



Project management in medical publication writing: A less explored avenue in pharmaceutical companies and clinical research organisations

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Abstract

Drug development forms the core of the pharmaceutical industry. Medical writing is a key function in pharmaceutical companies and clinical research organisations that works on scientific publications and regulatory dossiers. Regulatory writing steers the drafting and submission of regulatory dossiers and safety reports to health authorities; medical publication writing on the other hand deals with scientific publications such as manuscripts, abstracts, presentations, and posters. Project management is essential for the expedited execution and seamless delivery of publication writing projects with a quick turnaround time. End-to-end project management of publication writing projects on the lines of five-stage process of the Project Management Body of Knowledge (PMBOK) is discussed in this article.

Introduction

Medical writing is a diverse field originated from the need of pharmaceutical companies to have a support function that works exclusively on regulatory submissions and commercial scientific communications.¹ This function is responsible for the analysis, interpretation, and dissemination of scientific information.² Regulatory writing steers the drafting and submission of regulatory dossiers and safety reports for health authorities; publication writing (PW) on the other hand deals with scientific publications, such as manuscripts, abstracts, presentations, and posters and falls under commercial writing.³ PW is regulated by many publication-specific guiding principles, such as good publication practice (GPP), recommendations of the international council of medical journal editors (ICMJE), consolidated standards on reporting trials (CONSORT), the committee on publication ethics (COPE) guidelines, and many others.^{1,3,4,5}

With new stringent trial disclosure policies and an industry-wide obligation to submit trial results with medical importance for publication, the importance of manu-

script publication has increased. The publication of drug research in reputed journals and at congresses increases the impact of the results in the scientific community and is a major channel of communication of scientific advances to a wide range of healthcare providers.^{1,2} A staggering number of scientific publications are published each year, with scientific output doubling every nine years.⁶ Many well-known universities across the globe, such as the John Hopkins University,⁷ the University of Chicago Graham School,⁸ and the Massachusetts Institute of Technology⁹ to name a few, have already launched courses and curriculum on medical publication/science writing and editing. Many universities even have a department dedicated to scientific publishing that keeps track of all publications and supports their drafting and editing. Nowadays various international research institutes and government agencies fund academic research with potential, with a component of the grant allocated for publication support.^{1,2}

McGuigan and Russell¹⁰ noted that the scientific, technical, and medical segment of the academic journal publishing industry generates more than US\$19 billion revenue globally. Scientific publication has increased

rapidly with the advent of highly sophisticated publication planning tools such as PubSTRAT™ (from Sylogent) and DataVision™ (from Envision pharma group). Publication planning tools have revolutionised the publication industry by accelerating the planning and execution of publication projects.^{1,2,3,6}

All these particulars illustrate that medical PW is emerging as one of the most important departments in pharmaceutical companies, publication houses, and clinical research organisations (CROs). Due to the huge expenditure of time and money in addition to regular expenses such as research and manufacturing, many pharmaceutical companies outsource PW work to CROs or pharma knowledge processing and outsourcing (KPO) companies. Irrespective of the type of company, there is always a requirement to have set processes in place for the seamless execution of a project, which brings the principles of project management into the picture. Challenges faced in the execution of PW projects are unique and different than those faced in conventional regulatory medical writing. In this article, we discuss project management in the PW department of a pharmaceutical company or a CRO/KPO.

