



From the guest editor's desk:

## What sort of a regulatory writer could YOU be?

by Sam Hamilton

### Exploring the regulatory medical writing portfolio in our changing world

Regulatory medical writing provides the bread and butter for a significant proportion of EMWA members, so it is fitting that this is the theme for the forthcoming May 2009 Ljubljana conference. This issue of *TWS* supports the conference theme and, I hope, will spark discussion about the evolving regulatory environment and the pharmaceutical industry in general.

The discipline of regulatory writing with all its attendant guidelines and regulations is considered liberating by some, and stifling by others. Liberating, in that objective and uniform reporting of data can be powerful enough to launch a much needed first or alternative therapy for an important disease or condition; stifling, in that the templates and rules the writer is expected to adhere to can bludgeon individual creativity to death! A bit strong perhaps, but the general idea is worth exploring further.

We all have a writing journey. Mine was from the creative to the prescriptive and is, for now, a comfortable combination of the two. As a child at junior school, I loved creative writing, and found I was good at it. My creative ability was underpinned by the teachings of my formidable headmistress (now undoubtedly over 100 years of age), Miss Collingwood, of Wakefield Girls' High School (Junior Department). Her common-sense guidelines for writing have remained with me ever since: every story needs a beginning, a middle and an end, and the detail must be sufficient to place the reader in the story, without boring them. By adhering to this general formula, I wrote good yarns and developed an understanding of the power of the written word. Throughout my career as a pre-clinical scientist in academia and subsequently in clinical research, I built on that early foundation and married science and writing to good effect. To my surprise, the basic creative writing formula still held, with allowance for differing levels of detail depending on the target audience. However, there was that nagging (although only slight) worry early in my regulatory writing career that my original creativity—of which the 8-year-old me had been so proud—was being blunted. I now see that my childhood creative writing formula fitted my then undeveloped scientific bent. Having developed this general formula along its natural course to suit my professional needs, I now find myself in a well-structured and more than occasionally creative place—as a regulatory medical writer—and I rather like it.

The spectrum of regulatory writing may be split in any number of ways: division according to document type and field, which in turn apply to therapeutic area, disease (or condition) and drug class (or drug), seems reasonable enough (see Figure 1). Exposure to different types of regulatory writing varies enormously from one writer or organisation to another. However, broadly speaking, new writers often cut their teeth on compilation documents such as the Investigator Brochure (IB), progressing to sections of, and then, full Clinical Study Reports (CSRs). The ideal for new writers should surely be to gain as broad an experience as possible, across a variety of document types and therapeutic areas, diseases or drugs, to cement a firm foundation either to serve as a platform from which to continue to diversify, or to develop in-depth expertise in a limited number of specialised areas. These specialised areas usually encompass one therapeutic area or disease, or a drug class or even a single drug, and such expertise is commonly gained inside pharmaceutical companies (Pharma). Contract research organisations (CROs) provide broader training in terms of variety of therapeutic areas, diseases and drugs (generalisation). Whilst there are merits to generalisation and specialisation, a third, and perhaps less obvious choice exists. Freelance medical writing provides flexibility and enables experienced writers to step outside the pure regulatory writing arena. Alison McIntosh, a seasoned freelancer who straddles two very different writing arenas serving both medical communications and regulatory audiences, presents her personal view of what she terms 'broad-spectrum' medical writing. This approach must take account of different audiences and therefore encompasses different writing styles. It also allows for responsiveness to market needs—and in our changing world, that is not unimportant. Alison's views on broad-spectrum writing are challenged by representation from the CRO sector. Mary Jane Lunsford, Premier Research Group's Executive Director of Global Medical Writing puts the case for pure regulatory writers, and in particular the efficiency they bring to complex regulatory projects, when starting from 'cold'. Even within the constrained context of regulatory writing, we still have to think of our audience. Laurence Auffret, a specialist in Patient Information Leaflet (PIL) readability testing reminds us that although regulatory assessors are our *first* audience, the *prime* audience is the patient when preparing certain regulatory documents. Laurence explains the general associated processes to ensure that material intended for the lay audience is comprehensible and appropriately written.

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Whatever the approach—pure regulatory generalisation, pure regulatory specialisation or broad-spectrum medical writing—our skills can be honed in many areas of regulatory medical writing (see Figure 1). Besides the more obvious afore-mentioned areas, there is the interesting and arguably less well-known area of ‘fields’. This issue of *TWS* showcases a small selection of regulatory medical writing fields, including early phase clinical drug development, well-established use (WEU) medicines, orphan drugs and imaging technologies, as viewed by a contingent of highly experienced writers. These fields, like document types, can (mostly) apply to any number of therapeutic areas, diseases (or conditions) and drug classes (or drugs), so the possibilities are endless. Our good fortune as writing professionals is to have such an interesting and challenging portfolio to tackle in this global climate of change.

