

August 2022

A writer's role in drug development

A guide to

*getting started
in regulatory
medical writing*

Written by Dr Debbie Brix Reynolds

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Acknowledgements

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A writer's role in drug development: a guide to getting started in regulatory medical writing

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Foreword to 2022 edition



I've been running MedComms Networking activities for many years now and talking with post-graduate students and others about career opportunities for medical writers who are interested in working within specialist medical communications (MedComms) companies. But MedComms writing doesn't suit everyone and many people who attend our FirstMedCommsJob careers meetings ask about other closely related options, such as regulatory medical writing. Whilst the style of writing is different to MedComms and aimed firmly at satisfying the rigorous needs of the regulatory and licensing authorities, regulatory writers need just the same enthusiasm for science,

ability to work as part of a team and pedantic nature to succeed. I hope this guide will help you better understand the options. We welcome your feedback.

Peter Llewellyn

For more information see: www.linkedin.com/in/networkpharma

About the author

Debbie is a freelance medical writer and communications consultant, specialising in regulatory



writing, based in Southport. After gaining her BSc in applied biochemistry from the University of Liverpool and her doctorate in cardiovascular physiology from the University of Glasgow, Debbie undertook post-doctoral research at the University of Glasgow and at the Wales Heart Research Institute, University of Cardiff. After realising that academia wasn't for her, Debbie made the leap from academic to medical writer in 2005, securing a role at Dianthus Medical where she gained experience in the many aspects of medical writing. In 2011, she became a freelancer, working for a variety of clients within the pharmaceutical industry.

Debbie Brix Reynolds

For more information see: www.linkedin.com/in/debbie-brix-reynolds-b3321a59/

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Introduction

So maybe you're coming to the end of your post-graduate degree or you're currently a post-doc who is ready for a change. Perhaps it's time to leave academia and look into alternative roles that will use and build on the skills that you honed during your research career.

If you enjoyed writing your thesis, you are pedantic when collating and communicating data in meaningful ways to your peers, and you have excellent attention to detail, then maybe medical writing is a career for you.

Regulatory writing is a specialist type of medical writing that supports the drug development and approval process. But it doesn't stop there. The safety of drugs is monitored and collated for as long as they are marketed. Regulatory writers play a key role throughout this process and, hence, in improving patient care.

*Regulatory writing supports drug development,
approval and beyond...*

About this guide

This guide aims to provide an insight into regulatory medical writing with a focus on drug development as opposed to medical devices, although writers work in both areas. It explores the roles and attributes of the writer, tips on winning your first regulatory writing role and help in deciding whether this would be the career for you, drawing comparisons with working in MedComms.

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Also available

See also...

Ensuring timely dissemination of research
A guide to working as a medical publications professional

The business of medical communications
A guide to getting started in account management

From academic to medical writer
A guide to getting started in medical communications

Making it my own business
A guide to being a freelance writer in MedComms

Evidence generation and communication
A guide to getting started in HEOR/market access medical writing



Regulatory writing or medical communications (MedComms) writing?

As a discipline, medical writing caters for a variety of audiences, from regulatory experts and healthcare professionals to the lay public. It can broadly be divided into MedComms writing and regulatory writing, although there is some overlap.

MedComms writing

Medical writers who work in MedComms provide the pharmaceutical industry with writing services that aim to raise physician/patient awareness of medicines. MedComms writing can involve working on a wide range of projects, including manuscripts as part of a strategic publication plan. MedComms writers may also be involved in preparing slide decks, educational materials for healthcare professionals, website copy or documents intended for patients. More details on MedComms writing is provided in another of our guides, '*From academic to medical writer: a guide to getting started in medical communications*'.¹

Regulatory writing

The role of the regulatory writer is to prepare the formal and scientific documents that pharmaceutical companies need during the development of a drug. Such documents support development programmes and are required by drug licensing authorities, such as the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA). Hence, regulatory writers play an important role in helping to get new drugs to the market and in improving patient care.

Regulatory writing requires a different style to MedComms writing. Regulatory writers have to develop documents according to the standard templates and requirements mandated by regulatory authorities, in line with Good Clinical Practice (GCP) and other specific guidelines. This style of medical writing requires meticulous crafting and attention to detail to ensure that medical and scientific evidence is presented

in a comprehensive, standardised and rigorous manner. Individual documents may be concise and standalone, but may also form part of a larger submission. Working within the regulatory writing arena can sometimes be viewed as being

more formulaic in style than MedComms writing. However, while MedComms must necessarily focus on key messages and findings, regulatory submissions must be a complete record of years of development work. This represents a fascinating challenge for the writer: how do you craft a large body of data into a logical and understandable story while maintaining transparency of potential risks and limitations?

Regulatory writing requires a different style to MedComms writing

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The drug development process

Developing a new drug can take up to 15 years and cost in excess of \$1 billion.² The process can be broadly divided into three parts: target discovery and validation, pre-clinical testing and clinical research.

Target discovery and validation

Advances in bioinformatics technology and methodology have permitted easier identification of potential drug 'targets' (e.g. proteins or genes) and their validation. After a target has been identified, pharmaceutical companies have a number of processes that allow the screening of what could be up to thousands of compounds. A 'hit' is a compound/molecule that has demonstrated the required activity during compound screening, with confirmed activity upon retesting, and once identified, development focuses on improving the potency and selectivity of the compound/molecule (lead optimisation),² ultimately leading to a potential new drug.

