
The Write Stuff

The Journal of the European Medical Writers Association

Getting Started



Covidence is a clinical development service organization, formed from the global clinical research, medical writing, pharmacovigilance, data management and biostatistics of Aventis Pharma in Frankfurt. We have over 200 highly skilled and experienced staff members who are working on regional and global projects ranking from phase I to IV studies and global submissions.

Access

to over 3,000 investigator sites and monitoring capacity on 4 continents

Excellence

in oncology
in cardiovascular disorders
in diabetology and endocrine disorders
in musculo-skeletal disease
in dermatology

Evidence

100 international clinical studies in phase II and III in the past 6 years

Confidence

over 20 approved submissions in Europe and in the USA in the past 6 years

Proficiency

in designing, managing and reporting full clinical developments
in data management and statistical analysis
in pharmacovigilance and health outcomes research
in global regulatory submissions

Validity

leading-edge information technology with highest standards of data security and systems validation

Stability

sound financial fundamentals through secure service contracts and world-class investors



Getting Started Vol. 12, No. 2, 2003

The 12th Annual Conference in Lisbon, 14-17 May 2003 37

Nic Evans

EMWA travelled to the land of Port wine for another great meeting featuring all-time EMWA records of 40 workshops and over 170 participants. This year participants came from the 4 corners of the world: Japan, Lithuania, Israel . . . even Texas!

Networking Lunches: 12th Annual Conference in Lisbon 39

Network lunch leaders present summaries and the highlights of discussions ranging from Style Guides through Cross-cultural Communication to The Meaning of Life [INT]

Ethics with Ease 42

Elise Langdon-Neuner

Read about the highlights of the European Association of Science Editors meeting in Bath, UK and find out what EMWA's twin association is up to. I, for one, would like to know more about that journal devoted entirely to bananas.

Writing for a Small Biotechnology Start-up Company 44

Carol Wood

Many of us got into Medical Writing after becoming disillusioned with a career in biotechnology. Now everyone is talking about "all those Biotech companies" and all the writing they need. Here's one member's actual experience behind all the rumours.

Mentoring Medical Writers 47

Adrienne Edwards

Mentoring - that magical word and key to fame and glory in all the career guides and management handbooks. Find out what it is, how it works and what it means for a medical writing group from someone who established one in a CRO in Germany.

From Over the Pond: Better a Galley Slave in Turkey than a Freelance Writer in America 52

Susanna Dodgson

If that title doesn't make you want to check out this lament on the current state of affairs across the pond, then nothing I can say will. Grab an oar!

The Quizzical Conundrum of the Collective Noun 54

Ian Metcalfe

A stack of librarians, an exaggeration of fishermen, but what is a group of medical writers called?

Regular Features

- **From the Editor's Desk** 32
- **Message from the President [INT]** 34
- **News from the EPDC** 50
- **The Lighter Side: "A Writer - ooh, that is exciting"** 56
- **Meetings of Interest** 58

[INT] - this symbol indicates that the article will be published on the EMWA internet site: www.emwa.org

Cover image from the internet.

Journal Insights

The Write Stuff is the official publication of the European Medical Writers Association. It is issued 3 times a year and aims to provide EMWA members with relevant, informative and interesting articles and news addressing issues relating to the broad arena of medical writing. We are open to contributions from anyone whose ideas can complement these aims.

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

Subscriptions

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

- €35 within Europe
- €50 outside Europe

Instructions for Contributors

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

Back Issues

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

Advertising Rates (in euros, €)

Corporate	
• Full page	€1000
• Half page	€500
Private	
Freelance members only	
• Full page	€200
• Half page	€100

Behind the Press, The Editorial Board

Editor-in-Chief
Barry Drees

Deputy Editors
Judi Proctor
Elise Langdon-Neuner

Artistic Director
Hilde Joosen

Linguistic Diversity Editor
Patricia Bünz

Copy Editing
Chris Priestley

Columnists
Adam Jacobs
Karen Shashok,
Alison McIntosh
Diana Epstein,
Susanna Dodgson



From the Editor's Desk: Endings and Beginnings

by Barry Drees

In my 13-year medical writing career, I have been approached by many people with a number of different requests (you'd be surprised). By far the most common, however, are the people telling me that they have heard a little bit about medical writing, they've visited the EMWA website and medical writing seems like a great profession (right on that score, friend), but they would like to know how to get started. The problem seems to be that all the people hiring medical writers want someone with experience, and how are you supposed to get this experience if you can only get hired after you have it?

Well, unfortunately, there is no simple solution to this problem, other than the old chestnut, "Just keep on trying". I realize that this advice is not going to be very inspiring to people in this day and age of soundbites, quick fixes, cosmetic surgery and 30-page summaries of a complete clinical development, but we can't have everything handed to us on a silver plate. If someone told me that there was a profession that was personally rewarding, paid relatively well and for which there was still a healthy job market, which was also easy to get started in, I would think that there was something wrong ("If it sounds too good to be true, then it probably is") and in any case, it probably wouldn't stay that way for long.

Of course, people seem to spend their lives thinking "Now if I could only achieve X, then all my problems would be over" (I know I have at times!), whether X is a job, partner, child, lottery win, tenure, or the Nobel Prize. However, no sooner do we attain one goal than we begin striving for another; the human species seems to have evolved to strive ever onward for something. No sooner do most people achieve their dream than they begin to seek another goal. The famous pioneering British mountain climber, George Mallory once said in answer to a question about why he climbed mountains, "So, if you cannot understand that there is something in man which responds to the challenge of this mountain and goes out to meet it, that the struggle is the struggle of life itself upward and forever upward, then you won't see why we go."

So it is with medical writing as well. We all eventually face potential changes, whether from the need for new challenges, the need to accommodate a family, or having finally gained that all-important experience, we are then faced with the temptation of corporate headhunters looking to fill medical writing positions with experienced writers. Any change, of course, means that something will end and something will begin, and this means that we feel a bit of fondness or nostalgia for what was as well as excitement for what will be. In this issue, we look at various aspects of this cycle, some involving changing what kind of writing we do, how we do it, or changing the structure of the writing team within which we work.

I am particularly pleased to be able to offer the article in this issue on mentoring. As those of you who follow this column (or who've taken my new workshop, *Interpersonal*

From the Editor's Desk

Skills for Medical Writers) will know, I have always been fascinated by the intangibles of medical writing or indeed any team activity. It almost seems a tired cliché about the importance of corporate culture or team ability, but sadly, we all know about this issue more from cases when it was done poorly rather than when it was done well. Although there are no simple solutions to this problem either, I am convinced that a well-planned and executed mentoring system can make a huge difference between a positive atmosphere at the workplace which encourages and supports employees and a negative situation where everyone is contemplating change, whether more or less actively. I would be very interested in hearing from other EMWA members about their experiences, especially about such programmes that have been running for a while.

As most of you will have heard, EMWA is currently facing change, as we are changing our front office. Phillipa Clow has decided that her company could not continue as the front office for EMWA given the way the organisation is growing and developing. Thus we have had to seek a new partner (see Message from the President, page 34). This represents the end of an era that I helped to initiate when I was president way back in 1997, that of EMWA as an independent professional organisation (we had been a chapter of AMWA prior to this), and the start of a new era of EMWA as a first-rate professional and career development organisation, now that the European Professional Development Programme is so well developed. I am grateful to Phillipa Clow and all her associates for all their hard work and charming personalities over the years but also look forward eagerly to working with our new partner.

Barry Drees

Editor-in-chief

barry@trilogywriting.com

Statistical Thinking for Clinical Trials

**20 CME
credits**

PAREXEL.

Presented by
Dr Richard Kay
Vice President

Ann Gibb
Consultant Biostatistician

Biostatistics and Programming
PAREXEL International

Venue
The Lancaster Gate Thistle Hotel
Lancaster Gate, London W2 3NN

2003 Dates
13 - 15 October

*A course specifically designed
for **non-statisticians** in the
Pharmaceutical Industry*

Clinical Trial Personnel

The course is aimed at Medical Advisors, Clinical Research Associates, Senior Clinical Data Managers, Medical Writers, Quality Assurance personnel and other **non-statisticians** working in the Pharmaceutical Industry.

You will understand all the key relevant statistical concepts, be better able to communicate with statisticians and have a clear understanding of statistical methods used in reports.

