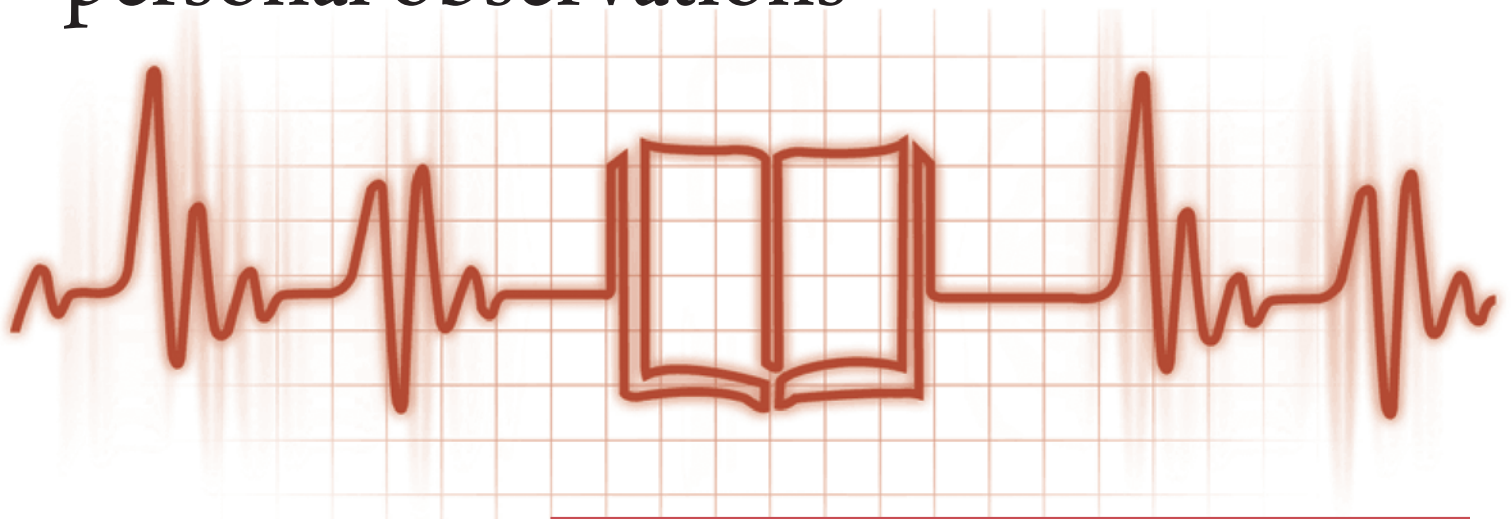


Writing for pharmaceutical or medical device companies:

A survey of entry requirements, career paths, quality of life, and personal observations



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Abstract

The spectrum of medical writing activities across the pharmaceutical and device industries is vast. We conducted a limited survey of medical writers predominantly working in industry or for agencies to learn of their personal and professional experiences. Our results showed that writers entering the medical communications world came from diverse backgrounds and had a variety of reasons for choosing this career path. Most had a scientific background and were highly qualified. Though at times stressful and involving long hours, medical writing was generally a satisfying and well-rewarded career choice. Several individual responses suggested a lack of appreciation and poor cooperation on the part of some clients and/or authors. Quality of life differed little between pharmaceutical and device employees. While many skills are transferable, those wishing to change focus from pharmaceuticals to medical devices or vice versa may face challenges. Respondents offered a range of advice for new recruits.

Introduction

The need for medical writing continues to grow, influenced in part by increasing regulations and governmental scrutiny of pharmaceutical and device companies. Activity is currently high in China and other parts of Asia in response to the volume of research in these areas. In order to restrict headcounts many companies now outsource writing to agencies and freelancers, resulting in a multibillion dollar medical commun-

ications sector.¹ Those involved in developing publications, presentations, and regulatory documents are often highly qualified, with a background in research, medicine, or education. Projects requiring their inputs span the whole field of medicine from medicinal products to medical devices, with a small but increasing overlap between some of these areas. A recent study showed that the use of professional writers was associated with more complete reporting of clinical trial results and a higher quality of

written English, demonstrating the value of medical writers in raising the standard of clinical trial reporting.²

The features of medical devices that differentiate them from drugs may shape the kind of activities a medical writer is required to support. Medical devices span a spectrum of complexity from tongue depressors through implantable pacemakers to in vitro diagnostic devices (IVDs) found in doctors' surgeries or large laboratories. Research study designs and data endpoints differ between pharmaceuticals and devices. For pharmaceuticals, clinical studies focus on proving safety and efficacy relative to the intended purpose of the therapeutic agent. In contrast, endpoints for medical device trials are as diverse as the devices themselves. For example, therapeutic devices must prove safety and efficacy; measurement devices must prove precision and validity; and diagnostic devices must prove sensitivity and specificity.³ Importantly, device performance outcomes and safety are often highly dependent upon the experience and skill of the user. Also, while devices are subjected to continuous and rapid innovation resulting in a short product life cycle,

pharmaceuticals undergo continuous, slower innovation and hence have a longer product life cycle.⁴

Another area of contrast is legislation. The pharmaceutical industry is heavily regulated, in the USA by the Food and Drug Administration (FDA) and in Europe by the European Medicines Agency (EMA), as well as by each individual country's competent authority, such as the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK. The legislation applied to medical devices, compliance with which is also the responsibility of the national competent authorities, is currently less demanding but is likely to increase appreciably in response to calls for greater safety monitoring.⁵ These differences are reflected in the lead time from development to market: an average of 13.9 years for drugs in the USA and UK,⁶ compared with an estimated 3 to 7 years for medical devices.⁷

Anecdotal evidence suggests that writers entering the medical communications world generally travel down one of two paths: pharmaceuticals or devices, with limited crossover between these two areas. How did they get there, what is life really like, how

easy is it to change fields, and what advice would they offer to aspiring juniors? The aim of this study was to answer these questions and provide a comparison of the two industries for new writers or those contemplating a change in direction.

