



# Pharmacovigilance Medical Writing: A Good Practice Guide

*Justina Orleans-Lindsay*

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*Pharmacovigilance Medical Writing* covers the preparation of pharmacovigilance documents for all stages of the drug development process (i.e. from clinical development through to applications for marketing authorisations to the post-marketing stage). For each document, the book presents a review of the regulatory framework that governs the content of the document, followed by practical guidance (e.g. scheduling, source data, department/functions involved in document preparation/review, appropriate timelines and planning activities), ending with a generic model document compliant with the current guidelines, which can be modified to meet specific company and product requirements.

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