1. Record Nr. UNINA9910830636003321

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Titolo	Pharmacovigilance medical writing [[electronic resource]] : a good practice guide / / Justina Orleans-Lindsay
Pubbl/distr/stampa	Chichester, West Sussex, U.K., : John Wiley & Sons Inc., 2012
ISBN	1-118-30206-0 1-280-79269-8 9786613703088 1-118-30191-9 1-118-30190-0 1-118-30205-2
Edizione	[2nd ed.]
Descrizione fisica	1 online resource (287 p.)
Disciplina	615.4 615.7 615/.4
Soggetti	Drug monitoring Communication in medicine - Methodology
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Note generali	Description based upon print version of record.
Nota di bibliografia	Includes bibliographical references and index.
Nota di contenuto	Pharmacovigilance medical writing : an overview across the drug development process -- Pharmacovigilance medical writing for clinical trials -- Pharmacovigilance medical writing for CTD submissions -- Pharmacovigilance medical writing in risk evaluation & management -- Pharmacovigilance medical writing for marketed products -- The Ad-Hoc safety review & response to questions document -- The rest of the world.
Sommario/riassunto	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