
The Write Stuff

The Journal of the European Medical Writers Association

Teamwork



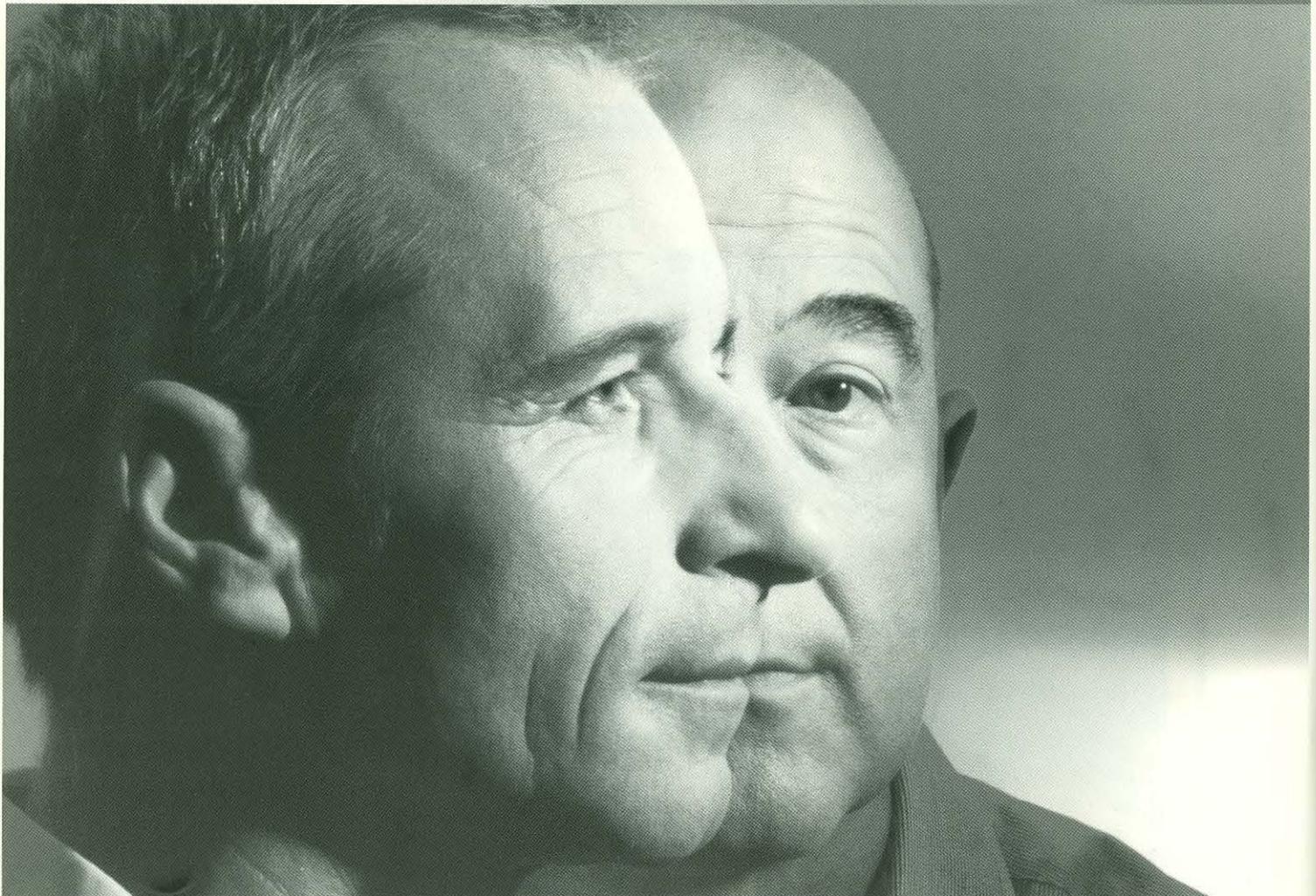
EMWA European
Medical Writers
Association

Vol. 11, No. 1, 2002

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<http://www.emwa.org>

Journal Insights

The Write Stuff is the official publication of the European Medical Writers Association. It is issued quarterly and aims to provide EMWA members with relevant, informative and interesting articles and news addressing issues relating to the broad arena of medical writing. We are open to contributions from anyone whose ideas can complement these aims.

Articles or ideas should be submitted to the Editor-in-Chief (see back cover) or another member of the Editorial Board.

Subscriptions

Subscriptions are included in EMWA membership fees. Non-members can subscribe at an annual rate of:

- £20 within Europe
- £30 outside Europe

Instructions for Contributors

- **The Write Stuff** typically publishes articles of 500 - 1500 words although longer pieces or those with tables or graphics will be considered.
- All articles are subject to editing and revision by the Editorial Board. Any changes will be discussed with the author before publication.
- Submissions should include the full address of the author, including the telephone and fax numbers and email address. Suitable quotes for side boxes can be indicated or they can be selected by the Editorial Board.
- Material should be submitted electronically on computer diskette or by email as an MS Word file using Arial font (or equivalent), 11 point size, and single spacing.
- Published articles generally include a recent photograph of the author (portrait picture, CV or passport style).

Back Issues

Subject to availability, previous issues of **The Write Stuff** can be obtained for the cost of mailing by contacting the EMWA Head Office (see back cover for address).

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From the Editor's Desk: Diversity makes for good teamwork

by Barry Drees

In this age of the corporate buzzword, the one with the longest tradition is probably teamwork. Long before corporate mission statements were merrily sprinkled with things like "breakthrough quality initiatives" or "maximising interdepartmental synergies" we had the concept of the importance of teamwork. It seems so simple and yet the secret to getting it right remains elusive. Obviously, teamwork is complex and affected by many variables but my experience in teams over the years has convinced me that one important aspect that is frequently overlooked is the diversity of the team and the acceptance of this diversity by the team leadership. I recently experienced two examples of how the positive potential of diversity can often be overlooked.

I have a long commute to work everyday and so I hear a fair amount of what is usually called popular (or "pop") music. As those of you who ever listen to this sort of thing know, the lyrics are pretty monotonous. In fact, it is little short of amazing how many repetitions there can be of the basic "love and heartbreak" themes, all sounding as mind-numbingly similar as the worst corporate mission statements. The other day though, I heard an extraordinary song with one line that was, "I would climb the Andes solely to count the freckles on your body". My first reaction when I heard that was, "Oh my, what a bizarre concept, is that supposed to be romantic?" Yet, I just couldn't get the image it created out of my mind. I looked up the song on the internet and it turned out to be a Colombian woman named "Shakira" (*Whenever, Wherever*, Epic Records), whose native language is Spanish but who learned English to write her own song lyrics. The striking image of the line makes it really stand out among all the other interchangeable song texts by everyone else. I had to recall what I wrote in an earlier comment about celebrating linguistic diversity (TWS 2000;9(3): 3), "writing in English when it is not your native language brings a different perspective from which even we native speakers can definitely learn".

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by everyone else***

Another case of a fresh approach making a bigger impression on me comes from the periodical "The Editorial Eye, focusing on Publications Standards, Practices and Trends".