Methodology

An anonymised and multifactorial survey was developed using SurveyMonkey®. It was tested amongst a group of senior writers and managers working in pharmaceuticals or in medical devices and subsequently revised. The design of the survey included multiple choice questions, Likert scales, and free text options. Where appropriate, respondents were encouraged to tick more than one answer. A covering letter and electronic link were sent to contacts known to the co-authors from the pharmaceutical and medical devices world in the USA or Europe. Contacts were invited to forward it to their colleagues (industry, agency, and freelance), with the aim of receiving 50 completed surveys. The survey was made live on 8th March 2016 and closed on 14th March 2016. Results are presented in terms of absolute numbers, percentages, means, and individual quotes. In some sections we focus on comparing the responses from industry and agencies; 'Freelancers/consultants' are here excluded because their working conditions are likely to be much different from those in established companies.

No patients were involved and ethical committee approval was not sought. There was no compulsion or inducement to complete the survey and respondents were allowed to leave questions unanswered.

Results

The survey was cascaded to an estimated 200 contacts. 112 responses were received (response rate ~56%), with most respondents completing the survey and adding valuable text comments.

Overview of respondents

Approximately two thirds of respondents worked in Europe and one third worked in the USA. Of those answering the relevant question (n=108), 68% worked principally

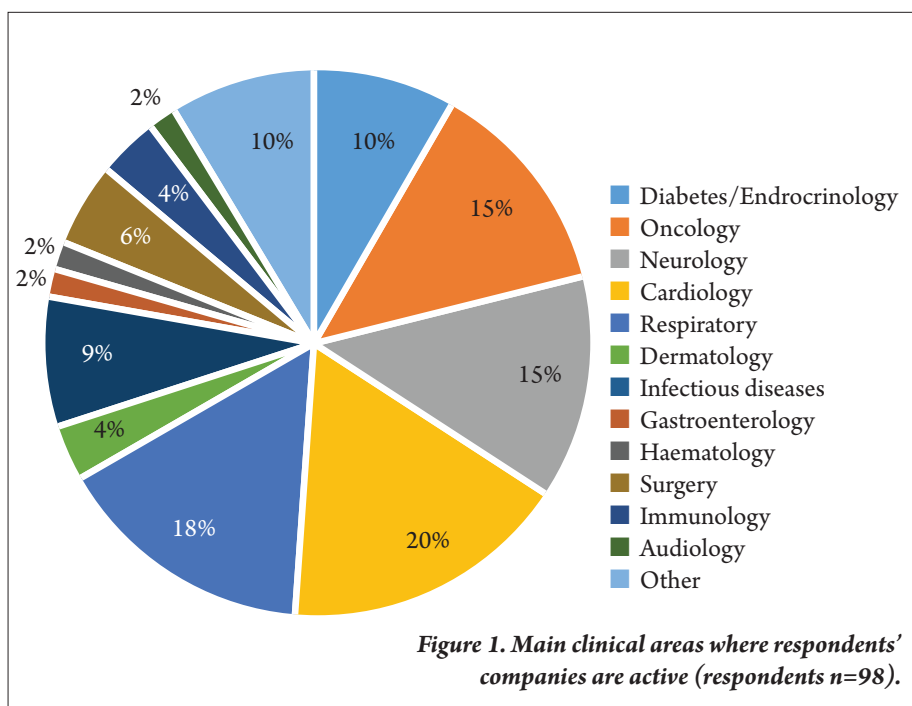


Figure 1. Main clinical areas where respondents' companies are active (respondents n=98).

