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FOR Medical Affairs Professionals
BY Medical Affairs Professionals

Medical™ Affairs Professional Society

The Mission, Value, and Roles of Medical Affairs in MedTech

Co-First Authors:

John Pracyk, Chief Medical Safety Officer; SVP, Medical & Scientific Affairs, **Olympus**
William Sigmund, EVP and Chief Medical Officer, **Becton Dickinson**

Contributing Authors:

Greg Christopherson, VP, Medical Affairs, **Medline Industries, LP**
Ann Ford, Partner; Managing Director, **HPS Advise**
Dee Khuntia, Chief Medical Officer, SVP, **Varian, A Siemens Healthineers Company**
Sean Lilienfeld, VP Global Medical Affairs, **Boston Scientific**
Mark Miller, Chief Medical Officer, **bioMérieux**
Hany Moselhi, SVP, Chief Medical Officer, **Roche Diagnostics**
Ross "Rusty" Segan, Chief Medical Officer (former), Medical & Scientific Affairs, **Olympus**
Ronald Silverman, SVP, Chief Medical Officer, **3M HealthCare**

Writing support provided by:

Garth Sundem, Director of Communications and Marketing,
Medical Affairs Professional Society (MAPS)

This paper represents the personal perspectives of the authors and not those of the companies for whom they work.

INTRODUCTION

The global healthcare market for medical technologies has become more challenging. Demand for high-quality evidence demonstrating that our science and technologies benefit patients has become crucial for approval. Objective measures showing differentiation and value against important unmet patient needs are required for provider (hospital) acceptance, physician adoption, and successful reimbursement by payers. Intense competition and a higher burden for innovation creates a risk vs. return profile that increasingly marginalizes iteration while rewarding only the most differentiated technologies. Meanwhile, changes in the healthcare landscape such as personalized medicine, targeted treatments, and shared decision-making drive an increased need for timely, expert evidence, and information not just for traditional audiences but also for patients and caregivers.

This article draws on the expertise of 10 senior Medical Affairs leaders across diverse global organizations to describe the role of Medical Affairs in ensuring the MedTech industry meets these demands. The authors hope that readers from within and beyond Medical Affairs will use this article to establish a baseline understanding of the profession within their organizations, as well as the aspirational north star when evaluating Medical Affairs actions, structure, and strategy. In short, this paper provides a concise answer to critically defining Medical Affairs questions of who we are, why we are, and what we do within the MedTech industry.

The Definition of Medical Affairs in MedTech

Medical Affairs is made up of medical, scientific, and clinical experts focused on understanding unmet medical needs and helping patients and society achieve maximum benefit from emerging health technologies. Because Medical Affairs is composed primarily of clinical experts who have practiced and/or conducted research in healthcare settings, Medical Affairs is uniquely positioned to engage in peer-to-peer dialogue to address knowledge gaps with healthcare providers (HCPs) and other decision-makers in patient access and care. Through this scientific exchange, Medical Affairs also generates proactive, independent, consistent, well- documented medical insights to benefit our Commercial, R&D, Quality, and Regulatory colleagues. Beyond scientific exchange, Medical Affairs accurately defines the risk, benefit, and safety of products from a clinical standpoint and generates evidence through Human Subject Research, Real-World Evidence (RWE) and other study types to define and substantiate the clinical value of our products.

The Diversity of Medical Affairs Across "MedTech"

The umbrella term "MedTech" in fact describes an incredible range of products, from defibrillators to insulin pumps, MRI scanners to in vitro diagnostics (IVDs), along with connected care, software-enabled surgery, and products that enable patient care in new settings. Accordingly, the practice of Medical Affairs differs across these types. For example companies specializing in IVDs may have chemists and biologists in R&D roles, meaning that Medical Affairs may collaborate more closely with development scientists on activities such as academic journal publications. Similarly, a company developing an internet-connected implantable, computer-assisted diagnostic or robotics solution will have different information/messaging hurdles that Medical Affairs must address than a company would have in developing an endoscope or capital equipment type of imaging technology. Traditionally, in all of these companies, it has been the role of R&D to develop products and the role of Commercial to sell them. Today, innovation goes beyond pure technical product development to include procedural innovation to address unmet clinical needs along the patient care pathway. And in these companies, despite the diversity of products and the diversity in the practice of Medical Affairs, the purpose of the profession remains the same: To ensure that patients and society benefit from industry innovations.