Pre-clinical testing

Candidate compounds/potential new drugs then move on to pre-clinical (sometimes termed non-clinical) *in vitro* and *in vivo* testing to obtain preliminary safety, tolerability and efficacy data. Conducting *in vivo* studies informs decisions about what dose(s) should be used if the drug moves into clinical testing.

Clinical research

A clinical development programme involves a series of clinical trials, conducted in human volunteers or patients with the disease for which the drug is being developed, usually termed Phase I–IV studies.

Phase I

Phase I studies are 'first-in-human' studies – usually conducted in healthy volunteers. These preliminary studies investigate the safety and tolerability of a compound, as well as its fate in the body (pharmacokinetics [PK]) and sometimes its effect(s) on the body (pharmacodynamics [PD]). These studies can give an indication of the appropriate dose range for the drug. Phase I of the development programme can also involve drug interaction studies, as some drugs affect the metabolism of others.

Phase II

Phase II studies are predominantly carried out in patients. These studies may be placebo-controlled (to assess the efficacy, safety and tolerability of the drug versus placebo) and double-blind (neither the study personnel nor the patients know which treatment was received, which helps to reduce bias). Phase II studies are also used to confirm the therapeutic dose of the drug being studied.

Phase of clinical development	Description
Pre-clinical	Testing in vitro and in suitable animal models
Phase I	Testing in healthy human volunteers
Phase II	Testing in patients
Phase III	Testing in comparative trials
Phase IV	Post-marketing surveillance following the launch of the drug

Phase III

During Phase III, studies are almost always conducted in large numbers of patients and may involve multiple countries. Usually, the drug under study is compared with the current best treatment/standard of care for the target indication/disease and/or placebo. Phase III studies are typically randomised and double-blind. These studies generally exclude specific groups of patients (e.g. those with renal impairment) to which the drug under study *should not* be given (i.e. for whom the drug is contraindicated).

Phase IV

Phase IV studies, most often designated post-marketing surveillance or post-authorisation safety studies (PASS), are conducted after the drug has been granted approval by drug licensing authorities. The safety of an approved drug will continue to be monitored as long as it is marketed.

Regulatory writing and the drug development process

Regulatory writers prepare a variety of documents that are required during the drug development process, examples of which are described below. Typically, they will lead the writing of these documents with input from team members, which can include a study clinician, statistician, drug safety representative and regulatory affairs, as well as quality assurance personnel.

Development (Phases I–IV)

Clinical study protocols

In order to conduct a clinical study, a protocol is required. A clinical study protocol describes, in detail, all of the processes, assessments and requirements for that study to run smoothly. The protocol also includes a description of which statistical analyses will be performed, with specific details usually defined in a separate statistical analysis plan.

Informed consent forms

Before clinical study volunteers/patients can undergo any study-related procedures, they must provide informed consent, or assent by parents/caregivers in the case of paediatric or vulnerable patients. The informed consent form (ICF) provides potential clinical study participants with details about the nature of the study and the anticipated benefits and risks. It should also clearly explain that they can withdraw their consent at any time.

Clinical study reports

A clinical study report (CSR) is prepared at the end of a study and presents a complete record of the methods and results obtained. Data presented in CSRs are the results of the analyses that were pre-defined in the study protocol and statistical analysis plan.

Investigator's brochure

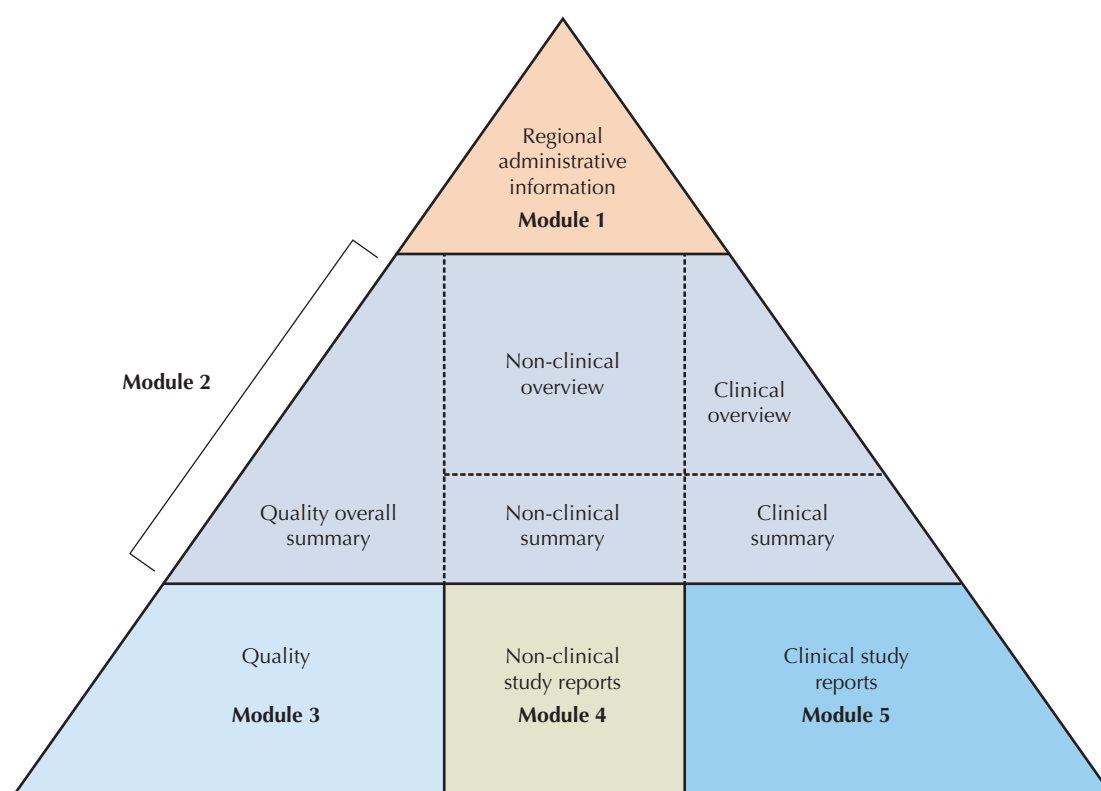
The person responsible for conducting a clinical study at a particular site is referred to as the investigator. An investigator's brochure (IB) details all known information to date on a study drug and is distributed to those involved in conducting the study. The IB acts as a valuable resource for an investigator when making an informed decision on the benefits and risks associated with a study drug. The pharmaceutical company that markets the drug being investigated should review the available information annually and, if necessary, initiate an update to the IB. Regulatory writers may prepare either the initial IB and/or subsequent updates.

