

TOPICAL FEATURE

PART 1 IN A 3-PART SERIES

The Business of Medical Writing: Understanding the Value Proposition and Successful Business Models

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ABSTRACT

A high-performing medical writing team begins and ends with talented writers, editors, and leaders who understand their mission and their business. A panel of writers comprising the authors convened virtually on October 28, 2021, at the American Medical Writers Association National Conference to discuss this topic. The topics of value proposition and business models, communication and leadership, and financial acumen and corporate responsibility will be reprised in this 3-part series, along with thoughts from the authors looking to the future of the business of medical writing, including what we can do in the medical writing community to introduce these topics earlier in the medical writing career path.

A high-performing medical writing team begins and ends with talented writers, editors, and leaders who understand their mission and their business: the value proposition, the finances that drive strategy and decision-making, the financial goals, and effective communication. To execute the organization’s goals, leaders must orchestrate resources and often have to balance dynamic variables including budgets and governance that provide bidirectional input into the business strategy.¹

A panel of writers comprising the authors convened virtually on October 28, 2021, at the American Medical Writers Association (AMWA) National Conference to discuss this topic.² The authors felt the topic was apropos given that they themselves have experienced—and often hear from other writers—that business-related topics in medical writing are learned on the job, mid- to late-career, when writers are expected to be able to analyze and synthesize knowledge across the business portfolio of assets,¹ often in high-stress and rushed circumstances without the benefit of prior observation.

The panel members shared their own journeys as business leaders and the methods they used to strengthen the business acumen of their teams. Discussion topics included

identifying and defining a compelling value proposition; models to teach financial understanding and oversight; business leadership skills, anchored by simple, clear communication, to keep teams motivated and engaged with their mission; collecting data to measure the effectiveness of teams and prioritize and allocate resources in support of business goals; and communication styles to support critical business drivers such as team focus and engagement.

The topics of value proposition and business models, communication and leadership, and financial acumen and corporate responsibility will be reprised in this 3-part series, along with thoughts from the authors looking to the future of the business of medical writing, including what we can do in the medical writing community to introduce these topics earlier in the medical writing career path.

The authors’ collective experience comprises the following medical writing work environments:

- Freelance business
- Small business/vendor
- Department leadership of small- to mid-size biotech company and large-sized pharmaceutical company

The moderator’s (Joan Affleck - JA) prompt is provided for each topic, followed by each perspective on the topic. In some cases, text from the session has been paraphrased for optimal clarity in this medium.

DEFINING VALUE

Value Proposition

JA: Let’s start today with a fundamental question for each of us. We often hear the buzz phrase “value proposition.” That’s the idea that there’s a service or product that is attractive and valuable to a customer or end user.¹ In my regulatory medical writing department, our value proposition, in brief, is that we develop documentation to support the research and development objectives of a much larger organization. *So, what does your value proposition mean in your organizations, and why is your value proposition important in the big picture?*

Jeanette, could you start?

Jeanette Towles (JT): I'll start by saying what our value proposition is: "We apply our years of experience and current regulatory and technical knowledge to help deliver important new therapies to patients in an expedient manner. We are a best-in-class firm and take pride in our operational excellence." For me, a value proposition means: 1) what we bring uniquely to the table if a customer wants to work with our company; 2) what we stand for; 3) what challenges we solve; and 4) what gains we offer (Figure 1). Hopefully, by convincing the customer [that] we can use our years of experience, we make the sale—and the company not only chooses us but also keeps coming back to us. We strive to leave the impression with our customers that we should really be their go-to to get things done. This proposition also translates well to the in-house setting.



Figure 1. Defining a value proposition.

JA: Dom, is that something that resonates with you, being in Big Pharma?

Dominic De Bellis (DD): Being the go-to to get things done always resonates with me! It's important to understand that, regardless of whether [you're] independent or in-house, your goal is really the same: to provide [an] excellent product to the client. For the freelancer, that will be another organization, and for the in-house medical writer, that's your clinical team or your document development team. You're a smaller piece of a bigger organization if you are in-house, but the requirements from the writers' or teams' perspective are very similar; it is a question of how you manage the team to affect the success of the document as a whole.