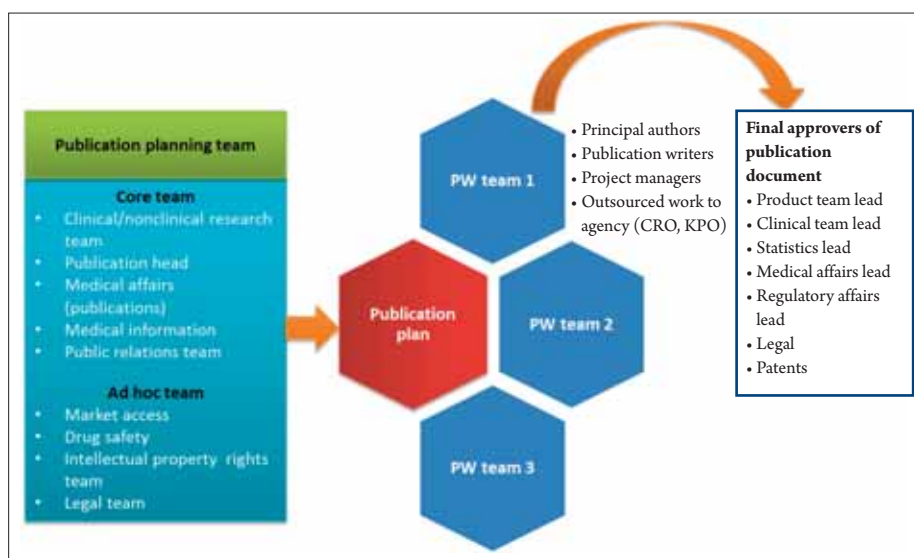


Figure 1: Publication writing team structure Abbreviations: PW, Publication writing; CRO, Clinical research organisation; KPO, Knowledge processing and outsourcing Note: PW team 1, 2, 3 represents PW teams working on various deliverables/projects.

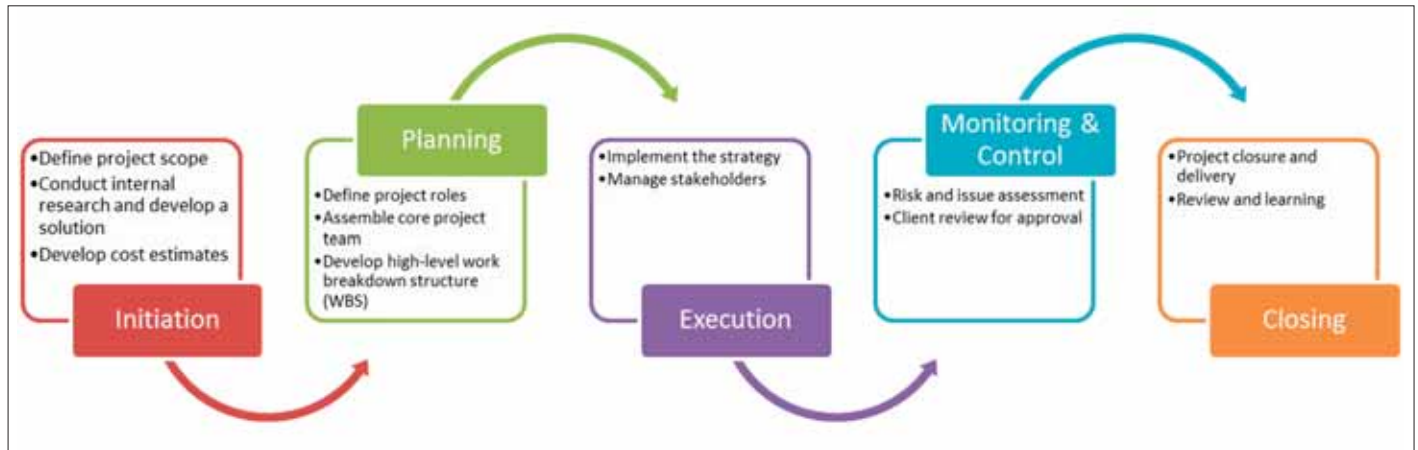


Figure 2: Implementation of project management based on PMBOK framework

Project Management in Medical Publication Writing in line with the PMBOK Framework

Before discussing the actual process of project management in PW, let us first understand the structure and function of a PW team in a pharmaceutical company or CRO. A PW team comprises trained professionals who have higher degrees in the life science domain, including, but not limited to, pharmacy, medicine, and clinical research. The schematic depiction of the working of a PW team is shown in Figure 1. The structure of a PW team may however vary depending on the functionality and size of the organisation.^{1,2,3}

