An introduction to medical affairs for medical writers

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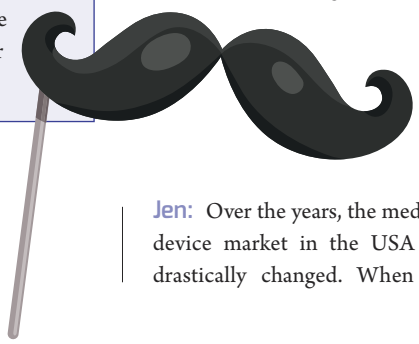
Abstract
The role of medical affairs in pharmaceutical and medical device companies is gaining prominence. Medical writers will increasingly find themselves supporting medical affairs activities or, indeed, transitioning to jobs within medical affairs departments. But, what does this field allied to medical communications involve? To learn more, the authors explored the literature and interviewed two senior medical affairs professionals from different industries. They discovered that medical affairs professionals have a strategic role, handle scientific dialogue, promote partnerships between stakeholders, and anticipate trends in the healthcare sector. While an MD or PhD is desirable for potential candidates, a scientific degree is acceptable. Working with medical affairs can be demanding, but there are attractions: good work-life balance and salary, diversity of activity, and opportunities to attend international conferences. Medical writers may be involved in publications, regulatory activities, research, meetings, and educational outputs. Medical affairs continues to evolve into a bridge between science and commerce which strives to be the 'honest broker'. It is increasingly becoming the face of the health industry and a strategic pillar within many companies.

Introduction
Medical affairs professionals (MAPs) within pharmaceutical or device companies have a unique and evolving role.[1] They are increasingly regarded as the medical face of the organisation. Those of us outside of industry often have a limited understanding of their role and the potential career opportunities and sources of work medical affairs offers to medical writers. The present article provides an overview of medical affairs, focussing on current activities, entry requirements, career prospects, as well as some personal experiences. In preparing this information, we have explored selected literature, reviewed information provided on the Medical Affairs Professional Society website (https://maps.within3.com/maps-community), and interviewed two senior medical affairs professionals from very different organisations: Dr Leticia Orsatti MD, Global Medical Advisor at Boehringer Ingelheim GmbH and Jen Doyle, Vice President Medical Affairs, Medtronic LLC.

The evolving role of medical affairs
Individuals responsible for medical affairs are found across all pharmaceutical and medical device organisations. Most established companies will have a dedicated team. Medical affairs originally occupied a supporting role within the health industry. Over time, the role has evolved to become the third strategic pillar within many companies, alongside research and development and commercial/market access.

Leticia: The role of medical affairs has increased to match the evolving healthcare environment. Scientific dialogue has never been so important. Medical affairs is no longer seen solely as supporting or functioning as an approver, rather it has taken on a key strategic and leading role.



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Jen: Over the years, the medical device market in the USA and Europe has drastically changed. When I began in the industry 15 years ago, you could just sell the [surgical] product, without strong evidence of clinical benefit, direct to the surgeon. I personally feel medical devices require economic evidence, as well as clinical. Buyers are interested in how we can cost-effectively train hospital physicians. Medical device regulations have changed the regulatory landscape.

The importance of physician training and regulatory landscaping has significantly contributed to the importance of medical affairs in the past 10 years. I think medical affairs is a great place to be in and it's not going to go away anytime soon.

What do medical affairs departments look like?
There is no fixed medical affairs structure, function, or universal job description.[2] MAPs may come from a variety of backgrounds e.g. medicine, nursing, science, business, education, and marketing. Newer recruits may include data scientists, medical writers, and translators. Many will be office-based, with some working from home. Medical scientific liaison (MLS) staff are a group within medical affairs who are generally active across hospitals and primary care. They are therapeutic area experts trained to discuss treatment trends and scientific research.

While there will be working links to other specialist groups such as publications ad legal affairs, the need to avoid conflicts of interest means that there is generally a clear organisational separation between medical affairs and marketing.

