



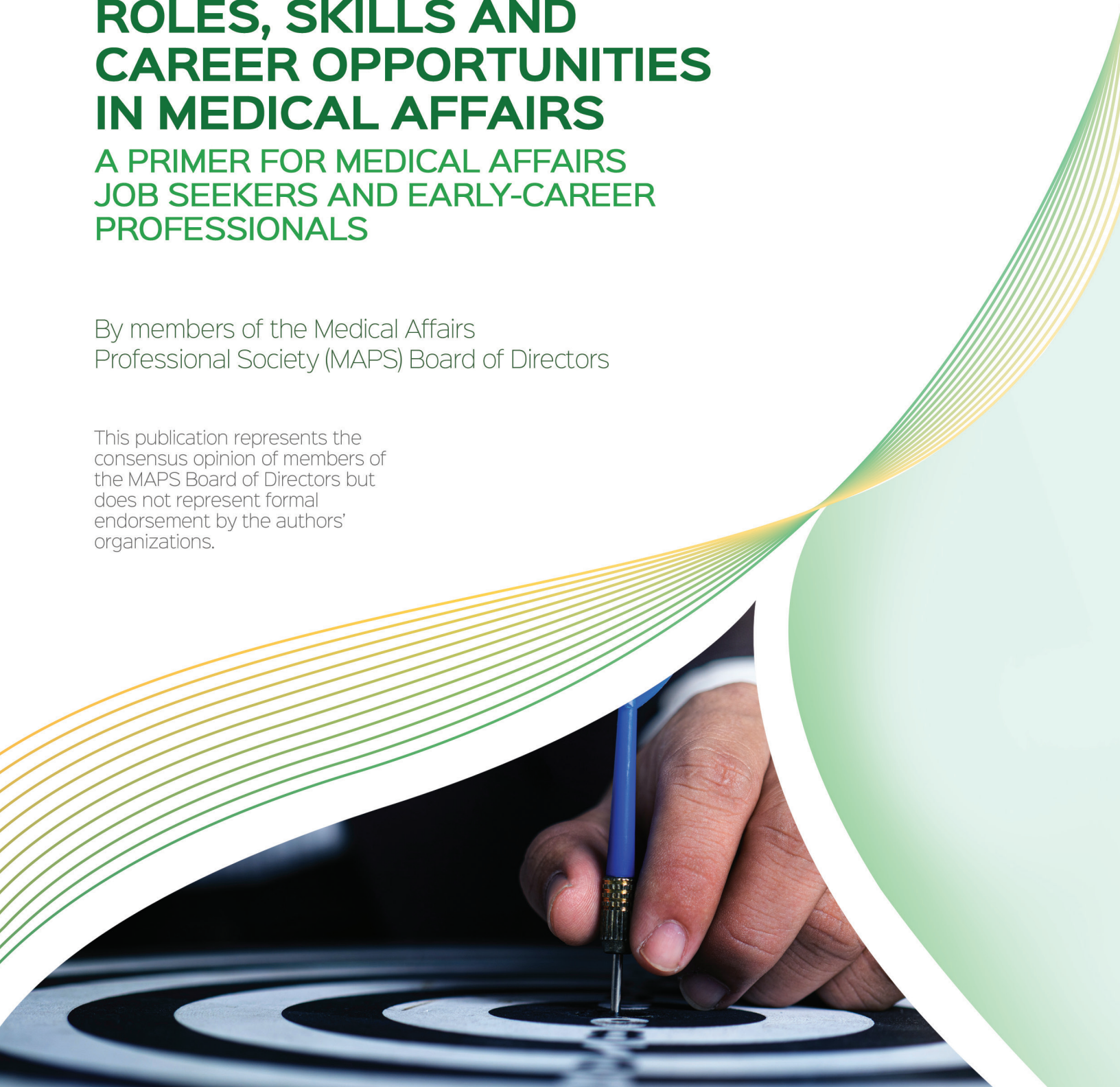
Medical™
Affairs
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ROLES, SKILLS AND CAREER OPPORTUNITIES IN MEDICAL AFFAIRS

A PRIMER FOR MEDICAL AFFAIRS
JOB SEEKERS AND EARLY-CAREER
PROFESSIONALS

By members of the Medical Affairs
Professional Society (MAPS) Board of Directors

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consensus opinion of members of
the MAPS Board of Directors but
does not represent formal
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What Is Medical Affairs?