The Roles & Value of Medical Affairs in MedTech

The pillars of Medical Affairs value are evidence generation, scientific communication, insights, and strategy. Within MedTech, Medical Affairs provides additional value to the organization through unique clinical expertise, professional education, and medical safety. Following are descriptions of these ways Medical Affairs drives value for the organization.

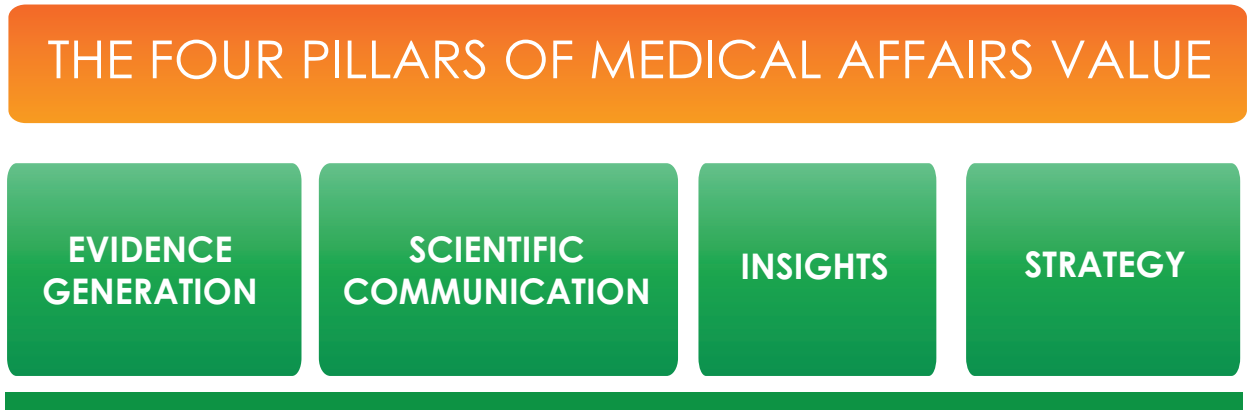

Figure 1. The Four Pillars of Medical Affairs Value

Clinical/Scientific Expertise

In pharma, R&D (Clinical Development) consists primarily of physicians and scientists. Conversely, in MedTech, R&D is made up of predominately mechanical or electrical engineers, chemists, or biologists. This means that, in MedTech, clinical expertise may exist only within Medical Affairs, and it is the responsibility of Medical Affairs to establish a clear and medically valuable "intended use" to support products that are safe, effective, and perform from a clinical standpoint. Medical expertise is also required to generate and communicate evidence through publications and other scientific dialogues to describe the appropriate therapeutic use of products to demonstrate their differentiated value. Throughout the lifecycle, Medical Affairs has the clinical lens to help identify and characterize iterative changes and inflections that create improvements in the care pathway or treatment of disease, allowing devices/diagnostics to continually evolve to be "state of the art" throughout the lifecycle.

From the perspective of business strategic priorities, Medical Affairs provides the clinical context for Market Access and other Commercial activities.

Evidence Generation

Especially through patient-centric evidence generation and use of Real-World Evidence (RWE), Medical Affairs is helping the MedTech industry meet new, higher bars set for clinical evaluation accompanying regulatory submissions for market access. This has become even more important in the European Union where clinical evaluation reports based on clinical evidence are now required for most MedTech products. The National Medical Products Administration (NMPA), the regulatory body of China, has also increased its focus on clinical evidence, often requiring prospective multi-institutional trials for products that did not previously require trials in any global regulatory environment. In short, evidence to substantiate the clinical and scientific validity of new devices or IVDs is increasingly required for every claim, meaning that aspects of the evidence generation package that used to be "nice to haves" are now "must haves."

