

AROUND THE CAREER BLOCK

Medical Writing Academy: Fostering Cross-Functional Expertise and Professional Growth

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ABSTRACT

Medical writing is a complex multidisciplinary field that requires scientific knowledge, writing skills, and regulatory understanding. Recognizing the transferable skills that exist among diverse medical writing roles, a leading clinical research organization developed an internal training academy. The goal of the initiative was to enhance skills, support career development, and build flexible organizational capacity by providing robust interdisciplinary training and learning for medical writers, capitalizing on transferable skills, and fostering cross-functional networking.

The Medical Writing Academy was established in 2024, offering programs across 4 departments specializing in medical communication, regulatory affairs, medical writing, and safety medical writing. The flagship intermediate-level program was rolled out to in-house medical writers with 3 to 5 years of experience.

The training curriculum combined self-paced learning, offering participants flexibility with study, and periodic meetings led by program leads, ensuring ongoing support and guidance. The program blended 3 key developmental principles: education, exposure, and experience. Spanning 6 to 8 weeks, the curriculum covered key workstreams, featuring customized assignments to enhance writing skills and understanding of industry regulations and guidelines.

Providing medical writers insight into different aspects of medical writing and typical workdays across functions, the inaugural program broadened expertise and supported cross-functional understanding. All 34 participants successfully completed the training, reporting enhanced skills, knowledge, and confidence in their roles. The Academy helped writers identify transferable skills across different writing functions, building a versatile talent pool and improving career prospects.

INTRODUCTION

In the rapidly evolving landscape of health care and pharmaceuticals, medical writing stands as a cornerstone of effective scientific communication. This multifaceted discipline demands a unique synthesis of scientific acumen, writing expertise, and regulatory comprehension. As the vital link between complex scientific data and diverse stakeholders—including health care professionals, regulatory bodies, and patients—medical writers play a pivotal role in translating and disseminating accurate, accessible medical information. The exponential growth in demand for skilled medical writers reflects the growing complexity of the health care and pharmaceutical industries.¹ However, the increasingly intricate nature and range in the scope of medical writing roles pose significant challenges for both newcomers and experienced professionals in the field.²

Cross-functional training enables medical writers to hone their abilities in conveying scientifically precise, well-structured, and regulatory-compliant information.³ This skillset contributes to the advancement of health care knowledge and, thereby, improves patient outcomes.⁴

Consequently, fostering a multidisciplinary approach to writing expertise empowers writers to transition between functions, ensuring adaptability to shifting industry demands and effective communication across contexts and audiences.

As a leading clinical research organization with robust training programs and over 3 decades of experience in medical writing, Parexel recognized an opportunity to enhance medical writer training across diverse functions. This stemmed from 2 key observations. First, medical writers were increasingly expressing interest in broader learning and development opportunities. Second, although medical writers possess transferable skills, there was no formal structured program to apply these skills to different well-established medical writing disciplines within the

organization. To address this need to nurture talent, the 4 departments specializing in medical communication, regulatory affairs, medical writing, and safety medical writing collaborated to design and formalize the Medical Writing Academy.

The primary goals of initiating the Medical Writing Academy were 3-fold:

1. Broaden medical writing skills: provide medical writers with the knowledge and skills to competently support medical writing functions.
2. Strengthen career development: provide new avenues for professional growth and diversify networking opportunities.
3. Build up organizational capacity: develop a versatile workforce capable of meeting diverse client and regulatory needs.

The inception of this initiative was not just a response to internal needs but also a recognition of larger industry-wide challenges. By addressing this gap, the Academy aimed to set a new standard for medical writing training, potentially supporting the broader medical writing community.

THE MEDICAL WRITING ACADEMY

The Medical Writing Academy launch involved extensive preparatory work. A cross-functional global team from the United States, the United Kingdom, Ireland, and India was formed across 4 medical writing departments. This team collaborated to review and update existing curricula and engage with the organization's training experts. The thorough groundwork included structuring discussions, creating a dedicated Academy webpage, and producing informative videos on the Academy's mission and a day in the life of a medical writer from each discipline. The team carefully designed the program framework and developed an outreach strategy to ensure it met the diverse needs of medical writers across the organization.

The launch of the global Medical Writing Academy in 2024 marked a significant milestone in the organization's commitment to professional development in the field of medical writing. The training program focused on 3 key principles for effective learning: education, exposure, and experience.⁵ Within the curriculum, writers were provided with foundational knowledge, exposure to industry best practices, and opportunities to apply their skills in real-world settings. This structure ensured that participants would be exposed to the full spectrum of medical writing functions, fostering a holistic understanding of the field.

