

# Where have all the UK entry level pharmaceutical regulatory medical writing jobs gone?



Elsa Lewis and Jonathan Oliver

Lioness Writing Ltd, Canterbury, UK

## Correspondence to:

Elsa Lewis  
Lioness Writing Ltd  
16 Ersham Road  
Canterbury, Kent, UK  
lionesswritingltd@gmail.com  
+44 1227 453682

## Abstract

The ways onto the regulatory medical writing ladder appear to be disappearing. Is there a reason for this recent scarcity of entry level jobs in the UK? Is this indicative of a larger problem – that of an impending danger of a skills drain from the UK in this field? The authors examined advertised job vacancies, conducted interviews and canvassed opinion on social media to explore a possible skills drain in the context of the outsourcing of regulatory medical writing. Partnerships between experienced individual independent medical writers and industry brokered by professional organisations might be a solution.

## Where have all the UK entry level pharmaceutical regulatory medical writing jobs gone?

### Introduction

At careers fairs for life sciences graduates and postgraduates, there has been a noticeable absence of entry level jobs for graduating students, working clinical technicians, or even for experienced regulatory affairs personnel looking for a sideways career move.

In the UK, an active seeker of medical writing posts through online job searches and recruitment agencies will discover 97% currently advertise for posts openly requiring at least two years' medical writing experience. The remaining 3% give veiled impressions that both a PhD and prior experience is still likely to be required. The only posts not requiring previous experience seem to be in the US, or elsewhere in Europe and India.

The ways onto the regulatory medical writing ladder appear to be disappearing. Is there a reason for this recent scarcity of entry level jobs in the UK? Is this indicative of a larger problem - that of an impending danger of a skills drain from the UK in this field? The authors examined advertised job

vacancies, conducted interviews and a possible skills drain in the context of the outsourcing of regulatory medical writing.

### Is regulatory medical writing for the pharmaceutical industry a proper career?

For many careers within a highly qualified industry, most graduates or postgraduates starting a post might expect a probation period as they become accustomed to the workplace and the role they are expected to fulfil. Law students have articles, medical doctors have the hierarchy of a hospital to guide them and architects would have work experience before practising unsupervised. For scientific or technology teams, there would be a team for new starters to join, mentors on hand to help and training to undertake. Summer jobs and internships also help new graduates taste and see whether this might be the job that would suit them, while equipping them with experience and basic training for the post. These new starter training programmes/constructs appear to be on the decline for the medical writer, despite an increase in demand for the role.

Various medical writer journal articles give the impression that a medical writing

post is something that is a temporary position or a post occupied while one is between jobs – perhaps something to try once all other avenues are exhausted.<sup>1</sup> This is exacerbated when higher education and academic organisations struggle to identify what the role actually entails.

Nevertheless, the introduction of the International Council for Harmonisation (ICH) clinical study report guideline (E3), adopted in 1995, formalised the content requirements of a study report, together with specifying associated appendices and the requirement for a documented quality control and quality assurance process. This resulted in a rising demand for the medical writer role within a drug development team and the subsequent regulatory requirements to write up reports for every study enrolling patients further increased this demand.

Prior to 1995, drug development teams might only have included a medical writer as an afterthought once a project neared a study's end. Today's teams include at least one writer throughout the clinical phases. Documents now written by regulatory medical writers include protocols, which describe how each study will be run, through to submissions to regulatory authorities, which describe the benefits and risks associated with a new drug and present a case for why it should be approved for use. As identified on the ABPI website,<sup>2</sup> in recent years, the value of medical writing has been increasingly recognised, the status of medical writers has risen, and the range of opportunities for experienced writers has grown.

The competitive salary and volume of work for experienced medical writers in the field reflect this picture, suggesting more

that it is a recognised and significant role throughout the clinical phases of drug development.<sup>2</sup> Opportunities for medical writing are clearly shown from the increase in advertised posts and the commitment of recruitment agencies dedicated to finding suitably qualified individuals.

The profession entails a unique mixture of technical writing and project management in a team environment and is well suited for life sciences graduates who prefer the communication aspects of the field. An effective medical writer needs experience to understand the 'shepherding' role that is required, the regulatory environment with its guidelines, and a team's working practices.

### What was the entry route for graduates previously? What has changed?

As departments for medical writing emerged in pharmaceutical companies at the end of the last century, entry level jobs, internships and secondments were available for life sciences graduates and also for individuals moving from other departments within the pharmaceutical industry. Employee development structures appeared for regulatory and writing training, mentoring, development of good practice and quality control. Hierarchies emerged and managers organised lead, principal, senior and junior posts: the medical writer role became established.

However, as is also the case for the statistics role, there is a natural rise and fall in demand during the life cycle of a drug. There is a

heavier workload for the medi-

cal writer as studies reach their conclusion and the final dossiers are compiled. In the increasingly difficult economic environment around the 2008 financial year, coupled with scientific challenges to the drug pipeline, the outsourcing of Research and Development roles became a way to make short-term savings.

