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Medical promotional review: Current trends, challenges, and strategies for success

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This article aims to report on the current trends in medical affairs departments related to promotional material review, offering valuable insights for industry professionals. Using data collected through a survey of pharmaceutical and medical device companies, the authors examine how medical affairs aligns its responsibilities, dedicates time, leverages essential training, and orchestrates staffing during product launches. The article will also discuss approaches, various support options, and strategies to elevate medical promotional review.

Keywords – medical affairs, medical directors, medical promotional review, resource allocation, review expertise

Introduction

The pharmaceutical industry relies on rigorous evaluation and approval processes for promotional materials to ensure accurate, balanced, and evidence-based communication about products. The primary function of the medical reviewer within the promotional review process is to verify the medical and scientific accuracy of data supporting claims and content. This involves ensuring a balanced and substantial presentation of data in content, with figures, tables, and graphs providing adequate context for readers in a manner that is neutral and not misleading.

Beyond the role of data quality control and fact-checking, the medical reviewer bears the responsibility of assessing data within the promotional context from a regulatory perspective. It is crucial to prevent any potential false or misleading implications in the overall net impression or takeaway when the content is reviewed in its entirety. In addition, the reviewer must confirm that the data supporting claims are not only accurate but relevant and appropriate for the target audience.

Furthermore, the medical reviewer contributes to organizational alignment by offering therapeutic area insights during the creation of promotional materials. This role encompasses the responsibility of verifying that references are up to date, suitable, and consistent, thereby enhancing the overall integrity of the promotional content.

Limited information is available for benchmarking how companies currently support and address the crucial role of medical affairs in the promotional review process. To better understand how medical affairs meets this need, the authors conducted an anonymous online survey.

Survey methodology and findings

Using Google Forms, a 15-question online anonymous survey was developed to measure various elements of medical support of promotional review. The survey was distributed across 556 pharmaceutical and medical device companies in the US from December 2022 to January 2023 and achieved a 7.6% response rate (n = 42). Representatives from large, midsized, small, and start-up companies were invited to participate. All respondents completed all the survey questions. Questions in the survey focused on how medical affairs aligns its responsibilities, dedicates time, leverages specialized training, and orchestrates staffing during product launches. The findings are discussed below.

Responsible role in medical affairs

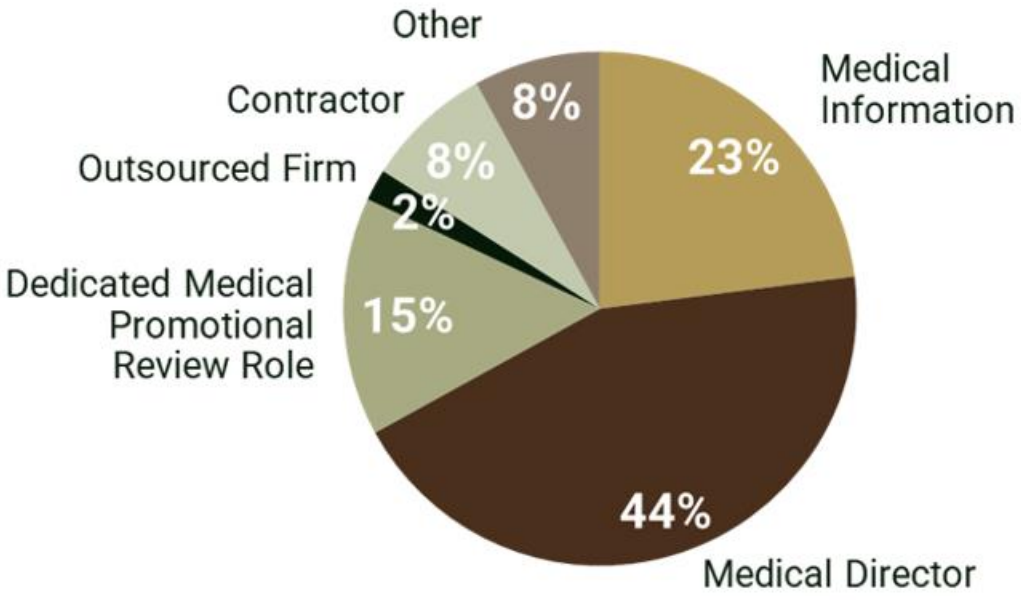
The majority of those surveyed (44%) reported that the medical director is responsible for promotional review, followed by 23% of companies assigning this responsibility to the medical information team (**Figure 1,** p. 3). The latter percentage poses a slight deviation from earlier findings, as previous surveys have alluded to many, if not most, medical information professionals acting as the medical reviewer for promotional materials.[1]

Fifteen percent of respondents reported having a dedicated medical promotional review role. Fewer respondents reported that contractors (8%), other (8%), and outsourced firms (2%) handle their medical promotional review needs.