Course Topics

- Statistical Aspects of Trial Design
- Sampling and Standard Errors
- Confidence Intervals
- Intention-to-treat and Analysis Sets
- Hypothesis Testing and p-Values
- The t-Tests
- Multicentre Trials, ANOVA, Regression and Analysis of Covariance
- The Analysis of Binary, Categorical and Ordinal Data
- Power, Sample Size Calculations
- Clinical and Statistical Significance
- Non Parametric Methods
- Practical Issues in Multiple Testing
- Testing for Equivalence or Non-Inferiority
- Meta Analysis and Large Simple Trials
- Methods for Survival Data Analysis
- Crossover Trials
- ICH Guideline E9 'Statistical Principles for Clinical Trials'

Delegates comments

"Altogether excellent, what I needed and very relevant to my work!"

"Explanations made very clear, lucid, understandable, interesting, stimulating, thought-provoking!"

"Superlative course, well designed, well taught, definitely beneficial and enlightening!"

For further details, contact

Neena Kohli
PAREXEL International
The Quays
101-105 Oxford Road
Uxbridge, Middlesex UB8 1LZ
United Kingdom
Telephone +44(0) 1895 614202
Facsimile +44(0) 1895 614419
Email: biostatistics@parexel.com
www.parexel.com

*Also available on an in-house
basis to help maximise
your training budget*



Message from the President

by Isabelle Thirolle

Yet another annual conference has gone by. This was the largest ever (you must have noticed we say this every year but this is the honest truth!), but it was still small enough to keep the camaraderie, openness and enthusiasm that make the EMWA conferences so special. They are the opportunity to reunite with old friends and colleagues, meet new people, and for little lambs that are all alone in their writing department, they give the chance to find a community to belong to. This is, of course, in addition to working hard on acquiring new skills and keeping up to date with the legislation and current trends (in case some people get the idea that we only go there to have fun).

The diversity of the educational programme, designed by the previous Education Officer, Stephen de Looze, attracted almost 200 people who managed to turn up despite the French strikes that impacted many of us. It was the first EMWA conference for a fifth of the delegates. I would like to thank again all the workshop leaders - we often forget how time-consuming it is to develop a workshop, give a workshop and (for many of them) to correct the pre-and post-workshop assignments. Note that workshop leaders do all this without an honorarium despite their valuable experience and skills. I would like to also thank the speakers who happily gave away some of their time to speak at the Annual General Meeting (AGM) - the speeches on ghostwriting, glossaries and chocolate obviously captivated the audience. Needless to say, the conference would not have run so smoothly without the help of Phillipa and Nicky. We were also fortunate to have the capable assistance of the venue staff and of the Lisbon Consortium, a local agency.

I really hope that other non-native writers will follow in my footsteps.

As always, you will also have seen Barry Drees trying to lure some innocent souls into writing articles for TWS: I believe he has found some very fine talent this year in Lisbon. So, if you are looking for quality training, business associates, fruitful discussions or even climbing partners, EMWA conferences have what you need!

The AGM marked the beginning of my year as President. As many of you know, I am a non-native English speaker. I really hope that other non-native writers will follow in my footsteps. If you are one of them, please come forward - every little thing you do is meaningful. I know that things are often harder for non-native English speakers working in medical communications, some doors will be shut but hey, nobody said that life was easy! It is a fact that the number of non-native English speakers working in medical communications is increasing, so fear not, let yourself be heard, we want to hear from you.

As I am writing these words, EMWA has changed the secretariat, as previously announced. Thanks to Barbara Grossman and Julia Cooper who invested a significant amount of time, in addition to their everyday work, in identifying potential replacements, an appropriate candidate was found. European Association Services (EAS), which has

Message from the President

its office registered in Belgium and has a European branch office in Switzerland, will be taking over the duties of EMWA secretariat. EAS is a member of a network of companies providing professional services to associations and non-profit organisations.

As announced in the last TWS, renewal of membership fees have been increased to keep pace with the rising cost of living and costs involved following the growth of EMWA. However, we have kept the increase as low as possible. I would like to point out as well that in order to ensure the high quality of the workshops given at conferences and so that EMWA delegates can benefit from the best expertise, EMWA, unlike most other associations, reimburses most of the workshop leaders' expenses, if they are not borne by their employers.

The Autumn event in the UK is being organised (see advertisement on the following page). We have decided to experiment and make the brochure available only electronically, rather than as a hard copy. This will be a one-day event so that people can easily pop in and out on the same day. Ground work has also started as well for the 2004 annual conference, to be held in the fabulous city of Budapest, Hungary. More details will be available in the next issue of TWS and on the EMWA website.

Isabelle Thirolle

GlaxoSmithKline Biologicals
rue de l'Institut 89
B-1330 Rixensart, Belgium
isabelle.thirolle@gskbio.com



FOOD FOR THOUGHT

"It is of interest to note that while some dolphins are reported to have learned English -- up to fifty words used in correct context -- no human being has been reported to have learned dolphinese."

Carl Sagan, US astronomer and writer (1934-1996)

**Continuing education
& professional training
for medical communicators**



Fifth Autumn Meeting

21 November 2003

London, United Kingdom

MORNING	
Workshop 1	Essentials of Editing and Proofreading , Editing & Writing Barbara Grossman (Covance) and Marian Hodges (NICE)
Workshop 2	Advanced Word Processing , Foundation Adam Jacobs (Dianthus Medical Limited)
Workshop 3	Using Statistics in Medical Writing , Foundation Barry Drees (Trilogy Writing and Consulting)
AFTERNOON	
Workshop 4	Writing Global Clinical Submission Dossiers Using the Common Technical Document , Pharmaceutical Stephen de Looze (Covidence GmbH)
Workshop 5	The Clinical Study Protocol , Pharmaceutical Virginia Watson (Omnicare)
Workshop 6	Writing a Manuscript for Publication , Not for credit Pamela Johnson (Freelance)

Further information will be available on the EMWA website (www.emwa.org).

Exhibition booths

Exhibition booths will be available - for further details, please contact

Dr. Julia Forjanic Klapproth

Tel: +49 69 750 89687

Fax: +49 69 750 89688

E-mail: julia@trilogywriting.com



The 12th Annual Conference in Lisbon 14-17 May 2003:

Conference Review

by Nic Evans

As a new member of EMWA, I had been counselled by some more experienced conference-goers in what to expect from an EMWA meeting. Alcohol was regularly mentioned, as was Barry Drees, so having managed to successfully avoid all requests for articles throughout the welcome buffet I must have let my guard down. Before I knew it, I was signed up to give my thoughts about the conference, so here they are.

I have to admit that it was a little daunting going to a conference entirely by myself, not knowing any of the other delegates, but the first thing that struck me was how friendly everyone was, and how easy it was to socialise. There was always someone making me feel welcome. In many ways, I feel that there was more to be gained by attending the conference alone, primarily because it encouraged me to interact more fully with the other EMWA members.

The majority of delegates seemed to be staying in the conference venue hotel, which proved to be an excellent location. Although a little way out from the centre of Lisbon, the airport was only a short taxi ride away, and with a station for the underground system just opposite the hotel, getting into the city was incredibly easy. I was also very impressed with the facilities at the hotel, which was well equipped with a gym and swimming pool for the more active types, and a large bar for the rest of us. On the whole, the food at the venue was very good; there was always a wide choice that catered for most tastes, although there was less selection for the vegetarians at our table. The conference rooms were also comfortable, when the thermostats were behaving.

The workshops were everything I was led to expect from an EMWA conference, interesting, relaxed and informative.

ence rooms were also comfortable, when the thermostats were behaving.

The workshops were everything I was led to expect from an EMWA conference, interesting, relaxed and informative. While I was initially disappointed at being limited to 4

accredited workshops, and it was difficult to choose from the broad selection, there was more than enough information to absorb, and homework to do.

As a relatively new medical writer, I was keen to attend workshops that would provide a good background to the field. With that in mind, my first 2 choices were *From Protocol to Study Report - What's in Between?* and *The Clinical Study Protocol*. The first of these courses clearly illustrated the many different aspects of the clinical trial process, and the influence of these components on overall success. Similarly, *The Clinical Study Protocol* emphasised the importance of a good protocol in both running a trial and writing the final Clinical Study Report. I found both courses very useful, although I think that the less experienced medical writers like myself benefited more from these courses than writers with a lot of experience. My other 2 workshops were the 2-part workshop, *Pharmacology for Medical Writers - Parts 1 and 2*. In these workshops we were introduced to the field of pharmacology, illustrated by examples of different medications in several therapeutic areas. While I appreciate the difficulty in scheduling a timetable for

a large number of courses, I do feel that insufficient time was allocated for these workshops, which were otherwise excellent.

