NEWSLETTER



Chapter of the American Medical Writers Association

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The Editor's Red Pencil

Well, well. So this is what happens when you decide to go to Spain on football team tour instead of attending the EMWA conference in Edinburgh. Still "elected" to be Editor of the Newsletter, no free samples of whisky brought back, and the whole organisation goes independent! Well, from what I can gather everyone had a good time, thanks to a fine job by the organiser - *Julia Spivack*.

One of the new things to arise and which will hopefully be evident by the time this is sent out to you is the investment in professional help to produce this newsletter. This will be handled by the new Association Secretary, Phillipa Clow (just when my kids were asking when they have to fold papers and stuff envelopes again!). This should markedly improve our image in the increasingly professional and competitive marketplace of medical writing, so please avail yourself of the opportunity to get yourself and your business known through our pages...as I have said before, all submissions are welcome (please!). Write in to criticise, complain, laud or praise...but write.

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6th International EMWA Conference, Edinburgh, May 1997

Many thanks to *Julia Spivak* for all the hard work which helped to make the Edinburgh Conference such an enjoyable event.

As Programme Manager for the conference, Julia was responsible for organising a busy and varied social programme.

She brought us an opportunity for new and 'old' EMWA members to get to know each other at a champagne reception - a process continued enthusiastically through the Scottish Banquet and Ceilidh on Wednesday evening. On Thursday some members opted for whisky tasting, while others preferred to make the acquaintance of some other Scottish spirits on a Ghost and Gore tour.

New President

After a year 'in waiting' *Barry Drees* took over the EMWA presidency from *Ben Young* at the Business Meeting in Edinburgh. During his year in office, Ben has skilfully overseen the discussions and negotiations with AMWA that have resulted in EMWA's new status as an independent organisation. Barry and the new committee will carry the work forward to establish EMWA in its new role.

As Vice-President, Barry took responsibility for much of the organisation of the very successful 1997 EMWA Conference in Edinburgh. In a reversal of roles, Ben has been appointed Programme Manager for the 1998 conference, which will be held in Madrid, Spain. Ben says "au revoir" on page 4 and Barry makes his own introduction on page 5.

We wish them both the best of luck in their new respective roles.

Independence Day

EMWA delegates at the Business Meeting held at the Edinburgh Conference unanimously approved affiliate status for EMWA. The key points of this status are:

- EMWA members will be primarily EMWA members and affiliates of AMWA.
- Membership subscriptions will be paid to EMWA.
- EMWA will not be represented on the AMWA Board of Directors.
- AMWA will not send publications to EMWA members, except for those who elect to become paid-up 'dual citizens'.
- AMWA will continue to provide a Core Curriculum and an Advanced Curriculum leading to certificates, on the same terms as before.
- EMWA members will be able to attend the AMWA Annual Conference and enrol in Core and Advanced workshops held there;
- EMWA members attend at membership rates.
- EMWA will continue to hold an Annual Conference at which Core and Advanced Curriculum workshops are offered.

This is an exciting development for EMWA, and there is much work to do to put in place the organisational structure needed to establish an independent Association. The new committee will have a busy year.

Past President's Farewell Address

Its impressive how far EMWA has come in just a very short time. So many things we rightly take for granted today seemed out of reach only a few years ago. I hope it will not be forgotten that it was only a couple of years ago, in 1995, when then-Prez Leen Ashton-Vanherle organised the first EMWA conference to take on even remotely the contours it has today. Leen put together a briskly paced two-day conference in Bruges, with a combination of workshops, general session and business meeting, not to mention a fantastic banquet. It was at that meeting that your humble author and Gerold Wilson volunteered to host the 1996 conference in Berlin, and to expand it to three days. And, of course, Barry Drees and Julia Spivack outclassed us all with the 1997 Edinburgh meeting, which set new standards of organisation both within and without the workshop venue.

