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TOPICAL FEATURE

PART 2 IN A 3-PART SERIES

The Business of Medical Writing: Communication, Leadership, and Corporate Responsibility

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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, leadership, and corporate responsibility; and financial acumen will be reprised in this 3-part series. The series will also include 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 concepts earlier in the medical writing career path. This Part 2 manuscript focuses on communication, leadership, and corporate responsibility.

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.

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 theme.[1]

The topics of value proposition and business models,[2] communication, leadership, and corporate responsibility, and financial acumen 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. This Part 2 manuscript focuses on communication, leadership, and corporate responsibility.

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.

COMMUNICATION IN A BUSINESS CONTEXT

JA: ***There's so much to being a business leader. We've talked about value proposition, business models, finances;[2] another area I want to touch on is communication. Now—communication: this is our stock-in-trade, right? We should get this part. But I'm willing to bet you have all discovered that communication is a little bit different in the business context, and I wonder what kinds of communication situations you've run into and how you've used communication to help your business succeed. Maybe you've had to speak differently with potential or actual customers, employees, and collaborators, maybe even a detractor. So, how do you see communication as being an essential element of business leadership or business acumen?***

DD: It will make or break you, regardless of where you sit. That's the bedrock of what we do, and people ask you all the time as a medical writer—"So, *what* is it that you do?" If you can explain that to them clearly and communicate what you're doing, that's half the battle because you've explained what the baseline is in terms of this conversation you're having. Within teams it's the same requirement: you need to explain to the team what it is you bring to the table, why you're doing it, and what they need to know. The important thing for me and for my teams is to answer the questions before my teams ask them of the writer or the writing team—to anticipate things, to have a contingency plan in place, and to be able to communicate that to put the client (and that is the team, in my case) at ease with the sense that the writer and the writing team have been here before and can see what's coming before I can see it. If we can do that,

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MENTORING IS CRITICAL to learning how a medical writer can communicate with stakeholders who value return on investment.

it takes away a lot of the tension within the team that really doesn't need to be there. And it comes with experience, I agree, but you can communicate to the team, "This is the first time doing this kind of project; we need to learn a few things from you, but I'd like to help you with what we bring. We know how to write the document, but we have to work together." And that's OK, too, but as long as that's explained up front, people understand where everybody's coming from. Again, it's this same transparency of communication that carries the weight of the work forward in a good way.

JA: ***That "taking away the pain" that Jeanette talked about earlier.***[2]

DD: Right, as much as possible. The writers are the document development experts, and they know many things about the regulations and all the trappings around what has to take place with the document. The team members have to focus on their expertise, or the client has to focus on whatever this product is that you're contributing to; we have to help them not worry about our piece of it to the degree we can, and that's important.

JA: ***As some of you have mentioned earlier—everyone learns to write; therefore, they think they are the writer, so we may need to get them to stay in their swim lane!***

JT: I think communication is so important, too, in just being able to explain to your clients what you think the gains are going to be. The best example of this I had was when I was working in-house in a department and was in a meeting with a senior regulatory person and the president of the company, who was a typical MBA—very focused on the return on investment and [having] very bold goals for her company. They were talking about narratives and how those are done, and I made the mistake of saying, "This is the industry-standard way of doing this," and I found out later that this was a phrase that tended to make her head explode! But it took that other senior leader in regulatory leading me down the path in this meeting to say, "OK, well, I understand that, but which parts of this process can we break down—which parts do we need to stay married to, to maintain the quality, and which parts can we potentially try to be a little more bold about?" I immediately saw where she was going with it, too;...I understood that what I had said was maybe not the right thing to say. Having someone who you can observe and who can model that behavior to help you translate what you are trying to say from a medical writing standpoint into something that makes sense to someone who is interested in that return on investment is critical. Again, that's where that mentoring comes back in; and it doesn't even have to be someone within a medical writing group, it could be a senior leader in regulatory or some other adjacent function who can help navigate and model some behaviors.

