

THEME ARTICLE

Advantages and Applicability of a Master Class Series as a Training Model for Mid-Career Medical Writers: Our Experience From the Perspectives of the Manager, Trainer, and Participants

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ABSTRACT

Advancement of mid-career medical writers (MWs) to senior levels requires augmentation beyond the traditional training provided to MWs at all levels. In response to this need, online training and classes taught by more experienced writers in-house, external lecturers, or a mixture of both delivered through didactic presentations should be supplemented with methods that allow for interaction between the trainer and trainees and for a tailored approach.

We therefore designed an interactive, engaging, and dynamic training model that would draw on varied perspectives of colleagues. This Master Class Series was led by an external instructor and was based on a structured critique of regulatory document organization, content, and style. In this article, we share our experience from the perspectives of manager, trainer, and participant.

The Master Class Series was successful in part because of its dynamic content. The participants felt that this training greatly improved their understanding of the broader contexts in which documents are used and their ability to develop coherent documents. Participants further felt that their ability to implement a top-down approach in strategy documents and in applying lean writing principles was enhanced. They all agreed that they greatly benefit from exposure to each other's creativity in solving challenges in data and content presentation and concurred that it is very likely that they would sign up for a course with a similar model in the future. Our experience indicates that a Master Class Series is essential to the training of mid-career MWs.

engaging, and dynamic training model that draws on the varied perspectives of their colleagues was needed. With this goal, we developed a Master Class Series based on a structured critique of regulatory document organization, content, and style. In this article, we share our experience from the perspectives of the manager (AP), trainer (AM), and participant (LB).¹

THE MANAGER'S PERSPECTIVE: WHY WAS MASTER CLASS SERIES FOR MID-CAREER MWS NEEDED?

Hiring mid-career MWs presents various challenges, the greatest of which is the limited pool of experienced MWs looking for a position. Most companies prefer to invest in growth from within because the MW's skills are acquired on the job. For these reasons, promoting people that already know the company culture and its internal procedures provides a significant advantage. However, the advancement of MWs to senior levels requires augmentation beyond the traditional training provided to writers at all levels.

In response to this need, clinical research organizations and pharmaceutical companies dedicate significant resources to developing structured, high-quality training programs for their MWs. Such training programs include classes taught by more experienced writers in-house, external lecturers, or a mixture of both. Classes are often taught online as single or multiple sessions to large groups of participants who do not necessarily know each other and who have varied backgrounds and experience. Generally, such classes are based on a standard syllabus with limited flexibility to accommodate the needs of the participants that might become apparent during the course. They are

What training format is best suited for instilling in mid-career medical writers (MWs) both the knowledge and the mindset they need to become effective and independent? To move writers upward and forward, an interactive,

¹Initials in parentheses refer to the authors serving these 3 roles in the present manuscript. Hence, reference to "I" in each of the 3 sub-sections to this article refer to AP for the manager's perspective, AM for the trainer's perspective, and LB for the participant's perspective.

delivered through didactic presentations with little or no interaction between the trainer and trainees.

As such, this type of training lacks sufficient interactivity and does not allow for learning through participation, engagement, and exposure to others' perspectives—approaches that are well known to have a wealth of advantages. To move senior MWs upward and forward, an interactive, engaging, and dynamic training model that would draw on varied perspectives of colleagues was needed. This is what we set out to accomplish when designing the Master Class Series.

From the managers' perspective, we did not want the participants' experience to be limited to the knowledge of their managers (which they get through other forms of training), nor did we want to take many hours from our project work to develop this Master Class Series. Thus, we chose to invite an external instructor.

The specific goals of this program were to

- provide MWs with the skills and mindset they need to become effective and independent, creating capacity as document leaders,
- enhance their ability to understand and use relevant guidelines,
- develop their holistic perspective of documents in the context of the sponsor's regulatory strategy, and
- help them identify the proper target audiences for each document and write the documents with those audiences in mind.

