
The Write Stuff

The Journal of the European Medical Writers Association

Education Issue



EMWA European
Medical Writers
Association

Spring 2000

Vol. 9, No. 2



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[INT] - this symbol indicates that the article also has been or will be published at the EMWA internet site:
<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 for address) or another member of the Editorial Board.

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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/fax numbers and e-mail 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 disc or by e-mail as an MS Word file using Arial font (or equivalent), 11-point, and single spacing.
- Published articles generally include a recent photograph of the author (portrait picture, CV-style).

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From the Editor's Desk

by Barry Drees

Greetings fellow members,

Well, another great conference has come and gone and, as usual, there were lots of great workshops, presentations and social events. I know that what I'm about to say is really going to sound like one of those tired clichés of corporate-speak, but EMWA truly has entered a new era. With the establishment of the EMWA Professional Development Programme (EPDP), EMWA really has grown up and achieved maturity. On a personal note, I have to add that it is extremely gratifying to see something which was only a dream when I was President come to fruition so quickly.

Partially to celebrate this new era, but also to give a more individual look to each issue, I've decided (with a little prodding from the new president, Keith Veitch) to put pictures on the cover to give each issue of TWS a distinctive look. Apparently, people complained that when they looked for a specific article they could never tell one issue from the next (and I just know how often many of you are frantically searching your TWS stacks in search of specific articles). As I always state in my Advanced Data Presentation workshop, we are visual animals and we respond best to visual images, so I agreed that it was time to give our baby a new suit.

One of my primary goals in Dublin was to recruit (impress?) some new people onto the editorial board of TWS. Ever since the new format, I have been thinking about creating the role of Deputy Editor, as someone who could help me with editorial decisions and take over the preparation of one issue every year. Not only would this take some of the load off of my shoulders (desirable enough on its own), it would also make the role of Editor-in-Chief a lot less onerous, and thus more attractive to my eventual successor. Of course it would also serve to get someone else involved and familiar with the whole process of putting out TWS should anything happen to the Editor-in-Chief and would be the natural place to prepare someone to take over the function. Thus I am very excited to be able to announce that we have a new deputy editor here at TWS, Judi Proctor. I've worked with Judi here at TWS both in her roles as contributor and Copy Editor and I think she'll do a great job putting together the Winter 2001 issue (and now she can't back out!). I'm sure we're all looking forward to see the first TWS from another perspective.

In addition, inspired and impressed by their spontaneous performance at the banquet, I was able to recruit both Susan Quinn and Beccy Seward onto the TWS team in the roles of Artistic Director (vacated by Julia Forjanic Klapproth who is the new Vice-president) and Copy Editor (vacated by Judi Proctor), respectively. If they show the same initiative and creativity that they displayed at the banquet, TWS will be in very competent and innovative hands.

From the Editor's Desk

During the conference, I was asked two questions which seemed initially unrelated, but eventually I came to think that they are just different aspects of the same issue. The first question was to what did I attribute the fact that EMWA meetings tend to be so worthwhile and enjoyable. Aside from the obvious things like good workshops, fun social events, etc., I think what really makes the annual conferences so good, is that EMWA is a very open organisation that works hard to involve as many members as possible. I know from personal experience that although many people will not volunteer to participate on their own, with a little encouragement they will often surprise everyone, including themselves, and make valuable contributions. Many of the current members of the Executive Committee had to be "pushed" a bit to get involved, but I'm sure that they, and EMWA, are really glad they did.

I was asked by another member about why TWS uses only a single column of text when two parallel columns are supposedly easier to read. There's certainly no denying that most publications use more than one column. However, as any of you who have ever wrestled with desktop publishing will know, the time and effort involved in putting an issue together increase exponentially with the complexity of the layout. This may be no problem for publications with sizeable budgets who can afford to pay people to do it for them, but at the all-volunteer TWS, it would make the already difficult task of editing so distasteful that I doubt we would find people willing to do it for free.

The guiding principle of EMWA could be considered the active promotion of member involvement and participation.

So, how are these two ideas related, you ask?

What connects these two ideas is a concept, which, if I may be so bold, could well be considered the guiding principle of EMWA - member involvement and participation. As I mentioned before, this does not happen by accident. It has to be planned and actively promoted. Like liberty, it requires constant vigilance. By actively encouraging members (new and old) to participate in the organisation, and by keeping organisational processes simple and pragmatic, EMWA stays proactive and dynamic. This is the primary factor making an organisation vibrant, exciting, and worthwhile; rather than the fossilized, clique-ridden club that many become. This is what I strive for both in the design of TWS (keeping it simple with defined processes for each step) and with the editorial board (providing training as well as fresh input). It is also what EMWA as an organisation does with the ever-changing Executive Committee.

Thus the reason EMWA is an organisation that is not only worth the money we pay each year to help run it, but actually is so much fun at the meetings, is that EMWA really **is** made up of its members. EMWA is an organisation we can all be proud of because we are what makes it worthwhile. So whether it is teaching a workshop in your area of expertise, working on the Executive or Professional Development Committees, or sending a contribution to TWS or the EMWA website, find a way to be a part of it!

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Message from the President

by Keith Veitch

Deadlines, deadlines, deadlines - my proposed motto for EMWA. Those insidious dates which seem so far off when you are first presented with them, but then seem to creep up on you unexpectedly. I am sure that time passes exponentially as a deadline approaches. The Dublin conference was not even over when I was being asked for my President's piece to include in TWS. Deadline: two weeks - just the time I was hoping to relax and actually temporarily forget EMWA, perhaps even get around to doing some of the work I am paid for. They had told me that being Vice-president was the hard job, when you are responsible for organising the annual conference, and then you can relax when you take over the role of President. I realised that this was only a partial truth because most of the work for Dublin was done by other people (thanks Kay, thanks Phillipa and Nicky, thanks Julia). That is why I had this nagging doubt that something was going to catch up with me at some stage, and sure enough, here comes the Editor-in-Chief asking for material for TWS!

