Pharmaceutical medical writing competencies: Comparing self-perception with employers' expectations

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Abstract

In the recently published 'Pharmaceutical Medical Writing Competency Model', a group of medical writers describes the knowledge, skills, and behaviours they considered essential for successful medical writers. Thus, this model represents a list of essential job requirements from within the medical writing profession. Using the job postings of the EMWA website (in total 146 adverts from 2009 to 2011), we investigated whether the competencies listed in the model are in line with the expectations of the employers of medical writers. In these adverts, we found that familiarity with the techniques of scientific writing and editing, a science background, the ability to comprehend scientific concepts, and the capability to author quality documents were the most frequently mentioned requirements. Generally, the Competency Model matched well with the requirements mentioned in the job adverts. However, certain essential attributes were rarely mentioned in job adverts; examples include proficiency in statistics and knowledge about publication guidelines. With regard to social skills, job adverts tended to ask for more general skills than those described by the Competency Model. The Competency Model distinguishes between publication and regulatory writers, and this distinction was reflected in the attributes mentioned in the job postings with adverts for regulatory medical writers listing a broader skill set than did those for publication medical writers.

Keywords: Competency model, Medical writing, Regulatory writing, Publication writing, Qualifications, Job market requirements

Introduction

The 'Pharmaceutical Medical Writing Competency Model', published in 2011 was developed by an international committee of 22 medical writers with diverse backgrounds and experience.[1] The group aimed to '… help define what makes a medical writer different from other professionals involved in the development of therapeutic products'.[2] Hence the Competency Model is a form of 'wish list' developed for use by the profession and others. The Competency Model has two parts: the first part describes nine work functions of medical writers and outlines benchmark activities that should be mastered and the second part identifies the knowledge, skills, and behaviours that are required for medical writers. In the print version, the items in the Competency Model are described in considerable detail (some nine pages in total). The authors define competency as 'the ability of an individual to perform a specific role successfully …'[1] The model has been used in hiring and training medical writers and in reviewing their performance.[2,3]

We were interested to establish whether the 'self-prescribed'competencies, listed in the second part of the model, concur with the expectations of the employers of medical writers. To identify what employers want from medical writers we used the job postings of the EMWA website in the years 2009–2011. We worked on the assumptions that the requirements listed in the job postings are chosen carefully to attract the most suitable candidates, and that they had undergone considerable scrutiny because they convey the values and self-perception of the company. Job adverts also help to position a company within its competitive environment. We further assumed that the costs of job adverts (although low in the case of EMWA) generally encourage advertisers to be selective in the requirements presented.

The length constraints that commonly apply to job adverts may also be a limitation of our comparative

DOI: 10.1179/2047480612Z.00000000049

approach since they preclude the level of detail that was applied in the Competency Model. Also the wording of the requirements of the position advertised is usually more general than the items that are used in the model. Therefore we had to devise rules to ensure that the wording in the job adverts is appropriately linked to items in the Competency Model (see the Methods section). Our analysis concentrated on the section of the Competency Model covering 'Knowledge, skills, abilities and other characteristics' because job adverts usually list these attributes while they rarely give details of work functions and critical behaviours.

"Posting" refers to the display on the website and "advert" denotes an individual job offer. One posting could comprise several adverts and one advert could offer several positions.

Methods

Categorizing job adverts

Upon request, the EMWA web team provided us with copies of the job adverts posted from 2009 to 2011 as pdf files. One posting from 2009 was excluded because it lacked relevant content and three from 2011 were excluded because of technical problems (e.g. non-functional links) or lack of relevant content. According to the predominant tasks mentioned, all adverts were categorized as targeting either 'regulatory medical writers' or 'publication medical writers'. In about 90% of cases this categorization was straightforward. If, however, the description of the tasks did not indicate the nature of the position advertised, the professional focus of the company was used to guide the allocation, e.g. if the posting of a medical communications company was unclear in this respect the position was assumed to be for a publication writer. The listed order of requirements was assumed to reflect their priority for the employer.