In one issue they had an example of a business message, an attempt to get the recipient to respond to a questionnaire, which they used as an example of using a wildly inappropriate style. Admittedly, the style was rather flippant and probably was more appropriate for snowboarding society. One memorable line stated, "So drop everything you're doing, which ain't much in this economy anyway and go to (URL for survey)". Now, I'll agree that such a style isn't ideal for every target group (although it made me laugh), but for the author to conclude "it is a sign of rank amateurs at work—mischievous, egotistical risk-takers with a lot to learn about doing business." That sounds more like personal vindictiveness than an objective assessment. On the other

From the Editor's Desk

hand, there's no denying that it got my attention and that had I received such a request to fill out their questionnaire, I would have been much more likely to do so than if faced with the usual "Please help us to serve you better" routine that one sees so often.

I don't want to argue for diversity only for diversity's sake, but I think these two examples point out how easy it is to react with instinctive negativity to something different and thereby miss out on something interesting or important. Of course (in case you were starting to wonder where I was going with this), acknowledging and utilising diversity in a group is also critical for good teamwork. No doubt you've all heard the sports team analogy applied to all kinds of other team endeavours; yes, it even applies to clinical study report or submission dossier writing teams. Just as you wouldn't want a football team made up of 11 goalkeepers or strikers, having diversity and being able to appreciate, motivate, and utilise different kinds of skills (clinical, biometrics, drug regulatory, etc.) as well as personal styles (flamboyant, stubborn, shy, etc.) is the only way to have a successful team. How often do we see teams become dysfunctional because the leader tries to force everyone into a single mould conforming to the leader's idea of how to work, rather than respecting the different styles different members will undoubtedly bring?

I have always been encouraging diversity at TWS. Last year our linguistic diversity editor, Hilde Joosen, told me that after doing it for 2 years she felt it was time to move on and would like to let someone else have a chance. So there I was at the EMWA CTD conference in Brighton, looking for a replacement. As you'll be reading soon in a coming issue, I was indeed fortunate to be able to recruit Patricia Bünz, who seems very enthusiastic, has a fine scientific mind and is an excellent writer. However, I'd also like to take this opportunity to thank Hilde for helping me establish the whole linguistic diversity editor concept and for writing and commissioning articles for me. The truest test of success is not just what one achieves, but how viable achievements are after you have moved on.

Another thing that is almost as dear to my heart as diversity, is controversy, which in a way is the truest sign of diversity. I have always tried to encourage more real exchanges of differing viewpoints in TWS. So far, however, only two topics have generated any response: alternative medicine and peer review. So I was excited when a former contributor, Diane Klein-Franke, offered to start a regular column of opinion on controversial medical writing topics. Too often, I get the feeling that TWS is just preaching to the converted. Hopefully, we can now generate some real exchanges and find out where EMWA members don't agree. Naturally, if any of you read one of these pieces and would like to offer the opposing view, please do! That's the whole point. If imitation is the sincerest form of flattery, controversy is the sincerest form of diversity, with all its promise and potential.

Finally, we initiate a new series in this issue with the article by Isabelle Thirolle where members of the EC reminisce about their experiences. This should serve both to let members know what the various positions actually do and, hopefully, convince a broader spectrum of members to participate.

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Message from the President . . .

by Julia Forjanic Klapproth

The past year has gone by so fast. I can't believe that my term as president is almost over. Last May I came into office with a clear vision of some of the things I wanted to tackle and at least set in motion. There was the constitution in need of amending, as it no longer accurately reflected what EMWA had grown up to become. And there was the awareness that EMWA was moving forward at a rapid, but rather undirected pace, and it would be a good idea to start thinking about how to focus that progress. I had also had some vague, undeveloped thoughts on getting a more regular money flow for the organisation, through some kind of sponsorship. So when Barry asked me for my "last" president's message, it made me stop and reflect on what I and the rest of the Executive Committee had actually managed to do since last May.

The constitution is the foundation for transparency and understanding among members of an organisation, imparting a common awareness of what everyone is doing (or meant to be doing), how each member can participate relative to the whole, and clearly defining what it is everyone is meant to be striving for. It becomes an even more essential tool and point of reference as an organisation grows and the lines of communication become multilayered, due to the sheer number of people involved.

As in any dynamic organisation, EMWA has changed and developed since the creation of our first constitution, only just a few years ago. Hence, our constitution was in need of amending to reflect EMWA's current goals and operating procedures. To this end, the Executive Committee went through the constitution carefully and produced a new, revised edition that, in our opinion, reflects the current state of affairs within EMWA.

Now it's over to all of you. All amendments to the constitution need to be agreed upon by the membership, to be sure it accurately reflects what we want to achieve together. A copy of the amended constitution is included with this issue of TWS, and I ask you to read it through carefully. Acceptance of this new edition will be put to a vote of all members at the Annual General Meeting in Prague on May 16, 2002. If you will not be present, you may also vote by proxy in advance, by sending your vote to myself **and** Julia Cooper prior to May 14.

Now on to the future. Where is EMWA heading? Where do we want it to go? In an attempt to harness EMWA's intrinsic energy and move the organisation forward in a directed way, I have created the EMWA Long Term Planning Committee. This committee will be headed each year by the Immediate Past President, and will additionally comprise the 4 previous Immediate Past Presidents. This serves 2 purposes. It gives the incumbent Immediate Past President an official function for their year in office, and capitalises on the experience and insight of our previous Presidents.

Message from the President

The Long Term Planning Committee will always be open to suggestions from all members and will report directly to the Executive Committee, through the current Immediate Past President. The Long Term Planning Committee is going to think about the options that EMWA has in the years to come and will prepare a report that outlines recommendations for where they think EMWA should focus its energy. The report will be presented to the Executive Committee, who will vote on it and decide how to follow its recommendations.

As part of their mandate, the Long Term Planning Committee will also address how to develop sponsorship opportunities for EMWA. This is an area that has always been somewhat sidelined, due to the time-intensive demands of not only finding but also nurturing and maintaining sponsors. This is a demanding responsibility for any one person to take on as a volunteer. Recognising this, the Executive Committee has put the responsibility into the hands of the 5-member Long Term Planning Committee, who will come up with ideas on how to develop a sponsorship programme that will give EMWA a little bit more breathing room to develop other activities.

This issue of TWS focuses on teamwork, something that is crucial to working in the field of medical writing. Indeed, it is teamwork that makes EMWA function and able to provide the services it does to the medical writing community. It was the efforts of each individual on the Executive Committee, working together as a team, that made it so productive in the last 9 months. However, the work of running EMWA is an ongoing process, and it depends on everyone to continue to work together towards a common goal and ensure that the organisation is what everyone wants it to be.

As usual, at this point in the year EMWA is busy with the build-up to the next annual conference, this year situated in the beautiful city of Prague. Also in line with tradition, this year's conference will be the biggest yet, offering 30 different workshops as well as a full range of leisure activities that provide the opportunity to acquaint yourself with friends, old and new. New this year, the Annual General Meeting will be held in the middle of the conference to avoid the problems caused by delegates having to leave to catch their flights home. So plan to participate - this is not an opportunity for sight-seeing and shopping! It is only by the active participation of members such as yourself that EMWA can continue to grow and thrive.

