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Medical Writing

Generics and biosimilars

When I first stepped into the biosimilar world as part of my medical writing career development, I was both excited and surprised. I was entering this fascinating setting with an originator mindset, as many of us do, and discovered that there are many aspects to be considered for biosimilar documents, not all of which are entirely obvious.

Later, from chats with other writers during coffee breaks at EMWA conferences, it became clear to me that more conversations across different areas of development (originators, biosimilars, and generics) were needed. While general information on biosimilars and generics is increasingly available, there aren't many hands-on resources for medical writers who have broad medical writing experience but who don't have any experience specifically in these areas.

This MEW issue aims to bridge this information gap. The nine feature articles included here address both the 'bigger picture' and provide hands-on tools for developing fit-for-purpose documents throughout a biosimilar/generic product's life cycle.

Regulatory pathways in the EU and the US in the generic and biosimilar industries are critically discussed in detail by **Yousuf Mohiuddin Mohammed**, with real-life examples when available. He focuses on clinical development requirements for generics and biosimilar in order for region-specific regulatory requirements to be met, but also covers the impact of such requirements on other parts of the respective submission dossiers.

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The particulars of biosimilar development are further developed by me (**Diana Radovan**). My feature article provides information about biosimilar-specific terminology, addresses the typical challenges of writing biosimilar dossiers and how medical writers can provide strategic support in overcoming them, and summarises future directions in biosimilar development in the context of a changing competitive landscape.

Statistical considerations for biosimilar development are outlined by **Alison Balfour** and **Susanne Schmitt**. These considerations include clinical trial design, covering choice of endpoints, types of required analyses, choice/justification of equivalence margin (based on statistical and clinical considerations), and imputing missing data for efficacy.

Katharina Brauburger and **Sabrina Heisel-Stöhr** provide best practices for developing clinical biosimilar documents, paying close attention to a number of typical challenges, and how fundamental biosimilar concepts, such as immunogenicity and extrapolation, must be used in writing fit-for-purpose documents. The authors also run the only EMWA workshop on biosimilars, which is always fully booked in no time; so keep an eye out for it when registering for the next EMWA conference!