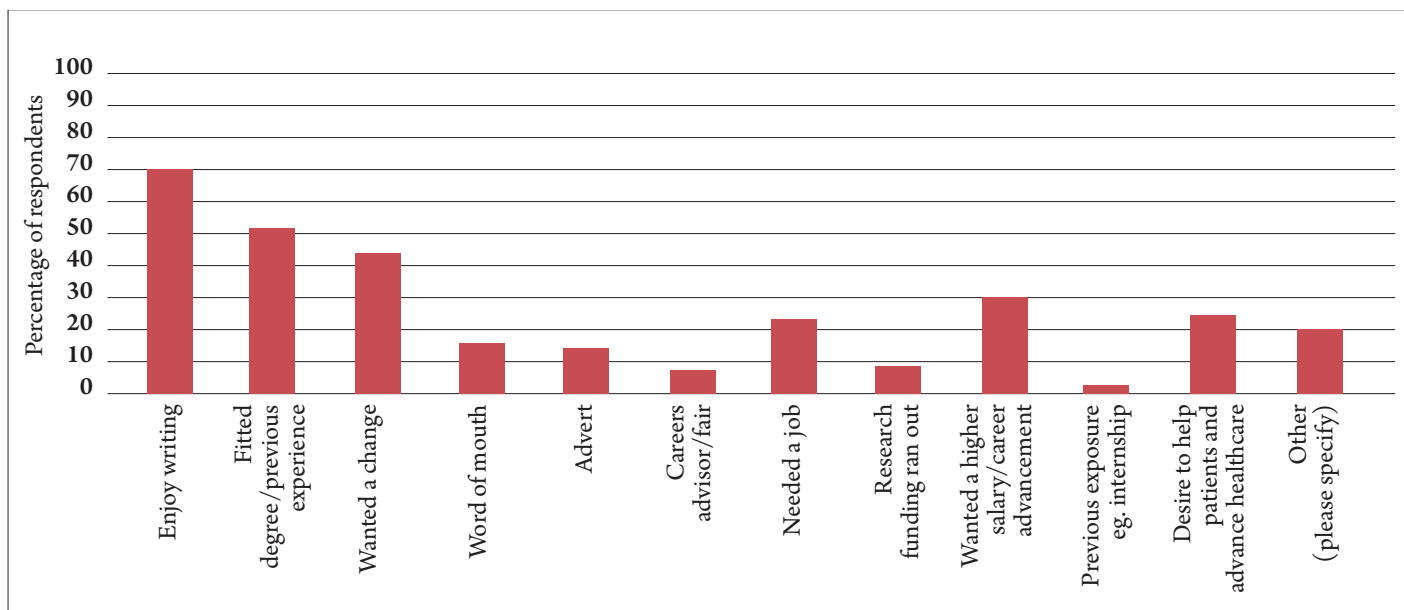


Figure 2. What made you originally consider medical writing as a career? (respondents n=110, multiple responses were encouraged).

in pharmaceutical writing, 28% in medical devices, and 5% as freelancers/consultants. Some provided their company name, indicating a spread of industry and agencies. There was much diversity in the therapeutic areas where the respondents' organisations were active (Figure 1). Respondents displayed an impressive range of degrees (110 respondents, multiple answers requested): 69% had a PhD or equivalent, 24% a Master's, and 53% a Bachelor's degree. At least two respondents were medically qualified.

Job titles varied widely: of those responding (n=109), 36% occupied managerial/directorial posts or higher, 37% senior writing positions, and 20% writing roles. The majority of the 112 respondents had occupied their post for 5 years or less (<1 year 21%, 1-2 years 24%, 3-5-years 28%), while 16% had occupied their post for 5-10-years and 11% for longer than 10 years.

Career path

The top answers to the question 'What made you originally consider medical writing as a career?' (n=110) were 'Enjoy writing' (70%), 'Fitted degree/previous experience' (52%), and 'Wanted a change' (45%) (Figure 2). A minority of respondents (20%) offered additional reasons, 'flexibility' and 'work/life balance' being the most common. Notably, 25% had a 'Desire to help patients and advance healthcare'.

What had our survey group been doing prior to starting their current posts? As evidenced by the 88 respondents who

provided free text answers, medical writers came from a diversity of backgrounds. Many were postdoctoral researchers from academia or had worked as laboratory technicians, researchers, or scientists in industry before following a common career path equivalent to 'Medical Writer, senior medical writer, senior programme manager, editorial team lead, VP medical and scientific services'. Some had a pharmaceutical, medical, or editorial ('Journal Editor') background. Others came from teaching ('English language teacher'), copyediting, translation, or medical marketing. Some had started their writing career in industry and others in clinical research organisations or agencies, with some movement between these three.

How did respondents obtain their current post (n=107)? About a third (33%) replied to an advertisement, while 'Internal advancement' (21%) and 'Invited to apply' (20%) occurred in around one fifth of cases. Recruiters were responsible for 14% of placements. Amongst 'Other' answers it is interesting that several respondents had been encouraged to apply through friends, or had contacted their company directly.

Entry requirements

What are the usual entry requirements for a career in medical writing? The majority of respondents (n=102) considered a science degree to be a necessity (90%); indeed some companies may stipulate the need for a PhD and/or experience of working in a medical/bioscience area (54%). Conversely

some respondents commented: 'Doesn't always need a science degree. I've known people with arts degrees make successful medical writers' and 'A PhD isn't really necessary for junior level positions.' Among other desirable attributes are 'Able to understand/interpret complex data, interpersonal skills, communication skills, computer proficiency, statistical knowledge' and 'An interest in medical writing.' Candidates are also often required to pass a writing test as part of the interview process (74%).

Activities, guidelines, and clinical areas

In the following sections we focus on the responses from respondents in industry and agencies and exclude the responses from the five participants who described themselves as freelancers/consultants.

There appears to be broad overlap in the types of medical writing documents and daily responsibilities of respondents working in pharmaceuticals and devices (Figure 3). The medical communication industry and regulatory guidelines followed by employees of medical device and pharmaceutical companies were also similar and included GPP3 and ICMJE, CONSORT/STROBE/PRISMA (as appropriate), plus all applicable regulatory guidelines. Several pharmaceutical respondents mentioned ICH, ABPI (Association of the British Pharmaceutical Industry), and FDA guidelines, while STARD (Standards for Reporting of Diagnostic Accuracy) and MedDev (European standards) appear in the answers



Figure 3. Word cloud representation of free text responses depicting the activities reported by pharmaceutical and device writers.