It is teamwork that makes EMWA function and able to provide the services it does to the medical writing community

As I prepare to pass on the baton to my very competent successor, Julia Cooper, I feel content with what the Executive Committee has achieved during my term as President. EMWA is truly an organisation that functions by the members for the members... and what is that other than a well orchestrated team?

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Meet the Candidates . . .

Candidates will be elected based on voting by members present at the Annual General Meeting in Prague on May 16, 2002. If you will not be present, you may also vote by proxy in advance, by sending your vote to Julia Forjanic Klapproth and Julia Cooper prior to May 14.

For the position of **Vice-President:**

Isabelle Thirolle

You have probably seen my name already as I have been an EMWA Public Relations Officer since the 2000 conference in Dublin, especially interested in promoting EMWA in those parts of Europe where we are under-represented. Having an early interest in medical communication, I took a postgraduate degree in bio-medical writing, translation and documentation, and I have now been working for four years as a medical writer in the pharmaceutical industry. So, although you never stop learning in this job, I am familiar with most of the ups and downs we come across in this profession. I have now decided to run for the position of Vice-President in order to have more empowerment to continue what I have successfully started in my current function, that is to increase awareness of our profession and of the existence of EMWA. In addition, I also want to expand to areas as yet uncovered and to promote the importance of continuing education in our development. I believe that it is worth putting something into EMWA to justify what we get out of it. I look forward to seeing you in Prague.

Teresa Roberts

Each year, EMWA becomes better and stronger. I'd like the chance to help the committee to continue this trend, making further improvements and changes that will raise the profile of our profession and our organisation, allow us to share expertise with other science writers and editors, and help us to meet the shifting challenges of our work. I am really enjoying my current role as University Liaison Officer and I've been working to promote medical writing as a career option, including putting together a careers leaflet, and contacting universities and the organisers of careers events. If I'm elected as Vice-President, I'll work just as hard and enthusiastically, supporting Julia Cooper and bringing ideas of my own to the table to make sure that we meet the needs of our members.

I have a lot of ideas, but I'm particularly interested in continuing to make contacts with organisations linked to the pharmaceutical industry, and other medical and scientific editing and writing organisations. This is important in today's climate, with the increased public awareness of the way in which the pharmaceutical industry conducts itself and the condemnation of "ghost writing". A good Vice-President has to have many skills and qualities and I believe that I have the key elements: enthusiasm for my career and EMWA, the ability to work proactively, knowing when to talk and when to listen, motivating and supporting people to achieve their aims, and learning from others, especially the people who've been there and done it before.

Meet the Candidates

For the position of **Public Relations Officer:**

Varsha Imber

So why do I want to take on this post? Well, I have been a medical writer for a fairly long period of time and have been a member of EMWA for over 2 years and attended two EMWA conferences. The first one I attended was in Copenhagen and the second one was in Dublin, and I was very impressed with what I saw. I have never done any PR work before (at least not knowingly!), but I am always willing to take on a challenge. Overall, I would like to be more involved in promoting EMWA and letting people know of the benefits of EMWA and passing on any other knowledge of medical writing. I made a start with being more involved in EMWA by volunteering to do some work on the EMWA journal, *The Write Stuff* (TWS 2001; 10 (3)), and ended up editing my own issue, which was great fun. Now, I would like to take this one step further and become a committee member where I can offer more of my skills to the organisation. I have a good knowledge of medical writing (at least I like to think I have!), therefore, I feel that I could help to positively promote EMWA.

Michelle Derbyshire

I feel that I have a lot to offer the position of Public Relations (PR) Officer; from my previous experience to my vitality and commitment, all of which will be at the disposal of EMWA. I am of British origin and previously worked for the European Commission, where I also carried out my PhD work. I am therefore not a stranger to developing relations with persons from many different countries and backgrounds. One of my duties at the commission was to encourage the involvement of the accession countries (the countries in line to join the European Union) in research projects currently being carried out by the European Commission. I was also involved in the organisation of meetings with accession countries and was a member of the organising committee for the International Conference on Nuclear Tracks in Solids in Antwerp in October 2000, which attracted participants from as far afield as China. My duties for that conference involved preparation of promotional material as well as organisational aspects and editing of manuscripts for publication in the proceedings (a special issue of *Radiation Measurements*). I joined my current company in Belgium a little more than a year ago as a scientific writer, where I have had the privilege to work closely with the current PR officer of EMWA, gaining invaluable insight into this role. I am now a committed and dynamic writer, ready to face the challenges of a position such as that of PR Officer.



CTD Seminar in Brighton

by Alison McIntosh

Many of you might have read my article in the last edition of TWS entitled "Medical Writing at Home". If so, you will know that I have spent the last year as a freelance medical writer working from home and from that you might understand my growing excitement as I eagerly anticipated attending my first EMWA conference in Brighton last November. The opportunity to meet other medical writers with whom I could share information and experiences was something I could not afford to miss. As such, I was probably one of the first delegates to register with the EMWA office, making sure of my place at the conference.

The advertised two-day programme was packed with all sorts of goodies and I was particularly interested in the EMWA one-day seminar on the Common Technical Document (CTD). As a freelance medical writer for the pharmaceutical industry, the onus is on you to make sure that you keep up to date with new regulations or ways of organising documentation. The one-day seminar was a very timely and cost-effective way of helping to achieve this. A very good review had been provided by Paul Gisby in an earlier edition of TWS and, having read this, I was looking forward to hearing about how it should all be put into practice.

The day of the seminar arrived, and we all gathered in the conference hall of the Brighton Hilton at the appropriate time only to be ushered out again to face the bracing cold morning sea air after the fire alarm had sounded in the hotel. Following the arrival of the Brighton fire brigade, we were finally allowed back into the hotel to resume our meeting - a good start!

However, all the disruption was soon forgotten as Françoise de Cremiers from Wyeth Ayerst presented a very useful outline explaining what each section of the CTD was expected to contain, and also provided us with a guide to a typical table of contents. Hilda Boone from EMEA and Patrick Salmon from the Irish Medicines Board both alluded to the fact that the regulatory authorities also had to undergo training in the CTD and review process - a reminder that this is a new process for all the parties involved, not just the medical writer. Andrew Marr, representing GlaxoSmithKline, shared some of the challenges facing the pharmaceutical industry as it acquires the ability to transfer an electronic CTD (eCTD) to a regulatory authority. In the afternoon, via the wonders of technology, we were joined via teleconference by Linda Carter from the Food and Drug Administration (FDA) who supplied us with a useful insight into the US perspective on the CTD.

This conference was not a perk or a couple of days away from the office, but a very serious part of my job

Brighton Conference

Following the presentations, there was plenty of time for discussion. We were told that so far (*as of November – ed.*) there had only been a single submission using the CTD format, although we were not told by whom. As an aside, if anybody in EMWA was involved in this submission and is willing to share their experience with us I am sure many of us would like to hear about it.

