
The Newsletter from the European Medical Writers Association
Chapter of the American Medical Writers Association

Winter, 1994

EMWA Fourth Annual Meeting 9-10th March 1995, Bruges

The fourth annual EMWA meeting will be held in Bruges and you will find details enclosed with this newsletter. The annual meeting, while not yet on the scale of the AMWA jamborees described by several members in this issue of the journal, is still an event not to be missed, so persuade your bosses, start massaging your budgets, or, if you are a freelancer start setting aside valuable time and pennies, to make sure you get there! The deadline for registration is *January 20th 1995*, so please make sure you return your form on time.

Bruges seems an ideal spot for the European Medical Writers gathering, set at the heart of Europe, close to the bureaucratic capital of Brussels it is a fascinating place to explore with its winding canals, cobbled streets and fantastic architecture. As we will be in bilingual Belgium we can even argue about the correct spelling. The annual meeting offers an opportunity to meet old friends and make new ones. I always enjoy the chance to exchange views and experiences with people who work in different countries and different companies. Brenda Mullinger's letter in this issue also reminds us of how important this kind of contact can be for the freelance writer who may otherwise feel isolated.

The first day of the meeting offers a range of AMWA accredited workshops. They range from correct punctuation to project management, so there is bound to be something for everybody. On the Friday, our speakers also cover a wide range of topics from European regulatory affairs to medical journalism and health economics.

Anyone interested in getting more involved in EMWA as an organization, should try to attend the business meeting on Wednesday, 8th March -- we always need more volunteers! Anyone considering a place on the committee as one of the EMWA officers, should make sure they read the note about elections on page 3 and get themselves nominated. The deadline for nominations is *December 30th*, so please start thinking about this.

I hope you enjoy this issue of the journal, my thanks to Leen who persuaded all the members attending the AMWA meeting to contribute articles, and who has been busy with the Bruges meeting and arrangements for next year. There's just space to wish you all a very Happy Christmas and successful New Year and look forward to seeing you in Bruges in March.

Liz Healing
Newsletter Editor

EMWA and AMWA, species convergence or divergence?

One of the main reasons I went to the AMWA meeting in Phoenix was to represent the European Chapter of AMWA and to voice the pro- and anti-feelings of members living in Europe. I mostly found the committee members very willing to listen and enthusiastic towards their goal: to provide writers from all streams of life with feedback, tuition and encouragement. The good intentions are indeed there and the AMWA Board of Directors realizes very well that the addition of the European Chapter has changed the perspectives of the organisation. There is a sudden dawning that there is not just Europe out there; what about Japan, Russia, Asia, Africa, Australia.....? Expansion of the organisation therefore poses problems of coordination and responsibility which I think the European members have already experienced. I think EMWA can therefore play a catalysing role in the future process of the Medical Writers Association. Two solutions present themselves for the moment: 1) People in Europe remain disgruntled over the lack of support from America and the singular frame of mind of the organisation and go their own way, setting up a new, parallel organisation with a higher focus on European problems, or 2) EMWA continues its effort towards making the organisation grow into a more global, INTERNATIONAL movement with a head office (already with years of experience) in America. I personally favour the second solution. As the membership of the organisation grows internationally, more staff in the central office could be made available to coordinate regional conferences and workshops. That way, a pool of expertise from different countries can be built up

and international conferences, organized every so many years, can bring together all that knowledge from around the globe. In the present climate of globalisation, I feel that writers should not lag behind and remain on our little islands of "we know it better" and "let them come to us". The efforts should be individual, but all headed in the same direction so that the result is harmonious.

With this in mind, I would like to stress again that your impact as AMWA/EMWA member is important and I invite anybody who wants to voice their opinion to come to the business meeting on March 8, 1995 and to help shape our future.

Leen Ashton-Vanherle
EMWA President

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Election of the EMWA Executive Committee

Due to the ever-increasing size of EMWA Leen Ashton-Vanherle and I (John Aitken) would like to break with previous practice and invite members to nominate candidates for the following positions on the Executive Committee, which will become vacant at the meeting in Bruges in March, 1995:

- Vice-President
- Membership Secretary
- Treasurer

In the past, these positions have been filled without elections by enthusiastic volunteers; however, we know that many of our members would like to become more involved in EMWA but don't feel that they get the opportunity. Well, here's your chance!

Vice-President: 1995 - 1996

Current holder: John Aitken

The main functions of the Vice-President are to support and succeed the President. There are no clearly defined functions for the Vice-President at present, but this is something to rectify next year.

Membership Secretary: 1995 - 1997

Current holder: Remy Brossel

The Membership Secretary is responsible for the upkeep of the database containing members' names and addresses and to provide labels and lists when required. Candidates for this position must have an IBM-compatible PC and a printer which can print labels.

Treasurer: 1995 - 1997

Current holder: Philip Cooper

The Treasurer handles EMWA's financial affairs, which mainly consist of subscriptions and the costs of the Annual Meeting.

