Essentials of Health Communication for New Professionals

A multiauthor guide for medical writers developed by Stgilesmedical London & Berlin as a service to education and healthcare

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Introduction

The journey taken by a drug or medical device from 'bench to bedside' is a mystery for many, while the medical writer's role in that process is even less well understood. Those new to medical writing often do not appreciate the varied nature of the discipline they are entering and their important part within it. There is no point in undertaking great research unless the results are widely and clearly disseminated. Similarly, the contribution made by innovators in the laboratory and the needs of healthcare professionals and patients are easily forgotten.

To cope with the growing demands of pharmaceutical and medical device companies in the face of ever increasing regulation, there is a need for additional medical writers. Such individuals generally come from a scientific background and are often highly qualified. Their role is to develop the mass of documents necessary to bring a new product to market. This field—medical writing—has become a multibillion-dollar global industry.

In this guide, we introduce core aspects of medical, regulatory and device writing, and provide information on advancing your career along with some hard-learned survival tips.

On reaching the end of this guide, the reader will have gained a better understanding of the following:

- The pharmaceutical and medical device industries.
- Stages of product development.
- Publication planning.
- Medical writers' important role in preparing manuscripts, regulatory documents and meetings.
- How to plan and develop a career in medical writing.

Digitalis is extracted from purple foxglove (*Digitalis purpurea*)

Overview of the drug and medical device development process

Taking a drug from design to clinical trials takes an average of 10–12 years. Learning about the stages in this process, which are set out in the following pages, will give you a better understanding of what goes into early clinical development and the subsequent steps required for drug approval.

Whereas finding or creating a successful drug requires expertise, there also an element of chance or luck (e.g. seeing the potential in an unexpected finding). Knowing how to optimise the process is an essential skill for those involved in drug discovery.

Drugs are not invented by an individual scientist working at a lab bench. They are the result of a large interdisciplinary team of researchers working for many years to understand a disease process, identify a suitable drug target (usually proteins or nucleic acids), and screen numerous compounds for their ability to bind to and inhibit that target and ultimately prevent disease.

Section objectives

- To understand the steps required in bringing a new medicine from the research laboratory to market.
- To gain insight into the resources, costs, time frame and complexities of the drug development process.
- To understand the type of research data that need to be generated at each stage of the drug development process.

How do successful drugs and medical devices come about?

Applying traditional treatments, often without an understanding of their actions (e.g. digitalis).
A chance discovery—the genius is in recognising what you have seen (e.g. penicillin).
Modifying a molecule (e.g. acetylsalicylic acid).
***De novo* laboratory research** in response to patient need (e.g. cardiac pacemaker).
Utilising an unexpected side effect of a drug (e.g. minoxidil).
Finding new applications for a current drug portfolio (e.g. piracetam).

Digitalis and dropsy

Dropsy, an old term for the excessive accumulation of tissue fluid in the limbs and trunk (oedema), is classically due to congestive cardiac failure (CCF). Digitalis (digoxin), which increases cardiac contractility while reducing heart rate, is still used worldwide to treat CCF. Its discovery is accredited to William Withering, a Scottish doctor practicing in Birmingham. In 1775, a patient with severe dropsy sought his advice. Withering was unable to offer any treatment and sent him away. Undaunted, the patient subsequently obtained an herbal remedy from a travelling gypsy, and much to the physician's surprise, got better!

Withering searched the lanes of Staffordshire for the gypsy, from whom he eventually purchased a bag of powder. On analysis, it was found to contain purple foxglove, *Digitalis purpurea*. He performed trials using various formulations of digitalis plant extracts on 163 patients. Small regular doses of the dried powdered leaf proved to be effective. In 1785, the use of digitalis as a drug to treat CCF was officially introduced.

Penicillin and bacterial infections

In 1928, the Scottish physician-scientist Alexander Fleming accidently discovered a bacteria-destroying mould (*Penicillium notatum*) growing on a dirty culture plate while working at St Mary's Hospital in London. Howard Florey, Ernst Chain and Norman Heatley isolated and purified penicillin in Oxford some ten years later. A practical problem was producing the medicine in sufficient quantities. The team linked up with researchers in the United States, where a chance finding led to the identification of a more productive species of penicillin, *Penicillium chrysogeum*.

In 1942, Anne Miller, suffering from a severe postpartum streptococcal infection, became the first civilian to be treated with penicillin. She survived, and three years later, Fleming, Florey and Chain shared the Nobel Prize for Medicine.

Acetylsalicylic acid and pain relief

Since ancient times (3000–1500 BC), willow extracts have been used to treat pain and inflammation. In 400 BC, Hippocrates administered willow leaf tea to ease the pain of childbirth. In 1763, Edward Stone, a vicar from Oxfordshire, reported to the Royal Society that powdered willow bark could cure fevers.

The first successful extraction of the active compound was performed in 1828 by Johann Buchner, professor of pharmacy at Munich University. He named the yellow crystals 'salicin'. Charles Frédéric Gerhardt, a French chemist, determined the chemical structure of salicin and subsequently synthesised salicylic acid in 1853.

The first clinical trial of salicylic acid, performed in 1876, confirmed remission of fever and joint inflammation in patients with rheumatism. Twenty-one years later, Felix Hoffmann, a German chemist, added an acetyl group, thereby reducing its irritant properties. Bayer patented the process and named the new compound Aspirin. It was only in 1971, however, that Aspirin's mechanism of action through the inhibition of prostaglandin synthesis was elucidated by University of London pharmacology professor John Vane.

Pacemakers and heart block

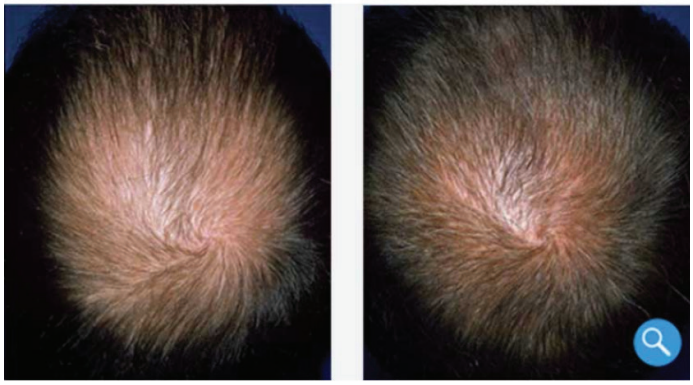
After surgery, 10% of patients operated on for congenital heart abnormalities suffer post-operative heart block, a situation that is generally fatal unless immediate, effective treatment can be provided. In the first half of the 20th century, patients were managed by the insertion of pacing wires to provide temporary rhythm support until the electrical conduction system of the heart recovered. The wires were then connected to a stimulator. The early stimulators were large, relatively static and required an external main power supply. In 1957, a municipal power failure in Minneapolis resulted in the death of a baby girl who had

just undergone cardiac surgery. Surgeon C Walton Lillehei asked local electrical engineer and Medtronic cofounder Earl E Bakken to find a solution.

Bakken and colleagues developed a small box containing a 9.4V battery and a circuit based on one described in *Popular Electronics*. The pacemaker device was tested once on a dog and the very next day it was put to clinical use in a patient!

Minoxidil finds a role in hair loss

In 1960, chemists from US pharmaceutical company Upjohn (now part of Pfizer) were undertaking preclinical trials in dogs using the molecule N,N-diallylmelamine (DAM) in the hope of finding some potentially useful anticholinergic effects, which proved not to be the case. Instead, the molecule was found to induce a prolonged reduction in canine blood pressure, an effect that did not occur in humans. This finding spurred researchers to find a DAM metabolite with an antihypertensive effect in humans. Minoxidil, an analogue of DAMN-O (an N-oxidation product of DAM) proved initially promising. Unfortunately, toxicity studies demonstrated a number of adverse effects such as refractory hypertension, salt retention, tachycardia and atrial lesions. Despite these effects, the drug was approved by the Food and Drug Administration (FDA) some ten years later for short-term emergency use in severely ill patients.



Before-and-after images showing the effects of treatment with a 5% minoxidil solution
Source: www.rogaine.com

Clinical experience in a minority of patients to whom minoxidil was administered for longer than the recommended treatment duration demonstrated several cases of hypertrichosis (excessive hair growth), which led Upjohn to develop a topical formulation. Clinical trials of minoxidil to treat alopecia began in 1978, with approximately one-third of subjects experiencing significant hair growth after one year of application. Overall, around 80% of patients are likely to see some non-vellus hair growth. Application of minoxidil for at least three months is recommended to gauge effectiveness.

An early advertisement for Aspirin in *The New York Times*, 1917

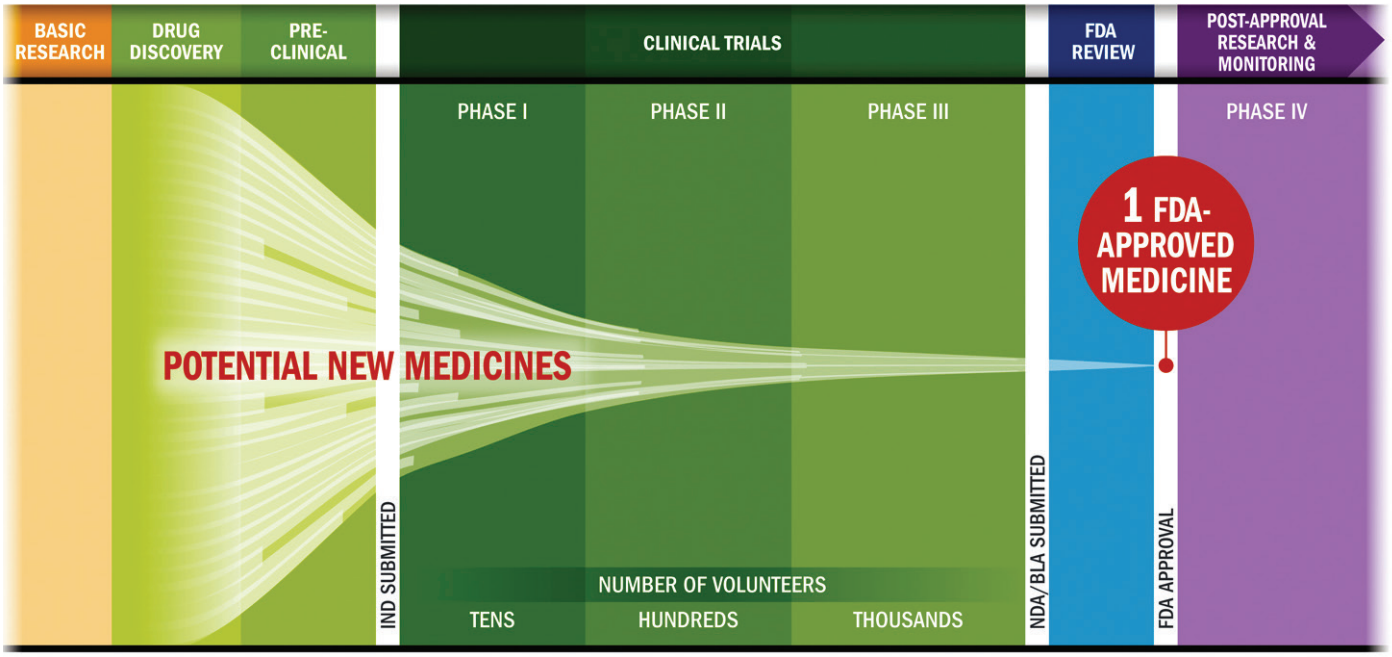
Piracetam and epilepsy

In 1964, piracetam was synthetically developed by pharmaceutical company UCB as a 'smart drug' to enhance communication in the corpus callosum, which modulates communication between the two sides of the brain. Chemically, piracetam has a structure that is close to that of pyroglutamate, an amino acid. Eight years later, piracetam was approved as an enhancer of cerebral cortex function, with positive effects on learning, movement, reasoning, thought and perception.

Piracetam may have additional applications: recent clinical reports suggest that the drug can mitigate some features of Parkinson's disease, improve neurological symptoms associated with dementia, help children with dyslexia and reduce the frequency of attacks in epilepsy. Although piracetam's mechanism of action is not fully understood, scientists postulate that it increases cellular absorption, thereby having a protective effect on synapses and neurons in the brain.

The biopharmaceutical research and design process

The figure below represents the drug development process. The process extends from early research aimed at understanding a disease's mechanism and finding an appropriate drug target through to later stages where the drug is monitored for adverse effects after market release. A vast number of molecules is screened in the search for a single medicine. At any stage during this process, it is very likely that a drug candidate may fail due to a lack of safety or efficacy. Whereas there are many stages in the process, they can be broadly grouped into the **discovery**, **clinical** and **post-licensing** phases.



Key: IND: Investigational New Drug Application, NDA: New Drug Application, BLA: Biologics License Application

The development process of new medicines | Source: http://www.phrma.org/advocacy/research-development/clinical-trials

The **discovery phase** often brings new insights into a disease process, allowing researchers to design a product that stops or even reverses the effects of disease. Thousands of molecular compounds are usually tested before arriving at a bank of possible drug candidates. Before testing a drug in humans, researchers must find out whether it is toxic.

The two types of preclinical research are *in vitro* (in test tubes) and *in vivo* (in animal models). *In silico* testing, where computational models of known toxic chemical groups are used to compare novel compounds, can also be used.

Before a new drug can be tested in humans, it must be tested in suitable animal models. During this phase, important pharmacological data about drug dosing are obtained, and potential risks are identified. This stage allows regulatory authorities to assess risk and consider a drug's suitability for testing in humans.