In the evening, an outing to an English Medieval Banquet had been organised. This excellent night of medieval fare began with the tasting of English wine. Although for many it was probably their first taste of English wine, judging by how the rest of the evening went it was certainly not the last. We were entertained by Mary the minstrel girl, Stewart the court jester and Justine the exceptional EMWA helper. It was a thoroughly enjoyable evening with a grand finale entitled "moo moo, oink oink, woof woof, quack quack" performed by four EMWA members who shall remain nameless though infamous.

The following day it was back to business. The day had been set aside for the EMWA Professional Development Programme (EPDP) workshops. I have enrolled in the EPDP and am gathering my credits for the certificate. As a freelance medical writer, you are totally responsible for determining your own personal development and these workshops can form a major part of continual learning. For new writers, they are a superb way of learning from people with relevant experience. When I started out more than six years ago, there was no structured learning available, it was on the job training - not always the most efficient way to learn how to do things. My two workshops were very well organised and presented, and I will be enrolling in others in Prague.

Was there a difference attending this conference as a freelance? I cannot submit an expense claim form to pay for my attendance; as a consequence, if I want to attend, then I must earn enough money to enable it to happen. I found that I had a very positive attitude towards the seminar and the workshops in trying to ensure the maximum return for my investment. Hence it is not a perk or a couple of days away from the office, but a very serious part of my job.

Did I enjoy my first EMWA conference? Absolutely. This was a conference that dealt with my issues and understood what I needed to remain a good medical writer. I am really looking forward to the meeting in Prague. I thought the one-day seminar was a great idea and hope that there are plans for more. Finally, I would like to thank the organisers for their huge effort in making the conference such a success.

Alison McIntosh
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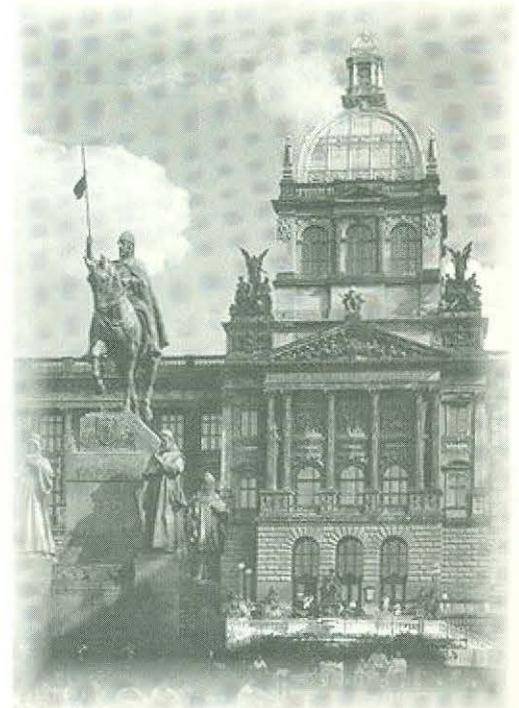
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You are Never Alone as a Medical Writer

by Virginia Watson

The complete version of this article was published in The Industrial Pharmacist, Sept 2001.

After nearly 20 years in community pharmacy I was feeling restless. I wanted a change. Could I re-enter the pharmaceutical industry which I had left for domestic reasons many years earlier? What could I offer? Six years later, looking back at that turning point, I have absolutely no regrets about the change in direction. I have discovered the world of medical writing!

Medical writers within the pharmaceutical industry are involved primarily in writing regulatory documents such as investigator drug brochures, protocols, clinical study reports, expert reports and efficacy and safety summaries. Some medical writers are also required to write package information leaflets or manuscripts for journal publication. We work in a global environment and many writers are involved in writing documents specific for the Food and Drug Association (FDA) regulatory process.

The scope of the writing work varies from company to company. I am employed by a contract research organisation (CRO) and our writers have to have the experience and the flexibility to undertake any medical writing work required by the clients. Thus we have also become involved in working on projects within the marketing arena such as product monographs, conference abstracts, and posters.

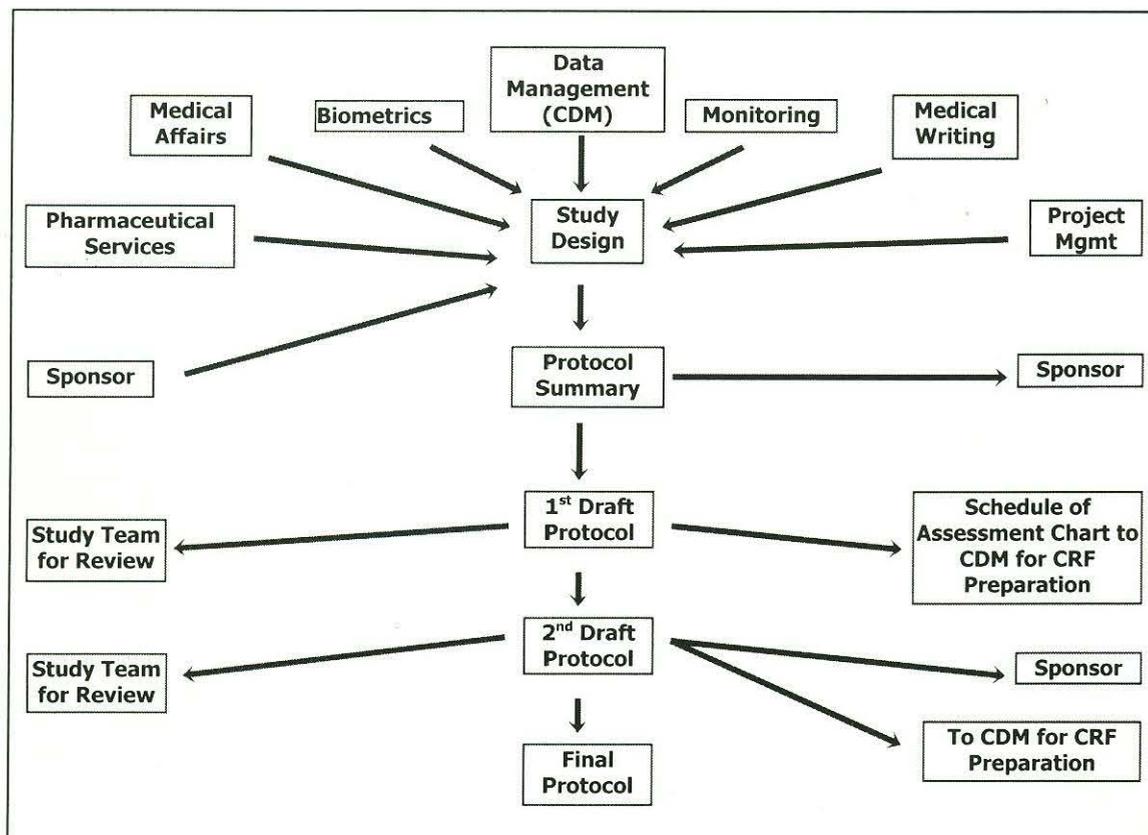
Medical writers are often perceived as being people who are slightly introverted and who beaver away quietly in a corner of the office. Nothing could be further from the truth! Medical writers are an integral part of any clinical team. It is essential that there is good communication between the medical writer and other departments. For example, the clinical study report is the end product of the clinical study. As such, it is based on the information provided directly or indirectly by the other study team members.

