

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 and healthcare leader

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.



Recognized as a Life Sciences Practice Group of the Year



Ranked for U.S. Healthcare: Life Sciences



Mansfield Rule[™]
Certified *Plus*



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



Most Impressive Investigations Practice of the Year, noted for strength in the Life Sciences industry



Recognized for "deep knowledge of the pharmaceutical and wider life sciences sector."



Ranked among the Most Successful Firms in the U.S for 11 years in a row



Ranked Top 5 for Best Overall Diversity



Ranked Top 10 for Best Overall Law Firm to Work For



Winner of Four Life Sciences Awards

Our global reach



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21

Offices across the Americas, Asia & Europe

Americas

Atlanta
Century City
Chicago
Houston
Los Angeles
New York
Orange County
Palo Alto
San Diego
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



Our legal expertise in the life sciences and healthcare

Paul Hastings' attorneys bring a global, interdisciplinary approach to address our life sciences and healthcare 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.

PAUL
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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 rollout, proactive privacy and cybersecurity assessments, and related litigation & investigations

FDA/Regulatory

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

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

Employment

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

Environmental, Social, and Governance

Advising on human rights programs, access to affordable healthcare, alleviating poverty and social exclusion, preventing environmental degradation, and securing access to housing and equitable education

Real Estate

Providing insight on issues that may arise in the acquisition, disposition, leasing, and development of office, manufacturing, R&D, and logistic facilities



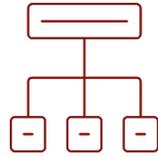
Our life sciences and healthcare consulting services

Our 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.



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.



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 enforcement trends. We then deliver a detailed, resourced roadmap to guide you as you work towards increasing the value that your compliance program provides, and we support and advise you as we work to implement the updated ways of working together with you.



Risk Assessment Processes

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 and reporting capabilities, and execute the program together with you.



Fair Market Value (FMV) Services

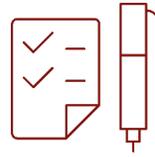
We understand your activities, your competitive positioning, and corporate strategy, and help you to identify your valuation needs — whether related to HCP payments, payments to wholesalers and distributors, or clinical study-related payments. We create advanced valuation models that enable your business 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 processes.

Our consulting services



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 explore your use of data and analytics and strengthen capabilities to enable real-time monitoring. We then refine the program and related reporting, link it to related processes, 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.



Training and Communication Design

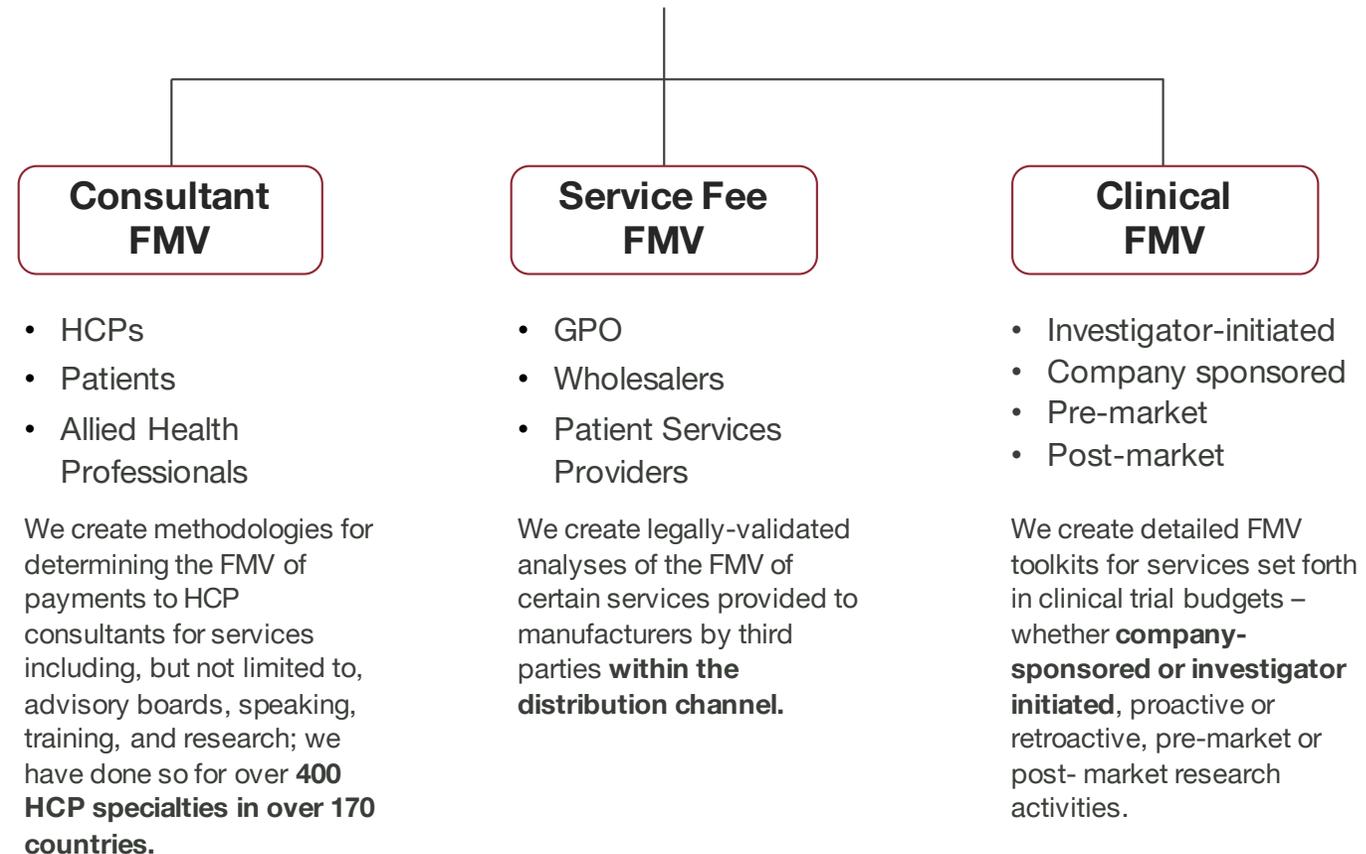
We gather perspectives and information on training practices and goals, identifying opportunities to improve the timeliness and efficacy of your company's compliance training. We then design and support rollout of the updated training plan and content together with you.

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)



Life sciences 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



Risk Domains & Interactions

- HCP Interactions
- Patient Interactions
- Government Interactions



Geolocation

- US only
- International



Therapeutic Area(s)

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



Risk Management Operations

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



Addressable Functions

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



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

Healthcare company context assessment

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



Compliance Context

Reactive

- Conducting an internal investigation
- Under external investigation
- Under terms and conditions of a settlement

Proactive

- Desire to improve program alignment with company risk posture
- Desire to reduce risk of non-compliance / investigations / government actions
- Desire to proactively evaluate current and emerging risks and related compliance implications
- Perform compliance due diligence in connection to Mergers and Acquisitions



Organizations

- Hospitals
- Health systems
- Academic Medical Centers
- Physician practices
- Outpatient clinics
- Post-acute care and senior living (Home Health Agencies, Hospice)
- Health Care Investors
- Health Care Technology / Services



Clinical Services Areas

- Hospital Inpatient / Outpatient
- Professional
- Psychiatry / Behavioral Health
- Home Health Care
- Hospice Care
- Clinical Research / Clinical Trials
- Pharmacy



Addressable Functions

- Corporate Compliance
- Compliance Operations
- Privacy
- Clinical documentation, coding and billing for government and commercial payors
- Telemedicine
- Retail Health and Wellness



360° 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



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