

EDITOR-AT-LARGE

A Shoe in the Door: Regulatory Writing Internships for Promoting Diversity and Building the Talent Pool

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ABSTRACT

Demand for qualified medical writers is high and expected to continue to grow. With competition for experienced writers getting fierce, the need for alternative pools of talent has become evident. This article describes a pilot internship program developed at an independent clinical and regulatory consulting company designed to allow an alternate path for entry into the field of medical writing and to foster and retain talent. The internship will provide novice writers with relevant training, connections, and job experience to aid in attaining a position in regulatory writing. We discuss the challenges and opportunities discovered during the inaugural internship year and provide lessons for developing an internship program.

Demand for qualified medical writers is high and expected to continue to grow, with the global medical writing market expected to reach 7.7 billion US dollars by 2027.¹ This market growth is driven in part by increasing investments in research and development by pharmaceutical companies and the rise in contract research organization outsourcing.¹ Despite the demand for medical writers, there are few degree or professional development programs that prepare students directly for medical writing. Existing training programs comprise a combination of degree and certificate programs and include the American Medical Writers Association (AMWA)'s Essential Skills Certificate program, the University of California San Diego Extension's medical writing certificate program, and the University of Chicago's medical writing and editing certificate program. Although these programs are useful for building technical knowledge, they often do not provide students with training in the soft skills or practical skills necessary for day-to-day work as a medical writer, including project management, professional communication, emotional intelligence, time management, and conflict resolution (Figure 1).

Medical writing and the biotechnology industry generally have been experiencing a significant degree of staff turnover as part of the “Great Resignation” phenomenon that has followed the economic turmoil of the COVID-19 pandemic.² This competition for top talent, combined with significant growth, has left the biotechnology industry looking for ways to increase interest in the field, create alternate tracks for entry, and retain talented employees. These include mentoring college students interested in science, technology, engineering, and mathematics careers, hiring

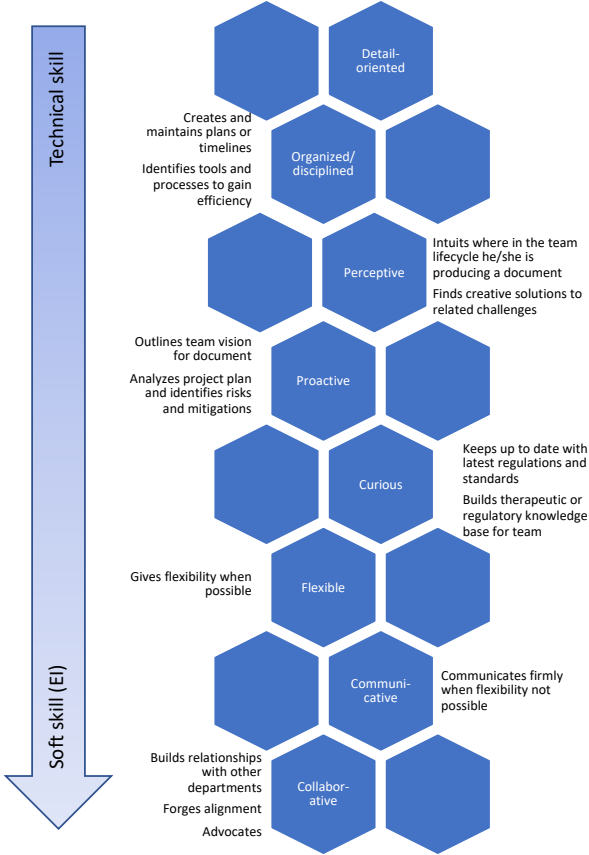


Figure 1. Key attributes of successful medical writers. Figure previously presented at AMWA New England Brunch Roundtable Meeting, March 21, 2021.

foreign-born talent, and developing a robust corporate culture of inclusion.³

Many job positions in medical writing require multiple years of industry experience. A search of job postings on April 26, 2022, on Indeed.com for entry-level medical writing positions found that 14 of the first 15 listings required either an advanced degree (master's or above) or more than 1 year experience; 7 of 15 required both. One job listing did not specify experience requirements.

As is true for other medical writers in the field who are advanced in their careers, the senior leaders in our consultancy benefited from colleagues who were willing to provide mentoring early in their careers, which has engendered a sense of corporate responsibility in contributing to the development of the next generation of medical writers. Thus, Synterex has developed a medical writing internship program to foster new professionals and help medical writers enter the field of regulatory medical writing.

Synterex partnered with a local agency promoting engagement in the life sciences for Massachusetts residents to create an in-house medical writing internship. This program provides sponsorship for 2 students from local colleges and universities. Two additional students may be sponsored if chosen from an associate degree program or from historically Black colleges and universities (HBCUs).