Drug safety/pharmacovigilance documents

During the development of a new drug and following marketing approval, safety is closely monitored. This necessitates the production of specific documents reporting on the safety of the drug. These include development safety update reports (DSURs), periodic safety update reports (PSURs) and risk management plans (RMPs).

Documents for submission to drug licensing authorities

In order for a drug to be marketed for the first time or in a new disease area, approval must be obtained from drug licensing authorities. Pharmaceutical companies compile a dossier of all of the available data that have been collected during the quality, non-clinical and clinical development programmes for a potential new treatment. In July 2003, the Common Technical Document (CTD, see figure below) became the mandatory format for new drug applications in the European Union and Japan, and the strongly recommended format of choice for new drug applications submitted to the US FDA.³ Regulatory medical writers are most often involved in writing CSRs (Module 5; for more information, see page 8), clinical summaries and clinical overviews (Module 2), but may also be involved in preparing the non-clinical components.



The CTD triangle³

Clinical summaries

The clinical summary is a detailed, factual narrative of all of the clinical information in the CTD, including individual components covering biopharmaceutics, pharmacology, efficacy and safety. This includes data presented in CSRs, information obtained from any pooled analyses and post-marketing data for products that have been already marketed for other diseases. The results presented should focus on factual observations.⁴

The clinical overview

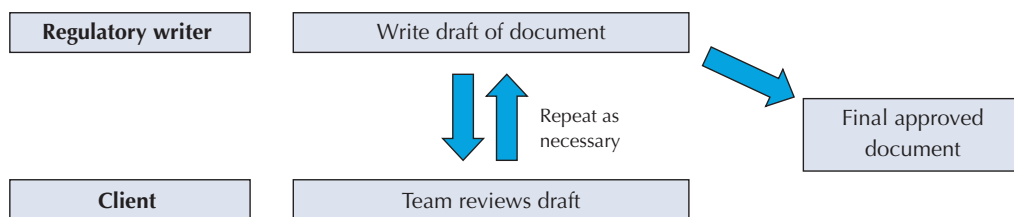
The clinical overview is intended to provide a critical analysis of the clinical data in the CTD. It should factually summarise and critique the data provided in the clinical summary documents, presenting clear conclusions and implications as well as a comprehensive benefit–risk analysis.

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What will my role be?

Your main role will, of course, involve the writing of regulatory documents. Other responsibilities will depend on your employer (see page 11 for details of potential employers). For example, if you work for a specialist medical writing company, you will likely work directly with client teams. In simple terms, you will write a document for a client, who will review your work, and you will implement review comments before the document is finalised. As part of the process, quality control checks will be carried out by other personnel who have not previously been involved with the document.



Other aspects of your role will depend on your level of experience and could include project management, coordinating comment review meetings, managing several documents at the same time (usually at different stages of development) and mentoring/training more junior writers.

Who will I work with?

Regulatory writers rarely work in isolation and usually work as part of cross-functional, internal and external teams, which can include clinicians, statisticians, regulatory affairs personnel, pharmacovigilance personnel and other specialised functional lines. Depending on your employer and the client, teams may also be global and include high-level regulatory and clinical personnel.

How do I start?

You've made the decision to begin your career in regulatory writing. The majority of regulatory writers come to the profession from a scientific/medical research background. Although a post-graduate degree is deemed as desirable by many potential employers, this is by no means universal.

