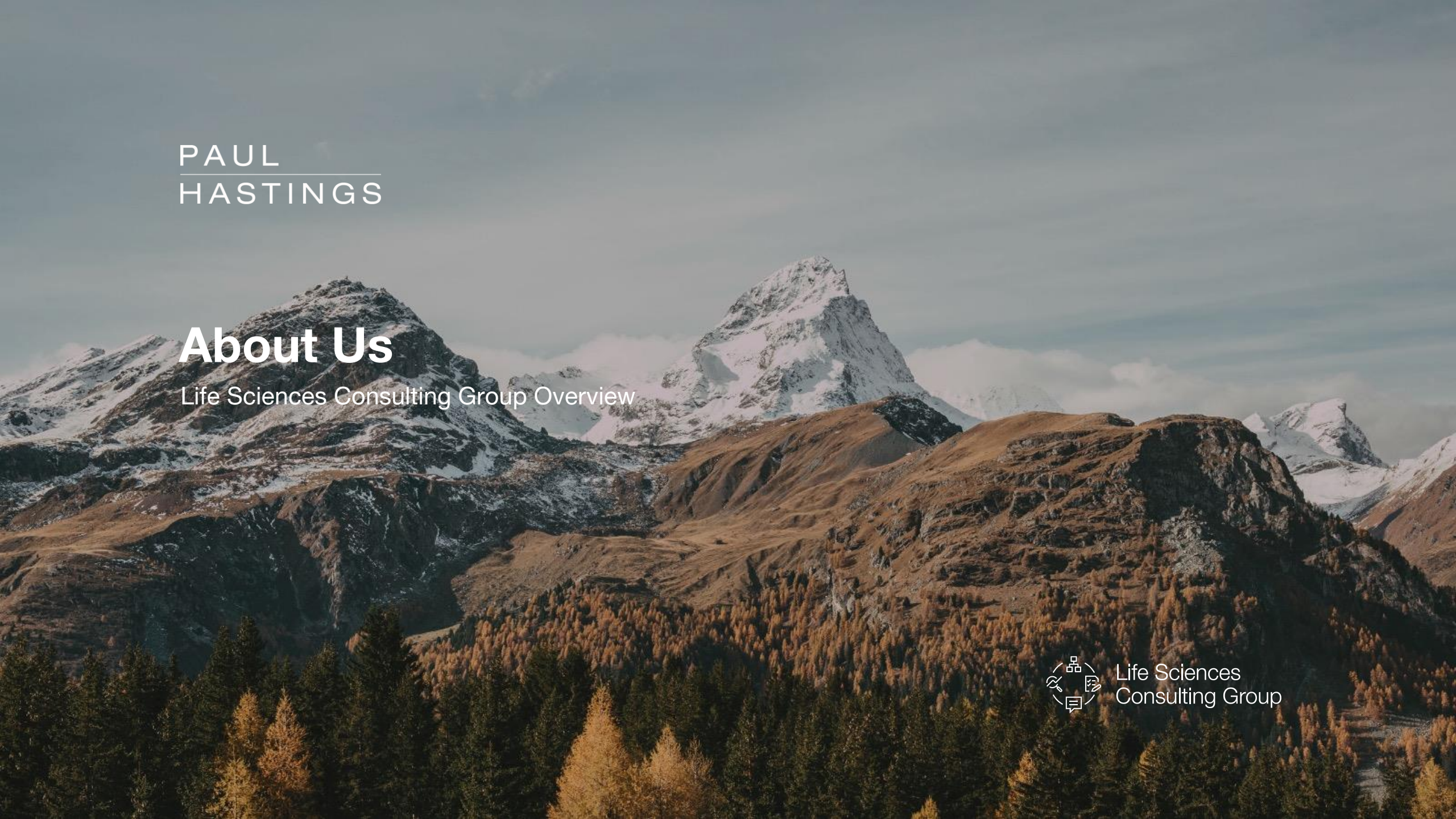

PAUL
HASTINGS
About Us
Life Sciences Consulting Group Overview
Life Sciences
Consulting Group

In today's world of transformative change, our purpose is clear —to help our clients and people navigate new paths to growth.

A diverse life sciences leader for legal services

Founded in 1951, Paul Hastings has grown strategically to anticipate and respond to our clients' needs in markets across the globe. Our innovative approach and unmatched client service have resulted in us becoming one of the world's leading global law firms within a relatively short timeframe.

