Value of Medical Writing: The Regulatory Writer's Perspective

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ABSTRACT

The American Medical Writers Association formed a working group in 2020 focused on understanding and communicating the value that regulatory medical writers contribute to project teams, companies, and the wider research community. The working group developed a survey designed to gather information about the value that regulatory writers represent. The survey was targeted to regulatory medical writers, included 25 questions, and was administered by using SurveyMonkey. A total of 548 responses were received, and 522 of the respondents were active regulatory medical writers. The survey revealed that writers felt most valued when they were consulted or had their opinion sought (n = 154, 30.8%), contributed to patients and the community (n = 89, 17.8%), and were well compensated (n = 80, 16.0%). Writers felt that their most valuable contributions to document preparation were clarity (n = 196, 44.1%) and organization (n = 80, 18%). Although most writers indicated that their employers provided sufficient opportunities for training and advancement (strongly agree, n = 131, 29%; agree, n = 197, 44.1%), writers also indicated they would benefit from additional training in leadership skills, project management, and collaborative skills/diplomacy. This insight is invaluable for shaping the future of the regulatory writing profession.

INTRODUCTION

At its core, medical writing involves gathering, organizing, interpreting, and presenting complex information in a clear, concise, and coherent manner to a variety of audiences. Specific responsibilities can vary greatly across the industry, with roles and opportunities for medical writers constantly evolving. In this ever-changing environment, the role of regulatory medical writers is not always clear, and there is evidence to suggest that medical writers' contributions are not always fully understood or recognized.[1] To better appreciate the concrete value regulatory medical writers contribute to projects, teams, companies, and the wider biopharmaceutical industry, the American Medical Writers Association (AMWA) Executives Forum established a taskforce to define and quantify the value of medical writing. The 3 focus areas of the taskforce include writers' perceptions of their own value, regulatory agency perceptions of a writer's value, and other key topics related to the value of medical writers. This article describes the work of the subgroup tasked with determination of regulatory medical writers' perceptions of their own value. The main goals of this subgroup were to discover the views of regulatory medical writers regarding the nature of the value they contribute, identify aspects of the role that make writers feel most valued, and inquire about team feedback and dynamics. We also sought to identify additional skills, training, and opportunities for development that would benefit writers while also increasing the satisfaction of their teams.

METHODS

A 25-question survey was designed to evaluate multiple domains regarding the perceived value and contributions of regulatory medical writers. The intended time taken for respondents to complete the survey was 10 minutes, and the average duration of participation was determined to be less than 10 minutes. Many of the survey questions were multiple-choice questions, with some requesting a single answer and others allowing multiple answers (check all that apply). Additional questions allowed participants to rank their preferences. Other questions were presented in a 5-point Likert-scale format. One question was an open field that allowed participants to provide general comments on the topic at hand.

The survey was targeted to regulatory medical writers; the first question in the survey was binary (yes/no) and confirmed this status. The survey was administered by using SurveyMonkey to members of the AMWA medical writing community, the European Medical Writers Association (EMWA) medical writing community, and the DIA Medical Writing Community. Working group members also distributed the survey to colleagues who were known to be regulatory medical writers and to partner companies who had regulatory medical writing groups who agreed to participate.

The survey was completely anonymous. However, some analyses utilized the anonymized participant number to track responses to different questions from the same participants in attempting to identify trends in the data.

PARTICIPANT PROFILE

To better understand the characteristics of survey participants, several survey questions focused on demographics and work history. In response to the question, "Are you currently working (or have you worked within the past 5 years) as a regulatory medical writer?" we received a total of 548 responses, and 522 respondents (95.3%) confirmed current employment as regulatory medical writers. The second question in the survey inquired about work status. A total of 548 responses were also received for this question, and 488 (89.1%) were "employed," whereas 53 (9.7%) were "freelance or self-employed," 4 (0.7%) were "retired or unemployed," and 3 (0.5%) chose "other" as a category of employment. When asked about the type of company the respondents were employed by, a total of 518 responses were received, and the top 3 responses were (1) pharmaceutical company, (2) clinical or contract research organization, and (3) biotechnology company (Table 1).