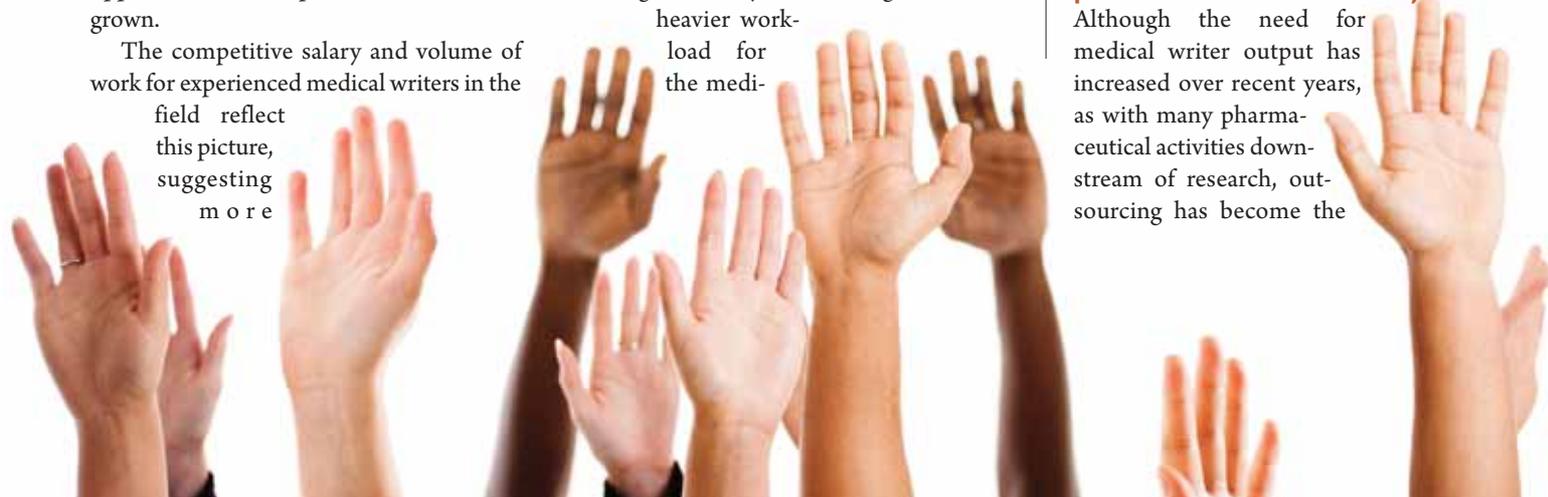
### What is the long-term future of the profession?

The release of ICH E3 in its modern form (1995) led to an increase in entry level jobs as medical writing departments grew to write the study reports and dossiers required for drug applications. The demands on the role within the development team has continued and expanded as regulatory requirements become more stringent, including, for instance, the mandatory requirement for a report for all clinical studies within 6 or 12 months of last patient visit.<sup>3</sup> The ICH agreement has English as the international language, which in theory would give native English speakers an advantage, especially when the UK has a good track record in providing well-qualified life science graduates and postgraduates. One would therefore expect that the UK would have little difficulty in filling a rising demand for entry level roles.

Medical writing appears to be a thriving profession with a healthy long-term future – so where are all the entry opportunities?

### Outsourcing in the pharmaceutical industry

Although the need for medical writer output has increased over recent years, as with many pharmaceutical activities downstream of research, outsourcing has become the



model of choice due to perceived cost savings, risk reduction and the possibility of a more flexible response to changing demand depending on drug development success.<sup>4</sup> This is based on the premise that a medical writing contract is easier and cheaper to cancel than keeping a department during the times that a drug pipeline plateau is on a downward trajectory.

Most of the medical writing departments in the pharmaceutical industry have shrunk considerably and in most pharmaceutical companies, a small group of outsourcing managers have replaced the in-house writers. The pharmaceutical company looking to outsource medical writing has three overall choices of who to outsource to:

- individual independent medical writers,
- small to intermediate medical writing specialist providers, or
- larger full service clinical research organisations (CROs)

So what are the current entry level job opportunities within these organisations?

### Individual medical writers

There are currently no opportunities in development teams for an inexperienced independent medical writer. Gaining and undertaking training under the auspices of a professional organisation is currently expensive and still does not provide the on-the-job training required. Moreover, the two-year experience criterion would still be lacking. Internships and summer posts are in the decline as the medical writing departments within pharmaceutical companies disappear. At present, the only theoretical entry opportunity for a new starter in this area would be to find an experienced medical writer who is prepared to not only train and provide the experience, but also negotiate contracts that allow for a mentoring arrangement. In terms of business practice, however, this potentially looks as though individual writers would be investing a great deal in order to create their own competition.

