Global Pharmaceuticals and Life Sciences Industry Group

How can pharmaceutical and life sciences companies effectively meet the challenges of negotiating and implementing a corporate agreement?

Corporate Integrity Agreement and Independent Review Organisation Advisory Services

Over the last several years, the government has increased its scrutiny of compliance with federal healthcare programme laws and regulations, and has turned the compliance crosshairs toward the pharmaceutical and medical device industry. As a consequence government investigations, 'whistleblower' lawsuits, criminal prosecutions and civil settlements have become a fact of life and have resulted in fines totalling in the billions of dollars.

Pharmaceutical manufacturers, retail pharmacy chains, medical device companies, pharmacy benefit managers and other organisations currently face the challenge of negotiating a Corporate Integrity Agreement (CIA) with the Office of the Inspector General (OIG).

CIAs are complex, multi-year agreements that require an organisation to implement or maintain an effective compliance programme. Additionally, certain circumstances require an organisation to contract with an Independent Review Organisation (IRO) to provide an independent evaluation of their compliance with the CIA.

How can PwC help your organisation?

PwC has developed a portfolio of services that enable pharmaceutical and life sciences industry organisations to comply with regulatory requirements and to prepare for the increased government attention. We work closely with clients to develop compliance programmes that mitigate the impact of a CIA, provide advice on how to effectively negotiate CIAs with the government, and develop and implement anticipated IRO workplans.

CIA consultation *– PwC works with senior management, internal and external counsel, and the government to help clients negotiate their CIA and anticipated IRO work plan. We leverage our in-depth pharmaceutical industry knowledge and significant CIA experience to help clients achieve a balance between IRO workplan efficiencies and the objectives of government representatives.*

Implementation of CIA requirements *– PwC has a long and successful track record of helping organisations successfully build and implement effective compliance programmes based on the mandates of a CIA and other industry guidance.*

IRO services *– PwC serves as the IRO for more than 50 companies that operate under a CIA, including most of the recent CIAs in the pharmaceutical and medical device industries. For a firm to serve as an IRO, it is required to perform the assessment and evaluation procedures in an independent manner, taking into account any other business relationships or engagements that may exist. As an independent audit firm, PwC has established global standards, policies and monitoring processes that ensure our firm maintains independence.*

Evaluation of existing CIAs *– PwC has helped organisations successfully modify the scope and impact of their IRO requirements under a CIA. Through our extensive experience, we know how to balance the interests of our clients and the objectives of the OIG. We help clients tailor the CIA to their culture and operational environment to achieve an efficient and effective implementation of the agreement.*

pwc

Contacts

Tony Farino
Partner
anthony.farino@us.pwc.com
+1 (312) 298 2631

Brian Riewerts
Principal
brian.riewerts@us.pwc.com
+1 (410) 659 3390

Benefits you can realise

PwC is established within the pharmaceutical and life sciences industry as the premier professional services firm providing CIA and IRO services. While other professional services firms seem to have discovered the importance of regulatory compliance only recently, PwC has made compliance services, including CIA and IRO services, a key focus for years.

Our professionals were pioneers in the field and are widely recognised for their proven ability to drive efficiencies in the review process. PwC was the first to negotiate scope reduction to CIAs and has developed innovative approaches to sampling.

We assess existing processes and policies, and develop an IRO workplan to achieve the IRO testing requirements for each individual client. We establish a plan to gain insights on systems, policies, and procedures, and we know how to work with client personnel in the quickest and least-intrusive ways.

Experience and credibility with the OIG *– Based on our experience serving as the IRO for more than 50 companies, PwC has in-depth technical regulatory experience and a proven track record of work with the OIG. This experience gives PwC unique insight and credibility in the industry. We leverage these qualities to develop tailored IRO workplans to test drug price reporting, sales and marketing activities and managed care contracting.*

Global compliance practice *– For years, PwC has provided our clients with comprehensive regulatory risk assessments, focused government pricing reviews, sales and marketing assessments, clinical compliance risk assessments, and compliance programme design and implementation services.*

www.pwc.com/pharma

150213-145024-SS-OS

Global Pharmaceutical and Life Sciences Industry Group

The Global Pharmaceutical and Life Sciences Industry Group at PwC is dedicated to delivering effective solutions to the complex business challenges facing pharmaceutical and life sciences companies. A global leader in serving the pharmaceutical and life sciences industry PwC has extensive experience working with companies on industry-specific strategic, operational, and financial issues. Our expertise includes assurance, tax and advisory services, as well as specialised capabilities in regulatory compliance, risk management, performance improvement and transaction support. In helping our clients, we draw on the full knowledge and skills of PwC's professionals. More than 195,000 people in 157 countries connect their thinking, experience and solutions to build public trust and enhance value for clients and their stakeholders.