BB: From a freelancer's standpoint, I think there are 3 key communication areas that freelancers need to pay most attention to, and if they do, it will really help with their success (and by that, I mean delivering their value to their clients) (Figure 1). The first is responsiveness. The only thing worse than when a client reaches out to you with a new project and they don't hear from you, is when you are in the middle of a project and the client reaches out to you and gets crickets. Nothing will instill apprehension faster than that. We're all busy and know how hard that is, but one of the things I've worked very hard at is responding almost immediately to clients, even if it's just to say, "Hey, I got your message; I'm in the middle of something, and I'll get back to you later"—just so they know I'm here and on top of things. The second thing is confidence when I'm speaking with clients—trying to speak the language of the project and the work that needs to be done so my client knows that I get it, that I understand what we are all talking about. This gives them the confidence to move past "Can they do the job?" and get into "Let's get them the information they need to get the job done." The third thing is frankness. Where the other 2 things are probably mostly of benefit to the client, this third thing is really of benefit to the freelancer. People who are on staff don't think about certain business aspects the way freelancers do, and I find myself having to explain in very lay terms why things work differently for freelancers than they do for staff people. As a quick example, I estimate projects and invoice on a project basis rather than an hourly basis. A lot of clients don't get this. I find it helps clients to understand me better when I explain to them that if a project is ultimately, let's say, $1,000 for the sake of argument, does it really matter if it takes me 10 hours or 2 hours to get to the end result, or 20 hours? It shouldn't, because the bottom line is, can it get done within the budget, and is it done properly? The better we get at what we do, [we] also get faster at it. Because there is a limit to what anyone will pay on an hourly basis for someone, it forces us to work more the better we get in order to earn the same money we made when we were less experienced. When I lay it out in those terms to clients, you can see a little lightbulb go on that they understand the dynamics involved, and I find that helps build the relationship.

JA: ***Is that the same for you, Jeanette, in your business?***

JT: Slightly different. I think historically—and I totally agree with everything Brian just said to a large extent—we do tend to go in the time and materials direction for the main reason that when you have an expanded network, you would really have to have a lot of capital behind you to be able to absorb the type of risk you would need to. Say the project gets delayed and you can't bill for a unit until 3 months from now—well, you still have to pay your people. It really depends on the individual circumstances and what type of business model makes sense. But [as] we've also been considering lately, does that make sense for some of our clients but not all of them? I think you have to have the acumen to know when to reexamine your model, and it should be done frequently to make sure that it still makes sense and is optimizing the amount of time you put into what the dollar amount actually ends up being in the business. A kind of dual approach is needed there—and the ability to be self-reflective about it.

JA: ***And look at that: you've brought in the finance with communication and business model all in one example, and you added in that really interesting factor of being able to assess risk in business. Fascinating! We have described this panel discussion in the brochure for the conference as being for midcareer writers. But afterward, I realized we don't really know when we should be talking about and teaching writers business skills. What are your thoughts about that: is midcareer the right time, or do you have a different idea?***

BB: I vote for teaching it from the very beginning.

DD: Day 1—agreed.

BB: When we're learning how to write, we should be learning economics and finance—and teaching it.

JT: I completely agree. From the freelancer perspective, one of the things I've intentionally done recently is talking about the sales funnel in our operations group (Figure 2). Again, for us, that's people coming in earlier in their career and learning the operational aspects; they may or may not aspire to be medical writers, [but] they need to understand where those touch points are with the clients, and why those things are important to that concept of operational excellence, which is our pitch. Because if they don't, we're not able to achieve that operational excellence. They also need to understand what keeps the client coming back in the sales funnel, which is the ultimate goal; you don't want to court a client once and then have them leave you—that wouldn't be time well invested. So, helping people who are coming into the department understand where they fit into it—not only once but continually—is a return on investment for [my taking] the time to talk about that.

Figure 1. Three key areas for communication for medical writers.