A major part of an EMWA conference must be the social events. An event was held almost every evening, and all were well-organised. The welcome buffet was an excellent way to ease people into the conference, and as it was held at the conference venue, late arrivals could also easily take part. The following evening there was a choice of activities: a port tasting, a trip to the oceanarium or a dinner in downtown Lisbon. I chose to go to the port tasting, which was held at the Institute of Port in the city centre. Although the venue was impressive, I found the port tasting itself a little disappointing. I was expecting an event similar to a wine tasting, where the port would be described as it was tasted, but instead we were seated in small groups and the port expert was to talk to each table in turn. We were given 2 glasses of port, one white and one ruby, but after about an hour, and having finished both glasses, the expert seemed no closer to our table than when we had first arrived. Nevertheless, we were lucky enough to have an experienced port drinker in our party, who regaled us with the history of port (according to Geoff Hall). The evening was still a success, and I am reliably informed that the other events held that evening were also thoroughly enjoyed. The final event that should be mentioned is the conference banquet, which offered the chance to walk around the Botanic Garden of Ajuda and provided excellent food.

Participants were also treated to the keynote address and 2 plenary sessions during the general meeting. Anne Hudson Jones of the Institute for the Medical Humanities of the University of Texas (and EMWA workshop leader: *Literature and Medicine*) gave the keynote address in which she discussed the always controversial topic of ghostwriting in the medical literature, which has also been covered in a number of past issues of TWS (TWS 1998;7(2):9 and 1998;7(3):7-8). Since it seems that certain elements of the medical profession are still deeply suspicious of the ethics of ghostwriting in the medical research literature, we medical writers need to increase our efforts in educating them as to what we do and do not do. Rute Costa, the current president of the European Association for Terminology, introduced the audience to the setting up of glossaries. Following an explanation about the process, she took some examples from a project she is currently working on: a multilingual glossary on mastology. One of the main messages was that setting up such databases is quite a lengthy process which is easy to underestimate. Finally, Suzann Johnson of Johnson & Johnson Health Care Systems gave a lively and fascinating presentation entitled, "From Taste Buds to Tantalizing Tales: Writing About Nutrition", which lived up to its enticing title and won over the audience with a distribution of chocolate samples as a grand finale to illustrate the message.

To sum up, my first EMWA conference provided valuable training and advice in a relaxed and friendly atmosphere, and I would whole-heartedly recommend that fellow members, new and old, attend next year's event. You won't be disappointed!

Nic Evans would like to thank Barry Drees and Isabelle Thirolle for helpful discussions concerning the parts of the conference which she missed.

Nic Evans

Medpharma MW Ltd, Units 3 and 4
Manor Business Park
Finstock, OXON, OX7 3DG UK
Tel: +44 (0) 1993 869 302
Fax: +44 (0) 1993 868 844

12th Annual Conference in Lisbon: Networking Lunches

The Common Technical Document

On average, since the implementation of the new format, the writers at the table had been involved in 3 CTDs, including some already completed and some currently being written. A common practice with respect to keeping the tables in the appendices of the summaries as short as possible was to select a key set, and otherwise to refer to tables in the CSRs. In one case, a company had created a further appendix for a more complete set of tables to those in the appendices of the summaries. This "appendix to the appendix" was placed in Module 5.

Some companies have submitted CTDs without inclusion of an additional ISS (i.e. in addition to the CTD Safety Summary), with the blessing of the FDA. Other companies have been given the message from the FDA that the ISS is definitely required. In the opinion of the group at the table, it was considered likely that this may be the result of how the regulatory department of a company approaches the FDA when confirming the need for an ISS.

In general, it seemed most companies were not adequately prepared to begin writing CTDs, and are still in the process of developing their templates, processes, etc.

Style Guides

In Europe, style guides are mostly "in-house" style guides whereas in the US the AMA Manual of Style is widely used and accepted. One exception to this is that for publications, each journal's "Instructions for Authors" need to be followed. In-house style guides can be created either from scratch or from existing style guides, e.g. CBE manual, AMA Manual of Style.

The following disadvantages of in-house style guides were identified:

- They are not widely accepted and may need to be defended.
- They need to be updated (which is a time-consuming activity).
- CROs and freelancers need to adapt to each different customer's needs.

A counterpart to the AMA Manual of Style for Europe might overcome these disadvantages. It was suggested that the WHO style guide could be followed, but it is not yet widely known. An alternative approach might be to create a European style guide based on the AMA Manual of Style and different in-house style guides (whether these could be made available to a broad audience depends, however, on each company's policy).

Overall, the group felt that there is a need for a generally accepted European style guide. Ideally, such a European style guide would eventually also be used by scientific journals as a basis for setting up their "Instructions for Authors".

Why did you go Freelance?

The main reasons cited for going freelance were redundancy, wanting a change after many years in a company, wanting to combine work and having a family, and "it just happened". The problems experienced with freelancing included liability (insurance), keeping up-to-date with things happening in the industry, and networking, especially for those starting their business who have not been in a company before. It was agreed that the EMWA conference is a very valuable event for freelancers.

How to Manage Review Cycles Effectively

The conclusions reached by the group were that sequential review is more efficient than parallel review, it is essential to have a meeting after a review, and it is the writer's responsibility to chase reviewers. Advice on how to obtain comments from reviewers included sending a copy to the reviewer's boss (*Better check out that interpersonal skills workshop, Ed.*) or telling reviewers that if no reply is received by the deadline set that this means acceptance of the document as it is (i.e. no comments).

Making the Transition from Research to Medical Writing

Long working hours, poor pay, and unfruitful research projects were the most frequently cited reasons for leaving research. Medical writing is still not a widely known career option and many participants had "stumbled across" medical writing during their job search rather than actively pursuing a medical writing career. Some participants expressed frustration at their lack of input into the practical aspects of clinical research, e.g. developing research strategies or designing study protocols. In general, it was felt that a career in medical writing was associated with shorter and more flexible working hours, greater cooperation between colleagues, less stress, and better pay (*Really, where is that? Ed.*).

Cross-cultural Communication: Enervating or Stimulating?

Most people who participated in the discussion sat down at this table without knowing it was a networking lunch or what the table theme was. However, everyone seemed to become interested in the discussion and to appreciate being there. The different countries represented were Singapore, Belgium, France, Scotland, England, Norway and Sweden. Some differences between cultures were discussed, such as the differing value of non-verbal forms of communication. Participants also reflected on differences between Western and Eastern thinking and how Europeans sometimes have the impression that Americans think Europe is one culture (very far from the truth). Knowing something about which personality types dominate in which countries is important, in addition to having an idea about main cultural differences. The discussion ended by emphasising that we must never forget that we are always dealing with individuals, many of whom are multicultural themselves (especially medical writers).

Interviewing Techniques

Candidates experience a wide range of interviewing techniques and style, which can positively or negatively influence the impression that the company leaves with the candidate. Companies should not forget that today's candidates might be tomorrow's

Networking Lunches

clients. Not least, as a matter of routine courtesy (but also of company image), applications should be acknowledged promptly and the candidates should be notified of the outcome of the interview within a reasonable time afterwards. The interview should focus on the interpersonal skills of the candidate. The skill and experience of the interviewer are the best way of ensuring an appropriate assessment. A written test of medical writing skills is also very useful. If it is completed and returned by the candidates before the interview, candidates should be asked questions on the assignment during the interview to help verify that they did the test themselves (this is not foolproof!).

Sharing Experiences on Writing Publications

Three main categories of "publication activities" and an information manager were represented: 2 medical writers occasionally involved in manuscript/marketing writing, one medical writer involved in communication writing, one clinical information manager, 2 medical writers dedicated to publications (either R&D or clinical), and 2 freelancers (one writing manuscripts only; one writing manuscripts occasionally). The main topics discussed included publication writing vs. publication strategy, contacts with journals, writing software (e.g. manuscript template), and the ethical aspects of publications.

The Meaning of Life for Medical Writers

Participants at this table (particularly the leader) were somewhat surprised to discover that, apart from the topic leader, everyone else at the table was female. This prompted one participant to cynically observe that "men don't care about the meaning of life". It was generally agreed, however, that although the meaning of life is a highly personal and individual concept, striving towards some kind of goal, no matter what kind, tends to make life more meaningful. The participants felt that medical writing had basically supported a meaningful life, unlike some careers pursued prior to medical writing by the participants, which had actively hindered the pursuit of meaning.