Within MedTech, Medical Affairs makes critical decisions regarding what different domains of evidence may be most appropriate to weave together a comprehensive and compelling clinical value narrative and to answer questions that are important to our clinical customers in caring for their patients using our products. Working with cross-functional partners in Regulatory Affairs, additional decisions can be made for what will meet Regulatory needs. Medical Affairs evidence generation can also influence future research and development, in that Medical Affairs has the responsibility and clinical/scientific expertise to identify treatment gaps and clinical unmet needs. As a result, Medical Affairs evidence generation activities have become critical both to meet the elevated regulatory requirements required to bring new technologies to market and to steer the MedTech industry toward developing technologies to meet the real-world needs of patients.

Scientific Exchange

One of the most important responsibilities of Medical Affairs is external engagement with healthcare providers using clinical acumen in order to understand, anticipate, and evolve patient care and to meet the needs of those clinicians that provide these therapies. Although commercial teams are responsible for providing on-label medical information, Medical Affairs does this also, but then quite a bit more. Throughout the world there is an understanding that clinicians may and frequently need to ask questions that are broader than the Instructions for Use (IFUs) of products and that companies should have a defined process to answer these unsolicited off-label questions. This is done through scientific exchange, which should be conducted by clinical experts who are distant from sales and marketing activities. In the MedTech industry, this responsibility falls to Medical Affairs. Medical Affairs is the only group that should answer off-label questions and have appropriate, compliant off-label discussions.

From these roots, the communication and evidence dissemination role of Medical Affairs has grown to encompass activities including the following:

- **Publications:** The planning and communication of industry scientific and real-world evidence studies in academic journals and peer-reviewed open access platforms.
- **Congresses:** The planning and communication of industry studies at scientific congresses and medical society meetings from poster sessions to podium presentations.
- **Professional (External) Education:** Company-led and independent professional education providing education and training for healthcare professionals on the best use of industry innovations. In MedTech, this can often be in the operating room or clinic itself during a case – On-label, professional education can also be provided by commercial organizations. Off-label questions should be forwarded to Medical Affairs for a response.
- **Medical Information:** Answering Medical Information inquiries and managing content and product information for these responses. In many healthcare companies, MedInfo is becoming increasingly automated through self-service and AI platforms.
- **Field Medical:** Many MedTech companies may have the need to place Medical Affairs in geographic locations based on local healthcare practice and the local need to conduct Scientific Exchange. The Medical Science Liaison within Medical Affairs is becoming more popular at some MedTech companies.

Professional Education or Affairs

Whereas the optimal use of a pharmaceutical product often hinges on providing the right treatment to the right patient at the right time, the optimal use of MedTech products often goes beyond these considerations to include proficiency in attaining skilled use of the technology. Of course, ensuring skilled use requires education. In general, product-focused education and implementation is the remit of roles such as Field Service Engineers (FSE) and Field Application Specialists (FAS), nurses, or clinical educators. However, when training moves beyond product education and implementation to product implications and impact for patients, moving education into Medical Affairs is becoming a best practice. Generally, education describing why innovations do what they do, the scientific background behind innovations, or mechanisms of action are often best managed by Medical Affairs, which may also educate beyond a technology's IFU to answer questions regarding off-label uses. Because Medical Affairs is not compensated directly based on sales, Medical-led education helps to remove the appearance of promotional intent. Medical Affairs may also provide internal educational value to the organization, for example by leading educational activities to equip employees with a better understanding of product safety and/or how products fit into the healthcare environment. Additionally, during the COVID-19 pandemic, many organizations leveraged the scientific/clinical expertise of Medical Affairs to help the business navigate crises to help create a safe working environment.