Medical writers are often perceived as being people who are slightly introverted and who beaver away quietly in a corner of the office. Nothing could be further from the truth!

Likewise, a study protocol cannot be written in isolation. Protocol development is, of necessity, a team function (see figure). A good protocol must reflect a well thought out study design, be practical from the investigator, monitoring and patient perspectives, and be clearly written with no ambiguities.

Whatever the document, we need to interact with our colleagues such as statisticians, project managers and medical advisors, and as a CRO we also need to work closely with the sponsor. With this in mind, I believe that the cross-departmental training which we give to all new writers joining our international writing group is extremely important. Having tried different methods, as part of this training I now send new writers on a 5-day internal International Clinical Research Associate (CRA) Training Course [1].

These complex scientific documents must be accurate. There can be no errors in the data presented and therefore all medical writing departments require a document quality control (QC) procedure to ensure accuracy. A medical writer cannot QC or proofread their own work. After a draft document has been written it is sent out for review. The stages and the extent of the review process will vary from company to company, but will principally involve an internal department review by another medical writer or manager, and subsequent review by other departments who have been involved in the provision of information for the document or who will be the end users.



Therefore medical writers must not be sensitive to criticism. When writing, there is a tendency for a writer to have a very personal relationship with a document, but it is important to remember that it is always easy to improve what someone else has written; the skill lies in starting from nothing - with a blank page - and producing the first draft. Writers are probably never entirely satisfied with their work but in this industry, timelines and financial pressures do not allow us the luxury of trying to achieve perfection.

Human resource personnel would probably categorise medical writers as “finishers” or “completers”. It can be interesting to write the first draft of a document, but it becomes less so after it has been out for review and when, sometime later, you are expected to revisit the document to incorporate changes and produce further draft(s) prior to

You are Never Alone . . .

finalisation. The longer the interval between the drafts, the harder it is to work on the document. Added to this is the fact that the document has to be complete. There must be no loose ends, and inevitably it is the medical writer who has to resolve outstanding issues, chase colleagues for missing information, and plough through study master files trying to find that one piece of paper which is essential to complete the appendices!

Apart from being sat at a computer all day what else does medical writing offer? While the profession is still small and growing, there are many opportunities for advancement if one is looking for a management or supervisory role. For those with an interest in training, as well as participating in the in-house training of writers or colleagues in other disciplines, experienced writers can become involved as workshop leaders for EMWA or as invited trainers for commercial training organisations. There are also opportunities to present at conferences and meetings.

Currently, with the introduction of the Common Technical Document (CTD), many writers at managerial level are working with their regulatory colleagues on the division of activities and the implementation of this new dossier format. Some medical writers have been involved at an earlier stage as members of advisory committees to the CTD Working Group. Likewise, writers are involved in working closely with colleagues on the move towards electronic submissions.

In a CRO it is necessary to be able to sell medical writing as a service to clients. Generation of new or repeat business through formal and informal client contact, proposal writing, project pricing and negotiation and client presentation or bid-defence meetings are part of the medical writing department's activities. The financial aspects of working in a CRO such as predicting sales, meeting targets, measuring productivity and tracking project slippage and the impact on revenue predictions will appeal to some.

Last, but not least, there is friendship. Maybe it is because we are a small profession but the camaraderie, the exchange of information, the sharing of frustrations, the mutual support, and the wide circle of friends and acquaintances that I now have across many countries and continents surpass anything I have encountered before.

There are times when the hours are long because of an approaching deadline, the brain is tired, the eyes ache, the words won't flow, the PC crashes and the stress levels are high - but the stimulation and satisfaction of having written evidence of my labours and the diversity of the work are more than adequate compensation. No, I have no regrets. I am glad I discovered medical writing!

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The Medical Writer and the Clinical Development Team

by Graham Diggory

Although it is really not an issue that medical writers have skills and expertise that facilitates preparation of critical clinical submission documents on behalf of drug development project teams, the role of the writer is not uniform across the pharmaceutical industry or the clinical support organisations. This article offers a personal view from within a rapidly changing environment by describing a model for effective working relationships between medical writers and other key skills group members in clinical development for producing high-quality submission documents to demanding timelines. As part of this model a cross-functional, multidisciplinary team or Clinical Development Team (CDT) is now increasingly pivotal in managing the complexity of clinical development by bringing together the skills needed to execute the clinical plan for the development, registration and life-cycle management of a drug. For the medical writer, the essential component of this process is the production of the clinical submission documents. The writer must ensure that these documents communicate the required efficacy and safety claims in a clear, logical and scientifically valid manner. So how does a CDT operate and how can the medical writer work most effectively within such a framework?

What is a Clinical Development Team?

Within AstraZeneca the CDT is defined as: "one efficient, effective cross-matrix team capable of managing the production of all clinical strategic and operational deliverables associated with the development of a pharmaceutical product from pre-Candidate Drug nomination through to the end of Life Cycle management". In order to provide this cross-matrix approach, the CDT is composed of key skills groups required for the clinical development process and typically represents core project functions such as biostatistics, regulatory affairs, pharmacovigilance, medical communications, medical expertise as well as project management. The composition of the CDT is variable and evolves with the specific phase of development and/or the complexity of the clinical programme. For example, during early clinical development it would be appropriate for a clinical pharmacology expert to lead the CDT whereas in the later, more complex stages of development the CDT would be led by a dedicated programme leader to provide overall project direction for the CDT. The AstraZeneca CDT definition refers to "...managing the production of all clinical strategic and operational deliverables..." This includes the documentation generated by the development process that ultimately forms the clinical sections of the drug licensing application or dossier. Although this objective is the collective responsibility of the CDT the medical writer has specific expertise and is best placed to support the team in achieving this goal.

The medical writer's role within the CDT

In today's cost-constrained environment, the primary objective of a successful clinical development programme should be to ensure "right first-time" regulatory submissions.

MW and the Clinical Development Team

This places much greater emphasis on the medical writer whose involvement in the development process encompasses a wide range of clinical documents including study protocols and clinical study reports, to name just a few, through to the extensive clinical sections of the submission packages for drug registration specified by the major regulatory authorities. One significant role of the medical writer is to provide the CDT with expert advice during the planning of the clinical development project ensuring the process and timings for delivering the clinical regulatory documentation form part of a cohesive and workable plan. Although the clinical development plan is a team deliverable, the writer can serve to co-ordinate the process to achieve consensus within the team and ensure the plan is focussed on important attributes of the new product's profile that represent the key components of the proposed label. This ensures that the data from the clinical programme translate into regulatory submission documents that deliver optimal labelling, by justifying and supporting the key elements of the registration strategy. In this manner, the medical communicator helps the team focus on key issues and elements critical to the success of the project.

