

The Medical Affairs Company: Our Story

Over four decades ago, a novel role was introduced to the pharmaceutical industry—the Medical Science Liaison (MSL). The Upjohn Company first used MSLs to engage with customers on a scientific level that traditional sales representatives were unable to achieve. Since then, the MSL has become an essential function for many pharmaceutical, biotechnology and medical device companies, and is most commonly housed within the medical affairs department. A number of changes in the industry, including more stringent regulations, fewer drug approvals and pressure to reduce headcount have resulted in many pharmaceutical companies looking to outsource the MSL and other related Medical Affairs functions. Successful outsourcing of these functions, however, requires a partner who understands the business and the science of the industry both inside and out. This is where The Medical Affairs Company (TMAC) begins its story.

TMAC, established in 2007, has a seasoned leadership team that understands and monitors important trends in the pharmaceutical industry. The team recognized early on that many companies require outside assistance to capitalize on the value of their medical affairs or medical science liaison functions. Evan Demestihis MD, who joined as CEO of TMAC in 2008, created the very first contract medical organization offering outsourced medical science liaison staffing back in 1997, along with other members of the current TMAC leadership team. In recent years this group saw the need to expand their original business model in order to meet the broader array of clients' medical affairs needs, concentrating on compliance, advanced training, and technology applications. The Medical Affairs Company fulfills this purpose.

Since its inception, TMAC has rapidly emerged as the leading provider of comprehensive medical affairs solutions for the pharmaceutical industry. TMAC provides pharmaceutical, biotechnology and medical device industries a complete array of strategic and tactical medical affairs solutions, including contract and consultative MSL programs, MSL knowledge management solutions and medical communications services. All programs are managed by highly credentialed directors with industry experience leading medical affairs activities.

TMAC has engaged several top ten pharmaceutical companies as clients, and partnered with numerous smaller specialty pharmaceutical companies to provide field-based program support aligned with their disease state focus, product life-cycle stage and therapeutic class complexities. Clients appreciate our ability to customize and integrate medical affairs solutions seamlessly into their organization, as well as our focus on establishing credibility with internal and external stakeholders.

TMAC's greatest strength, as well as the reason for its success, is its singular focus on medical affairs - it is our only business. The pharmaceutical industry has been under tremendous scrutiny during the past few years, criticized for the use of aggressive sales and marketing tactics. There has been a trend, additionally, to greatly limit physician access to traditional sales activities. A net result is that sales representatives are now severely limited in their ability to introduce and engage high value customers about established and new products. Another issue is the increasingly complex nature of new products, calling into question who is the best disseminator for ideal scientific exchanges. Healthcare professional-credentialed MSLs, acting as regional extensions of companies' medical affairs departments, have significantly impacted this issue, ensuring the exchange of appropriate, thoughtful and clinically robust dialogues on a peer-to-peer level. TMAC's ability to maintain its focus solely on the practice of medical affairs communications, and predominately MSLs, has enabled us to keep a constant check on the pulse on the most current regulatory guidances and requirements. Further, it has provided us with the ability to responsibly incorporate these guidances into MSL program best practices.

TMAC clients benefit from our flexible business model. Because TMAC is set up to run as a fully functioning medical affairs department that is simply external rather than internal, clients can call upon TMAC for assistance across the spectrum of medical affairs responsibilities for small or large projects. Some clients have even chosen to outsource their entire medical affairs department. Flexible staffing can be particularly attractive in today's environment where many pharmaceutical companies are facing decisions about downsizing. Outsourcing also may be an important option for companies that have a product in clinical trials but are reluctant to invest in a permanent in-house medical affairs department until they better understand its status with the FDA or know how the product will perform in the future. Further, the flexibility to internalize some or all of an outsourced MSL team after a period of time may be attractive to some companies with limited initial

resources because it allows them to leverage this investment at an earlier stage and yet maximize the value in building their product franchise long-term.

TMAC customizes each program based on the client's culture and stakeholder needs, as well as the therapeutic area and lifecycle stage of the product. The result is a highly credentialed, field-based, therapeutic-specific MSL team devoted to providing key stakeholders with unmatched value through a variety of scientific exchange activities. Critically, the scientific community embraces this regional scientific resource and further acknowledges and respects the commitment that is being made by the pharmaceutical company. While the significance and role of traditional sales is in a state of flux and evolution, not in question is the increasingly important value MSL-led scientific exchange can provide in building and enhancing the success of today's pharmaceutical product portfolios.

All TMAC MSLs are required to complete an extensive training program tailored to each client engagement. This training curriculum includes both home study and live classroom participation, and provides an industry overview, disease state review, product-specific training and in-depth discussions on laws and regulations relevant to the MSL function. To ensure that all TMAC MSLs are prepared to work within the confines of applicable laws and regulations TMAC has formed an alliance with a prominent law firm specializing in healthcare compliance. A properly trained and managed MSL team will be able to establish immediate credibility with the client's internal management and, importantly, the external thought leaders who are paramount to shaping and influencing the healthcare community's adoption of the client's products. As we believe innovation is critical, TMAC will soon expand its training program to offer MSLs and clients a graduated curriculum of courses designed for a variety of experience and knowledge levels.

TMAC will continue its rapid growth because the company is guided by a visionary team that understands the industry and their clients and is therefore able to provide valuable strategic direction for each engagement. TMAC understands that to be successful we must unwaveringly serve our clients' needs. To this end, we also offer knowledge management tools and systems that allow clients to own and analyze the voluminous data collected by their MSL teams, which can support future strategic planning efforts across a franchise's multidisciplinary team. One such system, known as mslConnect™, is widely regarded as one of the most well designed MSL reporting systems for its ability to clearly and elegantly

capture data critical to the success of any MSL program. This proprietary software is offered through our valued partner, Akuta Labs.

As a testament to TMAC's ability to implement solutions so seamlessly into client operations, some clients have said working with TMAC is no different than working with an in-house medical affairs team and at times cannot distinguish between an internal MSL and an outsourced TMAC MSL.

TMAC's management team has by far the most significant medical affairs experience to be found in the industry. TMAC is also unique in that we truly help our clients build for the future, assembling best-in-class field-based MSL teams that clearly will be the sole purveyors of scientifically sound and vigilant communications moving forward.