What do medical affairs professionals do?
Responsibilities include understanding the constantly changing healthcare environment and providing strategy and leadership throughout the lifecycle of the company's products (Figure 1).[3] Generally, MAPs support innovation, research, and data generation. They are the custodians of information relating the

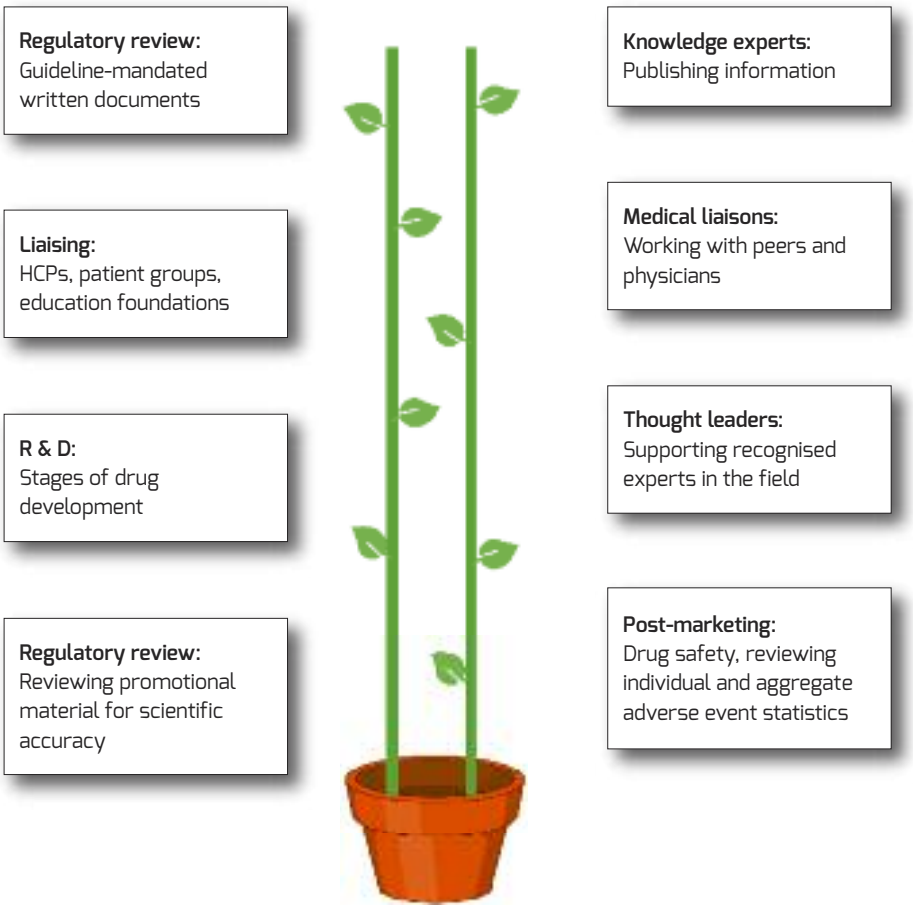


Figure 1. Some of the activities supported and led by medical affairs departments.

HCP = Health care provider, R & D = Research and development

company's products and their application to relevant therapy areas. A core activity is to interact with healthcare professionals (HCPs), payers, service providers, universities, governmental departments and, increasingly, patients/patient organisations. MAPs are required to appreciate the needs of all these stakeholders and provide them with timely and balanced information.

Leticia: We can be involved at all phases of product development. Activities tend to be most intense during phases II and III. Medical affairs is responsible for the scientific strategy. To that end, we must generate unbiased medical evidence to educate the scientific community, train internal teams, understand key gaps that can be addressed with additional studies, engage with external experts to gather insights and feedback, and more.

Jen: Medical affairs has a seat at the table for all product development projects. We create what we call a 'medical affairs strategy', to comprehensively look at a product and to outline the clinical trial, reimbursement, physician training, and medical science strategy. Do we need a trial to register the product or for post-marketing and to drive adoption? What's the reimbursement strategy? How will we train people on this? What are the preclinical test plans? This is just a very holistic approach to all the things that need to be done to support product development. There are many people on my team that work in this area and it is a big part of our job.

What does a typical day look like?

Leticia: My focus is usually on generating data of value to the scientific community, along with building medical events and training materials for our colleagues worldwide. I also lead activities such as advisory board meetings. These require a lot of work. I spend quite a lot of time travelling, in particular attending international congresses and meetings.

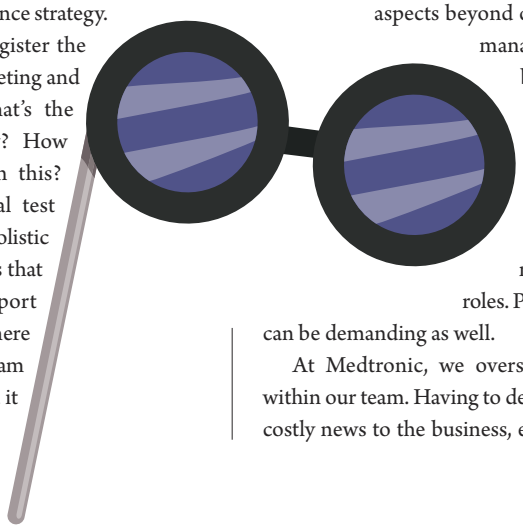
Jen: If I am not travelling then I am usually on the phone. Because my team is spread throughout the world, I try and visit them all regularly. Around 50% of my time is travelling. At other times, I am in meetings or on the phone. Some days I have meetings from early until late at night.