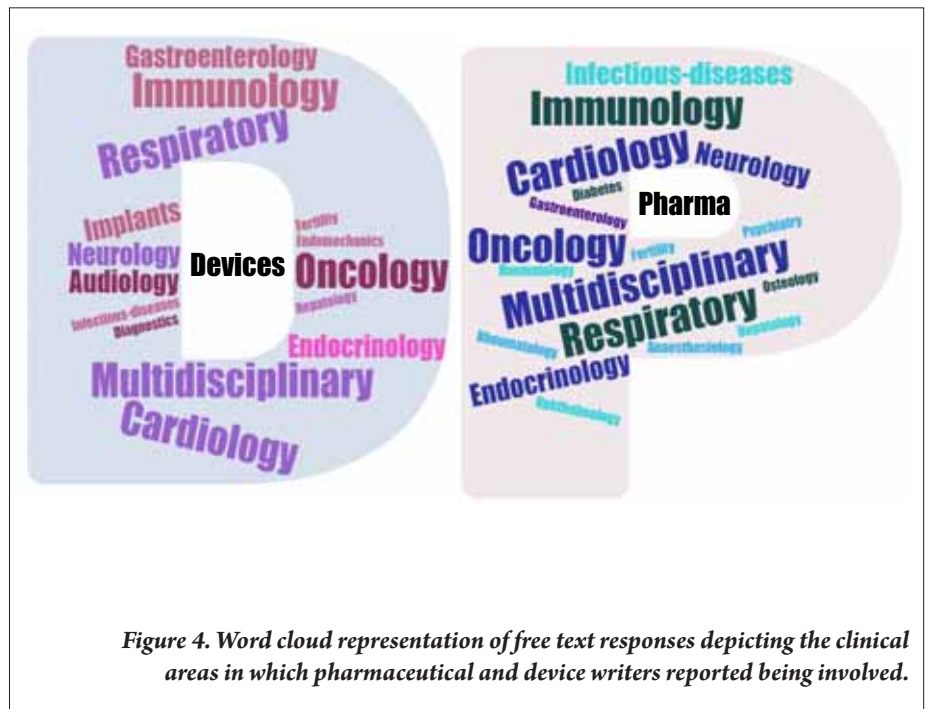


Figure 4. Word cloud representation of free text responses depicting the clinical areas in which pharmaceutical and device writers reported being involved.

given by device writers. However, there are differences in the clinical areas of activity which pharmaceutical and device writers reported being involved in (Figure 4).

Location and training

The majority of respondents (n=97) were solely office-based (pharmaceutical vs device, 54% vs 57%). It was rare for staff to work solely from home (10% vs 8%). Around a third (36% vs 35%) attended the office occasionally or regularly. The usual structure was to work in a small team in one office (19% vs 39%) or in a small team across more than one location (30% vs 36%). Pharmaceutical respondents were more likely than device respondents to work in large offices with multiple locations (39% vs 14%). Most respondents had at least daily interaction with colleagues, with those in the pharmaceutical world (70%) more likely than those in devices (50%) to have contact several times each day.

Opportunities for training and profes-

sional development (90 respondents) were generally available, although 39% of pharmaceutical and 22% of device respondents were not attending any courses at the time of completing the questionnaire.

Working hours

Out of 96 respondents, only five (5%) worked <30 hours/week. The majority reported working either 30-40 hours (pharmaceutical vs device, 50% vs 14%) or >40-50 hours (34% vs 68%); some reported working >50 hours per week (9% vs 11%). Paid holidays (excluding weekends and public holidays) were generally in either the range of 15-20 days (pharmaceutical vs device, 22% vs 43%) and >20-30 days (64% vs 36%) per year. Holidays were generally less in the USA, where 44% of respondents received 15-20 days; 75% of European staff were entitled to 25-30 days.

Career prospects, salary, and benefits

The 89 respondents gave a mixed picture.

For some, it was only possible to move up 1-2 levels before reaching a ceiling (pharmaceutical vs device, 17% vs 35%), while for others progression meant a change in role e.g. from writer to manager (35% vs 43%). Many respondents, however, selected the option ‘Progression up to senior level is possible but takes time’ (56% vs 43%). One respondent reported that it ‘depends on who you know’.

Salaries varied widely (Table 1). In response to the question ‘What do you expect to earn this year before tax and deductions?’ it can be seen that the mean (analysable) figures amongst US pharmaceutical and device respondents are broadly similar. Those working in medical devices in Europe may be better remunerated than their pharmaceutical counterparts, although numbers of respondents were small. At today’s exchange rate (March 2016) UK salaries were approximately half those in the USA.

Employees frequently received benefits

	USA	Switzerland	UK	EU excluding UK
Pharmaceutical	\$111k (n=14) (\$75k-199k)	CHF 167k (n=2) (CHF 165k-170k)	£40k (n=32) (£24k-95k)	€42k (n=4) (€24k-60k)
Devices	\$108k (n=17) (\$82k-250k)	CHF 129k (n=1)	£50k (n=1)	€62k (n=6) (€36k-130k)

Table 1. The mean (range) salary (to the nearest thousand, k) that respondents expected to earn this year before tax and deductions.