Table 1. Analysis of Employment for Regulatory Medical Writers

Type of Employer	Responses (n)	Responses (%)
Pharmaceutical Company	261	50.4
Clinical or Contract Research Organization	118	22.8
Biotechnology Company	56	10.8
Medical Device Company	29	5.6
Medical Communication Company	23	4.4
Full Service Provider/Staffing Company	15	2.9
Other (Please Specify)	13	2.5
Medical School or University	2	0.4
Medical Marketing, Advertising, or Public Relations Agency	1	0.2

When writers were asked about the larger group in which the regulatory writing group resided, the top response indicated that medical writing stood alone as a group (Table 2). However, as this is contrary to the experience of the members of the AMWA working group, it may be suggestive of some ambiguity inherent in the question, although it may be a predictable response in smaller companies or in clinical research organizations (Table 1; 22.8% of respondents). Some of the responses in the "other" category included "Clinical Affairs," "Data Science and Safety Reporting," "Document Solutions Group," and "Regulatory Documentation and Submissions."

Table 2. Organizational Structure Housing Regulatory Writing Group

Parent Group/Organization	Responses (n)	Responses (%)
Medical Writing Stand-Alone Group/Function	198	38.2
Regulatory Affairs	115	22.2
Clinical Development	68	13.1
Clinical Operations	52	10.0
Other (Please Specify)	32	6.2
Biostatistics or Biometrics	18	3.5
Not Applicable	16	3.1
Medical Affairs	11	2.1
Strategic Operations	4	0.8
Pharmacovigilance	2	0.4
Quality	2	0.4

The tenure of the regulatory writers who responded to the survey reflected long-term experience and the longevity of their dedication to the profession. A total of 444 writers responded to our question about years of writing experience, 242 (54.5%) of whom had more than 10 years of experience in the regulatory writing profession. A total of 84 (18.9%) respondents had between 6 and 10 years of writing experience, whereas 91 (20.5%) had between 2 and 5 years of experience and 27 (6.1%) had less than 2 years of experience. More than half of respondents had either a PhD degree (n = 206, 46.4%) or another advanced degree (n = 27, 6.1%); 147 (33.1%) respondents had a master's degree, 56 (12.5%) had a bachelor's degree and 8 (1.8%) respondents specified a degree of "other." A total of 440 writers responded to a query regarding gender, with 330 (75%) writers identifying as women, 83 (18.9%) identifying as men, and 27 (6.1%) choosing "prefer not to say." Overall, professionals responding to this survey were highly educated, a high proportion were women, and most had long-term experience as regulatory writers. This is indicative of a profession that generally requires a high level of education and offers

long-term employment and development. The paucity of respondents with less than 2 years of experience (6.1%) may reflect slow recruitment of writers or a slow growth rate for the pool of regulatory writing professionals. Alternatively, it could represent our inability to reach more junior medical writers. However, if this rate is representative of the industry at large, it is concerning, given the high growth rate for medical writing needs in the biopharmaceutical industry.

ROLES AND CAREER PROGRESSION

We inquired about specific roles of medical writers to better understand how they are contributing, to learn what employers expect from medical writers, and to explore the relationship between required level of skill and the various roles of the writer. These survey questions categorized medical writing roles to reflect increasing levels of both technical skill and responsibility in order to understand the distribution of skills within the respondent pool (Table 3). The majority of respondents report involvement in activities beyond basic document preparation following a template. Most provide strategic guidance to teams and participate in some form of project management activity. Consistent with the long duration of tenure in the respondent pool, a relatively large proportion of respondents identified themselves with role C, representing a very high level of technical skill, knowledge, and responsibility.