To take the first step in securing your first regulatory writing position, it is a good idea to contact companies directly. Most importantly, don't underestimate the value of a well written CV and covering letter. Medical writers are professionals at spotting the smallest errors in grammar, spelling and consistency. This is a good opportunity to show your excellent attention to detail. Leading regulatory companies provide the necessary training for potential candidates. This may include training performed in-house or by external organisations such as the European Medical Writers Association (EMWA).

What makes a good regulatory writer?

Employers look for a number of attributes in addition to your writing skills. These include, but are not limited to: excellent attention to detail, good communication skills, the ability to work independently and as part of a team, computer literacy, time-management and the ability to quickly get to grips with new therapy areas. In addition, writers are required to multi-task, as you may be expected to manage several projects at the same time. However, one of the most important attributes for any medical writer is the ability to accept critique positively. No matter how experienced you are, your work will be reviewed and commented upon.

Who employs regulatory writers?

Specialist medical writing companies

Specialist medical writing companies, as the name suggests, provide only medical writing services to the pharmaceutical industry. You would work with a diverse array of clients in multiple therapeutic areas. Some companies also provide MedComms medical writing services.

Contract research organisations

Contract research organisations (CROs) provide services to the pharmaceutical industry, which can include clinical trial management, data management, statistical analysis and medical writing.

Pharmaceutical companies

Working as a regulatory writer within a pharmaceutical company will generally involve working within one or a few therapy areas, which you would be suited to if you enjoy getting to grips with topics in great detail.

What can I expect to earn?

Salaries for regulatory writers vary according to location and employer. As an entry-level regulatory writer, you could expect to earn £30,000–£35,000 per annum. There is considerable demand for experienced regulatory writers in the industry, and your salary will increase as your career progresses. Your earning potential could also increase for contract and freelance roles.

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Applying for a job

Securing your first job as a regulatory writer can be a challenge. Employers are often looking for specific experience, which is a Catch 22 situation as you won't have specific experience without having worked as a regulatory writer. However, don't be disheartened. Entry-level positions do exist as some employers are keen to recruit new writers with no previous regulatory writing experience who can be trained. Despite the fact that you may have written manuscripts, abstracts, posters and grant applications, regulatory writing has very specific conventions and requirements that are likely to be new to you.

The writing test

As part of the recruitment process, it is usually necessary to complete a writing test, either before or during the interview. Potential employers will use this test to assess several things, such as: grammatical skills, attention to detail, ability to follow instructions, writing 'flow' and scientific knowledge.

The format and length of the writing test will vary from company to company. Examples include writing an abstract from a publication or from provided data, summarising data, proofreading to identify and correct mistakes in a passage of text, or writing a specific section of a document such as a CSR. You may be asked to follow a specific writing style and to follow guidelines when completing your writing test.

Test your attention to detail!

This test is designed to test your proofreading skills. See if you can spot and correct the errors in the example piece of text below.

Name of Sponsor: A.N. Other Pharma Ltd	Name of Finished Product: CHIPS
Name of Active Ingredient: Potato	Study Number: AN-002
Study Title: A phase III, randomised, double-blind, placebo-controlled, study to investigate the efficacy of CHIP'S in treating hunger in patients	
Principal Investigator:	Dr John Doe
Study site:	A Hospital A Road A City United Kingdom
Studied Period: First patient, first visit: 05 October 2017 Last patient, last visit: 21 December 2017	Phase of Development: Phase II
Objectives:	
Primary:	To assess the reduction in hunger score in response to a 90 g of CHIPS or placebo administered orally in 3 doses
Secondary:	<ul style="list-style-type: none"> To assess the mean mass of CHIPS required to reduce the hunger score by 2 points To assess the safety of CHIPS
Study Design This study was planned as a single-blind, placebo-controlled study in patients with hunger. Patients provided informed consent and were randomized to either CHIPS or placebo. At Visit 1, patients were administered 90 g CHIPS or 90 g placebo in three 30 g doses given 30 minutes apart. Hunger score was assessed 5 minutes before administration of dose 1 of study treatment (CHIPS or placebo), immediately before doses 2 and 3, and 30 minutes after each dose.	

The answers are given on page 15 of this guide. Did you spot them all?

The interview

Your interview is your opportunity to really sell yourself. Make sure that you show your interviewer that you have the relevant transferable skills and the potential to be successful as a regulatory writer. Preparation really is key here: if you feel prepared, you will be more likely to be relaxed and come across well to your potential employer. Before you walk into your interview, make sure you take some deep breaths and try to relax.

When preparing for your interview, do your research on the company. You may be asked why you would like to become a regulatory writer. Think of a good reason as this is a potentially very important question and your interviewer will be judging how you answer. Perhaps you have always enjoyed the writing aspects of your current job/previous degrees? And/or that you feel that you are skilled at research and would like to apply those skills to a new career? With each question posed to you by the interviewer, try to relate your answers to what the potential employer will be looking for in a regulatory writer (see the section 'What makes a good regulatory writer?' on page 11).

A good idea would also be to highlight your ability to work as part of a team. This is a very important attribute in a regulatory writer because you will often be working with personnel from multiple disciplines. Another attribute that you may want to highlight is the ability to quickly assimilate knowledge about a new subject/topic, which is also a key skill that regulatory writers need.

If you have attended any introduction to medical writing courses or completed any medical writing/editing work placements/internships, make sure you talk about them. This will show the potential employer that you mean business and are committed to becoming a regulatory writer.