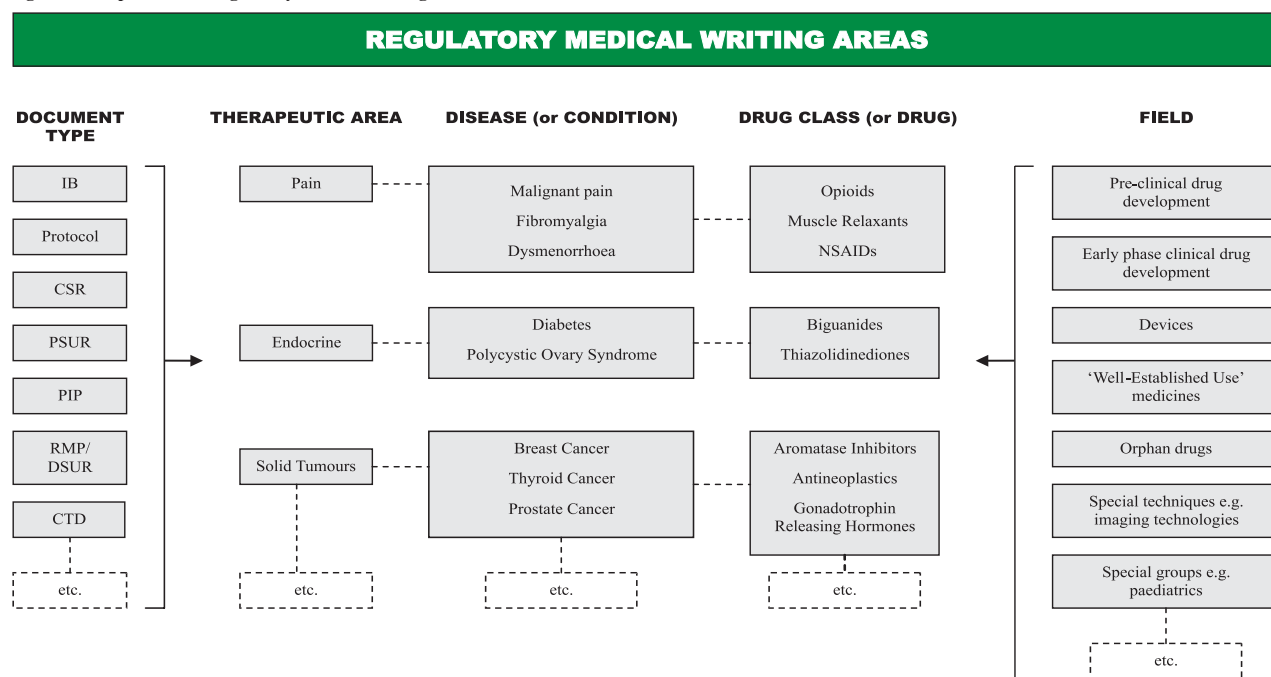
Economic and political factors are affecting our professional world now more than usual. In the past year, we have seen large shifts in the strength of the US dollar and Sterling, and an ever-strengthening Euro. Currency fluctuations can influence where business is sought out and conducted. Let us also consider in simplistic terms the effect of the worldwide economic downturn on the pharmaceutical industry. We are beginning to see the results of reduced availability of venture capital for smaller biotechnology companies. Fewer new chemical entities (NCEs) now make it out of the laboratory and into drug development pipelines, or they are transferred earlier to Pharma with a higher level of risk. We may also see reductions in permanent Pharma headcount, including writing professionals. This should be tempered by the fact that pharmaceuticals

historically represent a relatively stable sector in times of economic turmoil and that there is no reason why the current downturn should be any exception—after all, we still need drugs. And there remains plenty of work to do in supporting product labelling through the huge variety of areas and clinical regulatory documents that feed drugs out to market.

That said, we cannot escape politics. Change will undoubtedly be felt in our industry in the medium to longer term. The European Union (EU) Competition Commission estimates that delaying or blocking the development of cheaper generic versions of medicines by pharmaceutical companies cost EU healthcare providers approximately €3 billion between 2000 and 2007. This alleged practice is under investigation at seven major Pharma companies, and, as the Competition Commission can impose substantial fines (AstraZeneca was fined €60m for its attempts to block generic versions of its anti-ulcer medication, Losec in 2005) [1], European Pharma may have to rethink its current strategy. US Pharma may be forced to do the same—planned US healthcare reforms will prevent drug companies from blocking the release of generic drugs onto the US market [2]. As there are also plans to allow US consumers to import safe drugs from other countries, it will be interesting to see how far the new American government goes in controlling pharmaceutical drug pricing. Continental Europe is attempting to control healthcare spending; most countries are increasingly reliant on the evaluation of the relative effectiveness and cost-effectiveness of drugs to guide reimbursement decisions. Germany, for example, has recently introduced this type of evaluation into the legal

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Figure 1: Spectrum of Regulatory Medical Writing



IB, Investigator's Brochure; CSR, Clinical Study Report; PSUR, Periodic Safety Update Report; PIP, Paediatric Investigation Plan; RMP, Risk Management Plan; DSUR, Drug Safety Update Report; CTD, Common Technical Document; NSAID, non-steroidal anti-inflammatory drug.