THE TRAINER'S PERSPECTIVE: HOW DID I DEVELOP AND CONDUCT THE MASTER CLASS SERIES?

I was excited about developing this Master Class Series for mid-career regulatory MWs. My experience delivering half-day and two-day workshops had provoked an interest in working with a small group of MWs over a longer period. I thought that leading a structured critique of their own documents and documents written by their peers was the best method to address the needs of MWs at this stage in their careers. Collaborating on this Master Class Series gave me an opportunity to test this proposition.

I began by conducting a needs assessment. The MW managers and I discussed the skills that they felt these newly promoted MWs could improve. I also proposed qualities and practices that I believe define good regulatory writing.

The managers and I decided on a series of two-hour classes, starting with an introductory session. Each of the four subsequent sessions focused on the review of a single document. The managers felt that 1 session per month was the best timing to keep the participants engaged and focused without detracting from their job responsibilities.

It also gave them enough time to prepare for each session and to incorporate what they learned into their everyday writing.

Over the five sessions, three themes that emerged in the needs assessment were addressed: style, document organization and content, and strategic leadership. In the introductory session, I led a discussion of the guiding questions for this Master Class Series:

- What makes an MW senior?
- How does a senior MW differ from a junior MW?

Or translated to a more practical level,

- What did you not do before that you do now?
- What did you use to do that you don't do now?

Answering these questions led to a lively discussion of all three themes. The introductory session concluded with preparation for the first review session with a few more questions:

- Who are the obvious and not-so-obvious audiences for this document?
- How do these individuals use this document?
- What do they need?

The group ended each document review session with a similar evaluation for the next document type.

Over the four review sessions, the participants and I continued to address the three themes. I designed a structure that enabled us to balance the big picture of documents as long as 100 pages with the finer details of clear, coherent, meaningful writing. The first part was a document review worksheet based on the topics discussed in the introductory session. The worksheet contained 14 questions, including whether the document tells a coherent story and if the key messages are clear. The participants completed this worksheet before each of the review sessions, and I used this same worksheet to prepare myself to lead each session. They also rewrote a short section (one to three pages) of the document, addressing style, content, and organizational issues. They sent me their rewritten sections a few days before the session so that I could lead a discussion of the problems they noted and their solutions.

Discussion of their "homework" inevitably led to brainstorming on how strategic leadership by the MW could prevent and resolve the issues noted. Key skills addressed included meeting planning and conduct, time management, communication, leading the team, and acting as an authority on relevant regulation, guidance, standards, and the needs and expectations of document users.

The Master Class Series was successful in part because of its dynamic content. Teaching mid-career MWs requires a more flexible approach than the static curriculum

appropriate for junior MWs. For example, I noted that many issues raised in the first review session were related to lean writing. Therefore, I started the next session with a short review of the rationale and implementation of these techniques.

THE PARTICIPANTS' PERSPECTIVE: WHAT DID THE MASTER CLASS SERIES DO FOR US?

To capture my fellow participants' experience in a systematic manner, I conducted a survey that solicited their opinions on the Master Class Series and what they learned. The survey comprised 5 open-ended questions and 11 five-level (fully agree, somewhat agree, neither agree nor disagree, somewhat disagree, disagree) questions (Figure 1). The main points are narrated below.

Becoming a senior MW typically requires a number of years in the profession that optimally (but not necessarily) coincide with the accumulated experience in writing regulatory documents. It is also expected that advancement to a senior level occurs after a sufficient exposure to a variety of regulatory documents and the ability to undertake projects with increasing scope of responsibility and leadership. Although the change in title is quick, the transition is gradual with the question, "are we there yet?" frequently occurring.

Much of the learning required for transition to this new proficiency level happens implicitly as the MW gains experience and understanding in the new role. MWs benefit from the experience and leadership of their managers and peers, they learn on the fly, and some are just naturally good at some new aspects of their roles. However, at times, writing a document is a lonely craft because typically projects are written by a single MW. MWs walk our own paths and rarely get the opportunity to discuss the principles, golden rules, and methods; to be exposed to alternative ways of thinking, writing, and leading; or to share the ways in which we are not there yet. This was the starting point for participants in this Master Class Series. We were all fresh senior MWs—with a shared feeling that we were not quite there yet.

