A Single Solution:

How to Improve Biopharma Medical Writing Efficiency & Accuracy

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Custom content for Cardinal Health by **BioPharma Dive's Brand Studio**

Successful drug development hinges not only on sound research and strong data but also on accurate, efficient medical writing. Medical writers work behind the scenes in almost every stage of a product's life cycle: from preclinical development to patient education.

As drugs become more complex, and as regulatory agencies require more documentation and data, medical writers' roles have evolved. No longer do they merely prepare documents — **they are essential to the clinical development team.**

"As world health authorities work together on improving patient safety and transparency of clinical trial data, we've definitely seen more deliverables," said Kelley Hill, senior director of global medical writing for Alexion Pharmaceuticals. "More complicated mechanisms of action and the need for health economics and outcomes research also affect the volume of work for medical writers."

To streamline operations and ensure on-time delivery of all documents tied to a drug or device, pharma and biopharma companies often outsource medical writing to one or more vendors. However, using multiple vendors — one for clinical trial documents, another for regulatory submissions, for example — often creates inefficiencies. These inefficiencies can lead to costly and time-consuming errors and resubmissions.

Companies that outsource medical writing needs to one vendor benefit from efficient, consistent communication. A single, ongoing relationship with that vendor helps ensure scientific accuracy, uniform branding and messaging, and long-term cost savings.

What Does a Medical Writer Do?

Medical writers, aka medical communicators, develop a wide range of scientific, academic and regulatory materials. A few of these include:[1]

- Abstracts for medical journals and medical conferences.
- Advertisements for pharmaceuticals, devices and other products.
- Advisory board summary reports.
- Continuing medical education materials.
- Patient education materials.
- Grant proposals.
- Health care policy documents.
- Health education materials.
- Medical and scientific journal articles.
- Marketing materials.
- Poster presentations for medical conferences.
- Regulatory documents, including regulatory agency submissions.
- Sales training aids.
- Objection handlers.
- Scripts for commercial advertisements.
- Slide presentations for medical conferences.
- White papers.

Pharma and biopharma companies, health care organizations, and contract research organizations (CROs) rely on medical writers to prepare the full gamut of drug development materials. Medical writers organize and prepare clinical study protocols, investigator brochures, informed consent documents and study reports. They prepare documents needed for regulatory submission, whether for the Food and Drug Administration (FDA), the European Medicines Agency or Japan's Pharmaceuticals and Medical Devices Agency.

A medical writer's role doesn't stop when a drug or device receives approval. Medical writers develop materials for safety reporting, sales representatives and medical science liaisons, brochures for patients, and advertising copy. As digital health becomes more integrated with pharmaceuticals, they also write copy for mobile apps.

Considering the complexity of the subject matter, many medical writers have doctoral degrees. In a 2019 survey of American Medical Writers Association members, 77% of members who responded said they held an advanced degree; 46% said they held a doctorate or an advanced degree other than a masters.[2]

Experience and personal interest help determine whether an academic with a doctorate moves into regulatory writing or a physician with a medical degree moves into medical affairs writing. "Different types of medical writing benefit from different levels of expertise," said Andrew Kusmierczyk, Ph.D., chemistry, manufacturing and controls scientist for Cardinal Health Regulatory Sciences. "Some types of writing benefit from having Ph.D.-level individuals on board, and many companies, understandably, demand this level of expertise from their vendors."