Regulatory authorities such as the European Medicines Agency (EMA) require researchers to use good laboratory practices (GLP), setting the minimum basic requirements for study conduct, personnel, facilities, equipment, written protocols, operating procedures, study reports and a system of quality assurance oversight for each study.

Usually, preclinical studies are not very large but must provide detailed information on dosing and toxicity levels. After preclinical testing of a drug, researchers review their findings and decide whether the drug should be tested in humans.

After discovery comes the **clinical phase**. Phase I studies assess the safety of a drug for the first time in humans,

and Phase II studies begin to assess its efficacy. Phase III studies, sometimes referred to as 'pivotal studies', demonstrate whether a product offers a treatment benefit to a specific patient population. This stage provides most of the safety data, as it is possible that less common side effects might have gone undetected in previous studies.

If clinical testing of a drug shows success, the drug becomes available on the market and the **post-licensing phase** begins. Manufacturers must continue to monitor safety once the product is on the market. Sometimes, this monitoring involves conducting protocol-driven safety studies as a condition of having been granted a license.

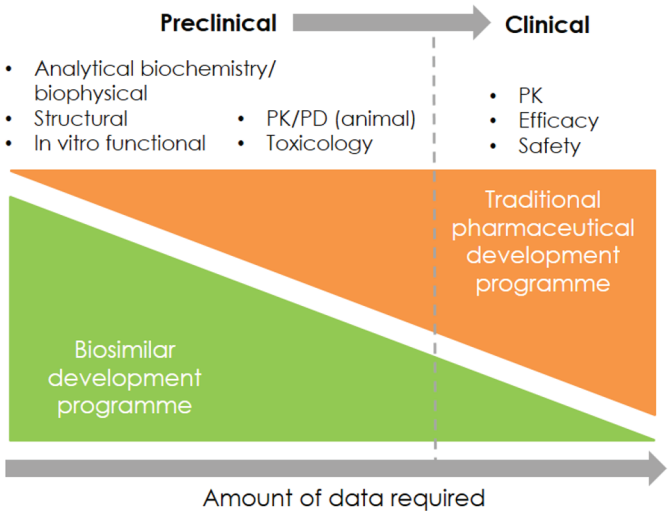
The manufacturer of a drug may also seek new indications for the medicine (its use as a treatment for a condition other than that of the original label). This phase involves conducting additional Phase III studies for these new indications in order to submit a further application to regulatory authorities for a licence.

Clinical approval success rates

Since many compounds fail in testing, the costs of carrying out the above phases to determine a compound's safety and efficacy must be weighed against the probability of finding a treatment that can go to market at a price payers are willing to pay.

Introducing a new drug is neither easy nor cheap. Currently, there are more than 7,000 medicines in development globally, with the cost of bringing one drug to market estimated at approximately €2 billion–€3 billion. However, fewer than 12% of compounds in Phase I will survive to Phase IV and receive marketing approval. In addition, the complexity of clinical trial requirements has increased remarkably since 2003, doubling research and development (R&D) costs over the last decade. A further consideration is that each new molecule has a 25-year patent life from the point of patent registration, meaning that some products may not recoup investment costs in their 9–10 years on the market before the patent expires and other manufacturers can start selling lower-cost versions.

An innovative company's overall clinical approval success rate is used to translate cost per investigational compound to cost per approved compound. A specific database of investigational compounds is used to estimate these probabilities. Information on attrition rates and failure distribution by phase are of great interest to investors.



Key: PK/PD: pharmacokinetic/pharmacodynamic

Innovative biologic products vs. biosimilars: the amount of data required in the preclinical and clinical phases of development

The case of generic drugs and biosimilars

Once a drug is off-patent, other pharmaceutical manufacturers can make and market the same drug. Referred to as 'generic', these drugs are cheaper, as the companies involved do not usually need to conduct any research before selling the rebranded products.

Biosimilars are biologic medical products that are usually almost identical to an original innovative product. As with other generic drugs, they can be manufactured once the original product's patent has expired, but require some new research to prove their similarity. In contrast to the development program of a new biologic, the preclinical phase of biosimilar development encompasses more structural, biophysical and functional *in vitro* characterisations as well as *in vivo* pharmacokinetic/pharmacodynamic and toxicology studies. These steps aim to prove its similarity with the biologic of reference. Conversely, fewer data are necessary for the clinical phase of a biosimilar development process than for a biologic. Safety pharmacology, reproductive toxicology, genetic toxicity and carcinogenicity studies are not routinely included in a biosimilar development programme. Examples of biologic drugs now facing competition from biosimilars are granulocyte-colony stimulating factors, which stimulate the production of white blood cells in patients receiving marrow-toxic chemotherapy.

Discovery phases (at least 5–6 years)

Basic research/pre-discovery

- Scientific research to help understand a disease.

Drug discovery

- Selection of a target (e.g. gene or protein, often an enzyme).
- Identification of a molecule or compound that may act on the target to alter a disease.
- Chemical synthesis and characterisation of the identified molecule or compound.

Preclinical testing

- Early toxicology, safety and efficacy studies using computer models, cell culture studies and administration to laboratory animals.
- Pharmacokinetic studies to examine absorption, bioavailability and excretion.
- Pharmaceutical development (i.e. Can the molecule or compound be successfully manufactured to a consistent standard?)

Investigational new drug (IND) application submitted. Approval required before compound can be administered to humans.

Clinical study phases (~7 years)

Phase I

- 'First time in humans' using 20–100 volunteers.
- Ascending doses (to check toxicity), administration in the presence of disease (e.g. liver or renal failure), safe use in combination with other medication.
- Determine bioavailability.

Phase II

- Initial efficacy and safety studies in 100–500 volunteer patients with the disease.
- Data used to refine research questions, development methods and design Phase III protocols.
- Pharmaceutical development.

Phase III

- Pivotal studies of efficacy and safety in 300–3,000 volunteer patients. These are usually placebo controlled, or involve comparison with a 'gold standard' treatment by means of a randomised double-blind trial.

Licensing approval required from regulatory agencies (e.g. FDA, EMA).

Dossier for application prepared from results of all studies.

Typical post-licensing activities

Lifecycle management

- Further indications (using the drug for a different disease/condition) will require additional Phase III studies and submission of new licence applications to authorities.

Phase IV & post-marketing surveillance

- Post marketing efficacy and safety assessments, real-world-evidence (RWE) studies and studies in additional subpatient groups or geographical locations (e.g. China, Japan).

Health economics and reimbursement

- Pharmaco-economic studies to demonstrate the value of the medicine. Cost effectiveness and outcome studies.

Medical devices

Measurement devices must demonstrate precision and validity.
Diagnostic devices must demonstrate sensitivity and specificity.
Therapeutic devices must demonstrate safety and efficacy.

Along with biopharmaceuticals, medical devices also fall within the domain of medical writing. Medical devices range from relatively simple objects such as tongue depressors and thermometers to devices implanted in the body such as stents and pacemakers, or devices that work outside the body, such as *in vitro* diagnostic devices.

Medical devices must also pass regulatory hurdles to prove they are a useful tool for the treatment of a condition. Unlike drug trials, which must prove efficacy and safety, the tests a device must pass depend on the device itself (e.g. fewer tests are required for a thermometer than for implants).

Unlike drugs, which take a long time to produce, medical devices see rapid and continuous innovation. The legislation required for medical devices to be brought to market has been less rigorous than that for drug products, resulting in medical device development being only around 3–7 years. However, regulatory authorities are becoming more demanding and the duration of this process is increasing.

Medical writers tend to write about either pharmaceutical or medical devices, with little crossover between the two disciplines.

Take-home message

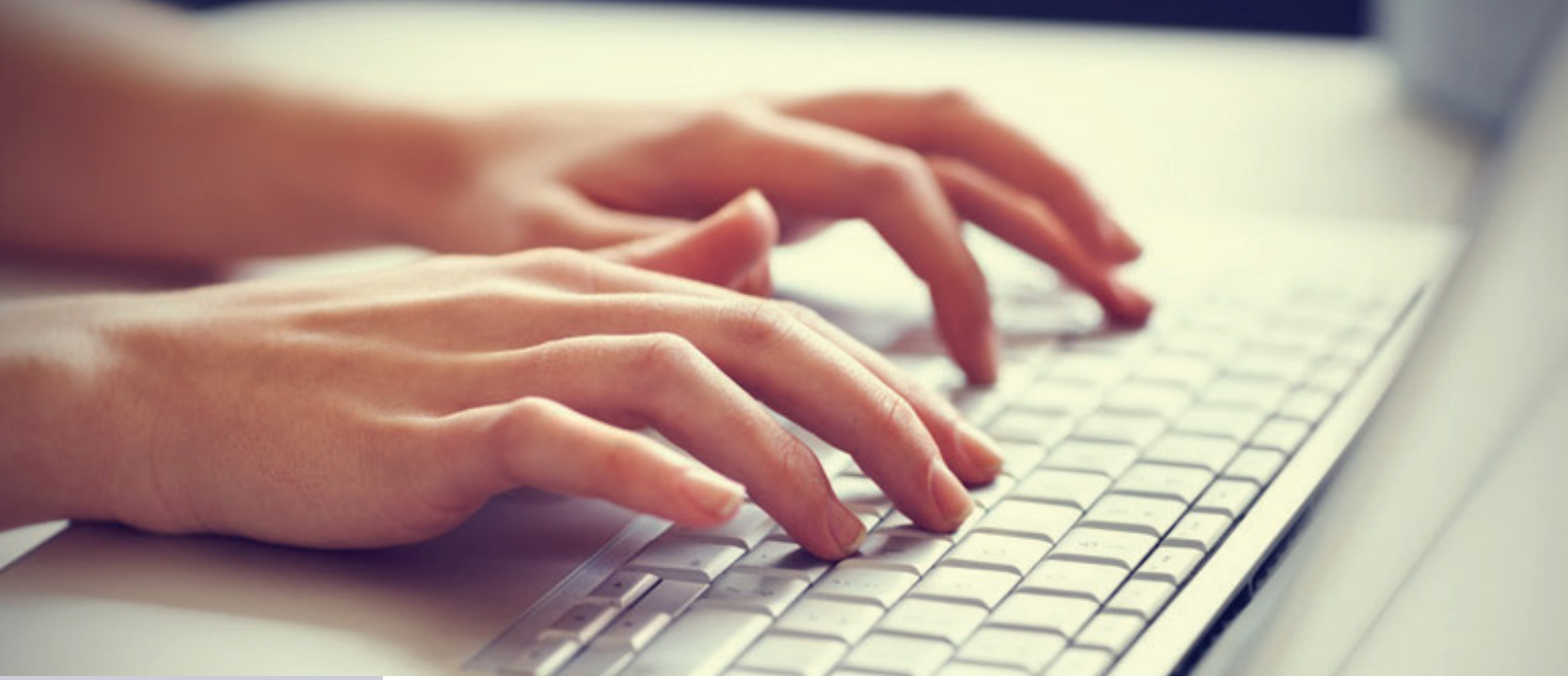
Drug discovery and development is a costly, research-intensive, high-risk activity. Many products fail for a variety of reasons. Even products that get to market may not recoup the investments made to get them there. Generic products are allowed to compete in the market place once patents expire, with the likely result that the original manufacturer will have to reduce its pricing and capital return.

More information

The Pharmaceutical Research and Manufacturers of America
www.phrma.org

The Association of the British Pharmaceutical Industry
www.abpi.org.uk

United States Food and Drug Administration
www.fda.gov



Life as a medical writer

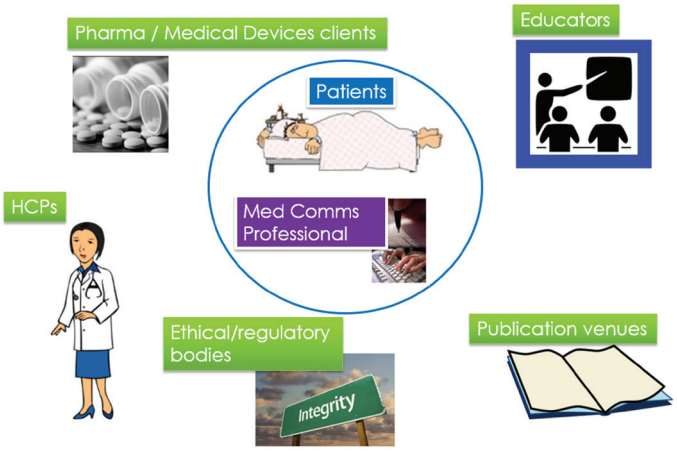
A typical subject for small talk often centres around what you do for a living. As a medical writer, this question might not be so easy to answer. The medical writing industry is not well known and even less well understood. It is likely that you will be called a ghost writer or worse. Once asked, you now have an opportunity to educate people about the important role of medical writers in healthcare. What you do is part of science.

In a recent survey, medical writers reported that their role was generally well paid, compatible with family life and provided job security and a high level of personal satisfaction (Walker *et al.*, 2016). Many liked the supportive atmosphere and being able to work with the latest scientific data. However, medical writing is not without its own pressures (e.g. deadlines, varying volumes of work, difficult clients). Also, it can take time to adapt and some may miss the atmosphere of an academic environment or the drama of working in a hospital. Others may question the value of writing yet another article about breast cancer. It is worth remembering that you are playing a part in a process that ultimately may relieve suffering or save lives. While it is estimated that the average GP saves 4–5 lives a year, through your writing, you have the potential to save and improve many more.