Mapping job adverts to the Competency Model

We limited our evaluation to the second main part of the Competency Model covering technical knowledge, technical skills and abilities, and behavioural skills for technical contribution. As the original descriptions of the behavioural skills (all writers: 17 items) in the model are often lengthy they were condensed into 15 keywords for tabular presentation. Some items in the model are for all medical writers and there are additional separate lists for regulatory writers and for publication writers. All items were transferred to a Microsoft Excel file.

Each job posting was initially read by the two authors. To limit potential bias in allocating the items in the job adverts to the categories of the Competency Model, mapping rules were devised prior to a second thorough reading of the postings. The individual items mentioned in job adverts were 'coded' and subsequently entered into the appropriate Competency Model categories in an Excel file. SHS read and analysed all job postings, TMS categorized a sample of 15 job postings (ca. 10%). In most cases, the items mentioned in the adverts could be directly assigned to Competency Model categories. Unclear categorizations were discussed and agreed between the authors. Absolute numbers and frequencies were calculated for the total number of jobs advertised as well as for the number of regulatory writing and publication writing positions.

When a job advert asked for relevant experience in scientific or medical writing this was allocated to the category 'techniques of scientific writing and editing'. If a qualification in life science or medicine was requested, this was entered as 'science'. Whenever knowledge of life sciences or clinical research was required, this was mapped into the category 'ability to comprehend scientific concepts'. Only if the words 'statistics' or 'statistical [knowledge, competence, etc]' were used in an advert, was this requirement entered. However, no advert contained text that could be construed as making reference to statistics without mentioning the word. When the ability to analyse data was asked for, this was entered as 'ability to comprehend statistical concepts'.

If working within a matrix environment or according to standard operating procedures (SOPs) was explicitly mentioned, this was entered as knowledge of 'company policies'. The categories knowledge of 'regulatory guidelines', 'regulatory authorities', and 'publication guidelines' were only ticked if these were explicitly requested in the text. Knowledge of 'publication planning software' was assumed when the use of publication planning tools was asked for. The category 'rewrite existing documents' was ticked when rewriting was explicitly mentioned and also when updating of SOPs was on the list of responsibilities. The model term 'build positive and productive relationships' was renamed to 'networking' and entries were made whenever the establishment of relationships with clients, team members, collaborators, or opinion leaders was mentioned. The abilities 'to globally share work' and 'to effectively work in multicultural teams' were combined to 'intercultural competence'.

In parallel with the above analyses, the job adverts were screened for terms alluding to soft skills that were not mentioned in the model using these same terms such as 'communication skills' and 'interpersonal skills'.

Observations

From 2009 to 2011, 61 different companies used the EMWA website to place 118 job postings. This included medical communications agencies, large pharmaceutical and biopharmaceutical companies, biotechnology companies, contract research organizations (CROs), and recruiting agencies. Over the 3 years, 152 positions were advertised and 146 could be included in the analysis. Exactly half of the positions were for regulatory medical writers and half for publication medical writers (Table 1). Overall, 83% of adverts specified the need for a scientific background or knowledge of life sciences or clinical research. A total of 68% expected a university degree (B.Sc./M.Sc. or M.D./Ph.D.) in life sciences or medicine; 39% of adverts preferred or required a Ph.D. This is in line with previous analyses of the EMWA website job postings.[4] Assuming that items were listed in adverts in order of importance, we found that the first requirement mentioned was a scientific degree in 49% of adverts or relevant work experience in 30%. The second requirement mentioned was relevant work experience in 38% of job adverts, followed by language skills in 21%. The second item mentioned showed greater diversity than the first one (e.g. knowledge of ICH, management skills).