We propose a process of managing a PW project in line with the five process groups recognised in the Project Management Body of Knowledge (PMBOK) published by the Project Management Institute (PMI).¹¹ Among the many different deliverables in PW projects, most frequently encountered are abstracts, posters, and manuscripts. Development of any medical publication document can be divided into five process groups: Initiation, Planning, Execution, Monitoring and Control, and Closing (Figure 2).¹¹

Initiation

Publication planning is a key aspect in the project management of PW. A publication plan is developed by the publication steering committee and scientific publication team, with the involvement of the publication lead and writers. The publication plan is developed in line with the drug development and product life-cycle by considering

evaluations such as the needs assessment, and internal and external gap analyses. The publication planning team plans publications at every stage of drug development and also based on the medical queries they receive at the medical information management department.^{12,13}

Project management in medical PW begins with the definition of the objectives and scope of the project. While pharmaceutical companies have a publication plan¹² ready as part of a drug's development, project management of a PW project in a CRO varies in the processes followed. In the case of CROs, the project is understood by communicating with the client (usually a pharmaceutical company or other service provider agency) and the drafting of a statement of work or a project charter. This is often achieved by conducting a kick-off meeting following a formalised handover from business development to operations. The very first step to initiate the project is requirement gathering, where open-ended questions are asked to determine the project specifications. For example, to develop a manuscript, the following particulars can clarify project specifications: author documentation (debarment, legal agreements with external authors, authorship invitation), availability of data sources (reports, existing publications, study protocol, statistical plan, or any other data source), the need for a comprehensive literature search (important for reviews and meta-analyses), quality control (data and editorial checks), and the number of review cycles.^{14,15} In the case of a CRO project, the scope should be discussed in great detail

with the client so that the expectations of both parties are aligned. For example, if the CRO is requested to use the client's standard operating procedures (SOPs), they should be analysed to see if they will affect the time management aspects of the project. After the scope is defined and understood, internal research and discussion are conducted and a solution is devised. Internal team meetings are arranged where the project manager and medical writers discuss how to proceed with the project. The strategies and processes to be followed for the timely delivery of the project are defined, i.e. the project is set up in a publication planning tool where timelines and stakeholders for each draft stage (initial draft, first draft, second draft, and final draft) of the deliverable (manuscript/poster/abstract) are defined.¹⁶ After the requirement gathering, internal research and preparatory activities are carried out to determine the deadline for each milestone. This includes the sharing of a content outline and getting its approval from the client. Cost estimates for publication planning in pharmaceutical companies are prepared by the publication steering committee and the finance department. In CROs, they are usually prepared during the business development phase while negotiating with the client. Estimated project hours and billable hours per resource are taken into consideration to develop a cost estimate.^{11,12,13}

Planning

The planning stage begins once all project specifications are defined and a unique solution has been proposed. The first step is

Pharma company	Brand Name	Study ID (Generic name)	Deliverable	Write	Subject matter expert reviewer	Quality reviewer	Start date	End date	Actual project hours
A	X	1A	Manuscript	P	CD	DE	1-Jun-15	12-Aug-15	105
B	Y	1B	Congress poster	Q	GH	HI	7-Jun-15	28-Jun-15	64
C	Z	1C	Scientific abstract	R	LM	MN	2-Jun-15	11-Jun-15	18

Table 1: An example of a project tracker sheet

Tasks	Technical Assistant	Project Manager	Publication Writer	Review Team	Authors	Approvers	Graphic Designer
Requirement gathering and project set up	R	R, A	C, I	O	C	O	O
Kick-off and author documentation	R	R, A	R, I	O	R, C, I	O	O
Drafting and comment addressing	O	A	R	O	C	O	O
Review of the first draft	O	A	I	R	R	O	O
Design work; creating tables, figures, layout, etc	O	A	R, C	I	C, I	O	R
Review of the final draft	O	A	I	R	R	O	O
Final approval	O	A	R	O	I	R	O
Submission	R	A	A	O	I	I	O

Adapted from: Dubois B. Fostering collaboration. *The Write Stuff*. 2011;20(4):219-21.

