Pharmacovigilance Medical Writing: A Good Practice Guide
Justina Orleans-Lindsay

DESCRIPTION

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.

ABOUT THE AUTHOR

Justina Orleans-Lindsay  BSc, MSc, PhD is a Director of Acadustri (Medical Writing) Limited and Visiting Lecturer in pharmacovigilance at the University of Hertfordshire, UK.

For additional product details, please visit https://www.wiley.com/en-us