Medical Affairs is a function within the biopharmaceutical, consumer healthcare, and MedTech industries that sits alongside other functions including Research & Development (R&D) and Commercial as one of the strategic pillars of the industry. R&D develops new drugs, devices and diagnostics; Commercial markets and sells these products; and Medical Affairs generates and communicates data that help healthcare professionals (HCPs), payors, policy makers and others make informed decisions that ensure the best use of treatments to benefit patients. In this way, Medical Affairs plays a vital role in providing scientific evidence and understanding to appropriately change clinical practice.

Just as there are many roles within R&D and Commercial, individuals working within Medical Affairs are responsible for many activities, especially including the following:

- Communicating unbiased, evidence-based expert scientific and medical information to HCPs, scientific leaders, patient advocacy groups, payors, policy makers and others within the healthcare ecosystem
- Bringing insights from external sources including healthcare professionals, opinion leaders, advisory boards, patient advocacy groups and more back to the organization to better inform decision making in areas such as education, research, development, compassionate use, publications, strategy, etc.
- Generating new data about marketed and emerging treatments, often through the use of Real-World Evidence (RWE), Health Economics and Outcomes Research (HEOR), Investigator-Sponsored Studies or pre- and post-approval studies that may support product registration or can be non-registrational in nature
- Collaborating with industry leaders from other functions including R&D, Commercial and Business Development to drive the strategic direction for the organization to benefit patients



Who Works in Medical Affairs?

Medical Affairs is composed of medical and scientific professionals, many of whom have advanced, Doctoral-level degrees, usually in the life sciences. Supporting these scientific experts are a range of roles including data analysts, communications specialists, experts in adult education, technologists, business leaders, administrative associates and many more. Some Medical Affairs professionals enter the function immediately upon completion of their training; others come to the function having worked elsewhere in healthcare, industry, business or academia. Some Medical Affairs roles are external-facing and tend to attract individuals who are naturally drawn toward relationship building and scientific exchange with peers in the healthcare community. Other roles are involved in evidence generation and knowledge creation through studies, research projects or analyses and often appeal to those with technical and scientific backgrounds. Still other roles are involved in strategic leadership, offering opportunities for individuals to lead goal-directed teams. Thus, the skills and training required for a successful career in Medical Affairs are varied and depend on the specific role within the function, but often include a mix of scientific, technical, business, leadership and emotional intelligence expertise.

How Medical Affairs Benefits Patients

Medical Affairs works from an explicitly patient-centric perspective, ensuring the voice of the patient drives organizational actions while working primarily through HCP interactions to ensure patients and patient groups are appropriately informed about and engaged in the development and use of new therapies. Following are some of the ways Medical Affairs benefits patients:

- Amplifying needs of patients, families and caregivers in drug, device and diagnostic development and clinical trials
- Expanding equity and access to treatments, including clinical trial diversity
- Providing data to support personalized medicine
- Increased public and patient awareness of clinical trials
- Helping to address quality of life issues
- Providing solutions to treatment challenges to improve the patient journey
- Identification of unmet patient needs for education and further drug development
- Patient-centric communication of scientific data and information
- Increased data transparency
- Helping HCPs appropriately use new treatments
- Creating new knowledge about emerging treatments through evidence generation and Real-World Evidence studies

The History and Current Practice of Medical Affairs

The concept of a Medical Science Liaison (MSL) started at the Upjohn Company in 1967 as a primarily executional role within the industry's Commercial/Marketing function. At Upjohn and then elsewhere, experienced and scientifically oriented sales reps were designated as MSLs to answer more in-depth scientific questions about the appropriate use of drugs and devices; later, these early MSLs whose expertise grew from sales experience were replaced by MSLs with scientific and medical degrees. With increased regulation, scrutiny and complexity of the pharmaceutical industry, the MSL function moved out of Commercial and into the new function called Medical Affairs, which now takes the lead in providing HCPs

and others within the healthcare ecosystem with non-promotional, accurate and fair-balanced scientific information. This direct interaction with HCPs with the intent to improve clinical outcomes for patients was the genesis and remains at the heart of the Medical Affairs function.

