

# Five questions for Ruggero Galici on nonclinical medical writing



**Ruggero Galici** is Senior Director of Nonclinical and Clinical Pharmacology Medical Writing at Alexion Pharmaceuticals Inc, AstraZeneca Rare Disease Unit and heads up global early phase regulatory medical writing activities. In this role, he facilitates the transition of early phase programmes from first-in-human research to clinical trial applications and investigational new drug submissions.

Ruggero has a background in drug discovery, nonclinical and clinical development, a PhD in

pharmacology, and post-doctoral training. He has led pharmacology teams to advance small molecules and biologics to the clinic and has served as subject matter expert to compound development teams. Ruggero has more than 20 years of experience in scientific and regulatory writing. He can be found on LinkedIn at <https://www.linkedin.com/in/rgalici>.

*Medical Writing* Editor-in-Chief Raquel Billiones asked him five questions about his career and expertise.

doi: doi:10.56012/msng4369

**Raquel Billiones (RB): How did you get into this profession?**

**Ruggero Galici (RG):** I got involved with scientific writing early on in my career. As I go back in time with you, I realise that it has been a natural transition for me to switch from leading translational pharmacology laboratories to writing scientific documents. For example, when I was a post-doctoral fellow in the US at the University of Texas Health Science Center and at Vanderbilt University, I wrote several grants sponsored by the US National Institutes of Health, submitted abstracts to scientific meetings, and published several articles in peer-reviewed journals. Eventually, I ended up working in large pharmaceutical companies within R&D where I progressively shifted my role from scientific writing (e.g., research technical reports [RTR], pharmacokinetics/pharmacodynamics [PK/PD] reports,) to regulatory writing (e.g., briefing documents, investigator's brochures, protocols, clinical study reports [CSRs], clinical development plans, and non-clinical and clinical modules in preparation of investigational new drug [IND] and new drug application [NDA] submissions).

**RB: What are the documents that nonclinical medical writers develop?**

**RG:** Within the pharmaceutical industry, there is a variety of documents requiring nonclinical writing support. They typically fall into 5 major areas of expertise (chemistry, manufacturing, and control [CMC], bioanalytical, pharmacology [PK], and toxicology), and in 3 general categories (RTRs, publications, and regulatory documents). RTRs and publications are typically written with a scientific mindset and approach. Regulatory documents summarise the RTRs (e.g., the source documents), and are written for regulatory agencies using strategic and lean writing approaches (e.g., briefing documents, summary of nonclinical pharmacology). These kinds of documents provide the regulatory agencies with an overview of the nonclinical package supporting clinical development.

**RB: From your perspective, is there a difference between clinical and nonclinical medical writing?**

**RG:** It depends on the purpose and content of the documents, so I am tempted to avoid generalisations. For example, Phase 1 clinical study reports, summaries of clinical pharmacology studies, and summaries of pharmaceutical studies and associated analytical

methods are highly technical documents with great similarity to nonclinical summaries and RTRs. These nonclinical and clinical regulatory documents require knowledge and understanding of pharmacology, PK/PD relationships, toxicology, and safety. On the other hand, writing a nonclinical pharmacology summary is fundamentally different from writing a summary of clinical safety.

Within the regulatory space, there are several important similarities between nonclinical and clinical writing that should be highlighted. For example, regardless of the type of document, the typical operational steps medical writers undertake are the same from planning to submission readiness. Also, nonclinical and clinical regulatory documents are typically written with the same strategic and lean authoring approaches.

Another similarity is that, regardless of the type of document, significant investigative work from medical writers is needed. For example, we analyse and synthesise the content of source documents, whether we review an RTR to support the development of an investigator's brochure, or we review a CSR to support the development of a summary of clinical pharmacology.

Regardless of the type of document, the typical operational steps medical writers undertake are the same from planning to submission readiness.

**RB: Do you have any pearls of wisdom you want to share with students and young scientists who may be interested in the medical writing profession?**

**RG:** There is no magic bullet to break into the profession of medical writing. Medical writers have diverse education and training, but they typically have a common passion for science. Broadly speaking, the ability to understand and talk science is an advantage in medical writing, particularly when authoring nonclinical documents and actively engaging with subject matter experts (e.g., pharmacologists). For example, this is when we add value to teams by cross-checking the scientific accuracy of content, by asking questions to clarify the meaning of sentences, and by making suggestions on experimental design and statistical analysis. By quickly absorbing complex scientific and medical concepts and data, we can effectively and efficiently summarise the content in regulatory documents and/or scientific publications.

Medical writers add value to teams in other ways as well. We typically own the document,

and we provide subject matter experts with templates and guidance on content and, to some extent, regulatory requirements. We also keep abreast of novel platforms aimed at assisting with the development of documents (i.e., automation technologies). Medical writers wear multiple hats. Soft skills are essential, particularly the ability to effectively communicate complex scientific and medical content and distill it into key messages, storyboards, nonclinical and clinical summaries, and plain language summaries. We act as psychologists when we manage different opinions and people with different backgrounds during a document conflict resolution meeting. We are project managers when we take care of all operational aspects of document development from planning to approval.

**RB: In keeping with the theme of this issue, can you tell us why nonclinical writing is very important in biotechnology?**

**RG:** Nonclinical writing is essential in determining the success of programmes throughout

the clinical development lifecycle from Phase 1 to registration. Nonclinical writing is particularly important in early phase programmes from small biotechnology companies with a single asset at pre-IND stage, to large pharmaceutical companies with multiple assets at different phases of clinical development. For example, as early phase programmes make the transitions from research to first-in-humans, regulators around the world review for the first time the nonclinical data and provide their feedback based on the quality and completeness of these data.

**RB:** Thanks so much for sharing your expertise with our readers!

#### **Disclosure and Disclaimer:**

The interviewee and interviewer work for the same company. The views and opinions expressed in this article are the authors' own and are not necessarily shared by their employer or by EMWA.

**EMWA's 57th Conference**

**VALENCIA**

**May 7 - 11, 2024**  
Valencia, Spain

Featuring workshops, a one-day symposium on the use of AI in medical writing, Expert Seminar Series, the Freelance Business Forum, Getting Into Medical Writing, networking, and more!