Table 1: Medical writing job postings on the EMWA homepage from 2009 to 2011

	2009	2010	2011	Total
Number of companies with at least one job posting	25	27	34	61
Number of job postings[#]	37	36	45	118
Number of positions advertised*	48	46	58	152
Number of non-analysable job adverts	3	0	3	6
Number of analysed job adverts	45	46	55	146
Number of positions for regulatory medical writers**	17	24	32	73
Number of positions for publication medical writer	28	22	23	73

[#]Job postings could include several adverts.
*The number of positions advertised is not easily determined as some postings offered several positions. In these instances, two positions were assumed.
**A total of 30 job adverts (2009: 10; 2010: 8; 2011: 12) described items for both regulatory and publication writing activities. However they were categorized as regulatory medical writer adverts because of the dominance of regulatory writing aspects.

Technical knowledge

Most job adverts (84%) required the medical writer to have mastered the techniques of scientific writing and editing (Table 2); this requirement was more frequent in adverts for publication writers (93%) than for regulatory writers (75%). A science background was specified in 68% of adverts and the preponderance of this requirement was higher for regulatory writers (78%) than for publication writers (58%). More than one-third (38%) of all adverts asked for knowledge of software and systems including document management programs, word processing software, or reference management software. Again, the frequency of this requirement was higher in job adverts for regulatory writers (49%) than in those for publication writers (26%). A quarter of the adverts required the ability to train or mentor less experienced writers or to instruct external writers. The other items in the 'technical knowledge' section of the Competency Model (statistics, company policies, industry guidelines, knowledge about the functional roles of team members, and publishing standards) were only rarely asked for (<10% of all adverts). While job adverts for regulatory writers specified the requirement for knowledge about regulatory guidelines (53%) and authorities (27%), knowledge about international guidelines was substantially less frequently required in adverts for publication writers (1%).

Technical skills and abilities

The majority of adverts wanted medical writers who are able to comprehend scientific concepts (83%). About 45% of the job adverts asked for the ability to 'author quality documents', which denotes the writing of compelling, clear, concise, and correct texts. Project management skills were also in high demand (38%) and this includes the management of deliverables, timelines, responsibilities as well as communication planning and meeting organization. One-third of the job adverts required editing skills such as formatting, proof-reading, micro-editing, and macro-editing.

The ability to interpret and communicate clinical and numerical data was requested in 42% of job adverts for regulatory writers but only in 7% of those for publication writers. Similarly, the abilities to comprehend statistical concepts (regulatory writers 29% vs. publication writers 5%) and to report and summarize information (regulatory writers 33% vs. publication writers 1%) were required predominantly in adverts for regulatory writers. In contrast, the ability to layout posters and slides was more frequently mentioned in adverts for publication writers (27%) than in those for regulatory writers (13%).

Table 2: Representation of the technical knowledge and technical skills and abilities categories from the Competency Model[1] in EMWA website medical writing job adverts for 2009–2011

	Regulatory medical writers	Publication medical writers	All medical writers
Number of positions advertised	73	73	146
Technical knowledge			
All medical writers			
Techniques of scientific writing/editing	75%	93%	84%
Science	78%	58%	68%
Software and systems	49%	26%	38%
Training/mentoring	26%	26%	26%
Statistics	12%	0	6%
Company policies	3%	3%	3%
Industry guidelines	0	3%	1%
Functional roles of team members	0	0	0
Publishing standards	0	0	0
Regulatory medical writers			
Regulatory guidelines (e.g. ICH M2, M4)	53%	0	27%
Regulatory authorities	27%	0	14%
Standardization initiatives (CDISC, CDASH)	0	0	0
Publication medical writers			
Publication coordination	3%	23%	13%
Publication planning software	0	15%	8%
Publication guidelines (e.g. GPP, ICMJE)	1%	1%	1%
Reporting guidelines (e.g. CONSORT)	0	0	0
Technical skills and abilities			
All medical writers			
Comprehend scientific concepts	92%	74%	83%
Author quality documents	41%	48%	45%
Project management	36%	41%	38%
Document editing	26%	36%	31%
Interpret clinical/numerical data	42%	7%	26%
Quality control	23%	29%	26%
Review documents	30%	16%	23%
Layout slides/posters	13%	27%	20%
Report/summarize information	33%	1%	17%
Comprehend statistical concepts	29%	5%	16%
Conduct effective literature search	7%	3%	5%
Transcription	10%	0	5%
Rewriting existing documents	5%	1%	3%
Information management	3%	0	1%
Interview for information	1%	0	1%
Publishing	0	0	0
Regulatory medical writers			
Prepare regulatory documents	79%	0	40%
Prepare communication strategy	15%	0	8%
Prepare publishing ready documents	7%	0	3%
Publication medical writers			
Prepare publication documents	41%	53%	47%
Prepare publication plan	3%	18%	10%
Meet journal guidelines	1%	0	1%