We have a strong presence throughout Asia, Europe, Latin America, and the U.S., and we offer a complete portfolio of services to support our clients' complex, often mission-critical needs.

TOP 10

THE AMERICAN LAWYER

Most Successful Law Firms in the U.S. 7 years in a row

TOP 10

FT

Innovative Lawyer's Report across APAC, EU, and NA

TOP 5

vault

Best Overall Law Firm to Work For

TOP 5

vault MCCA

Best Overall Diversity

Mansfield Rule™ Certified Plus

The LEGAL 500	2019 U.S. Ranking for Healthcare: Life Sciences
Chambers USA	Recognized for "deep knowledge of the pharmaceutical and wider life sciences sector."
LAW360	2017 Life Sciences Practice Group of the Year
GIR Global Investigations Review	2017 Most Impressive Investigations Practice; cited strength in life sciences

PAUL HASTINGS

Our global reach

PAUL HASTINGS

21

Offices across the Americas, Asia & Europe

Americas

Atlanta
Century City
Chicago
Houston
Los Angeles
New York
Orange County
Palo Alto
San Francisco
São Paulo
Washington D.C.

58

countries where we serve our clients

Europe

Brussels
Frankfurt
London
Paris

50%

of the Fortune 100 are served by us

ASIA

Beijing
Hong Kong
Seoul
Shanghai
Tokyo

1

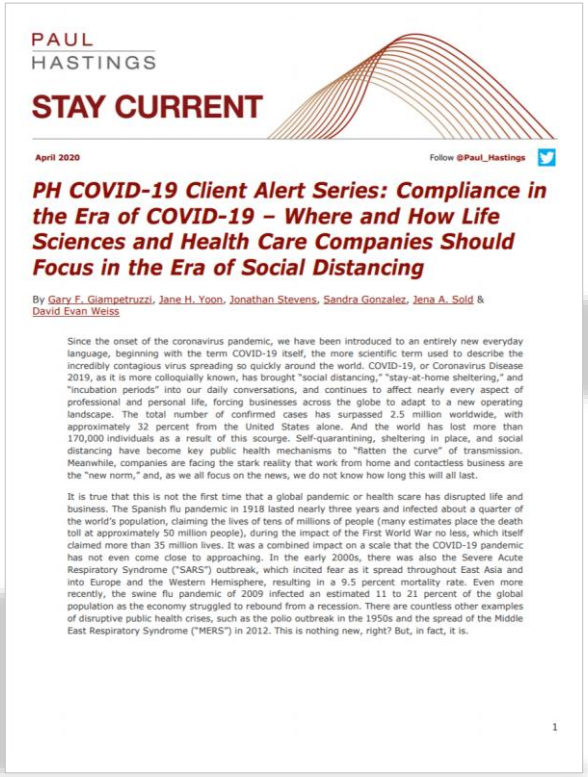
team integrated

with the strategic goals of your business

Life sciences thought leadership

As business leaders around the world grapple with a wide range of questions, Paul Hastings is here to help.

Our publications leverage our team's industry knowledge, diverse backgrounds, and expertise to provide novel and thoughtful insights applicable to our clients in an evolving market.


PAUL HASTINGS

STAY CURRENT

April 2020 Follow @Paul_Hastings

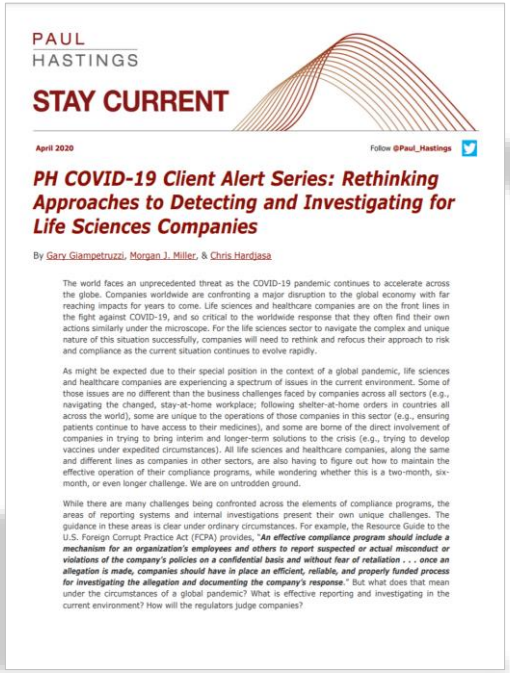
PH COVID-19 Client Alert Series: Compliance in the Era of COVID-19 – Where and How Life Sciences and Health Care Companies Should Focus in the Era of Social Distancing