Something else to bear in mind for the interview process is that you are also interviewing the potential employer. Can you see yourself working for a particular company? Informally chatting with existing employees will give you a feel for the work culture and environment, so if the opportunity to chat with existing employees is not discussed, it would be a good idea to ask your interviewer if this would be possible.

Preparing questions in advance will help you to focus and will also make you look genuinely interested in working in regulatory writing. Questions about the company also show you have done your research. Some suggested questions are listed below.

- How is the department organised in terms of management?
- If I am successful with my application, would I have a mentor whilst I am learning the job?
- Could you give me some information on what training is provided?
- Will I need to travel?
- Is training internal and on the job or is there an opportunity to participate in external training (such as attending EMWA conferences)?
- If I am successful with my application, would I get to work within several therapy areas, or would I be restricted to a particular area(s)?
- What is the scope for career progression?

Good luck!

Further information

Books

Medical Writing: A Prescription for Clarity. 3rd Edition. Goodman NW et al., Cambridge University Press, 2006.

Writing and Publishing in Medicine. 4th Edition. Huth EJ, Williams & Wilkins, 2014.

The Complete Guide to Medical Writing. Stuart MC, Editor, Pharmaceutical Press, 2007.

Fundamentals of Clinical Trials. 3rd Edition. Friedman LM et al., Springer, 1998.

Randomised Controlled Trials: A User's Guide. Jadad AR, BMJ Books, 1998.

Professional bodies

European Medical Writers Association (EMWA)
www.emwa.org

American Medical Writers Association (AMWA)
www.amwa.org

General information

Learn about clinical studies from ClinicalTrials.gov –
www.clinicaltrials.gov/ct2/about-studies/learn

The drug development process from the US Food and Drug Administration –
www.fda.gov/ForPatients/Approvals/Drugs

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) – www.ich.org

Working in the industry from the Association of the British Pharmaceutical Industry (ABPI) –
careers.abpi.org.uk/working-in-the-industry

Career support

FirstMedCommsJob.com
www.firstmedcommsjob.com

PharmiWeb Jobs
www.pharmiweb.jobs

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4. European Medicines Agency. ICH M4E Common technical document for the registration of pharmaceuticals for human use – efficacy. Published July 2003. Available at: ema.europa.eu/en/documents/scientific-guideline/ich-m-4-e-common-technical-document-registration-pharmaceuticals-human-use-efficacy-step-5_en.pdf.

The answers to the test are below:

	Name of Sponsor: A.N. Other Pharma Ltd	Name of Finished Product: CHIPS		
	Name of Active Ingredient: Potato	Study Number: AN-002		
1	Study Title: A phase III, randomised, double-blind, placebo-controlled, study to investigate the efficacy of CHIPS in treating hunger in patients		2	
3	Principal Investigator:	Dr John Doe		
	Study site:	A Hospital A Road A City United Kingdom		
4	Studied Period: First patient, first visit: 05 October 2017 Last patient, last visit: 21 December 2017	Phase of Development: Phase II	5	
	Objectives:			
	Primary:	To assess the reduction in hunger score in response to a 90 g of CHIPS or placebo administered orally in 3 doses	6	
	Secondary:	<ul style="list-style-type: none"> To assess the mean mass of CHIPS required to reduce the hunger score by 2 points To assess the safety of CHIPS 	7 8 9	
10	Study Design			
11	This study was planned as a single-blind, placebo-controlled study in patients with hunger. Patients provided informed consent and were randomized to either CHIPS or placebo. At Visit 1, patients were administered 90 g CHIPS or 90 g placebo in three 30 g doses given 30 minutes apart. Hunger score was assessed 5 minutes before administration of dose 1 of study treatment (CHIPS or placebo), immediately before doses 2 and 3, and 30 minutes after each dose.			12

- | | |
|-------------------------------------|---|
| 1 Delete unnecessary comma | 7 Should be 'orally' |
| 2 Incorrect use of apostrophe | 8 Should be 'to' |
| 3 Should be 'Investigator' | 9 Should be upper case 's' |
| 4 Should be 'Study' | 10 Should be 'double-blind' (consistent with title) |
| 5 Phase III (consistent with title) | 11 Should be 'randomised' (UK versus US spelling) |
| 6 The word 'a' not required | 12 Objectives use the number (i.e. '3') |



Amy Ball

Senior Regulatory Writer Certara Insight

By the time I'd reached the final year of my PhD in pharmacology, it became clear to me that the mornings when I woke with a spring in my step were those when I was preparing for a conference talk or poster presentation, not a day of experiments. While I had a genuine passion for my PhD project, continuing lab research just wasn't something I could see myself doing.

When looking for career options I searched further afield than the traditional post-doc positions. I became so eager to work out what I might be best suited to that I organised a departmental careers seminar, and it was there that I first heard the words "medical writing". A quick Google search led me to the firstmedcommsjob.com website. I recall grinning as I read through the list of common characteristics of a medical writer, all of which resonated with me.

Shortly afterwards, I attended a MedComms careers event where I spoke with the team at Insight Medical Writing (now Certara Insight). After this introduction to regulatory medical writing, I applied to become a regulatory writer, and following a successful interview and writing tests, gladly accepted the position.