However, in the early 2000s, it became clear that the unbiased, scientific expertise of Medical Affairs had value beyond just these direct interactions with HCPs, and Medical Affairs teams started to grow even more into the external-facing voice for the organization's scientific communication and exchange. When HCPs reached out to the organization to ask questions about the real-world use of drugs, devices and clinical research, it was Medical Information teams working within Medical Affairs that provided (and still provide) the answers; when there were identified data gaps in our understanding, Evidence Generation groups within Medical Affairs built the capability to design and conduct post-approval studies to generate and disseminate new knowledge; and as it became clear that HCPs were only one of many audiences in need of expert, data-driven context describing the real-world use of emerging treatments, Medical Affairs developed greater capabilities in Scientific Communications, Publications, External Education and more.

Today, the scientific complexity of treatments has increased, with new drugs and devices targeting specific patient populations. For some time we've known that the safety and efficacy data from registration trials, performed with a narrow and carefully selected patient population, may not perfectly generalize to a real-world patient population that includes individuals with diverse geographic, racial, ethnic, age, compliance, comorbidity and treatment journey characteristics. At the same time, audiences desiring medical and scientific information have further expanded to include, for example, patients and patient advocacy groups, and all audiences expect near real-time, accurate information presented across a range of channels.

Medical Affairs is the function within the broader biopharmaceutical industry best positioned to help external stakeholders make sense of treatment complexity; it is the function best positioned to answer questions of real-world safety and effectiveness; and it is the function best positioned to not only disseminate scientific knowledge but to also listen and respond to external stakeholders' need for information.



These changes in the fabric of healthcare and society have elevated Medical Affairs to the point of no longer being simply a support group providing responsive, ad hoc information and education. With the expertise to better understand the challenges faced by patients, HCPs, and other stakeholders, the ability to address any gaps in understanding of data, and the means to contextualize these matters for clear communication by the company, Medical Affairs is now clearly one of the strategic pillars of the healthcare industry.

Roles and Teams Within Medical Affairs

As we have seen, Medical Affairs is responsible for a broad range of actions generally related to ensuring the safe and effective, real-world use of emerging treatments. These actions and responsibilities are “bucketed” into teams in various ways across companies of different size, geography and phase of treatment development (among other factors). In fact, even more so than for R&D and Commercial functions, there is no single structure for Medical Affairs – and even roles within teams may differ across organizations. For example, HEOR, Pharmacovigilance and Compliance may sit within or be independent from Medical Affairs, and many organizations combine one or more Medical Affairs functional groups into single teams. Please consider the following list an overview of Medical Affairs teams and/or activities, but by no means an exhaustive catalogue of possible roles within the function.