By Gary F. Giampetruzzi, Jane H. Yoon, Jonathan Stevens, Sandra Gonzalez, Jena A. Sold & David Evan Weiss

Since the onset of the coronavirus pandemic, we have been introduced to an entirely new everyday language, beginning with the term COVID-19 itself, the more scientific term used to describe the incredibly contagious virus spreading so quickly around the world. COVID-19, or Coronavirus Disease 2019, as it is more colloquially known, has brought "social distancing," "stay-at-home sheltering," and "incubation periods" into our daily conversations, and continues to affect nearly every aspect of professional and personal life, forcing businesses across the globe to adapt to a new operating landscape. The total number of confirmed cases has surpassed 2.5 million worldwide, with approximately 32 percent from the United States alone. And the world has lost more than 170,000 individuals as a result of this scourge. Self-quarantining, sheltering in place, and social distancing have become key public health mechanisms to "flatten the curve" of transmission. Meanwhile, companies are facing the stark reality that work from home and contactless business are the "new norm," and, as we all focus on the news, we do not know how long this will all last.

It is true that this is not the first time that a global pandemic or health scare has disrupted life and business. The Spanish flu pandemic in 1918 lasted nearly three years and infected about a quarter of the world's population, claiming the lives of tens of millions of people (many estimates place the death toll at approximately 50 million people), during the impact of the First World War no less, which itself claimed more than 35 million lives. It was a combined impact on a scale that the COVID-19 pandemic has not even come close to approaching. In the early 2000s, there was also the Severe Acute Respiratory Syndrome ("SARS") outbreak, which incited fear as it spread throughout East Asia and into Europe and the Western Hemisphere, resulting in a 9.5 percent mortality rate. Even more recently, the swine flu pandemic of 2009 infected an estimated 11 to 21 percent of the global population as the economy struggled to rebound from a recession. There are countless other examples of disruptive public health crises, such as the polio outbreak in the 1950s and the spread of the Middle East Respiratory Syndrome ("MERS") in 2012. This is nothing new, right? But, in fact, it is.

1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STAY CURRENT

April 2020 Follow @Paul_Hastings

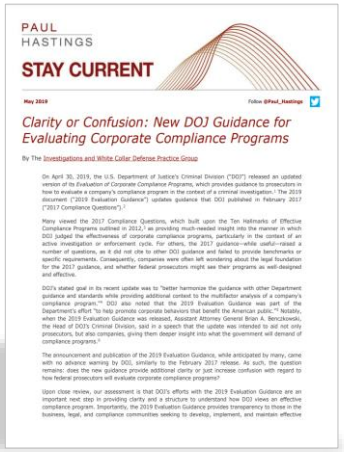
PH COVID-19 Client Alert Series: Rethinking Approaches to Detecting and Investigating for Life Sciences Companies

By Gary Giampetruzzi, Morgan J. Miller, & Chris Hardjasa

The world faces an unprecedented threat as the COVID-19 pandemic continues to accelerate across the globe. Companies worldwide are confronting a major disruption to the global economy with far reaching impacts for years to come. Life sciences and healthcare companies are on the front lines in the fight against COVID-19, and so critical to the worldwide response that they often find their own actions similarly under the microscope. For the life sciences sector to navigate the complex and unique nature of this situation successfully, companies will need to rethink and refocus their approach to risk and compliance as the current situation continues to evolve rapidly.

As might be expected due to their special position in the context of a global pandemic, life sciences and healthcare companies are experiencing a spectrum of issues in the current environment. Some of those issues are no different than the business challenges faced by companies across all sectors (e.g., navigating the changed, stay-at-home workplace; following shelter-at-home orders in countries all across the world), some are unique to the operations of those companies in this sector (e.g., ensuring patients continue to have access to their medicines), and some are borne of the direct involvement of companies in trying to bring interim and longer-term solutions to the crisis (e.g., trying to develop vaccines under expedited circumstances). All life sciences and healthcare companies, along the same and different lines as companies in other sectors, are also having to figure out how to maintain the effective operation of their compliance programs, while wondering whether this is a two-month, six-month, or even longer challenge. We are on untrodden ground.