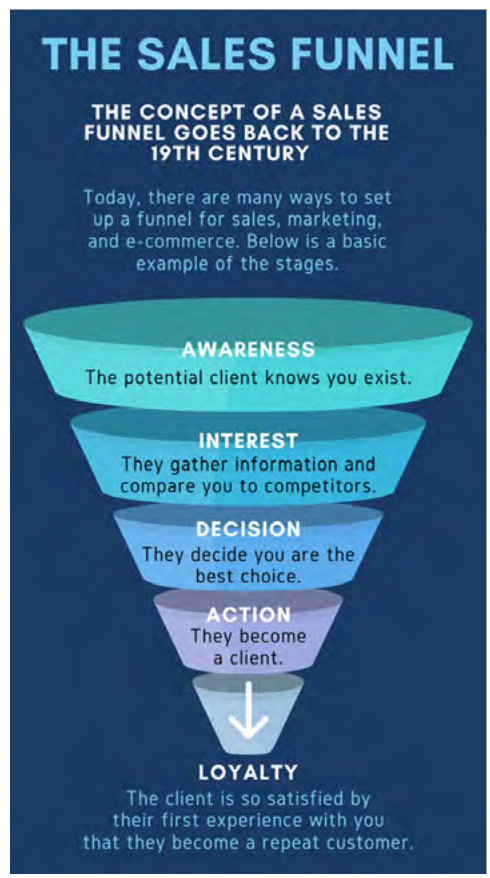

Figure 2. The sales funnel. *Adapted from: Crail C, Bottorff C. Sales funnel template and examples for 2023. Forbes Advisor, July 3, 2023.*[3]

DD: In particular—more so for the freelancer than for the in-house employee—each of us has to know what our value is in terms of what we bring to the client. And if we don't know how much we can bill, or how much we are worth, or what it is we think we can demand for what it is we are asked to do, then the whole idea of business dissolves. If you're providing something and expecting to be paid for it, by definition you're in business, like it or not; and you have to understand that if you're offering someone a product and expecting them to give you money, then all of the trappings of that understanding have to go hand-in-hand—you can't have the work product and the money be separate and not think about or not understand [the relationship of] one to the other.

JA: ***I think that, too, even in a corporate situation in which you might feel a little bit more removed, there's benefit in owning your project more, owning those cycle times, owning the quality rating of your project—to take pride in that and work toward higher standards.***

BB: Freelancers need to understand where they are in the food chain. It really comes back to this value proposition[2]; in order for everyone to be able to make money and justify costs, there has to be that "wow factor" at the end that makes everyone say, "That was really a great experience—let's do that again."

JA: ***Love it! [Because] none of us benefited from a formal program to teach us about the business aspects of medical writing, let's do a little futuristic thinking, a little pie in the sky: if you could help design a program, what would that include? What are some examples of the best ways for writers and editors and leaders in medical writing and medical communication to actually acquire business literacy—what do you think we need to put in place?***

BB: From a financial standpoint, I would recommend courses in bookkeeping, estimating, budgeting.... Whether you are a freelancer or someone who is ultimately going to run a department, you need to know all those things.

DD: You have to be an expert project manager. You have to understand time and materials and how much you can accomplish in a unit of time. [That emphasizes] the importance of the right metrics calculated and maintained routinely [to] give you data from which you can better cost your projects. To Brian's point on the project basis, if he didn't know what he could do in a unit of time, he would never be able to come up with a project estimate that was of any value; you have to understand what you can do. We have to teach the writer to understand themselves at the beginning, [to] know what they can do and say, "OK, I can write 1,000 words in 2 hours," and that means I can write a manuscript every 3 days [or whatever that happens to be], and therefore I can do 2 manuscripts per week. [Only] then you can begin to see how all these pieces add up, and that's the important part—to make the connection between the academic work we know as writing and the numeric concepts we associate with business. But the 2 things have to go together; they can't be separate.

JT: One component I might add to that—and this might surprise you—[is] emotional intelligence. One of the hinging points of my career was [when] someone handed me [Daniel Goleman's] book *Emotional Intelligence*,[4] and we read it as a group in the department. Again, this was in the context of a regulatory department, so there were lots of benefits in terms of being able to use that material if you were presenting to the [US Food and Drug Administration], but you could also use it to leverage conversations with your colleagues in other departments and bring them to a point of alignment on certain issues.... Studies have actually shown that [although] for certain skills you can't teach an old dog new tricks, emotional intelligence is not one of them; it's one you can continue working on no matter how advanced you are in your career. So, [this applies] not only for those just coming in, but also continually throughout your career, as well as in leadership [positions].