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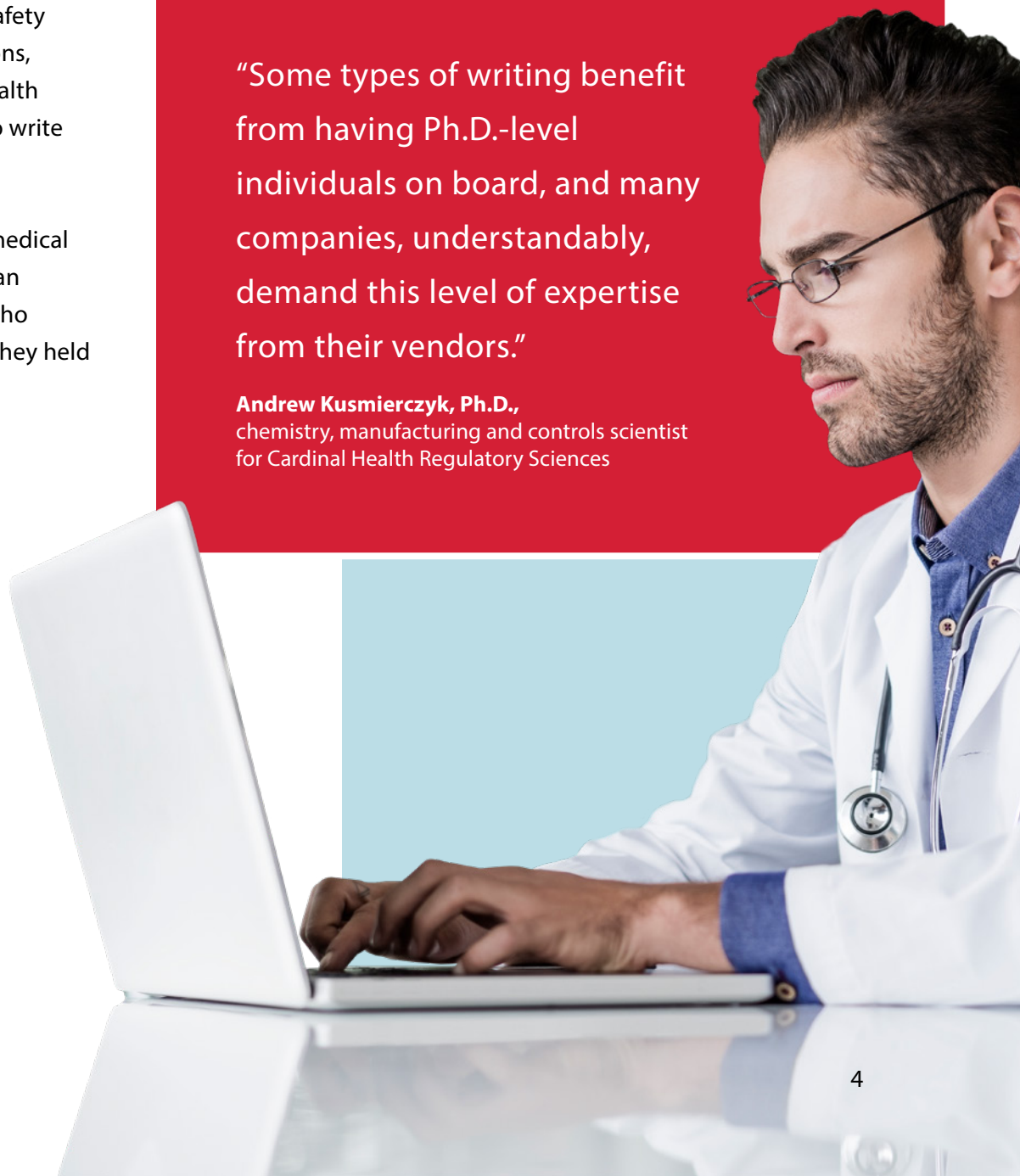

Partnering with Multiple Vendors

Pharma and biopharma outsource at least a portion of their medical communications, and they often do so with multiple vendors. BioPharma Dive's Brand Studio survey of pharma executives found that four out of five companies outsource medical writing. Most use two to four vendors; at least one company surveyed uses more than 10.

In some cases, pharmaceutical companies have to outsource to multiple vendors. For example:

- The company has firewalls between brands, departments or therapeutic areas, necessitating separate vendors for each.
- The company requires medical writing agencies to submit bids every two to three years to ensure the company receives comparable quality for the lowest cost.
- Their preferred vendor in one area doesn't offer the breadth of service to cover other types of medical writing or related services.

79% of pharmaceutical companies outsource about **39% of their medical writing.**

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Hill's team at Alexion contracts with one full-service provider and a handful of specialists for quality control (QC) review and pre-submission documents, such as investigator brochures, clinical study reports and risk management plans. These writers have highly specialized knowledge related to rare and ultra-rare diseases and are based around the globe. When Alexion has a large project with a tight deadline, it can use what Hill calls a "follow the sun" writing model.

"We've built a pretty sustainable model where they can literally hand off the document around the clock," Hill said. "It takes a lot of trust and a process — we have a kickoff meeting and a forum to share information. Communication is so important when you take this approach."

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Multi-Vendor Drawbacks

In BioPharma Dive's Brand Studio survey, pharma executives reported drops in efficiency and quality as the top two drawbacks of using multiple vendors. Of the pharma executives surveyed, 24% said using multiple vendors created silos that hampered communication and coordination. When preparing a document that's hundreds of pages long and involves input from a dozen people, organization and communication are key.