Time supporting promotional review

The promotional review process places a significant demand on resources and time, particularly for medical reviewers. To better understand the resource impact on medical affairs staff that did not have a dedicated role (nondedicated), these respondents were asked about the amount of time spent on review (85% of total participants). Approximately one-third of survey respondents that identified as a non-dedicated reviewer indicated spending 25% or more of each workweek on material review.

Figure 1. Responsible roles within medical affairs



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This translates to 10 to 15 (or more) hours devoted to this task (**Figure 2,** p. 4). Nearly two-thirds of respondents reported spending 15% or more of each workweek, translating to 6 to 15 (or more) hours allocated to reviewing material.

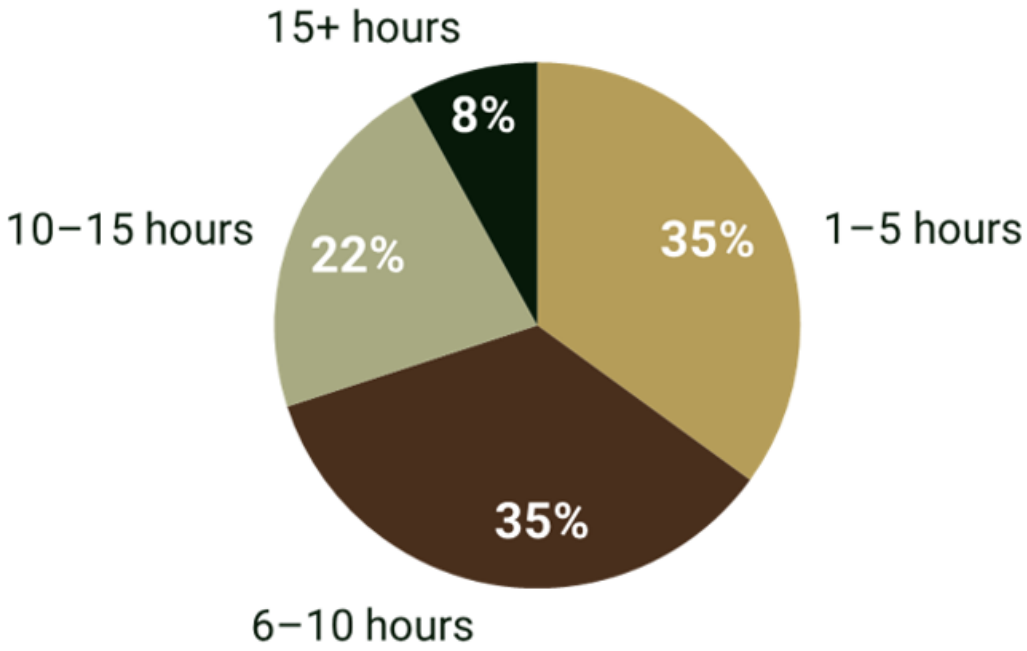
Most respondents reported spending 1 to 5 (35%) or 6 to 10 (35%) hours reviewing promotional materials. Twenty-two percent of those surveyed spend 10 to 15 hours of their week reviewing content, with the minority (8%) spending 15 or more hours.

Formal training

Applicable training can contribute to greater consistency, compliance, and efficiency across an organization, all of which are attributes that can enhance the promotional review process. Yet only 62% of respondents reported that their company provided formal training for medical promotional review (data not shown).

Promotional review is an effort that requires not only a profound understanding of the therapeutic area, drug product, and regulatory environment but also an ability to effectively communicate and negotiate with team members.

Figure 2. Average reviewing time per week for nondedicated[a] reviewers



[a]The dedicated reviewer group has been intentionally removed from this graph based on the assumption that dedicated reviewers are spending 100% of their time reviewing materials. The aim was to better understand the time burden for those roles in which the time is shared. Further context is provided in the body of the article.