Well it should be easy, shouldn't it. After all, I just have to recount what we intend doing over the next year to establish EMWA as a major factor in medical writing in the European pharmaceutical industry. And thanks to my predecessor, Geoff Hall, and the rest of the Executive Committee, EMWA is on a roll - membership is increasing, the conference just gets bigger and better (thanks again Kay, thanks again Phillipa and Nicky, thanks again Julia and especially thanks to all the workshop leaders who give freely of their time and expertise), and TWS has become something to be justifiably proud of (thanks Barry). I feel safe in predicting that Montpellier will be better again, the work has already been started by Julia Pearl with our colleagues at Sanofi-Synthelabo.

Before then we hope to see as many of you as possible at the one-day conference in Lille in November - we intend putting on as many workshops as possible so everyone can attend for the courses they want and get their EPDP qualification rolling along. I will not go any further into the details of the EPDP as people better qualified than I am are writing about it extensively elsewhere in this issue, but I am proud to be associated with the Executive Committee at the time that we launch our own education programme for I am sure that this is what will stand as the testimony to the original establishment of EMWA. We have the chance to learn from our experience with AMWA, and not to fall into the pitfalls of their programme, which personal experience suggests has become stagnant. Factors which seem evident to me, that qualification for certification necessitates some proof of understanding of the course after it, rather than before the course will be the most apparent difference. But also, making a fresh start with the best qualified people, those who are practising every

I want to emphasise that EMWA is not some monolithic organisation that is offering you a service for as long as you pay for it

Message from the President

day what they will be preaching, offers an opportunity that shouldn't be missed to make the EPDP the best available source of training for medical writers. As the workshop leaders' experience in the industry evolves with current trends, new legislation and the latest styles, so will their courses, to ensure that they are providing what is needed for current and aspiring medical writers. I hope that you will be passing that message on to your managers to ensure they provide you and your colleagues with the best chance to fully participate.

Passing messages is one of the aims of TWS, not only to you as a member, but also to your hierarchical seniors. This journal is physical proof of the quality and diversity of EMWA which ensures that it merits serious consideration within the industry as a source of information. It is also the window for putting yourself on show if you are a freelancer, and may even be a valuable addition to your CV if you contribute! We intend distributing copies to managers throughout Europe, so if you want to attract their attention to you, send something in.

Finally, I want to emphasise that EMWA is not some monolithic organisation that is offering you a service for as long as you pay for it. Yes, we are offering an increasingly proficient, dare I say classy, organisation for which we must pay, but at its heart EMWA is a group of fellow professionals from the medical writing industry working together to establish their critical role in medical communication. As a member both of that community and EMWA, you have just as much to offer as to gain.

As you will have noticed, this letter contains a great many thank-yous, because that is all I can offer to my fellow committee members who have worked so hard to allow me to send this message to you. Indeed, if you look back to this time last year, the letter from Geoff Hall expressed many of the same sentiments. So now is the time to get involved yourself so that next issue I will be writing a brief thank-you to you for providing so much material to Barry that he has to let me get away with missing another one of the deadlines which appear suddenly around the corner, like this one...

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The EMWA Professional Development Programme

by Virginia Watson

The EMWA Professional Development Programme, to be known as the EPDP, was introduced at the Ninth Annual Meeting in Dublin. An EMWA Professional Development Certificate will be awarded on completion of the programme.

Training will be provided through workshops at the Annual EMWA Meeting and at separate one-day meetings. Each course will consist of a pre-workshop preparation exercise and questionnaire, attendance at the workshop, and post-workshop homework, which should be completed within a defined period after the workshop and returned to the workshop leader. A credit will be awarded on satisfactory completion of all course requirements, including the homework.

To gain an EMWA Professional Development Certificate, candidates will be required to complete eight workshops as follows:

- four workshops from the 'foundation' section
and
- four workshops from the 'option' sections.

To qualify for the **multidisciplinary** certificate, candidates will be required to obtain credits for four workshops from two or more 'option' sections. To qualify for a **specialised** certificate, candidates will be required to obtain credits for four workshops from a single option.

All workshops in the EPDP will be led by an approved leader. At the moment there are 16 approved workshops and a further 6 are being assessed. A full list of approved workshops will be circulated to members after the next EMWA Professional Development Committee (EPDC) meeting.

What does it cost? A single fee (currently £50) to register for the programme plus the individual workshop fees.

How long do I have to complete the programme? Six years after registering for the programme.

I have partly completed the American Medical Writers Association (AMWA) Core Curriculum, what happens to me? Your AMWA credits will be valid for the EPDP; an EMWA Professional Development Certificate will be awarded on completion of eight workshops.

I wish to transfer to the EPDP but do not have a statement of the credits obtained through AMWA? Please contact Lillian Sablack (lillian@amwa.org) to request written confirmation and pass this information to Phillipa Clow or Julia Cooper so that we can update our database.

The EMWA Professional Development Programme

I do not wish to transfer to the EPDP. Can I continue with the AMWA Core Curriculum? Yes, you may continue in the AMWA programme but none of the workshops provided by EMWA will qualify for credit.