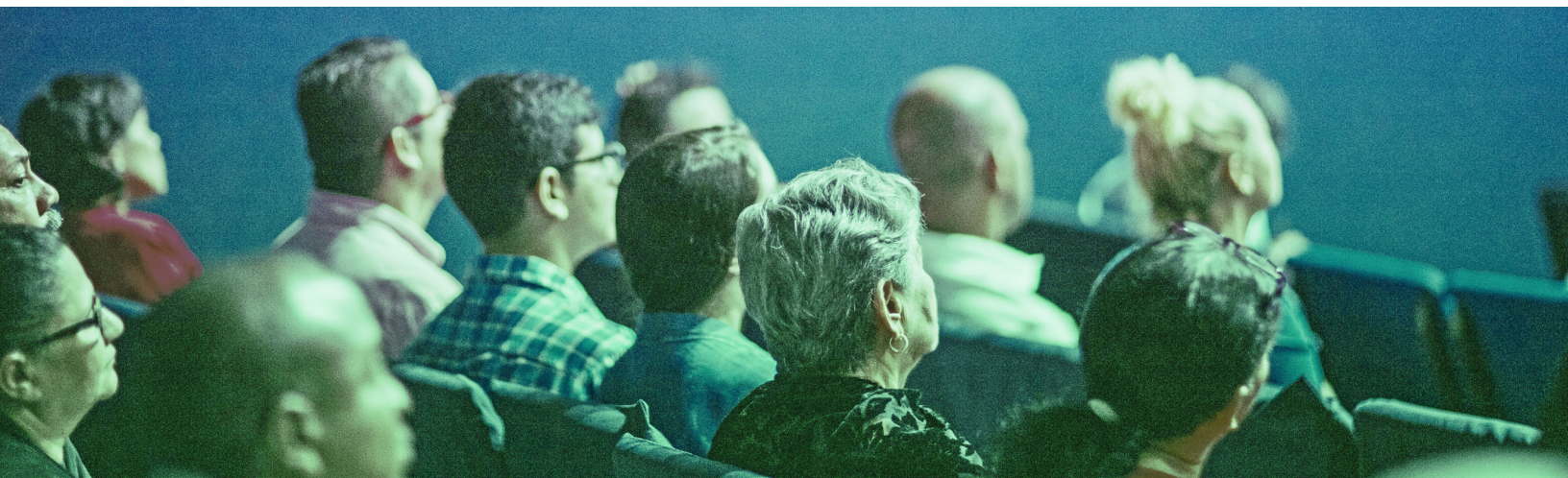
Medical Strategy

Medical Strategy leaders represent the value and impact of Medical Affairs alongside counterparts in R&D, Commercial, Market Access and other functions. These leaders often have medical/scientific training, organizational experience, and even additional business or leadership training. Especially important in Medical Strategy is the planning that takes place to support the development, launch and lifecycle management of products. For example, Medical Strategy leaders may provide input into registration study design to ensure data generated is clinically relevant to payors, HCPs and patients; or the Medical Strategy role may identify new projects needed to enrich understanding of a medicine’s safety and effectiveness beyond the data generated in a registration trial; or this role may help to define communication/education strategies to ensure that patients, providers and payors outside the organization receive timely and trustworthy information.

Evidence Generation

Medical Affairs professionals working in Evidence Generation design and oversee scientific studies aimed at enriching understanding of treatment safety and effectiveness, including in real-world populations. A variety of studies may be managed by Evidence Generation teams, including the following:

- Post-approval, non-registrational Phase IIIb and IV studies
- Real-World Evidence (RWE) studies, including the management and collection of Real World Data (RWD) through sources such as claims databases, patient support programs, patient-reported outcomes, electronic health information, digital health apps, wearable devices and more
- HEOR studies to generate data that can be analyzed to support market access and reimbursement in collaboration with colleagues dedicated to HEOR
- Collaborative research projects
- Investigator-sponsored studies



External Education

The External Education team provides unbiased education addressing therapy or knowledge/education gaps for various audiences such as HCPs, payors, patients and caregivers. Traditionally, External Education activities were presented in face-to-face formats including seminars or programs. Increasingly, these events are presented virtually or through technology platforms designed for the purpose. External Education teams may produce “company-led education” events or may choose to sponsor proposals from external groups such as scientific and patient advocacy societies for “independent medical education.” These events often offer Continuing Medical Education (CME) credits or other professional accreditation for HCPs.



Field Medical

Field Medical teams are composed primarily of scientific and medical experts known as Medical Science Liaisons or by similar titles. MSLs continue the traditional role of building long-term relationships with HCPs and healthcare decision makers (face-to-face and now, increasingly, through virtual interactions), to ensure scientific understanding of new medicines. An equally important role for Field Medical is listening to HCPs and others outside the organization, and returning these learnings to the organization as medical “insights,” which can influence additional education, decision-making or research activities. In addition to scientific exchange and insights, the Field Medical team may contribute to concise, timely and trustworthy communication materials, respond to questions from HCPs, patients, payors and other external groups in a non-promotional manner, provide research support and help provide context for HCPs’ patient care decisions. Working in Field Medical requires staying informed about recent treatment and scientific advances within an MSL’s designated therapeutic area. In addition to scientific expertise, Field Medical professionals must be expert communicators.

Insights

The term “insights” describes understanding that comes from outside the organization that can influence organizational actions and strategies. For example, analysis of MSL/HCP interactions might uncover a common misunderstanding about a new medicine that could be addressed by an External Education program; or an insight may identify patients in a disease community that have discovered how to manage side effects that allow them to stay on treatment or elucidate important trends. These insights come from many sources such as from MSLs working in Field Medical or from questions posed to Medical Information teams. The ever-increasing volume of insights combined with a growing appreciation for the importance of insights in driving strategy has led many Medical Affairs groups to create teams specifically dedicated to the analysis of data, often using Machine Learning and Augmented/Artificial Intelligence technologies. In this way, the Insights team helps determine what observations from the external environment are actionable – in other words, how a clinical development plan or strategy can change in response to the external environment and, very importantly, to measure the impact of these changes for the purpose of communicating the value of insights with internal stakeholders.