Abbreviations: R, Responsible; A, Accountable; C, Consulted; I, Informed; O, Omitted from the loop.

Note: the lead statistician is generally listed as an author; this matrix may change as per organisation structure and its requirements

Table 2: An example of a responsibility assignment matrix for writing a manuscript

the assignment of project roles, which can be achieved based on the skills documented in the work profile of the writer and the writer's position in the organisation. A writer's work profile should be well categorised with regard to their competencies, prior experience, and their therapeutic area expertise. Tasks such as complex manuscripts, manuscripts, or posters with limited data sources, review articles, and primary manuscripts can be handed over to a senior publication writer who has ability to interpret statistical data whereas the task of drafting an encore abstract or poster can be given to a junior publication writer.¹⁷ In the case of CROs where there are no dedicated project managers, the publication lead might work as a writer-cum-project-manager and manage internal and external communications. He/she also has to ascertain if the contribution of assistant teams, such as publication technical support (handling the publication tracking tool and other technicalities) or the graphic design team, is needed, and if yes, to what extent. The availability of resources with the required skills at a given time can be tracked using

online time management tools and a common project tracker sheet.^{11,17} An example of a project tracker sheet is provided in Table 1.

The availability of full-time employees should be assessed quarterly as to whether there is a need to allocate work to freelancers, other agencies, or vendors.¹⁷ Overall availability is calculated based on the number of project and non-project hours. Non-project hours include employee leave and activities such as skillset training, self-learning, corporate activities, SOP training, and the maintenance of the staff training folders. While assigning project roles, the project manager should always pay heed to the requirement of a back-up writer as part of the risk mitigation strategy. A back-up writer can do "fire-fighting" in cases where the primary writer is unavailable due to ill-health or other emergent work. Meticulous resource planning is important to the successful implementation of the project, since the definition of the project roles and the formation of the project team are based on this. A responsibility assignment matrix¹⁸ is one such tool to define project roles in

cross-functional/inter-departmental business/project processes. An example of responsibility assignment matrix in a PW project for writing a manuscript is given below (Table 2).¹⁹

Once the project roles have been assigned, a work breakdown structure²⁰ is created where an activity is divided into smaller tasks and these tasks are assigned to team members. An example of a work breakdown structure for writing a manuscript is given in Figure 3 overleaf.

Execution

The execution phase in medical writing includes working in accordance with SOPs to complete a particular task. For PW, it basically involves the drafting of the document, review cycles, performing quality checks, and addressing comments provided by internal and external stakeholders. Sometimes project managers also have to deal with external agencies, giving rise to vendor management. In the case of CROs, vendors could include translation agencies, printing and publishing support vendors, or freelance service providers.