The workshops I attended in Dublin required pre-workshop homework. There was no homework to be completed afterwards. Do these qualify for EPDP credit? The programme for the Dublin meeting was planned before the EPDP had been finalised. All approved workshops offered at Dublin qualify for credit. At future meetings, you will find that all newly approved workshops will follow the EPDP format but that during this transition period some of the original workshops will retain their present format.

Can I have both a multidisciplinary and a specialised certificate? Yes. When you have obtained your first certificate, you may register for a second programme. Your credits for the four foundation workshops that you completed for the first certificate will be valid for all subsequent certificates. It is not planned to impose any restrictions on the number of certificates a candidate may obtain.

Will EMWA be providing an advanced course? We hope to develop an advanced course in the future.

If you have any queries concerning the new EMWA Professional Development Programme, please do not hesitate to get in touch with Julia Cooper or any other member of the Professional Development Committee.

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ICH E3 “Structure and Content of Clinical Study Reports” – Template or Guideline?

by Stephen de Looze

And the Lord said unto Moses, Write thou these words: for after the tenor of these words I have made a covenant with thee and with Israel. And he was there with the Lord forty days and forty nights ... And he wrote upon the tables the words of the covenant, the ten commandments. Exodus 34:27,28

Whether the ten commandments represent the world's first written standard operating procedure is certainly a debatable topic, but the biblical account of how they were written makes those of us who have been involved in writing global SOPs, standards, and templates for clinical documentation quite envious. Moses knew that he was subject to an authority on the matter (some would say, *the authority*), and there wasn't a many-tiered international drafting committee to twist and turn every sentence according to a plethora of perspectives on a multitude of issues before the final document was issued.

Moses would have had a much tougher time if he had had to deal with several committees and subcommittees of angels

I first joined the ICH E3 expert working group under the auspices of the European Federation of Pharmaceutical Industries and Associations (EFPIA) in December 1992 and worked on the guideline until its release in 1995. Added together, the work was a lot less than forty days and forty nights, though at times it certainly felt much longer! I will give an overview of the labyrinthine ICH process for those not so familiar with it. An ICH guideline is initially drafted and redrafted by an expert working group, usually located in one of the ICH regions (Europe, Japan or the United States of America), until it is accepted by the ICH steering committee: step 1 of the ICH procedure. During step 1, there will be consultation between industry representatives across the regions. For step 2, the regulatory agencies in each region are additionally consulted, and drafts are circulated for comment: three regions with both industry and agency representatives in each region makes a total of six committees! During this stage, the document will probably be redrafted by the expert working group many times—I recall about a dozen drafts of ICH E3—before step 2 has been concluded. During step 3, the regulatory agencies and other official bodies exchange comments and resolve outstanding issues, possibly leading to yet more redrafting. Step 4 consists of endorsement of the final draft by the ICH steering committee, which recommends the guideline for adoption in the three regions. This is the stage at which, for our purposes, the guideline becomes “official”, though before this is formally the case, the guideline must be incorporated into domestic regulations: this is step 5, the final step.

ICH E3 Template or Guideline?

Lucky Moses, with everything straight from the horse's mouth (if that is an appropriate metaphor), and no redrafting. He would have had a much tougher time if he had had to deal with several committees and subcommittees of archangels and angels. I recall one particularly low point during a meeting of our expert working group when—rather late in the day and dead tired—as we were discussing laboratory safety variables (not a thrilling topic and one always discussed late in the day due to its location in the guideline), we received a fifty-page fax from the American regulatory agency spokesman with detailed comments on the last-but-one draft, which of course we had no option but to consider in full detail. Or another occasion, we arrived at a meeting thinking we were almost finished, only to discover that our redoubtable chairwoman had recently shared a railway carriage between New York and Washington with the aforementioned American agency spokesman, who promptly gave her a lengthy list of yet more suggestions for our next meeting.

During my regular EMWA workshop, "Preparing Clinical Study Reports", I am often asked by participants why the ICH E3 guideline seems vague, incomplete and contradictory, especially on the subject of structure of clinical study reports, one of the very topics it purports to address. Surely, I am asked, a group of experts could have come up with something better than this. For those who have not been involved in international committee work, it is hard to imagine the complexity and political dimension to these discussions. The participants from the six committees do not enter the debate from a neutral standpoint: politics soon erupt around seemingly harmless scientific issues. This usually results in those middle-of-the-road, rather vague, carefully-worded compromise solutions.

I am often asked why the ICH E3 guideline seems vague, incomplete and contradictory

This complexity inherent in the ICH process was enormously increased for ICH E3, because of the nature of the topic itself: clinical study reports are a funnel for all the wealth of issues, data and information gathered during a clinical trial. These

reports draw on a range of disciplines—clinical, pharmacological, statistical and regulatory—which may not speak the same language even within a single pharmaceutical company. From my medical writer's perspective, another unfortunate aspect of ICH E3 was that the various committees were composed largely of individuals who, whilst having much experience of regulatory issues, reviewing reports, quality assurance, etc., were much less experienced in actually applying guidelines to real-life writing assignments.

Those of us on the expert working group representing writing functions began the project with the aim of producing a flexible, user-friendly template. After all, many of us had done the same for our own companies. We knew that writers regularly have to resolve conflicts and integrate contributions across disciplines, and are therefore ideally qualified to produce guidance and templates for writing documents. Moreover, specialist topics such as clinical trial design, choice of control groups, biostatistics, safety reporting, and so on, were already covered, or soon to be covered, by other ICH guidelines. Alas, the progress of the ICH E3 document through the ICH labyrinth was not to be so straightforward. As the drafts were discussed and rediscussed, various experts insisted that ICH E3 must go into these specialist topics in some detail, thereby increasing the scope of the guideline to cover topics such as clinical trial design, data collection, data analysis and statistical issues. Soon, it became apparent that the

guidance was becoming so complex that whole areas such as clinical pharmacology could not be adequately addressed within the timeframe set by the ICH steering committee. The structure of the guideline, initially designed to reflect the structure of a clinical study report, became increasingly modified to accommodate new aspects of the guidance itself.