Quality and Performance Measures for Medical Writers

This table had an invigorating conversation on what constitutes "quality" and "performance" for documents. Overall, there appeared to be no consensus as to what quality IS because it depends on the type of document (publication vs. clinical protocols) and the reviewer's subjective opinions. Standardisation of guidelines to ensure quality in a document remains a formidable task, and each participant agreed that there was no ONE method of reviewing a document. It was mentioned that a standardisation process could start by circulating one document (regulatory based) by an experienced writer for review and suggestions of quality.

Ethics with EASE

by Elise Langdon-Neuner

The European Association of Science Editors (EASE) held its triennial conference in Bath, hot on the heels of EMWA's conference in Lisbon. My illusions about EMWA and EASE having more in common than just the word "European" were quickly dispelled when I met only one person in Bath who had also been in Lisbon.

The EASE conference, *Editing and Scientific "Truth"*, comprised plenary sessions followed by workshops with the emphasis on floor discussion rather than training. A daily bulletin, *The Bath Soap*, following a tradition of frothy EASE conference publications kept participants abreast of noteworthy events such as an American company's concomitant filming of *Vanity Fair* in the town and frivolities like the number of badges lost during the conference.

Generally, EASE members tend to fit into the journal box and EMWA members into the pharmaceutical company box although each group has its share of odd bods, e.g. free-lance authors' editors. With this polarisation is there anything a scientific editor's conference can offer a medical writer, apart from the novelty of lunching with an editor of a journal devoted entirely to bananas? Certainly there is: ethics touch editors and writers alike.

The keynote address would have been of interest to anyone, if for no other reason than as a potential patient. Iain Chalmers traced the evolution of evidence-based medicine. He is responsible for the James Lind Library whose website won an award from *Scientific American* this year and is well worth a visit (www.jameslindlibrary.org). The library is named after the naval doctor who proved that citrus fruit cured scurvy. He did so by dividing sick sailors into groups receiving identical diets but with different supplements: cider, tonics with sulphuric acid, seawater, nutmeg or citrus fruits. His conclusion was based on the last group's more rapid recovery. Chalmers stressed the need for fair tests and reliable methods to distinguish useful from useless or positively dangerous medical treatments. A paediatrician himself, he cited Dr Spock's advice to millions of mothers to put babies to sleep on their backs, which was responsible for many cot deaths, as an example of the danger of advice based on theory rather than practice.

Michael Farthing, editor-in-chief of *Gut*, gave the plenary session, "Grey areas in publication ethics". Farthing sensed that the spotlight is turning away from authors towards editors. Opportunely the BMJ had published an editorial on "Editorial misconduct" that week (7 June, 2003) proposing a general medical journalists council be established to deal with complaints against editors and develop a code of practice for editors. The ethics issues facing editors are not only the publication of politically incorrect text as detailed in the editorial but also include publication selection bias (positive results, studies in humans), renegeing on acceptance to publish and dealing with pressure from journal owners. The practice of manipulating impact factors by encouraging or coercing

Ethics with Ease

authors into citing other articles in the journal was also viewed with concern. Then there is the question of whether editors should publish in their own journals. The *Lancet* does not allow this but *Gut* does, using an associate editor to process these manuscripts. Farthing had published 7 articles in *Gut* in his 7 years as editor and over 100 in other journals. This, as pointed out in *The Bath Soap*, is an interesting statistic because in 2140 working days it would mean he wrote one article per 20 working days.

The *Authors' misconduct* workshop moderator set the scene by reeling off a variety of ways in which an author can misbehave: plagiarism, piracy from another author's unpublished work, multiple submissions of the same or slightly different articles, and falsification or manipulation of data. It was felt journals should make it clear that the responsibility for knowing ethics lay with authors, ignorance of the "law" being no excuse. Authors received some sympathy, with the blame for such outrages being laid at the door of the pressures of modern career ladders forcing authors to amass articles. The idea emerged of sending questionnaires to journal editors to ascertain the number of misconduct cases encountered. With the extent of misconduct established, it might be possible for EASE to compile some guidelines.

Another workshop I did not attend but which might have interested EMWA members was called *Is rewriting ethical?*. I attended *Author's editors' ethical dilemmas*. Apart from battling with pharmaceutical companies intent on odd culinary combinations of salami publications and cherry picking, what about, for example, the ethical dilemma of an author's editor who ghost-writes a thesis for a non-English native speaking student when one of the purposes of the thesis is to illustrate the student's command of English?

My last workshop, *In the public interest?*, tackled something that had been overlooked, *What is scientific truth?*. The first speaker addressed the fact that scientific truth should be concerned with verification. For example, in mediaeval times it was a scientific truth that the world was flat. The informed consensus now is that it is more spherical. Science must always be open to new data. Although science depends on evidence, our observations are imperfect and therefore, ultimately, only approximations of the truth (CF Gauss). Religious truth is based on faith without evidence. Scientific truth is based on evidence. The second speaker stepped down somewhat from these lofty heights describing the practical slant of the way in which the patent system, intended to protect inventions, has been manipulated by gene technology companies to restrict information passing into the public domain. He suggested a solution along the lines of open source access as used in the software industry, where those entering the system agree to put any improvements they make back into the system. The final speaker sank even further and spoke about publication planning and the marketing rogues who, while intent on maximum exposure of key advertising messages in respected journals, were indifferent to the rules of scientific publication. From the floor, we heard that the industry is doing itself no favours by failing to control its own rogues because not only journals but also the public mistrust studies funded by the industry. An argument exists for members of EMWA and EASE to work closer together to control the rogue elements all round.

Elise Langdon-Neuner

Baxter BioScience, Vienna

Tel: (+43) 1 20100 2067

langdoe@baxter.com



Writing for a Small Biotechnology Start-up Company

by Carol Wood

This is the story of how my career has progressed from that of a research scientist who was totally committed to work at the laboratory bench to that of a "medical writer" whose aim is to work as a freelance scientific and medical writing consultant. It recounts my experience of working for a biotechnology company, which extended over 16 years and encompassed several roles, all of which have included some form of scientific or medical writing.

I joined Delta Biotechnology Limited, currently a wholly owned subsidiary of Aventis Behring GmbH, in July 1986. Delta was "conceived" the previous year following light-hearted discussions in a bar during a conference on genetic manipulation of yeast. By chance, 2 molecular biologists from Oxford University, who happened to be funded by Bass Brewers, got talking to an entrepreneur who had previously worked in the blood fractionation industry. Have similar situations occurred during some of the recent EMWA conferences, I ask? Nine months later the board of Bass plc gave their approval for Delta's research laboratories to be established in Nottingham. We were given 5 years to develop a process for manufacturing recombinant blood proteins using waste brewing yeast.

My first position within Delta was that of Research Scientist reporting to the Head of Process Development. Our initial objective was to develop a method of purifying recombinant human albumin, the major protein in human blood, from yeast fermentation broth. Initially there were 4 people working in the laboratory, including the departmental head, but by the end of the first year the size of the team had quadrupled.

My first taste of scientific writing came about 6 months later when I had to produce a research progress report. These reports were largely required to convince the Bass Board of Directors that the project progress was satisfactory, although potentially they would be required for patent and product licence submissions. Over the following 5 years, the scope of my writing experience was limited to these reports and the occasional outline proposals for scientific publication.

By the end of 1991, the Bass board had realised that developing a pharmaceutical product, particularly one that is biotechnology-derived, was not the fast track route to the enormous profits that they had anticipated, so they sold the company to BOC Healthcare. By this time we had established a pilot-scale production process and completed a programme of preclinical testing. Thus we were ready to embark on phase I clinical studies in human volunteers in order to establish safety and comparability between recombinant and plasma-derived human serum albumin. It was during this phase that my input into the documentation required to support pharmaceutical product development rapidly expanded and became much more varied.

Writing for a Biotech Start-up

Over the next 5 years, although still employed within R&D, I began to recognise that my real talent lay in writing about science rather than in working at the bench. The company had very kindly allowed me time to complete a part-time MSc in Medical Immunology, which required me to submit a written dissertation on a laboratory-based project.

I had become Head of Bioanalysis, which was a small group of research scientists involved in the identification, characterisation and safety evaluation of residual yeast impurities in recombinant human albumin (rHA). Our primary goal was to develop immunoassays and bioassays that could be used to assess the quality and safety of the product and its impurity profile, a regulatory requirement under ICH guideline Q3B. It was this role that first introduced me to the enormous amount of documentation required by the regulatory authorities prior to issuing a pharmaceutical or biological product licence. Our support for the Quality Department was largely the conversion of the descriptions of bioanalytical test methods we had developed and which were described in our R&D laboratory notebooks into standard operating procedures suitable for use by the Quality Control technicians. As the Regulatory Affairs department within BOC Healthcare was unfamiliar with documentation required to support biotech product submissions, R&D was given the responsibility of writing the Chemistry, Manufacturing and Controls section of the IND. In my case this included describing the work we had done to characterise the yeast impurities as well as the product itself.