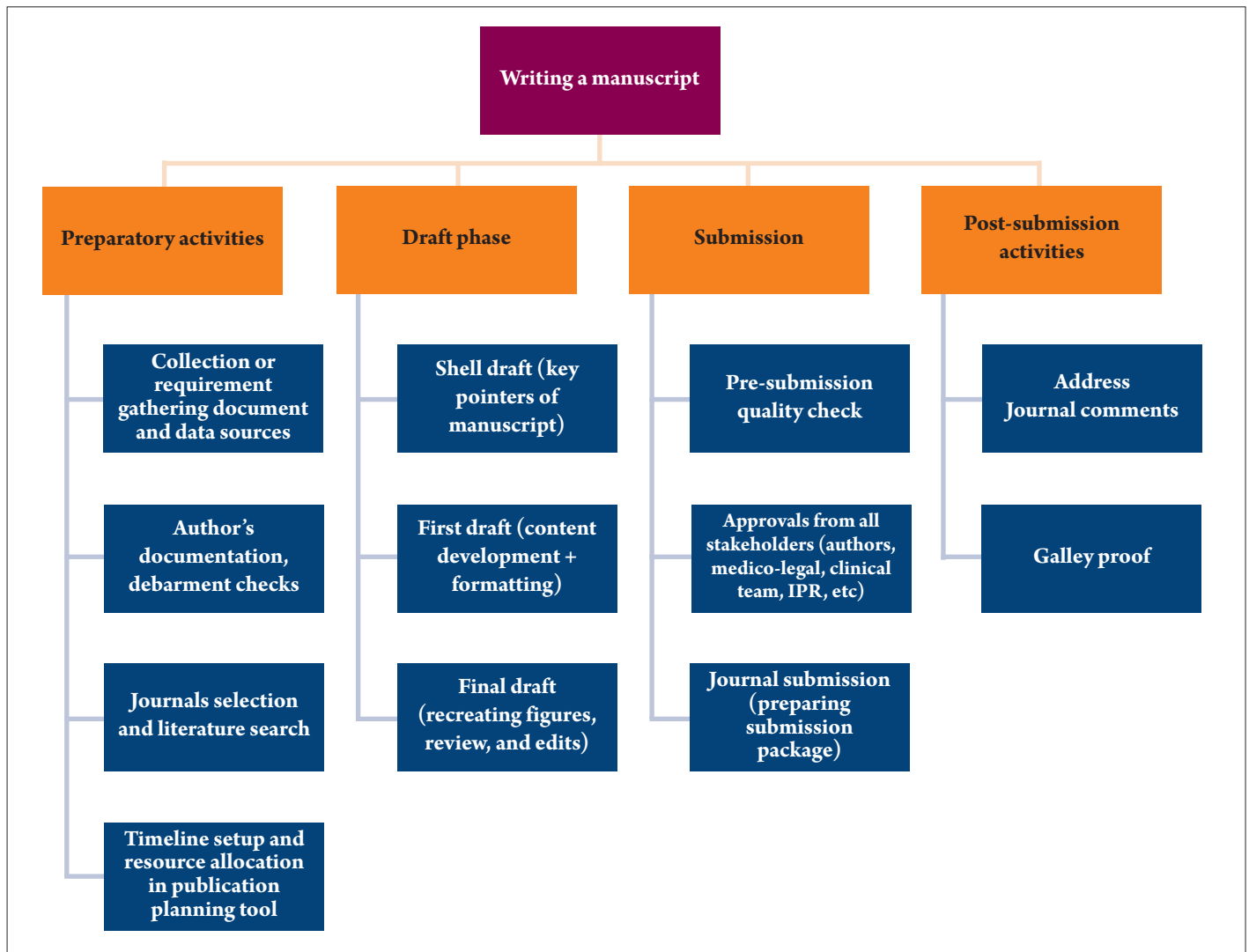


Figure 3: Work breakdown structure for drafting a manuscript. Abbreviations: IPR, Intellectual property rights

Offshore operations management is important for CROs working in different geographical locations all over the globe. Offshore operations are carried out through a global hybrid delivery model considering geographical, cultural, and chronological variations. The project manager drives execution against the plan and has to communicate regularly and openly with the sponsor.^{14,17,21}

We shall now review the important steps in the drafting of a manuscript. Initially, a shell draft is written that includes all important subject matter points in the form of bulleted text for the introduction and discussion sections and text paragraphs for the methods and results sections. Comments requesting input or suggestions to researchers or authors are put in the shell draft. Once the shell draft is approved, the

first draft of the manuscript is written with input from researchers and authors. Once the first draft is written, the scientific content of the entire manuscript is reviewed by the core publication planning team and comments are provided in case of inconsistencies, which are then addressed by the publication writers. Once the first draft is approved, the writers prepare the second draft in accordance with the journal guidelines. The second draft is generally considered to be the final draft; however additional drafts can be made depending on the number of review cycles and project requirements. Stakeholders involved in final approval are the researchers, medico-legal team, intellectual property team, regulatory team, statistics head, and the clinical team head.^{14,17,21}