LEADERSHIP

JA: ***Another thing that I think you all have touched on at one point or another is this idea of mentoring and observing and having access to leaders that you can just observe and learn what tricks they have up their sleeves to make the business work. Do any of you have an example from your own experience of how your understanding of business has helped you lead a team through a period of significant change? We all know change is the only constant, and I'm just wondering how it has served you.***

BB: For me, an area that's a good example is negotiating. Part of my goal—and maybe that's why my particular freelance model seems to work pretty well for me—is for all the freelancers on my team to make as much money as possible and make the client say, "Wow, that was fantastic—let's do that again!" Therein lies the value for all of us. But we all come to the table with various skills, and some of them are strong, and some of them are not. One of the areas I find myself working with the freelancers on my team on is when the client pushes back on an estimate. The one thing I think I've taught to everyone on my team is to be really open and honest in our conversations with the client about where they think things went off, so we can go back and look at the way we prepared the estimate to see where we may have gone wrong. As much experience as we all have, we're not always perfect, and to have the opportunity to have clients feel open enough that they can come back and discuss money with you, which is something no one is comfortable talking about, is really great for me. Because 9.5 out of 10 times, we end up coming to an agreement that works for everyone.

JT: Obviously, one challenge that everyone had is COVID. Within our business, when it first began, we saw a lot of early-phase stuff fall off the map if it wasn't in a critical area, so one thing that I think really preserved our business model at that point was the fact that we had diversified the types of things we work on. So, we work on a little bit of late-phase stuff, a little early-phase stuff, a little in rare disease, a little in oncology; and so, because we took that approach intentionally and are looking all the time at how healthy our clients are—what are they bringing in in terms of overall income, and do we need to pursue any new business—we were able to quickly balance our portfolio once certain things started falling off at that point.

DD: I guess things are a little bit different in-house, but from a negotiation standpoint and an emotional intelligence standpoint, [there is] absolutely the same obligation on the part of the writer to really know how to speak with the team, anticipate things, and really instill trust and confidence. COVID changed our work environment, as it did for almost everyone, and we all ended up working remotely, which is different than the in-house team members were accustomed to by and large. As a manager, you have to be resilient and [amplify] that resiliency to your staff and get them to remain motivated in the right ways; and oftentimes that comes down to a lot of interpersonal interactions—even more so from a 1:1 perspective than you may do otherwise in normal business because we were all under these unusual pressures we had never faced before. Making an open acknowledgment that we are all in this new world together was important for everyone to understand and say, "Look, whatever this is, we'll get through it one way or another, but we have to keep our eye on the work and give us some focus and a sense of purpose at the same time." I think that really carried a lot of people forward in the right way.... At the end of the day, we are still people.

CORPORATE RESPONSIBILITY

JA: ***I want to pull a little bit on this thread of corporate responsibility.[2] How does that fit into your role as business leaders? For example, Dom, I know that where you work, the company has a big investment in corporate responsibility, to the point where they give drugs away for free sometimes. Do you see that play out in your department?***

DD: Yes, because at least from the leadership standpoint, many of my colleagues are committed to medical writing, and they understand what the field is about. And that's really a unique component, in that having that breadth of knowledge about what medical writing is and what it takes to do it allows us to focus on the people in our teams and try as we can to develop them to their fullest potential. We have a responsibility to the people on the one hand, but the responsibility to society at large comes through at the end of the day when we bring the products through and market those drugs based on the filings we support. So, looking at all of these integrated pieces really allows us to contribute to that, and being at Merck has allowed us to be part of that.

JA: ***Others—comments on that piece about corporate responsibility?***

JT: I always like to say profit and progress are not mutually exclusive. So, in continuing our business, making sure it is profitable, and doing all of the things a responsible business owner can do, I think there are opportunities for the team to get involved in things they care about. As an example, this summer we ran an internship for the first time, [which both] afforded us the potential to expand the available resource pool to medical writing in general [and offered] something that wasn't really out there for this particular group of individuals. It was really a pilot for us, so we... are going to keep working on that [using our first intern's feedback]; everyone who was involved with that process was really energized by it, too, and that's something that is easy to forget sometimes. But it's something we really play close to the heart here because we have a particular viewpoint as a disability-owned business in terms of some of the challenges we have faced over time in industry, and we want to use that experience to make the pathways positive for anyone who does want to enter the field from any walk of life.

JA: ***Music to my ears! We have an internship program and an apprenticeship program in my department.***

BB: My company is not large enough to have an internship program, so I do a lot of mentoring. It's important to me to do that as a way of giving back to the industry I'm in and giving back to the world that I work in and live in, to help bring people up to that level of experience and expertise that make them someone I could bring onto my team. But unlike my colleague's groups in which you have a certain amount of work to do and need to bring people in to do it, my company doesn't have to grow to bring in people to do work; I'd rather not take work that we're not qualified and do not have the best people to do, so I'm in a position to be able to flex that in the opposite direction.