On another front, I find it hard to imagine now that its only been four years since we were courting AMWA for the privilege of becoming one of its chapters. It was hotly debated, and led to a nasty schism within EMWA. Undeniably, there are substantial advantages in working with AMWA; they are, after all, an experienced organisation that have aided us greatly in workshop standards and conduct, as well as providing us with a certain credibility and global perspective. However, the status of chapter was severely stunting EMWAs growth; as a chapter, we were forking over virtually all of our money to AMWA, on top of being subordinated in terms of policy. Not good. Well, after two solid years of this, just-turned-Prez John Aitken, AMWA charge d'affairs Art Gertel, and then-Prez-Elect yours truly set out to remedy this mess. The rest is history. Now EMWA is off and running as a full-fledged independent organisation, on an equal footing with AMWA, and finally with a decent budget.

The challenges of establishing a new EMWA are being confronted head-on by the impressive slate of officers elected in May of this year. Much has already been accomplished by the new leadership in the few weeks that have passed since gaining our independence. If things keep improving at this rate, I have absolutely no doubt that EMWA will secure its rightful place as the leading organisation for medical writers in Europe.

It's been a pleasure to serve. Adios for now, I'll see you next year in Madrid.

Ben Young Immediate Past President

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From the President's Desk

Greetings fellow EMWA members. As your new president, I'm going to try to communicate with you regularly, keeping you informed about what is going on with EMWA and what your Executive Committee is doing (or trying to do). Hopefully this will inspire more of you to contact me or someone on the Executive Committee with your thoughts, comments and wishes for our organisation, via either a message to our website, or directly using E-mail, telephone numbers or fax.

So, now that the annual conference is history, let me start off by thanking the many people I worked with last year in its planning and organisation. First and foremost, I'd like to thank our conference manager, Julia Spivak who did an incredible job organising the conference and rounding up corporate sponsorship despite some personal adversity that would have defeated many a lesser spirit. I'd also like to thank Phil Cooper, Ben Young and Gerold Wilson who worked tirelessly and provided constant support, advice, and sympathy during the many trials leading up to the conference. I'd also like to thank all of our workshop leaders and speakers, our corporate representative, Shirley Ingham and, of course, all of you who came to the conference and enlivened it with your medical writing experience, enthusiastic participation, and sense of fun. On behalf of all EMWA members, I'd like to give a special thank you to the creator and caretaker of our Internet site, Marion Hodges: EMWA may not yet be a big league organisation in every respect, but thanks to Marion, our website is first class and much better than those of many older and more established organisations.

I take over the presidency of EMWA at a very exciting time. Delegates voted unanimously at Edinburgh to change our status with AMWA from a chapter to an affiliate (see elsewhere for details) which will mean that we will have much greater control over our funds and future direction. We will be considering a number of possible ways to utilise this greater financial independence and would greatly appreciate any input you might have on this subject. I will be exploring this issue in further in a future communication.

I'm thrilled about the new Executive Committee (EC) elected in Edinburgh. Never before in the history of EMWA have we had such a large and enthusiastic committee and I'm really looking forward to working with them (for an introduction and photos see "committee").

For all of you who were at the conference, you know what a good time it was, and for all of you who weren't, let's hope we'll see you in Madrid - olé. The conference once again

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demonstrated that the real strength of EMWA lies in the great people who make it up. Our membership brings a high level of professionalism and a genuine friendliness to these meetings, making them both valuable learning experiences and a lot of fun.