As a result, many sections and subsections of ICH E3 can never be standard for all clinical study reports. For example, some sections describe several *possible* approaches to data analysis; there is even one section that only describes how to format an appendix. As a corollary, the section numbering also reflects the guideline, not a clinical study report based on the guideline. Several of us on the expert working group expressed our concerns that the structuring and numbering of the guidance would be taken directly and applied to the structuring and numbering of clinical study reports once the guideline was issued. Others thought that it would be *self-evident* that this could not be so. I well remember our chairwoman on several occasions declaring, "It is not a template!". As a compromise, the following statement was formulated and now appears in the "Introduction" to the guideline: "Each report should consider all of the topics described (unless clearly not relevant) although the specific sequence and grouping of topics may be changed if alternatives are more logical for a particular study. [...] The numbering should then be adapted accordingly". Unfortunately, this statement does imply that a run-of-the-mill study report might be able to preserve unchanged the exact structure and numbering of the guideline, though it can easily be shown that this cannot be so (for example, the title page is "chapter 1" in the guideline, but whenever is a title page "chapter 1" in a report?). This notwithstanding, the statement does provide quite unambiguously the possibility for optimising the structure and numbering of any and all clinical study reports.

Many sections and sub-sections of ICH E3 can never be standard for all clinical study reports. For example, some sections describe several possible approaches to data analysis

From the many dozens of comments that I have received as a result of my EMWA workshop, I know that all conscientious writers who try to apply the ICH guidance to the letter encounter major problems with superfluous, repetitious, and poorly organised sections. Can we, they ask me, simply write "not applicable" under superfluous headings, is a cross-reference acceptable instead of repeating information, can all the "non-applicable" sections just be deleted or at least grouped at the end of the report? What about studies that do not really match the guidance—vaccines, quality of life, phase I, phase IV, interim reports, and so on? Their healthy writing instincts are telling them that a document produced by following ICH to the letter may fall short of their own best writing practice. But they are unsure, despite the statement in the "Introduction" of the guideline that I quoted above, whether modification of the ICH E3 structure or numbering would constitute a contravention of the guidance. Even worse, they may have templates from clients who demand that ICH E3 be followed to the letter, as if it were indeed a template. (In a curious role reversal, a contract research organisation recently engaged by my company to write a clinical study report according to our internal guidelines, complained that these "did not comply with ICH E3".)

ICH E3 Template or Guideline?

This rigid interpretation of ICH E3 generally appears to have been produced by individuals who think it is "playing safe" to adhere to the letter of the guideline. I therefore took up the latter issue with regulatory reviewers during various international conferences. Their unanimous opinion is that writers should strive to make clinical study reports as reviewer-friendly as possible, if necessary by adapting the ICH E3 guidance to the study in hand. One European agency reviewer even admitted that potential problems of ICH E3 had possibly been overlooked because during its finalisation, a huge amount of European reviewers' resources were being diverted to establish the European Agency for the Evaluation of Medicinal Products. My advice, therefore, to all writers is: adhere to the spirit of the ICH E3 guidance, but do not treat it as a straitjacket in terms of report structure—follow your writer's instinct!

My advice, therefore, to all writers is: adhere to the spirit of the ICH E3 guidance, but do not treat it as a straitjacket in terms of report structure—follow your writer's instinct!

Well, I am sure that we have not heard the end of this story. I am often asked whether ICH E3 will be revised. Although the need to do so has been recognised by many of those involved in the ICH process, other initiatives, such as the Common Technical Document, now have a higher priority. I expect that for some time to come we will have to live with the ambiguities of ICH E3, and with "expert" interpretations of what the guidance was actually intended to mean. Come to think of it, even after three thousand years it is not so very different with the ten commandments either.

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Good Publication Practice...

Liz Wager, UK Head, International Medical Publications, Glaxo Wellcome
Leni Grossman, Director, Publications, Merck

If you work in or for the pharmaceutical industry you can hardly fail to have noticed the criticism published in major medical journals about publication practices. Editors and academics have criticised companies for selective reporting of clinical trials, duplicate publication and various other misdemeanours [1]. Yet ironically, attempts to raise publication standards by using professional medical writers have also met with displeasure and there seems to be much misunderstanding among journal editors and academics about the role of medical writers. The reaction of David Sharp, deputy editor of the BMJ, to information from a communications agency at the 1999 EMWA conference is a good example of such views [2]. We clearly need to educate journal editors about the importance of medical writers and one initiative is a set of guidelines developed from within the industry to address this problem and related issues.

Where did the idea come from?

Getting clinical trials published requires collaboration between company employees, external investigators and journal editors. The complexities and difficulties of this three-way relationship formed the subject for a retreat sponsored by the Council of Biology Editors in November 1998. Lack of understanding of how and why pharmaceutical companies handle publications as they do emerged as a source of many of the problems. After the meeting, participants from publication and medical writing departments within Astra Zeneca, Glaxo Wellcome, Merck, Eli Lilly and Hoechst Marion Roussel (now Aventis) were inspired to develop common publication guidelines for pharmaceutical companies. The aim was to encourage high standards of publication by pharmaceutical companies, to reduce editors' misunderstandings about the industry, to raise awareness within the companies themselves, and, ultimately, to improve relations with journal editors and investigators. The guidelines are entitled Good Publication Practice (GPP).