I have now been at Certara Insight for just over 3 years, and during that time I have been able to work on a wide variety of documents with multiple clients, initially under the guidance of a more senior writer. This hands on experience, supplemented with in-house training and attendance at courses run by the European Medical Writers Association, has enabled me to learn quickly and

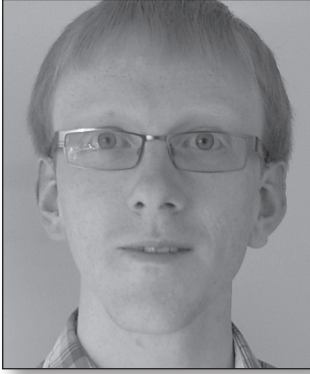
I feel confident taking the lead on an increasing number of complex projects.

I enjoy being able to contribute towards the successful development of novel therapies by the accurate communication of clinical research

While there continues to be a lot to learn, what I hadn't realised was just how transferable the skills I'd learnt at university would be. Incorporating the thoughts of my three PhD supervisors into my thesis was challenging at times – now I work with large, multidisciplinary teams;

and integrating their comments to generate a high-quality, coherent document is a large part of my job. I'd also spent most of my PhD managing time-critical experiments alongside teaching responsibilities and preparing for lab meetings and conferences. This taught me to prioritise tasks and manage my time efficiently, a skill I use every day as a regulatory writer.

Regulatory writing has provided me with the opportunity to be at the forefront of research across multiple therapy areas and I enjoy being able to contribute towards the successful development of novel therapies by the accurate communication of clinical research. Sometimes it can be daunting to work alongside physicians and scientists who are experts in their field, but it's also fascinating to see the diverse research that is going on – I'm able to quench my scientific curiosity without stepping foot in the lab!



Matthew Edmonds

Senior Regulatory Writer Certara Insight

I took the long route into regulatory writing. After an undergraduate degree specialising in pharmacology, I did a PhD in cell biology, and then fell into that trap laid by universities: the idea that continuing in academia is the only possible career choice. That is definitely not true, but I think that the experience of project management and awareness of scientific data and literature that I gained during my two subsequent post-docs were valuable when starting out in regulatory writing.

My first post-doc was my most productive time in the lab, but we couldn't get funding for me to continue. Not long into my second post-doc at a different university, I could see no real change in my experience and I didn't like the way that my career path was evolving. I felt that I had strengths that were ignored by colleagues, such as taking a systematic and meticulous approach to lab work and making suggestions to improve readability of manuscripts. I enjoyed teaching, and feedback from students of all levels told me I was good at explaining scientific and technical concepts. Perhaps I could better use these strengths in another career?

I had already heard of medical writing and had been to a MedComms careers event during my PhD. Since then, medical writing had stuck in my

mind as a possible alternative career to research. As a post-doc, I started entering science writing competitions to try out different writing styles. At a careers fair, I took the opportunity to find every medical writing company exhibiting. Talking directly to the employers was valuable in discovering the characteristics and scope of each company. This way, I came across regulatory writing for the first time. I signed up for an open day held by Insight Medical Writing (now Certara Insight) to find out more. It seemed perfect for me, and I successfully applied for a medical writer position there.

That was over 5 years ago, and I haven't looked back. I found a supportive and collaborative environment where I could apply skills I already had and learn new ones. My work has included all kinds of clinical, regulatory and pharmacovigilance documents, and even some website content. As part of my role as a medical writer, I am in contact with client project teams on a daily basis. As I have gained more experience, I have also had the opportunity to lead more complicated projects and to mentor new colleagues. A major positive of the job is that I am constantly learning about new and diverse fields of medicine. Quite the change from the narrow focus of academia!

I believe that anyone with a scientific background can become a regulatory writer. The big challenge is presenting large amounts of complex data in a clear and understandable way that is relevant to the purpose of each document. Experience of the pharmaceutical industry or specific documents isn't necessary, and there is plenty of internal and external training on the job.

There's a growing body of online resources to help you move into regulatory writing. I'd advise using them as a starting point to discover the best fit for you. I'm glad I found my way into regulatory writing, and I hope you will be too!

A major positive of the job is that I am constantly learning about new and diverse fields of medicine



Caroline Kay

Associate Director, Regulatory Services Management Certara Insight

After completing my PhD at the University of Bath, I landed a post-doc position at a small drug discovery company in Oxfordshire. Unfortunately I was made redundant within 18 months of starting my career as a research scientist. When I started to think about what to apply for next, I decided that I didn't want to look for another lab-based job. I found lab work frustrating when experiments or equipment stopped working, and

did not enjoy the repetitive nature of the day-to-day tasks I was involved in. I knew someone who had recently moved into medical writing and thought it sounded like an interesting way to move away from the bench while still using the knowledge and communication skills I'd gained in my PhD. I was a little apprehensive about moving to a desk-based job but decided to give it a go.

As I started to look for a job in medical writing, I discovered that there are quite a few medical writing and MedComms agencies based in and around Oxford. I sent speculative applications to a few local companies and, after an interview and a writing test, was lucky enough to be offered a job at Insight Medical Writing (now Certara Insight).