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One of the main things I learned helping to organise the conference this year was that if we want to be a legitimate professional organisation, we desperately need professional staff to organise our membership list, dues payment, and other administrative chores (including, at some point, organising our conferences). Volunteers are great (and we've been very lucky so far) and certainly inexpensive, but unfortunately, it is dangerous to rely on people who have other priorities because of other, full-time jobs. Thus, our first priority as a newly independent organisation is to hire someone to handle. administration. Because we don't yet know how extensive our administrative requirements are actually going to be, the first year will be a test situation in which, rather than hire someone for a set amount of time per week or month, we will assign them certain responsibilities and pay them hourly for whatever work is necessary. By closely monitoring this every month, we will get a rough idea of how much time EMWA needs and at the same time, not have to pay for time we don't need. I mentioned this at the Edinburgh business meeting and that there were two different possibilities: either a freelance member of EMWA who would be willing to do these jobs on a semivolunteer basis (e.g. paid by EMWA but at secretarial rates rather than medical writing rates) or by using a professional secretarial organisation who could provide someone by the hour according to our needs. The EC considered bids by several freelancers and two professional firms and decided to use the services of Phillipa Clow Ltd. because of her experience performing exactly this kind of work for other European organizations (including organizing conferences), her flexibility and enthusiasm for the job, and her reasonable rates. My thanks and appreciation to those EMWA members who offered their services but whom we did not choose and I hope you'll all join me in welcoming Phillipa to EMWA.

I would like to briefly mention some of the other projects your EC is working on and their progress at the time of writing. First of all, although we have been blessed with generous corporate sponsorship for all of our conferences so far, it is not a financially healthy situation if we have to seek new corporate sponsors every year. What we need is some form of program to develop perennial sponsors who will receive a number of benefits varying according to the magnitude of the donation (appearing on the conference brochure, Internet messages/advertisements, access to our mailing list, space to set up a stand at our conferences, etc.). We are currently working on a concept we are provisionally calling "Corporate Friends of EMWA" which we hope to have ready to send out to the pharmaceutical industry around September.

At the Edinburgh conference, almost 50% of our questionnaires were filled out and returned (see p.9-12 for complete results). The results were pretty much as we had anticipated, although there were a few mild surprises and it is always good to see some evidence for what one only suspects from talking to people. The conference is apparently the introduction to EMWA for many members. Almost half of our respondents had been in EMWA less than 2 years and were attending their first EMWA meeting. A somewhat surprising 61% had visited the Internet site and a further 22% said they'd like to but hadn't known about it. Despite fears of limited Internet access in Europe, only 15% said that they didn't have Internet access yet. The vast majority of respondents felt that membership and workshop fees were "just right" (76% in both cases) but only 54% felt that way about the conferences (as opposed to 43% who felt they were too high). Clearly we need to try and keep our conference costs down! Most of our respondents were already enrolled or certified in the AMWA Core Curriculum program (only 15% were not interested) but this dropped to about one half for the advanced program (48% were not interested). This, together with the fact that we will be unable to offer many advanced workshops in the future, suggests that EMWA members who desire this certification will have to obtain it by attending meetings in the USA. Several questionnaire respondents mentioned that they would like to widen the scope of EMWA from the almost exclusively regulatory outlook it now has, to perhaps include people who work with patient information, medical journalists, etc. I agree that this would be a good idea and perhaps the best way to approach it is by developing workshops in these areas together with trying to get more exposure for EMWA with these kinds of writers. I welcome your thoughts on this topic, especially in terms of how best to go about it.

Finally, we are currently discussing the idea of a masters degree program in medical writing with two universities (one in the UK and one in the Netherlands). The way this would probably evolve is that the university would provide courses in basic background subjects (anatomy, pharmacology, statistics, grammar, etc.) and EMWA would provide courses in medical writing subjects (tables and graphs, the EU dossier, document management, etc.). For this to become reality, however, we will need enough workshops and workshop leaders to offer a viable program, which, unfortunately we don't quite have at the moment. I'm optimistic, however, that based on the rate of expansion of our workshop program so far, we will have achieved such a program in the near future.

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Once again, we're your Executive Committee, but we can only fulfil this role if you tell us what you want us to do. So don't be shy, drop us a line and tell us what you think or just to say "Hi"; any contact with our members is appreciated.

Barry Drees, EMWA President

Surf's up at the EMWA World Wide Web site!