The Program Framework

The Medical Writing Academy's inaugural program was at

the intermediate level, designed for in-house medical writers with 3 to 5 years of experience. Spanning 6 to 8 weeks, the part-time curriculum blended self-paced learning with professional guidance. Participants dedicated approximately 10 to 15 hours to the coursework hosted on the Learning Management System and an average of 8 to 10 hours to online discussions with line managers, program leads, and administrative tasks. This duration was carefully chosen to allow for in-depth exploration of topics while accommodating ongoing work responsibilities.

The program was meticulously crafted to cover key workstreams across 4 medical writing functions. Its structure comprised 4 main steps, each designed to provide a holistic understanding of the medical writing landscape while developing specific skills relevant to each function.

Step 1: The Medical Writing Academy Overview

A precourse briefing was provided to interested medical writers through newsletters and a Medical Writing Academy webpage offering a detailed overview of the course and each medical writing specialty. This session outlined the course objectives, structure, and expectations.

A unique feature of this step was the video series, *A Day in the Life of a Medical Writer*. These role-specific videos were available on the Academy webpage. They offered participants a glimpse into the daily responsibilities and challenges faced by medical writers in different functions, helping them identify areas of interest and potential career paths. Along with the videos, participants were also given a topline overview of each medical writing function (Figure 1).

Step 2: Invitation and Selection Process

Managers and team leaders were asked to nominate medical writers who demonstrated potential for growth and cross-functional development. The potential candidates were introduced to the Medical Writing Academy via the webpage and given the opportunity to select their preferred top functions for further development. This approach ensured that the program would benefit those most likely to apply the learning and benefit from the knowledge gained, maximizing the impact of the training investment. Shortlisted candidates were then given orientation by program leads. This briefing covered an overview of the respective functions, the scheduled curriculum, and program expectations, preparing participants for the training ahead.

Step 3: Fundamentals of Drug Development and Clinical Research

Before specific functional training, the participants were provided with a brief 2-hour refresher on a few topics such as concepts of drug development, drug development process,

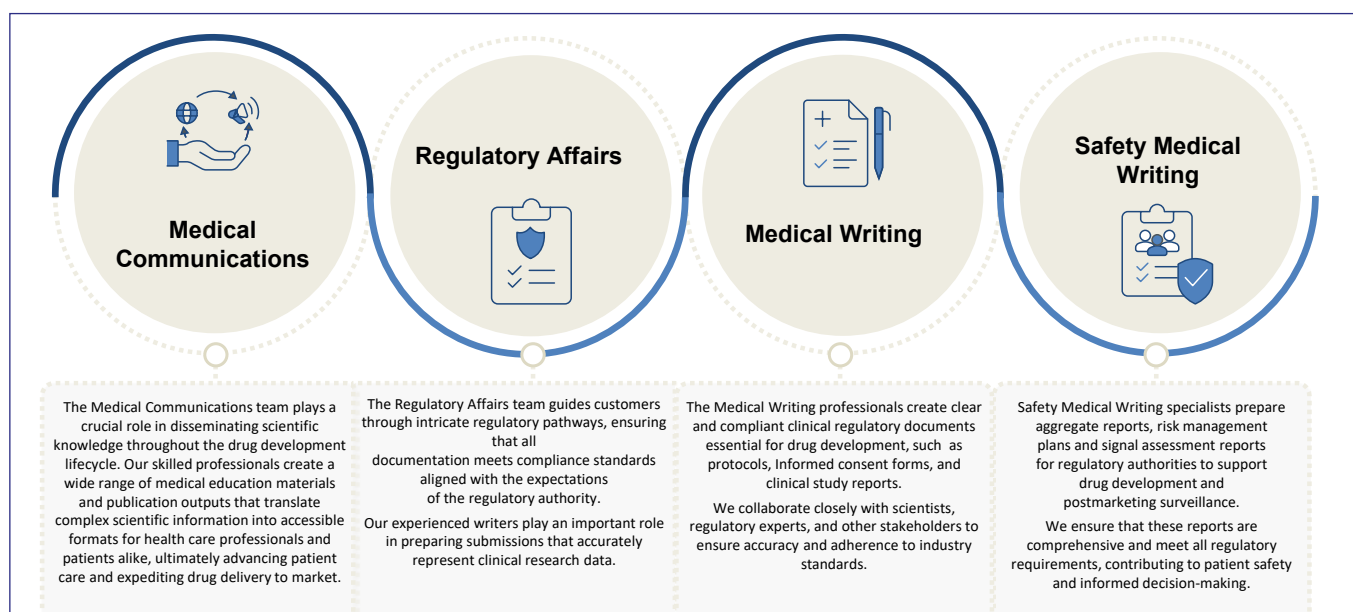


Figure 1. Overview of the Medical Writing Functions. *ICF, informed consent form.*

clinical research, and fundamentals of regulatory writing.

Step 4: Medical Writing Functional Trainings

This step involved enrollment in a course curriculum for the selected medical writing discipline (Table 1). In each curriculum, the Academy employed a blended learning approach, leveraging multiple instructional strategies.

