



## SOPs—Pitfalls in the process

by Ruth Whittington

Here at Rx Communications we were recently audited by one of our client companies, to ensure that our policies and standard operating procedures (SOPs) were sufficient to ensure the confidentiality and security of their data and projects.

I'm pleased to say that we passed with flying colours, but the temporary mayhem induced by the visit reminded me of a previously difficult experience we encountered early on in our existence, that taught us all a very valuable lesson about SOPs, policies and compliance.

At Rx we've always prided ourselves on our processes—the company was founded on systems and processes that we put in place from day one. I had a firm belief in the need for SOPs. The outcome of this belief was that every major company activity, from sales, finances, to project management and quality assurance, had standard procedures for conducting those activities. All written down, logical, approved and in place. All well and good.

We were particularly proud of our procedures for project management of manuscripts. All 108 steps in the production of a manuscript were documented, and all the processes were in place, from file naming to ensure version control, to how to set up a secure and logical filing system, how to work with clients, authors, writers and reviewers to maintain ethical good publications practice, to tracking the article through to publication. We had it all. Quite unusual for such a young agency, and we used it as a selling point with our clients.

Then in one nightmarish moment, our complacency was rocked irrevocably by accusations of ghost-writing, that reverberated throughout the industry. Wrongly, as it happened—but as we tried to defend ourselves and protect an innocent author, we found to our horror that having our lovely SOPs had failed to protect us.

So, with all these wonderful quality procedures in place, how can things still go so radically wrong? In this article, I want to explore why SOPs are important, how to write them and put them in place, and how to ensure, having gone to all the trouble to produce them, that they actually work as they should.

(You may think, perhaps, as a one-man or woman band, i.e. a freelance writer without anyone else to manage or support, that SOPs are not for you. After all—you are the one who knows what you are doing, you don't need it written down. However, more and more pharma companies are looking for the reassurance that their data are safe, that you have good practices in place, and that you have the quality

controls they need. How better to do this than to have policies and SOPs in place that clearly demonstrate your commitment to their requirements? Another useful reason is as a double check that you are maintaining vigilance. It is very easy, with children, other distractions around and urgent deadlines to find your standards slipping. A written document can be an excellent reminder and safety check to ensure you are still on track.)

### What is an SOP?

Here is the Wikipedia definition of an SOP as at October 2008:

*'A standard operating procedure is a set of instructions having the force of a directive, covering those features of operations that lend themselves to a definite or standardized procedure without loss of effectiveness. Standard Operating Policies and Procedures can be effective catalysts to drive performance improvement and improving organizational results. Every good quality system is based on its standard operating procedures (SOPs).'*

Thus, an SOP is a written step-by-step process for achieving something. At Rx, our SOPs start with a statement of what the SOP is, what it sets out to achieve, who should use it, what situations it applies to and when it should be used.

Here are some pointers you may find helpful in drafting your own SOPs.

1. Have a clear idea of what the SOP needs to achieve.
2. Have some form of approval process and version control—in our company, we have an SOP for creating SOPs! This may be over the top, but it prevents people who are somewhat too enthusiastic about control, from putting draconian measures in place. Another useful technique is to keep the old SOPs accessible; i.e. keep a document history. This not only allows people to see what has changed from the previous version, but can also help prevent the wheel being reinvented.
3. Use a template to keep consistency. You can see ours in the example SOP given below: Figure 1 = SOP PM01. We have based ours on :
  - a. What the SOP covers
  - b. The rationale for the SOP
  - c. Who is responsible
  - d. The SOP procedure
4. Where possible, clarify processes with flowcharts and diagrams. Most of our publications processes have these, because with complex and lengthy procedures it is much easier to follow on a flowchart.

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<b>Operating Procedure</b>		
Title: Project Allocation and Handover		Ref No: PM 01
Created by: XXX XXXX	Approved by: Ruth Whittington	Date:
Supersedes:	No of Pages : 3	
<p><b>This SOP Covers:</b></p> <ul style="list-style-type: none"> <li>▶ Rationale for project allocation and handover of projects from business development to project management</li> <li>▶ Who is responsible for project allocation and handover</li> <li>▶ Procedure for project allocation and handover</li> </ul> <p><b>Rationale</b></p> <p>The appropriate allocation of projects among the project management team (project managers, senior project managers, project leaders, project directors etc.) is imperative to ensure the efficient functioning of the project management team, client satisfaction, and to avoid any conflicts of interest (see separate SOP on Conflicts of Interest) when the company has been tasked with working on projects in similar therapeutic areas/indications involving competitor companies/compounds. The effective handover of new projects helps ensure that projects are managed in a manner that meets overall budgets, timelines, and quality targets, and gives the client a seamless experience.</p> <p><b>Who is Responsible?</b></p> <ul style="list-style-type: none"> <li>▶ The allocation of new projects is done after a team discussion involving the Head of Global Business Development, Project Director, Project Leader, and any other relevant members of the company including possible project managers of the new project.</li> <li>▶ Subject to full agreement among the team, this same team is responsible for the effective handover of the project.</li> <li>▶ The CEO of the company has ultimate responsibility for the allocation and handover of projects.</li> </ul> <p><b>Procedure</b></p> <p>Upon the emergence of a new project...</p> <ul style="list-style-type: none"> <li>▶ The Project Leader would consider the following in their preliminary decision <ul style="list-style-type: none"> <li>● Overall project workload of individual project managers available to take on new projects</li> <li>● Potential conflicts of interest</li> <li>● Experience and suitability (and ability) to manage the project</li> <li>● Training requirements (if any)</li> </ul> </li> <li>▶ The Project Leader would discuss his/her findings and suggestions with the team.</li> <li>▶ The CEO ratifies the decision of the team.</li> <li>▶ The project is allocated following a comprehensive briefing and handover to the project manager by the project leader and other relevant members of the team.</li> <li>▶ The comprehensive briefing and handover of new projects could involve any number of the following items being handed over to the project manager <ul style="list-style-type: none"> <li>● Approved proposal</li> <li>● Project brief</li> <li>● Client's request for proposal</li> <li>● Notes on discussions prior to project approval</li> <li>● Relevant call reports/meeting minutes</li> <li>● Datapackage(s)</li> <li>● Verbal briefing</li> </ul> </li> <li>▶ As a general rule, unless there is a conflict of interest, new projects for new clients are managed by the project leader. This is to ensure the development of a good client-agency relationship for future projects.</li> </ul>		