Our findings from the first year of the internship program indicated that the internship provided a potential pipeline for talent acquisition and retention. We hope that this outline of our experience may serve as a base model for implementation of an internship program for companies of any size considering starting a program and will lower the barriers for entry into the field for medical writers, in particular those from diverse backgrounds and historically disadvantaged communities.

METHODS

In early 2021, our team observed that there was a concurrent increase in requests from associates of staff and consultants for mentoring and tips on how to enter the medical writing field, a higher demand for medical writing resources, and fewer contract medical writing resources available for ad hoc projects. Although historically we had not hired many entry-level medical writers due to the fast pace of the work and lack of demand from clients for medical writers with less than 5 years of experience, we began thinking of ways we could expand the medical writing talent pool in the long-term to eventually align client demand with interest from entry-level potential candidates.

In May of 2021, our executive leadership team initiated development of an internship program. The team discussed goals and gathered requirements for the internship program, including

- The scope of the program: did we want the internship to be focused on just medical writing, or would we open it up to other business functions?
- The geography of the program: did we want a national search, or did we want to anchor the program near headquarters?
- The logistics of the program: did we want a program that had a database of candidates we could search, or did we want applications to come directly to us to vet? Did we want to consider only students studying medical writing, or would we consider students studying in adjacent scientific fields?

Ultimately, we decided that we wanted at least one of the intern roles to be open to IT and business operations in addition to medical writing because we felt providing opportunities on those sides of the business would be equally beneficial for potential internship candidates as well as being areas of the clinical trial talent pool that also need development and that may have potential employment needs in our company in the future. We also decided to anchor the internship program at our headquarters in Massachusetts, given the high concentration of our clients and staff in the state and the potential for in-person interaction (pandemic permitting) within our primarily virtual workforce. In addition, given that we wanted to ensure our first internship program would be successful and manageable in scope because we are a company comprised largely of working subject matter experts with lean administrative/operational staff to vet applications, we opted for a program that had an existing database of interns we could search. Although this may present some limitations because the database is finite and not tailored to our core services, we felt this would be more manageable for us in the timeframe given to start up the internship program. Lastly, for medical writing interns, we opted to search for students in any scientific studies and try to identify writing-related or clinical trial-related experience or interests on their profiles, rather than limit our search to only medical writing-related applicants, as we did not want to bias our resourcing pool to those students who already had exposure to medical writing as a career choice.

In selecting an institution to partner with for internships, we wanted to select one that would be consistent with our hiring goals as a woman-owned and disability-owned

business in terms of making sure that our workforce represents the people who will ultimately receive the medicines we work on. Massachusetts Life Science Center's (MLSC) Internship Challenge program appealed to our mission because this program provides sponsorship of up to \$8,160 (\$17 per hour for up to 12 weeks) for 2 students from local colleges and universities as well as 2 additional students if chosen from an associate degree program or from HBCUs.

Massachusetts, where our headquarters is, has a particularly robust life science industry that provided us with multiple partner organizations to consider. These partnership opportunities may vary in areas with less biomedical infrastructure.

A full-time employee was identified to act as the Internship Coordinator. This person acted as the main contact for the intern to answer questions and direct programming. In our case, a junior staff member was chosen as someone who was able to relate to recent entry into the field. This team member also had more availability for ad hoc meetings, questions, and hands-on direction.

The Internship Coordinator then applied to the MLSC Internship Challenge program and searched in their database for intern candidates who would fit our consultancy's needs (educational background in the life sciences or information technology, career goals in line with our areas of expertise, experience with relevant software systems, etc). Any student who meets the MLSC program requirements of Massachusetts residency and enrollment in an accredited college or university in Massachusetts or at an HBCU can submit a resume and cover letter to the program database for companies to search. Six potential applicants were identified for each internship, and the executive team reviewed their application materials. None of the medical writing internship candidates were from associate degree programs. Two of the IT internship candidates were from associate degree programs. The Internship Coordinator reached out to one applicant for the medical writing position and 4 applicants for the IT position and signed formal agreements with the medical writing intern who confirmed her interest in the program. None of the IT applicants contacted chose to pursue the internship opportunity.

A single intern was hired for our pilot internship season. The intern was selected for her interest in pursuing regulatory writing professionally and her educational background in a regulatory affairs master's program. She was assigned to work 40 hours per week for the 12-week period with pay sponsored by the MLSC internship program.

The executive leadership team worked with the Internship Coordinator to develop a curriculum that

involved meetings and shadowing sessions to pair the intern with team members in various departments. This allowed the intern exposure to various facets of the business (Figure 2).