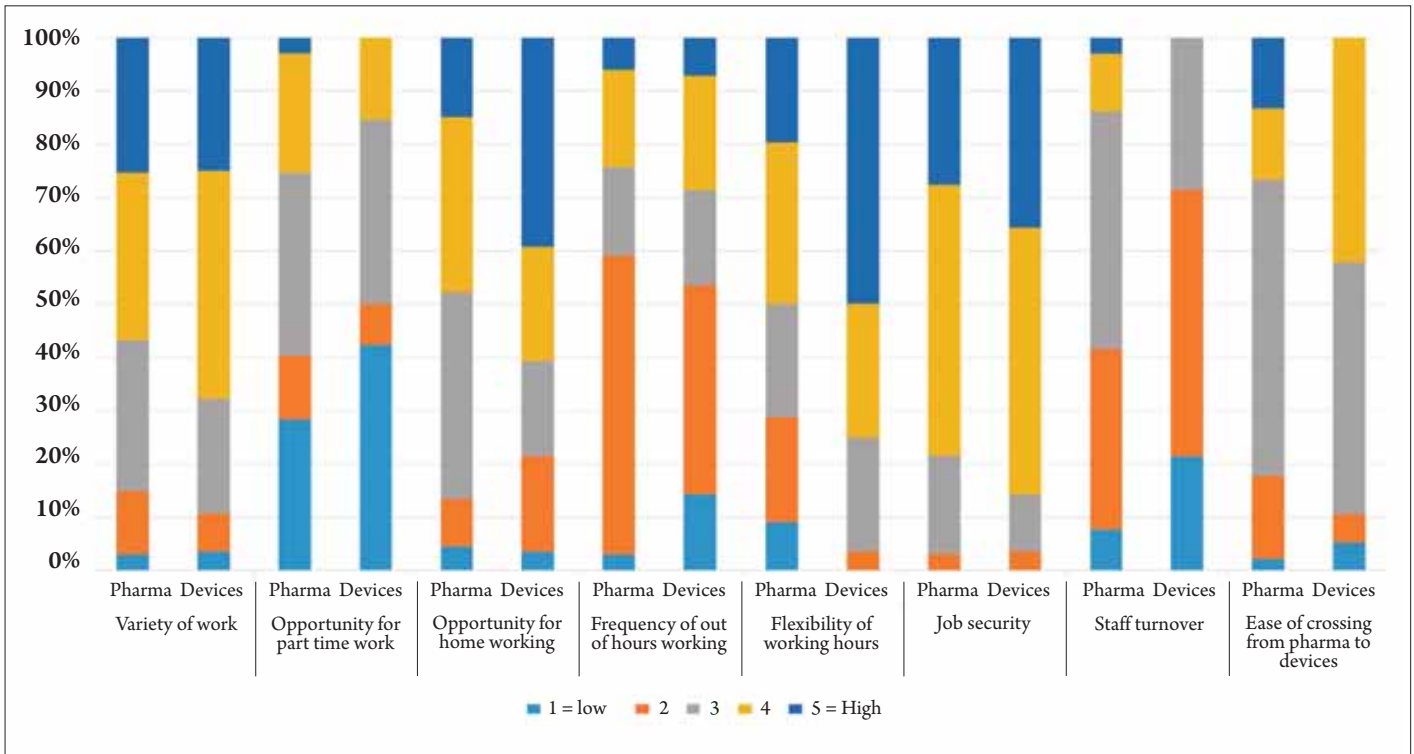


Figure 5. Employment characteristics of pharmaceutical versus device respondents (Likert scale). Number of respondents: pharmaceutical 64-67, device 26-28.

