TEACHING THE NEXT GENERATION OF REGULATORY MEDICAL WRITERS

Speakers

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General Session Overview

The speakers at the 2021 American Medical Writers Association (AMWA) Medical Writing and Communication Conference, *Kim Jochman* and *Marsha Caton-Faustin*, discussed the importance of having standardized regulatory medical writing (MW) training programs, with a focus on the need for structured training programs for entry-level and early-career regulatory MWs. The speakers also discussed how their organization adapted and implemented industry-level guidelines to develop training programs for new regulatory writers. Sharing this approach can help other organizations train new regulatory MWs and provide them with all of the essential skills required for performing this job.

Why Do We Need A Training Program For Regulatory Writers?

Caton-Faustin explained why organizations need a standardized training program for regulatory writers. People generally envision writers sitting at their desks, pounding away at the keyboard, and completing writing chores, especially in a regulatory or scientific writing career. Most people with scientific degrees know how to write and present scientific data, but how many of them have had one-on-one coaching from a mentor or coach to bridge the gap between academic writing and regulatory writing? How many writers were given no guidance at all and learned to write regulatory documents by trial and error or by sink or swim?

A regulatory or scientific writer, whether working for a sponsor organization, a contract research organization, or a medical agency, works with cross-functional teams, manages multiple projects, and juggles a lot on daily basis, all while completing their writing tasks. Many organizations do not provide formal training to their writers, and experienced writers have a varied baseline experience. Looking at the landscape of regulatory writing, it is important to provide MWs with thorough training so that they understand what they're entering into and what they'll be required to do in this dynamic profession. Developing skills in regulatory writing takes a long time. It's tough to create a training program that fits all writers because of the wide range of regulatory documents and leadership skills.

Developing a Structured Training Program

Jochman shared some of the resources that can be used to provide some guidance—the DIA's Medical Writing Competency Model and the AMWA Recommended Training Outline for Regulatory Writers (Table 1).

Table 1. Brief Overview of Industry-Level Guidance

Available Industry-Level Guidance	
DIA Medical Writing Competency Model (2018)[1,2]	**AMWA Recommended Training Outline for Regulatory Writers (2020)**[3]
• Focuses on professional medical writing within the life sciences industry. • The working group consisted of experts from multiple companies, medical writing specialties, and industry sectors.	• Based on DIA Competency Model (especially Section 2) and experience of AMWA Workforce Training Committee.
Consists of 2 sections **1)** Core work functions divided into functions, tasks, and activities: **a)** Core role delivery eg, document preparation, development, and finalization **2)** Knowledge and skills to successfully perform these functions for all MWs, regulatory MWs, and MW managers **a)** Knowledge at different levels **b)** Skills and abilities **c)** Behaviors **3)** Does not distinguish competencies of novice MWs from experienced MWs	**Consists of** **1)** List of recommended training topics and priorities for training, from entry-level to more advanced levels **a)** Core knowledge and skills **i)** Drug development process **ii)** Medical writing skills **iii)** Technical aptitude **iv)** Analytical skills **b)** Documents (3 levels) **c)** Soft skills **i)** Management skills **ii)** Personal development **2)** List of independent reading for regulatory MWs **3)** Customizable training checklist template

Jochman also talked about how their company used these guidelines to develop rotational training programs for entry-level MWs (Table 2).

Caton-Faustin discussed their early-career development program, designed for employees from varied backgrounds, including those who have finished the entry-level MW program as well as those who have come in from other organizations or even different departments within their own company (Figure).

Key Takeaways

In summary, a MW training program provides the foundation for entry-level and early-career writers to succeed in their careers. In a nutshell, the mentoring program may include

1. preparing a coaching framework and a partnership between the coach and manager,
2. rotations across several specialty groups within the MW department,
3. hands-on activities and shadowing experiences,
4. lecture-type training sessions, and
5. on-the-job training with careful coaching.

The training program helps novice regulatory writers gain document-specific knowledge, general MW skills, a strong regulatory foundation using industry-standard resources such as AMWA and DIA guidance, statistical understanding, data interpretation ability, and leadership skills.

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Resources

1. Clemow DB, Wagner B, Marshallsay C, et al. Medical writing competency model – section 1: functions, tasks, and activities. *Ther Innov Regul Sci.* 2018;52(1):70-77.
2. Clemow DB, Wagner B. Marshallsay C, et al. Medical writing competency model – section 2: knowledge, skills, abilities, and behaviors. *Ther Innov Regul Sci.* 2018;52(1):78-88.
3. Yih L, Alexander L. *AMWA Recommended Training Outline for Regulatory Writers*. American Medical Writers Association; 2020. Accessed October 2021, https://info.amwa.org/hubfs/Offers/regulatory-writer-training%20ebook/regulatory-writer-training.pdf.

Table 2. Case Study of Rotational Program for Entry-level MWs (<1-year experience)

Month 1	General orientation	
Months 2-4	Rotation with assigned document* team	Hands-on training, writing style, clinical trial data
Months 5-7	Rotation with clinical technical editing team	Quality control review; clinical study report trainings and shadowing experiences also begin
Months 8-9 (6 weeks)	Rotation with clinical content standards team	Technical aptitude
Months 9-10 (3 weeks)	Rotation with the document* team	Health literacy concepts
Month 11+	End rotations; begin supporting MW team on regulatory documents	Hands-on training

**The first rotation is with the narrative team—narratives are the brief, participant-level documents that they learn at the beginning of the training program. The next rotation is with the teams writing informed consent documents. Shadowing opportunities for more complex documents, such as clinical study reports, are also provided throughout the rotational program. Overall, the training program includes core knowledge, soft skills, networking, and corporate culture.*

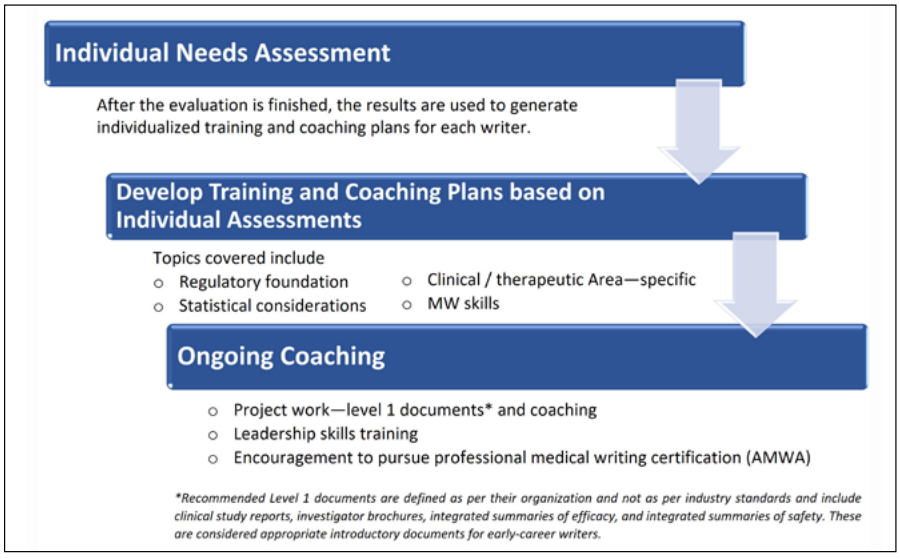

Figure. Overview of training programs for early-career MWs (1-2 years' experience). AMWA, American Medical Writers Association; MW, medical writer.