While there are many challenges being confronted across the elements of compliance programs, the areas of reporting systems and internal investigations present their own unique challenges. The guidance in these areas is clear under ordinary circumstances. For example, the Resource Guide to the U.S. Foreign Corrupt Practice Act (FCPA) provides, "***An effective compliance program should include a mechanism for an organization's employees and others to report suspected or actual misconduct or violations of the company's policies on a confidential basis and without fear of retaliation . . . once an allegation is made, companies should have in place an efficient, reliable, and properly funded process for investigating the allegation and documenting the company's response.***" But what does that mean under the circumstances of a global pandemic? What is effective reporting and investigating in the current environment? How will the regulators judge companies?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May 2019 Follow @Paul_Hastings

Clarity or Confusion: New DOJ Guidance for Evaluating Corporate Compliance Programs

By The Investigations and White Collar Defense Practice Group

On April 30, 2019, the U.S. Department of Justice's Criminal Division ("DOJ") released an updated version of its *Evaluation of Corporate Compliance Programs*, which provides guidance to prosecutors in how to evaluate a company's compliance program in the context of a criminal investigation.[1] The 2019 document ("2019 Evaluation Guidance") updates guidance that DOJ published in February 2017 ("2017 Compliance Questions").[2]

Many viewed the 2017 Compliance Questions, which built upon the Ten Hallmarks of Effective Compliance Programs outlined in 2012,[3] as providing much-needed insight into the manner in which DOJ judged the effectiveness of corporate compliance programs, particularly in the context of an active investigation or enforcement cycle. For others, the 2017 guidance—while useful—raised a number of questions, as it did not cite to other DOJ guidance and failed to provide benchmarks or specific requirements. Consequently, companies were often left wondering about the legal foundation for the 2017 guidance, and whether federal prosecutors might see their programs as well-designed and effective.

DOJ's stated goal in its recent update was to "better harmonize the guidance with other Department guidance and standards while providing additional context to the multifactor analysis of a company's compliance program."[4] DOJ also noted that the 2019 Evaluation Guidance was part of the Department's effort "to help promote corporate behaviors that benefit the American public."[5] Notably, when the 2019 Evaluation Guidance was released, Assistant Attorney General Brian A. Benczkowski, the Head of DOJ's Criminal Division, said in a speech that the update was intended to aid not only prosecutors, but also companies, giving them deeper insight into what the government will demand of compliance programs.[6]

The announcement and publication of the 2019 Evaluation Guidance, while anticipated by many, came with no advance warning by DOJ, similarly to the February 2017 release. As such, the question remains: does the new guidance provide additional clarity or just increase confusion with regard to how federal prosecutors will evaluate corporate compliance programs?

Upon close review, our assessment is that DOJ's efforts with the 2019 Evaluation Guidance are an important next step in providing clarity and a structure to understand how DOJ views an effective compliance program. Importantly, the 2019 Evaluation Guidance provides transparency to those in the business, legal, and compliance communities seeking to develop, implement, and maintain effective

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Our legal expertise in the life sciences

Paul Hastings' attorneys bring a global, interdisciplinary approach to address our life sciences clients' multifaceted needs.

We partner with clients to understand and advise on their business and legal objectives, delivering tailored solutions, innovative value-add offerings, and seamless service across practices and regions.

Compliance, Investigations & Enforcement

Navigating compliance, investigations, and enforcement issues in this highly-regulated sector across the globe

Privacy & Cybersecurity

Advising on unique data governance issues, Internet of Things (IoT) development and roll-out, proactive privacy and cybersecurity assessments, and related litigation & investigations

FDA/Regulatory

Providing strategic FDA regulatory advice on development, clinical, manufacturing and post-marketing obligations

Capital Raising

Guiding capital raising from early-stage private placements to registered equity debt offerings; advising securities exchange listings on U.S. and international exchanges

Transactions

Structuring complex cross-border transactions, from M&A to first-of-their-kind innovative strategic partnerships to licensing arrangements

Intellectual Property

Strategic counseling with respect to critical intellectual property; handling complex, high-stakes patent litigation

Litigation

Advising on disputes, from class action and single-plaintiff litigation to global benefits, labor, and employee mobility cases

PAUL HASTINGS

Our life sciences consulting services

Our Life Sciences Consulting Group works arm-in-arm with our legal services professionals to design, build, implement, and operate effective compliance risk management programs—as well as the organizational constructs and resource models that support those programs across the enterprise.

Whether the context in which we work together is reactive (i.e., an investigation or government action) or proactive (i.e., borne out of a desire to enhance your risk management program), we have the experience necessary to tailor our approach to your unique needs.