Do not forget that everything you are reading in this newsletter is already old hat! Get the latest EMWA info in real-time direct from the EMWA Home page on the World Wide Web. Get your feet wet in the Internet and paddle out your browser to surf on over at http://www.emwa.org Any comments can be send directly to Marion Hodges at marian@molesoft.demon.co.uk.

The latest feature of the site are actual photos of the EMWA committee members - dare you take a look?

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PHARMACEUTICAL INDUSTRY GAINS FROM FREELANCE SUCCESS

How many other pharmaceutical companies have you worked with? How do we compare with other pharmaceutical companies?

I am a freelance medical writer with a small medical writing business and these are two questions I am often asked when I first discuss a contract with a client. The first question is usually asked in the early stages of a telephone conversation, because, understandably, the potential client wants some reassurance that I fully understand the scale and importance of the job at the outset. The second question usually comes later, often while relaxing over lunch after the first meeting when details of company-specific procedures have been discussed and the ink on the contract is still wet. The first question is easy to answer, the second not so easy. In fact, in reply to the second question I usually make vague but positive comments about the many commonalities I have found between organisations and how in my opinion their own organisation would appear to compare favourably with others. I am never comfortable about the way I duck this question, but I remind myself that the ink on the contract is now drying, I have a job to do and that job is to produce some study reports or write some manuscripts within the next few weeks. I always regret that I never seem to have the time (or the contract !) to analyse how their particular approaches differ or to suggest ways in which I think their efficiency could be improved.

When I first reflected on my own lost opportunities to convert client interest into further contracts (if not for myself then for other freelance medical writers), I wondered about other ways in which the freelance medical writer could be giving a fuller service to the client and how the pharmaceutical industry may be failing to make the most of the freelance medical writer. But first I needed to know a little more about the freelance medical writer; specifically, our qualifications, our relevant experience, our professionalism and the strength of our technology.

In May this year, through the EMWA Web Site and at this year's EMWA conference in Edinburgh, I asked European freelance medical writers to answer a few questions. I had responses from 15 freelancers and I can summarise the data in the table below.

I would like to make two main observations from the responses to my questionnaire.

Qualifications:	
(a) I ito colomoo amoduoto	
Higher degree	10
Doctorate	
(b) Medically qualified	
(c) AMWA/EMWA membership	8
(d) Gained or working towards AMWA/EMWA curriculum certificate	C
Experience:	
(a) \geq 3 years (\geq 10 years) as freelance medical writer	12 (4
(b) \geq 3 years within pharmaceutical industry as medical writer	6
	6
(d) Industrial experience other than within pharmaceutical industry	9
(e) Medical writing experience within industry other than pharmaceutical industry	
(f) Post-doctoral research experience	6
$(g) \ge 5$ different clients "	10
(h) ≥ 1 client within world top 10 drug companies ^a	9
(i) Gained repeat business with all or most of clients ^a	13 ^b
the rectoral welling working officers (as some greater cost) by a	
Professionalism:	
(a) Work with formal contract with client:	
(i) 50-100% of time	5
(ii) 100% of time	A start was
(b) Have own formal working practices that include a system for quality control	9
(c) Undergone personal professional training (course/seminar based or self-taught) ^a :	for matime
(i) medical writing	. 11
(ii) software systems	
(iii) industry awareness	
(d) Undergone training offered by client ^a	4
(e) Spent 1-10% of own time on training each year ^a	8
(f) Spent 1-10% of gross income on training each year ^a	
Systems/technology:	
a) Had (or acquired) systems/technology that satisfied client requirements ^a	
b) Invest 2-15% of gross annual income in improving systems/technology	
the company, but also to analyse any possible areas to making the start of	
Type of medical writing:	Cond Viel
a) $\geq 50\%$ regulatory	3
b) \geq 50% non-regulatory biomedical material	For an
c) $\leq 10\%$ consulting	4
d) >10% consulting	0
time provide a knowledge many days of the standard and	
over last 3 years	
three remaining freelancers in husiness < 1 year	
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First, the population of freelance medical writers who took part were generally well qualified (several had higher degrees and post-doctoral research experience and had gained AMWA or EMWA credits); had extensive medical writing experience (some with more than 10 years as freelancers); worked within a framework of professionalism; and had technology and systems that satisfied clients. The number of contracts gained with the world's leading pharmaceutical organisations and the extent to which business was repeated with clients are a measure of the freelance medical writer's competence and success.