What are the challenges and pleasures of working in medical affairs?

Working in medical affairs is not an easy option. There will likely be lots of meetings, calls, and emails to contend with, as well as bureaucracy and pressure from line managers. On the plus side, being at the forefront of medical research and interacting with scientists and health care professionals is stimulating. For some, it is an escape from patients and the laboratory.

Leticia: I enjoy deep diving into our scientific data and responding to questions coming from the scientific community. I also enjoy interacting with global experts; it is such a great opportunity to learn. On the other hand, administrative tasks and managing lengthy processes can be challenging.

Jen: The pleasurable part is the variety. Clinical research is my first love, but I enjoy working on aspects beyond clinical trials. I like managing people. It brings me great pleasure to help develop the 100 staff that I'm responsible for and see them move into new roles. People management can be demanding as well.



At Medtronic, we oversee medical safety within our team. Having to deliver unpleasant or costly news to the business, even if it's the right

thing to do, is challenging and requires a sensitive approach.

Does being a medical affairs professional damage your health?

Leticia: When I started, I was concerned about the workload. I was not used to the huge amount of emails received daily and the different definitions of urgency. It took me a while to learn how to prioritise, delegate, and say "No". A good work-life balance is important. On the other hand, my work is rewarding, it gives pleasure and a sense of accomplishment.

Jen:When I am not travelling, I work from home most days. Medtronic is great about work-life balance and provides flexible working situations. My work-life balance varies from one week to the next, but I feel like I work hard when I'm supposed to be working hard. We have a good understanding of having personal time off.

What skills and qualifications are required?

Those that survive and prosper are typically clever, resilient networkers, often with foreign language skills, who are comfortable in an international environment. Valuable professional and personal skills include:

- The ability to successfully initiate and lead projects
- Effective communication with internal colleagues and external customers
- Business acumen and strategic vision
- Technical skill e.g. understanding compliance, medical and scientific expertise, and digital/analytical ability.

Most individuals working within medical affairs will have a higher degree. Medical doctors are much in demand, notably when project sign-off is required. Having a Master's degree or doctorate will also serve you well, especially if you have clinical or research experience in areas relevant to the company's activities.

Leticia: An effective MAP needs insight. They must understand and address the needs of all customers; prioritise patient safety and welfare; be innovative and curious; and grasp the basics of business. The latter includes supporting company priorities and developing business acumen. Anticipating future needs and communicating well are successful MAP attributes.

Jen: It depends on the position. We have a need for medical doctors, but there are also roles for non-clinicians, as long as certain work is signed off by an experienced MD. Reviewing the literature, understanding the different disease states, and then translating that into a good strategy is generally the role of PhD graduates. But even with just a science degree (I have a Master's degree in regulatory affairs) you can support a lot of the work that we are delivering to the business. Personally, I think a PhD is one of the most useful degrees in the field.

What are the typical salary range and opportunities for career development?

Leticia: Salary range is wide and depends on the role in the organisation. There are many opportunities for career development in medical affairs. It is important to grasp development opportunities and experience different positions.

Jen: There is a lot of variety, depending on the type of position and whether the employee has a higher qualification (e.g. a PhD). In the US, a team member without managerial responsibility might expect to earn $90,000 to $150,000. There are very good career tracks for individual contributors. At a managerial level, typical salaries range from $130,000 up to around $200,000 at director level, higher still if you are managing a large team of 20 or more people.

Where do medical writers fit in?

The role of medical writers within medical affairs generally depends on the different phases of product development. It may include producing familiar outputs such as study protocols, regulatory documents (e.g. clinical study and evaluation reports), and the full range of publications targeted at professionals and lay audiences.

