Regulatory Writing

The essence of regulatory writing as defined by its jargon

Section Editor:

Greg Morley
greg.morley@docuservicio.com

In this issue of *Medical Writing* dedicated to regulatory writing, many of the articles provide some glimpses of the day-to-day problems and dilemmas faced by regulatory writers. It is hard, however, to describe the essence of regulatory writing in a succinct and comprehensive fashion. For my column in this issue, I have provided a glossary (by no means exhaustive) of some of the more common terms used by regulatory writers, with an description of what they mean in the context of day-to-day working life. My hope is that through describing the way jargon is used by regulatory writers, I can transmit a feel for the less intangible aspects of the job.

Alignment	A submission contains many different documents and components, authored by many different people. It is important (and not always easy) to ensure that these convey the same key messages, that is, that they are aligned.
Backburner	The first of the entries related in some way to time management. At a given time, a regulatory writer will usually have several projects at various stages of completion. It is important to *prioritise*. Projects that are not on a *critical path* can be relegated to the backburner.
Best practice	In an ideal world, we would always follow procedures that through collective experience have been shown to produce the best results (best practice). Most of the time, this is the case, but sometimes the singularity of a project, or extremely tight timelines might require a certain deviation from best practice and demand a *workaround*.
Critical path	A project where there is absolutely no slack in the timelines is said to be on a critical path. Usually, this means leaving other projects on the *backburner* to ensure that the project on a critical path is completed successfully.
Debrief	When a hectic project comes to an end, especially one that has not gone entirely according to plan, a debrief is often held to identify mistakes and discuss learnings from the experience in the hope that the next project may go more smoothly.
Downtime	Work will often come in fits and starts, and often there will be gaps in your work schedule. Ideally, this downtime should not be spent just reading the newspaper online but rather filling in knowledge gaps, or possibly *frontloading* projects on the *backburner*.
Drop-dead date	The absolute last date when a project (or project component) should be completed.
Escalate	A large part of a regulatory writer's job involves resolving conflicts within a *team*. When, despite your best and most creative efforts and *workarounds*, the conflict remains, you may hear mention of escalation, usually to senior management for arbitration. You can also threaten to escalate, for example, if a reviewer repeatedly fails to provide timely review comments.
Fit for purpose	It seems stating the obvious that documents should be fit for purpose, that is, the content, level of detail, and presentation are sufficient for the particular purpose of the document. Some might say that dotting all the i's and crossing all the t's might be too much effort for too little reward (providing of course the actual data are accurate). The threshold between what is fit and unfit for purpose is, however, subjective and poorly defined. If in doubt, it may be best to dot those i's and cross those t's if not doing so may detract from the authority of the document.
Frontloading	As mentioned in some other entries, *timelines* can often be tight and so frontloading is common practice to alleviate stress later on down the line. For example, as Sam Hamilton explains (see p86), in a clinical study report (CSR), the patients and methods section, or front-end of a CSR, is largely independent of the actual results and so can be written before the final statistical outputs are available. But too much frontloading can be a waste of precious time if the work has to be thrown away, and can also be dangerous if a lot of fiddly adjustments are needed later (with the risk that they are overlooked).
Heads-up	Reviewers of regulatory documents are often busy people involved in many projects at the same time. A heads-up e-mail is a courtesy to them to help them plan their schedule. Personally, I do not think these should be sent too early (except in holiday season) as people might forget and the *timelines* may well shift.
Heavy lifting	I have heard this term used to refer to work that is fairly straightforward, but quite repetitive and time-consuming (and boring). An example would be putting together tables. Once this work has been done, you can then move on to more creative tasks such as writing the wrap-around text and adding the interpretation.

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In the loop	To keep someone informed of the situation. The number of people kept in the loop is a judgement call, though. There are only so many threads that someone can reasonably follow, and too many mails can create excessive background noise. Often, keeping someone in the loop is merely a question of covering your back. If something goes wrong, you can say 'well you were copied into the discussion'.
Mentor	Regulatory writing is not something that you can study at university (though there are some medical writing courses that include aspects of regulatory writing). And of course, the workshops on offer at EMWA conferences are a valuable source of knowledge and an opportunity to share experience. But the fact remains that most writers need to learn on the job and there really is no substitute for direct experience. In this respect, it is common practice for senior medical writers to mentor their more junior colleagues.
On-boarding	On-boarding refers to the process of integrating new writers into the team and helping them learn not only about medical writing itself but also the idiosyncrasies of the company. In many cases, this will involve the figure of the *mentor* as an efficient way to bring a new recruit up to speed.
Prioritise	An important aspect of time management is knowing what project should take priority. The equation can be a complex one and involve not just the *timelines* themselves, but also the consequences of missing a deadline.
Pushback	If someone (an internal reviewer within the company or perhaps an external reviewer in a health agency) demands actions perceived as being unreasonable, you (or the team depending on the context) may decide to pushback. This often requires tact and diplomacy (and occasionally *escalation*).
Rapport	A big part of regulatory writing is negotiating compromises between different *team* members. Your job will be easier if you have managed to build up a good rapport with the team.
Sanity check	Ideally, we would like all projects to go smoothly with no mad rushes at the end. Meanwhile, in the real world, substantial changes may be made late in the process. In such cases, another look at the document after a good night's sleep and a rest (sanity check) may be highly desirable to pick up any fatal flaws.
Team	A team is a group of people assigned to a particular project, each with a particular responsibility or competency (e.g. safety scientist, toxicologist, regulatory partner). In a big pharma company, the team may be at different sites and in different time zones. Most documents a regulatory writer will work on require contributions from different team members, and many will be developed in a team context with meetings or teleconferences to discuss the salient points and resolve issues. As a medical writer, it helps to have a good feel for team dynamics and a good *rapport* with team members.
Timelines	Timelines are an omnipresent aspect of medical writing. Many regulatory documents come with very specific deadlines, and the route to completion will involve many milestones. Developing timelines to reach those milestones, taking into account document complexity and availability of *team* members, is not an exact science and another aspect where experience is important.
Touch base	This jargon for contacting someone often has certain connotations. Thus, 'I just wanted to touch base about … ' can sometimes be translated as 'you haven't forgotten about me have you/you will provide those comments won't you … ?'.
Workaround	In an ideal (though ultimately rather boring) world, everything would go smoothly and according to plan, and we would follow *best practice*. The real world often throws up problems that need a certain creativity (thinking outside the box). The resulting workaround recognises that not everything follows the ideal pattern, while still striving to adhere as closely as possible to *best practice*.
Work–life balance	The concept of work–life balance is not unique to regulatory writers, of course, but I have heard it mentioned from time to time, usually during the *debrief* of a particularly tortuous submission with tight *timelines*. On average though, my impression is that regulatory writers enjoy a reasonable work–life balance.