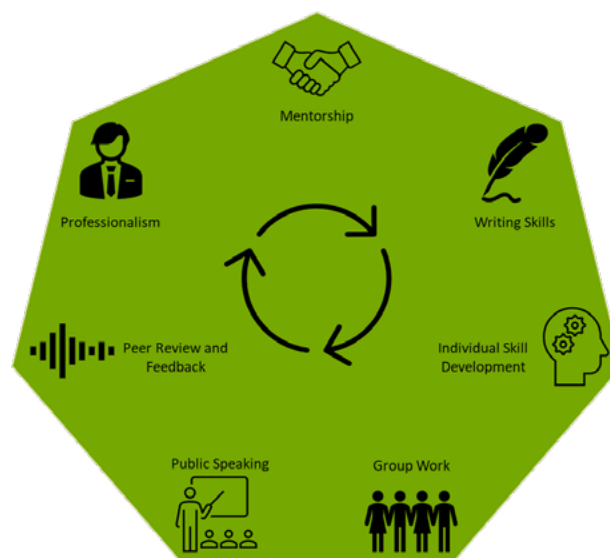


Figure 2. Components of the pilot internship.

We also agreed on critical success factors for the internship, including

- exposure to the concept of peer review and feedback,
- review and tips on developing their CVs for future opportunities,
- practicing summarizing medical content (eg, a regulatory guidance of interest),
- practicing public speaking (eg, discuss a science-related webinar they attended), and
- general work tips and day-to-day expectations for how to work and communicate in an office environment.

The Internship Coordinator set up an orientation to convey these success factors, our company values and organizational structure, and expectations to the intern. The Internship Coordinator also set up a Microsoft Teams channel in which the extended team could create a queue of projects that would be both appropriate for the intern to work on and meaningful in terms of gaining experience. We also sent a company-wide email introducing the intern so that the wider team could get to know and connect with her.

The intern was invited to weekly business operations meetings and assigned various internally facing projects such as the development of a company style guide. The intern was also assigned to externally facing projects with the supervision of a staff medical writer including social

media blog posts on health-related projects. These projects allowed the intern to gain experience with professional writing tools and reference citation management software.

Although the intern did not work directly on client materials, she was involved as an observer in several active documents with Advance permission from the client and an active nondisclosure agreement. This allowed the intern to experience the collaborative authoring process and comment resolution meetings. After the meetings, the intern met with the Internship Coordinator to discuss professional communication and conflict resolution tools.

At the beginning of the internship, an exit interview was put on the calendar with the intern, as well as prospective regular meetings with select other team members to discuss specific business functions outside of the medical writing function. In addition, our own impressions and reflections on the internship were discussed at a regular internal meeting at the end of the internship period. The intern completed training in Good Clinical Practice and our company standard operating procedures. Our intern provided feedback at her exit interview on the aspects of the program that worked and things that could have been done better. This feedback is reflected in the lessons learned section below.

LESSONS LEARNED

Consider Work Environment

Our company is a fully remote workplace, with team members spread across the United States. This remote set-up may be an advantage for interns from areas without a developed biotechnology industry or for individuals without reliable transportation to and from work. The remote workplace can present a challenge, however, as the intern will not organically get to meet the team in the course of their work, and at this juncture in their career development they most likely do not have existing in-office experience to draw from to make their own connections. We had to go out of our way to encourage team members to interact with the intern and to include her in ongoing projects.

When hiring interns for remote work, recognize that in order to participate fully, interns may need to be provided with laptops and other tools to access company resources.

Setting Expectations

It is important that both the intern and the company set realistic expectations at the beginning of the internship both in terms of requirements and availability. Although our intern had 40 hours of availability in the week to dedicate to the internship program, it was understood and agreed at the outset that she also had a part-time job and a capstone

project that cut into some of our regular business hours. This arrangement may not be feasible for all companies and all individuals, as it puts the onus on the intern to communicate their availability and the hosting company to work around it.

Have a frank conversation with the intern prior to hiring on the expected hours and commitment that will be required in order to provide real, meaningful work for the company. In retrospect, we decided to make a formal job description for the internship position to state these expectations in writing. Recognize that if your internship requires full-time hours but does not provide a living wage or benefits, many individuals will need to maintain outside employment. Restricting outside concurrent employment or expecting interns to work for experience rather than pay will limit applicants to only those privileged enough to be supported by family or external means. The more you are able to invest in your intern, the more they will be able to invest in your company.