Section objectives

- To gain an overview of the important role of the medical writer in the 'bench-to-bedside' journey.
- To learn about medical writers' typical background and what is generally required to enter the profession.
- To obtain information on the varied projects on which a medical writer may find themselves working.
- To learn about the professional relationships of importance to medical writers.
- To understand the differences between the principle branches of the profession: medical communications (MedComms) and regulatory writing.

The role of MedComms and regulatory writers in the pharma sector



It's often difficult in the day-to-day bustle of medical writing to remember that you are part of a much bigger picture. At the centre of that picture are the patients, whose health may depend on the drugs you have helped bring to market. Alternatively, a medication currently in development may provide hope where existing therapies have been exhausted.

Doctors, nurses and allied healthcare professionals want to be kept up to date regarding new developments in medicine, but can be overwhelmed by an ever-increasing burden of information from multiple sources in the advent of online journals and social media. They need to quickly identify key facts relevant to their practice and make decisions based on evidence. As continuous professional development (CPD) is an essential element of modern medicine, the quality of information presented at courses and meetings is similarly important.

The needs of pharmaceutical and medical device companies complement those of treatment prescribers (i.e. they wish to announce the results of their preclinical and clinical studies widely and loudly). The challenge the industry faces is presenting data in an accessible format to the right audiences, at the right time and via the right publication medium, while complying with numerous rules and guidelines.

There are more publication avenues available now than ever before. Previously, these were limited to printed academic journals and traditional congresses. Now, virtual meetings, social media, websites and webinars are gaining ground as the leading platforms for disseminating pharmaceutical and medical device information. This trend is likely to continue in line with technological advancements.

In this 'brave new world' of online media, most researchers, academics, clinicians and patients continue to write their own text and develop their own meeting presentations. Where industry is involved, many will have their own in-house medical and regulatory writing teams. Despite this, an estimated 70% seek varying degrees of agency support during the development process.

Medical writers are needed because:

- Developing regulatory documents and writing up major study reports that comply with ever-changing rules require specialist knowledge and experience.
- Some clients may not have the time, writing ability, background knowledge nor English language skills to develop material of acceptable standards for publication.
- The amount of written material required has increased. In the past, information from unsuccessful trials or about negative results tended not to get published, which in turn risked biased interpretation of the evidence. Nowadays, there is a requirement for all trial data to appear somewhere in a searchable format.
- Using specialist medical writers has been shown to improve the quality of medical publications.

What do medical writers do?

- They produce scientifically accurate, unbiased and clinically relevant materials to educate and inform the healthcare community and patients.
- They develop regulatory documents required for all elements of the clinical development process and drug approval.
- They facilitate relationships between industry and healthcare professionals.
- They maintain integrity by ensuring adherence to ethical guidelines, requirements of regulatory bodies and industry standard operating procedures (SOPs).
- They advise on best practice in medical communications.

Required skills and experience

People have rarely set out to become medical writers, though this may now be changing. More commonly, people become medical writers after deciding to leave a career in research, medicine, pharmacy or pharmacology for something better suited to their circumstances and aspirations. Writers generally come from a science background, already have industry experience and are often highly qualified—one study found that 69% of medical writers had a PhD or equivalent (Walker *et al.*, 2016).

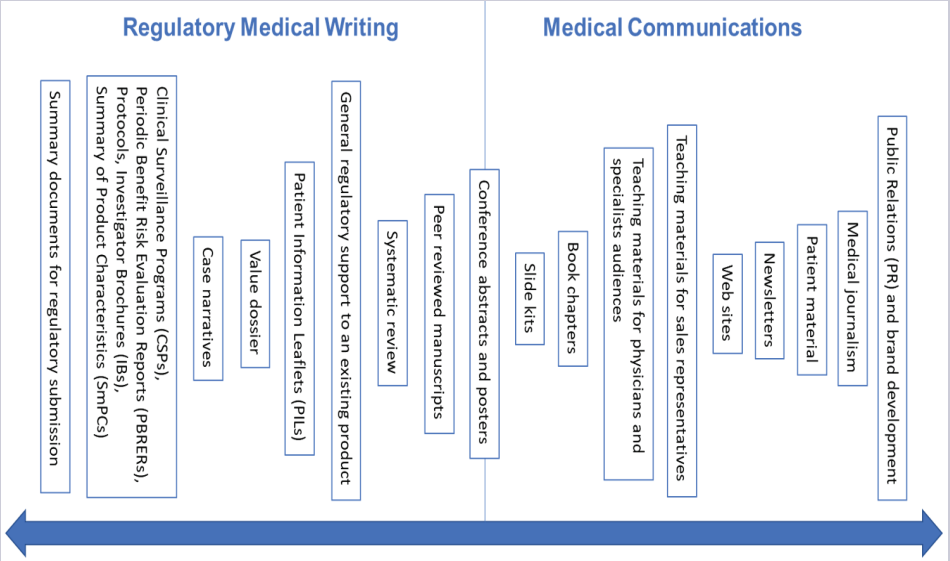
Many agencies offer internships, allowing newcomers to medical writing to get a foot in the door and gain experience, notably in MedComms. Any prior writing experience—such as developing your own research papers, submitting pieces for a student magazine, public engagement in science activities or blogging—will be useful in gaining your first role. Be prepared, as companies will usually require you to complete a writing test beforehand. Also, training a medical writer takes time, to which some organisations are reluctant to commit. Consequently, competition for training positions can be fierce, with many aspiring medical writers finding themselves in a 'Catch-22' position of not being able to gain experience without prior experience.

As a writer, you must enjoy writing! Finding the right words to get an idea across should bring you joy—if not, you may want to consider a different career direction. Desired attributes include being meticulous and well-organised, committed, reliable and hard-working. Often, multiple projects you are working on will run concurrently. For example, you might find yourself dealing with numerous conflicting reviewers' amendments to a 200-page document while facing a competing deadline for the first draft of a slide kit. Therefore, good time and workflow management are essential. Enjoying collaboration is another trait worth having, along with being passionate about good communication.

There are many different types of medical writing, so it is a good idea to get a taste of as many as possible early in your career to find out which you are best suited to and enjoy the most.

Different types of medical writing

Medical writing is traditionally classified into medical communications ('MedComms') and regulatory writing. The types of output commonly associated with each branch are summarised in the adjacent figure. While peer-reviewed manuscripts and systematic reviews are generally considered MedComms, there can be overlap.



What are MedComms?

Target audiences for MedComms output include healthcare professionals, academic researchers and patients. This area is further divided into two broad categories: publications ('pubs') and wider communication activities ('non-pubs').

Whereas some agencies provide both 'pubs' and 'comms' support to pharmaceutical and device companies, others concentrate on just one area. There are opportunities to specialise, for example, in continuing medical education activities (CME), real-world evidence (RWE) and market access.

Your workplace options are varied. Some medical writers become in-house writers in a pharmaceutical, medical device, or clinical research organisation, while others work in agencies or become freelancers.

Publications ('pubs')

For many agencies, developing 'pubs' is their bread and butter. Those working in this area generate copy, which is often part of a tactical delivery programme.

Publications are considered by some to be the more technical end of the MedComms spectrum. While this may be true, it should be remembered that publications form the bedrock of all other communications. Basically, as you will need a published reference to use material in any communication, without 'pubs', there are no 'comms'.

Frustrations of MedComms writers

- Unappreciative and disorganised clients and authors who fail to respect writers' qualifications and experience.
- Peaks and troughs in workload, tight deadlines, sudden alterations in priorities, multiple demands and an expectation to work extra hours.
- Some projects can be repetitive and may appear to be of questionable value.
- Missing academia and interacting with scientists and healthcare providers.
- Not being included as an author.
- Too much paperwork, tiresome travelling and endless rounds of reviews and comments.

Developing publications tends to be a highly scientific process and will suit those who really love getting into data. For others, publications can seem rather dry, with limited opportunities for creativity. If you find yourself working on publications within an agency, it is likely that your client contact will be a publications manager or publications lead at a pharmaceutical or device company. As they will likely be under a lot of pressure, you may experience some as well.

Publication accounts tend to have predictable peaks and troughs of work around congress submission deadlines and presentation dates, along with a steady background of manuscript development.

As a medical writer, you will not only play a pivotal role in forming the link between investigator authors and pharmaceutical or device companies, but also in ensuring that ethical standards are upheld. You will sometimes find yourself responsible for resolving disagreements between authors on manuscript content, or gently pointing out to a client that the data do not support a particular assertion. Your contribution should always be acknowledged somewhere in the publication you have worked on. Where you have done more (e.g. developing a review article), then you may qualify as an author in your own right.

Once you have considerable experience in medical publications and have demonstrated depth of knowledge in ethical and practical aspects of the discipline, you can work towards various forms of certification. One such programme is run by the International Society of Medical Publication Professionals (ISMPP). Upon passing a multiple-choice examination paper, you to become a Certified Medical Publication Professional™ and can add 'CMPP' behind your name. This credential is a testament to the expertise you have gained. Once earned, the ISMPP CMPP™ credential is valid for three years, and upon expiration, certificants must recertify (http://www.ismpp.org/recertification) or retest.

Comparing 'pubs' and 'comms'

Pubs	Comms
PAPERS, REVIEWS AND ASSOCIATED MATERIAL	**CONGRESS MATERIALS**
Primary manuscripts (based on core data and primary research endpoints)	Booth activities
Secondary manuscripts	Panels
Secondary/tertiary endpoints	Animations
Post-hoc analyses	Quizzes
Subgroup analyses	Augmented reality
Review articles	Satellite symposia
Opinion pieces	**COMPETITOR INTELLIGENCE (CI)**
Letters to the editor	Core slide kits
Response documents	Congress reports
CONGRESS MATERIALS	Response documents
Abstracts	**SCIENTIFIC EXPERT ENGAGEMENT**
Posters	Expert panels
Contents and slides for oral presentations	Advisory boards
Poster slides	**MEDICAL SCIENCE LIAISON (MSL) MATERIALS**
AUTHOR LIAISON COMMENT RESOLUTION	Training materials
	Objection handlers
	Rapid response documents
	PATIENT-SUPPORT MATERIALS

Communications ('comms')

'Comms' encompass all non-pubs. While comms clients are often based in medical affairs, you may also work with professionals from other disciplines, including scientific communications, publications, medical information and marketing.

Pubs and comms require different skill sets, so writers often specialise in one or the other. There is often a clear division preventing individuals or some organisations from working on both pubs and comms. This delineation is required to avoid unethical practices (i.e. marketing unduly influencing medical publications).

Whereas you still require exemplary writing skills and a sound scientific background as a comms professional, the style of writing tends to be more succinct than that of publications and there is more opportunity to spread your creative wings.

Comms tend to be faster paced than publications and the workload can be less predictable. However, there is inevitably a peak around the time of congresses. The requirement for on-site work and business travel is usually greater for comms, particularly where meetings are involved. There are opportunities to specialise in

- continuing medical education (CME).
- market access: value dossiers to support approval, reimbursement, etc.
- real-world evidence (RWE): observational trials, registries, etc.
- public health.

The rise of the medical writing industry

According to a CenterWatch market research report, the medical writing industry doubled in size between 2004 and 2008, from $660 million to $1.3 billion, and is likely to continue to do so. Between 2008 and 2015, global R&D spending grew at a compound annual rate of 1.7%; and between 2016 and 2022, it is expected to grow 2.8%. The year-over-year increase is expected to remain at around 3% despite some dramatic jumps in 2013, 2014 and 2015. Overall spending is projected to reach $182 billion in 2022. Top spenders in 2015 were Roche and Novartis ($8.5 billion each), Pfizer ($7.7 billion), Johnson & Johnson ($6.8 billion), Merck ($6.6 billion), and Sanofi and AstraZeneca ($5.6 billion each).

The growing need for medical writers

With increasing regulatory requirements and a focus on transparency in sharing clinical data and pharmacovigilance strategies during clinical development, the demand for writing services is expanding. Current trends towards more disclosure and publication of biomedical research results are increasing the demand for medical writers. Several leading pharmaceutical companies have been continually publishing their clinical trial data in scientific journals and clinical trial registries. The number of biomedical journals and publications based on clinical trial data has increased significantly during the past decade. There has been a huge increase in downloads of scientific information, indicating that more healthcare professionals and researchers are reading and making use of clinical trial data available in the public domain.