Another aspect of a medical writer's role that I became very familiar with during my period as Head of Bioanalysis was document review, editing and proofreading. The documents I was required to review included research progress reports written by my staff, manuscripts written by other research scientists, sub-sections of the IND written by other departments, preclinical and clinical study reports written by CROs and the occa-

sional glossy brochure or poster prepared by Business Development. All these documents often required substantive editing, particularly the research progress reports and the sales and marketing information.

Word soon spread throughout the various R&D departments that there was a native English speaker within the company, and my role quickly developed to include review of all types of English-language documentation

One could say my real medical writing experience began in late 1997 following the purchase of Delta by Centeon GmbH,

now Aventis Behring, the previous year. The circumstances that created this opportunity for my career change were that their preclinical and clinical R&D departments were based in Marburg, Germany and that their expertise lay in performing studies associated with the development of plasma derived protein pharmaceuticals. My initial role was that of scientific expert and adviser for the clinical development of Delta's recombinant human albumin. However, word soon spread throughout the various R&D departments within Marburg that there was a native English speaker within the company, and my role quickly developed to include review of all types of English-language documentation. Over the next 2 years, I built up a healthy rapport with my German colleagues and in 1999 I was appointed as Scientific Writer reporting directly to the senior project manager responsible for Delta, who was based in Marburg.

This role was to whet my appetite for freelance medical writing because it was essentially home-based and ended, at least temporarily, what had become a nightmare daily

car journey of over 60 miles between my home near Burton on Trent and my office in the centre of Nottingham. It was replaced by the occasional face-to-face project meeting which I was able to arrange at my convenience, either in Germany or Nottingham. More importantly, this period of my writing career gave me experience of preparing pre-clinical and phase I clinical study reports as well as having the opportunity to prepare the pharmacological and toxicological expert report for our rHA.

However, as the saying goes "all good things come to an end", and following a management decision that Delta should become a stand-alone business unit, I had to seek a position back in Nottingham. This was not before I had attended a 3-day course entitled "*Successful Medical Writing*". Many of you may know that the speakers employed by Management Forum Ltd were none other than Stephen de Looze, Barry Drees and Alistair Reeves. Needless to say, Barry did his public relations bit for EMWA, and before I knew it, I was a member and on my way to the 2001 annual conference in Montpellier. I returned from this conference fired with enthusiasm for medical writing as a career and determined to establish myself as Delta's scientific and medical writing specialist. I could see that there was almost no limit to the areas within the Company where my writing skills could be utilised.

I returned from this conference fired with enthusiasm for medical writing as a career

In August 2001, I returned to a full-time position within Delta and to my nightmare daily commute to the centre of Nottingham. Although my title was Product Development Manager, Regulatory Affairs, my responsibilities were primarily writing and review of all regulatory documentation. My writing experiences were largely confined to creation of the submission dossier (USA) for "excipient" uses of recombinant human albumin, which the FDA had agreed should be in the form of a Biologics Master File (BMF). Having attended the Brighton conference, which included the one-day seminar on the Common Technical Document (CTD), I was convinced that our BMF should follow the format proposed in the recently published CTD guideline (Notice to Applicants Volume 2B, July 2001). The Head of Regulatory Affairs gladly agreed to this proposal, and my remaining year at Delta was spent happily writing the Non-clinical and Clinical sections of Module 2 (Overviews and Summaries), together with the Product Development and Characterisation sections required for Module 3 (Quality).

It was during the Prague conference (May 2002) that the seeds were sown with respect to my decision to go "freelance". While talking to several people that I had first met in Montpellier, my impression was that there was an opportunity for a writer whose expertise lay in the field of "biotech" product development. Although it took until December 2002 for me to negotiate my redundancy package, this has given me a further 6 months experience in writing regulatory documents and thus increased the value of the services I can provide as a Scientific and Medical Writer.

Carol Wood

Scientific & Medical Writer, Warfdale Consultancy Ltd.
Farlea, Bladon Gardens,
Newton Road, Burton on Trent, DE15 0TF, UK
Tel/Fax: (+44) 1283 542814
E-mail: Carolwfarlea@aol.com



Mentoring Medical Writers: Using Your Most Valuable Resource

by Adrienne Edwards

- 1) You're a new medical writer, and you want the tips and essential know-how of how to get on in your new organisation.
- 2) The office politics are driving you mad. You come home and let rip at your spouse/partner/friend/cat, but the following morning the frustrations are still there.
- 3) You're in a rut and aspire to greater things, but can't seem to get noticed.

Who do you turn to? Your mentor, of course! So, what is a mentor and what makes the mentoring relationship so special? First a couple of definitions:

Generally: Mentoring is a process of building a mutually beneficial partnership to help develop the skills, behaviour and insights to reach goals in which the mentor has no stake in the outcome.

For us: Mentoring is a process by which less experienced medical writers are enabled to evaluate their own skills and development needs assisted by an experienced medical writer who will use their own experience and knowledge to motivate and facilitate the development of their colleagues.

In our company, the mentoring scheme is intended for new staff, where it is designed as an introduction and aid to the settling-in process, but it can equally well be used for existing staff. In both cases, the emphasis is on bringing out the best in our staff, to produce motivated, involved individuals, as part of longer-term career development, and to aid the retention of key people.

Before going any further, let's look at it from the other side - what's in it for the organisation? Why should you devote the time and effort, and therefore expense, of setting up such a mentoring scheme? Anyone who has been a manager will know (sometimes from painful experience) that your department, and therefore you, are only as good as your staff. They are your most valuable resource by far, in terms of percentage overhead, reputation and getting the job done. Knowledge, skills and experience are painstakingly gathered and are hard to find and replace.

Compare the profitability of a well-motivated, progressive, enthusiastic, cohesive and experienced team with that of the demotivated, stuck-in-a-rut, everyone-out-for-himself, inexperienced team. It's obvious, isn't it? So, managers who neglect their staff do so at their peril! But how do we get these well-motivated, progressive, enthusiastic, and experienced individuals? They probably say it on their application (so it must be true!), but how do we make it happen?

We value them. More jargon! How often do we see this phrase in job adverts and company marketing material? But, if you really value your staff, what does this mean and what do you have to do?

- Welcome newcomers, orientate them, assimilate them and give them the tips and essential know-how they need to do the job
- Listen and respond to the concerns and difficulties they raise and anticipate those they don't
- Develop and extend their roles, offering new challenges in a structured way, helping them to network and raise their profile.

Hey presto - the needs and expectations of your staff match the requirements and goals of your organisation! Set up a mentoring scheme, demonstrate that you value your staff and get a cohesive, motivated and upwardly mobile team - it's as easy as that! Um, yes, with a bit of effort on your part, maybe. So, how do you set up this mentoring scheme?

Any mentoring scheme is only as good as its mentors, so the first step is to get all potential mentors on board. Ideally, involve them from the start. Get ideas together and agree what a mentor is, what the scheme will offer and what it hopes to achieve (see first column of table below). Think about what it is NOT, as well as what it should be. It is important to distinguish between the role of the mentor and the role of the supervisor or line manager. The supervisor and line manager are project-orientated and are responsible for getting the task done, i.e. they have a stake in the outcome (see definitions above); the mentor is focused on the individual and their development. For the mentoring relationship to be open and impartial, the mentor ideally needs to be outside the supervisory loop.

To be a mentor you must want to be one, and so it ought to be voluntary. Doing it as a duty is a recipe for disaster and a doomed mentoring relationship. However, being a mentor requires time, effort and commitment, so what is in it for the mentor?

- You learn from your mentored person (you'd be amazed how much . . .)
- The satisfaction of seeing your mentored person succeed, in small as well as big ways
- A chance to have a people-orientated role in the organisation without being a manager
- Adding a host of new skills to your repertoire (communication, listening, problem-solving and coaching skills; giving positive and negative feedback)
- Overall, increased job satisfaction.

In view of the importance of the mentor's role in the success of any mentoring scheme, ideally the mentors should themselves receive training. Although the mentoring relationship is a very individual thing and will develop according to the styles and preferences of the participants, there are common themes and goals that are best explored and understood at the outset to maximise the success of the relationship. After all, mentoring itself is a new skill to be learnt.