High quality clinical study reports form the basis for successful submissions since they provide credible building blocks of clinical conclusions from which the summary documents can be logically derived. Global standards for the key clinical submission documents (i.e. the Clinical Overview and Clinical Summary within the new common technical dossier (CTD) format) need to be monitored continuously and the components of individual clinical submission dossiers written and reviewed in line with best practice (in-house SOPs, ICH etc). This expertise is provided most effectively by a single skills set and those of the medical writer are uniquely suited to provide relevant leadership to their clinical development teams.

The reader will appreciate that this is a wider and strategic role for today's medical writer requiring good project management skills in addition to those traditionally required for writing clinical documents. It is therefore a challenge for the medical communicator to develop his or her skills continuously. AstraZeneca provides an example of where the medical writing role has evolved into that of the medical communications scientist. This reflects the medical communicator's strategic input and submission leadership skills to the CDT by providing the optimal clinical documentation package.

Levels of medical writing expertise

Different levels of expertise will be required within a project or programme depending on its complexity. For a smaller project a single writer might undertake both the roles of study team and project writer. A more complex project may require both a project medical writer together with several study team writers. The study team writers would be essential members of their respective study teams whereas the project writer would deliver strategic input to the CDT and guarantee consistency of content and messages within and across the key clinical documents. Preparation of the summary documents requires contributions to be obtained from many functions within the clinical team and requires excellent project management abilities. The project medical writer becomes accountable, alongside the CDT leader, for those activities that will ensure consistent review of all clinical submission documents. The advantage of this approach today is that the writer can operate as an integral member of the CDT and this facilitates rapid cross-functional resolution of emergent issues - as is often necessary.

Responsibilities and accountabilities

Study team managers are responsible for delivering final clinical study reports to agreed timelines. They are also closely involved in the review process because they have a comprehensive knowledge of both the study design and conduct. However, the responsibility for authoring the final clinical study report remains with the medical writer to co-ordinate expert contributions from the relevant skills groups (including biostatistics, pharmacokinetics, drug safety and clinical review etc). In this manner, the study medical writer provides specific final clinical study report assembly expertise and ensures the quality and consistency of the final document. The final report is the definitive output of a clinical study as well as a major component of the clinical sections of the regulatory submission. It is still the responsibility of the regulatory affairs function to liaise with the licensing bodies (EMEA, FDA) and ensure the submission is made in line with current requirements.

By working to clearly defined accountabilities and responsibilities, within the umbrella of the CDT, the project medical writer can help eliminate the protracted review cycles and iterative loops that often lead to documentation with a somewhat eclectic nature. The medical communications scientist fully integrated within the CDT brings added value to the production of high-level submission documents by ensuring that there is:

- A consistent message and clear cross-reference between clinical study reports and the clinical overview and clinical summary
- A clear and logical link between the key conclusions of all clinical study reports and the product's labelling claims.

Conclusions

The CDT is a multidisciplinary, cross-functional and co-ordinated team that can deliver the clinical component of a submission dossier with maximum efficiency. The value of this expanded medical writing role within the CDT, and the efficiencies it affords, are becoming increasingly recognised by the pharmaceutical industry. The integration of the medical communicator within the CDT offers both traditional document writing skills together with a more strategic awareness of the importance of communicating clinical data and key messages to the regulatory reviewer as clearly as possible. The pressure to get products approved as quickly as possible is an aspect of today's drug development process which is well recognised. However, high quality (in terms of effective communication of key messages to regulatory authorities) is also essential to ensure rapid approval of the regulatory submission package. Today's medical communicator has a pivotal role to play in this process.

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This article is based on a presentation delivered at a one-day seminar "Medical Writing Today", 20th September 2001, London, organised by Henry Stewart Conferences. The author also wishes to acknowledge the helpful comments of other members of the medical communications science group within AstraZeneca in finalising this article.



Medical Writers as Quality Control

by Adam Jacobs

At the EMWA conference in Montpellier in May 2001, one of the lunchtime sessions was set aside for informal discussions of various topics relevant to medical writing. Our table discussed the role of medical writers in the quality control process in writing, which might otherwise be described as "Medical writers as the last line of defence against the cock-up". Although medical writers can provide a useful quality control function in any project in which they take part, our discussion focused mainly on how medical writers can contribute to quality control in clinical study reports.

In a perfect world, when a medical writer is asked to write a clinical study report, he or she would be given a protocol, which was followed to the letter, and a set of tables and listings which accurately record all the data collected in the study in an easy-to-understand format. Well, we don't live in a perfect world. All of the participants at our table agreed that such a perfect situation is an extremely rare, if not non-existent, creature. Our collective experience allowed us to conclude that the quality of data we are expected to work with varies enormously. It is sometimes very poor, sometimes very good, usually in between, but seldom perfect.

So is this lack of perfection a result of incompetence on the part of data managers and statisticians? Our general feeling was that it is not, and is just an inescapable fact of the complexity of clinical trials. Kew Gardens may be the best botanical gardens in the world, but there were still weeds there last time I visited. Why should we expect to find perfection in clinical data listings? However, we did feel that some data management and statistics departments produced consistently higher quality output than others, and that the imperfections in our data listings could certainly be reduced if all were produced to the same standards as the best.

Our collective experience allowed us to conclude that the quality of data we are expected to work with varies enormously

Nonetheless, some imperfections in clinical data listings are inevitable, and medical writers have a valuable role to play in spotting and correcting them. We felt that the sorts of problems we find when writing up clinical trials can usefully be divided into two categories: those that can be remedied, and those that can't. For example, we might be given a set of data listings that contain no mention of ECG data, even though the protocol told us that ECGs would be recorded. This could be because the statistician forgot to list the data, in which case the omission belongs to the first category, or because the investigator forgot to record the ECGs, in which case it belongs to the second. In each case, medical writers can play a useful part in solving the problem. In this simple example, the problem can easily be solved if the ECG data are available, but other situations occur when the problem is more complicated. For example, we might come across a tabulation of some data which is technically correct,

but hard to understand. Medical writers are well placed to work with the statistician to come up with a less confusing way of presenting the data.

In fact, a theme that cropped up repeatedly in our discussion was that medical writers are uniquely well placed to help ensure that the final study report is as close to perfect as possible. Particularly in phase III studies, the personnel involved in running the study will have been living and breathing their study for a long time, whereas a medical writer often comes to the study late in the process, and can offer a fresh perspective. This may mean that deficiencies in the way data are reported are glaringly obvious to the medical writer, whereas someone who has worked on the study may have got so used to something being done improperly that they no longer notice it. A medical writer also needs to become familiar with the whole of the study, and therefore has a good overview. It is entirely possible that a problem with a blood sampling schedule will be hard for either the clinical staff or the pharmacokineticist to detect, but will become obvious to the medical writer when he or she tries to put all the data together.