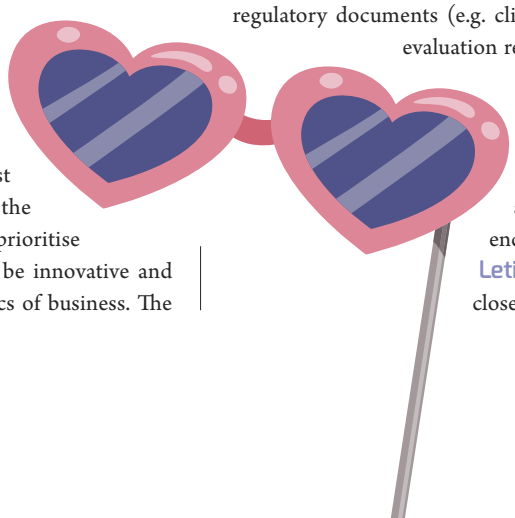
Leticia: I work very closely with amazing medical writers, and they assist our department with many activities: publications, abstract submissions, regulatory documents, scientific meetings, slides for training, etc. I probably interact with medical writers on a daily basis and acknowledge the great value they bring to our work.

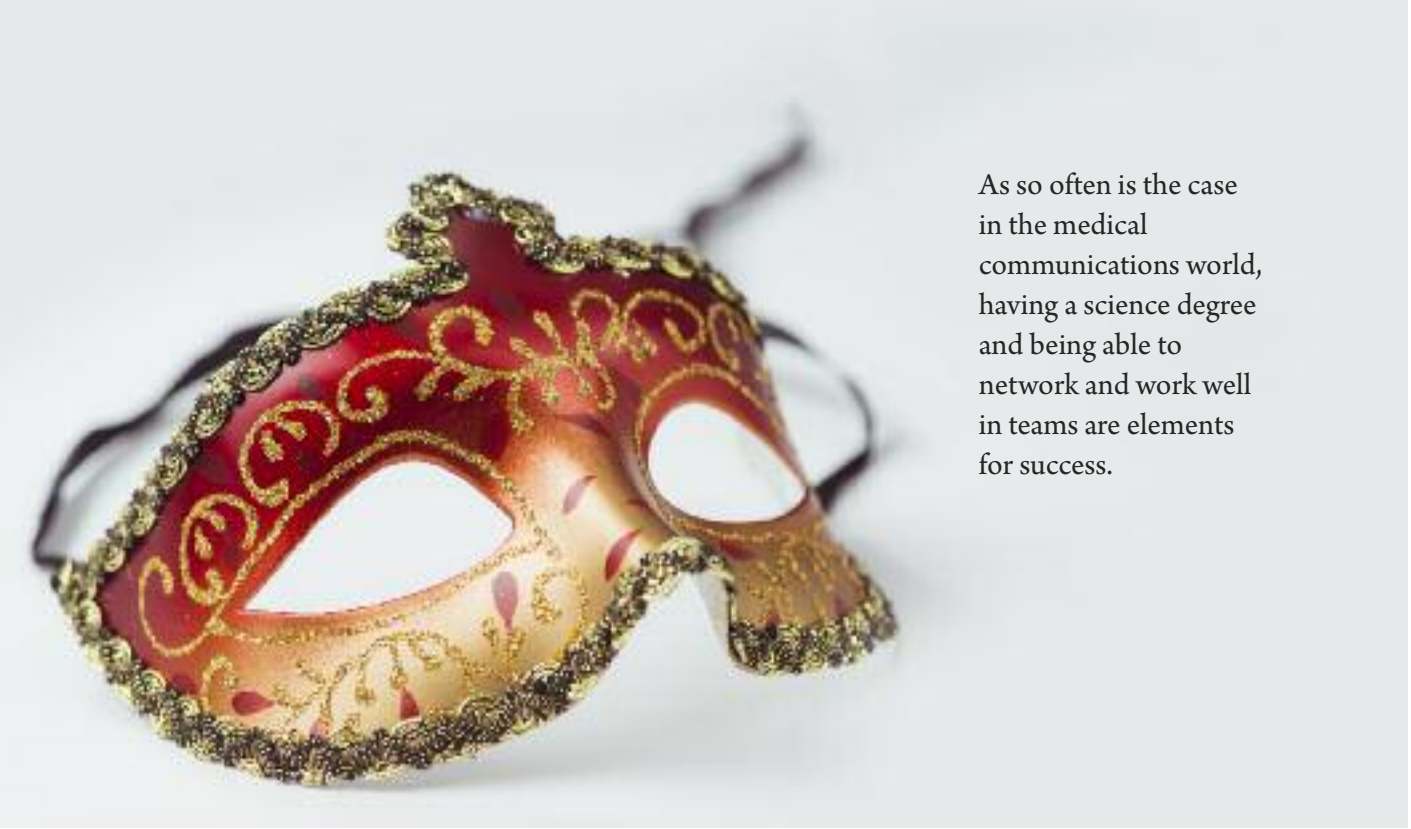
Jen: If you had asked me this question 10 years ago, I probably would have said *'I have a bunch of people in my clinical team and they are pretty good writers'*. About 8 years ago, we hired our first medical writer, despite the team being sceptical about having a dedicated writer. Now my team will not make a move without their medical writer. We have writers working on multiple clinical trials or scientific communication to reimbursement authorities etc. Having this exposure early on can benefit the publication strategy, and the medical writing team has proved to be a huge asset. The other part of medical writing is preparing the clinical evaluation report. It is becoming so critical that we now have 30 writers in the group helping with regulatory writing across Europe and China. We usually insource and occasionally outsource as well. Medical writing is vital for most of what we do.