JA: And Brian, in the freelance context, what's that like?

Brian Bass (BB): In the freelance world, value is paramount. If we are not bringing value to the table, we are not going to be able to make a living wage and ultimately keep our clients. The value proposition from the freelance standpoint is to remember that first and foremost we are problem-solvers. Clients come to freelancers when they do not have someone on staff (or another freelancer they have worked with) who can get the job done. Especially when clients reach out to you as a new freelancer, they are coming to you with a problem, and our job is to solve that problem. We happen to do it by medical writing, but what we need to understand is what is driving the client's need to reach out to us. They need us to be confident, and they need to be confident in us. They need to know that we are going to make their job easier. And that's how freelancers ultimately put forth their value in making their clients' lives easier.

JA: Have any of you run into challenges with defining or clarifying that value proposition with your customers? Any situations [in which] they didn't quite understand what it was you were bringing to the table or perhaps misinterpreted it?

JT: This comes up fairly often, to be honest—and earlier in my career this was surprising, but it no longer is. I enter each client relationship and document saying I need to prove myself to this client continually for them to keep coming back to me—for example not only that we can execute a clinical study report but also that we can execute a supplemental new drug application in its entirety. Needs, requests, and the regulatory environment change over time, so I have personally faced continual challenges. I also worked with an organization that was in such a funding situation that we kept getting questions about every dollar and

cent. So, I said to myself that I need to have a conversation with this customer to walk them through what goes into this work. That exercise ended up building trust; they came to understand how many hours went toward producing a particular type of document and all the steps that went into it. In the long run, we received fewer questions, and the tone shifted to a more trusting partnership. If you are having challenges, it is worth having a conversation about them.

JA: Interesting that trust is something we don't usually think of as being part of a business plan—but you and Brian have both pointed out it most definitely is: trust and confidence.

Trust is something we don't usually think of as being part of a business plan, but it most definitely is: trust and confidence.

BB: I find that clients often don't realize what I strive to deliver to them makes their job easier because I anticipate where other freelancers go wrong: not staying in touch and on top of projects, calling at the last minute to say they are behind schedule, things like that. All of those mistakes really are so easy to avoid if you focus on them. But many clients don't expect that, and they are naturally very pleased. As a matter of fact, I just received an email this morning from a client who said, "you are everything that so-and-so said you were." And to me, that is the proof of why I work hard to deliver that value proposition.

JA: *Dom, when you are embedded in a company, do you still have the same challenge—do you have to keep proving yourself to customers?*

DD: It's very much the same, you are only as good as your last document. That maxim holds true in-house in the same way. The problems we solve may differ: we may be more focused on navigating complex internal processes on behalf of the team, we may be more aware of certain regulations that may be more relevant, and we have to keep our finger on the pulse of those changes. But from a document development and writing standpoint, it's the same thing: quality is expected, and we need to provide that level of service. I think of our teams as our clients, so there's "client education" to get the team to understand what's involved in the work you are doing. Everyone learns to write, which is wonderful, but not everyone writes the way we need them to

write for a particular document or in a way that's applicable to the audience you're writing for. There are many nuances to the craft, and it's necessary for us to explain that to the client or team as we build trust and get them to see the value proposition.

BUSINESS MODELS

JA: OK, so you've got your value proposition—this is the value we bring. But then you have to have a way to operationalize that—you've got to have a business model that hooks up with your value proposition. Let's talk a little bit about the kind of business model you have today. Is it a group, one person, [a] freelancer, in-house employees? *What are some factors you consider as a business leader when you're building a business model? Brian?*

BB: I was an independent freelancer for the first 15 years or so of my business. Since the early 2000s, I have been bringing in other freelancers who subcontract with me, including both medical writers and medical editors. My business model had to evolve because I was no longer just responsible for paying attention to how I delivered for my clients in terms of the value I bring to the table. I had to make sure that the other people on my team understand that as well and take that to heart as much as I do. Therein lies the challenge for any manager; even though I'm not operating a big department within a large corporation, I am still operating my own department. I am ultimately responsible for any project and any person on my team who is working on it. So, I had to adapt my model to consider the amount of time it takes me to manage the projects, to work behind the scenes with the writers and editors to make sure they are delivering the way I need them to deliver. One way that I am perhaps a little unique compared with other freelancers who bring in subcontractors is that the people on my team are as qualified if not even more qualified than I am, so they are all at the top of their craft. I find that by starting with the very best people, it takes away some of the challenges you might run into with people who have less experience and are still learning their way through the processes. That is what has been working for me.