Workshop Accreditation Secretary: 1995 - 1997

New Position

The Workshop Accreditation Secretary will be responsible for supervising the accreditation of new workshops for the Annual Meeting. At the 1995 meeting there will be four workshops which can count towards accreditation.

We will also need a **Program Manager** for 1995 - 1996, to assist the President in organizing the 1996 Annual Meeting. The location of this meeting has not yet been confirmed; however, the current favourite is Edinburgh.

Anyone who feels they have the time and the enthusiasm necessary to fulfil one of these positions should nominate themselves on the enclosed form as soon as possible. If you would like more details please contact John Aitken or any of the current committee members. All nominations should be sent to John Aitken at the address on the last page of this newsletter.

**THE DEADLINE FOR
NOMINATIONS IS
DECEMBER 31, 1994**

Report from three AMWA workshops

*John Aitken
Hoffmann-La Roche*

1 Building a New Drug Application

Homework The first part of the homework involved identifying sections from selected pages from the Code of Federal Regulations, which was fairly straightforward. The second part required reading the sections on the Integrated Summaries of Efficacy (ISE) and Safety (ISS) then discussing their differences; this exercise was repeated for Case Report Forms and Case Report Tabulations. The final part of the homework was a short discussion on the expertise of medical writer/editors useful in NDA preparation.

Workshop The workshop leader provided background information on the history of US Food and Drug Law, definitions of the terms used by the FDA, key elements of an Investigational New Drug Application and an Investigator's Brochure, and a list of FDA publications. The workshop began with an overview of the drug-development process and the outline of an NDA dossier. The class then split into groups for two exercises: the first contained five examples of tables/text for improvement; the second involved the allocation of 15 clinical studies to different parts of an NDA dossier. The homework was covered only briefly.

This topic required a bit more time than the three hours of the workshop, but served as a brief introduction to the content of an NDA. One drawback was splitting the class into groups to perform different parts of the workshop exercises, because this allowed only those in a particular group to solve a particular problem.

Rating: Average.

2 Project Management

Homework The first part involved planning medical writing activities and resources for a fictitious NDA. The second part required the planning of an extra clinical study requested by the FDA, with two possible scenarios for resubmission.

Workshop The workshop began with a brief introduction to project management theory. Projects can be broken down into small well-defined activities which can be organized graphically into a GANTT chart to give an overview of the timelines and resources required to carry out the entire project and identify the critical path. Participants then carried out exercises to confirm their understanding of this process. The homework was covered only briefly. This was a very well organized, informative and clearly presented workshop.

Rating: Very good.

3 Package Inserts

Homework The homework consisted of identifying the deficiencies in three package inserts based on the Code of US Federal Regulations. This was done using the regulations as a check list. Two of the inserts were then compared and differences highlighted.

Workshop The workshop began with a review of Federal Regulations. The rest was taken up with going through the homework exercises in detail. The main message was that the regulations on package inserts are very clear, and no pharmaceutical company should submit an incomplete package insert if the regulations are carefully followed. The small size of this workshop (held on a Saturday afternoon) enabled much more open discussions than the others.

Rating: Very good.

Postscript of a newcomer to AMWA

Zubair M Kunze
Bayer AG, Germany

As a newcomer to AMWA I did not know what to expect of the Annual Conference, Full marks to AMWA for choosing sunny Arizona as the location and for holding the conference at a resort hotel. The latter facilitated networking and arranging extra-curricular events. The conference was well organized with conference staff always at hand, if only to help me find my way. Also, 'older' members made an obvious effort to welcome newcomers like myself, who were easily identifiable by a green ribbon; in fact I ended up with six sticky hearts on my name badge.

The standard of all three workshops I attended was generally high, with the content of one of them being the only downer. I was disappointed that the Advertising workshop focused exclusively on the US market. However, the leader assured me that, in future, a European perspective would be incorporated. The *Scope of Medical Communications* gave me ample food for thought to establish a medical writing concept for my company, whilst *Project Management* was directly applicable to my medical writing group. Since the pre-conference homework is the best preparation for a workshop, I was surprised that there was no feedback on this. Perhaps the accreditation committee could look at this and the presentation skills of workshop leaders rather than focus only on their expertise.

An irritating factor was the limit on the number of workshops each participant could attend. This was raised during the *New Members Orientations* and the argument put forward by the conference

committee, that the number of workshops is limited because participants can only cope with three was, if anything, feeble. Most European members feel that we invest a disproportionately large amount of time and money to attend the annual AMWA conference and expect good value. I realise that for seasoned campaigners, the workshops take second place to the plenary sessions and general networking but for new members, the workshops are of greater value. I would also like to have seen workshops with a European angle, eg issues arising from the European Medicines Evaluation Agency.