In addition to the skill of the mentor, critical to the success of the mentoring relationship is the mutual understanding of the purpose of it. It is important to acknowledge this early on, by discussing it together and drawing up some sort of agreement as shown in the second column in the table below.

A mentoring scheme is only one piece in a manager's armoury for valuing staff and is part of a bigger picture in the way an organisation operates. I set up such a scheme in my company to support a new in-house training programme, and it was seen as critical in underpinning that training programme. Individual performance reviews and career development plans are further very successful complementary tools in managing and motivating your staff.

Mentoring Medical Writers

The mentoring scheme here is relatively new, and so far seems to have been well received. A bit further down the mentoring road, I would like to assess our progress, and whether the scheme has lived up to expectations (a future article?). The last word: you don't have to be the manager to implement a mentoring scheme, but you do have to have their support and commitment in doing so.

<p>Mentoring:</p> <ul style="list-style-type: none">• Is when the more experienced help the less experienced• Facilitates the transfer of experience• Helps with filtering information• Provides guidance in prioritising• Provides direction• Is not patronising• Is carried out by a defined person• Provides a gatekeeper role• Requires the allocation of time• Has involvement in <i>actual</i> work• Provides feedback• Actively seeks feedback• Is ongoing• Is a 2-way process• Requires frequent contact• Contributes to the formulation of training• Helps to identify individual training needs• Cannot to be carried out in isolation <p>Mentors need to be:</p> <ul style="list-style-type: none">• Clear about their own role• Experienced enough to be effective in this role• Voluntary• Able to commit the time	<p>Needs and expectations of the mentoring relationship</p> <p>Meetings should:</p> <ul style="list-style-type: none">• Be confidential, to enable open and honest communication and trust• Be managed, not allowed to "just happen"• Be unstructured, to allow for spontaneous needs• Add value to our work <p>Both parties should:</p> <ul style="list-style-type: none">• Agree on a definition of mentoring• Show commitment to the scheme• Be flexible, as needs change• Be willing to give and receive feedback, both positive and negative• Be prepared to share experiences, tips and goals <p>The mentor should:</p> <ul style="list-style-type: none">• Support and encourage• Facilitate (not decide)• Be a sounding board• (there are no stupid questions)• Be non-judgemental• Be a confidant• Challenge <p>The mentored person should:</p> <ul style="list-style-type: none">• Be proactive• Possess a desire to develop their potential• Act on agreed advice• Put things into effect• Be prepared to reflect on experiences• Be clear about their own goals
---	--

Adrienne Edwards

Covidence GmbH
Phillipp-Helfmann-Str 18
D-65760 Esborn, Germany
adrienne.edwards@covidence.com

News From The EPDC

by Wendy Kingdom

At the end of another successful and enjoyable conference, the EMWA Professional Development Committee (EPDC) met to review the new workshops under assessment, get feedback on the Train the Trainer (TT) programme, and make plans for the future.

This year, in addition to the 22 credit workshops, there were 4 new workshops under assessment. Two of the new workshops were approved for credit straight away and the other 2 will be run for credit when they have undergone some revisions. Also, as the number of workshop leaders is increasing, the TT programme was expanded to meet this need. Virginia Watson and Alistair Reeves have now joined Pamela Johnson to create a TT team to develop and extend the programme for workshop leaders. The aim of this programme is to ensure the continuing quality of workshops presented at the conferences and to support new and potential workshop leaders.

There was some experimenting this year with 2 different workshop formats: 2-part workshops and short workshops. The 2-part workshops were introduced for topics that need a whole day in order to cover the subjects properly. There were 2 of these workshops this year, both of which were well attended, and they seemed to be well received. There were also 8 short workshops. The short workshop format was introduced for a number of reasons, including topics that simply don't take long to cover, an opportunity to try out a subject perhaps with a view to presenting a full workshop in the future, or a chance for a new workshop leader to present a topic without having to prepare a full workshop. As part of this programme, a Workshop Leaders Forum (WLF) was also organised, and following the enthusiastic response from those who were able to attend, the WLF will become a regular event at Spring conferences. On the whole, we found that the short workshop format was very successful and we welcome suggestions from anyone who has an idea for a short topic that they would either like to present, or to lead a discussion on, in the future.

We found that the short workshop format was very successful and we welcome suggestions from anyone who has an idea for a short topic that they would like to present

A new name is needed for the Public Relations and Marketing (PRAM) section of the EPDP certificate. This section is one of the few remaining legacies of the AMWA certificate, and it doesn't really fit the profile of EMWA members at this time. At the moment, we have only one credit workshop in this section, which is Geoff Hall's workshop on crafting a press release. We thought that the new IT workshops, such as Adam Jacobs's workshop on writing macros as well as media based workshops such as web page design could go into this section. Therefore, PRAM doesn't seem to be an appropriate title. Does anyone have any suggestions?

EPDC News

As always, we ran short of time and felt that we couldn't do justice to the volunteers for the vacancy on the EPDC. So, the position remains open until the Autumn meeting. The people who have applied already will stay on the list, but if anyone else would like to apply, please send me a brief summary about yourself and what you feel you can bring to the committee. We are pretty well represented in the pharmaceutical, regulatory and training areas, so it would be good to hear from people who work in other areas of medical writing.

Some good news is that the time limit for completion of the certificate has been removed. This had been set at 6 years with a view to keeping the learning current, as well as a method of renewing the administration fee for people who have to be tracked on the database for a long time. Our experience has been that few people ask for an extension in gaining their certificate but, where this does occur, the reason is always a change in circumstances or career break. On reflection, the process of having to apply for an extension is not of sufficient value to justify continuing with it. The bad news is that the administration fee will now be payable every 5 years until the certificate is completed.

The Autumn programme this year will be a selection of 6 workshops, 5 for credit and one under assessment. The Autumn meeting was introduced to give members who are working for their certificate an opportunity to get some more credits and so this year's programme will be a selection of the most popular workshops.

We have to start planning the programme for next year's meeting straight after finishing this year's. We have a few proposals for new workshops already but more are always welcome. The aim is to include around 4 new workshops for assessment at every main conference, so it is not possible to include all new proposals. However, it is important to keep the programme fresh and dynamic and if a proposal is not included the first time it is submitted, it may well be included next time. We are keen to hear from people who can offer a workshop where they can see a gap in the Professional Development Programme, or if they can offer a different approach to a topic that is already included in the programme. If anyone feels shy of offering their services as a workshop leader, I should like to reassure you that you will be assigned a mentor who will guide you through the process, be invited to attend the TT Forum, and be welcomed at the WLF. EMWA is a membership association, not a training company, and all EMWA members who are interested in becoming workshop leaders have the possibility to do so (and should contact the EPDC).

Looking to the longer-term future, the EMWA Professional Development Certificate is now established. It is time to start thinking about introducing an advanced certificate. What form this should take (same format as the first certificate but including "advanced" topics, longer workshops, longer assignments etc.) is open to debate. So, if you have an opinion on the subject, please let me know.

That's all of the news for now. I look forward to hearing from anyone who has any comments or suggestions, ideas for the new name for PRAM, thoughts on an advanced programme etc., and I hope to see you in the Autumn.

Wendy Kingdom

EMWA Education Officer
info@wendykingdom.com



From Over the Pond: Better a Galley Slave in Turkey than a Freelance Writer in America

by Susanna Dodgson

When I joined the National Writers Union in July 2000, I was sold a black t-shirt with white writing on the front saying "Better a galley slave in Turkey than a freelance writer in America" with the quote astonishingly attributed to Karl Marx. I bought 6 of these shirts and liberally spread them around my relatives. I have been told that the general public's response to this message has not been all positive. We are offending Turks or galley slaves or something. The comment that freelance writers are badly off in America has never been argued.

So why am I a freelance writer in America? I will answer that slowly. First, we need to define our terms. What is a freelance medical writer? I thought I knew before I became one. My definition 5 years ago was a writer who earns a huge amount of money not working in a cubicle. Then I discovered that companies are hiring full-time employees to telecommute, working out of their home office entirely for a single employer and getting paid vacations and sick leave. Which makes them not work in cubicles while being paid regularly, and probably well. I discovered more recently that writers self-described as freelance are frequently working 5 days a week onsite in cubicles but with contracts that pay them hourly.