Do we need yet more guidelines?

The guidelines are designed to supplement documents such as the ICMJE Uniform Requirements [3] and the CONSORT statement [4]. As you might expect, they cover some similar ground, but they add detail designed specifically to aid those working in or for the industry. The GPP guidelines also break new ground in recognising the important role of professional medical writers.

Role of professional medical writers

The existence of professional medical writers is not acknowledged in journals' instructions to authors or standard texts about writing, yet many companies use them to assist with writing, editing and preparing manuscripts. Although professional writers can raise the quality of manuscripts, ensure that guidelines such as CONSORT are adhered to, increase the chance of acceptance and accelerate publication, many journal editors view them as 'ghost writers', exerting a hidden, shadowy and malign influence[2]. The GPP guidelines therefore provide detailed recommendations on this topic with particular emphasis on the relationship between the writer and the named authors. Some of the recommendations will seem obvious to EMWA members but they have been included because of concerns expressed by editors.

The GPP guidelines state that the named authors must determine the content of the publication and retain responsibility for it. All authors should have access to the statistical reports and tables and should be given adequate time to comment on both early and final drafts of the manuscript. The guidelines emphasise the need for named authors to be closely involved with the development of the paper, from agreeing on an outline before the first draft is prepared to submitting the final version to the journal.

At the original three-way meeting, many journal editors accepted that medical writers could play a legitimate role in publishing results from clinical trials, especially in coordinating publications from large, multicentre studies. However they remained adamant that they did not wish to publish editorials or opinion pieces which had been ghost-written. They felt strongly that an article purporting to represent the views of an opinion leader must originate from the named author, although it would be acceptable for a professional writer or author's editor to assist non-native English speakers to polish an article for publication. These views are therefore reflected in the guidelines.

Commitment to publication

The GPP guidelines state that companies should endeavour to publish the results from all of their clinical trials. Getting papers published takes time and resources and, perhaps understandably, companies have often been unwilling to spend money and time on publications that they fear may damage sales or aid competitors. However, pressure is increasing on companies to take responsibility to endeavour to publish results from all clinical trials, and many now feel that this is an ethical imperative for any research involving patients. This commitment should therefore improve relationships with investigators and opinion leaders. Publications should present results accurately, objectively and in a balanced fashion and should follow the ICMJE Uniform Requirements and CONSORT guidelines.

Relationships with investigators

The GPP guidelines recommend that companies have written agreements with investigators that set out policies about publication and ownership of the data. Companies should take responsibility for preventing misleading or duplicate publications of data subsets from multicentre trials but they must not suppress or veto legitimate publications prepared by investigators.

Authorship

Many editors recognise that the so-called 'Vancouver criteria' for authorship [1] no longer reflect the complex organisation of institutional studies, and some journals therefore list contributors stating who did what. Since journals operate a variety of authorship listing systems, the GPP guidelines recommend that the individual requirements of the selected journal be respected. They go on to state, however, that whatever criteria for authorship are used, they must be applied in the same way to both external investigators and company employees. It seems only fair that scientists, whoever their employer, should be on equal terms when it comes to recognition. This recommendation may result in more company personnel being named on publications and, in the long -term, may perhaps increase awareness of scientists working within industry and appreciation for the calibre of their work. When medical writers are involved, the guidelines recommend that their contribution should be stated in the acknowledgements.

Good Publication Practice

Release of results

Before a paper is published, abstracts, posters or lectures at conferences are useful and well-accepted ways of informing the scientific community about new results and generating discussion about their significance. However, most peer-reviewed journals will not consider papers that have already appeared in, are under consideration by, or have been accepted by, other journals. Similarly, they may impose embargoes preventing media contact such as press releases before full publication. The GPP guidelines recognise these standards and encourage companies to adhere to them.

The guidelines recommend that all publications should include a unique study identifier (e.g. a protocol number) so that abstracts can be linked with full papers, and the relationship between primary papers and secondary publications such as interim analyses or long-term follow-ups is apparent. This is a simple, but important measure to reduce the effects of publication bias on systematic reviews and to increase confidence that companies are not attempting covert duplicate publication.

Where do we go from here?

It took almost a year to agree to the wording and obtain approval from senior management in our five companies. Because the GPP Working Group was self-appointed, we considered it only fair to share our efforts with others before we published the document, and have therefore sent copies to over 50 pharmaceutical companies encouraging them to sign up. So far we have received eight endorsements (from 3M Pharmaceuticals, Astra Zeneca, Aventis, Eli Lilly, Glaxo Wellcome, Merck, Otsuka America and Serono). If you would like to receive a copy of the GPP guidelines, please do get in touch. Once we have a list of endorsing companies we will submit the guidelines, together with the list of signatories, to a major medical journal for publication [5].

After this, we will continue to spread the word about GPP and hope that the guidelines will become as well accepted as GCP. Ultimately, we hope they will serve to raise publication standards for clinical trials and increase respect for the role of professional medical writers working in or for the pharmaceutical industry.