Medical Communications/Publications

These professionals develop and execute comprehensive strategic plans for the release of clinical trial results and other relevant data and scientific information to the scientific community via abstracts, posters, manuscripts, presentations and publications. They align plans with release of clinical trial results and safety updates at medical meetings and develop a consistent medical communication platform (narrative) and lexicon (dictionary) to describe the value proposition of a therapeutic agent within a disease state or therapeutic area.

HEOR

Increasingly, Medical Affairs professionals with expertise in epidemiology, economics, data analytics, Real World Evidence and related fields generate data and insights to provide context and information for payers evaluating the value of industry innovations. Depending on organization structure, HEOR teams may be within or outside Medical Affairs, and may collaborate with colleagues in Commercial to create the Core Value Dossier, which summarizes the value proposition including safety, efficacy and economic information for new drugs, devices and diagnostics.

Medical Operations

Medical Operations coordinates across all Medical Affairs areas/teams and defines processes, policies, documentation and reporting on key activities, and may be responsible for budget planning/oversight. Some activities may include technology training, program management, status and metrics reporting to internal stakeholders, compliance meeting planning, contracting, business analytics and intelligence, grants administration, congress and meeting planning and more. Many of these roles may be specific to Medical Operations or can be broken out into their own functional areas.

Digital

In Medical Affairs, the term Digital describes a true paradigm shift in the way organizations, teams and individuals conceptualize problems and go about creating solutions. In this way, Digital is a mindset, a philosophy and a way of thinking that goes beyond any single technology. At the same time Digital is not a strategy that exists in a silo; rather, it enables Medical Affairs strategy to be taken to the next level. In short, Digital describes the emerging reality of technology embedded in and enabling the ways we think and work as individuals, teams and society. Medical Affairs professionals working in Digital may support the activities of other groups or may demonstrate new possibilities that drive organizational thinking and strategy.

Medical Information

Medical Information teams are composed of drug/device/diagnostic experts who, in most companies, develop responses to anticipated or actual questions received from HCPs to provide concise, accurate, non-promotional information in a timely manner. Thus, Medical Information is primarily a responsive role – an expert resource that prepares answers to medical and scientific questions and trends. When answers do not exist, the Medical Information team may identify knowledge gaps that can lead to further studies

and education opportunities. Proper analysis of medical information questions may also be a source of medical insights. Like many areas of Medical Affairs, Medical Information teams are making increased use of digital tools and formats such as webinars, interactive platforms, video summaries, etc. to respond to the need for virtual interactions and real-time responses.



Compliance/Medical Governance

The Pharmaceutical Industry is highly regulated, with clear separation between Medical and Commercial activities. In other words, regulations ensure that Medical Affairs does not engage in marketing activities. Note that Compliance teams commonly exist at the organizational level in addition to working specifically within Medical Affairs, and that final accountability for compliance varies across geographies. In fact, even within Medical Affairs, Compliance teams that exist as independent entities may be augmented by compliance specialists embedded across Medical Affairs teams. Specific Compliance activities may include the following:

- Establishing the processes and policies for teams that reflect guidelines, codes and regulations
- Providing medical quality oversight for the work performed by the team and ensuring it is consistent with guidelines, codes and regulations and the highest professional and medical ethics standards
- Defining and leading expected behaviors for compliant activities for the engagement of HCPs
- Working with internal partners in Quality and Compliance to promote transparency and reinforce behaviors aligned with the internal and external codes of conduct
- Reviewing and approving all materials for use with external audiences to ensure they are medically and scientifically accurate
- Assessing scientific rigor and clinical relevance of investigator-sponsored research and the quality/independence of medical education grant requests

Roles Outside Larger/Established Pharmaceutical Companies

In addition to roles in large pharmaceutical companies, Medical Affairs professionals work in smaller biopharmaceutical organizations (often targeting new or emerging areas such as rare diseases) and also in Medical Technology companies. In the space of rare diseases, patient groups are often even more intimately involved in drug development, requiring additional engagement provided by Medical Affairs teams. Medical Affairs professionals working in smaller companies may have to “wear multiple hats,” while sometimes overcoming education barriers including unfamiliarity with emerging treatment paradigms such as gene-directed therapies. However, working in emerging areas or underserved populations also offers Medical Affairs professionals the opportunity to play an important role in providing treatment options for patients who are often without an existing therapy. In MedTech, technology-powered diagnostics and devices tend to require significant training for skilled use, and product hardware/software is updated frequently (as opposed to pharma in which products are more static and use depends more on identifying the most appropriate populations and situations than it does on technical skill). Also, whereas Medical Affairs professionals in pharma tend to cultivate a deep expertise in one product, Medical Affairs professionals in MedTech may be generalists, providing education and training on a range of devices. MedTech also comes with its own set of regulatory concerns based on categories such as implantables, combination products and internet-connected medical devices. In these roles outside traditional pharmaceutical companies, the goal of Medical Affairs remains the same: To generate, evaluate and communicate data to benefit patients.

