expensive litigation and resulting settlement costs.

In short, regulatory compliance risks for the life science industry have continued to increase dramatically. To control these risks, these entities and their legal counsel need access to sophisticated and high-powered resources, with a global reach, to assess compliance-related risks, develop and implement state-of-the-art compliance tools and resources, perform compliance investigations, and remediate compliance-related gaps and deficiencies.

HOW DO WE DO IT?

FTI Consulting's Regulatory Compliance, Investigations, and Disputes (RCID) team uses an integrated approach to best address the unique needs of each of our clients. We emphasize cross-collaboration amongst our multi-disciplinary group of industry-experienced compliance and investigative professionals, to bring the right mix of experience and skills to bear on each assignment. This approach enables FTI to use our resources efficiently to best meet the needs of each client and assignment, while remaining nimble, responsive, and creative. Our approach combines the skills of industry specialists with those of compliance and strategic communications experts, investigative professionals, forensic accountants, computer forensic specialists, and electronic evidence and technology consultants. These are supplemented, as necessary, with experts in healthcare provider and payer matters.

FTI's distinctive approach enables us to help our clients confront issues intelligently and efficiently, whether we are assessing the effectiveness of compliance programs, helping to develop and implement strategic solutions to challenging problems, conducting investigations, responding to information requests and subpoenas, supporting litigation-related activities, or supporting decision-making by management and boards.

Our investigations and litigation support work is based on proven, efficient, and cost-effective approaches that emphasize benchmarking, advanced statistical sampling approaches, development of complex databases, and solid risk assessment techniques.

FTI's compliance investigations professionals have sat side by side with legal teams and participated in settlement negotiations with a wide variety of government agencies including the DOJ, CMS, OIG-HHS, the USAO, and numerous state AG offices.

REPRESENTATIVE EXPERIENCE

Compliance Risk Assessment and Program Development –

FTI's RCID team has vast experience assisting clients in assessing compliance-related risks and in developing, implementing, and maintaining an effective compliance program. We routinely perform compliance risk assessments and compliance program effectiveness reviews to help organizations understand their full range of compliance exposure, determine whether key regulatory risks have been identified, evaluated, and addressed, and identify opportunities to strengthen and improve those programs.

Compliance Policy Optimization– FTI has developed an innovative set of tools and services that enables its clients to streamline and standardize compliance-related policies and procedures, together with training materials and other job aides, and to place this entire set of resources onto a secure, searchable, web-based platform accessible from any computer, tablet, or smartphone. This platform not only makes compliance-related resources accessible and user-friendly, but it enables the use of sophisticated data analytics to better understand how and when these resources are utilized.

Compliance Auditing & Monitoring – FTI's RCID team has extensive experience developing and assessing compliance auditing and monitoring plans. This includes developing policies that govern the overall process, auditing and monitoring tools, and creating procedural and work instruction documents to accompany the overall program. FTI personnel have also conducted compliance auditing and monitoring activities on behalf of life sciences companies.

Medical Affairs and Research & Development – FTI provides a broad range of services related to activities of clients' Medical Affairs and Research & Development functions. Our work across these functions includes: non-promotional off-label communications, medical information, grants, interactions with HCPs and payers, investigator-sponsored trials, post-approval research, fair market value processes, submissions to compendia, and authorship/publication practices.

Government Pricing – FTI has been involved in a wide variety of investigations, including concerns with various manufacturers' government pricing obligations under the Medicaid Drug Rebate Program, the 340B Drug Pricing Program, and Medicare Part B Average Sales Price reporting; as well as investigations into companies' AWP price-reporting practices.

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Fair Market Value – FTI has extensive experience working with Life Science companies to develop the framework and strategy for determining Fair Market Value (FMV) for fee-for-service and other arrangements that they maintain with HCPs and related entities, both within and outside the U.S. To help our clients remain compliant with laws that regulate financial relationships with HCPs and government officials outside the U.S., FTI's RCID team members have significant experience developing and implementing policies, procedures, tools, and training to help clients ensure that these financial relationships are bona fide and based on FMV for services or items that are legitimately needed and actually provided.

Investigation Support – FTI has been involved in a wide variety of investigations and governmental inquiries focused on the promotional practices of pharmaceutical and medical device manufacturers, including concerns with off-label promotion, pricing, and anti-kickback violations. We have assisted our clients in negotiating resolutions with many government agencies, including the Department of Justice, U.S. Attorneys' Offices, Centers for Medicare and Medicaid Services, and the HHS Office of Inspector General. Our RCID team members have also been retained as experts to testify on behalf of many life science companies and healthcare providers.

Corporate Integrity Agreement Services – FTI assists pharmaceutical and medical device manufacturers in assessing their readiness for an upcoming Corporate Integrity Agreement (CIA) or other form of settlement agreement. This may include an operational and compliance gap analysis, or examination of specific areas of exposure to an organization. FTI also has extensive experience providing Independent Review Organization (IRO) services for life science companies, as required in CIAs or other settlement agreements. Our IRO work has included some of the largest and most complex CIAs to date, which has given us knowledge of the government's current position on many topics, and has helped us to develop strong working relationships with various government monitors and investigators.

Compliance Expert/Board Advisory Services – To meet the increasing demands and responsibilities of corporate directors and their counsel, FTI has developed a service line focused on their needs. FTI professionals have served as compliance experts and board advisors to large, global life science organizations. We also provide board training and education, and can assist with the development of effective management reporting tools.

CRITICAL THINKING
AT THE CRITICAL TIME™

About FTI Consulting

FTI Consulting, Inc. is a global business advisory firm dedicated to helping organizations protect and enhance enterprise value in an increasingly complex legal, regulatory and economic environment. FTI Consulting professionals, who are located in all major business centers throughout the world, work closely with clients to anticipate, illuminate and overcome complex business challenges in areas such as investigations, litigation, mergers and acquisitions, regulatory issues, reputation management and restructuring.

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