Roughly the same number of leaders — about 20% — felt "too many cooks" led to inconsistent or inadequate content. Quality may vary between vendors, or vendors may not have access to the same information because of legal or intellectual property issues. At times, vendors simply lack experience in a therapeutic area or with specific regulatory requirements.

"For regulatory writing, you have to have a good understanding not just of the guidances involved but also the actual process," Kusmierczyk said. "Document preparation is often very regimented and has specific guidelines. The ability to translate these guidances into practical action requires a specific skill set."

The Single-Source Model

A single-source model streamlines complex medical writing projects. Pharmaceutical companies know their vendor has the required skill sets to prepare documents for federal agencies, payers, providers and patients. A single-source model also offers built-in consistency.

45% of pharmaceutical companies named efficiency as a top benefit of using **a single medical writing vendor.**

Efficiency, cost and scientific accuracy were the top benefits of using a single medical writing vendor, according to BioPharma Dive's Brand Studio survey. Working with one vendor streamlines the communication process, which means the medical writing team is more likely to meet (or beat) deadlines.

"You want all the various types of medical writing harmonized and consistent," said Yolaine Jeune-Smith, senior manager of scientific communications for Cardinal Health. "As you move through the development process from pre-IND to NDA to post-marketing and commercial writing, the efficiency gained has a cumulative effect. Having a single team reduces the number of external vendor meetings, the number of review cycles and the amount of time spent to get fully briefed on the program. A company with regulatory and commercial capabilities can streamline the entire process."

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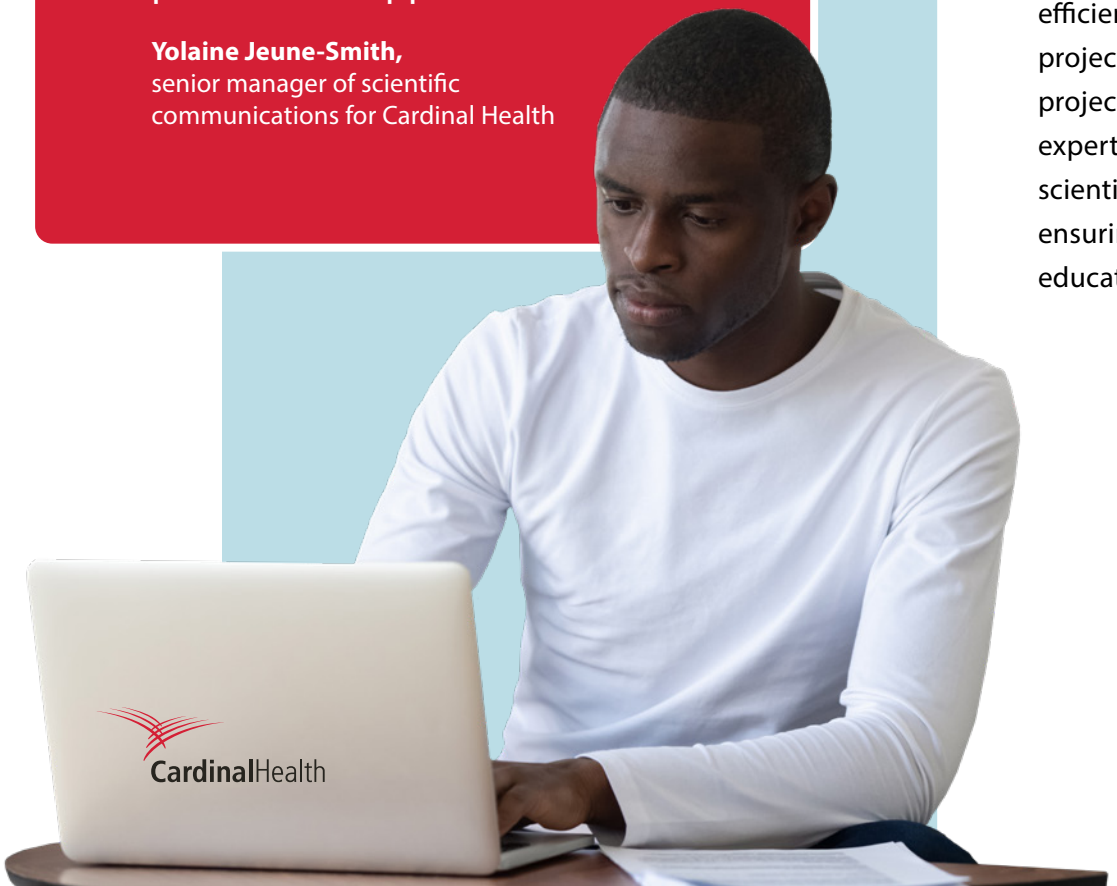

As the relationship with that vendor develops, the efficiency gains extend to subsequent brand projects. "When you work with one vendor, you maintain continuity and build upon lessons learned and insights gained along the way," said Jeune-Smith. "Once you start looking at how to market and brand a product and start developing sales materials, working with the same vendor makes it more impactful because you don't have to get a new vendor up to speed on your product and approach."