What Skills are Needed for a Successful Medical Affairs Career?

As we have covered in this paper, the wide range of Medical Affairs roles involve a wide range of skills. Many roles require advanced scientific training in the mechanisms and clinical uses of emerging treatments. However, roles in operations or compliance may require business and/or legal acumen. And roles in Medical Strategy (and elsewhere) may require leadership skills. Thus, each role has a unique path for the training and further development of Medical Affairs competencies – and many Medical Affairs professionals continuously augment these competencies as they adopt different roles and even different careers within the function. That said, broadly speaking, Medical Affairs capabilities fall into the following categories:

Strategic Vision

As Medical Affairs assumes an increasingly strategic role within the organization, the competencies needed for a successful career in the function are expanding beyond scientific and technical skills to encompass the skills needed to collaborate with other organizational leaders to drive company direction. The capability of Strategic Vision includes skills/competencies needed to demonstrate the value/impact of the Medical Affairs function in alignment with the organization’s overall strategic direction.

Business Knowledge

In order to be a strategic pillar in a medical business, the capability of at least basic business acumen is undisputed. Individuals within Medical Affairs increasingly collaborate with, inform and are informed by the activities of other functions within the organization. Knowing how Medical Affairs activities fit with those of Marketing/Sales, R&D, business development and with the wider landscape of the healthcare ecosystem is essential in recognizing opportunities for collaboration and delivering value.

Evidence Generation

While Evidence Generation is often a discrete role within Medical Affairs, professionals across the function will need to know the basics of research and data analysis strategies and activities. In short, Evidence Generation is the knowledge engine that Medical Affairs uses to refine and create new understanding of product and disease state science. As such, all Medical Affairs professionals need at least a basic understanding of clinical trial and Real World Evidence study design, analysis, and reporting.

Scientific, Technical & Technological Knowledge

Competencies in this category should be considered the basis for entry into most Medical Affairs positions. In addition to the therapeutic, scientific and clinical expertise that defines the Medical Affairs function, Medical Affairs professionals are increasingly expected to be proficient with new and emerging technologies for use in communicating complex ideas to stakeholders with varying scientific understanding.



Compliance

All aspects of the biopharmaceutical and MedTech industries take place within the framework of global, regional, country and local regulations. While compliance teams at the organizational and functional level will oversee Medical Affairs activities, it is essential for all Medical Affairs professionals to have a basic understanding of the regulatory framework that sets guardrails for their activities and the highest professional ethics and standards.

Customer Engagement & Scientific Communications

Medical Affairs is the external-facing voice of the organization's scientific communication activities. As such, the true impact of activities including Evidence Generation or HEOR or pharmacovigilance is only realized when information reaches external stakeholders in ways that create new understanding or actions that benefit patients. With the mechanics of scientific exchange and communication changing at the pace of technology, Medical Affairs professionals require a flexible set of competencies that allow engagement with these external audiences in the scientific and healthcare landscapes.

Leadership & Management

In a way, it's easy to focus on knowledge and technical/scientific skills – these are discrete topics that can be taught and learned. But realizing the full value of these skills requires the personal and emotional intelligence skills needed to collaborate with peers and lead teams. There is growing awareness within the function and within the industry as a whole that competencies that might have previously been known by the dismissive term “soft skills” (such as listening skills and learning agility), are no less essential than the abilities needed to generate and communicate data.

MAPS Capabilities/Competencies Framework

In Medical Affairs, individual skills are often called “competencies,” whereas a team's ability to complete actions is referred to as a “capability.” Thus, a Medical Affairs professional may have competency in data analysis, which augments the team's capability for insights management. One of the central questions asked by the MAPS organization has been What capabilities and competencies do individuals and teams need to be successful in Medical Affairs? To answer this question, MAPS has worked with members of our Executive Program Committee, Learning & Development Committee, Executive Consortium and Board of Directors, synthesizing the expertise of over 60 Medical Affairs leaders into the following capabilities & competencies framework. Different roles and teams will require different levels of expertise in these capabilities/competencies; however, MAPS believes it is important for all roles/teams to have at least basic proficiency in the listed skills.