JA: ***I think we do a little bit of both, right Dom?***

DD: At times, yes. We try to provide balance for our people, and we try to move the work around in a way that's manageable for all involved. It doesn't always work out the way we'd like it to, but again, nothing is perfect.

JA: ***In terms of taking on new work, though, we are similar in philosophy, Brian, in that we don't just take on work for the sake of taking on work. We take on work for which we feel we are qualified and to which we feel we will really bring added value.***

BB: That really is the bottom line. The worst circumstance anyone could find themselves in professionally is to realize down the line they should have said no.

JT: Yeah, absolutely, and I would say the converse is also true. Some of the best experiences I've had professionally have been when I was afraid to say yes. I was offered a promotion, and I had a 9-month-old. Well, that was a tough one, but I said yes, and I was better in the long run for it as hard as it was. But weighing those options is important no matter what you decide.

BB: And that is how we stretch ourselves—you're exactly right, Jeanette. If we don't say yes to things that we're not positive we can do, then we never learn how to do them. We never prove to ourselves we can do them. I guess it's being sensitive to where that magical line is.

DD: But knowing who to ask if you have questions along the way also helps, right Brian?

BB: Oh yes, indeed, Dom—absolutely. Yes—someone you can turn to, to get that leg up when you need it.

LOOKING TOWARD THE FUTURE

In Part 1 of this 3-part series, the authors discussed how 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."[1] The authors concluded that having a comprehensive business curriculum, namely 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, would benefit the writer toward the goal of developing a strategic mindset while learning fundamental business topics.[2]

One of the key functions of leaders is to execute on a business's strategic plan, which outlines corporate goals that are intended to "trickle down" to departments and individuals.[5] Well-stated goals might even ensure the goal is in a specific, measurable, achievable, relevant, and time-based (SMART) format—but, typically, a strategic plan only tells you *what* the goal is (eg, file New Drug Application [NDA] for Drug XYZ in Q1 of 2023") and occasionally the metric it will be measured by (eg, authorization of XYZ in the US by start of Q2 2023). The plans most often do not cover the how or the why of arriving at that particular outcome. If you are a leader focusing intensely on doing your best to meet the company's goals, you could still be missing a very important part of the equation. Here is an example: as a leader, you looked at the above corporate goal for filing the Drug XYZ NDA, and you did your diligence and determined you need to hire a new vendor to be able to complete the work. You did not realize that procurement has been given a directive to increase diversity and inclusion by trying to onboard small and diverse vendors, so your vendor selection and qualification process became delayed and could now comprise a risk to the submission deadline. This background discussion was not part of the corporate goal but became critical toward understanding how the company wanted the goal met and wanted business to be done to optimize corporate responsibility.

After all, learning to communicate about business—and, most importantly, how to listen to what is important to business leaders—is currently not a distinct component of medical writing education.[6-8] As previously discussed,[2] the AMWA Recommended Training Outline for Regulatory Writers[6] acknowledges that the skills in the outline are only some of the skills and proficiencies needed for professional success but does not distinguish business knowledge as a separate training topic, although it does note that "soft skills are crucial for working efficiently, gaining trust, communicating and collaborating effectively with colleagues, and achieving personal and company goals." The outline also highlights leading without authority, influencing and persuading, and negotiation, which are some of the skills medical writing leaders need to acquire, but applying these skills in the day-to-day with teams on documents and applying them to a management audience are different endeavors. Exactly how these skills can be acquired and understood as early as possible in medical writers' careers remains our fundamental challenge.

At the end of the day, whether we are the CEO of a medical writing group within a corporation, of our own corporation, or of our own freelance business, we all work for a company, and a company must have a way of doing, or an ethos, that guides its daily work. It is the responsibility of leadership to build a bridge and ensure not only that a company's goals are met but also that its ethos is incorporated into everyday work in an authentic way to make certain that the outcomes will be positive and sustained over the long term. This means that medical writers in leadership (or pondering leading) should strive to understand the importance of corporate responsibility and actively seek to connect their personal ethos with that of the company, as well as to communicate that outward to their medical writing teams and customers.

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