If the place of work (home or onsite) or the method of payment (per hour or per year) may not define freelance workers, what does? I think freelance is a state of mind rather than a tax code or whether you work in your night-clothes. If you believe that at any moment you can fly to

Iceland to trudge through the snow to bathe in the open thermal pools or visit your daughter's class to watch a play, you probably describe yourself as freelance. If you know you can do these things after you have completed your assignment and are constantly in fear of being fired, you are probably not freelance. Freelance writers own their days, understanding that any combinations of the 24 hours can be used for working. Further, they cope well with contract terminations, looking forward to the next contract and enjoying the present one as long as it lasts.

So why am I a freelance writer? Not by choice. Of all the permanent jobs that I would have liked in the past 5 years, 95% have involved sitting in a cubicle for 9 hours a day preceded and followed by an hour's drive. My ideal job is 15 to 20 min from my house, does not involve a cubicle but does include natural light, a few plants and preferably some cello music. I had a job like that 3 years ago, I shared an office with a graphic designer, from whom I learned Quark and basic design, and I wrote disease monographs happily and purposefully, watching the pine tree outside my window. After 8 months, my boss moved me into a closet without windows or ventilation. The tricky part

What is a freelance medical writer? My definition 5 years ago was a writer who earns a huge amount of money not working in a cubicle

From Over the Pond

was that any word I said was amplified by the air-conditioning pipes and overheard by the President of the company. Around that time, the 2 major accounts were lost and the need for an expensive medical writer churning out disease monographs vanished. I remember asking a sales manager whether she was worried that she and I were the only 2 employees who were over 30 and not short and gorgeous. This conversation was overheard and resulted in instant dismissal. The company has since purged itself of the sales manager too. It is now a young and gorgeous company, and they no longer prepare disease monographs. And the labour laws have not changed.

Fortunately, after that I fell onto my feet spectacularly, instantly acquiring 2 clients. In the month of my 50th birthday, I made more than twice the amount I had made all year when I came to America as a post-doctoral fellow 23 years previously. I have written about my trip to Athens covering an HIV-lipodystrophy conference in a previous column on HIV/AIDS. Since then, October 2001, I have been hired by about 6 clients for specific projects on short-term contracts lasting 6 to 12 months, with one contract continuing. Some of these contracts have been primarily onsite, and some have been so remote I have not even spoken with my client on the phone.

I understand from talking with other freelance medical writers at the EMWA conference in Lisbon that some parts of our lives are similar, like trolling for jobs through pharmaceutical company websites and "help wanted" adverts. What differs between American and European medical writers is that we are on our own. We can earn considerably more than writers with permanent jobs, but we had better stay healthy. A major hurdle for those of us with children is the spectre of university fees, which can exceed \$40,000 per year for 4 years. The cheapest health insurance I have been able to find for myself and my 2 minor children costs over \$1,000 per month, and I would still be expected to pay \$25 per doctor visit. I have not had health insurance since I left my 18-year job at the University of Pennsylvania in 1995. I take my children to their physician, dentist and optometrist once a year and pay about \$400. Fortunately we are all healthy and do not have chronic diseases.

I am a member of the National Writers Union subgroup, NWU Medwriters. Before the whole country changed into war mode, the Medwriters were having a civilized dialogue on healthcare. I have always found the inability of the richest country on Earth to care for its sick appalling, a view held by many Americans, but not by enough Americans to change the situation. I sponsored a resolution that was passed by the National Writers Union Delegates Assembly calling for support of universal health care. I had originally asked for a resolution supporting single-payer insurance, but that was shot down amidst arguments including "The Canadian system doesn't work!" "Single-payer is too socialist!" "Do you really want to give that power to the government!"

I have thought about what I can do to make life easier for myself. I ask only for a commute that is under 30 min, healthcare and to be able to see daylight while I am working. These goals are impossible in the United States, and yet standard in the European Union. I can try to fight the system in the United States, or I can relocate to the European Union. Anyone in Europe need a medical writer?

Susanna J. Dodgson, Ph.D.

<http://emeraldpademelon.com>



The Quizzical Conundrum of the Collective Noun

by Ian Metcalfe

It all began with an innocent question, as most things do. Take for example Sir Edmund Hillary asking, "I wonder what the view is like from up there?". In this case it was a bit more down to earth, some of my colleagues were describing a subgroup from a population, a proportion of which had shown differing results of a nature worth commenting upon. Being non-native English speakers they turned to me and asked "When is it proper to use the terms: a group of, a sample of, a number of, a selection of, a proportion of...?"

Not an easy question to answer with a mouthful of croissant, unless the questioner is satisfied with an "it depends" and a few crumbs. But it started me on a random, almost Brownian-like course of thinking. The English language is full of quirks and foibles designed to undo the unwary, particularly if they are non-native English speakers. People have written whole books on it. The number of ways one can say practically the same thing using a broad spectrum of vocabulary can sometimes be astounding (however, as with the above, the subtle nuances of definition and context often come into play). A classic and amusing example that sprang into my mind is that of collective nouns. One of the most intriguing oddities of the English language is that there is such a variety of collective nouns, some of which appear logical but for the majority the origins are obscured in history and myth.

Having just returned from the EMWA conference in Lisbon (which was excellent), I found myself asking, "What would the collective noun be for a group of medical writers?"

One of the most intriguing oddities of the English language is that there is such a variety of collective nouns, some of which appear logical but for the majority the origins are obscure

After a few moments on the World Wide Web, I discovered to my dismay that most of the good collective nouns had already been taken: A smack of jelly-fish; a rabble of butterflies (I don't really see the association there, must be chaos theory); an ostentation of peacocks (that one would have been perfect); a murder of crows; a memory of elephants; a fall of woodchucks, an exaltation of larks and a crash of rhinoceros (or is it rhinoceri?).

Even inanimate objects have been given the courtesy of the collective noun: A card of wool; a cluster of diamonds; a flat of bricks; a franchise of restaurants; a head of steam; a paper of pins; a quire of paper; and a shag of tobacco.

As my fixation deepened, I began to wonder about the description of sub-groups within a population. This in turn led me stumbling (as is the way with the World Wide Web) into a few, perhaps light-hearted, collective nouns for professions: An amalgamation of met-

Collective Nouns

allurgists; a cloud of theoretical meteorologists; a shower of applied meteorologists; a complex of psychologists; an exaggeration of fishermen; a grid of electrical engineers; an intrigue of council members; a radiance of radiographers; a set of pure mathematicians; a stack of librarians (taken from "Fave collective nouns". Available at: <http://www.lizzie.net/html/collect.htm>; accessed May 2003, try also <http://www.ojo-haven.com/collectives/>)

By now I was truly addicted. I could feel myself on the brink of discovery. What were we as we huddled around the coffee and tea at the workshop intervals? How would people describe us as we wandered aimlessly around Lisbon in search of a restaurant to seat 13?

I decided I needed an objective view and took a poll from my colleagues and peers. The responses were less than satisfactory, ranging from a "mess" to, my personal favourite, a "marvel" of medical writers.

Not truly sated I'm now turning to the professionals. To the people to whom it matters most, my comrades in arms and I ask you "What are we?".

Ian Metcalfe

Berna Biotech Ltd
Rehhagstrasse 79
CH-3018, Bern, Switzerland
Tel: (+41) 31 980 6359
ian.metcalfe@bernabiotech.com

Editor's note: I suspect that this has been discussed at many a medical writing office tea time or water cooler meeting. Some of the suggestions I have heard over the years, and some are clearly meant for subgroups of writers, include: a "Quill", a "Babble" (if we include all languages?), a "Summary", a "Synopsis", an "Abstract", a "Clarity", and an "Approval".

Have you heard any good possibilities or thought of a few of your own? We at TWS would like to hear of them. Suggestions from other readers will be published in a future edition of TWS.

The Last Word

**"The editing urge:
The strongest drive is not love or hate.
It is one person's need to change
another's copy."**

BMJ 2001; 323: 435 (25 August)



The Lighter Side: "A Writer - ooh, that is exciting...."

by Nicola La Grue

"What do you do?"

"I'm a Medical Writer".

"Oh. What's that then?"

"I prepare documents for clinical trials of new medicines."

"Hmm. That sounds interesting. Did you see EastEnders last night . . ."

Has anyone ever found a satisfactory, punchy description of what a Medical Writer does? I've been a Medical Writer for about 10 years and still my offpat description varies with every telling. I find it also depends on who I'm talking to . . .

Stylist: "Doing anything nice tonight then, love?"

Me: "No. Not really. Just some paperwork."

Stylist: "Oh dear, but it's Saturday night."

Me: "Well, I know it's a bit of a drag. But I work for myself and have to fit in the paperwork whenever I can."

Stylist: "What is it you do then, love?"

