UNDERSTANDING MEDICAL AFFAIRS IN PHARMA

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AT A GLANCE

Pharmaceutical and biotechnology companies (ie, 'Pharma') began building medical affairs organizations about 15-20 years ago. The primary purpose of medical affairs is twofold: (1) educate and communicate scientific information to healthcare providers in an objective unbiased manner and (2) generate new data for the medical community or for the purpose of enhancing a product's on-label indication (typically in a post-marketing setting via investigator initiated studies (IIS) or phase IIIb/IV studies). As the shift towards specialty products, biologics, and rare/orphan disease increased, the demand for professionals with strong clinical and scientific acumen also increased. MD, PharmD, PhD and other healthcare professionals (NP, DNP, DO, DPM) were optimal candidates for the role.
Although variations exist among companies, most medical affairs organizations contain the following departments:

1. Medical Strategy
2. Medical Operations/Excellence
3. Field Medical Affairs (Medical Science Liaison Teams)
4. Scientific/Medical Communications
5. Health Economics Outcomes Research (HEOR)
6. Pharmacovigilance (Drug Safety)
7. Medical/Drug Information (i.e., Call Center)

As the name implies, the medical strategy teams set the strategic direction for the department determining the issues, gaps and opportunities that exist. Medical strategy includes medical directors, who may collaborate with marketing and clinical development teams to ensure proper alignment.

Medical operations (sometimes referred to as Medical Affairs Excellence) is involved in running the logistics to help support successful execution of strategic imperatives. This group is typically involved in systems and disease state training, capturing insights and supporting study execution in certain cases.

Field medical affairs is an extension of the internal (in-house) medical affairs team and consists of the medical science liaisons. Their primary role is to (1) educate healthcare providers (HCPs) (2) facilitate opportunities for collaboration with academic centers of excellence (research, study support, advisory board nominations, IIS study identification, etc..) and (3) capture insights and important competitive information for their organizations. The insights MSLs capture should help drive strategic direction internally.

Scientific Communications traditionally serves two functions: (1) Strategic Publication Planning and (2) Execution & management of Continuing Medical Education (CME) submissions.
As mentioned above, one of the hallmark roles of medical affairs is providing a continuous flow of new information to the medical community. Scientific communications ensure that this is done in a strategic manner. These teams help determine which congresses, journals and other venues are most appropriate for the new data that the company is interested in sharing. CME management helps to ensure that the company is supporting CME grants that enhance the overall educational mission & objectives of the organization. Pharmaceutical companies need to be ‘hands-off’ when it comes to CME grants. Meaning that the company cannot influence the educational content of CME programs. This is to reduce the chances of subjectivity or bias presentations.

**Health Economics Outcomes Research (HEOR)** has become an increasingly popular and important function within medical affairs. HEOR supports the value proposition for a drug, device or diagnostic. HEOR teams play an important role in helping products receive favorable positioning on drug formularies, increasing the chance that the drug will be used with minimal constraints when prescribed or recommended.

**Pharmacovigilance (PV) or (Drug Safety)** is focused on monitoring, assessing, and evaluating drug safety concerns from HCPs and patients. PV groups may screen the literature, write periodic safety reports, analyze safety databases and provide important risk assessments for upcoming clinical trials. PV’s primary focus is to ensure patient safety as well as helping the medical community be as informed as possible about the safety profile of the product. PV teams need to be familiar with both the regulatory requirements in the U.S. and EU (FDA & EMA). For those teams involved in other countries/regions, ensuring a key understanding of the regulatory climate in each country is crucial.

**Drug Information** teams provide a twofold function: (1) developing and maintaining a repository of information (FAQs, standard response documents (SRDs)) for both
HCPs and patients. Drug info teams may also be responsible for managing a 'call center' which will receive physician and patient inquiries related to a wide variety of questions about the drug or device. Drug info teams may also manage the library services for a pharmaceutical company, ensuring that the medical affairs organization has access to important journals, databases, and competitive information.

A successful medical affairs professional who understand all aspects of a medical affairs organization will bring more value to pharma and be significantly more effective in working cross functionally within medical affairs.

ACMA
Accreditation Council for Medical Affairs

BOARD CERTIFIED MEDICAL AFFAIRS SPECIALIST (BCMAS) PROGRAM

Being a registered board certified medical affairs professional via the BCMAS program provides all of these foundational elements. The Board Certified Medical Affairs Specialist Program (BCMAS) is accredited to provide continuing education for physicians and pharmacists and is the most widely used program around the globe.

The program focuses on all aspects of medical affairs, (including presentation & communication skills) and therefore provides the most comprehensive training in the space. Most importantly, BCMAS offers increased career mobility for those looking to transition into different roles in the future and keep their options open.

Visit www.medicalaffairsspecialist.org for more information.