Table 3. Analysis of Roles Among Regulatory Writers

Role	Responses (n)	Responses (%)
A. I Provide Medical Writing Support/Service to Teams That Is Mainly Focused on Document Preparation, Using Knowledge of Templates, and ICH and Other Guidance(s).	138	27.6
B. I Provide Support Described in Item A, but Also Provide Strategic Guidance to the Teams.	126	25.2
C. I Provide Support In Items A and B and Manage Submissions Documents and Lead Teams Through CTD Preparation Routinely.	171	34.2
D. Management and/or Project Management.	43	8.6
Other (Please Specify).	22	4.4

CTD, Common Technical Document; ICH, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.

To better illustrate the relationship between experience and role, we analyzed the responses for each role by years of experience (Figure 1). Although there was not an exact linear correspondence in the relationship between increasing years of experience and increasingly challenging roles, there was certainly a trend for professionals with longer tenure to fill the more challenging roles. Most individuals in the management/project management category had at least 10 years of experience in regulatory writing. These data indicate that regulatory writing is a highly technical discipline, and development of the necessary expertise to assume more strategic and management responsibilities appears to require several years to develop. This also suggests that regulatory writing is a career that offers long-term progression and development.

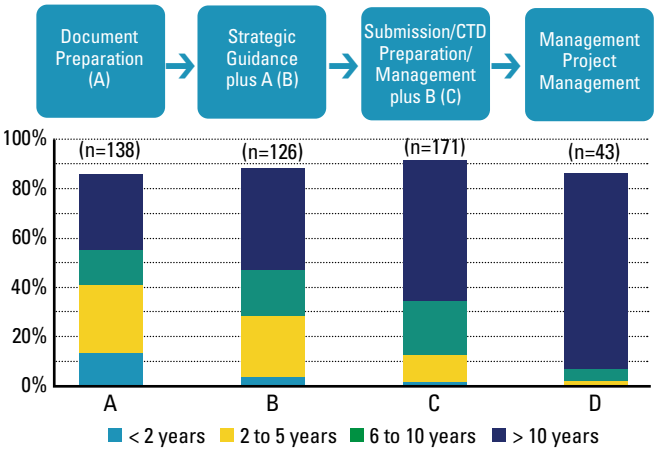

Figure 1. Relationship between experience and roles. CTD, Common Technical Document.

VALUE ASSESSED BY WRITERS AND TEAMS

Understanding and harnessing the skill set of experienced regulatory writers can keep writers engaged and make them feel satisfied and fulfilled. When writers were asked what made them feel most valued as a medical writer (and were forced to choose one answer), there was a clear leader among the options provided (Table 4). Medical writers felt most valued when their opinions were sought and when they were included in decision-making. This aspect of feeling valued was chosen by more respondents than any other aspect, including compensation and other forms of recognition. Some responses in the "other" category were (1) "medical writers have unique skills that fill a need, unmet by any other discipline involved in healthcare"; (2) "coaching and training of new or junior writers"; and (3) "authorship and being consulted; having my ideas taken seriously and acted upon."

The same question was posed with a requirement to rank these items and there was an identical response pattern, except that "autonomy/flexibility" and "recognition" switched

Table 4. What Makes Regulatory Writers Feel Valued

What Makes Me Feel Valued?	Responses (n)	Responses (%)
Consulted/Opinion Sought/ Decision-Making	154	30.8
Making a Contribution to Patients/Community	89	17.8
Compensation	80	16.0
Involvement in Scientific Research/Developing Your Own Scientific Knowledge	77	15.4
Autonomy/Flexibility	32	6.4
Recognition	31	6.2
Career Progression/Job Title/ Opportunity for Movement	28	5.6
Other (Please Specify)	9	1.8

positions in the rate of response/rank. Interestingly, "career progression/job title/opportunity for movement" remained at the bottom of the list, with only 4.7% of respondents choosing this as their top ranked item.

Many writers felt that their tactical and technical skills were fully utilized, as well as their scientific and strategic skills (Figure 2; n = 495).

Additionally, most writers felt that the teams they supported fully recognized their value and skills. A total of 265 (53.5%) respondents agreed with this statement, whereas 107 (21.6%) strongly agreed. Interestingly, only 48 (9.7%) respondents disagreed, and 6 (1.2%) strongly disagreed. Consistent with these positive responses, most writers also felt that they were empowered by management to provide clear guidance to their team regarding the document development processes and felt they were included in most necessary meetings that enabled them to remain aware of strategic decisions that could impact document development (Figure 3; n = 495).