An ongoing relationship with one vendor also ensures scientific efficiency. With one vendor in charge of multiple medical writing projects, information flows freely between multiple teams — all projects fall under a single legal and IP framework. Subject-matter expertise also builds: When a vendor works on a pharma company's scientific publications, it develops deep knowledge in that product, ensuring consistency and accuracy in regulatory strategy and educational materials.

A Matter of Cost

As health care shifts to value-based pricing, payers and regulatory bodies are putting pressure on pharmaceutical companies to shorten timelines and lower drug development costs. As pharma companies focus on getting highly specialized drugs to market faster, with less overhead, using a single medical writing vendor helps pharma companies meet these goals.

In most cases, single-source vendors can offer more competitive pricing compared with multiple vendors. The efficiency gains also lead to lower operational costs overall. For example, a principal medical writer can spend less time editing for brand consistency and more time on new projects.

Scale Up, Scale Quickly

For Alexion, it made more sense — financially and ethically — to outsource. "If a project ramps up and you suddenly need 10 people, you have that capacity," Hill said. "You don't want to have to set employees adrift as clinical development ebbs and flows; you don't want to have to let someone go because a program gets paused. That's not Alexion's model. They're committed to keeping their employees, but it's important to be able to staff up when we need to."

Kusmierczyk said Cardinal Health's prospective medical writing clients shared this concern: Can one vendor ramp up quickly when a company has multiple projects and deadlines?

"If your shop has a large enough pool of experts to draw upon, you can more easily handle the overflow," he said. "Cardinal Health has over 200 experts on the regulatory side alone. Smaller vendors may not be as well positioned to scale up quickly."

THE CHALLENGE

A pharmaceutical company's on-time submission depended on completing about 75 patient narratives for an oncology product with orphan designation. The company's CRO did not have the medical writers available to complete the narratives on deadline. Meeting the deadline was impossible, the CRO said.

THE SOLUTION

Cardinal Health Regulatory Sciences accepted the project. They wrote, reviewed, QC'd and finalized about 75 patient narratives in two weeks. A project of this scope typically takes at least two months.

THE RESULT

The company met its deadline, and its application was approved. This wouldn't have happened without an efficient medical writing vendor with an experienced, robust team.

Putting Your Eggs in One Basket

A few pharmaceutical executives surveyed wondered if a single vendor could provide the breadth of services that they'd experience with multiple vendors. Would they deliver different presentation ideas? Would they have the resources to cover diverse needs within an accelerated timeline?

If that vendor has broad medical writing capabilities, subject-matter expertise and the people to fill the demand, it can meet those needs more efficiently than a piecemeal approach. "Based on your need, a single, larger vendor provides the contingencies you expect when working with multiple vendors," Smith said. "We have the ability to provide volume discounting. We have full recruiting services to meet the pursuit of 'high quality, low cost'."

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A Single Solution for Complex Needs

As biologics, gene therapy and digital therapeutics become more common, medical writers will continue to expand their knowledge to stay relevant in a demanding field. Their expertise provides value, and it can't get lost in disorganization or lack of communication.

"As medicines become more complex, it will be a lot harder to get medical writing done right," Kusmierczyk said. "In my view, the future will be with companies that have the expertise to guide pharmaceutical companies through the different types of medical writing needed to get to successful approval and post-approval."

SOURCES

1. Ultimate Guide to Becoming a Medical Writer, info.amwa.org.
2. Select results from the *2019 Medical Communication Compensation Survey* AMWA Journal / V34 N4 / 2019 / amwa.org.

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Cardinal Health Specialty Solutions is an experienced team of trusted advisors developing solutions for the opportunities and challenges facing biopharma companies and healthcare providers. We enhance product success on the path to approval, launch and commercialization with configurable, integrated offers to meet unique needs. We also offer knowledge, scale and proven technology to enable providers to deliver high-quality and efficient patient care.

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