Our experiences of the ways different companies expected medical writers to provide this quality control function varied considerably. Our table had freelancers and employees of CROs and pharmaceutical companies, so we had experience of a range of different ways of doing things. However, there didn't seem to be many consistent differences between the different types of employment in the way things were done: the main variation seemed to be simply because different companies have different ways of working. One of the things that varied was the stage at which medical writers become involved in writing up a trial. Some writers would only get to find out about the trial once final tables and listings had been produced, whereas others would be involved right from the stage of drafting the protocol. We generally felt that it was easier to help the earlier we are involved. Some of us, even if we had come to a study after it had been completed, were at least asked to comment on draft tabulations, which is often a stage where medical writers can spot some glaring errors before they become harder to correct. Another variable was the recognition given to the quality control function of medical writers. In some companies, it was very much an optional extra, but in others it was considered an integral part of the job. An example of this was where the medical writer was asked to comment on draft tabulations, which were not considered complete until the medical writer's opinion had been sought. Some medical writers are in the habit of using checklists to make sure that all the various features of a study report are in place, which we thought was probably a good thing and should be more widely adopted.

Of course, when a medical writer finds errors in a study, diplomatic skills can be very important. There may be times when we discover that a whole analysis is flawed, and will have to be completely redone. This is not something that is going to make any statistician's day, so tact and sensitivity are essential. Excessive nit-picking is best avoided: there is usually plenty to do in correcting the things that really matter, without upsetting people by complaining to them about the occasional out-of-place comma.

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**Go For It!
Or Life as the EMWA
Public Relations (PR) Officer**

by Isabelle Thirolle

Friday 12 May 2000. Here I am attending my first EMWA Annual General Meeting, when the question is posed "Who would like to be PR Officer?" Facing an ocean of silence, Barry Drees feels the urge to intervene and, as usual, finds the right words. Indeed reassured, I thought: "Well, why not?" And that was it.

To start with, this position is defined in the Constitution as follows:

1. "The Public Relations (PR) Officer plans the public relations strategy for the organisation in association with members of the Executive Committee (EC).
2. Where appropriate, the PR Officer may liaise with the Education Officer for PR purposes within training organisations (both graduate and undergraduate).
3. The PR Officer is responsible for checking all promotional literature relating to EMWA and informing the EC."

This is one part. The other is that you can make it as exciting and interesting as you want it to be. It is, of course, up to you to grasp opportunities as they come. At my first EC meeting, it was agreed that the one-day EMWA meeting in 2000 would take place in Lille. Being not bad at French and having gone on a few shopping trips to the city, I thought I was playing it fairly safe when I volunteered to put the venue together, all the more so as I was to be chaperoned by the new President. However, I was responsible and I didn't want to mess up on my first assignment. Therefore my adrenaline was running high on a few occasions in the course of the preparations. It was also quite exciting to arrange everything, select a hotel with the relevant facilities and within our price range, choose the menu, and see everything fall into place on the big day.

For those who want to express their creative side, one gets to write material to promote EMWA or to get new members on board. There are still fields to explore here. More needs to be done in contacting companies so that they'll think of EMWA when it comes to advertising for jobs. Medical writing is a fairly new occupation in Europe. True, people have been doing it for a while but this profession hasn't had name recognition until recently and many people working in the pharmaceutical industry still do not know what the job entails. So, you can actively participate in the promotion of your occupation.

In EMWA documents, you often read that "EMWA is an organisation run for and by its members, and we actively encourage and seek out participation from all our members". Well, that's true, EMWA practises what it preaches. And as an EC member, I had the opportunity for my interests to be heard at the highest level, even though I am not an expert in the profession. That is an opportunity that you do not often come across. Personally, I think being PR Officer for EMWA greatly spiced up my life as medical writer.

Isabelle Thirolle
EMWA Public Relations Officer



Hey, it's Only My Opinion

by Diana Klein-Franke

Peer review seems to be a problem for some medical writers. Is it because they have suffered under the process? Have some writers been taking peer review too personally? Do my fellow EMWA members understand the peer-review process? The answer to the first 2 questions is definitely - YES. To the last and most important question of all - the answer is NO.

Peer review is an important and democratic process. The submitted paper is usually sent to two referees who are considered experts in their field. The corresponding author has the right to mention in the covering letter which potential experts should not be chosen due to conflicts of interest. Not only does the editorial office take this letter and request into account, but in addition, on the cover letter addressed to the referee in question, the reviewer is reminded that if there is any conflict of interest regarding the paper it should be returned immediately. In most serious peer-review journals this is certainly taken into account. The previous articles in TWS [1,2] have shown that some EMWA members appear not to understand the complexity and beauty of the peer-review process. If one would follow the general message given in the original article [1], then chaos and disinformation would break out resulting in innumerable cases of plagiarism and slander due to the bombardment of useless information which would be repetitive and inconsistent, resulting in and causing more harm than good.

One has to understand the reasons for the sometimes lengthy review process. Despite what some unsuccessful authors think, politics is rarely the reason. Peer-reviewed journals do not exist to educate, they are there to disseminate new scientific information. Therefore if a paper is not accepted due to insufficient new information, then this is a fair criticism. The paper should be submitted to another kind of journal with a more educational scope and point of view.

Assuming that many members show the same disdain for the peer review process, think about it this way - would it be better to produce a drug, skip the trials and see what the side effects would be like? I don't think so. Peer review is a democratic process, many papers submitted for publication have insignificant new information; are just copies of other people's work (with different authorship) or have misleading facts. Surely it would not be in the interest of mankind to publish a scientific paper on the internet without checking the facts. This would ultimately cause more harm than good and end up misleading people.

But hey, it's only my opinion!

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1. Albert T. The end of medical journals. TWS 2001;10(3): 59-61
2. Mizen L. Vital signs TWS 2001;10(4): 97-98



In the Bookstores... Shocking Exposé or Lesson in Ethics?

by Karen Shashok

John le Carré. The Constant Gardener. London: Hodder & Stoughton, 2001. ISBN 0 340 73337 3 (Hardback), 0 340 73338 1 (Paperback)

Those of you who still look at newspaper literary supplements probably know that this novel has been hailed as a hard-hitting exposé of drug company crime and corruption, and perhaps you felt, as I did, a twinge of vicarious guilt for your role in the creation and dissemination of medical and pharmaceutical literature. Actually, of the 504 pages in the hardback edition, the really gruesome details about twisted clinical trials, data manipulation, conflict of interest and publication bias occupy only six pages. (Go to pages 250, 251, 253, 382, 383 and 385 of the hardcover edition if you're browsing in the bookstore and want the dirt.) So phew, we're off the hook.

Or are we? The entire plot is built around a campaign mounted by a fictitious multinational pharma company to force an inadequately tested product to market despite concerns over unreported side effects, and to remove any (and boy, does le Carré mean *any*) bureaucratic, political and scientific obstacles in its path toward sale and distribution in developed countries. Now that may be hitting pretty close to home for some of us. Can a member of EMWA read *The Constant Gardener* and *not* reach the conclusion that we should all quit the profession and join a non-governmental organisation (NGO)?