- Self-paced online modules: hosted on the Learning Management System, these allowed participants to acquire foundational knowledge at their own pace. This format provided flexibility for participants to complete the training at their convenience, accommodating various time zones and work schedules.
- Expert-led sessions: prerecorded training sessions by subject matter experts (SMEs) provided in-depth insights into specialized topics.
- Interactive learning materials: self-reading materials supported by interactive PowerPoint slides enhanced engagement and comprehension.
- Regular check-ins: program leads hosted periodic online meetings throughout the program, providing participants with opportunities to ask questions and discuss their progress.
- Final assessment and certification: upon

Table 1. Training Curriculum Across Medical Writing Functions

Medical Communications	Regulatory Affairs	Medical Writing	Safety Medical Writing
• Publication Programs: Regulations and GPP • Practical Guide to Writing Congress Abstracts • Practical Guide to Writing Congress Posters • Practical Guide to Writing Congress Oral Presentations • How to Successfully Publish a Medical Paper • Medical Education 101 • Statistical Training for Medical Writers	• Overview of Key Deliverables in Regulatory • FDA/EMA Templates • Basics of Literature Search • Clinical Writing: Telling the Story • CTD • General Investigational Plan • FDA Diversity Plans • Biostatistics for Medical Writing • Assessor's Viewpoint • Clinical Writing—Considerations for Oncology Drugs	• Overview of Project Management & Good Medical Writing Practices • Overview of Clinical Trial Disclosure • Overview of Patient Narratives • Overview of ICFs • Overview of Protocols • Overview of CSRs • Overview of CSR Appendices	• Introduction to Aggregates and Ad Hoc Reports • Periodic Safety Update Report • ICH E2C R2-PBRER • ICH E2F: Development Safety Update Report • Overview of Signal Detection • Overview of Signal Management • Signal Management • Literature: Triage for Signal Detection, Management, and PBRER • Case Analysis • Risk Management Systems

CSR, clinical study report; CTD, common technical documents; EMA, European Medicines Agency; FDA, Food and Drug Administration; GPP, Good Publications Practice; ICF, informed consent form; ICH, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; PBRER, Periodic Benefit-Risk Evaluation Report.

completion of the training modules, participants underwent a multiple-choice assessment encompassing 15 to 20 questions with a requirement of 80% correct answers to successfully pass the training. Successful candidates were awarded a certification recognizing their achievement in cross-specialty medical writing expertise.

Overall, the program offered learning exposure through an overview of different functions, insights into various types of deliverables within the domain, and the necessary skills required. It also included networking opportunities with diverse functional teams. The learning experience was provided through an instruction design-led curriculum featuring relevant case studies and practical opportunities. The training assignments focused on various document types such as clinical study reports, protocols, safety narratives, case assessments, Periodic Benefit-Risk Evaluation Reports, and clinical trial publications, culminating in an overall assessment. These assignments and the training material allowed participants to apply their skills in supporting different functions as needed.

This holistic approach ensured a thorough understanding of each function's specific requirements while maintaining flexibility for participants' schedules.

THE PROGRAM OUTCOME

From a pool of 82 candidates nominated by their line managers, 34 medical writers with 3 to 5 years of experience in their discipline were selected for the intermediate-level program. Others were not selected due to group size limitations, experience level requirements, and relevance of current experience in role to the curriculum. These participants from different locations (China, India, Germany, South Africa, Spain, the United Kingdom, and the United States) were distributed across 4 medical writing functions based on their top preferences and seat availability. The inaugural run of the Medical Writing Academy's intermediate-level program saw all 34 participants achieve an average score of 91% and successfully complete the assigned training.

Participant Benefits

The program's success was evident in the positive feedback

from participants (Figure 2). Key benefits reported included

- **Enhanced medical writing skills:** participants noted significant improvements in their writing proficiency, particularly in areas outside their primary specialties.
- **Broadened knowledge base:** the cross-specialty approach provided participants with a comprehensive understanding of the medical writing landscape. This broader perspective enabled them to see connections between different areas of medical writing, fostering valuable insights into their work.
- **Increased confidence:** armed with new knowledge and skills, participants reported feeling more confident in their roles. This self-assurance paved the path for their professional development with the willingness to take on more challenging projects. Many reported feeling more confident in tackling diverse writing tasks, from regulatory documents to patient education materials.
- **Career development:** several participants noted that the program opened up their awareness of new career possibilities within medical writing. Some even initiated transitions to different specialties based on their newfound interests and skills.
- **Networking opportunities:** the program facilitated connections between medical writers from different departments, fostering a sense of community and encouraging knowledge-sharing across functions.