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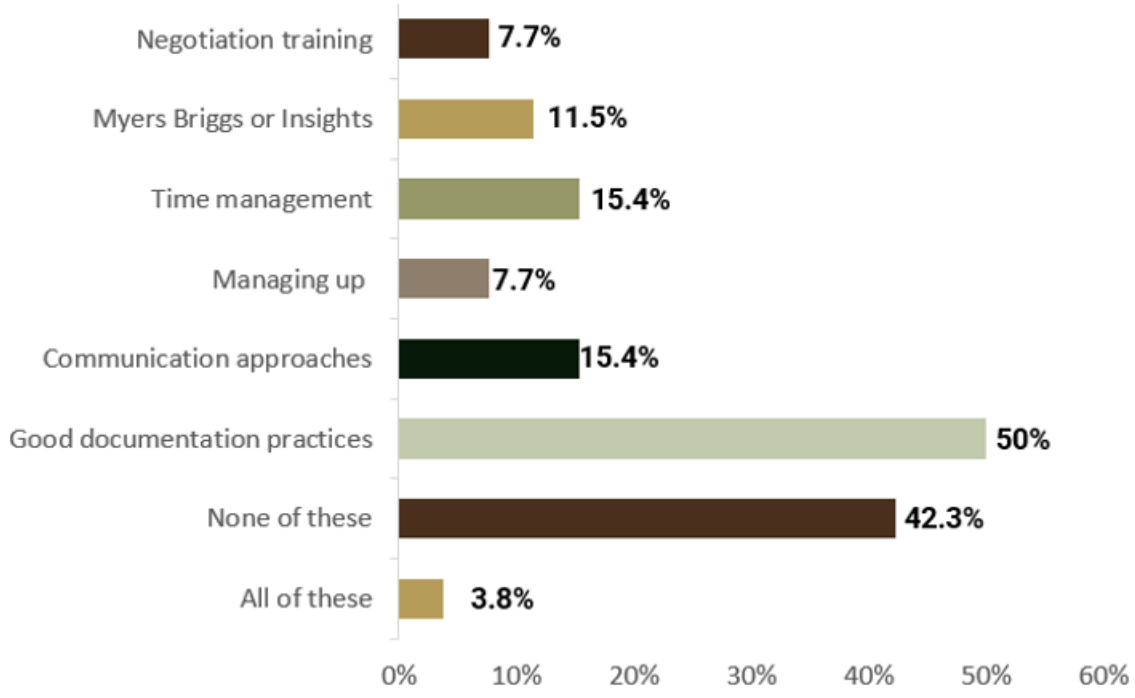
Communication and negotiation traditionally fall into the soft-skills category and are typically associated with customer-facing roles that depend on exercising such attributes for success, such as sales. Low rates were reported for negotiation training (7.7%) and communication approaches (15.4%) training opportunities, with 42% of companies reporting that training is not provided for negotiations, time management, managing up, understanding personality types, communication approaches, or good documentation practices (**Figure 3,** p. 5).

Launch preparation

Launching a new product necessitates additional resources throughout the organization, including within medical affairs. Sixty-nine percent of respondents revealed that existing resources are stretched to cover the increased promotional review needs to support the commercial team during a product launch.

Figure 3. Soft-skills training for medical promotional reviewers



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Summary and discussion

Based on the survey results, the authors were able to ascertain and benchmark the current state of medical promotional review within medical affairs. The medical director role is the most common role supporting promotional review, followed by medical information. Based on previously published data,[1] this implies a shift from medical information primarily providing review of commercial materials over the last decade. Alternatively, this perceived trend of medical promotional review transitioning from medical information to the medical director could reflect the limitations of both sets of data (including sampling bias, response bias, and reliance on self-reporting), and more research will need to be conducted to determine the accuracy and potential relevance of this finding.

Medical directors are often tasked with reviewing these materials because of their medical background and expertise, but available bandwidth can lead to resource constraints when the other functions of their role are taken into consideration. Furthermore, having clinical expertise does not automatically correlate with the necessary skills for effectively supporting medical's role in the review process. The role of a medical director in a medical affairs organization is typically diverse and varies across companies. This role may encompass responsibilities serving as subject matter expert, support for clinical development, relationship-building with key opinion leaders, oversight of

medical science liaisons, involvement in medical education and publications, and participation in promotional review. While wearing multiple hats can offer cross-functional benefits, it inevitably strains available capacity. Resource-intensive tasks such as promotional review may lead medical directors to deprioritize other vital projects. We learned that 30% of respondents that are nondedicated to medical promotional review are spending greater than 25% of their time reviewing materials (Figure 2), highlighting the resource impact on the medical director role, which is typically focused on broader company strategic objectives. This result raises the question about what other deprioritized initiatives will suffer from a lack of bandwidth if the medical director is primarily focused on review tasks.

Alternative approaches include assigning promotional review responsibilities to the medical information function. Traditionally responsible for addressing unsolicited inquiries from patients and healthcare providers, the medical information department possesses valuable insights into the patient experience and has a real-time understanding of trending topics related to their covered products. Integrating this perspective into external materials has the potential to enhance their contribution in the promotional review support role.