JA: I like how you talked about thinking of your group as your own department because I do just the opposite. I say, okay, I have a department within a large corporation, but I think of it as my own business. So, I like that cross-pollination.

BB: Clearly it must work if we are both approaching it that way; we are doing the same thing, just from a different direction!

JA: Exactly, and we are borrowing across each other's worlds! Jeanette, I bet that with your value proposition and that quality element, you, too, must spend a fair amount of time in your business model making sure that other people who are delivering on behalf of your company's name are doing it at the very highest level and in the way you want them to deliver. Is that true?

JT: That is absolutely right. "Operational excellence" is part of our pitch, and we make sure we deliver on it. Similar to what Brian was saying, if you are going to pitch yourself as a best-in-class firm, you really need people who have the experience behind that. And not just on paper—we administer a test to make sure, pragmatically speaking, that they live up to the basic standards, that they are focusing on the right things if they have a short period of time to do something. Something we introduced recently was a pathway for people who don't have as much experience in industry; and the reason we did that is two-fold: 1) our resource pool is finite by nature, which COVID emphasized because there was a lot of competition for really great talent; and 2) a sense of corporate responsibility to help people coming in at a lower level to work up to where they could eventually do tasks on their own. So, we created a Medical Writing Operations group, and we have folks come in through that pathway, learn what it's like to be in this function, learn what it's like to manage a project day-to-day, and approach it that way. By learning the basics in a lower-pressure environment, they have the opportunity to really learn and get exposure to items so they could eventually live up to those same standards that we have to offer on the medical writing side.

JA: It's really interesting that Brian and Jeanette both touched on resourcing; the care, feeding, and development of medical writers and medical communicators; and the search for top talent all as part of the business model. *Dom, is it the same in your space?*

DD: I may be repeating myself, but yes, it is in the sense that we also need top people here on our team to do the same kind of work. The finite resource pool is a known challenge for all of us; however, we have to provide the right environment—whether it be training, resources, infrastructure, or established process: these are the things we offer as an in-house environment versus someone who may start out freelancing independently or work with someone more established. It's the same need for personnel, and the one difference we have in-house is we have the resources available to us to develop and put plans in place or put opportunities in front of people for them to have a broad experience and to become marketable across the industry in medical

writing, rather than to become pigeonholed in one particular skill set or document type. We need the same high-quality people. We may have an advantage in what we can offer in terms of training people and developing them, but again, we cannot do that at the expense of quality or the work that has to be done, so it's a delicate balance.

LOOKING TOWARD THE FUTURE

As the moderator of this AMWA Business of Medical Writing discussion noted, this panel was an initial dialogue meant to "kick off a broader discussion of the many aspects of business leadership as it applies to our work as medical communicators."²

Learning about business is part of regular training in adjacent fields in industry, for example, for regulatory affairs professionals (Figure 2).^{1,3} The business acumen domain of the Regulatory Affairs Professionals Society (RAPS) competency framework, for example, as a cross-functional domain, is characterized as representing "knowledge content that is broadly relevant to those employed as regulatory affairs professionals."³ The domain descriptor is the "ability to leverage systems and processes to successfully operate a regulatory function to manage product and organizational risk," and the topics covered include industry-specific, operational, project management, quality management, and continuous improvement knowledge.