References

- 1 Angell M. Is academic medicine for sale? *New Engl J Med* 2000; 342: 1516-1518.
- 2 Sharp D. A ghostly crew. *Lancet* 1998; 351: 1076 and responses from Wager E and Grossman L. *Lancet* 1998; 351: 1741.*reprinted in *The Write Stuff* 1998; 7, (2 and 3).
- 3 Uniform requirements for manuscripts submitted to biomedical journals and separate statements from the International Committee of Medical Journal Editors. American College of Physicians, Philadelphia 1997.
- 4 Begg C, Cho M, Eastwood S, Horton R, Moher D, Olkin I, et al. Improving the quality of reporting of randomized controlled trials. The CONSORT statement. *JAMA* 1996; 276: 637-639.
- 5 Sharp D. Drug industry code proposed on "ghost" writing. *Lancet* 2000; 355: 1084

Acknowledgement / contact details

The GPP Working Group comprises Liz Wager & Betts Field (Glaxo Wellcome), Leni Grossman (Merck), John Tumas (Astra Zeneca) and Brad Glazer (Takeda). For more information or a copy of the GPP guidelines, please contact Liz Wager (ew33645@glaxowellcome.co.uk, fax (+44-208-966-4117). A longer version of this article will appear in *Clinical Research Focus* (vol. 11, no. 5). We thank Guy Moody for agreeing to the publication of this version.



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Responsibilities

The individual holding this position will manage the process of publishing scientific communications and the production of preclinical reports, summaries, and expert evaluations transmitted to Regulatory Affairs for submission to authorities. To this end the individual will:

- Supervise and perform the review and editing of such communications for logical organization, internal consistency, readability, style, syntax, grammar and punctuation.
- Supervise the process of manuscript preparation and submission to scientific journals.
- Provide training and consultation to authors in English usage and in issues involved in scientific and medical writing.
- Participate in strategic planning of scientific communications and regulatory submissions and contribute to resolution of scientific/drug development issues.
- Participate in the process of information management in regards to scientific literature.
- Participate in the process of document management and standard template implementation to ensure consistency of product information.

Requirements

- Bachelor's degree or higher, professional training or certification in medical/scientific/technical writing. Bioscience background preferred.
- Experience in writing and editing in the life sciences.
- Experience in teaching/advising other professionals.
- Experience as laboratory scientist is highly desirable.
- Excellent verbal and written communication skills in English.
- Good interpersonal and teaching skills.
- Willingness to participate in a team approach.
- Should be Computer literate and familiar with scientific research and the drug development process in general.

Are you interested in this challenging position? Send your resume and a cover letter describing your career objectives to: BAXTER AG, 1220 Vienna, Industriestraße 67, Phone 43-1/20100 DW 2008, Dr. Elisabeth Pullez, e-mail: pulleze@baxter.com; Homepage: www.baxter.com

EMWA Conference 2000: In Dublin's Fair City

by Claire Wilson

As a first-time attendee at an EMWA annual meeting, I was unsure quite what to expect when I arrived in Dublin, and being late due to a fog-delayed flight was not the ideal start. Straight from the airport into my first workshop, the intricacies of pharmacokinetics, however, I was soon appreciating the main purpose of the conference: the opportunity to learn new skills and discover more about specialised subjects in medical writing.

This year, workshops offered at the conference were many (18 in total) and varied, ranging from the specific, such as 'The Patient Information Leaflet' and 'The Study Protocol', to those offering more general skills training, like 'Punctuation' and 'Flawed Word Usage: Taxonomy and Revision'. It really is surprising how much information it is possible to absorb in only two and a half days! With three or four workshops offered every session, there was plenty of choice available, and it was not hard to find something of interest. The hardest thing, in fact, was choosing between workshops in a session; there is at least one workshop that I will have to try and fit in on another occasion.

The venue, the Dublin Hilton, was excellent, particularly in the all-important area of catering, providing huge buffet lunches, and lots of biscuits during the tea breaks! This year's conference was the biggest yet, with about 140 EMWA members attending, a fact that certainly became obvious during the breaks in the workshop programme, when the whole ground floor of the hotel seemed full of medical writers. During the breaks, as well as 'mingling' with other delegates, there was also the opportunity to visit the Clarendon Medical bookstall. This offered titles of interest to a medical writer,

from medical dictionaries to writing style manuals, and was very popular, at least judging by the number of books that left the shelves.



The conference dinner was held on the second evening, at the Old Jamesons whiskey (spelt with an 'e' in Ireland) distillery in central Dublin. After introductory drinks and a tour of the distillery to explain the whiskey production process, whiskey tasting (some of the EMWA whiskey tasters are shown

above) and dinner followed. During dinner, we were entertained by live Irish music, and audience participation was actively encouraged. While the assembled guests' rendition of 'Molly Malone' might not have won any prizes, there was certainly much enthusiastic clapping along to the songs! There was also a display of Irish dancing, which was very impressive.

The social events, however, did not end with the conference dinner. On the last evening of the conference, there was a choice of a Dublin 'literary' pub-crawl, with actors supplying extracts from Irish literature, or a visit to a re-created Georgian house, both followed by dinner at an excellent Dublin restaurant. You definitely need stamina to attend an EMWA conference...

On the last day of the conference, the EMWA Annual General Meeting was held, and was well attended. Keith Veitch was formally elected as President of the Association for 2000-2001, and Julia Forjanic Klapproth was elected Vice-president. The keynote address was given by Dr Patrick Salmon of the Irish Medicines Board and was concerned with what regulators really want to see in submissions. This was followed by the plenary session, based around the theme of communication with the different audiences in the pharmaceutical arena, from regulatory authorities to the general public. It included a brief but entertaining introduction to the world of pharmaceutical advertising, with examples of both print and film advertising campaigns.