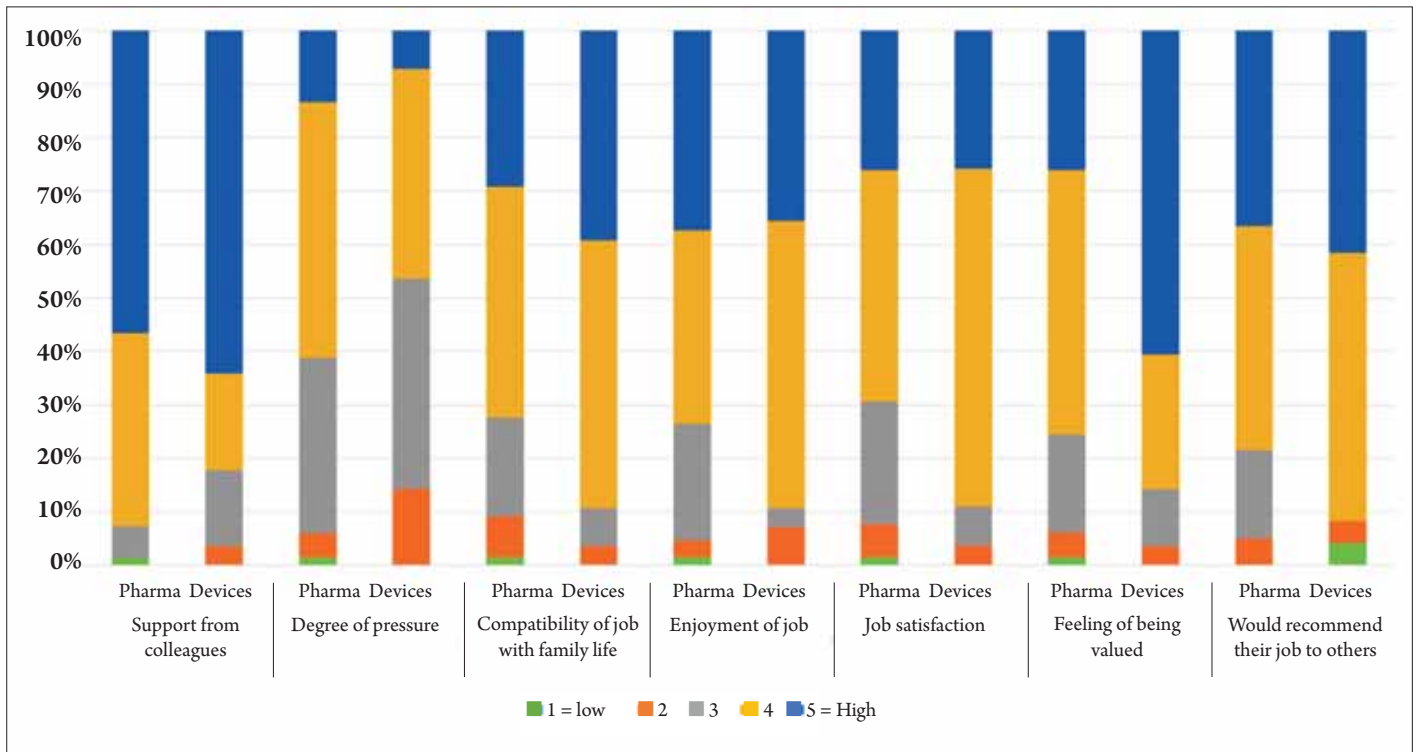


Figure 6. Factors relating to job satisfaction and quality of life for pharmaceutical versus device respondents (Likert scale). Number of respondents: pharmaceutical 64-67, device 26-28.

(94 respondents), typically health insurance (pharmaceutical vs device, 63% vs 82%) and pension or retirement plans (92% vs 68%); less frequently they received childcare/nursery placement (14% vs 32%), canteen/food vouchers (8% vs 32%), and gym membership (27% vs 54%). A few respondents mentioned other benefits: a bonus/profit share scheme, life insurance, a bicycle or travel assistance, a relocation package, and free fruit and soda. The distribution of benefits was broadly similar between Europe and the USA, although 95% of writers in the USA had health insurance and 58% gym membership (Europe 55% and 15%, respectively).

Quality of life in current role

Figures 5 and 6 provide a summary of a number of factors which may be important to the quality of life of a medical writer. Most responses to the 15 Likert scale questions about quality of life showed a positive picture with broad agreement between pharmaceutical and medical device writers, although those working in medical devices showed slightly higher ratings (4 or 5 on the Likert scale) for 'Variety of work', 'Opportunity for home working', 'Flexibility of working hours', and 'Job security' (Figure 5). Staff turnover was higher among pharmaceutical staff. Two negative aspects in both pharmaceuticals and devices were the requirement for some out-of-hours working and limited opportunity for part time employment.

As shown in Figure 6, while staff in pharmaceuticals may receive greater support from colleagues, working in the devices world was possibly associated with less pressure, greater compatibility with family life, more enjoyment/job satisfaction, and a feeling of being valued. A greater proportion of device writers considered that their job brought patient benefit (87% vs 67%, 87 responses).

Overall, the majority of respondents (n=84) would recommend their job to others (pharmaceutical vs device, 78% vs 92%).

What is bad about being a medical writer?

A total of 44 pharmaceutical respondents and 21 from devices provided free text answers. A recurring theme amongst pharmaceutical writers was unappreciative and disorganised clients and authors who failed to respect the qualifications and experience of the writer. One respondent described their job as 'Repetitive', another as 'Boring'. Other negative comments included: 'Pressure and expectation to work extra hours can put pressure on home life', 'Multiple people demanding things at the same time', 'Long hours' ('have had to work 50-hours/week for 6 months before now'), and 'Insufficient resources'.

Some clearly missed academia and felt that they were not receiving the benefits that their peers at a similar level may enjoy. Other frustrations were the peaks and troughs in workload, tight deadlines, lack of resources, sudden alterations in priorities, and changes in management. Some mentioned too much paperwork, tiresome travelling, and endless rounds of reviews and comments. It was generally not possible to link such comments to organisation type (i.e. industry or agency), although some clearly originated from agencies, such as this respondent reporting an area of frustration: 'Losing staff to other agencies with better pay.'

The range of responses from device writers was similar, although not always negative: two respondents claimed that their job had no bad points.

Out of 65 pharmaceutical respondents, seven (11%) claimed to have experienced discrimination, compared to six (21%) of the 28 device writer respondents. In response to the question 'Have you ever faced any ethical dilemmas?' 20 of 58 pharmaceutical writers (34%) reported that this had been an issue, compared to seven of 18 device writers (39%). Generally these issues were around compliance and authorship and appear to have been successfully resolved. One respondent wrote: 'This may have been the case 15 years ago but not now.'