The practical benefits of this cross-functional training were demonstrated when 5 participants from the Medical Writing department, who had undergone training in safety

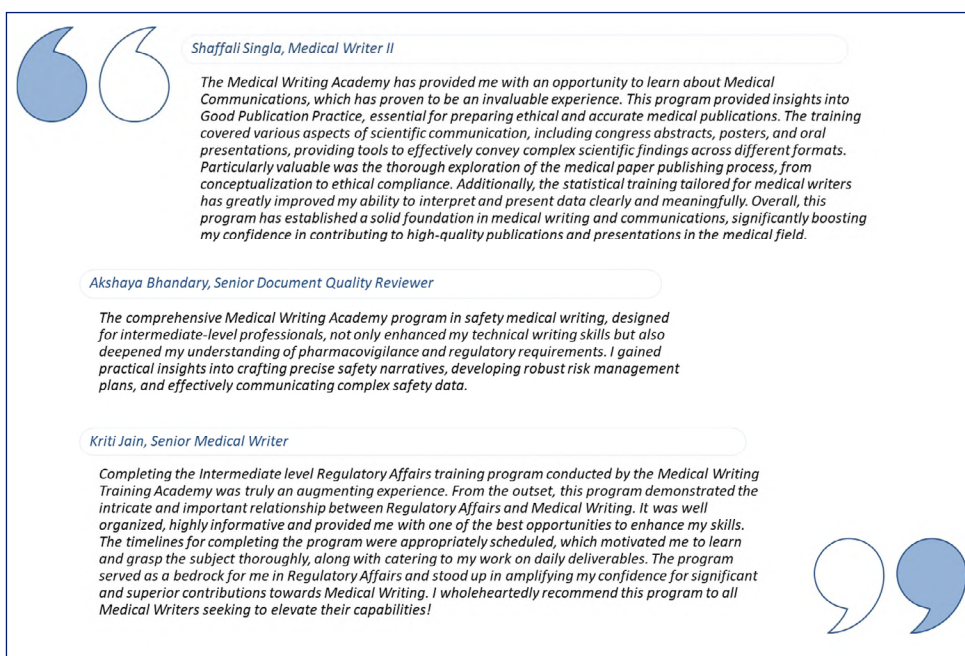


Figure 2. Participants' Testimonials.

medical writing, were able to provide crucial ad hoc support for an urgent Food and Drug Administration request involving high case volumes. They efficiently assessed nearly 800 cases with satisfactory quality showcasing the program's immediate value in meeting critical business needs and enhancing operational flexibility.

To improve on the inaugural intermediate-level program, feedback was solicited on the course curriculum and overall experience (Table 2). Building on the success and valuable suggestions received from participants, the Medical Writing Academy will be evolved over time. There are currently plans to expand into an additional curriculum appropriate for basic-level and advanced-level participants, as well as enriching the curricula at the intermediate-level for future participants. The Academy will update the program based on participants' feedback by including instructor-led sessions, more case studies, advanced writing techniques, query-response sessions with SMEs, detailed safety documents, and so on. The iterative approach is designed to ensure that the program remains relevant, effective, and aligned with the evolving needs of medical writing professionals.

Table 2. Participants' Feedback

Feedback Category	Summary
Overall Experience	Positive; improved skills and confidence in medical writing reported by participants
Confidence Enhancement	Significant boost in confidence from hands-on experience and feedback sessions
Course Structure and Materials	Structured courses with comprehensive materials; desire for more interactivity and real-world examples
Content Relevance	Highly relevant for roles, especially in understanding complex documents
Valuable Aspects	Practical exercises, flexibility in timing, and one-on-one feedback sessions highly valued by participants
Areas for Improvement	More instructor-led sessions, case studies, and regular check-ins suggested
Future Topics	Interest in advanced writing techniques, communication strategies, and detailed safety documents
Recommendation Likelihood	High likelihood of recommending the Academy to colleagues

CONCLUSIONS

The Medical Writing Academy made a significant positive contribution to the professional development of participants by exposing them to other disciplines of medical writing and using their transferable skills, thereby improving their professional versatility. This approach will help to address the evolving needs of the medical writing profession by broadening the knowledge and skills of individuals. As reflected in the feedback from the participants, the initiative demonstrated the value of comprehensive, cross-functional training and

could redefine best practice in future medical writing education. Notably, participants' ability to apply newly acquired skills to urgent interdepartmental requests highlights the program's effectiveness in developing adaptable, multiskilled professionals, thereby building organizational capacity.

Building on this achievement, the Medical Writing Academy initiative will explore ways to improve and evolve the program, identifying where further innovation may be appropriate. Plans are underway to expand the curriculum to cater to basic-level, intermediate-level, and advanced-level participants, ensuring comprehensive coverage across all career stages. The existing intermediate-level curricula will be enriched to provide even more value to future participants. This model of cross-functional expertise, practical application, and continuous learning can inspire and guide similar initiatives across the industry.

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