Trends in medical writing

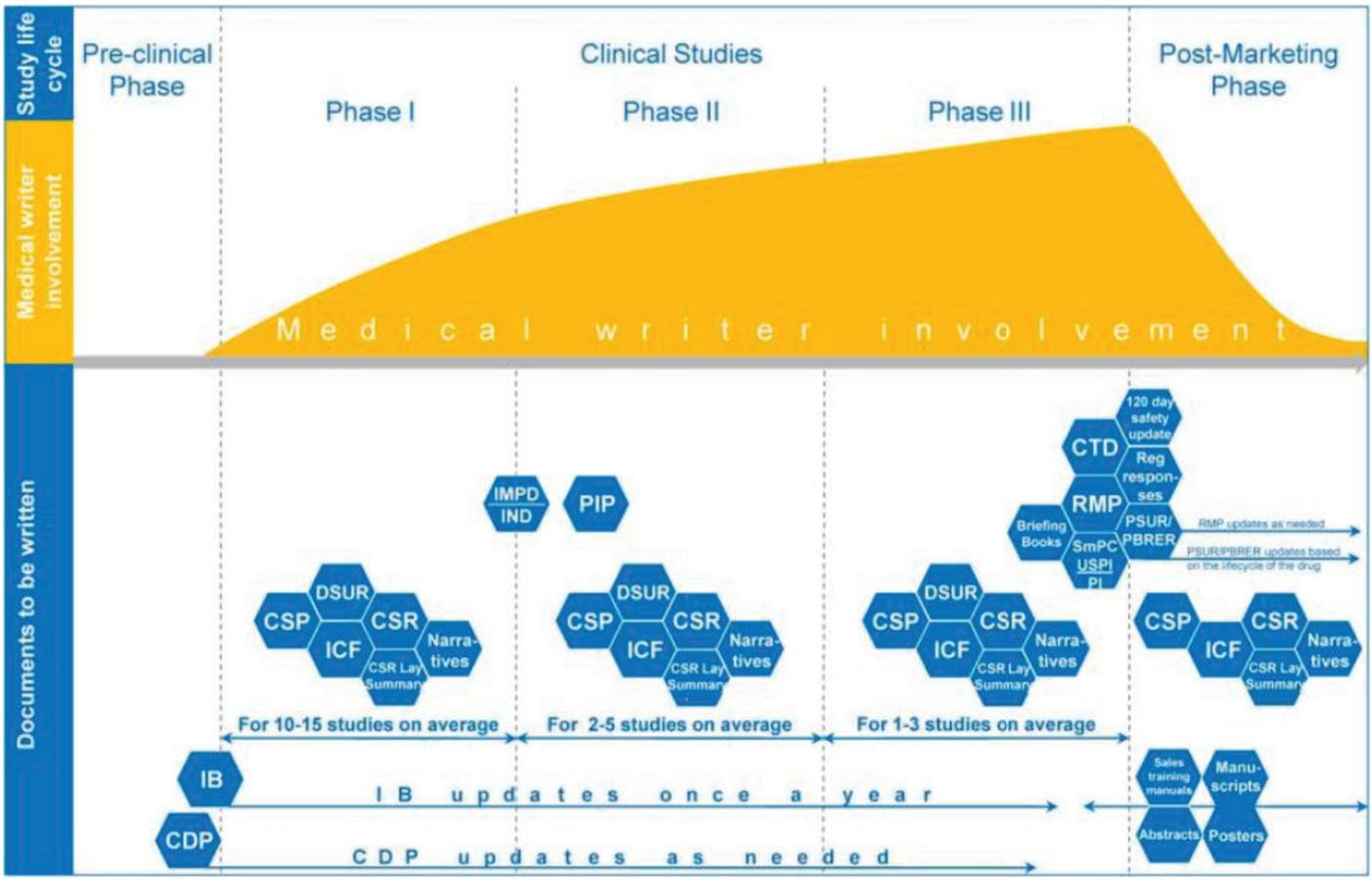
Pharmaceutical companies increasingly recognize medical writing as a specialist skill and function imperative to the drug discovery process. Professional bodies such as EMWA and AMWA have contributed to this trend. At the same time, there is an increase in outsourcing: A 2005 CenterWatch survey found that medical writing was the fourth most frequently contracted service from contract research organisations (CROs), following monitoring, data management and drug supply management. The same survey reported that 41% of respondents used outsourced medical writing services. In-house pharma medical writers are now uncommon in many companies.

What is regulatory writing?

Regulatory writing is a branch of medical writing separate from MedComms. It involves creating clear pharmaceutical development documents for clinical trial personnel, investigators, pharmaceutical companies and regulatory authorities. Healthcare providers are not generally the target audience. Like other branches of medical writing, regulatory writing is both a science and an art.

For any new drug to be marketed in a country, the national regulatory authority must grant approval. In the United States, this authority would be the Food and Drug Administration (FDA), while in Europe, the European Medicines Agency (EMA) has umbrella responsibility (i.e. approval by the EMA will generally permit marketing across member countries). It is likely that, with the UK's decision to leave the European Union, the UK Medicines and Healthcare Products Regulatory Agency (MHRA) will take on a larger role.

It is regulatory writers' job to assist in producing the clinical documents required by these authorities to assess the safety and efficacy of a medicine. The range of documents they may assist in creating include applications to regulatory bodies for approval of a new drug (New Drug Application; NDA), annual safety reports and patient information leaflets. All of this information must adhere to International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines and comply with clients' style and terminology preferences and standard operating procedures (SOPs).



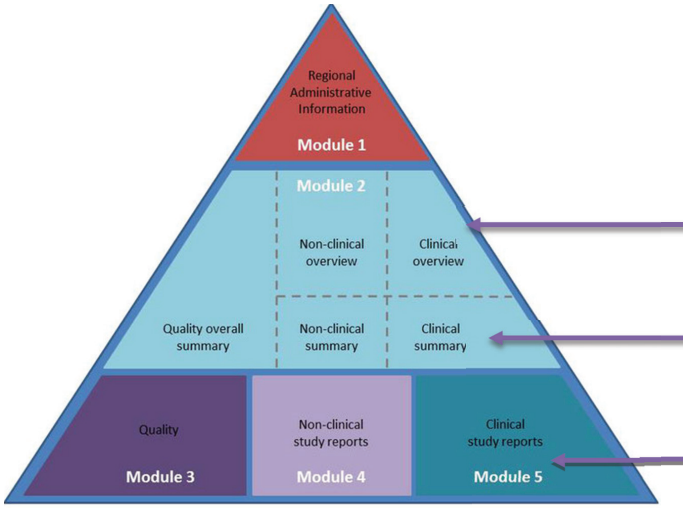
The timing of regulatory documents (see the end of this booklet for abbreviations) | Courtesy of Julia Forjanic Klapproth, Trilogy GmbH

Involvement of regulatory medical writers in drug development

Regulatory writers may be involved across all aspects of the clinical research programme. As shown in the figure opposite, those involved are generally busiest during Phases II and III. There is limited need for regulatory documentation during the chemistry, pharmaceutical/formulation, preclinical research and toxicology stages of drug development.

When the time comes, regulatory writers typically work closely with professionals involved in data management, clinical trial management, biostatistics and regulatory affairs, as well as therapeutic or scientific experts. See Page 17 for a summary of the different documents that regulatory writers typically produce across the different stages of drug development.

The scope and time required for different documents can vary widely. Writing a clinical study protocol, for example, may take many weeks, while developing a clinical study report (CSR) needs several months of careful labour and repeated checking. Each of these documents must be written for every study. In the case of a small Phase I study, regulatory writers may find themselves intermittently being called upon for help during the 1.5-year period it generally takes from receiving permission (Clinical Trial Authorisation; CTA) to starting a trial in humans. The relevant period will be much longer for a Phase II or III efficacy study. The CSRs then become part of the Common Technical Document (CTD), which is eventually submitted in hope of receiving marketing approval.



Overview of the CTD. Regulatory writers are involved in delivering the arrowed modules, mostly Modules 2 and 5.

Common Technical Document (CTD)

The CTD is a vast document that regulatory writers often find themselves contributing sections to. It is divided into five modules:

1. Administrative and prescribing information
2. Overview and summary of Modules 3 to 5
3. Quality (pharmaceutical documentation)
4. Preclinical (pharmacology/toxicology)
5. Efficacy (clinical trials)

The CTD is a set of specifications for an application dossier for the registration of a new drug or an already approved drug to be administered for a new indication. It is set out in an internationally agreed format designed to be used across Europe, Japan and the United States. The guardianship of its various components is under auspices of the ICH. The paper CTD is destined to be replaced by an electronic counterpart, the eCTD.

A plea for good regulatory writing

Regulatory readers at the FDA and the EMA are swimming in a sea of documentation. Make it easy for them to navigate your document. Regulatory agents in public forums and private sessions talk about how they sometimes gasp and choke their way through data and documents in submission packages. Good regulatory medical writers clearly understand that they are writing for a decisionmaking reader.

Stage	Document	Content	Readers
Individual clinical studies	Clinical study protocol	Clinical trial objective(s), design, methodology, statistical considerations and organisation. Ensures safety and integrity.	Those who will conduct the study
	Investigator's brochure (IB)	Summary of the body of information about a drug. It provides insights for management on study conduct and subject safety during a clinical study.	Investigators
	Informed consent form (ICF)	Document that participants must sign before participating in a clinical research study.	Participants
	Safety narrative	Brief narratives describing each death, serious adverse event or any other adverse event of clinical importance.	Regulators who will assess the drug application
	Clinical study report (CSR)	Very detailed document about the methods and results of a clinical study. It addresses efficacy and safety. Part of the Common Technical Document (CTD).	Regulators who will assess the drug application
Clinical study programmes	Clinical overview and clinical summary	Integrated documents. Summary of all information contained in individual study documents.	Investigators, regulators and industry
	Regulatory response	Queries raised by regulatory authorities concerning details in a particular study or regulatory submission. They are answered by the drug developer by means of formal written regulatory responses.	Regulators
	Investigational medicinal product dossier (IMPD)	Investigational Medicinal Product (IMP) data required when a clinical trial will be performed in one or more European Union Member States.	Regulators
	Clinical development plan (CDP)	Complex documents entailing the entire clinical research strategy of a drug. They are created by the pharmaceutical company.	Regulators and investigators
	Paediatric investigation plan (PIP)	Detailed plans ensuring that the necessary data are obtained through paediatric studies to support authorisation of a medicine for children.	Regulators
Pharmacovigilance and product safety	Periodic benefit-risk evaluation report (PBRER)	Important regulatory updates on the worldwide safety experience of approved drugs according to Good Pharmacovigilance Practices (GVP). The format is the same for the EU and the United States.	Regulators
	Safety update report (DSUR)	Documents providing a summary of safety issues for medicinal products in development or undergoing clinical studies.	Regulators
	Risk management plan (RMP)	Include information on a drug's safety profile. RMPs clarify what measures are being taken to prevent or minimise risk to patients.	Regulators
Others	Quality control (QC)	Standard Operating Procedures (SOPs) set up for provision of formal QC.	Regulators
	Translations	Translation of clinical and scientific documents.	Healthcare professionals, patients, industry and the general public

The documents regulatory writers produce across the different stages of drug development.

Skills required by medical regulatory writers

Regulatory writers must navigate a mass of data, guidelines and company SOPs. Many writing tasks that used to be the responsibility of clinical researchers or biostatisticians are now performed by regulatory medical writers. Regulatory writing is sometimes unfairly regarded by those outside this branch as dull and robotic. An attraction is knowing that you are working at the cutting edge of medical research and that your work could improve health and save lives. Desirable skills for regulatory medical writers include the following.

Attention to detail. Documents are highly prescriptive, with clients always on the lookout for cut-and-paste errors or a decimal point in the wrong place.

Experience, knowledge and message management. Different documents have different requirements. Regulatory writers must be able to balance demands from reviewers and deliver clear messages.

Highly organised. Ability to cope with tight timelines, huge documents, input from multiple stakeholders and diverse processes such as internal reviews, quality control (QC) and quality assurance (QA). The author needs to be one step ahead.

Ability to analyse complex data. While you are likely to have others to call on for advice, you will need to help analyse and interpret data. For example. Phase I studies include pharmacokinetic and pharmacodynamic data, laboratory test results and electrocardiograms that can do unpredictable things and need explaining.

Knowledge of statistics. Basic statistical knowledge is a must. Understanding tests such as regression analysis and analysis of variance (ANOVAs) is an advantage.

Excellent diplomacy skills. CSRs involve input from biometric, clinical, pharmacovigilance (PV) and QA departments. Pleasing all parties and keeping to timelines can be challenging. Excellent communication is key because the documents regulatory writers work on are highly collaborative.

Highly proficient in Microsoft Word. Many people feel confident of their Word skills until they start regulatory medical writing. Using tables of contents and watertight formatting of text and numbers are essential.

Career progression

If you have scientific experience, can write, are adaptable and get along with clients and colleagues, medical writing is a good place to be. Career prospects remain good, both through agencies or freelancing. There are plenty of options for those who wish to move into other areas within the industry or have a desire to travel or work abroad.

In recent years, demands on pharmaceutical companies from regulatory bodies have grown exponentially. As a result, the need for regulatory medical writers is probably increasing faster than for MedComms writers, and this is reflected in salary expectations.

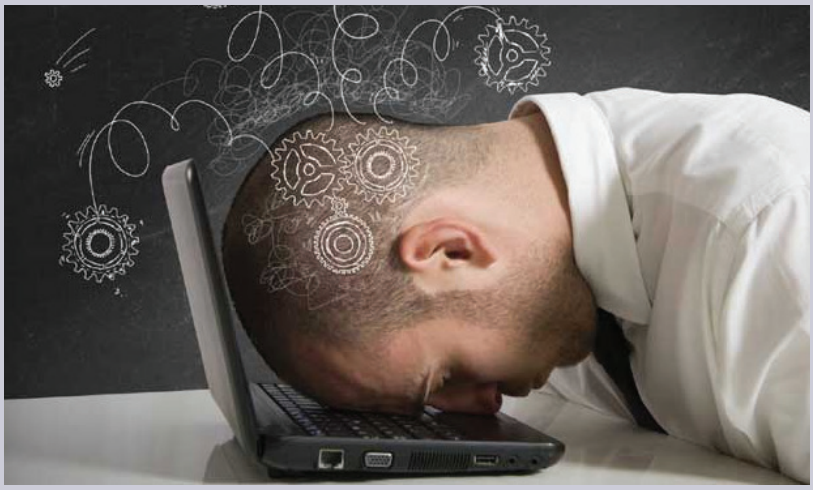
Frustrations of regulatory writers

Prepare for negative feedback and develop a thick skin. Comments such as 'late delivery of documents', 'spelling and grammatical errors', 'not collated' and 'containing contradictory statements' are not uncommon despite repeated reviews.

Reviewers can be reactionary forces stifling creativity. Playing safe, they tend to push for styles and layouts that are conventional but not optimal. Good writing techniques can be overturned by reviewers. Sometimes reviewers will conflate review comments with QC comments. There is often a difference in emphasis between clinical and statistical requirements.