What is clear, however, is that solutions to a possible medical writer skills drain needs to be considered now before we lose these skills from the UK in the long-term.

### Medium-sized medical writing specialist groups

With the transition into outsourcing models over the past 10 years or so, some forward-thinking independent writers (in some cases alongside statisticians and other departments under threat) set up small specialist organisations.

Whole pharmaceutical industry medical writing departments were relocated off-site and re-employed by new independent service provider groups. Some of these specialist groups have grown to be nearly full service CROs and others have remained specialised (for example, purely medical writer or as an adjunct to statistics) and grown more established over the years. Based on observation of the lack of posts advertised, entry level jobs have existed in the past within these organisations, but in recent years in the UK it would appear that recruitment for many of these groups has been in decline or on hold. Entry opportunities in this area may well be diminishing as a result of increasing competition with the economies of scale possible in larger CROs. Experienced specialist expertise is the one staple competitive edge that such groups would offer. Indeed, these were the only organisations that were identified at the time of our research that currently offer any training posts for new graduates.

### Clinical research organisations

These can be full service organisations providing for example a full team of clinical, statistical and regulatory writing support to the pharmaceutical industry. The largest 10 CROs are currently Quintiles, Parexel, Pharmaceutical Product Development (PPD), INC Research, Covance, Medpace, PRA Health Sciences, inVentiv Health, Meditrial Europe and Chiltern. A casual job search conducted in April 2016 revealed only one potential medical writer entry level position within the UK. A small number of jobs were available in USA, but not many at all in Europe. Vacancies appear to be in locations elsewhere than the UK, for a

number of possible reasons: because head offices of these CROs are not in the UK, or the 2008 financial downturn is casting a long shadow, or in the US they have had more experience with outsourcing. Given the advantages that UK medical writing has to offer, the current situation seems inadequate and unsustainable.

### What does this mean for the future?

The outsourcing model remains in a state of flux for drug research and development with differing levels of in house or outsourced roles for each company. If it is anything like the general global trend in outsourcing, it is likely to come under more frequent review. What appears to be the tendency is for roles further downstream, such as medical writing, to remain outsourced, which in the long-term will lead to a move away from using new medical writers based in the UK unless proactive, more long-term solutions are considered.

Universities have been challenged, for instance by the government's partnership approach for equipping the next generation with relevant suitable skills.<sup>5,6</sup> They have attempted to rise to the challenge, for instance, Worcester University had a Medical Writing Masters course, Canterbury Christ Church University was considering a regulatory module to its course, and University College London has a clinical trials module. However, none of these initiatives will lead to careers unless there are vacancies for new starters. Indeed the Worcester course has closed down and the regulatory module has now been refocused on research.

### Possible solutions

The globalisation of recruitment and the advance of communication technologies is one trend that will continue to aid future experienced individuals. The role of a medical writer can be performed adequately remotely by an experienced writer – indeed it is quite common for development teams to be based on two or even three continents with large teleconferences and screen sharing technology bringing them together on a regular basis. But this still does not



address the problem of individuals within the UK, even those looking for a sideways career move, getting a foot on the ladder without some forward planning.

Partnerships between experienced individual independent medical writers and industry brokered by professional organisations might be a solution. Indeed, it looks as though moves are being made in this direction by larger organizations. Mentoring of new graduates over a two-year period is very costly to a small company, since extensive work shadowing, training and oversight is required. Only a handful of small specialist medical writing companies currently seem to have this environment open to new starters. Yet, if this effort could be shared within a collaborative structure, coupled with appropriate contractual agreements, there is more chance of it happening. If a highly organised, industry wide collaboration took place it would work to enhance a higher level of quality and add a more professional and competitive edge. Without such pressure, there is little incentive for independent medical writers to undertake this, as after the apprentice period is served, any enterprising experienced medical writer would currently leave to find their own contracts.

Perhaps one of the most forward-thinking solutions can be found through the recruitment agencies themselves. It is possible for a more specialist recruitment organisation to set about creating both a training academy and funding pool for graduates to gain the necessary experience and skills to join the industry.<sup>7</sup> Such

programmes do exist and are in their infancy. Ensuring the necessary two years experience to take on such a role, however, remains something that is still being developed and would require considerable financial backing and resources.

Currently efforts are being made to bring industry and new graduates together at careers fairs and indeed regulatory professionals looking to move sideways into different roles. These efforts aid the process of communicating different vacancies that exist, and maybe could be expanded to seed partnering within the industry.

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## Author information

**Elsa Lewis**, Director and Regulatory Medical Writer with Lioness Writing Ltd with 18 years writing experience in the Pharmaceutical Industry.

**Jonathan Oliver**, an independent consultant for Lioness Writing Ltd, with experience in publishing and outsourcing.