Examples given for Document Type, Therapeutic Area, Disease (or Condition), Drug Class (or Drug) and Field are non-exhaustive.

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framework of its healthcare system [3]. We now also see sophisticated, and often unsafe, counterfeit copies of world-leading drugs made in China, flooding into the UK via National Health Service (NHS) pharmacies. In 2008, fake consignments into the UK included the antipsychotic Zyprexa, and more than £3 million of heart disease and cancer medicines were intercepted in the first 10 months of the year. The high price of medicines in the UK means cash-poor NHS Trusts are vulnerable to offers which really are too good to be true [4]. With availability of generics, pharmaceutical drug pricing and counterfeit medicines such topical issues, it is hard to imagine that industry and governments won't reconsider current policy. Resulting price reforms on either side of the Atlantic will impact the industry. It may be too simplistic to speculate that drug development may accelerate to maximise returns sooner, but for those of us concerned with workflow within the industry, it makes sense to watch these areas closely.

The advent of personalised medicine could be another potential watershed. As the implications of decoding the human genome become clearer, the potential to develop more targeted medicines based on the personal genetic map of the patient cannot be ignored. Clinical programmes could be redesigned to develop therapeutics for the micro-markets of receptive subpopulations instead of the existing blanket approach—and this may have untold impact on the way the industry brings new products to market.

So, economic and political change combined with potential new approaches to drug development and a constantly evolving regulatory environment make for a heady mix! In changing times, flexibility is paramount and we should be encouraged to arm ourselves with knowledge and prepare to be responsive to market needs. The experiences of colleagues in some of the more off-beat regulatory corners are worth considering. The area of early phase (I and IIa) clinical drug development is ably introduced by freelancer Bidy Schilizzi, who describes pharmacokinetic and pharmacodynamic reporting and the associated available training and guidelines. Iain Colquhoun, a respected consultant in the field of devices and WEU medicines, introduces the concept of demonstrating the required safety and efficacy of ubiquitous WEU products through the humble literature review, when seeking marketing authorisation in a new regulatory region, because of the absence of clinical and pre-clinical studies. It is also relevant to note that devices and drug-device combinations are now being held to higher standards of Good Clinical Practice (GCP) compliance than has previously been the case, and are therefore likely to generate more regulatory submission documentation. Christiane Breithaupt, a regulatory affairs associate experienced in the field of orphan drugs brings to our attention diseases justifying orphan drug status and the associated regulatory environment which ensures the continued development of medicines for rare conditions, despite low economic returns. Claire Gillow, a medical doctor writing for the specialist imaging CRO, Perceptive Informatics, describes the role of medical writers in independent imag-

ing review. These contributors highlight the tip of the iceberg when it comes to the available wealth of interesting regulatory writing fields, should we choose to venture onto less well-trodden paths.

So whatever your personal journey, and your view of our changing times, a good stop along the way would be to attend the May 2009 Ljubljana EMWA Conference. Many of the accredited courses and special themed events, including seminars and discussion forums, deal with regulatory areas as wide-ranging as Paediatric Investigation Plans (PIPs), medical writing for vaccines, pharmacogenetics, devices, orphan drugs, advanced therapeutic medicinal products, and risk management. There will also be representation from the regulatory agencies and authorities, including The European Medicines Agency (EMA), the US Food and Drug Administration (FDA) and the Association of the British Pharmaceutical Industry (ABPI). This agency perspective is key for us as a group because unless our writing activities are appropriately directed to support product labelling in the eyes of the assessors, then it opens to question the purpose of what we do.

I hope that in drawing together this selection of articles, and highlighting the range of exciting possibilities in an ever-changing world of regulatory writing, I have provided a taster to whet your collective appetite. See you in Ljubljana!

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**Tip for English grammar and word usage resource**

The Grammar Curmudgeon site operated by Rich Turner at <http://www.grammarmudge.cityslide.com/Home.html> is a good resource for writers. The site includes sections on grammar, words and usage, and it has links to articles and to sites where writers can contact other writers or discussion groups.