The participants' collective experience with the Master Class Series can be boiled down to the following key points:

- We got to have a group discussion led by an experienced professional in an approachable, comfortable, and educational setting.
- Through hands-on writing exercises, we

shared our approaches to writing and tried the newly learned material.

- We were exposed to each other's creativity in solving data and content presentation challenges.
- We learned the techniques of lean writing, immediately implementable in ongoing projects.

Testimonials from Master Class Series participants highlighted these points (Figure 2).

The Master Class Series received highly positive feedback. Despite the differences in experience with the documents discussed, the participants agreed that it improved their understanding of the broader contexts in which documents are used and increased their ability to develop coherent documents. Most participants (80%) fully agreed with the following statements:

1. The training helped with our understanding and implementation of a top-down approach in strategy documents and in applying lean writing principles.

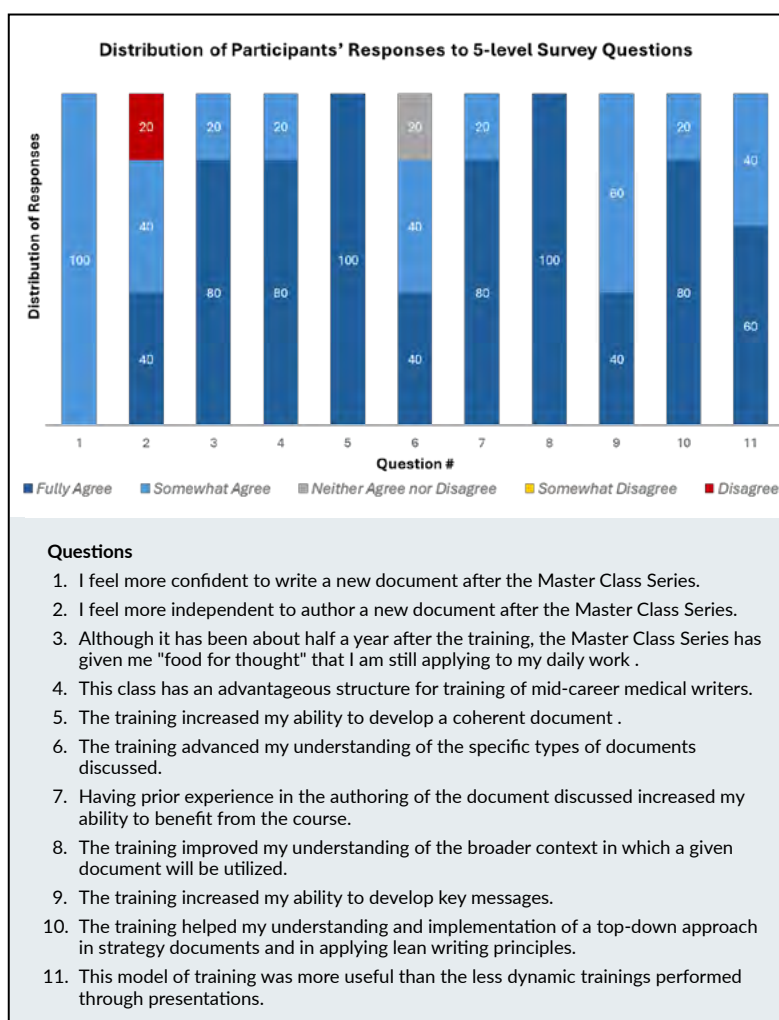


Figure 1. Participant survey results.