Figure 2. Regulatory professional competency framework, including business acumen domain. Source: Regulatory Affairs Professional Society (RAPS). Regulatory Competency Framework Model Concept. 2021.³

The similarity of the regulatory framework's business domain description to what medical writers encounter in their daily job function—for example, leveraging systems and processes to manage risk—is striking. What is

equally remarkable is that the business domain is considered “broadly relevant” to all in the job function—not just for those considering being in a management position. In this framework, leadership and ethics are “the foundational domains, providing the underpinning for professional success” and are considered as additional skills separate from the business acumen domain, whereas the panelists for the Business of Medical Writing discussion considered them within the same overall umbrella of business skills but placed them with the same level of importance in terms of contribution to overall professionalism.

Although the DIA medical writing competency model references the need to deliver to business objectives and interact with business partners to meet customer needs as part of the writer’s regular functions, tasks, and activities,⁴⁻⁶ it is not clear what business literacy skills medical writers should acquire to prepare them for such interactions. In fact, this model not only prescribes key activities like mapping of a “product’s key messages to customer needs, critical success factors, medical/scientific objectives, clinical plans, and data results across phases of development and global regions,” but assumes that the writer is familiar with how to create important business documents like a business continuity plan. So, the question remains—what content from these disparate sources is most relevant in the medical writing context?

Furthermore, managers of medical writers are expected to understand many tenets of business interconnectivity, management principles, innovative concepts and organizational theories, finance and budget management, resource and performance management, vendor management, strategic planning, change management, metrics, and more.⁶ The AMWA Recommended Training Outline for Regulatory Writers, although acknowledging that the skills in the outline are but some of the skills and proficiencies needed for professional success and are subject to regular review and update, similarly does not distinguish business knowledge as a separate training topic and broadly covers the topics of analytical skills, self-management, people skills, and personal development across 2 primary categories that make up the competency along with a third category for document-specific training.⁷ Having a comprehensive business curriculum would benefit the writer in these circumstances toward the goal of developing a strategic mindset while learning fundamental business topics.

Realizing a value proposition that solidly complements the now-accepted medical writing competencies requires a pathway whereby medical writers can readily learn the skills needed to demonstrate leadership while also participating in decision-making activities earlier in their careers. Along with such a pathway is the need to develop the infrastructure of their departments that supports the development of business-savvy medical communicators.

The panelists of the Business of Medical Writing discussion (the authors) hope to use the momentum of the interest and enthusiasm of the medical writing community on this topic from the national conference to propel our community forward into further discussions about how business literacy can be incorporated into our training curricula and our practices and processes—and ultimately, perhaps our competency frameworks—so that it becomes an intentional element of training for all writers, enabling them to best support the needs of their organizations and businesses.

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References

1. Towles J. The business of medical writing: the small business perspective. Presented at: American Medical Writers Association Indiana Chapter conference [virtual]; April 29, 2022.
2. American Medical Writers Association (AMWA). *National Conference Brochure*. AMWA; 2021. Accessed July 03, 2022. https://cdn.ymaws.com/www.amwa.org/resource/resmgr/conference/2021/2021amwa_conf_program_june15.pdf
3. Regulatory Affairs Professional Society (RAPS). *Regulatory Competency Framework Model Concept*. RAPS; 2021.
4. Clemow DB, the Drug Information Association Medical Writing Special Interest Area Community Competency Model Working Group. *Pharmaceutical medical writing competency model*. *AMWA J*. 2011;26(2):71.
5. Clemow DB, Wagner B, Marshallsay C, et al. *Medical Writing Competency Model—section 1: functions, tasks, and activities*. *Ther Innov Regul Sci*. 2018;52(1):70-77. doi: 10.1177/2168479017721585
6. Clemow DB, Wagner B, Marshallsay C, et al. *Medical Writing Competency Model—section 2: knowledge, skills, abilities, and behaviors*. *Ther Innov Regul Sci*. 2018;52(1):78-88. doi: 10.1177/2168479017723680
7. Yih L, Alexander LL. *Recommended training outline for regulatory writers*. American Medical Writers Association (AMWA); 2020. Accessed March 3, 2023. <https://info.amwa.org/hubfs/Offers/regulatory-writer-training%20ebook/regulatory-writer-training.pdf>