The difference between the technical knowledge item 'statistics' (6% of all adverts) and the ability 'to comprehend statistical concepts' (16% of all adverts) seems likely to be attributable to a distinction between the need for a formal background in statistics and an ability to understand statistical concepts. As expected, regulatory writers were required to prepare regulatory documents (79%) while publication writers were not (0%). Conversely, publication medical writers should prepare publications (53%), although this is also requested in a fairly high percentage of postings for regulatory writers (41%).

Soft skills

In addition to the technical knowledge and abilities, the Competency Model provides a list of necessary behavioural skills (Table 3). The ability

to build positive and productive relationships with clients, team members, collaborators, or opinion leaders (networking skills) as well as strong leadership and team working skills were the most frequently requested soft skills for all types of medical writers. About 20% of the job adverts mentioned an exceptional eye for detail, organizational skills, or time management in their profiles. These skills are, however, more frequently asked for in job adverts for regulatory writers than in those for publication writers. Likewise, the ability to 'multitask' and to 'manage conflicts' are more prevalent requirements in adverts for regulatory writing jobs. All other soft skills such as proactive attitude, flexibility, and creating solutions were mentioned in less than 10% of all adverts.

Intercultural competence was almost never mentioned as a requirement. Compared with the Competency Model, job adverts tend to use more general terms for behavioural skills (Table 4). The most prevalent social skills listed in adverts were communication skills, interpersonal skills, and the ability to work independently. All of these were asked for more frequently in adverts for regulatory writers than for publication writers.

Most frequently listed requirements

Based on our analysis of the adverts, the most frequently (≥20%) required skills and competencies for all medical writers were (in order from higher to lower frequencies):

Technical knowledge

- knowledge of the techniques of scientific writing and editing
- having a science background
- familiarity with software and systems
- ability to train and mentor

Technical skills and abilities

- comprehend scientific concepts
- author quality documents
- perform project management
- edit documents
- interpret clinical and numerical data
- perform quality control
- review documents
- layout slides and posters

Table 3: Representation of the behavioural skills from the Competency Model in EMWA website medical writing job adverts for 2009–2011

	Regulatory medical writers	Publication medical writers	All medical writers
Number of positions advertised	73	73	146
Networking (5)	56%	56%	56%
Leadership and team working skills (12)	62%	36%	49%
Detail oriented (3)	27%	22%	25%
Time management (2)	30%	12%	21%
Organized (1)	33%	7%	20%
Multitasking (4)	15%	3%	9%
Commercially astute actions (14)	7%	10%	8%
Conflict management (8,9)	10%	3%	6%
Proactive attitude (13)	7%	5%	6%
Flexibility (10)	7%	4%	5%
Create solutions/resolve problems (11)	8%	3%	5%
Intercultural competence (16,17)	3%	3%	3%
Work ethic (15)	4%	1%	3%
Learning agility (7)	1%	4%	3%
Effective decisions (6)	0	0	0

The Competency Model uses the term 'Behavioural Skills for Technical Contribution'; however, as no other skill sets are mentioned we interpreted this as the overall skill set. The numbering (order) of these skills in the Competency Model is given in parentheses.