The line of reviews includes an in-house

review by an internal subject matter expert (SME) and an editor. SME review involves a diligent check of the scientific content, the correct interpretation of the data, important discussion points, tone of the overall message (language should not sound promotional), and the proper citation of references. In the case of CROs, points of contact (POCs) from the sponsor (i.e. the client) will review the content from their perspective. Editorial review is done by the medical editors to check grammar and language. The writer-cum-project manager acts as a bridge during such reviews as they communicate and address comments, meticulously check content, propose solutions, and involve the statistician or main author regarding any queries.

Submission of the manuscript to the journal or conference involves a mock

Deliverable	Risk	Impact	Action Plan
Conference abstract or oral presentation or poster	Difficulties updating results from ongoing clinical trials or late-breaking clinical trial results	Failure to disseminate key results of trial during conference	<ul style="list-style-type: none"> • Publication team should plan pre-presentation meeting with clinical lead to incorporate final data/results
Poster and oral presentation for medical conference	Failure to capture important data due to limits on word count, slide count, or poster size	Poster with no scientific impact, poster does not convey the intended scientific message	<ul style="list-style-type: none"> • Prepare ancillary (back-up) slides in case of presentation • In case of poster, prepare handouts or generate a QR code linked with additional information
Manuscript writing	Minimal data sources provided by study sponsor	Manuscript may lack impact	<ul style="list-style-type: none"> • Ask for credible sources, especially the CSR of the study and arrange a kick-off meeting with the authors to discuss future directions and flow of manuscript
Manuscript writing	Targeting high-tier journal with high rejection rate	Manuscript might be rejected or major revisions suggested by journal leading to delayed publication	<ul style="list-style-type: none"> • Prepare a list of preferred journals with their specifications (impact factor, rejection rate, circulation) from publication planning tools and discuss with authors • Draft a pre-submission query to journals regarding their interest to publish particular research work • Be ready with back-up journals and their submission guidelines <p>Abbreviations: CSR, clinical study report; QR, quick response.</p>

Table 3: Example of a risk register for publication writing projects

submission with the help of the publication technical expert, preparation of a submission package, and communicating with the journal or conference secretariat.

Monitoring and Control

The monitoring and control phase of a project consists of risk management measures and review by the stakeholders. As Murphy's Law says 'Anything that can go wrong will go wrong' and risks are associated with every project. Risk management is one of the most critical aspects of project management. Hence the risk identification and mitigation plan should always be at the disposal of the project manager. It is important to list all possible risks that may be encountered in the project and have an action plan ready so that the risks do not become issues. An example of a risk register is shown in Table 3.^{11,16,22}

Corrective action and preventive action (CAPA) is another approach for managing risks.²³ Corrective action aims at correcting

an existing non-conformity and to avoid recurrence of the same non-conformity. Corrective action comes into the picture when issues have been logged or risks have been identified during audit findings, major client reviews, etc. Preventive action on the other hand aims to avoid the initial occurrence of non-conformity by proactively implementing improvements. In brief, CAPA acts as a solution to the issues or risks encountered in the light of integrated quality management. Gantt charts can be used to note employee engagement and to track the timelines of the project. One more way of tracking deviation in the process and keeping corrective measures ready is by employing a fishbone analysis (Ishikawa diagram). A fishbone analysis for deviations and their proposed solutions for a PW project are given in Figure 4.

Closure

Project closure involves close-out documentation and review meetings. Close-out

documentation is a final information dossier and includes all the relevant project-related logs, minutes-of-meeting reports, business emails, etc. These documents contain all important project specifications, decisions made, and measures employed, as well as information on the overall course of the project. Important aspects captured in the close-out dossier include risks and issues, project quality, lessons learnt, and an overall analysis underlining achievements made and pitfalls encountered during the execution. From the kick-off meeting to project delivery, many lessons are learnt in each phase of the process, which can be discussed and shared as a group. The mistakes made in the execution of the project and solutions offered therein go into a knowledge base to be used for future reference. Special lessons learnt meetings are arranged to broaden the knowledge and troubleshooting experience of the resources involved in the project.