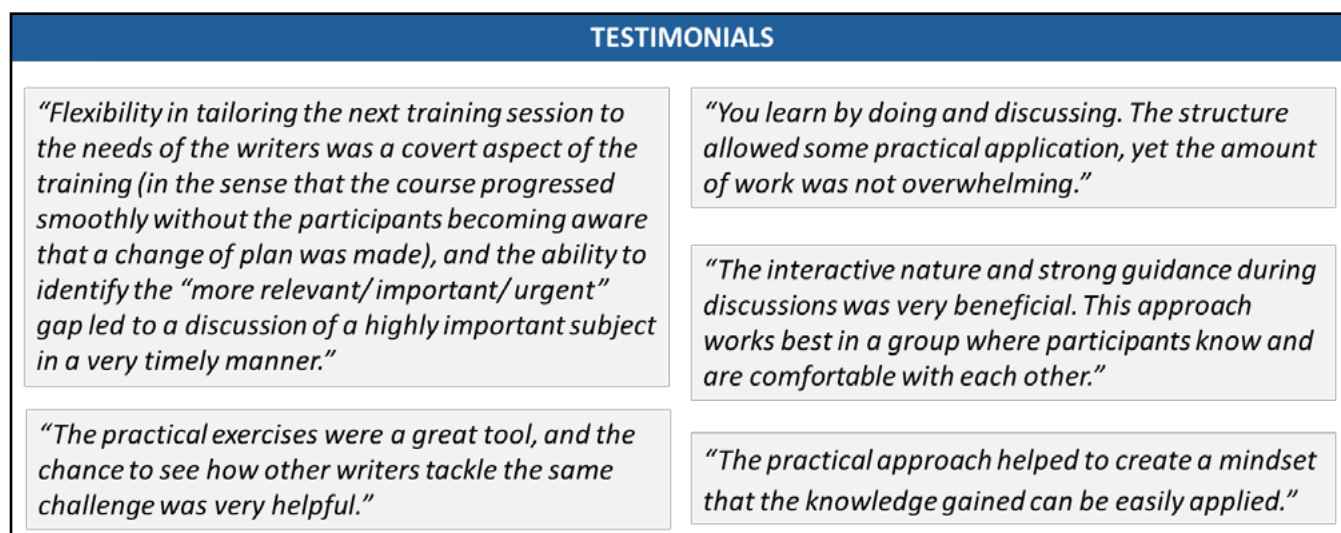


Figure 2. Participants' testimonials.

2. Having prior experience in the authoring of the documents discussed increased our ability to benefit from the class.
3. This class had a beneficial structure for the training of mid-career MWs.
4. Although after the survey was conducted approximately six months after the completion of the class, it has given us food for thought that we are still applying to our daily work.

The participants also felt more confident in writing new documents. All participants agreed that it is very likely that they would sign up for a course with a similar model in the future.

The topics that elicited higher response variability concerned the advancement of understanding of the document types discussed and the feeling of independence when writing a new document. One participant commented, "it seems that introduction to the types of documents was out of scope, unfortunately." These results reflect the impact of previous experience on the potential to benefit from such a class and the importance of providing a side-by-side introduction to the expected content of document types discussed in the Master Class Series for the participants new to such documents.

HOW COULD YOU DEVELOP A MASTER CLASS SERIES IN YOUR COMPANY?

The content, structure, and implementation of such a Master Class Series can be customized to meet the needs of your group. The starting point is a thorough needs assessment. Set the goals and content depending on the

participants' needs and experience level. Then decide the interval between sessions that is best for your group. The goal is to allow sufficient time for the participants to work on each assignment, applying the knowledge gained from the previous session(s), and for the trainer to have the time to tailor the next session to needs identified in the previous session(s), making it a dynamic form of training. Consider having an outside trainer who liaises with the managers before each session to renew and discuss the goals for the next session from their perspective. Keep the group size small; four to six is probably an optimal size. Larger companies could divide their MWs into small groups, perhaps by therapeutic area or document type. This type of interactive training could be offered in parallel with structured didactic training on the document types to be reviewed in the Master Class Series, especially if the participants are inexperienced with them. The only absolute is that a Master Class Series is essential to the training of mid-career MWs.

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