In my first few weeks and months as a medical writer I was introduced to the different types of regulatory documents and where they fit into the drug development process. Coming from a background in drug discovery, I had a lot to learn about the clinical side of drug development.

While timelines can be tight and clients demanding, I find there is a great sense of satisfaction in successfully delivering a final document

Furthermore, we use client templates and editorial style guides in order to produce high-quality documents that are consistent with each client's document format, something that I'd never had to think about before. As well as receiving excellent in-house training, I was able to attend European Medical Writers Association conferences where I completed workshops on various aspects of

medical writing. It was also a great way to meet other writers and share experiences of documents, guidelines and clients, as well as exploring a different European city each year.

I've now been at Certara Insight for 14 years and have progressed from medical writer through senior and principal medical writing roles, to my current position as Associate Director, Regulatory Services Management. Thanks to the variety of products we work on and clients we work with, I've never been bored! I have had the opportunity to work on all types of regulatory documents, including non-clinical, clinical, submission and post-approval documents such as pharmacovigilance reports. As regulatory writers, we have to adapt to the new documents and guidelines that are introduced by the regulatory authorities, as well as adjusting to working with new clients and their different therapeutic areas. While timelines can be tight and clients demanding, I find there is a great sense of satisfaction in successfully delivering a final document. Above all, I really enjoy being able to write and talk about science with interesting and intelligent people, without having to spend long days in the lab performing the same experiments over and over again.

I'm so glad I made the switch from scientist to medical writer. Fourteen years after taking the leap, I really can't imagine myself doing anything else!



Rebecca Ley

Regulatory Writer Certara Insight

Before I started my PhD I knew that I wasn't interested in a career in academia. I wanted to do a PhD and was very interested in my research field (the control of a replicative endonuclease using phosphorylation), but beyond that, academia didn't feel like the right place for me. That's not to say that I knew what I wanted to do; my plan was to finish my PhD, go travelling and then figure that out. In January 2020 I submitted my thesis and left for Australia. I planned to spend 6 months travelling, but instead

found myself in the middle of a global pandemic on the other side of the world. I returned to the UK shortly before it locked down to work on the family farm.

After a few months of lockdown and farming, I decided it was time to start looking for a job. Reflecting on my PhD experience, I realised that while many people had told me that writing their thesis had been the least favourite part of their PhD, I had really enjoyed writing mine. I also loved the work I had done with an educational charity, which involved visiting schools and teaching pupils about my research, although I knew I didn't want to be a teacher. I started to research science communication jobs and soon discovered medical writing.

Before stumbling across it, I didn't know that careers in medical writing existed. My time at university had been largely spent

in a chemistry department and most of the careers advice we received was tailored to chemists. Reading about the role of a medical writer I realised this was something that I would enjoy and could do well, so I began to apply for medical writing jobs. Knowing that I was interested in this area, a friend sent me a job advert for Insight Medical Writing (now Certara Insight) and I applied for the post. Following an interview (with a few technical difficulties due to my farm-based internet connection) and completing the writing tests, I was offered, and accepted, the position.

Starting a new job and moving to a new city in a global pandemic was not something I thought I would ever have to do. Nor was it without challenges. On my first day I went into the office, had a brief, socially distanced introduction to life as a medical writer and collected some IT equipment. Very shortly after, I was supporting on a document for a client and have subsequently worked on an array of projects for a variety of companies. Alongside this I have received in-house training and attended courses run by the European Medical Writers Association.

Eleven months after starting at Certara Insight I started going into the office. Working from home was challenging in those first few months; however, the support I received from my colleagues was exceptional and it wasn't long before I felt settled!

Medical writing gives me the opportunity to use the transferable skills I developed during my PhD to manage projects, interpret data and write high-quality documents. I also get to learn about new and interesting science in a number of different therapeutic areas without the stress of wondering why my site-directed mutagenesis *still* isn't working! Now that I have found medical writing, I can't imagine doing anything else.

*Now that I have found medical writing,
I can't imagine doing anything else*



Jade Lyons-Rimmer

Regulatory Writer Certara Insight

During my PhD, I believed that I would be a researcher forever. However, on completing my thesis I just couldn't find the right job for me. Finally, after working at a small pharma company and then as a post-doc in stem cell biology, I decided enough was enough and accepted that bench research wasn't going to give me the work-life balance, stability and opportunities for progression that I was looking for in a career.

I was aware of the medical writing industry, but I didn't feel that MedComms was quite what I wanted to do. At this stage I didn't realise that regulatory writing was an option, but as I explored further, it became apparent that it would suit me perfectly. Regulatory writing is much more structured than MedComms and involves working on both small and large documents to submit to regulatory authorities, rather than presentations or events. I also discovered that as a career it could provide me with the things that drew me to research in the first place: the opportunity to learn something new every day and to contribute in my own small way to the development of medicines that will improve patients' lives.

Living in Kent, I was a little hesitant about applying to a regulatory writing company based 100 miles away in Oxford, but Certara Insight gave me the opportunity to work remotely. Regular virtual catch-ups with my colleagues, as well as a few visits to the office, quickly made me feel part of the team. When I started at Certara Insight, it was a steep learning curve, but working alongside more senior writers, as well as regular in-house and external training opportunities, meant that I gained experience in a wide variety of documents in a short period of time. I also began to

appreciate that regulatory requirements don't end when a drug is approved. Clients often want to develop their product for different indications or gain approval from different health authorities all around the world. In addition, the pharmacovigilance requirements continue throughout a product's life cycle.