**What is a Policy?**

One thing an SOP is NOT, is a policy. This is an interesting distinction, and one that we learned to our cost. Here is the Wikipedia definition of a policy:

*'A policy is a deliberate plan of action to guide decisions and achieve rational outcome(s)..... Policies can be understood as political, management, financial, and administrative mechanisms arranged to reach explicit goals.'*

A policy gives the overall understanding of the company ideals and culture—it should be consistent with your vision

and mission and objectives. For example, a good publications policy for an agency or freelance writer should be comprehensive, covering all types of publications, clear, consistent with any important guidelines and should cover all contingencies—author relationships, data and security issues, what the agency standpoint is if the clients disagree with the authors, for example, dealing with journals etc. The important issue is that it reflects your ethics and standards, and guides the employee to the appropriate SOP that enables them to operate within those standards.

## SOPs—Pitfalls in the process

**The Pitfalls**

So what can go wrong? We had made two errors in our thinking—firstly we had assumed that our ethics and standards were clear in our SOPs so that we didn't need a policy document. This was a mistake, because even if the SOP has a clear rationale, without a policy document to tie it together an employee doesn't get the sense of the bigger picture, and will not look beyond the SOP to apply the principles in other areas of work. Our second and most important error was that we didn't monitor the use of the SOPs sufficiently.

It can be easy, when getting experienced staff from another agency, to assume that they are familiar with the processes and procedures you use, particularly if they appear confident and competent. And of course, when you hire staff it is because you are in a very busy period, so if they appear to know what they are doing, the tendency is to leave them to it. In our own case, we had also brought in staff with roles that we had traditionally out-sourced, and this again caused a problem. It is so much easier to just ask someone sitting at the next desk to assist, rather than go through formal channels and thus remember the other steps that are required first.

And what happened to our SOPs? Left in their folders, where they had been since the induction process for new employees. Unmonitored, we had no way of ensuring that they had been read, let alone being sure they were being followed. Without a policy document as another safeguard, our staff members had nothing else to prompt the right actions.

Simply having yet another company document does not necessarily provide an additional safeguard. Having a policy is very useful, and in the first flush of enthusiasm when a new employee reads all these documents, hopefully some of it stays in the memory sufficiently long enough to prompt further exploration of procedures when a new situation arises at a later date. It is difficult enough for us to ensure that we have read and are aware of the SOPs themselves, although one can usually only achieve a "certain degree of familiarity". The only real way you can find out if your staff are adhering to your SOPs (to an acceptable level) is to do spotchecks.

So we have instituted a system that when I sit in on project financial review (which in our company happens at the beginning of each month) I spend some time flicking through files and asking questions to ensure the staff are adhering to SOPs. This doesn't happen as often as I would like, but generally once a quarter it becomes quickly clear who does and who doesn't fully understand and follow the policy or SOPs.

**The aftermath**

There are always silver linings to clouds, I find. Following the ghostwriting debacle, we developed a good publications policy that guides our company actions. Is it foolproof?

Probably not, but we have established an excellent review process, and as we continue to work with our clients in this area we endeavour to strengthen its application. And while we can't take credit for the entire resurgence of interest in good publications practice throughout the industry, the experience has vastly improved the adherence of agencies and pharmaceutical companies to the standards set by CONSORT and ICMJE. Sadly, it still appears that journal editors and non-industry authors are lagging behind in consistent application of these principles, but as a whole I am optimistic that publications practice is becoming more ethical.

We have also set up an SOP review process that should stand us in good stead, and are slowly putting monitoring sheets and processes in place. In these straitened times it is difficult to find the time for such housekeeping among all the more client-oriented activities, but we do our best.

And another good point—we are so concerned with publication policy and management, clients are using us to help set up their own systems. After all—there is nothing like bitter experience to reinforce good behaviour.

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**False increase**

I seem to be alone in not seeing anything increasing here, just a higher proportion in the USA:

*An estimated 25% of adults aged 50–64 years suffer from at least one chronic illness in the UK (Meier, 2000), a proportion which increases to 34% in the USA (Smith 2006). Why not just: 25% of adults aged 50–64 years in the UK (Meier, 2000) and 34% in the USA (Smith, 2006) are estimated to have at least one chronic illness (if you can bring yourself to start a sentence with a percent! If not, you could say a quarter and one third!). If you want to stress the idea of 'more in the USA', then you might try: More adults aged 50–64 years in the USA (34%; Smith, 2006) than in the UK (25%; Meier, 2000) are estimated to have at least one chronic illness. Whatever, as far as I am concerned, nothing is increasing here. We just have two figures, one higher than the other.*

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