



## **Life after Medical Writing: Message from Outer Space**

by Leen Vanherle

The only reason I was allowed to leave the field of medical writing was the promise to my good old friend Barry Drees that I would provide you with a detailed report of life on the other side of the fence. You see, after 6 years of medical writing and intense involvement with AMWA, then EMWA, ending up as president of EMWA in 1994, I decided to cross over to the enemy in 1997. You know the saying, if you can't beat them, join them. So why has it taken me so long to tell you what it is I am doing now? Well, the initial shock, the doubts, the counselling and finally picking up the courage to tell you the truth has been a lengthy process... I have become an auditor. Now please don't go turning over this page in disgust.

I know that most of you, understandably, see the world of auditing according to the "truths" of Dilbert:

*"I'm exiled to the Quality Assurance Department. My career is doomed."*

or

*"The best of all worlds is to be asked to check the writing of a co-worker. You get to savor the experience of shredding another person's ego while taking no personal risk. It can be a very satisfying experience."*

*Adams, S. The Dilbert principle. Harper Business 1996*

How on earth does a medical writer of clinical trial documents become involved with audits and inspections? Well, let's look at what the qualities (there are some, believe me) of a good auditor are and maybe you'll be shocked by the results.

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First, a good auditor has to understand the science behind and development within the clinical trial world. As a medical writer, you also have to develop these skills through your involvement with protocol development, project team meetings, data and analysis review before finally writing the report. Secondly, a good auditor knows their GCPs, SOPs, guidelines, regulations, and what have you. Most of you writers are familiar with ICH and work according to GCP rules anyway, so this is not exactly new. This is a matter of constant studying and updating for an auditor. When we're not travelling or writing reports, we're usually updating our brain storage with new amazing rules to be complied with.

Thirdly, a good auditor understands the process and the pitfalls of clinical trial execution. How are sites selected, how are sites initiated and trained, what makes a good monitor tick, drug accountability, what are the systems that make a clinical trial run smoothly, what exactly is expected from an Ethics Committee, etc. This is maybe one area medical writers might be less familiar with, and a knowledge that has to be acquired (in case you want to join me!). Even so, this is also an area where you can develop your skill as a good communicator and analyst. An auditor has to understand, analyse and spot the pitfalls in a certain process.

Analysis and communication are actually the essence of auditing, and to me, these are actually the most fascinating and challenging aspects of the job. Auditing is a lot about ignorance, misunderstanding and broadcasting on parallel communication channels. I have been audited before, so I know what the feeling is when somebody comes snooping through your work with the only purpose to nail and crucify you (admit it, you think, "What the hell does this fool think they are doing telling me what I do wrong"). Well, if there are auditors like that out there, you have my permission to shoot them because that is not what auditing is about. Misunderstanding, huh, don't tell me that writers don't have years of experience of being misunderstood and misinterpreted. So there you go, another skill you have. Auditing is all about trouble shooting and not about trouble snooping. So, when you, the auditor, find that things have gone wrong, you first have to identify the correct cause, before you make the parties involved aware that something is wrong and what the consequences are if the situation is not rectified. It is important that you discuss the situation and not the people; and remember that you are the catalyst in process improvement or process quality maintenance.

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And where does all this lead to? That facts have to be presented correctly, diplomatically and clearly in an audit report! Yes, writers definitely have the advantage here compared with auditors who have had more practical experience in the clinical trial world. I have written long clinical trial reports before, but I can honestly say that I pour more brain power and energy into writing a 10 page audit report than into a 60 page trial report. While you are truly assessing processes and systems instead of people, no matter how you turn it, there are people behind those processes. Since most people take pride in their work, they often tend to identify themselves with those processes, so feel assessed in the end. You can see that skill is required to pour a bad message into a form that is acceptable to all parties involved. No matter how bad you feel about the situation yourself, you have to stick to the finding and present it in the fairest way possible. No matter how much bullying or cajoling you get subjected to, you must never lose your temper or give in. It is unbelievable what people will do to change an audit observation to their advantage or delegate the blame to someone else. I sometimes get tangled in endless dialectics and end up with a woolly brain. And then, I'm just talking about the discussion in English, I'm not even mentioning the German, French, Polish. Absolutely fascinating, I love this part of the job. It keeps me on my toes, and I make sure everybody else does too. So, an auditor has a thick skin, is firm, is the perfect diplomat. Do you recognise yourself?

## ***The Write Stuff***

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### ***Message from Outer Space***

There is maybe one area the auditor is easily defeated, and that's the travelling part. I've been sick on the Heathrow airport floor (no wonder it looks like a mess now); I've been stuck on the tarmac for three hours in a snowstorm; I've missed planes; I've had the Virgin Express experience (based on the intimate proximity the passengers are subjected to in their planes, I think maybe it was not opportune to choose the name "Virgin"). Considering we travel at least 25% of our working lives, this can be the most tedious, exasperating and challenging part of the job. But let's face it folks: this has nothing to do with auditing or medical writing. It's just the normal survival-of-the-fittest travel experience. To tell you the truth, I love being in different countries, to meet the people in our different affiliates, to see for myself how CROs work, to compare the differences in healthcare management, discover how interested and dedicated most trial teams and investigator sites are...

I'm no longer afraid to admit it, I love this job. I do not regret for one minute about saying medical writing farewell (sorry guys). Well, I must be honest. There is one thing I do miss. That's those great EMWA meetings and all that fantastic "networking". I think back with fond memories to those early rebel days when we wanted to go our own way, all the brainstorming sessions about AMWA's and EMWA's future, the development of our first newsletter, our own EMWA annual conference, the booze-ups afterwards, the great joke-telling sessions. I would not have wanted to miss that experience for the world. I've learnt a lot and made some great friends. Keep up the excellent work and make sure Keith keeps his word about keeping his speeches short!

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### ***Department of Corrections – Spring 2000***

At the very last second before printing, a very distracted, overworked, and underpaid Editor-in-Chief, following the advice of one of his copyeditors, added some information about David Sharp's position. Alas, although the Editor-in-Chief knows David personally and has even consulted with him on the layout of *The Lancet*, BMJ got typed in somehow instead! Just for good measure, the date of the Madrid conference was also wrong (just like the bags from that conference).

The first paragraph on page 14 of the article "Good Publication Practice . . ." by Liz Wager and Leni Grossman should read:

*"The reaction of David Sharp, deputy editor of The Lancet, to information from a communications agency at the 1998 EMWA conference is a good example of such views."*