The whole conference ran very smoothly, a tribute to the hard work of the organisers; many thanks must go to them for arranging the programme of events and all the behind-the-scenes details. Now that I have experienced my first EMWA conference, I certainly hope to have the opportunity to put the dates for next year in my diary.

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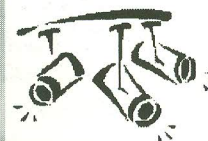
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In the Spotlight...

Frieda Ebes
Freelance Medical Writer



To tap into the diversity of our membership, Julia Forjanic Klapproth is spotlighting individuals from all areas of medical writing. This month she begins with a closer look at a member of 3 years who has never been to an EMWA conference (Gasp!).

Nationality: Dutch

Native language: Dutch

Languages spoken fluently: Dutch, English

How many years as a medical writer: Six

When did you join EMWA, and why?

I joined in 1997 (I think) shortly after I had started my own business (Scientific Writing/Advisor Services) because I thought it wise to invest in anything that would help me get going as a medical writer.

How important (e.g. for one's perception of medical writing, training, personal development, networking) are professional organisations to you (EMWA, AMWA, EASE, DIA, etc)?

The training offered by EMWA has drawn my attention and, although I believe certification in itself does not help, following these courses should help in improving one's quality. But I will never be a native English speaker and all the ats, ins, bys and the who, which and that, with or without comma, will never come naturally whatever courses I take. Networking for me is still a goal.

What qualities do you think a medical writer must/should have?

First of all, the person must have a mind for science, preferably an analytical mind. The person should have the right kind of conscience (tuned to GCP!), that is, the person should scrutinise the data at great length to enable him to say in the end that the report is a truthful and accurate account of the study results. And it would help of course if the person can express himself clearly, is unbiased and has some knowledge of the jargon used in this field.

What keeps you doing medical writing?

Every time when a report is finished I am still pleased with the result, particularly if there was some freedom in the presentation format. I really like struggling with ways of presentation, and with the progress I have been making the last year with all the graphs in Excel, and slowly discovering all the options there are.

Is all your medical writing done in English? Yes.

What is your most/least favourite type of document to work on and why?

Most favourite: a protocol for a Phase I or II study, probably because I really like to be involved in protocol design. Also because a good report starts with a good protocol.

Least favourite: rewording someone else's suggestions, particularly if the person thinks his English is fine.

If you could change one thing in your job as a MW, what would it be?

Having to work with draft data because this usually messes up your report.

Do you consider yourself foremost a writer or a scientist, and why?

A scientist, because I feel it is my responsibility to be a sort of detective, investigating all these data and trying to discover trends.

What is your perception of how others view the role of medical writing, e.g. high/low profile, level of influence on project decisions, etc.?

Low profile, I guess, as reporting is the last thing the sponsor has time for. All he wants is the report, written in the way he wants it. Senior medical writers can surely relieve the burden of the sponsor's clinician, but can they have influence?

Funniest sentence you ever came across?

This was a Dutch sentence. The mistake was made by an Englishman who mistranslated from English to Dutch. He announced that Mr X had made him pregnant, while he meant to say that he was expecting Mr X.

What do you consider your greatest achievement?

Overcoming my fear of PC's at the age of 40 by simply getting started all by myself.

Who are some of your favourite authors and why?

I just love the style and tension of Agatha Christie novels. I like detective stories in general, but I'm not a big reader otherwise.

If you know of an EMWA member who you think would give an interesting interview, particularly one who doesn't regularly come to the annual conferences or contribute to TWS, please make your suggestion to Julia at julia.forjanic-klapproth@aventis.com. Please understand that only a selection of questions with the more interesting or informative answers will actually be published.



The Physical Side: Are You Indisposed as a Medical Writer?

by Diana Klein-Franke

Do you remember from bygone days someone yelling: "Don't hunch your shoulders" or "Stand up straight" or "Don't slouch". That someone was most probably your mother and as - usual - she was right.

Are you curled up on the sofa while reading this issue of TWS? Or sitting at your desk? Are you watching TV? Or on the bus or train travelling to work? Wherever you are at this moment, take a few minutes to read this article and answer the following.

Do you have or suffer from any of the following?

- Tightness, discomfort, stiffness, soreness or a burning sensation in your hands, wrists, fingers, forearms, elbows, back, or shoulders.
- Tingling, coldness or numbness in your hands.
- Clumsiness or loss of coordination in your hands.
- Pain that wakes you up at night.
- The need to massage your hands, wrists, and arms.

If you answered yes to any of the above, you may be indisposed and should be concerned about your physical well-being.

As medical writers, many of us spend at least 5 hours sitting on a chair, at a desk, working with a computer, keyboard and mouse. There may still be a few of us who still use a typewriter for particular forms which cannot be scanned. How about those of us who give lectures and use pointers while explaining the ins and outs of tables and graphs, profit and loss? Not forgetting almost each and every one of us who reach out and pick up a phone.

Many of us (myself included) have a bad habit of tucking the telephone between our shoulder and ear in order to type and talk on the phone simultaneously. This can cause immense pain in the neck, shoulder and arms.

***Pain is your body's
way of telling you
that there is a
problem***

How is the heating or air-conditioning in your office? Are your arms and hands too warm or cold? Cold muscles and tendons are at a much greater risk of strain, as are overheated muscles.

Look at the chair you are using. Is it the correct height? This is imperative for our physical and intellectual well-being as medical writers. As we spend most of the day sitting down, we must ensure that our basic office equipment is optimally positioned. Try the following exercise.