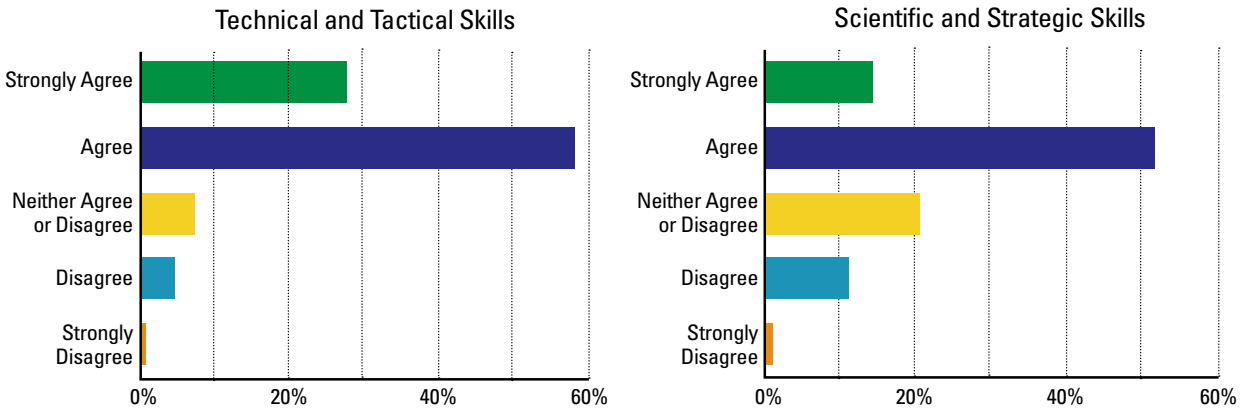

Figure 2. Utilization of skill sets.

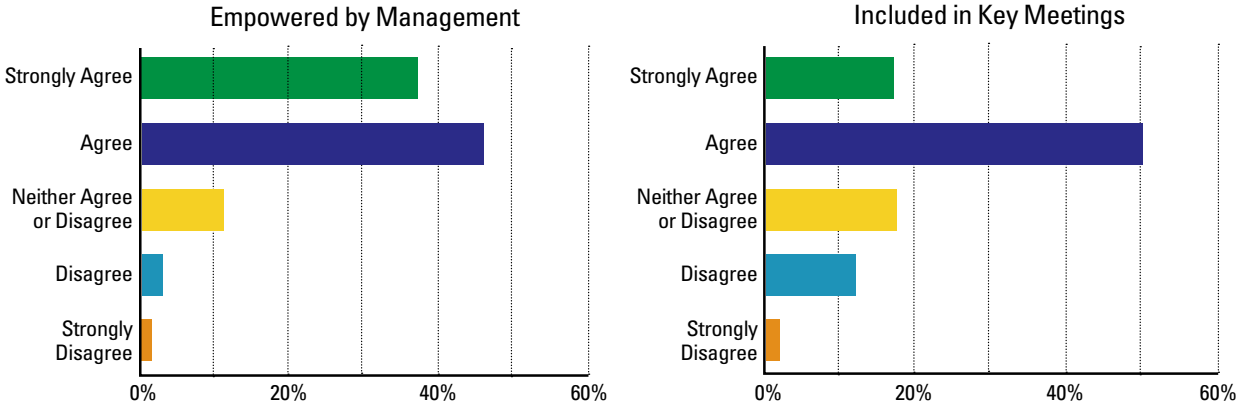

Figure 3. Key determinants of success.

Although regulatory writers provide value to teams in many ways, we sought to understand the perception of writers themselves in terms of the value they contribute. When writers were asked to select one area in which they provide the most value in document preparation, there was a clear top choice (Table 5). Writers indicated that they contributed the most value by providing clarity in documents (44.1%), followed by "organization" (18.0%), "completeness" (10.1%), "accuracy" (9.9%), and "adherence to standards" (9.9%).