Medical Affairs Capabilities & Competencies

Strategic Vision	Business Knowledge	Evidence Generation	Scientific & Technological Knowledge	Compliance	Customer Engagement & Scientific Comms	Leadership & Management
Measuring Impact	Basic Marketing & Sales.	Data Gaps/Unmet medical or access needs	Epidemiology	Robust Understanding of Governance & Industry/Country Guidelines	Platforms & Channels	People Development & Management
Medical Plan & Launch Excellence	Brand Planning	Market Access & HEOR	Medical Diagnostics & Devices	Appropriate Interactions with Commercial	Publication Planning	Facilitation Skills
Life Cycle Management	Business Performance Reports	Investigator Initiated Studies	Digital & Emerging Technologies	Interactions with HCPs & Government Officials	Medical Information	Conducting Effective/Efficient Meetings
Overview & Value of MA			Literature Evaluation	Interactions with Patients & Patient Organizations	Scientific Engagement Planning	Learning Agility
Insights	Finance 101	Real World Evidence	Statistics	Compliance Training	External Education	Coaching and Mentoring
Stakeholder Collaboration (Incl Research)	Business Development	Analytical Knowledge	Therapeutic Knowledge	Policies & Control Processes		Building strategic partnership with commercial and R&D (Boundary fluidity)
Patient Advocacy	Healthcare Systems		CCDS, PBER, PSUR, DSUR, RMP, REM	Medical Education	Medical Account Management	Leadership Models
Patient Partnership			Due Diligence re Business Development	Research Studies	Crisis Management	Listening Skills
			Phases of Drug Development & CT Design, incl registries	Fair Market Value	Presentation Skills & Effective Communication	Emotional Intelligence
						Managing virtual teams
						Basic project /time management/prioritization
						Change management
						Coaching Leadership
						Conflict resolution and consensus building

A Career in Medical Affairs

Medical Affairs is the fastest-growing function within the biopharmaceutical and MedTech industries, with career opportunities for professionals with scientific/medical, data/technical, business/leadership and many more training and experience backgrounds. Whether you are an HCP with two decades of experience looking to have a broader regional/global impact, or a recent PharmD graduate seeking a first position outside retail pharmacy, or a nurse wanting to move out of direct patient care, or a business leader hoping to make a positive impact in consumer healthcare, Medical Affairs offers a place to start and room to grow. However, while training and experience from all these backgrounds will serve Medical Affairs professionals well, there are additional skills you will need to master to become a successful Medical Leader in industry. MAPS seeks to support this growth. Following is a list of suggested resources for not-yet and early-career Medical Affairs professionals:

- **eLearning Course: Introduction to Medical Affairs**
<https://medicalaffairs.org/introduction-to-medicalaffairs/>
- **White Paper: Communicating the Value of Medical Affairs**
<https://medicalaffairs.org/communicating-the-value-of-medical-affairs/>
- **Journal Article: Promoting Best Practices for Medical Science Liaisons Joint Position Statement**
<https://medicalaffairs.org/msl-best-practices-maps-appa-ifapp-msls/>
- **Presentation: Essentials of Real-World Evidence**
<https://medicalaffairs.org/essentials-real-world-evidence/>
- **Medical Affairs Launch Excellence Standards & Guidance**
<https://medicalaffairs.org/medical-affairs-launch-excellence-standards-guidance-templates/>
- **Podcast: Opening Doors Podcast Series -- Paths Into Medical Affairs**
<https://medicalaffairs.org/early-career-professionals-paths/>
- **MAPS Mentorship Program**
<https://medicalaffairs.org/mentorship/>
- **MAPS Country/Regional Chapter Networking Events**
<https://medicalaffairs.org/chapters/>
- **MAPS Articles, Podcasts, Webinars and More**
<https://medicalaffairs.org/content-hub/>

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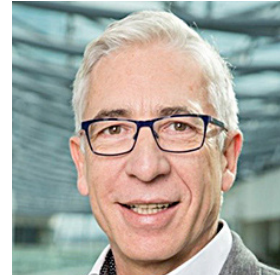
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