Sit on your chair and touch your computer keyboard. Are your hands placed in a way that enables your fingers to remain diagonally positioned at the keyboard? Where is your keyboard - is it at a lower position than your monitor? It is extremely important for your shoulders, arms and fingers that the keyboard - the most important part of our office equipment - is at the correct height. If your keyboard is on the same table as your monitor see if you can install a lower "shelf". They can be purchased for a reasonable price in furniture shops or at your local "Do-it-yourself" shop.

Aren't we as medical writers engaged in an "artistic" occupation. Just as musicians need to sit and work and maintain a correct posture, so do we in our daily work

Now stand up and measure your inner leg (from the inner knee to the floor - with shoes on, since some shoes with higher heels can have a big effect on this distance). Measure the distance from the seat of your chair to the floor. Is it higher or lower than the measurement taken of your inner leg? It is good if it is higher, as this will reduce muscle strain. If it is lower, you should increase the height of your seat. If you are still not sitting comfortably, you should consider getting a special cushion for your chair.

Now that I have your attention and you are aware of your chair and keyboard, look at your feet. How are they placed on the floor? Are they both on the floor? How are your ankles and toes, any cramps? All you may need is a foot rest. There are quite a lot of different types around. You basically need to try them out. The angle of some of them can even be adjusted.

After proofreading a book about the occupational ailments of musicians, I began to think about medical writers. Aren't we as medical writers engaged in an "artistic" occupation? Just as musicians need to sit and work and maintain a correct posture, so do we in our daily work. We are also using our shoulders and necks, and we should also be aware of ourselves and our posture. I do hope that a future conference will hold a discussion or presentation about the physical side of medical writing. I am sure it will help many of us, and make us all realise what our bodies are telling us.

In order to avoid repetitive strain injury, try to pay attention to your body. Although as writers we're employed more for our brains than our bodies, when you're in pain it is hard to use your brain to the best of its abilities. Pain is your body's way of telling you that there is a problem, but learning what is comfortable or awkward for your body **before** you are in pain may prevent injury and ill-health, and help ensure that your brain can deliver top performance for a long time.

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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. 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
Aug 31-Sep 1	Medicine and the Media, Berzelius Symposium 54 Swedish Society of Medicine P O Box 738, SE-101, 35 Stockholm, Sweden Tel: (+46) 8 440 88 78, Fax (+46) 8 440 88 84 e-mail: annie.melin@svls.se. Internet: www.svls.se/media.html	Stockholm, Sweden
Sept 18-19	Electronic Submissions: Standards, harmonisation and Regulatory Requirements IBC Global Conferences Ltd. Gilmooora House, 57-61 Mortimer St. London, W1N 8JX, UK Fax: (+44) 20 7636 6858; e-mail: cust.serv@informa.com Internet: www.ibt-lifesci.com/ly1185	London, UK
Sept 19	How to Write an Expert Report ROSTRUM PO Box 2467, Romford, Essex, RM7 9GR, UK Tel: (+44) 1708 776 016 or (+44) 1708 735 000	London, UK
Oct 3 [EMWA]	Effective Writing Tim Albert Training Paper Mews Court, Dorking, Surrey, RH4 9AU, UK Tel: (+44) 1306 877993; Internet: www.timalbert.co.uk	London, UK
Oct 4-5 [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
Oct 5-6	Survival Skills for Medical Writers Drug Information Association P.O. Box 7777-W8405, Philadelphia, PA, USA 19175 Tel: (+1) 610 341 2243, Fax (+1) 610 989 4580 Internet: www.diahome.org	Baltimore, USA
Oct 6 [EMWA]	Writing a Scientific Paper Tim Albert Training Paper Mews Court, Dorking, Surrey, RH4 9AU, UK Tel: (+44) 1306 877993; Internet: www.timalbert.co.uk	London, UK
Oct 25-27	Successful Medical Writing Management Forum Ltd., 48 Woodbridge Rd, Guildford, Surrey, GU1 4RJ, UK Tel: (+44) 1483 570 099	London, UK

Coming Next Issue . . . (Summer 2000)

Non-native English Speakers as Medical Writers

Regulatory Questions and Answers: the Investigator's Brochure

Douglas Fiebig

As the first offering in our new series, we look at the seemingly irreconcilable goals of making an Investigator's Brochure attractive enough to get the investigators to read it while still keeping it simple enough for the next update and getting it finished on time.

NEW FEATURE!

Life after Medical Writing: Message from Outer Space

Leen Vanherle

Well, it may be shooting ourselves in the foot, but since TWS strives to provide its members with the information they need, this article inaugurates our new series on life after medical writing. Here we will present pieces by former EMWA members who've moved on to new careers to give us an idea of what waits for us on the "Other Side". We start off with one of EMWA's most dynamic and influential early members, Leen Vanherle, (sometimes referred to as the mother of EMWA) who was instrumental in bringing EMWA into its modern, professional era. Now she's an auditor, of all things, and even more unbelievable, she seems to enjoy it! Find out why in the next issue.

On How to Become a Non-native English Freelance Medical Writer

Annemieke Van Hest

Another in our series by non-native English speakers, here we'll find out about a possibility which might at first glance seem challenging in the extreme – becoming a non-native English freelance medical writer!

In the Bookstores . . . A New Resource for Teachers of Scientific Writing: Turning Data into Manuscripts

Karen Shashok

This issue our intrepid book reviewer tackles a volume intended "to help scientists strengthen their mental powers by preparing their publications in a strictly logical fashion, expressing themselves straightforwardly, and working ethically". If it delivers on that promise, it should be required reading in every pharmaceutical company!

. . . and, the long-awaited return of Liz Wager's column "From the Literature"

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