However, both strategies necessitate drawing resources from established roles, potentially diverting attention from other critical strategic objectives. Regardless of which medical affairs function manages this task, it is essential to critically assess whether their qualifications and experience adequately equip them for this responsibility. The promotional review process relies on the input and oversight of medical personnel trained both in their therapeutic area and for the role of a promotional reviewer to ensure scientific accuracy and clinical and statistical relevance, check that claims are supported with appropriate data or substantial evidence, verify dosing information, confirm the appropriateness of patient populations, and ensure the overall suitability of the information for promotional use. These results emphasize the need for formal training for individuals supporting this crucial function. Alongside instructing team members on negotiation skills and fostering an understanding of risk tolerance levels during the review of promotional materials, additional measures for promoting growth and development could involve training on current US Food and Drug Administration regulations and guidance documents pertinent to pharmaceutical promotion.

The majority of those surveyed (69%) reported that medical affairs resources to support promotional material review are not added during launch, implying that existing resources are being stretched to meet the expanded needs of the commercial team, potentially underserving them at a critical time. Inadequate staffing can negatively impact a new product launch and lead to risks because of rushed and expedited reviews of promotional content.

To fully maximize the potential of a product launch, companies should consider investing in all functions involved in this critical juncture in a thoughtful manner that maximizes return on investment. Launch readiness depends on having the right staffing model in place, which means leaders need to plan and ask for resources to anticipate this increased effort.

An inherent drawback in the strategy of expanding resources specifically for a launch is the risk of overstaffing once the initial tasks are completed, incurring unnecessary costs. This challenge can be effectively mitigated by adopting more flexible approaches, such as engaging temporary contractors to manage the initial surge in workload. While this addresses immediate needs, it is essential to acknowledge potential limitations in weekly working hours of contractors, which can lead to limiting productivity. Additionally, training these contractors often falls on existing staff, creating an additional burden that impacts overall bandwidth.

Another viable model to consider is outsourcing the work to a specialized vendor or agency with a deep understanding of regulatory requirements, industry best practices, and the intricacies of medical promotional review. This can allow medical affairs to bring a level of expertise in the promotional review space that may be difficult to develop in-house. Outsourcing also provides increased flexibility and scalability, allowing companies to adjust coverage based on anticipated workloads without the financial and commitment constraints associated with maintaining a full-time, in-house medical review staff. This in turn frees up resources that can be strategically deployed to other areas of the organization.

Medical affairs departments may also consider consolidating their medical promotional review capabilities. Establishing a centralized team within medical affairs offers several advantages, such as leveraging specialized expertise for enhanced efficiency, ensuring more consistent guidance across products, improving the quality of reviews, ensuring compliance, and elevating overall quality. This approach also fosters increased consistency to minimize errors, facilitates focused specialization, enhances communication and collaboration, results in cost savings by eliminating redundant efforts, encourages the sharing of best practices, and enables the efficient allocation of resources. A centralized team allows for flexibility in reallocating reviewers to accommodate varying workloads across the organization, eliminating the need for nondedicated and inflexible resources for each therapeutic area, which may otherwise struggle to adapt to evolving needs.

Conclusion

This survey sheds light on the evolving landscape of medical promotional review within medical affairs. The prominence of the medical director role, surpassing the traditionally prevalent role of medical information, suggests a strategic shift possibly driven by the need for cross-functional harmonization. However, the

transition prompts questions about the impact on deprioritized initiatives and necessitates further research for a comprehensive understanding.

The findings underscore the imperative for formal training, especially on the communication skills that can enhance efficiency during the promotional review process. The resource strain on medical directors raises concerns about potential trade-offs in broader strategic objectives. Moreover, the lack of resource augmentation during launches poses a significant risk, potentially compromising the quality of expedited reviews.

To optimize product launches, companies must invest thoughtfully in staffing and consider flexible models such as temporary contractors or outsourcing. While overstaffing is a risk, these models offer scalability and expertise without the commitment of full-time positions. Centralizing medical promotional review emerges as a viable strategy, offering consistency, collaboration, cost-effectiveness, and efficient resource allocation across therapeutic areas. In navigating the complex landscape of medical promotional review, a strategic and flexible approach is paramount for sustained success in pharmaceutical launches.

About the authors

Janet Gottlieb, PhD, is head of medical review solutions at Canopy Life Sciences. Her experience in research, diagnostics, medical devices, and pharmaceuticals in a career spanning over two decades has provided critical insight into promotional review. She has expertise in the formation, expansion, and training of medical promotional review teams. Gottlieb is a recognized subject matter expert in the field, presenting as an invited speaker at multiple industry conferences. She holds a bachelor's degree in biological sciences and a doctorate in medical microbiology and molecular virology from the University of California, Irvine. Gottlieb can be reached at janet.gottlieb@hellocanopy.com

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References

All references were last verified on 31 January 2024.

1. Bonk L, et al. The role of pharmaceutical medical information in promotional review: Three benchmarking surveys. Drug Information Journal. Published 1 January 2012. Accessed 30 January 2024. https://journals.sagepub.com/doi/10.1177/0092861511427873