When writers were asked this same question but allowed to check all areas in which they contributed value, clarity was still at the top of the list (95.3% of writers included this in their selections), and organization was still in second place (90.8% of writers included this in their selections).

Table 5. Areas in Which Writers Provide Value in Document Preparation

Area of Document Preparation	Responses (n)	Responses (%)
Clarity	196	44.1
Organization	80	18.0
Completeness	45	10.1
Accuracy	44	9.9
Adherence to Standards	44	9.9
Explanation of Rationale	22	5.0
Brevity	9	2.0
Formatting	4	0.9
Linking	0	0.0

A general comment regarding the value of medical writers was provided by 102 (18.6%) writers. Key themes in the responses were the value provided to teams to ensure that the documents will lead to a successful submission. An example is this response: "The quality and delivery time of regulatory documents improved dramatically when my employer established a medical writing department within Clinical Operations." The responses indicate that clear, well-written, and accurate messages are an important part of the medical writer's role and that this is best achieved by integration into project teams. A response that expressed this was, "Clinical–regulatory writers are critical members of the team who guide development of documents with an overall perspective for program strategy and a document that is complete, accurate, and well-written." The responses indicate that this enables the medical writer to lead team collaboration, ensure that documents support project goals, and drive the process to speed delivery and ensure high quality/regulatory compliance. A representative response was, "We take ownership and drive/lead the document through the process, and only by guiding the team do we get through it." Several writers stated that the role of the medical writer is underappreciated. Insight is provided by this response: "Much of the value can go unnoticed by management as it is difficult to measure what good clinical–regulatory writers provide to documents and the document completion process."

Pivoting to inquiry regarding the value that teams perceive as writers' greatest contributions, the skills that writers felt they were most frequently recognized for were leadership and collaboration skills (Table 6), both considered to be behavioral skills or "soft skills" rather than technical skills directly related to writing.[2]

Table 6. Skills and Contributions Recognized Most Frequently by Teams

Skill Recognized by Team[a]	Responses (n)	Responses (%)
Leadership, Including Management of the Process and Maintenance of Timelines	148	32.8
Collaboration and Flexibility	116	25.7
Providing Strategic Guidance on Document Development and/or Submissions	79	17.5
Writing Skills With Respect to Vocabulary and Sentence Structure, Grammar, Improved Readability, etc.	34	7.5
Comment Resolution and Achievement of Consensus	26	5.8
Problem-Solving	19	4.2
Quality Control and Accuracy	19	4.2
Compliance	5	1.1
Input to Study Design and Project Decisions	5	1.1

[a] *Survey respondents had to choose only one skill.*

When asked to rank the frequency of recognition of skills, the 3 top responses remained consistent, with all the other skills/behaviors ranking at least 5% beneath the third most highly ranked skill (Table 6; 17.5%, providing strategic guidance on document development and/or submissions). Interestingly, when this line of inquiry was reversed and we asked writers to provide information about constructive feedback they received from teams about areas for improvement, responses in the "other" category represented the highest proportion of responses (Table 7; n = 110, 24.4%). However, the most common entries in the "other" category open field were "none" and "not applicable," and there was no consistent trend, suggesting that inclusion of that option/field may have detracted from the precision of the data. The next 2 most

frequent responses were (1) leadership, including management of the process and maintenance of timelines, and (2) improve flexibility. Therefore, the 2 items writers felt they were most frequently recognized for doing well were also the 2 specific items for which they felt that teams requested improvement or better support. These data suggest that leadership and collaboration should be key areas of focus for writer development.

When writers were asked to rank (from 1 to 7) the 7 skills for which teams had requested better support ("other" was not included), leadership and lack of flexibility were still cited as the top areas for improvement (Table 7).