Timelines. You can sometimes feel like you are spending as much time tinkering with timelines as writing. It is striking how often 'fixed' timelines move.

Writing comes last. Writers often experience a squeeze on their activities when an unmoveable deadline approaches and upstream activities have swallowed all the time. Meeting agendas tend to deal with topics in order, leaving writers to say their bit at the end and when participants are starting to leave.



Poor message management. Despite spending millions on a clinical trial, clinical teams often struggle to decide on what the message might be and then struggle again when the data appear. This issue particularly applies to CSRs. Teams tend to want to delegate this thinking to the writer, whereas the writer sees this as something that should be supplied by the team.

Everyone is an expert. Unlike other disciplines in the drug development world, which are typically perceived as repositories of special knowledge upon which outsiders should not encroach, it is always open season with writing, as everyone feels they have some expertise and valid opinions. This view can reinforce the perception that medical writing is a low-skill activity and that anyone could do it.

Cut and paste. There persists the notion that medical writing is, for the most part, a glorified cutting-and-pasting exercise. There is a lack of awareness of document consistency, integrity of style and the degree of editing required to achieve that.

Take-home message

Medical writers are scientists who have a central role in bringing pharmaceutical products and medical devices from the research laboratory to market. The vast array of documents requiring input from medical writers means there are multiple areas to choose from. 'Pubs', 'comms' and regulatory writing remain the lead contenders and offer the possibility of specialisation. Doing an internship or working as a junior employee at an agency are great ways to get into MedComms. Such opportunities are less common in regulatory writing.

References

Walker S, Opie J, Whitman S, *et al*. Writing for pharmaceutical or medical device companies: A survey of entry requirements, career paths, quality of life, and personal observations. *Medical Writing* 2016; 25(2).

Demystifying publication planning

A medical publication plan involves working out how a drug's clinical and scientific data are going to be made available to healthcare professionals via medical journals, scientific congresses and medical society meetings.

The dissemination of these data requires detailed planning to ensure they are available to the right people (those it is relevant and of interest to) at the right time (when it is relevant and in a timely fashion). Publication plans are generally developed by collaborative teams comprising contributors to data generation and analysis, authors, publication professionals and sometimes scientific and/or medical advisors. Medical communication agencies may be engaged by pharmaceutical companies to support plan development. Some communication agencies focus solely on publication planning.

Section objective

- To understand the components and goals of medical publication planning.

The basics of publication planning

The goal of publication planning is to make the right information available to the right audience at the right time through appropriate publications.

Effective publication planning results in

- timely publication of data.
- educational needs being addressed (i.e. of healthcare professionals).
- relevant and appropriate information for each audience.
- avoidance of duplicate/redundant publications.
- involvement of authors and contributors throughout the planning process.
- an insight into the workloads that will be required to complete the plan.

Publication plans differ in scale and scope, influenced by factors such as geographic reach, duration, indication(s) or products. Medical publication plans are often developed for a single product in a specific indication and region, and may be developed for a single study. The plan may need to align with other plans such as a broader global plan, or plans for other indications or disease areas/portfolios.

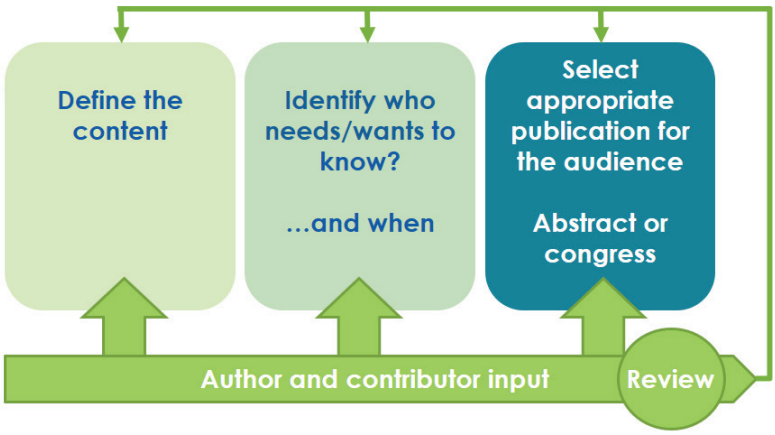
A stepwise approach to publication planning

Publication plan development can be divided into three phases, each aligned with the main elements of the plan:

Content. Data/content, which drives a medical publication plan, could comprise educational information, as well as preclinical and clinical data sets.

Audience and timing. Timing may be influenced by data availability, the need to make study data publicly available, or when it is relevant to an audience.

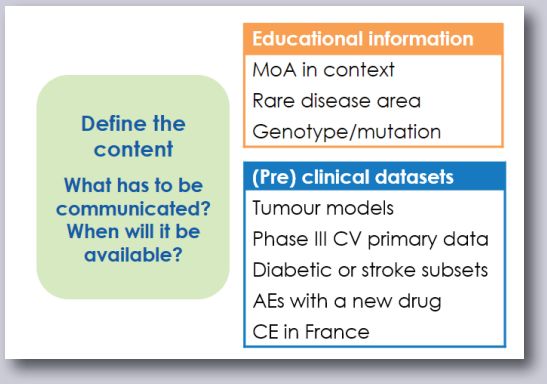
Publication. A journal or congress is selected to make the information accessible to the audience.



Step 1: Define the content

Start by defining the content of each publication. Prepare a list of potential publications by topic and think about if or how the topics will be combined in a publication—are they relevant to the same audience? The clinical development plan, if available, is often a useful starting point.

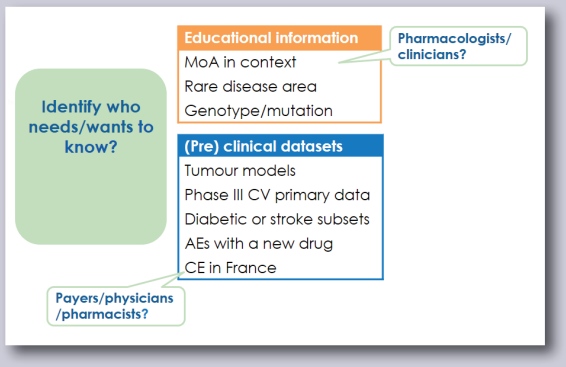
You will probably need to revisit the list as the plan develops, more information becomes available, or studies change.



Step 2: Understand who needs/wants to know

Next, identify the appropriate audience for the information/data. It helps to have a good understanding of the role of the healthcare professional team in the region of interest. Who treats the patients and where?

For each potential publication, appropriate timing and audiences are identified. While investigators may be interested in the rationale for clinical development now, many physicians may not find the information relevant until clinical data are available. Audience identification and data definition may overlap, so don't be surprised if you need to revisit the content and audience a few times.

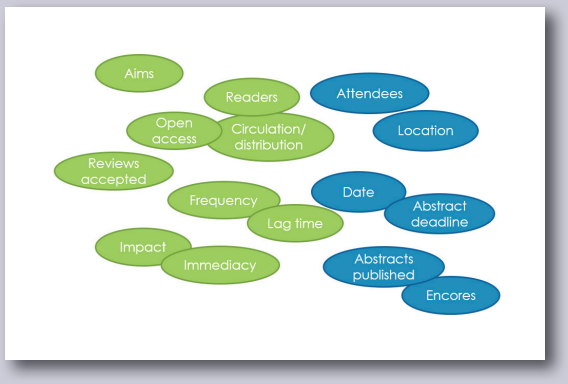


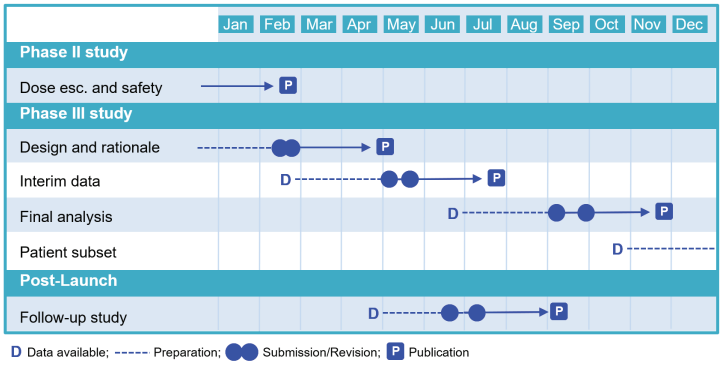
Step 3: Select the appropriate publication

Once we know which information needs to be communicated, to which audiences and when, we need to decide where to publish the information so that it is available to the audience at the right time.

Considerations when choosing a journal or congress:

- What are the aims of the journal?
- Do the reader profile or congress attendees match the target audience?
- How quickly are manuscripts published, and are they open access?
- When/where is the congress and what is the abstract submission deadline?





Example of publication plan by date. Once the target journal or congress has been identified, we can draw up a plan detailing the target journal/congress and authors for each data set, when we expect data to be available, timelines for preparation and the target publication date.

Publication planning: a collaborative and ongoing process

Publication planning is a collaborative process involving contributors, authors and publication professionals. Contributors' input is invaluable at all stages of publication planning. Authors and contributors can suggest appropriate analyses, highlight any educational gaps, identify relevant audiences and recommend suitable journals or congresses. They can also review the draft plan and guide its development.

Publication planning is an ongoing process. The plan needs to be reviewed regularly and revised as timelines and/or data evolve. Studies do not always go according to plan, and educational gaps identified when the plan was drafted may be filled by publications from other sources.

Take-home message

Publication planning, an area of medical writing that some agencies and medical writers specialise in, is a highly collaborative effort. Publication planning is essential for the timely dissemination of information regarding drugs in clinical development and those already on the market, meaning healthcare professionals are informed about the best medicines available for their patients. Publication planning provides appropriate information to relevant audiences in a timely fashion.

Publication plans need to be reviewed (and revised) regularly.

Key steps of publication planning:

- Defining the content.
- Identifying the audience.
- Selecting the appropriate journal/congress.

Different types of study design and the medical writer

Preclinical and clinical trials are experiments, or observations, designed to answer specific questions about biomedical or behavioural interventions, including new treatments such as vaccines, drugs, dietary choices, dietary supplements and medical devices. They generate data on safety and efficacy.

Research performed by Gattrell *et al.* (2016) found that the involvement of medical writing professionals improved the completeness of reported clinical trial data along with the quality of written English. The role of a medical writer is crucial in fully reporting clinical data, thereby helping pharmaceutical companies overcome the regulatory hurdles in bringing a drug to market. Given past incomplete reporting of clinical trial findings, with negative results often going unpublished, medical writers also play a role in avoiding positive bias in medical literature.

Study designs vary depending on the question to be answered, product development stage, and reliability of evidence. Whereas randomised controlled trials (RCTs) are the gold standard for assessing efficacy and safety, there is increasing emphasis on the need to collect real-world evidence (RWE) by means of observational studies measuring individual patient experiences. In this section, we provide some insight into the different types of study design.

Section objectives

- To understand the design of different study types.
- To understand study design application and the role of the medical writer in the different stages of the drug development process.

A short history of clinical trials and regulations

In 1747, James Lind, a Scottish physician with an interest in naval medicine and nutrition, performed a simple research study on 12 participants to determine whether citrus fruits could prevent scurvy.

The 19th century saw an explosion of exaggerated claims on the benefit of a range of 'wonder drugs' and medical devices.

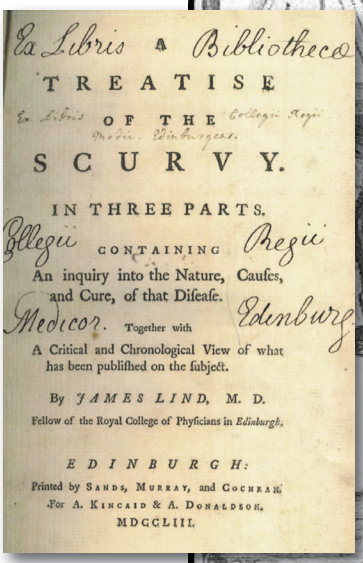
In the 20th century, the need for guidelines and good practice codes arose because of several high-profile examples of unethical research, such as studies where healthy individuals were unknowingly infected with diseases such as gonorrhoea and syphilis.

One of the most important documents in the history of research ethics, the Nuremberg Code, was created in 1947. It was developed in response to unethical clinical experimentation performed in Germany during World War 2. The code established the requirement for clinical research to have a scientific basis, the need for voluntary consent and the importance of protecting participants from harm. Though the Nuremberg Code was not officially accepted, it subsequently served as the basis for future international guidelines.

In 1964, the World Medical Association (WMA) published the Declaration of Helsinki. Again, this was not a law—rather, it set out the principles of human experimentation, influencing national legislations and regulations worldwide. Since then, it has undergone several changes, seeing its seventh revision in 2013.

More recently, the ICH issued guidelines on behalf of pharmaceutical companies and authorities. These guidelines, first implemented for clinical trials in 1997, were intended to overcome inconsistencies in good clinical practice (GCP) throughout participating countries.

An advertisement for a 'cure-all' patent medicine.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A Critical and Chronological View of what has been publiſhed on the ſubject.

By JAMES LIND, M. D.

Fellow of the Royal College of Phyſicians in Edinburgh.

EDINBURGH:

Printed by SANDS, MURRAY, and COCHRAN; For A. KINCAID & A. DONALDSON.

MDCCLIII.

In 1747, Scottish physician James Lind conducted the first clinical study of the treatment of scurvy on 12 sailors.

