Pharmacovigilance Medical Writing: A Good Practice Guide

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.

Publication Year 2012
Edition 1st
Author/Editor Orleans-Lindsay, Justina
Publisher Wiley
Platform Ovid
Product Type Book
Speciality Pharmaceutical Science
Pharmacology
Language English
Pages 286
Illustrations 0
Included In Wiley Drug Discovery & Development Book Collection