Preparing a data sheet comprising all

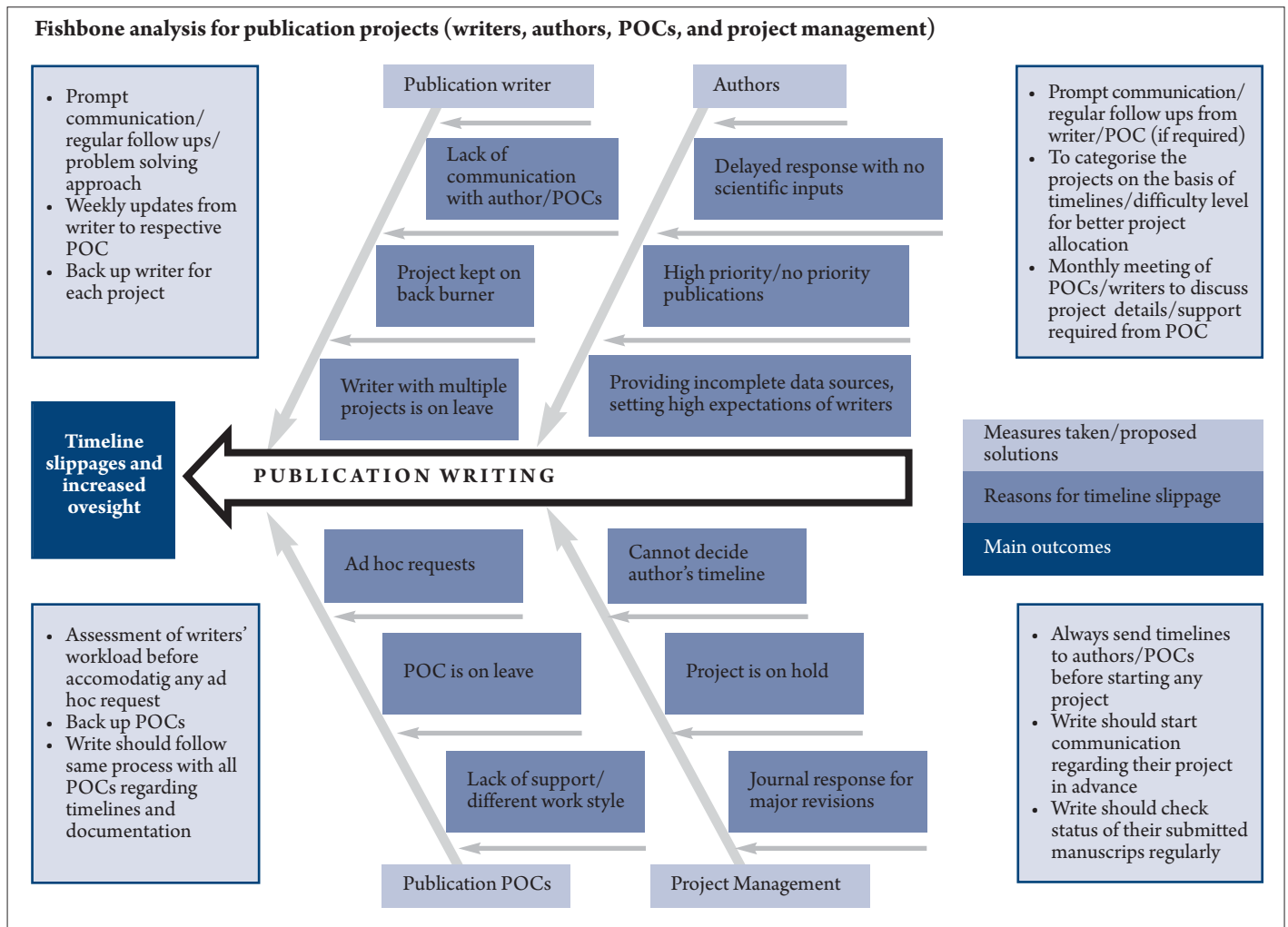


Figure 4: Risk mitigation fishbone analysis. Abbreviations: POC, Point of contact (Acts as a bridge between medical writer and authors and other stakeholders)