I have worked at Certara Insight for just over a year on a broad range of documents including investigator's brochures, clinical study reports, protocols and risk management plans. What I particularly

enjoy about the job is working for different clients who are developing products across a range of therapeutic areas. I get to interact with scientists and physicians who are global leaders in their field, and there is a real sense of achievement when a document is approved. While I am no expert yet, I feel that the skills I developed during my PhD have really helped me to thrive in this job and I'm excited to discover where a career in regulatory writing will take me!

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Paul McCormack

Senior Regulatory Writer Certara Insight

I came to regulatory medical writing in 2018, after finishing my PhD at the University of Birmingham, where I worked on the molecular biology of the papillomavirus life cycle and virus-driven carcinogenesis. Although I had an extremely positive PhD, surrounded by a great team, and thoroughly enjoyed my time in the lab, I had no interest in pursuing an academic career. I loved what I consider the 'communication' parts of my PhD – talking with biotechnology and pharmaceutical company reps, discussing science at conferences and teaching undergraduate students.

I also thoroughly enjoyed contributing to book chapters, publications and teaching material. Outside of my PhD, I worked as a freelance writer focusing on the preparation of medicolegal reports for expert witnesses dealing with personal injury, clinical negligence and criminal cases. Knowing that I didn't want to be an academic, I started to look at alternative career options and a former lab member and current colleague told me about medical writing. I thought it sounded like something I would be interested in and so I attended a networking event run by Peter Llewellyn of NetworkPharma.

I didn't know much about medical writing, never mind regulatory medical writing, when I went to the networking event. I learnt that regulatory medical writers work for a variety of companies and produce the documentation required by regulatory authorities to assess the safety and efficacy of drugs and medical devices.

These documents cover the entire development process, ranging from clinical trial documents to applications for new marketing authorisations and post-marketing safety documents, and must be prepared in line with applicable guidance from regulators.

This rather structured approach to writing appealed to me due to my background in medicolegal writing, which must also align to applicable codes of practice and numerous legal obligations as well as the preference(s) of the instructing party.

After some thought, and discussing the job with both management and medical writers at Insight Medical Writing (now Certara Insight), I took the plunge and forwarded my CV. Following an interview and some skills-based tests, I was offered and accepted a position as a medical writer.

I have been working at Certara Insight for almost 4 years now and have prepared a wide variety of documents, ranging from those in medical information, drug safety and risk management to applications for new marketing authorisations. I have also worked in diverse therapeutic areas, including oncology, neuroscience, respiratory, virology and rare diseases.

The most enjoyable part of the job is the sheer variety of documents that I have had the chance to work on. The opportunity to constantly learn and contribute to either getting a product to market or ensuring the safety of marketed products means I can satisfy my scientific curiosity without despairing over the thought of running yet another western blot.

*The most enjoyable part of the job is
the sheer variety of documents that
I have had the chance to work on*



Megan Stanton-Humphreys

**Associate Director,
Regulatory Services Management
Certara Insight**

I've always loved the creativity and curiosity behind the ideas and questions that drive scientific research projects. When I read the grant application for my PhD, I was so excited and enthusiastic to start tackling all that the lab could throw at me.

My research was in the area of biological chemistry, designing and synthesising chemical probes to study biological systems.

I had a supportive supervisor and a friendly group of research colleagues. I (mostly!) enjoyed my time at the bench. At the end of it, though, I couldn't quite imagine myself working in a lab or research environment forever. I found the day-to-day tasks could be discouraging. Why hadn't that experiment worked, when it had worked last time? When I honestly assessed what I enjoyed most about my PhD and 1-year post-doc, it was writing about the research – describing the problem or question to be investigated, how this was done, what was found and why anyone should care. I was worried that perhaps I was too specialised in a niche area to be able to change direction easily. That couldn't have been further from the truth. In fact my PhD was the perfect springboard into an interesting, challenging and rewarding career that I hadn't even known existed!

Through the University of Oxford Careers Service I got hold of a magazine with information about medical writing. Without knowing much about what a medical writer did, I got in touch with Insight Medical Writing (now Certara Insight) who invited me to an open day. The description of what makes a good regulatory writer resonated with me. I applied and, after my interviews and writing tests, I was offered a position as a medical writer.

I've always loved learning and that continues to be an exciting and stimulating part of my work

I've always loved learning and that continues to be an exciting and stimulating part of my work, even after nearly 11 years. I enjoy working with clients in a broad range of therapeutic areas, including oncology, gastroenterology, haematology, immunology, neurology and psychiatry. In my current role as

an Associate Director, I am responsible for managing the preparation of clinical documents for regulatory submissions, as well as providing scientific input and expertise. I am passionate about mentoring and training new writers, and spreading the word about the exciting and expanding field of regulatory writing.

After years of not being sure in what role I could apply my scientific interests and training, I am so glad to have stumbled upon medical writing. I would encourage anyone who is interested to consider this rewarding career path.

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