The behaviour of the pharma giant described in the novel is so wicked that I find it unrealistic. Still, in his concluding Author's Note, le Carré states, "As my journey through the pharmaceutical jungle progressed, I came to realise that, by comparison with the reality, my story was as tame as a holiday postcard."

If this is true I certainly hope le Carré has been able to report to the appropriate authorities what he found while doing his homework. But then, one of the themes of the story is that the appropriate authorities (including the UK Foreign Office and, by insinuation, the government itself) have, for the most part, conflicts of interest that paralyse any corrective action. In le Carré's world, there is no such thing as an honest, uncorrupted institution. The government, the industry, the NGOs—they've all got problems with corruption, mismanagement and duplicity, just as they all have one or two morally pure individuals whose will to do the right thing overrides their fear of retribution.

The novel is an entertaining read, with great dialogues (especially the lunch date between Justin, the recently bereaved but morally renewed main character, and his sly

In le Carré's world, there is no such thing as an honest, uncorrupted institution. The government, the industry, the NGOs—they've all got problems with corruption, mismanagement and duplicity

Foreign Office boss, “the Pellegrin”), plenty of spy-types chasing the hero all over the world . . . the regular le Carré stuff, I guess. Like just about every so-called novel nowadays, the book reads more like a proposal for a screenplay for a Hollywood film than a self-contained opus meant to be enjoyed as literature. But le Carré does bring up big moral issues that all people everywhere ought to be concerned about. In the end, his main message is that *doing* something about evil is worth the effort. Even if the reward is simply the personal satisfaction of doing what’s right rather than standing by and letting the powers that be have their way. And even though you may well pay a very high personal price.

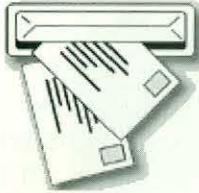
So, a good book, with several interesting issues for EMWA members. Enjoy it, but be prepared to face the ethical dilemmas it may raise in your mind.

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The Nick Thompson Honorary Membership Award

The Nick Thompson Honorary Membership Award is an award presented to members to recognise their outstanding contribution to EMWA. It is not an annual award, but is presented by the Executive Committee when they feel that someone has demonstrated a longstanding commitment and service to the organisation, with enthusiasm and selflessness, much as Nick Thompson had done up to his untimely death.

Anyone can make a recommendation at any time to nominate someone for the award. If you feel there is a suitable candidate to receive the Nick Thompson Honorary Membership Award, send a nomination to say why, in less than 250 words, to the head office. The Executive Committee will consider all nominations, and will award the honorary membership to those candidates that they feel are sufficiently deserving.



Vital Signs: Correspondence from our readers

Dear TWS,

One of the haiku computer responses in *The Lighter Side* of the last issue (TWS 2001; 10 (4): 94) contained the passage, "The Tao that is seen, Is not the true Tao". What exactly is a Tao?

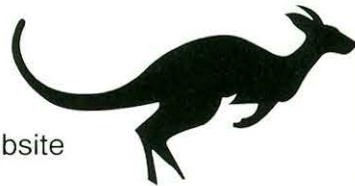
Oh no, I was afraid that we would get asked that. Tao (actually pronounced "Dao") is one of those Eastern philosophical or religious terms which have no simple explanation but can be translated roughly as "right way" or "being one with the universe". I know, I know, this is starting to sound like a Donovan song about Atlantis. My understanding, which is admittedly far from being very complete, is that Tao represents the state one works to attain throughout life (using meditation, contemplation, exercise, etc.) when one's true nature and purpose become apparent, are accepted and lived. In the haiku in the article,

The Tao that is seen, Is not the true Tao, Until you bring fresh toner.

I believe it is being used here to mean the true or essential nature of the document, i.e., what you see is not what you get until you put fresh toner in the printer. In all fairness, however, if you type "Tao" into any one of the common internet search engines, you will find tons of sites, but none of them give simple explanations of what it means. Most seem to suggest that one can only really understand "Tao" through years of study. Any readers who'd like to take a shot at a better or alternative explanation are welcome to write in for publication in the next issue.

NEWS FROM OZ:

New Website Address



Our colleagues down under have a new website address:

www.medicalwriters.org

So next time you're surfing the web, drop by, check 'em out, and see how they do things on the other side of the globe. I think you'll agree that it has a really nice layout and actually has a number of good ideas we might want to copy. Notice, too, the title of their most recent conference, "*Testing the Limits - Challenges for Medical Writers*". Hmm, kind of reminds one of the title of the last issue of TWS. I guess that there is more synergy going on than one would think.

Meetings of Interest

The following list is presented as a service to EMWA members and is not meant to be complete. EMWA does not endorse these meetings in any way. Those having the [EMWA] symbol include presentations from EMWA members. All meetings are conducted in the English language unless otherwise indicated. If you would like to have something listed here to share with other members, please contact Barry Drees (details on back cover).

Date	Meeting/Sponsor	Location
Apr 15-16	Biometrie praxisnah (German) Kendle Munich Stefan-George-Ring 6 D-81904 Munich, Germany Tel: (+49) 8999 3913 160; e-Mail: info.muc@kendle.com	Munich, Germany
Apr 22-23	Tackling the Regulatory Challenges of EU Accession Charlotte Adams, IIR UK 29 Bressenden Place, London, SW1E 5DR, UK Tel: (+44) 20 7915 5052 Cadams@iir-conferences.com	Vienna, Austria
Apr 24	Case Report Form Design Management Forum Ltd. 48 Woodbridge Rd, Guildford, GU1 4RJ UK Tel: (+44) 1483 570099; Fax: (+44) 1483 536424 www.management-forum.co.uk; info@management-forum.co.uk	London, UK
May 24	Mutual Recognition and Centralised Procedures Management Forum Ltd. 48 Woodbridge Rd, Guildford, GU1 4RJ UK Tel: (+44) 1483 570099; Fax: (+44) 1483 536424 www.management-forum.co.uk; info@management-forum.co.uk	London, UK
May 27-28	Successful Pharmaceutical Project Management Management Forum Ltd. 48 Woodbridge Rd, Guildford, GU1 4RJ UK Tel: (+44) 1483 570099; Fax: (+44) 1483 536424 www.management-forum.co.uk; info@management-forum.co.uk	London, UK
May 30	Making Sense of Medical Statistics Management Forum Ltd. 48 Woodbridge Rd, Guildford, GU1 4RJ UK Tel: (+44) 1483 570099; Fax: (+44) 1483 536424 www.management-forum.co.uk; info@management-forum.co.uk	London, UK
Jun 11-12 [EMWA]	Successful Medical Writing FORUM Institut für Management GmbH Postfach 10 50 60 D-69040 Heidelberg, Germany Tel: (+49) 6221 500 500; Fax: (+49) 6221 500 505	Frankfurt, Germany
Jun 25	Integrierte Studienberichte nach ICH (German) Kendle Munich Stefan-George-Ring 6 D-81904 Munich, Germany Tel: (+49) 8999 3913 160; e-Mail: info.muc@kendle.com	Munich, Germany

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