The following quote provides a picture of what life as medical writer can be like: 'Working internationally can bring up cultural differences and exposure to misogyny. Writers are sometimes not valued

as subject matter experts or valuable contributors; constantly handling criticisms and balancing different opinions is inherent to the document review process and can sometimes turn negative.' Another quote illustrates that writers may not enjoy all aspects of their job: 'I enjoy the data, teaching others, and working with doctors and regulatory agencies, but I detest putting pen to paper.'

And what would you change?

There were fewer responses from employees in devices (16) compared with pharmaceuticals (49) but the aspects of their jobs respondents would like to change were similar across both groups. Seven pharmaceutical and two device respondents would not change anything, while a pharmaceutical respondent would change 'Everything'. Themes around company organisation included additional resources, reduced workload, less bureaucracy, fewer meetings, greater variety of work, more opportunity to write, longer holidays, better salaries, opportunities for career advancement, better training for recruits, and ability to work part time or from home.

With regard to the job itself, some respondents would like improved interaction between scientists/authors and writers, more recognition of the value of publications, and a greater opportunity to become an author.

Writing for pharmaceuticals vs devices

Does writing differ between pharmaceuticals and medical devices, which do respondents prefer, and can writers easily move between the two? The limited number of respondents who had moved from one area to the other (n=26) or who currently work across both (n=8) expressed varied opinions (Figure 5). Nonetheless, demonstrating efficacy, safety, and affordability was important for both pharmaceuticals and devices. Other similarities were in authorship requirements, rules around honoraria, and 'Bizarre journal reviewer comments.'

There are, however, a number of differences which may complicate the life of a medical writer changing between

pharmaceuticals and devices (Table 2). For some, the unfamiliar regulations and types of analyses for pharmaceuticals versus devices were problematic, particularly in the early stages of clinical development. One respondent wrote: ‘I moved from devices to pharmaceuticals and did not find it challenging at all’. Another agreed, adding that having a focus on publications rather than regulatory writing and possessing Investigational Device Exemption (IDE) experience made the transition to New Drug Application/Investigational New Drug (NDA/IND) writing relatively easy. Of their experiences in transferring the other way, one respondent wrote: ‘I moved from pharmaceutical to devices and found devices to be a far more comfortable environment where the employees are respected significantly more.’

With regards to whether publishing strategies differed between pharmaceuticals and devices, opinions were divided: 11 respondents thought strategies were similar and nine thought that they were different (two were unsure). Moreover, there was no clear difference between those preferring to work in either branch (‘Pharmaceutical’ 6, ‘Devices’ 4, ‘No preference’ 5).

And finally, what advice would you give to a new writer or your younger self?

A total of 62 respondents offered advice covering a range of issues. This advice is summarised in Table 3. Among the most frequently offered advice was to gain wide experience, join the profession early, and realise that there is more to the job than just writing.

Discussion

Medical writers now comprise a sizable proportion of the scientific community. It is therefore surprising that little is formally known about their career path, working conditions, and current activity. Our survey, though selective and representing a limited number of respondents, provides some insight for potential new recruits or those considering a change in direction.

A job in medical communications seems for many to be a fulfilling career choice. It

Pharma

- Codes of practice and regulatory requirements differ and tend to limit medicinal products more than devices
- Slow development cycle
- Multiple studies involving large patient numbers
- Push for publications and congress activities across the product lifespan
- Different audiences and communication needs
- Differences in therapeutic areas and associated language
- Study designs, outcomes, goals, and messaging tend to be predictable and consistent
- More direct-to-patient communication
- Medical writers: less experience and shorter learning curve?

Devices

- Faster development and commercialisation
- Frequent product updates, e.g. laboratory software
- Regulatory requirements differ and depend on class of device, may be less stringent
- Less emphasis on publishing and more on commercial activities, e.g. building client relationships and educating physicians and payers
- Need to consider the outcomes from the perspective of the user as well as the device
- Emphasis on accuracy and precision, ergonomics, patient preferences
- Limited publications and fewer patients per study
- Publications and congress presentations are generally focused around regulatory approval and product launch, then tend to taper off
- Operator variability and training are big factors in device performance, so learning curves are often explored in publications
- Limited publications around diagnostics

Table 2. A comparison of issues facing medical writers engaged in pharma or device activities.

also brings benefit in terms of raising the quality of clinical trial reporting.² The types of activity and range of clinical areas requiring writing input are vast. Salaries, job security, and working conditions are generally good and seem reasonably compatible with family life. Some may miss academia, although there is plenty of intellectual stimulation in helping to bring a new cancer drug or hip prosthesis to market. Downsides include a degree of pressure and out-of-hours working, with some respondents raising a number of ‘moans and groans’. One suspects that complaints about unappreciative clients, limited resources, excessive meetings, and paperwork can be heard across many industries.

There is no formal route of entry into our profession. While many possess a scientific background, have worked in laboratories, and come with impressive degrees, a minority have followed less conventional paths such as teaching and marketing. The biggest hurdle is probably getting the first job; once you have experience then qualifications tend to matter less. Amongst the most frequent pieces of advice offered by respondents is to start early in medical writing, get lots of experience across multi-

ple areas, and build personal relationships.