Types of scientific studies

Researchers sometimes talk in terms of '**the hierarchy of evidence**'. This hierarchy classifies the different types of studies according to reliability of evidence—the higher a study type places in the hierarchy, the more reliable its evidence is considered.

1. Basic research studies

In vitro tests such as biochemical assays are performed to check the desirable activity of a new drug before it is administered to humans. These studies are part of the first stages of the drug development process and do not usually involve medical writers.

2. Case reports

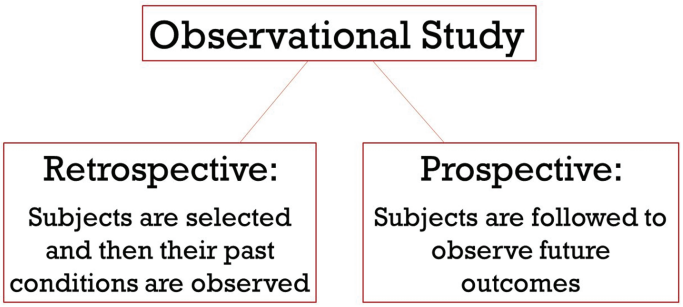
This term usually refers to a short article detailing unusual or unexpected findings (e.g. a previously unreported side effect linked to a drug). The aim is to flag this issue for other healthcare professionals. Sometimes, several similar cases are presented in the same publication as a 'series'. The CARE (CAse REport) guidelines detail how to best present case information while safeguarding patient information.

3. Observational studies

The essential feature of observational clinical studies (also termed 'non-interventional studies') is that patients are treated in the way they would normally be cared for by their physicians, without researchers seeking to influence management in any way. Subsequently, the treatment outcomes are measured and reported. Researchers are not allowed to intervene—they must simply watch and wait. Once again, writing guidelines (STROBE; STrengthening the Reporting of OBservational studies in Epidemiology) have been developed for this type of research.

Observational studies can be either retrospective or prospective. In retrospective studies, which are more common, information on the included patients, the treatment they received and their clinical outcomes are collected sometime after the event. Limitations of such studies can include heterogeneous groups (e.g. more elderly females in one group), missing values and variable follow-up. These limitations can be mitigated, to some extent, by large participant numbers and using appropriate statistical methods.

In comparison, researchers involved in prospective observational research must decide what they are going to measure, collect pre-study data and observe the clinical outcome. Such studies are also known as 'cohort' or 'longitudinal' studies—'cohort' because the group of patients being observed is called a 'cohort', and 'longitudinal' because they focus on the same variables over time.



4. Randomised controlled trials

Randomised controlled trials (RCTs) are considered the 'gold standard' of clinical research, seen as the most rigorous way to determine if a causal relationship exists between an intervention (e.g. a drug) and an outcome (e.g. the effect of a treatment). The main aim of an RCT is to detect a true treatment effect by minimising bias.

Whereas the aforementioned research study types play a valuable part in assessing the value of a new drug, ultimately, the drug must demonstrate a significant benefit over a placebo or the gold standard before it can be brought to market. Medical writers play a key role in

What are real-world evidence (RWE) and real-world data (RWD)?

Real-world evidence (RWE) is a general term referring to health information derived from heterogeneous sets of patients in real-life practice settings. RWE may include real-world data (RWD) and findings from patients involved in observational studies, but not patients taking part in a randomised controlled trial. There is increasing interest in RWE, specifically individual health journeys, and an emphasis on outcomes of greater relevance to patients, such as quality of life and long-term adverse events.

RWD is routine information relating to patient health status and/or the delivery of healthcare gathered from a variety of organisations. RWD does not usually involve data collected as part of a trial. Sources may include:

- Individual electronic health records (EHRs).
- Nationally held data, such as Hospital Episode Statistics (HES) and Office for National Statistics (ONS) data.
- Claims and billing information.
- Product and disease registries.
- Patient-related activities in out-patient or community settings.
- Health monitoring devices.

The role of RWD and RWE in healthcare decisions is growing:

- The FDA uses RWD and RWE to monitor post-marketing safety and adverse events and to make regulatory decisions.
- The healthcare community is using these data to support coverage decisions and to develop guidelines and decision support tools for use in clinical practice.
- Medical product developers are using RWD and RWE to support clinical trial designs (e.g. large simple trials, pragmatic clinical trials) and observational studies to generate innovative treatment approaches.

developing protocol and research documentation and writing up and disseminating study results.

At the core of an RCT is the random allocation of similar patients to a trial intervention. Typically, RCTs seek to measure and compare different events, called 'outcomes', that occur (or do not occur) after participants have received an intervention. As the outcomes are measured (or *quantified*), RCTs may be classified as quantitative studies.

An important element of RCTs is the assessment of the benefit-to-risk ratio for a particular treatment. No intervention is without risk, and the acceptable threshold varies depending on the pathology. A high level of risk may be acceptable if, for example, the alternative is almost certain mortality due to the disease being treated (e.g. advanced pancreatic carcinoma). By comparison, the frequent occurrence of serious adverse events in a trial of a medication intended to treat a relatively minor medical condition (e.g. alopecia) would be unacceptable.

Medical writers are heavily involved before, during and after RCTs. CONSORT (Consolidated Standards of Reporting Trials) guidelines should be followed when reporting RCT results. For more on RCTs, see Page 27.

Medical writers' involvement in RCTs

BEFORE	DURING	AFTER
Protocols	Interim reports	Clinical study reports
Patient information sheets	Newsletters	Lay summaries
Informed consent forms	Protocol amendments	Conference activities
Ethics committee approvals		Publications
Investigator brochures		

5. Systematic reviews

A systematic review seeks to find all relevant published evidence about one topic. The medical writer can help to define a search strategy (i.e. what the search is looking for and how the search will be conducted). The criteria for the selection of trials to be included should be clearly defined and should not be based on outcomes (e.g. positive results only). Publications reporting the results of systematic reviews should follow PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines.

6. Meta-analyses

A meta-analysis is a statistical analysis that combines data from more than one conceptually similar scientific study, with the aim of reducing certain error between individual studies. The key benefit of this approach is the aggregation of information, leading to a higher statistical power and more robust conclusions. As for systematic literature reviews, the rules for writing up a meta-analysis are provided by the PRISMA guidelines.

A closer look at randomised controlled trials (RCTs)

The main characteristics of RCTs are:

Randomisation
Controls
Blinded assessment
Measured outcomes
Data analysis
Alternative designs

Randomisation

It is essential to ensure that treatment groups have similar demographics and disease characteristics. Should one group, for example, contain more patients with advanced disease, it may subsequently be found to demonstrate less improvement after treatment. Ideally, the only difference between the treatment groups should be the intervention. There are two components of randomisation:

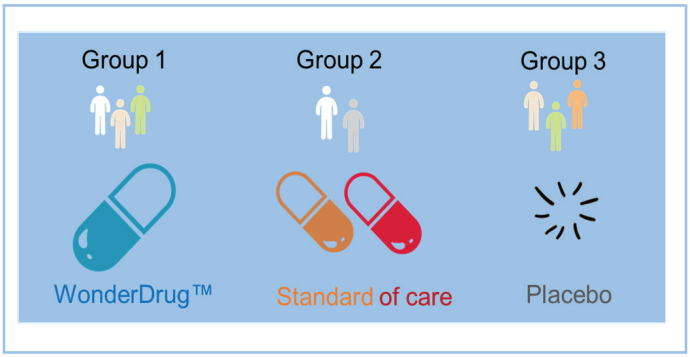
1. **Generation of the allocation sequence**
   - ***Simple randomisation.*** An example of this would be repeatedly tossing a coin.
   - ***Block randomisation.*** The aim here is to ensure an equal balance of study arms throughout all portions of the trial (e.g. blocks of six would have three Active and three Controls). Block size itself can be varied.
   - ***Stratified randomisation.*** Important covariates are identified (e.g. sex, age) and randomisation is organised to ensure that each group contains a similar proportion of individuals with these covariates.
   - ***Adaptive randomisation.*** The probability of treatment assignment fluctuates according to assigned treatments of patients already in the trial. This methodology is not commonly employed.
2. **Concealment of allocation**
   - Centralised computer.
   - Interactive voice response system (IVRS), an automated telephony system.
   - Opaque sealed envelopes.

Randomisation is achieved by generating random sequences of allocation in several different ways. Regardless of the method used, investigators should follow two principles:

- Define the rules that will govern allocation.
- Follow these rules strictly throughout the whole study.

Controls

Comparison with a control determines the additional benefit offered by the intervention. Therefore, the control must be selected with care. Researchers must first decide whether to use a placebo control or an active control. A placebo control is just that: no active therapeutic effect is anticipated. An active control, on the other hand, should have a therapeutic effect. As it would be unethical for healthcare professionals to refuse to provide care to patients in a control group, if a treatment with demonstrated efficacy is available, the control is generally an active control in the form of usual care (i.e. administration of what is currently considered to be the reference or gold standard treatment). Deliberately choosing an inferior treatment as a comparator is not acceptable.



Possible study arms in an RCT

Blinded assessment

To minimise opportunities for bias, some form of blinding is often employed. Types of blinding differ based on who is aware of which treatment has been given to a patient:

- **Open** means everyone knows what patients are receiving, including the patients themselves.
- **Single blind** usually means patient are unaware of what treatment they are receiving.
- **Double blind** means neither patients nor assessors know what treatment is being administered.
- **Triple/quadruple blind** means the following groups do not know who is receiving what:
  - Participants
  - Investigators administering the intervention
  - Investigators assessing the outcome (the clinician seeing the patients or an independent committee charged with reviewing their dossier)
  - Data analysts

Whereas the highest level of possible blinding is preferred, not all interventions can be adequately blinded. For example, blinding based on two drug therapies can be achieved by creating a placebo tablet that looks identical to the actual drug. Conversely, in the case of care interventions, blinding is effectively impossible since patients and investigators must be aware of the group allocation in order to deliver the intervention.

Measured outcomes

At the outset, a study protocol must define the primary outcome the study is going to measure (e.g. pain). However, many other outcomes can be measured alongside the primary outcome, such as whether the tested drug helps patients sleep better or reduces the frequency of headaches. The outcomes being measured should be made publicly available (e.g. on a website site such as ClinicalTrials.gov) so that the trial sponsor cannot change them once the study has started without issuing a formal amendment that explains the reasons for the changes. If the study achieves its primary endpoint (e.g. the drug reduces pain), it can be described as 'successful'. If it does not, then we usually describe it as 'unsuccessful' or 'failed', regardless of how the drug affects secondary outcomes.

Drug safety (i.e. the occurrence of any undesirable effects) is another important outcome in a clinical trial. The investigators may record a substantial number of adverse events during a clinical trial, although some of these may not be related to the drug under investigation (e.g., a study run over the summer months may result in many participants reporting hay fever symptoms).

Data analysis

Data are analysed based on the hypotheses being tested:

- **The null hypothesis** (H0) states that the intervention will have no impact on the outcome.
- **The alternative hypothesis** (H1) states that the intervention will have a meaningful, statistically significant effect.

The statistical methods used to analyse the data depend on the nature of the outcome.

Alternative designs

There are three alternative designs.

In a **simple parallel design**, participants receive one of two treatments in parallel (e.g. those in Group 1 receive 150 mg/day of the tested drug, WonderDrug, while those in Group 2 are given 300 mg/day). One treatment group may receive a placebo.

In a **cross-over study**, participants are given several different treatments one after the next (e.g. 150 mg/day of the tested drug, WonderDrug, followed by 300mg/day). Groups of patients in the study may be assigned to a different sequence of treatments to enable researchers to determine which sequence is most beneficial to health. Again, one treatment may be the placebo or a different drug.

Factorial clinical trials are useful in determining the effect of a combination of therapies. This study type is appropriate when the factors being studied (e.g. drug treatments) are potentially beneficial when used together and researchers want to understand how or under what circumstances they interact.

Take-home message

Progressing a drug from the research laboratory to market requires a range of research methods, the gold standard of which is the RCT. RCTs help minimise bias, but require specialist knowledge and are expensive to conduct. Medical writers may have a key role in protocol development, research documentation and bringing the results of an RCT from raw data to successful dissemination.

References and further reading

CARE guidelines http://www.care-statement.org/

CONSORT guidelines http://www.consort-statement.org/

Gattrell WT, Hopewell S, Young K, *et al*. Professional medical writing support and the quality of randomised controlled trial reporting: a cross-sectional study *BMJ Open* 2016; 6:e010329. doi: 10.1136/bmjopen-2015-010329

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Writing for pharma or devices: What are the differences?

Product development, obtaining marketing approval and dissemination of information differ for pharmaceutical and medical device companies. Consequently, medical writers tend to work for either one or the other, with limited crossover between the two. This may be changing as the regulatory requirements for both sectors become more aligned.

