

Life Sciences

Medical Affairs

The Pivotal Point Between Research and Product Commercialization in the Life Sciences Industry

Medical Affairs is the scientific and clinical face of the company. Strong relationships with healthcare professionals provide the conduit for the free flow of information between the medical community and the organization, positioning Medical Affairs to play a critical role throughout the product life cycle, from launch preparation through commercialization to late-stage life cycle management. At each step, Medical Affairs' role is to educate stakeholders through the generation and dissemination of meaningful, complete, accurate, and unbiased medical data through relevant channels, with the goal of providing healthcare decision-makers with the evidence and confidence they need to select appropriate therapies and improving patient care.

While commercial teams must limit their discussions with healthcare professionals to align with the labeling of an approved product, Medical Affairs staff can carry out scientific exchanges related to such topics as clinical trial results of investigational products. Such communications are not without risk, however, and Medical Affairs activities must comply with government, industry, and company regulatory and compliance policies.

The Future of Medical Affairs

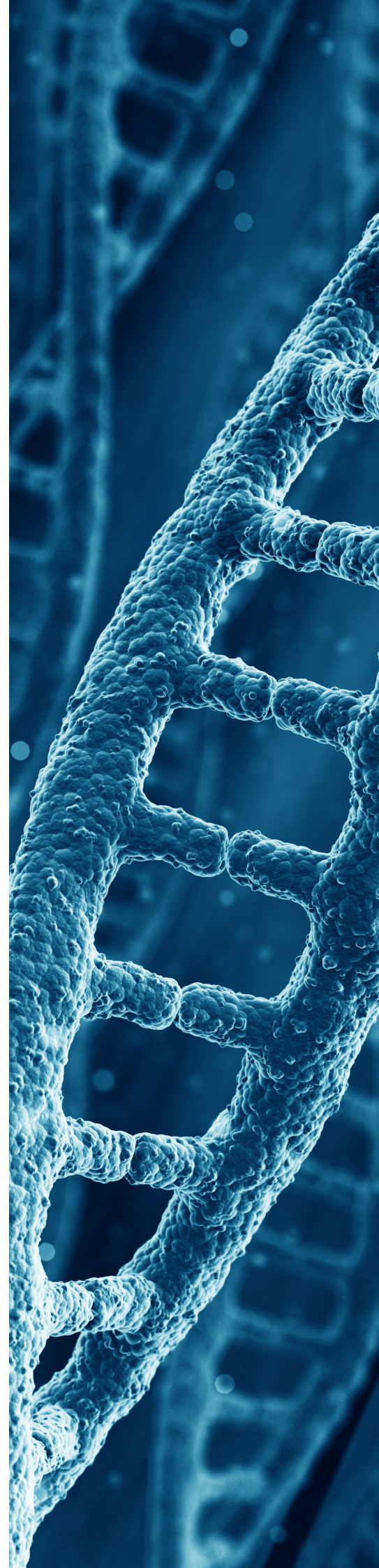
As the global regulatory landscape evolves, the call for transparent scientific and medical data communication increases and patients are rapidly becoming more engaged in healthcare decision-making. Transformational trends affecting Medical Affairs include:

- Generating meaningful medical data, including real-world evidence, both during product development and after product approval, to support product registration and to provide insights into medical product use in rare disease and real-life clinical settings.
- Supporting patient-centric healthcare by partnering with patient advocates and educating stakeholders in the healthcare community on the needs of patients.
- Optimizing patient access and use of medical treatments by demonstrating the economic value of medical products to healthcare professionals, payers, and other stakeholders.
- Innovating outreach to and engagement with healthcare providers and patients using social media, digital interfaces, and other technology solutions.

Guidehouse Provides Solutions to Medical Affairs Challenges

Guidehouse offers cross-functional expertise in scientific communication, evidence-generation, compliance framework development, and pharmacoeconomics that can jointly deliver strategic direction, operational structure, and tactical support to Medical Affairs functions within the life sciences industry throughout the product life cycle.

Guidehouse consultants have decades of hands-on industry experience working with emerging and established life sciences companies across pharma, biotech, and medical technology industries.



Case Studies

Positioning an Emerging Company for Successful Launch

Navigating the rules related to appropriate scientific communications can be challenging, so when a small biotechnology company with a novel therapy for the treatment of stroke was awaiting top-line data from their pivotal clinical trial, they needed a partner to help create a framework that would allow them to compliantly communicate their exciting new data to healthcare providers and payers.

Together with colleagues from our Compliance practice, the Guidehouse team developed corporate policies and procedure documents governing our client's Medical Affairs activities. Furthermore, we helped our client prioritize prelaunch activities to maximize the awareness of their product in the healthcare community without exhausting their limited funds.

Medical Affairs for the Medical Device Industry

Medical Affairs departments are currently not as widely established in the medical device industry as in the biopharmaceutical industry, although the benefits of creating Medical Affairs functions for the performance of certain activities such as key opinion leader engagement and professional education are increasingly being recognized.

Guidehouse was engaged by the North American division of a major global medical device corporation to perform a series of benchmarking studies to evaluate key activities and the organizational structure for the Medical Affairs department within various comparative life sciences companies, which included brief case studies of identified industry best practices. We also recommended an organizational structure for the client's North America Medical Affairs department, which was endorsed by the corporation's global headquarters.

Engaging Patients Through Targeted Advocacy

A multinational pharmaceutical company hired Guidehouse to help organize its patient advocacy and outreach activities for several of its major products in development. At the time, advocacy activities had been disparate, one-off engagements with little coordination across the organization or with partners.

The Guidehouse team evaluated the current state of activities while benchmarking competitor practices, and then facilitated a workshop to help the client team prioritize where the patient advocacy outreach budget should be allocated. Additionally, we tapped into experts from across Guidehouse's Healthcare practice, bringing clarity to the value expectations of payers and healthcare providers.

Contact Life Sciences Medical Affairs

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About Guidehouse

Guidehouse is a leading global provider of consulting services to the public and commercial markets with broad capabilities in management, technology, and risk consulting. We help clients address their toughest challenges and navigate significant regulatory pressures with a focus on transformational change, business resiliency, and technology-driven innovation. Across a range of advisory, consulting, outsourcing, and digital services, we create scalable, innovative solutions that prepare our clients for future growth and success. Headquartered in McLean, VA., the company has more than 8,000 professionals in over 50 locations globally. Guidehouse is a Veritas Capital portfolio company, led by seasoned professionals with proven and diverse expertise in traditional and emerging technologies, markets, and agenda-setting issues driving national and global economies. For more information, please visit: www.guidehouse.com.

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