Insights

Insights are the learnings from the external healthcare environment that can drive strategic actions and decisions. Historically, MedTech insights largely emerged from a joint Commercial/R&D understanding of the potential for products to address unmet needs. Today, Medical Affairs is being recognized as the "third leg of this stool," generating and interpreting insights to optimize concepts, development, commercialization, and lifecycle management. Interpretation of insights by internal medical and scientific professionals accelerates more insightful and actionable decision-making. Accurate insights allow companies to evolve based on external conditions; for example, insights may identify unmet medical needs that contribute to innovation, provide competitive intelligence, and identify gaps in knowledge or understanding that can be addressed with education, or may even pinpoint patient-centric endpoints for use in clinical trials (among many other uses). In MedTech, specifically, insights may help the organization crystallize decisions about when to exit older products from the market (requiring investment in developing new products) or provide critical direction in redesign and iterative improvements. In many ways, the value narrative and other strategies developed internally remain only hypotheses until they are confirmed or disproved by real-world reaction as demonstrated by Medical Affairs insights, along with the insights derived from Commercial and/or R&D interactions.

Medical Safety

Medical Safety is the science and practice of professional medical activities pertaining to the detection, assessment, understanding, and prevention of patient harms; thus, safeguarding patients throughout the product lifecycle. Whether within Medical Affairs or as its own standalone entity, Medical Safety is a key strategic partner to Quality Assurance Engineering pursuant to the Quality System Regulation (21 CFR Part 820) that furthers that medical devices developed for the U.S. market are safe and follow satisfactory quality processes at all stages of product development and throughout the entire product lifecycle as assessed via post market surveillance. The corresponding international standard for global markets is ISO 13485. A Quality Management System (QMS) provides the infrastructure to perform the Risk Management Process as specified in ISO 14971. Medical Safety and Quality Assurance co-execute the Risk Assessment process to identify product hazards, hazardous situations, and risks (severity x occurrence) that may result in patient harm as anticipated during new product development and reconciled with in market use. In addition to these pre- and post-market risk assessments, Medical Safety plays a crucial leadership role in the Health Hazard Assessment (HHA) process in identifying, assessing, escalating, adjudicating, and documenting health hazard decisions for Field Safety Notices and Field Safety Corrective Actions (product recalls) as well as then communicating these announcements to HCPs, health systems, and competent authorities worldwide. The fundamental objective is to reduce the risks associated with medical technologies, while simultaneously creating a patient safety culture across MedTech manufacturing by providing critical medical insights that drive accountable product stewardship. Medical Safety ultimately exists to safeguard patient well-being and protect the public's health.

- Medical Safety's provenance is product surveillance.
- Product surveillance is responsible for monitoring the safety of medical devices in normal clinical use and during clinical trials.
- Medical Affairs and Product Surveillance are distinct and purposely separated.
- In the US, Combination Products (possessing both a Drug & Device component), require the collaboration of Medical Safety and Product Surveillance.

Strategic Partnership

Because products are designed to benefit patients, the role of Medical Affairs is especially important for the clinical input needed for continued innovation and product lifecycle strategy. Through understanding the practice of medicine and defining unmet medical needs, generating clinical evidence to validate the use of our products, Medical Affairs has become a crucial need for MedTech companies. Medical Affairs is responsible for determining whether evidence substantiates claims and, importantly, identifying evidence gaps that can be filled and what types of studies are needed to advance the appropriate and effective application of our products. In fact, many MedTech companies are now requiring stage gate sign-off from Medical Affairs/Medical Safety across the product lifecycle, end to end, from initial conceptualization to obsolescence, benefitting from the strategic role that Medical Affairs can deliver.

CONCLUSIONS

Whether generating clinical evidence to support regulatory strategy or addressing gaps in therapeutic knowledge or care delivery, Medical Affairs is the engine that translates the science of clinical practice into value for the MedTech industry. When communicating and collaborating with healthcare professionals and others within the external healthcare ecosystem, Medical Affairs is the clinical voice of the MedTech industry, equipping society with the nonbiased, expert information needed to make appropriate use of MedTech innovations to benefit patients. When generating and analyzing insights regarding the practice of medicine, Medical Affairs evaluates external feedback while pinpointing areas for iteration or the development of transformative innovations. Through these actions, Medical Affairs not only demonstrates its value to the organization but helps industry to realize its purpose of ensuring patients worldwide benefit from the devices, diagnostics, and technologies we develop to advance human health.

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