

Beyond the SCIENCE

Medical affairs professionals are integral to creating new bridges that cross internal departments and connect to new stakeholders to share the increasing amount of scientific information available.

With the current healthcare system requiring more data, quality evidence, and proof of quality of care from manufacturers in increasing numbers, pharma companies are looking toward their medical affairs teams to effectively streamline the dissemination of medical information.

The role of the medical affairs group has grown steadily over recent years to include not only oversight of all scientific communications but product value marketing, publication planning, and dissemination of clinical trial data. Analysts have identified other areas of influence in which medical affairs professionals are also engaging, including: thought leader development, speaker programs, medical science liaison programs, medical grants, investigator-initiated trials, medical education, medical publications, medical information, compliance, regulatory affairs, and health economics.

Analysts say through a well-developed and executed plan, the medical affairs department can enhance product and brand awareness and value, which can lead to increased market access and, in turn, increase a product's market share.

The Evolving Role of Medical Affairs

George Betts, director, head of medical affairs operations, Ipsen Biopharmaceuticals Inc., says to best understand the evolving role of medical affairs it is important to know the external forces in the biotech and pharmaceutical industry that have impacted the medical affairs function over time.

"New OIG guidelines and PhRMA codes established regulations between physicians and pharmaceutical companies and these regulations focused on areas, including the scientific exchange of information, advisory boards, educational meetings, speaker training, promotional give-away items, and financial compensation to physicians," he says. "This was a primary cause for pharmaceutical and biotech companies to relook at their internal operations and struc-

"I believe we will start seeing a growing trend to have HEOR functions within medical affairs. This move can allow health economics teams to better concentrate on the science of the drug rather than the commercial promises."

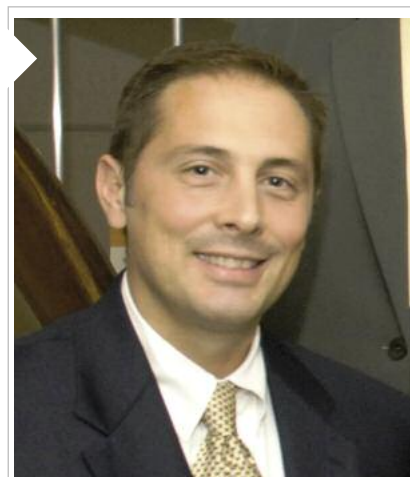
ture. A clear wall between medical functions and marketing was made. This also led to a greater accountability and increased set of responsibilities that bridge research, clinical development, publications, health economics and outcomes research, medical information, educational grants, and other areas."

According to researchers at Cutting Edge Information, now that most medical affairs groups have grown comfortable abiding by new regulations developed over the past several years and with this transition out of the way, they are now focusing on the ultimate goals of any medical group — to generate, package, and disseminate medical and clinical information for both internal and external clients.

To accomplish this mission, the modern medical affairs department has evolved into a global group charged with a growing number of specialized responsibilities in regions all over the world. With so many tasks at hand, teams face a new challenge: allocating resources in a manner that allows each subfunction to meet its goals and grow with the demands of the medical community.

Robert Matheis, Ph.D., senior director, evidence based medicine, Sanofi US, and immediate past president, International Society for Medical Publication Professionals (ISMPP), agrees the role of medical affairs is changing dramatically.

"In the past, there were certain skill sets — scientific and medical in nature — that a person needed to possess to be successful in his or her role," he says. "Today, with the evolution of



GEORGE BETTS
Ipsen Biopharmaceuticals

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“There are many opportunities for medical affairs professionals to bring expertise to their organizations.”

healthcare, the landscape has changed and medical affairs professionals require a broader skill set than ever before.

“For example, medical affairs professionals need to have excellent customer engagement skills, enabling them to understand the needs and perspectives of their customer.” Dr. Matheis continues. “The modern medical affairs professionals also must have an understanding of the regulatory environment, rules of engagement, and how and when it is appropriate to present various types of scientific evidence to customers. For example, subject to certain requirements, it may be appropriate for a medical affairs professional to present health economic evidence in helping to evaluate treatment options with healthcare decision makers.”

Best Practices for Successful Engagement

Medical affairs professionals are now engaging in unbiased, peer-to-peer, scientifically fo-



DR. ROBERT MATHEIS
Sanofi

cused discussions with a host of healthcare professionals, from physicians to payers. Experts emphasize that those discussions still must be grounded upon good science.

“We need to ensure medical affairs professionals, for example, MSLs, who are having dialogues with healthcare professionals have sound scientific backgrounds,” Mr. Betts says. “One measure of a scientific background is evident by their degrees. I would advocate for degrees such as M.D.s, Ph.D.s, as well as nursing

and pharmacy degrees. Furthermore, medical affairs professionals should have ongoing training on the rules of engagement. This training is typically developed by the company’s legal and compliance departments. This training is essential to ensure compliance with the company’s policies in this area. Training should be mandatory for all new hires who engage in the scientific exchange of information to the external community. Companies often forget to train global associates from other countries outside the United States, which places the company at greater risk.”