detailed information about a project compound (drug), such as the molecule ID, history, generic term, drug class, and pharmacology, safety, and efficacy studies of that molecule, creates a knowledge base, which can be utilised in the future. Closure also involves keeping all documents in an inventory, such as issue logs, logs of project risks and mitigation strategies, and the archiving of the published deliverable.

We have discussed how projects are executed in medical writing organisations. Let us now see the various issues faced in project management. Barriers to effective project management include communication hurdles, a lack of status-reporting measures, a low accountability culture, and conflicts in decision-making. Communication hurdles include language barriers or different interpretations of the intended message. Working with non-English speakers

can pose significant problems due to the incomprehension of or misunderstandings regarding requirements. Services of translation agencies and interpreters can help overcome these issues. The project manager should communicate clearly while interacting with the POCs. The project manager needs to be able to negotiate effectively with vendors and should be endowed with good interpersonal skills. Each resource working on the project should be given ample freedom as well as accountability for the seamless execution of the project. There should be an efficient risk reporting system so that the risks do not become issues. In addition, the project manager should be able to manage resources and resolve conflicts. The behavioural and communication aspects of a manager are instrumental to the progress of the project.^{24,25}

Project Management in Medical Publication Writing: Future Directions

The success of the project lies in the several process improvement methods and diligent contribution of the assigned resources promoting quick and smooth functioning. Process improvement methods can further help expedite project delivery timelines and reduce costs. Capability maturity model integration²⁶ is a sophisticated process improvement plan that can be implemented by pharmaceutical companies as well as CROs in medical affairs or medical writing departments. In the case of CROs, capability maturity model integration appraisal additionally wins the confidence of the client and can help attract new projects and business for service industries. The global hybrid delivery model, a relatively new approach to carrying out project work in

accordance with client specifications in CROs, enables the seamless execution and delivery of a project. It basically involves two working teams, one offshore and the other onsite, which coordinate with the client and each other to give effective output. The lean six sigma initiative is a business improvement strategy that aims to improve team performance by integrated efforts and removing redundancy. This business strategy improves cross-functional teamwork in any process driven service industry and also reduces the cost of poor quality resulting from late delivery, customer complaints, costs associated with misdirected problem solving, etc.²⁷ There have been attempts at harmonising and implementing lean six sigma and PMBOK principles in pharmaceutical organisations.^{28,29} The future of any product, process, or service lies in innovation. Novel and innovative approaches that minimise process hurdles and make project execution smooth and error free are the future ideals of project management.

Conflicts of Interest and Disclaimers

The authors declare no conflict of interest. The opinions expressed here are solely those of the authors and not necessarily those of SIRO Clinpharm Pvt Ltd.

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Never say never! Returning to full-time employment after freelancing

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Abstract

Alison McIntosh successfully operated as a freelance medical writer for 14 years and gave up the 'flexible lifestyle' of a self-employed freelance medical writer to become a full time employee. She has joined a growing band of 'decentralised' office workers and has become an employee of ICON Clinical Research, a full service, world-wide clinical research organisation (CRO). She has stepped from one end of the medical writing spectrum to the other in terms of working arrangement and organisational structure. The skills needed to work for a large CRO align well with those of a freelance medical writer. Whilst major benefits of joining a large organisation have included colleagues to share the workload, and well defined department structures, new company jargon together with the number of standard operating procedures have been a more challenging experience.

I have been a medical writer for the pharmaceutical industry for 20 years. My