Table 7. Constructive Feedback From Teams

Skill That Needs Improvement	Responses (n)	Responses (%)
Other (Please Specify)	110	24.4
Leadership, Including Management of the Process and Maintenance of Timelines	79	17.5
Lack of Flexibility	62	13.7
Compliance With Procedures	61	13.5
Comment Resolution and Achievement of Consensus	45	10.0
Writing Skills With Respect to Vocabulary and Sentence Structure, Grammar, Improved Readability, etc.	36	8.0
Quality Control, Too Many Errors	36	8.0
Collaboration	22	4.9

TRAINING OPPORTUNITIES AND NEEDS

One of the main reasons for conducting this research was to identify potential gaps between medical writer skills and team and/or employer expectations. Although this investigation relies on information gathered from regulatory writers and not teams or employers, we can compare our results with research conducted by another group[2] as it relates to the pharmaceutical medical writing competency model.[3] According to information Heisel-Stoehr and Schindler obtained from 73 job advertisements for regulatory medical writers, "science" and the "comprehension of scientific concepts" were important technical skills cited in 78% and 92% of those job advertisements, respectively.[2] Our survey suggests that writers are not primarily recognized for such contributions during document development. Additionally, writers themselves felt that their most important contributions to document development were clarity and organization, technical writing skills that may or may not require a deep scientific understanding. On the other hand, the 73 job advertisements described by Heisel-Stoehr and Schindler cited "leadership and team working skills" as the most frequently (62%) mentioned behavioral skill/skills for regulatory writers.2 In fact, our survey results find that these are the 2 areas for which writers are most frequently recognized by teams for commendable performance (Table 6).

Although most writers in our survey felt that their employers provided them with sufficient opportunities for training and development to enable success and advancement (agree, n = 197, 44.1%; strongly agree, n = 131, 29.3%), there were others in the survey who felt neutral (neither agree or disagree, n = 78, 17.4%) and some who disagreed (n = 30, 6.7%) or strongly disagreed (n = 11, 2.5%). These results speak well of management efforts to keep writers engaged and developing. When writers were asked to identify areas in which they needed more opportunities to learn, there was a significant focus on (1) leadership skills, (2) project management, and (3) collaborative skills/diplomacy (Figure 4). Once again, the notion that behavioral skills or "soft skills" play a prominent and crucial role in the successful execution of the duties of the regulatory writer is reinforced throughout the results of our survey.

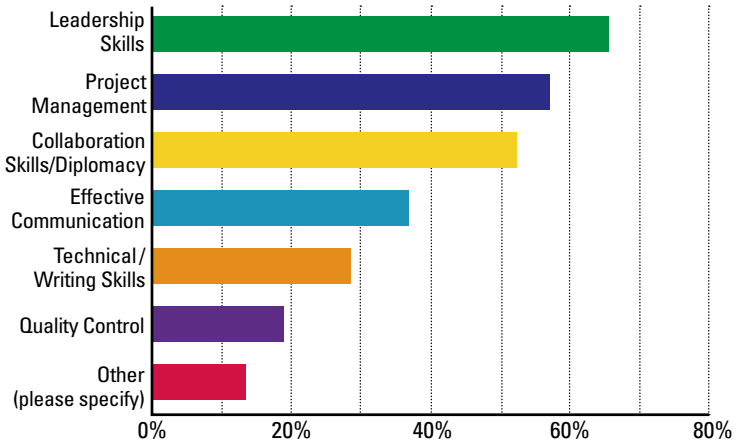

Figure 4. Areas desired for more training/learning.

SUMMARY

Results from the survey encompassing 548 respondents with regulatory medical writing experience revealed key information that is useful for understanding the value that medical writers bring to an organization and useful for further defining job responsibilities and skills needed for regulatory medical writers. Regulatory medical writers are highly educated professionals whose development to attain the skills necessary for leading regulatory submission preparation and managing projects and teams requires several years. The role requires both technical/tactical skills and scientific/strategic skills. Most regulatory medical writers report that their duties extend beyond basic

document preparation following a template to include providing strategic guidance to teams and participating in some form of project management activity. Project teams rely on medical writers for leadership and collaborative skills. Medical writers recognize these soft skills as both their key contributions and their key training needs. Data suggest that regulatory medical writers feel most valued when their opinions are sought and when they are included in decision-making.

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