Dr. Matheis agrees that as medical affairs professionals continue to break new ground, training is paramount to build skills and maintain compliance.

“To communicate effectively and appropriately with healthcare decision makers in a formulary setting requires deeper training and skill building in areas not often addressed as part of traditional medical roles,” he says. “Pharmaceutical companies must address the training needs of their medical affairs professionals so that they are aware of both the opportunities and requirements, including legal and compliance issues, related to engaging customers in evidence discussions. A best practice is to provide case-based approaches toward instructing medical affairs professionals to ensure they are having appropriate engagements.”

Beyond the science, Dr. Matheis says medical



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affairs professionals are working to better understand the payer environment and the priorities of various new delivery models, such as accountable care organizations and medical homes.

“In the past, a medical affairs professional might have delivered a product-specific pres-

entation about the distinguishing characteristics of his or her offering,” he explains. “Today, the goal for the medical affairs professionals is often to first understand the challenges within a particular organization, serving as a partner to appropriately work through issues collaboratively.

VIEWPOINTS



MELISSA HAMMOND

Managing Director
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Value Beyond the Clinic

In research we have conducted over the years with KOLs, we

have consistently found that medical affairs professionals provide valuable clinical insights beyond those focused on a given company's individual product. There appears to be a real desire among leading clinicians and researchers for information regarding the overall clinical market and changes within the industry. The key for the modern day medical affairs professional is to understand the needs of the physician communities they engage and how they can best prepare them for the challenges they are personally facing. Technology that drives clinical insights should be leveraged to get to this end.



DEBRA JOYCE

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Creating a Bridge

Medical affairs professionals can provide great value to their corporate colleagues by helping to bridge science with commercial aspirations. In the prelaunch phase of a compound's path to approval, medical affairs teams provide sound scientific interpretation of data and its implications, whether product-specific or disease state or both. In a similar manner, professional medical affairs teams may assist external thought leaders and clinicians by providing a solid understanding of specific disease states and the corresponding role of pharmaceuticals; in other words, helping all medical professionals stay current and translate

cutting-edge science to address clinical needs and potentially provide better patient care.

Scientific Exchange

Medical affairs teams have the opportunity to foster scientific exchanges with their medical colleagues, whether with thought leaders as expert educators or practicing clinicians looking to learn about new treatment options or how to improve patient care. These interactions, whether one-on-one or in group settings like advisory boards, can incorporate best practices to ensure professional dialogue, authentic feedback, and unbiased data sharing. For example, any planned physician group discussions can be guided by a needs assessment and corresponding discussion guide, which can help identify key issues needing clarity or exploration and set a framework for constructive feedback. Any formal interaction between healthcare providers and a medical representative of a pharmaceutical company can have specific objectives that ensure an educational discussion and promote sound scientific exchange.



ROBIN WINTER-SPERRY, M.D.

President and CEO
Scientific Advantage LLC

Creating a Demand

Recently, the medical affairs world has been experiencing an increase in visibility, which is creating greater demand. It goes beyond science to demonstrating business impact, translating science for increasingly varying audiences, and becoming more responsible for strategic initiatives. To maximize their worth, effectiveness and training, and often some “retooling” is necessary. Moving toward the future, new skills need to be added to their scientific acumen to enable them to work more efficiently and communicate more effectively while contributing to improving healthcare.

“Importantly, it may not be a product-specific solution,” he continues. “In some cases, it may be helping patients to remain on treatment or some other educational element of process of care. The difference today is that, in general, medical affairs professionals now begin with the customer need and work backward to a solution, rather than the other way around.”

Mr. Betts agrees that payer relationship management is complicated and understanding their challenges isn't easy.

“There is and will continue to be a growing demand by payers for more data on health economics and outcomes,” he says. “Medical affairs can help by including new endpoints and measures into their Phase IV studies. I believe we will start seeing a growing trend to have HEOR functions reside within the medical affairs function. This move can allow health economics teams to better concentrate on the science of the drug rather than solely on the commercial promises.”

Keeping the Focus on Education

Ensuring that medical affairs' exchanges with healthcare professional audiences are not perceived as promotional but educational is paramount to the medical affairs role.

According to Mr. Betts it helps if the medical affairs role is filled by true professionals, meaning Ph.D., M.D., etc. degrees

“Also, sales reps should be absent during these conversations,” he says. “Medical affairs professionals need to stay on label except when exchanging available scientific information to an unsolicited question and provide a balanced view of the data. Beyond that, it is important to have a real exchange with the healthcare professional and not a canned medical affairs speech with only key talking points.”

Dr. Matheis believes that because medical affairs professionals often touch multiple points within an organization, they can serve as a critical point to appropriately align different parts of organizations toward producing and communicating evidence that is relevant to customers.

Medical affairs professionals are at the nexus of the transmission of information; they are gathering insights and understanding what issues are relevant to customers.

“There are many opportunities for medical affairs professionals to bring expertise to their organizations,” Dr. Matheis says. **PV**

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