My second observation was that freelancers were rarely asked by the client to do work other than to produce biomedical documents (regulatory and non-regulatory). Freelance medical writers are clearly capable of giving a broader service to the client and I suggest some important ways in which the freelancer could provide a valuable service are being overlooked. The following are just some ways in which the freelance medical writer could be employed to improve quality and productivity for the pharmaceutical company:

1. For those tasks where the pharmaceutical company is looking for an alternative to the medical writing service offered (at much greater cost) by a medical communications agency (e.g. contract research organisation). So often the freelance medical writer is at least as qualified and experienced as the medical writer assigned to the task by an agency and operates with technology and systems that match the expectations of the client. However, for some medical writing tasks the pharmaceutical company may still feel the need for the infrastructure of a large organisation and want the comfort that brings in preference to the services of individual freelancers. In such cases, a pharmaceutical company who has already experienced the advantages of working with a freelance medical writer would be in a stronger position for negotiating with an agency to ensure any apparent additional benefit becomes a reality.

2. For an independent assessment of the contribution made by a medical communications agency. The freelance medical writer would have the objectivity not only to quantify the benefits of the relationship between the pharmaceutical company and the agency, but also to analyse any possible areas for concern should they arise.

3. For an independent review of the pharmaceutical company's internal medical writing processes. This would be especially useful for the procedures involved in creating study reports, as here there may be important differences between organisations. A freelancer with current experience of writing study reports for different organisations would be in a position to analyse the advantages and disadvantages of different methods and be able to advise the client on ways of improving their efficiency.

4. For an independent professional medical writing review of biomedical material produced internally. If the freelance medical writer is contracted to review the material simultaneously with those in-house reviewers routinely given the task, there is no additional time added in to the review process and the pharmaceutical company benefits from an independent medical writing viewpoint.

5. For short-term specialist professional help at short notice. A pharmaceutical company that fosters a good working relationship with a freelance medical writer could find that a freelancer is able to respond at short notice to their need for a medical writer. For example, a freelancer may be able to help when a member of the internal medical writing staff is on-leave or off-sick, or when a medical writing group needs to free-up individual medical writers for other projects. Although the freelance medical writer would not necessarily be free to work entirely from the client's offices, the trust that would have built up in a good relationship would give the client confidence that the full use of modern communication methods may be all that is needed to ensure a job will be well done.

Pharmaceutical companies tend to turn to freelance medical writers only at a time of crisis to help cope with a peak of work that cannot be handled easily by their own resources. Although there may not be enough freelance medical writers to go round (given only 15 responded to my questionnaire), I suggest that in light of the growing demand for experienced medical writers we look again at the existing relationship between the freelance medical writer and the pharmaceutical company such that more profitable use is made of the experience and competence the freelance medical writer offers. Currently, pharmaceutical companies (and contract research organisations) find no difficulty recruiting inexperienced medical writers, but there is a serious shortage of experienced medical writers to fill the present explosion of these vacancies. One way to meet the need for medical writers with experience is to use freelancers.

As with any successful working relationship, trust between the client and the freelancer is essential. In this respect I found the following most reassuring. One of my clients (a pharmaceutical company ranked within the world's top five) arranged a series of meetings in the US for all the medical writers working on one of their key regulatory submissions. All five of the medical writers (three from two European countries, two from the US) assigned to the project were freelancers; no permanent member of staff took part in those meetings. This client had sufficient trust that freelance medical writers could do the job.

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