Our hypothesis was that variations in development and markets between pharmaceuticals and medical devices would result in a different experience for many medical writers. Based on our limited findings, this is not the case: quality of life appears to differ little between pharmaceuticals and devices, with positive responses coming from both sides. A possible reason may be the increasing need to follow guidelines and regulatory edicts in pharmaceutical and device writing, which is causing any previous distinction between the two to blur. However, taking the data as a whole, one is left with an impression that the devices world may still just have the edge, possibly due to the supportive nature of their smaller teams compared to the more frenetic activities around bringing a new drug to the global market. Changing from pharmaceutical to device writing, or vice versa, is possible but is likely to necessitate time and effort to become familiar with new regulations, language, and approaches.

This has been very much an exploratory exercise; inevitably it has limitations in covering a large amount of ground, and several respondents found the survey too

Themes	Advice (edited)
Gain Experience	<ul style="list-style-type: none"> ● Gain wide experience across different types of writing/documents, regulations, standards and guidelines. These are readily adaptable if you are willing to commit the initial effort ● Start early - write for student magazine/internships etc ● Read, read, read. Learn about many therapeutic areas as possible ● Get practice prior to having deadlines or expectations set for you ● Work overseas and travel ● Speak up if you want to get involved or have relevant experience ● Get regulatory writing experience, the jobs are abundant ● Keep an up-to-date portfolio of your work
Acquire Skills and Participate in Training	<ul style="list-style-type: none"> ● The job is not all about writing, you also need good project management and client skills ● Begin working on presentation skills early. This is essential to being effective in your role and for career advancement ● Good communication is crucial, not scientific knowledge. Manage through influence not through authority. Learn how to resolve conflicts ● Improve your business skills
Timing	<ul style="list-style-type: none"> ● Move companies after first year to gain industry perspective ● If you want a writing career, start earlier (e.g. right after a PhD). Advancement in the lab does not bring a higher position or better financial reward
Qualifications	<ul style="list-style-type: none"> ● Get a health-related Master's Degree e.g. MPH, but experience trumps degrees (generally) ● You don't need to do a post-doc ● If you don't enjoy writing and the science perhaps you should do something else
Develop Personal Attributes and Qualities	<ul style="list-style-type: none"> ● Be enthusiastic and proactive, volunteer, don't be afraid to go with your good ideas and to innovate ● Be more confident to push back (where appropriate). Don't be afraid of clients/authors but try to build a partnership with them and they will value your input. Don't let people take advantage ● Ask questions. Be curious ● Stay calm, don't panic, take a breath and then deal with the problem. Try not to get too stressed if something goes wrong – most things are fixable. Don't worry about small stuff ● Don't be afraid to seek help from colleagues. Most like to be asked ● Don't be scared of comments – they're part of the job. Develop a thick skin and don't take clients personally ● Don't deliver rubbish work because you are under pressure. If more time is needed to complete a project accurately and well then say so ● Be rigorous with some flexibility. Always put science first ● Learn to be comfortable with uncertainty and ambiguity, it will not always be possible to lay out every step/action in black and white ● Don't work overly-long hours, it becomes expected and is very difficult to get out of. Don't read emails after hours ● Be more aggressive about authorship/recognition ● Focus on what you enjoy most (for me this is the writing) ● Be open to where the job may take you – be willing to change with the job and career
Network	<ul style="list-style-type: none"> ● Join a network of people in a similar role ● To help stay on top of the science, get involved in societies, e.g. ISMPP, AMWA, etc
Other	<ul style="list-style-type: none"> ● This is a one-way road. If you love it make the most of it, if you hate it get out quick! ● There are good opportunities in medical and scientific writing but finding the good ones takes time. ● Find somewhere where the people are happy – it's the team that makes it work ● Highlight your achievements to upper management ● Have a full appreciation of the job description. Ask for more money to start ● Get into writing and away from editing quicker ● You don't have to be a manager to be fulfilled. If you enjoy writing, try to avoid getting drawn into becoming a manager ● Relationship-building is usually the key to success; focus on this when you find yourself becoming too "task-oriented" ● If you don't work for your passion/dream, you'll be working for someone else's

Table 3. Advice offered by respondents to a new recruit or younger self (edited).

long. Questions remain around the discrimination and ethical issues reported e.g. what was the issue, who was involved and what was the outcome? Moreover, we do not yet understand why there are such differences in salaries between the USA and Europe, whether simply because of differences in living costs, selection bias, or differences in the nature of the job. On this point, our results for salaries in the USA are in line with the most recent American Medical Writers Association survey,⁸ but because of the limited number of respondents may not reflect what is currently being paid to writers in continental Europe.⁹ Some of the comments hint at differences in quality of life between working in industry or for an agency, an interesting area for future research activity. Given the preliminary nature of this survey and the possibly unrepresentative sample, we did not undertake any statistical testing. However, these limitations are typical of this type of survey.¹⁰ Future replication of this study would require question validation, some shortening of the survey, and application across a much larger sample. Despite the survey's limitations, we believe the results provide some useful insights for potential new recruits to our profession and offer encouragement to those considering a change between writing for pharmaceutical products and medical devices.

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Conflicts of Interest and Disclaimers

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