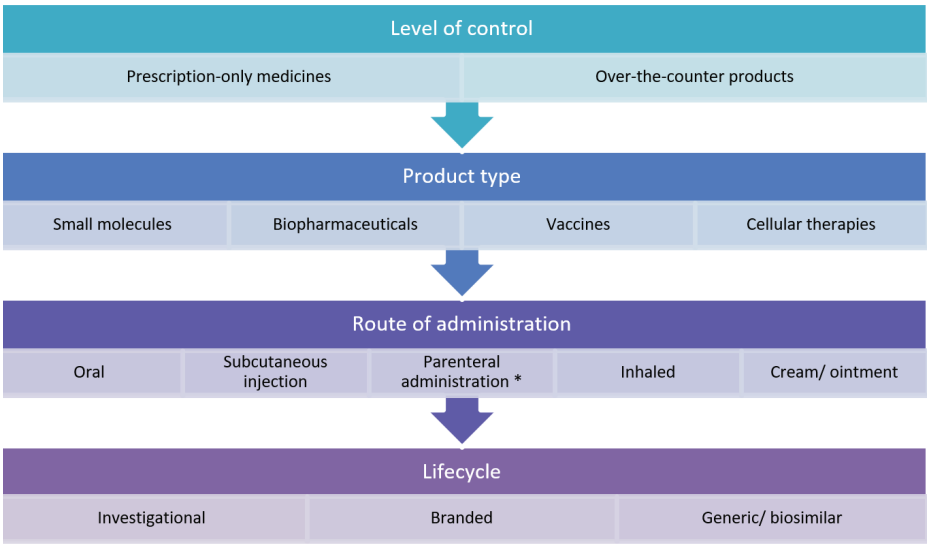
Section objectives

- To gain an overview of the similarities and differences between pharma and medical devices.
- To gain an appreciation of the regulations that apply to medical device and pharmaceutical product development and how these affect publication professionals.

Pharmaceutical product classification

Drugs are classified in various ways:

- By **level of control**, which distinguishes prescription drugs from over-the-counter drugs.
- As **traditional small-molecule drugs**, which are usually derived from chemical synthesis; or **biopharmaceuticals**, such as recombinant proteins, vaccines, blood products used therapeutically, gene therapy, monoclonal antibodies and cell therapy.
- **Mode of action**.
- **Route of administration**.
- **Biological system affected**.
- **Therapeutic effects**.

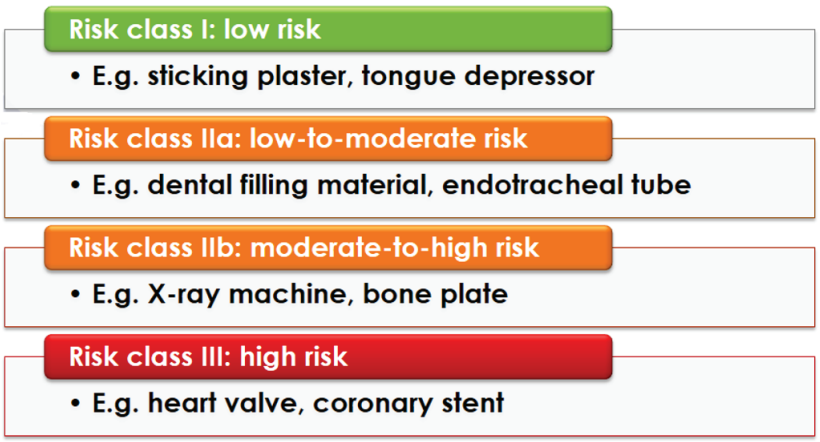


Methods of drug classification
*parenteral administration may include intravenous, intramuscular, intrathecal, etc.

There is an elaborate and widely used classification system called the Anatomical Therapeutic Chemical (ATC) Classification System, which takes these differences into account.

Medical device classification

Unlike drugs, medical devices do not achieve their principal action by pharmacological means. Medical devices can also have an application outside of the body, such as *in vitro* diagnostic devices and X-ray machines. Sometimes devices may include a pharmaceutical intervention, and in that case, their classification is more challenging. For example, the primary mechanism of action of a drug-eluting stent is to open the vessel mechanically, while the drug has only an ancillary function. This type of stent is therefore classified as a medical device.



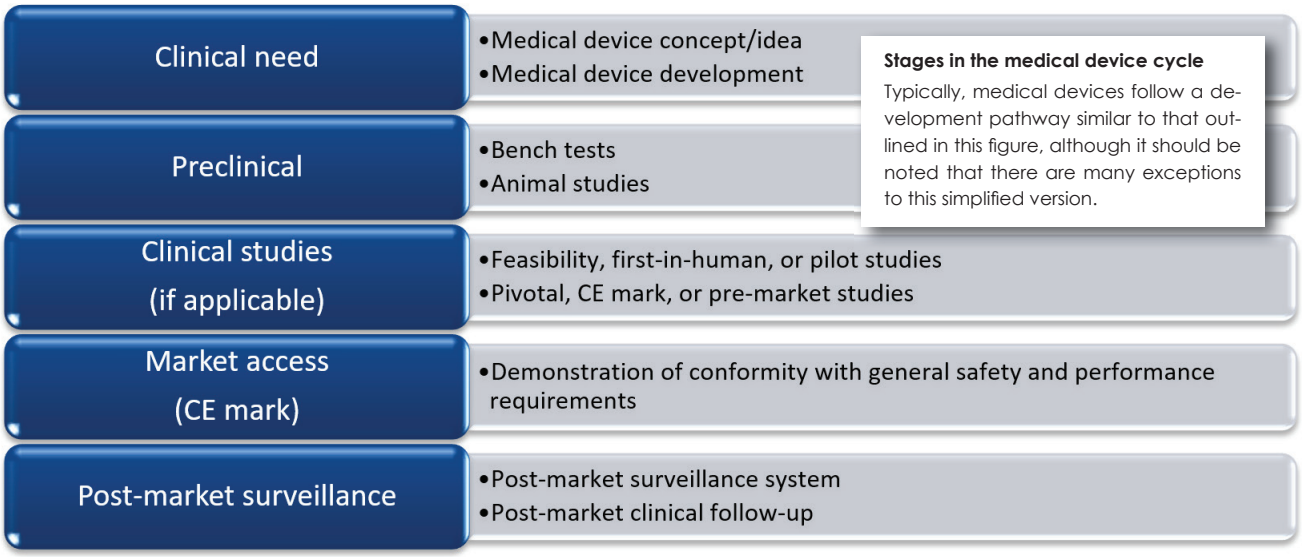
Medical devices are classified according to the level of risk associated with their use.

In the case of borderline products for which the mode of principal action is not clear, regulatory bodies should be consulted to clarify if the product is classified as a medical device or a drug. The risk entailed in using a medical device is largely what impacts the approval pathway required to bring the product to market:

- For low-risk devices such as sticking plasters, clinical data are rarely required.
- For high-risk devices such as heart valves, data from clinical studies are generally essential.

Medical device discovery and development

In general, the process of development is shorter for medical devices than for drugs. Often, a new product involves adaptation of an already existing device. Because medical devices are less likely to interact systemically, fewer patients are required to participate in clinical trials.



It all starts with **clinical need**. Based on that need, engineers develop a concept. If a device is truly innovative and not merely an upgrade of a previous model, its development is usually performed by engineers and physicians working in close cooperation. With their expertise in the field, physicians ensure that the device accommodates the identified need.

In **preclinical development** stages, bench tests are carried out to assess essential characteristics of a device (e.g. the breaking strength, durability, elastic recoil). Animal studies may be conducted to test aspects such as implantation technique and the degradation process. In general, fewer animals are required for testing medical devices than for testing drugs.

Depending on the risk class of a device, **clinical studies** may not be required to gain marketing approval. It may also be possible to avoid having to undertake expensive research in animals and humans by demonstrating equivalence. If, for example, you wish to sell a new urinary catheter that you can prove has the same biological, technical and clinical specifications as several others already on the market, you may be able to claim that yours is an equivalent device and needs no further testing. However, with new requirements (i.e. the EU's Medical Device Regulation, or MDR), avoiding further testing may no longer be so easy.

Another difference between the pharmaceutical and medical device industries is that, in the latter, it is not required to conduct clinical trials with healthy volunteers. In the case of high-risk devices, it would be unethical, for example, to implant a heart valve in a healthy volunteer. At the other end of the spectrum, low-risk devices rarely require clinical studies.

Medical device studies corresponding to Phase II drug trials are referred to as feasibility, first-in-human or pilot studies (the terms are often interchangeably). These early studies are only needed if the product is innovative, difficult to place, or if the ideal implantation technique is not yet known.

The counterparts to Phase III studies are pivotal, CE mark, pre-market or investigational device exemption (IDE) studies. In Europe, they normally include between 50 and 200 patients—much fewer than equivalent drug trials, which can include over 1,000 patients. In contrast, IDE studies in the United States usually include larger numbers because the FDA is more cautious and frequently demands randomised controlled trials as a prerequisite for approval.

An important consideration when comparing patient outcomes after complex implantation of medical devices such as heart valves and hip replacements is not just the device's performance but also the level of experience, knowledge and skills of the operator. Consequently, medical device companies invest highly in providing skills training and mentoring.

Once there is sufficient evidence of the safety and performance of an investigational device, the next step is **market access** with the submission of an application for a CE mark ('Conformité Européene'/'European Conformity'; Premarket Approval/PMA in the United States). If the product

meets all essential requirements in the applicable markets, it can then be commercialised with a commitment to conducting **post-marketing** follow-up studies. After approval, a variety of data sets may still be required, such as the following:

- Post-marketing safety studies.
- Observational studies/real-world evidence.
- Health economics analyses and models.

Any new indications, combinations, doses or formulations will also require evidence and regulatory approval.

Regulations and guidelines

The pharmaceutical industry is heavily regulated by a range of bodies covering issues such as legal matters, data disclosure, pharmacovigilance, involvement of healthcare professionals and clinical practice. By comparison, medical devices tend to be less strictly regulated but are catching up. Medical writers need to understand which guidelines apply and when.

European regulations relevant to medical devices

- ISO14155:2011: Clinical Investigation Of Medical Devices For Human Subjects – Good Clinical Practice (update expected 2018/2019)
- Medical Device Regulation (MDR) 2017/745 (http://eur-lex.europa.eu/legal-content/ENG/TXT/PDF/?uri=CELEX-:32017R0745&from=EN)
- MEDDEV guidelines:
  - MEDDEV 2.7/1 REV 4: Clinical Evaluation
  - MEDDEV 2.7/3: Serious Adverse Event Reporting
  - MEDDEV 2.12/2: Post Market Clinical Follow-Up Studies
- Country-specific guidelines

The new MEDDEV 2.7/1 REV 4 is a document listing all preclinical and clinical data required for a CE mark device application submission. It also includes new requirements for clinical evaluation reports such literature searches with more sophisticated appraisals, and specifies authorship criteria and the frequency of clinical evaluation report updates. These new requirements and the gradual introduction of the EU's MDR are expected to provide additional opportunities for medical writers in the future.

Regulations that apply to both pharma and medical devices

- The Declaration of Helsinki
- Disease-specific guidelines
- Standard operating procedures
- Publication guidelines, such as
  - Good Publication Practice (GPP3)
  - International Committee of Medical Journal Editors (ICMJE) guidelines
  - EQUATOR Network guidelines
  - Statistical guidelines

Who does what?

In the pharmaceutical and medical device industries, the same titles and job descriptions can be found among medical writers. Because the latter tends to be smaller, its medical writers may have dual roles (e.g. there may not be a separate Publication Manager).

Department	Responsibility
Clinical	running clinical studies
Medical Affairs	medical and scientific integrity, post-marketing or local studies
Publication Manager	publication planning and delivery of publications according to guidelines and SOPs
Statisticians	statistical design and analysis of studies
Regulatory	ensuring that the company adheres to all relevant industry regulations
Legal	legal protection of the company
Procurement	managing purchases and cost containment, oversee requests for proposal (RFP) processes
HEOR*/Market Access	ensuring support reimbursement

*Health Economics and Outcomes Research

Take-home message

Writing for pharma or medical devices is a personal choice based on your interests and the kind of writing you enjoy. Gaining experience in both areas will help you decide which avenue to pursue.

Further reading

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Considerations in the development of biosimilars http://biosimilars.elsevierresource.com/articles/key-considerations-preclinical-development-biosimilars/fulltext

Doerr B, Whitman S, Walker S. Writing for medical devices compared to pharmaceuticals: An introduction. *Medical Writing* 2017; 26:8-13.

Drug or medical device? https://www.gov.uk/guidance/decide-if-your-product-is-a-medicine-or-a-medical-device

EQUATOR Network guidelines for main study types http://www.equator-network.org/

International Committee of Medical Journal Editors; Recommendations for the conduct, reporting, editing and publication of scholarly work in medical journals http://www.icmje.org/recommendations/

Medical device classification http://www.mdco.gov.hk/english/emp/emp_trad/files/classification_rules.pdf

Medical journalism

The profession of medical journalism sits at the edge of medical communications. There are several notable differences between medical writing and medical journalism.

> 'Science writing is about explaining complex ideas that nobody wants to keep secret; science journalism is about explaining things that everyone can understand but that some might prefer to keep buried'.
>
> – Michael Kenward, former *New Scientist* editor

> 'Medical journalism has the potential to change somebody's outlook on the world and this influence is a great responsibility'.
>
> – Nigel Praities, *Pulse* editor

Section objectives

- To provide an overview of medical journalism.
- To highlight the differences between medical writing and medical journalism.
- To provide advice and guidance for those who want to switch between these professions.

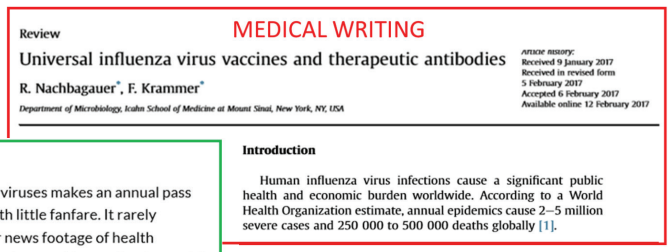
What is medical journalism?

Medical journalism seeks to provide balanced health stories that explain scientific facts and engage readers. The target audience may include healthcare professionals, patients, carers and relatives, and members of organisations, governmental bodies and the lay public. The contents and writing style must match and hold readers' interest until the last paragraph. Headlines, such as those adjacent, are designed to engage, inform and potentially shock a reader.