Getting started in medical affairs: Personal experiences

Leticia: I am a paediatrician and was approached by a pharma company initially to work as a medical science liaison. What attracted me to this role was the opportunity to discuss familiar scientific data with my peers. The transition to other clinical areas such as cardiology and pulmonology, as well as new leadership roles as a medical advisor, went well but required training. I think the challenge of constantly learning and developing new skills is what keeps me motivated.

Jen: After finishing an undergraduate degree in biochemistry, I wanted to go to medical school. Instead, I got into manufacturing of medical devices and eventually moved into clinical research and from there into medical affairs. About 6 years ago, I took on an expanded role. This included clinical research and medical science, with responsibilities similar to those of a science liaison lead/medical director. Other areas I look after include healthcare economics, policy, and reimbursement, as well as healthcare provider training.





As so often is the case in the medical communications world, having a science degree and being able to network and work well in teams are elements for success.

Advice for new recruits to medical affairs

Leticia: Improve your scientific and communication skills and work on networking.

Jen: Don't underestimate the importance of networking. Build a network and get to know people. Many of us have multiple bosses that we need to work with. Flexibility and learning to manage by influence are vital.

The future of medical affairs

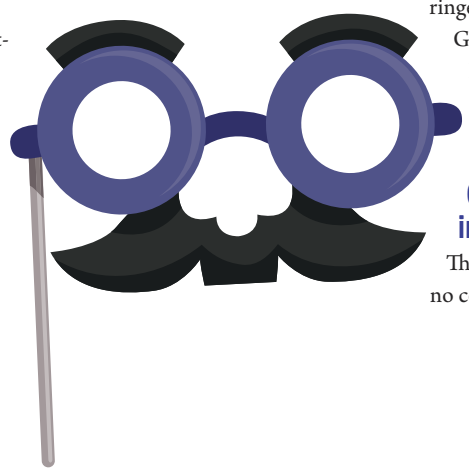
Leticia: I foresee medical affairs playing an increased and more relevant leadership role in our company.

Jen: One area that we are starting to become increasingly involved in is value-based healthcare projects. We are already starting to see some success and it is an interesting evolution beyond the traditional medical affairs work. It is about engaging better with customers, and that is exciting. We are setting up more of a governance around these projects and medical affairs, and I believe that is a future accomplishment for us.

Leticia: Medical affairs is here to stay. While relations and strategy will continue to be important, future activities will be driven by advanced analytics of patient data which go beyond a drug or device to include the whole therapeutic area. Successful companies will be those that can demonstrate effectiveness, safety, and an enhanced value proposition. In the future, there will be increased reliance on real world data, patient-reported outcomes, electronic medical records, and artificial intelligence. Other trends are likely to be even greater regulation, increased transparency, and a push for industry to work in partnership with stakeholders to optimise care. Many consider the future to be 'digital'; others emphasise the importance of patient centricity during treatment and product development. Within an organisation, someone needs to be responsible for this public-facing role. Step forward medical affairs!

Conclusion

Medical affairs departments have been established across many pharmaceutical and medical device companies. They are increasingly seen as the face of the health industry and a valued, professional bridge between science and commercial interests. Working in medical affairs appears an attractive option with a good salary and opportunities for career development. Depending on the organisation, there seems to be an increasing need for medical writers to work on a wide range of activities. As so often is the case in the medical communications world, having a science degree and being able to network and work well in teams are elements for success. Medical affairs is here to stay and being on board near the beginning of its evolution could be a good career move for many.



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Conflicts of interest

The authors declare they have no conflicts of interest.

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