Me: "I'm a Writer."

Stylist: (steps back and raises eyebrows, mid-snip): "Ooh. That is exciting. What kind of writing?"

Me: "Well, I like to see myself as a champion of health-related issues, bringing an unbiased and full perspective on the testing of new medicines."

Stylist: "Oh that's wonderful. Now my sister had an in-growing toenail last month and the doctor told her . . ."

The other common situation is that tricky meeting at the doctor's surgery. You've got an appointment with one of the general practitioners who doesn't know you, and you need to make it known relatively quickly, but in a non-confrontational way, that you're not going to be fobbed off with the usual spiel . . .

Doctor: "Let me just take your blood pressure then Mrs La Grue."

Doctor: (wrestling with arm cuff): "What do you do for a living then Mrs La Grue?"

Me: "I work in the pharmaceutical industry - helping to plan and report clinical trials for new drugs, assessing their safety and efficacy, and preparing dossiers for submissions to regulatory authorities."

Doctor: (stops instantly and looks slightly taken aback): "Well, that's something I don't get every day. Um, now let me explain what I think the problem is and see whether you agree . . ."

What I don't communicate to many people is the strange effect that this job has had on me. Where did this pedantic attention to grammar and punctuation come from? And then there's this irresistible urge to question everything. And not just at work. Take my

Nadnaslov

daughter's arm, for example. She broke it at one year of age and, despite being the distraught parent, I managed to question closely every single professional we came across. This included a poor consultant who was going to re-set the bones, with whom I pursued a detailed line of questioning as to his previous experience, how he was going to do the operation, what were the published and accepted methods for re-positioning the bones, and what was the correct setting and angle of bandaging! And then, not content with that, later at home I felt compelled to trawl the literature myself and became an expert on radius and ulna setting in the toddler.

Anyway, after some thought, I've come up with a reasonable description of a Medical Writer. It's not exactly punchy, but here goes:

To be a scientist. And a wordsmith. To be a diplomat. And a leader.
To read and understand the complex physiological theory
And with a calm mind, filter through the reams of data and analysis.
To identify the relevant and important
and transform it all into a succinct, useful message.
To reach the destination and remember why you made the journey.

Nicola La Grue is a freelance Medical Writer. She has recently had another baby and wrote this article whilst on maternity leave. Hopefully her brain cells are now re-kindled, as she has started work again.


Nicola La Grue

34 Cheylesmore Drive

Frimley, Surrey, GU16 9BN, UK

Tel/fax: (+44) 1276 691140

Email: nicky@medicalwritingservices.com; Website: www.medicalwritingservices.com



Thank you for welcoming us to our first EMWA meeting held recently in Lisbon. For those of you that we didn't get a chance to meet we would like to take this opportunity to introduce our services.

Candidates:

At ID-SS we specialise in the recruitment of Medical Writers, Editors and other communications specialists.

We currently have opportunities both Client side and within marketing and communications agencies at all levels of seniority in both the UK and mainland Europe. If you would like to discuss your next move with one of our experienced consultants in total confidence, please contact us on the number below.

Clients:

If you would like to engage the services of ID-SS on a no success no fee basis, please contact us to discuss your requirements.

ID Search & Selection 17 Hill Street, Mayfair, London. W1J 5LJ email: mail@id-ss.com
Tel: +44 (0)20 7079 0500 Fax: +44 (0)20 7079 0503

Meetings of Interest

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

Date	Meeting / Sponsor	Location
Sep 17-18	FDA Approval Process for Biological Products	London, UK
	Management Forum Ltd. 48 Woodbridge Rd Guildford, GU1 4RJ UK Tel: (+44) 1483 570099; Fax: (+44) 1483 536424 www.management-forum.co.uk; info@management-forum.co.uk	
Sep 18	Common Technical Document	London, UK
	Management Forum Ltd. 48 Woodbridge Rd Guildford, GU1 4RJ UK Tel: (+44) 1483 570099; Fax: (+44) 1483 536424 www.management-forum.co.uk; info@management-forum.co.uk	
Sep 24-26	Successful Medical Writing (Intensive Practical Course)	Brussels, Belgium
[EMWA]	Management Forum Ltd. 48 Woodbridge Rd Guildford, GU1 4RJ UK Tel: (+44) 1483 570099; Fax: (+44) 1483 536424 www.management-forum.co.uk; info@management-forum.co.uk	
Oct 13-15	Statistical Thinking for Clinical Trials	London, UK
	PAREXEL International The Quays, 101-105 Oxford Road Uxbridge, Middlesex UB8 1LZ UK Tel: (+44) 1895 614202; Fax: (+44) 1895 614419 Internet: www.parexel.com; biostatistics@parexel.com	
Oct 23-24	Efficientes Projektmanagement (German language)	Frankfurt, Germany
	FORUM Institut für Management GmbH Postfach 10 50 60 D-69040 Heidelberg, Germany Tel: (+49) 6221 500 500; Fax: (+49) 6221 500 505 Internet: www.forum-institut.de	
Nov 24-25	Successful Medical Writing (Intensive Course)	Munich, Germany
[EMWA]	FORUM Institut für Management GmbH Postfach 10 50 60 D-69040 Heidelberg, Germany Tel: (+49) 6221 500 500; Fax: (+49) 6221 500 505 Internet: www.forum-institut.de	
Nov 26-27	Medizin- und Pharma-Information aus dem Internet	Frankfurt, Germany
	FORUM Institut für Management GmbH Postfach 10 50 60 D-69040 Heidelberg, Germany Tel: (+49) 6221 500 500; Fax: (+49) 6221 500 505 Internet: www.forum-institut.de	

EMWA Executive Committee

President:

Isabelle Thirolle
GlaxoSmithKline Biologicals
Rue de L'Institut 89, 1330 Rixensart, Belgium
Tel: (+32) 2 656 9808
Fax: (+32) 2 656 8133
isabelle.thirolle@gskbio.com

Vice-President & Programme Manager:

Adam Jacobs
Dianthus Medical Ltd
Lombard Business Park
8 Lombard Road
London, SW19 3TZ, UK
Tel: (+44) 20 8543 9229
Fax: (+44) 20 8543 9885
ajacobs@dianthus.co.uk

Immediate Past President & Secretary:

Julia Cooper
Parexel International Ltd
River Court, 50 Oxford Road
Denham, Uxbridge, UB9 4DN, UK
Tel: (+44) 1895 614 403
Fax: (+44) 1895 614 323
julia.cooper@parexel.com

Treasurer:

Barbara Grossman
Covance
7 Roxborough Way
Maidenhead
Berks, SL6 3UD, UK
Tel: (+44) 1628 548 182
Fax: (+44) 1628 547 333
barbara.grossman@covance.com

University Liaison Officer:

John Carpenter
John Carpenter Medical Comm.
18 Nightingale Shott
Egham, Surrey, TW20 9SX, UK
Tel: (+44) 1784 470 203
Mobile: (+44) 7764 183 314
johnncarpenter21@aol.com

Membership Officer:

Judi Proctor
Freelance Medical Writer
144 Sheldon Rd, Chippenham
Wiltshire, SN14 0BZ, UK
Tel/Fax: (+44) 1249 461174
Mobile: (+44) 7890 350908
judi@jinx66.fsnet.co.uk

Public Relations Officer:

Michelle Derbyshire
GlaxoSmithKline Biologicals
Rue de L'Institut 89
1330 Rixensart Belgium
Tel: (+32) 2 656 7787
Fax: (+32) 2 656 9132
michelle.derbyshire@gskbio.com

Website Manager:

Marian Hodges
Nat. Institute for Clinical Excellence
Address for correspondence:
6 Highfields, Ashted
Surrey, KT21 2NL, UK
Tel: (+44) 1372 279036
Fax: (+44) 1372 275272
marian@medwrite.co.uk

Education Officer:

Wendy Kingdom
1 Red House Road
East Brent, Highbridge
Somerset, TA9 4RX, UK
Tel: (+44) 1278 769 214
Fax: (+44) 1278 769 214
info@wendykingdom.com

Journal Editor:

Barry Drees
Trilogy Writing GmbH
Gartenstrasse 54
68723 Ostersheim, Germany
Tel: (+49) 6202 52771
Fax: (+49) 6202-592483
barry@trilogywritng.com

EMWA Head Office

Baarerstrasse 110C, 7th Floor, P.O. Box 2246, 6302 Zug Switzerland
Tel: (+41) 41 766 05 81 Fax: (+41) 41 766 05 86
info@emwa.org

EMWA website: www.emwa.org