Provide Depth and Breadth in Programming

We found success with assigning the intern a mix of group work and independent projects. This allowed her to stay busy while allowing for feedback from other team members on rotations through each department. Having a long list of possible tasks, longer than you think you will need, ensures that the intern has other work to focus on if the Internship Coordinator is not immediately available to direct the intern to a new project.

Try to identify independent, low-pressure tasks that are conducive to skill-building. We assigned our intern to writing blog-style health posts for our social media site. We challenged her to write the piece for different audiences (graduate level peers, high school students, children) and to bring the reading level of her work within range for each group. These assignments also allowed her to also practice using citation management software in a low-risk environment before applying those skills in a client-facing document during collaborative authoring.

A limitation of our program was having only one intern in our pilot program. In the future, we hope to host a cohort of interns at the same time. This would allow for more group work and collaborative learning between interns of similar skill levels.

Provide Resources for Learning

In order to facilitate independent work from your intern, curate resources for self-guided learning. Note that many of these resources already exist and do not need to be created in-house. There is a wealth of tutorial videos available on

the Internet for the different software systems typically used in medical writing. Online training modules are available through AMWA and the DIA (see Additional Resources)

Additional Resources

DIA Learning Solutions: <https://www.diaglobal.org/en/learning-solutions>

AMWA Courses: <https://info.amwa.org/medical-communication-essential-skills-for-success>

Provide regulatory guidance documents for the intern to review. If you can show a redacted example completed document similar to the one under development, this will allow the intern to build context for the current assignment. Consider building a library (analogue or digital) for your intern and other staff members to peruse. Try sending your intern on an Internet search for additional resources on a certain topic; you may be surprised at what useful tools they are able to bring back to the team.

Allow Time for Feedback and Questions

After periods of independent and group work, it is important to allow the intern time to digest and process the learning experience. We established a standing weekly meeting between the intern and the Internship Coordinator to discuss recent work. We also planned weekly meetings with each department to allow for broader exposure to the company. Given how busy team members are, it is strongly recommended to set these meetings up in advance so that programming for the intern can be prioritized. We were limited in the quick development of our internship program, and more advanced planning would have allowed for a more regular meeting schedule.

Not All Assignments Have to be Directly Related to Medical Writing

Medical writers often wear many hats in the course of their normal work. Foster these adjacent skills in your interns as well. Provide time to discuss soft skills such as professional development, time management, and remote working strategies. Interns may have little experience with professional workplaces. Recognize that you may need to discuss and model professionalism in written and verbal communication as well as business etiquette. This may take the form of role-playing professional communication and conflict resolution scenarios. Consider offering training in emotional intelligence courses that will serve the intern in their future career, regardless of what they pursue.

Consider Future Benefit to the Intern

Try to provide the intern with experiences that will not only benefit the company but will benefit the intern going forward. This may take the form of resume-building experiences such as authorship or editing credit, industry connections for future professional development opportunities, or, more tangibly, a position within your company if possible. We had a very positive experience with our first intern, and we were able to hire her into a part-time project management position while she completed her graduate degree. She now works for us as a full-time employee. She has been able to smoothly transition into these new roles due to her previous experience during her internship and was able to make an immediate impact on our team. If you are not able to hire your intern, consider remaining in contact so that you can continue to provide mentorship, advice, or job references after the internship is complete.

PLANS FOR FUTURE INTERNSHIP DEVELOPMENT

We found our pilot internship program a resounding success. We are looking to expand the program in 2022 to take on multiple medical writing interns and have developed a pilot information technology internship position as well. We are looking to partner with other local life science outreach programs to reach a more diverse student base of first-generation college students. We also hope to partner directly with local colleges and universities to identify interested students. Many students plan their summer and semester experiences months in advance, and it is important to get your internship information to them early if you would like to be considered.

In the future, we would like to expand outside of our local area to partner with HBCUs, tribal organizations, and international student groups to cast a wider net for our internship candidates and provide opportunities for entry into medical writing to communities that have previously been under-represented.

Building on the success of our internship program, we are also developing a fellowship program to function like a medical writing apprenticeship. This program would be longer-term, a full year as compared with the 12-week internship. The fellowship is targeted to individuals who have completed an advanced degree in life sciences within the previous 2 years. This program provides a full-time, benefited fellowship position for individuals who are committed to entering the medical writing profession but do not have relevant job experience for entry-level positions.

CONCLUSIONS

Given demand for experienced medical writers and the dearth of qualified applicants, we have presented a basic model that small- to medium-size companies can customize to develop an in-house training and internship program to attract and retain medical writing talent from a diverse background.

Author declaration and disclosures: *The authors note no commercial associations that may pose a conflict of interest in relation to this article.*

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