Stories may arise from one's own research, by following the work of others, or simply by chance. The channels through which medical journalistic pieces are disseminated include print or online versions of magazines, newspapers and journals, and numerous forms of social media. Similarly, the range of content may include news items, features, opinion pieces, blogs, webinars and opportunities for continued professional development (CPD). Big organisations tend to feed on smaller ones, with the best stories getting picked up by the national media or television.

The life of a medical journalist can be varied and fast moving, if not well paid. While many medical journalists are employed as editors or staff reporters by a media organisation, the competition is intense, and companies are forever cutting back. Unless they have established workstreams, freelancers often struggle to get published and face competition from unpaid amateurs. Other problems include working with tight deadlines, especially in broadcasting and the newspaper world; not being able to check the validity or robustness of a story; and looking beyond biased press releases. These drawbacks are balanced by positive features such working with interesting people, a degree of flexibility and the satisfaction of making sense of a complex topic that will be commented on by others.

How does medical journalism differ from medical writing?



Left: A comparison of medical writing and medical journalism covering the same topic; one text appeared in a scientific journal while the other was published in the popular press.

Although both professions require an understanding of the scientific background of a piece of health writing, the contents, style, target audiences and featured topics of medical journalism and medical writing generally differ.

Whereas medical writers produce text on topics defined by a client or an institution that is primarily informative or intended for regulatory bodies, the priority for medical journalists is to narrate stories that will engage and maintain interest until the last paragraph. This process involves getting into the context of what is being reported, seeking comments, speaking to independent experts, and highlighting both positive and negative aspects of a story. As the audience for medical journalists is wider, style and vocabulary must be adapted, avoiding the technical scientific vocabulary used in medical writing for experts.

Medical Writing	vs.	Medical Journalism
Topic defined by an institution/client		Impactful contents
Informative/regulatory texts		Engaging/interesting texts
Expert audience		Wider audience, more popular
Work under time pressure		
High level of understanding of the science behind the story		
Scientific accuracy		

So, you want to be a medical journalist?

If you enjoy writing, can produce engaging pieces by a deadline, know your science, possess an investigative nature and can learn quickly, then medical journalism may be for you. Advice from experts on how to get your foot on the door:

Start writing and get published. It does not matter what or where.
Have a **scientific degree**.
A **journalism qualification** is helpful but not essential.
Get on an **internship program**. They are becoming rarer and competition is fierce.

All sources tend to offer the same advice for budding medical journalists: simply start writing, keep going and reach out to a wide range of potential outlets. Researching the published content of journals, websites and magazines is a good way to find inspiration. Approach companies using freelance writers and submit original pieces or suggest new ideas. If you are unsuccessful, ask for feedback to improve future submissions. The Association of British Science Writers' (www.absw.org.uk) and the Medical Journalists Association's (www.mjauk.org) websites are excellent resources and are used by editors to source freelance journalists.

Whereas formal journalism qualifications and in-depth experience are an asset, what matters more than anything is having a good writing style, desire to disseminate scientific stories and ability to learn quickly.

Medical writers looking to transition to medical journalism will have a good understanding of scientific writing. However, they will also need to be able to investigate and critically analyse, not only summarise and describe. While it is possible to be both a medical writer and a medical journalist, some may find switching between the different styles of writing challenging. As discussed, most commercial medical writing involves presenting data in the interests of companies and organisations, whereas medical journalism requires the evaluation of numerous sources to deliver what should be a balanced and unbiased story.

Take-home message

Medical journalism consists of writing engaging science pieces or news items for a variety of audiences. Contents, style and topics often differ from those covered by medical writers. You must enjoy writing, have a flair for it, know your science, possess an investigative nature and be able to produce corroborated text quickly.

Career and survival tips

While there are many options for career advancement in medical writing, the path is rarely smooth and straight. Reaching the height of publication manager or scientific director is interesting and well paid, but not without stress. Those who have achieved a medical writing career will usually say that they had never planned on it; rather, they fell into it from research or medicine. Their careers are often punctuated by a series of highs and lows, along with some well-learned mistakes. Our hope is that this final section will provide you with some guidance on your journey into medical writing.

Section objectives

- To provide career advice and survival tips to those venturing into medical writing.
- To suggest various tools and strategies for career management.
- To provide resources for further career management research.

Starting a medical writing career

A career is not a dream job. It is a journey through several roles involving continuous learning and development.

career:

(n.) progress and actions taken by a person throughout a lifetime, especially those related to that person's occupations. A career is often composed of the jobs held, titles earned and work accomplished over a long period of time, rather than just referring to one position.

— Business Dictionary

What experience/qualifications are needed to start a career in medical writing?

The main requirements for getting a foot in the door in medical writing are scientific qualifications and experience writing in English, the *lingua franca* of the pharmaceutical and medical device industry.

There are few formal medical writing qualifications worldwide, with only one undergraduate course in the United States and fewer than ten advanced degrees. In the UK, Manchester Metropolitan University offers an MSc in Science Communication with a module dedicated to medical writing. Those entering the profession usually hold a higher scientific degree, such as an MD, PhD, MSc or PharmD. Having a BSc may be sufficient.

Writing experience may come from developing one's own science publications as part of a dissertation, working on laboratory reports and producing copy for journals, magazines, websites and blogs. Some take advantage of the European Medical Writers Association (EMWA) professional development programme, which provides high-quality training in the form of half-day workshops at EMWA's biannual conferences.

Define and refine your transferable skills

All graduate-level jobs require fundamental transferable skills. Medical writers do not just need writing skills—they will find the following indispensable:

- Time management, planning and self-organisation skills.
- Project management skills.
- Communication skills.
- Presentation skills.
- The ability to get on with people (both colleagues and clients).
- Conflict avoidance/resolution skills.
- Managing through influence, not authority.
- Client management skills.
- Business skills.

Begin working on your presentation skills early on—communication is essential to being effective in your role and for career advancement.

Learn how to get on with people and how to resolve, or even better, avoid conflicts. Try to manage through influence, not through authority, and always be constructive. Do not get pulled into office politics—your peers may be your bosses or clients in the future!

The culture shock of changing roles

The first challenge after landing any job is the culture shock. In medical writing, you may be changing industries mid-career or moving from the lab to an office environment, from the client side to an agency or from a small organisation to a large one.

Changes in environment, sector and role can feel very much like moving to a different country (or planet) where you are forced to start from scratch. You will need to learn new rules and etiquette. Some tips that may smooth your process of adaptation:

- Know what you are getting into (and out of).
- Learn about the industry and the issues it faces.
- Educate yourself—Google is your best friend.
- Attend relevant training sessions.
- Seek feedback from peers to help you along the way.
- Network with people in your sector.

Navigating your career path

You would not leave a science experiment to chance, and you should not treat your career the same way.

Remember:

- No one else will do it for you.
- Have a plan and follow it.
- It takes some effort.
- Do a little every day.
- It's never too late to start planning!

Where to start?

When planning your career, ask yourself the following key questions:

- What do you like/dislike doing at work?
- What are you good at?
- What are your skills and education?
- What drives/motivates you?
- What is your measure of success? This measure must be your own and not come from society or your families—neither can provide you with internal motivation.

Take a scientific approach when analysing your career and deciding which step to take next—collect, analyse and intepret relevant data, draw conclusions and make recommendations. Use data about yourself: your personality, values, interests, abilities, strengths, weaknesses, preferences, learning style and, importantly, your hobbies and personal life. Remember what is important to you overall. Employers want healthy, happy, balanced employees who can contribute—not miserable, burnt-out workers who bring down others around them.

Have a development plan

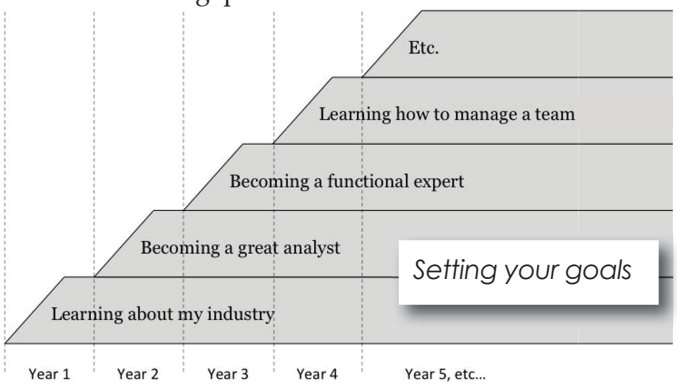
If you do not have a long-term goal, set some short ones. It is often useful to talk to people about this, as they might have good ideas and feedback from their experience of working with you. Making long-term goals does not mean that you must force yourself to follow that path if your priorities change—it gives you the coordinates to set your career GPS, measure your progress and make key choices as you travel forward.

Tips for your early days as a medical writer

Have a full appreciation of the job description.
Believe in yourself.
Stay calm, try not to get stressed.
Ask questions.
Don't be afraid to seek help from colleagues.
Try to be flexible—projects, goals and priorities change.
Don't take things personally.
Don't deliver rubbish work because you are under pressure.
Don't work overly long hours.
Relationship building is usually the key to success.

Moving forward or sideways

When seeking a new promotion or role, look at what is required for the position. Then, identify any gaps in your experience and skills and find opportunities to fill those gaps. For example, ask to be part of a project that will add to your experience or look for an intermediary role that will fill that gap.



Continue self-development

It is important to keep learning new skills, exploring areas of expertise and generally broadening your experience. Keep up to date in your current field and become a valuable part of your team, department and organisation.

Seeking feedback from peers, customers and competition is an indispensable way to determine where you need to improve. Make sure to celebrate your successes along the way and learn from your mistakes.

Build a network

Develop a short, personal presentation that you can use when introducing yourself to new contacts: say who you are, what you do and some relevant and recent key achievements.

Try to be memorable. Do not underestimate networking within your current organisation; make time to get out of your office and catch up with people over coffee or lunch. Network through tools, organisations and communities such as LinkedIn, ISMPP, EMWA and MedComms Networking (NetworkPharma). Build and sustain your network when you are employed so that you have a strong foundation when you need it.

The winding career road

The career road is often not straight—moving sideways within an organisation is as important as moving up. Sometimes, people are promoted too quickly to a level they are not ready for or to a job they do not enjoy.

The winding path will give you experience and exposure, ensuring that you have the skills and knowledge needed to be successful in a new role. When promotion becomes an option, make sure it is what you want. Does the new role fit your skills, drivers, values and lifestyle? Do not just do it because it is expected!

There is more than one road available and there will be many opportunities (usually via your network) to change your path. If you have spent time looking inward and assessing yourself, you will be in good shape to know which direction to take.

Constant reassessment

Regularly reassess your situation and whether you are still happy. Your needs and goals will change from year to year and decade to decade, depending on personal circumstances.

Change means growth, so even if it may look like you were taking a step down or sideways, you are taking a step forward that may translate into a step upwards later.

Changing roads (e.g. industry, department, function or sector) does come at a price. As you won't always be able to move to a different sector at the same level, moving to a new field can mean starting over. However, your transferable skills will be useful, and if you were unhappy on a previous track, this will likely be a price that you are willing to pay.

Some final personal words of wisdom from one who has made many mistakes:

- Get a mentor and treat them to regular dinners.
- Always consider every opportunity—it has come along for a reason.
- Accept disappointment and learn from it.
- Help often comes from unanticipated sources.
- Expect to be hit by unexpected problems (especially when all is going well).
- Don't do it just for the money.
- Encourage, praise and thank those around you. Take an interest. Buy cakes!
- Reflect and reread important e-mails.
- Remember that you are doing something worthwhile.

Resources

www.abpi.org.uk
www.amwa.com
www.emwa.com
www.firstmedcommsjob.com
www.hca-uk.org
www.ISMPP.org
www.medcommsnetworking.com
www.nextmedcommsjob.com
www.pharmaexec.com
www.pharmafile.com
www.pharmaphorum.com
www.pharmatimes.com
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Index of abbreviations

AE	adverse event
ASR	annual safety update report
ATC System	Anatomical Therapeutic Chemical Classification System
CARE	CAse REport guidelines
CDP	clinical development plan
CI	competitor intelligence
CME	continuing medical education
CMPP	Certified Medical Publication Professional
CPD	continuoWus professional development
CSP	clinical study protocol
CSR	clinical study report
CTA	clinical trial authorisation
CTD	common technical document
DSURs	development safety update reports
EHR	electronic health record
EMA	European Medicines Agency
EMWA	European Medical Writers Association
FDA	Food and Drug Administration
GCP	good clinical practice
GLP	good laboratory practice
GPP	good publication practice
HEOR	health economics and outcomes research
HES	hospital episode statistics
IB	investigator brochure
ICF	informed consent form
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICMJE	International Committee of Medical Journal Editors
IDE	investigational device exemption
IMPD	investigational medicinal product dossier
IND	investigational new drug
ISMPP	International Society for Medical Publication Professionals
IVRS	interactive voice response system
MHRA	Medicines and Healthcare Regulatory Agency
MSL	medical science liaison
NDA	new drug application
ONS	Office for National Statistics
OTC	over-the-counter
PBRER	periodic benefit-risk evaluation report
PIP	paediatric investigation plan
PK	pharmacokinetic
PD	pharmacodynamic
PSUR	periodic safety update report
PV	pharmacovigilance
QA	quality assurance
RCT	randomised controlled trial
RFP	request for proposal
RMP	risk management plan
RWD	real-world data
RWE	real-world evidence
SmPC	summary of product characteristics
SOP	standard operating procedure
USPI	United States Packaging Insert
WMA	World Medical Association