The vast majority of EMWA members are employed in pharmaceutical companies, with far fewer freelance writers than in the USA. Although not immediately relevant to me, I was amazed by the scope of freelance writing in the US and hope that this will develop in Europe. Perhaps EMWA needs to run accredited workshops at their annual meeting which both cater for European needs and introduce such new AMWA ideas. These need not necessarily be led by AMWA/EMWA members. Finally, I expected a more goal orientated network lunch rather than simply exchanging pleasantries.

In summary, I enjoyed my first AMWA conference immensely and returned home full of optimism, but also realise that EMWA has a somewhat different emphasis. AMWA needs to internationalise to retain its European chapter, if it does not want EMWA to evolve as a separate entity. However, if Phoenix was the yardstick for things to come, I look forward to autumn (or fall) 1995 in Baltimore.

You can't always get what you want

Ben Young
Schering AG, Germany

One of the most compelling reasons to join AMWA is the education programme. I know of no other non-commercial institution that offers such a comprehensive body of courses, leading to basic and advanced certification in our otherwise so ill-defined trade. In return, AMWA asks only that its members show a modicum of engagement, cover the expenses, and take the curriculum seriously, eg by completing homework and attending the courses in their entirety. Its a fair deal.

It may be tempting to jump right into the AMWA Advanced Curriculum. Anyone with five years experience may do so; it is not mandatory to complete the Core Curriculum first. However, as I learned at the 1994 conference, the core courses shouldn't be taken too lightly. The first core course I had was *Statistics for Medical Writers and Editors*, chaired by Tom Lang. The homework was a painless guide through types of variable, descriptive statistics, normal distribution, skewness, kurtosis, etc. and eased smoothly into hypothesis testing, probabilities, and, yes 'P'-ing. During the course itself, Tom Lang methodically went through the whole thing in more detail, fielding questions, backing up when necessary, and engaging the group in dialogue. As an indication of the clarity of the presentation, this is one of the few courses I have ever attended following which I can read my own notes. *Conclusion:* don't 'P' in the wind, take this course.

The second core course was *Writing Abstracts*, chaired by Flo Witte and Sherry Chandler Williams. To be honest, I signed up for this course because there was hardly anything else available. Otherwise, I really considered the subject too basic. Predictably, the homework was to revise

two abstracts, and to write another. I smugly completed the assignment within an hour, and sent it in long before the deadline. In the course itself, however, it turned out that most of the participants were no strangers to writing abstracts, the chairwomen had adjusted the course to address a broad range of experience, and I enjoyed it thoroughly. *Conclusion:* This course was a fine refresher, and I hope to take more 'basic' courses in the future.

The advanced course *Macroediting*, chaired by Elliott Churchill was an exercise to sink one's teeth into. The homework was grizzly, and took about 6 hours to complete but the course was well paced, and everyone got involved in the lively, critical discussions. Unfortunately, the other advanced courses I had chosen were fully booked by the time my completed registration materials reached AMWA, and there was a lesson to be learned from this. Time is of the essence in registering for advanced courses. Remember that many more core than advanced courses are offered. Also, advanced courses are limited to about 15 participants, as opposed to 20-30 in the non-credit or core courses. Therefore EMWA members striving for advanced certification should be quick to register, since overseas registrants are already at a disadvantage. I hope to minimize the disadvantage next time by following the advice of more experienced EMWA members, viz:

- 1 *Choose the courses ahead of time.* This is easy if you have this year's programme, as most of the courses will be offered next year.

- 2 *Give not only second, but also third, fourth, etc choices right away in the cover letter.*

- 3 *Secure funding well before the registration material arrives then you can guarantee the reservation with your credit*

card, and fax the registration material to AMWA the day it arrives in your office.

These are my views on just the educational side of the conference. I haven't even touched on the value of meeting colleagues from different environments and backgrounds, of comparing notes and perspectives, and getting a better idea of the market for medical writing and editing in general ... maybe some other time ...

EMWA Job line

MEDICAL WRITERS

ADELPHI COMMUNICATIONS is a medical education agency working for the pharmaceutical industry. We are part of the Adelphi group which employs over 90 people. Our sister companies include Adelphi International Research, a specialist pharmaceutical marketing research organisation, and MAPI Values, a quality of life and health outcomes group.

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Evans Medical Limited at Speke wishes to recruit experienced scientific writers/editors for a period of 12 to 18 months from early 1995 to help in the generation and internal approval of Development and Manufacturing documentation required for submission to the UK Regulatory Authorities. The writers will need to be on-site at Speke (near Runcorn) at least 2 to 3 days a week. Full time preferred.

Candidates should have a scientific background, preferably in biological sciences; experience in the healthcare/pharmaceutical industries; a proven track record in scientific writing/editing, demonstrating the ability to write clearly, concisely and accurately in English; organisational skills; good communication and team-working skills; computer (WP) experience preferably on AppleMac Word and Excel; based in N.W. England. Experience in microbiology, biotechnology, production, development, analytical testing and/or regulatory affairs is particularly relevant.

Write with C.V. to: Dr A. Jackson,
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