Table 4: Social skills as mentioned in EMWA website medical writing job adverts for 2009–2011

	Regulatory medical writers	Publication medical writers	All medical writers
Number positions advertised	73	73	146
Communication skills	47%	15%	34%
Interpersonal skills	22%	1%	12%
Ability to work independently	18%	0	10%

Behavioural skills

- being able to network
- having leadership and team working skills
- being detail-oriented
- having effective time management
- being organized

This 'condensed' list may constitute the blueprint for an 'ideal' medical writing candidate.

Discussion

Given the spatial constraints of job postings, we found that the technical aspects of the 'Knowledge, skills, abilities and other characteristics' section of the Competency Model matches well with what employers of medical writers want. This conclusion rests on two assumptions, namely that the categorization of job adverts as for regulatory writers or for publication writers was straightforward and that the mapping of items in the job adverts onto the categories in the Competency Model did not distort their content. The categorization of a job advert was simple and unambiguous with almost no differences between the two assessors. Mapping the items listed in the job postings to those in the Competency Model was more challenging. We tried to address this potential source of bias by defining rules for individual items. Nevertheless, even the most stringent application of rules inevitably involves some degree of subjectivity and interpretation.

Certain essential aspects in the Competency Model are or only rarely seen in job postings. Most medical writers work with data and should therefore be familiar with the methods of data analysis and data interpretation, i.e. they should have a certain statistical competence. However, knowledge of statistics was infrequently asked for (all writers 6%; regulatory writers 12%; publication writers 0%) as well as the ability to understand statistical concepts (all writers 16%, regulatory writers 29%, publication writers 5%).

In only 1% of adverts was the writer required to know international publication guidelines. This is in stark contrast with the multitude of international initiatives surrounding the writing of scientific publications such as the GPP, CONSORT, STARD, MOOSE, STROBE, and PRISMA guidelines. This is the more puzzling as these guidelines often have a direct impact on the way publications have to be written. Also, job adverts rarely ask for knowledge about standardization initiatives (e.g. CDISC), the ability to conduct literature searches, management of information, the ability to interview for information, or knowledge about publishing standards.

With regard to social skills, adverts for medical writers indicate that they should be able to network, to lead and to work in a team, to be organized and detail oriented, and to employ good time management. Other social skills were less in demand. Job postings tended to ask for more general social skills than those provided by the Competency Model. Requirements for intercultural competence, for strong work ethics, for the agility to learn, and for effective decision making were only rarely expressed. This is surprising because it is hard to see how a medical writer, who often works in a multinational and multicultural teams, can be successful without cultural sensitivity.[5] Likewise, how can a medical writer function without the willingness to behave ethically, i.e. ensuring appropriate copyright permissions and acknowledgements, and safeguarding against plagiarism or falsification?

As indicated in the Competency Model our analysis also shows that the skill sets required from regulatory medical writers and publication medical writers are distinct. In many instances, the adverts for regulatory writers asked for more skills and a more varied background than did those for publication writers. For example, regulatory writing adverts more often required a science background, the abilities to interpret scientific data to understand statistical concepts, and to report and summarize information. None of the 73 adverts targeting publication writers asked for a knowledge of reporting guidelines and knowledge in statistics was only rarely required. Surprisingly, not even the ability to devise a publication plan was in high demand in postings for publication medical writers.

The need for highly skilled medical writers in the regulatory field might be a result of the increasing complexity of documentation required by the regulatory authorities.[6,7] Our analysis suggests that for hiring purposes a more condensed list of competencies might be more useful than that provided in the fully fledged Competency Model.

Acknowledgements

We would like to thank the Shanida Nataraja, Melanie Foster, and Mark Allen from the EMWA web team for providing us with copies of the job adverts and our editor Margaret Gray for the excellent editing of our manuscript.

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