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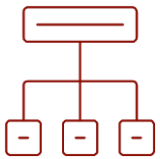
Our consulting services



Compliance Program Design

We absorb how your current compliance program and org structure works today, identifying key opportunities for improved clarity on risk management roles and governance. We then design and implement an improved program together with you.

Fair Market Value (FMV) Services

We understand your activities, your competitive positioning, and corporate strategy, and help you to identify your valuation needs—whether related to HCP payments, payments to wholesalers and distributors, or clinical study-related payments. We then create advanced valuation models that enable your business to operate in a manner that fits your company's unique needs, and walk alongside you and your colleagues as you implement the FMV rates in your contracting process.

Training and Communication Design

We gather perspectives and information on training practices and goals, identifying opportunities to improve the timeliness and efficacy of your company's compliance training. We then design and support rollout of the updated training plan and content together with you.

Auditing and Monitoring Design

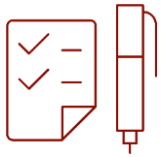
We engage with your current compliance auditing and monitoring program, identifying opportunities to sharpen your ability to measure key risk behaviors and activities—which in turn will free you to focus on action. We then refine the program and related reporting, link it to related processes, and execute the program together with you.

PAUL HASTINGS

Our consulting services

Risk Assessment Processes (RAMP, ERM)

We collect perspectives on how and where you currently assess risks, whether focused solely on compliance risk or looking across the enterprise, identifying opportunities to improve the span and accuracy of risk measurement. We then amend your existing risk assessment and mitigation techniques, enable them with key supporting workflows, data management, and reporting capabilities, and execute the program together with you.



Standards and Policy Design

We immerse ourselves in your current document architecture and content, identifying opportunities to lend greater precision and simplicity to both new and existing controls. We then design and implement improved policies, procedures, and other supporting documents together with you.

Compliance Health Checks

We evaluate your compliance program from end to end, or in focused areas of interest, identifying opportunities to improve key controls and other program attributes in light of industry practices and trends in the enforcement landscape. We then deliver a detailed, resourced roadmap to serve as your guide as you work towards your goal of increasing the value that your compliance program provides, and support and advise you as we work to implement the updated ways of working together with you.

PAUL HASTINGS

Our consulting services: FMV

Our professionals have provided Fair Market Value (FMV) services to **over 250** life sciences companies operating in countries **across the globe**.

Fair Market Value (FMV)

Consultant FMV

- HCPs
- Patients
- Allied Health Professionals

We create methodologies for determining the FMV of payments to HCP consultants for services including, but not limited to, advisory boards, speaking, training, and research; we have done so for over **400 HCP specialties in over 170 countries.**

Service Fee FMV

- GPO
- Wholesalers
- Patient Services Providers

We create legally-validated analyses of the FMV of certain services provided to manufacturers by third parties **within the distribution channel.**

Clinical FMV

- Investigator-initiated
- Company-sponsored
- Pre-market
- Post-market

We create detailed FMV toolkits for services set forth in clinical trial budgets – whether **company-sponsored or investigator initiated**, proactive or retroactive, pre-market or post- market research activities.

Company context assessment

We always start by understanding your unique needs and context, and tailor our experience and solutions to meet those needs.

Company Stage

- Early Stage/ Pre-Commercial
- Single Product
- Small to Midsize, Multi-Product
- Large Multi-Product

Geolocation

- US only
- International

Risk Management Operations

- In-House
- Third Party
- Joint Venture
- Alliance

Compliance Context

Reactive

- Conducting an internal investigation
- Under external investigation
- Under terms and conditions of a settlement (CIA/IRO)

Proactive

- Desire to improve program alignment with company risk posture
- Desire to reduce risk of investigations / government actions

Risk Domains & Interactions

- HCP Interactions
- Patient Interactions
- Government Interactions

Therapeutic Area(s)

- General Medicines
- Oncology
- Rare Disease
- Gene Therapy
- Medical Devices
- Drug/Device/Software Hybrids
- Orphan Drugs

Addressable Functions

- Sales
- Marketing
- Patient Services
- Market Access
- R&D
- Medical
- Quality
- Human Resources
- Learning

PAUL HASTINGS

360º Support

Paul Hastings' first-of-its-kind offering from an elite law firm "provides the opportunity for a more expansive view of the clients and their projects" which "means better and more cost-effective services for clients throughout a continuum of activities."

Source: Law360

Life Sciences Consulting Group

For further information, you may visit our home page at **www.paulhastings.com** or email us at **info@paulhastings.com**.