Medical Writing

1 REGULATORY SCIENCE

1.1 Module 2 of the CTD

Module 23 Quality Overall Summary (QOS)
23S: Summaries related to the drug substance
23P: Summaries related to the drug product
23A: Appendices, which may include information on the development of the drug, its manufacturing process, and control of excipients

Module 24 Nonclinical Overview

Module 25 Clinical Overview

Module 26 Nonclinical Written and Tabulated Summaries
261: Summarizes pharmacology studies
262: Summarizes pharmacokinetics studies
263: Summarizes toxicology studies

Module 27 Clinical Summaries
271: Summary of biopharmaceutic and analytical methods
272: Summary of clinical pharmacology
273: Summary of efficacy
274: Summary of safety

1.2 Periodically Updated Documents

1.2.1 Investigator's Brochure (IB)

1.2.2 Company Core Data Sheet (CCDS) and Safety Information (CCSI)

1.2.3 Periodic Adverse Drug Experience Report (PADER)

1.2.4 Periodic Benefit-Risk Evaluation Report (PBRER)

1.2.5 Periodic Safety Update Report (PSUR)

1.2.6 Drug Safety Update Report (DSUR)

1.3 FDA meetings and applications

1.3.1 Type A, B, C, and D Meetings Briefing Book

1.3.2 FDA Advisory Committees' Meetings Briefing Book

1.3.3 Investigational New Drug (IND) Application

1.3.4 Orphan Medicinal Product Designation Application

1.3.5 US Pediatric Study Plan (PSP) Application

1.3.6 Breakthrough Therapy Designation Application

1.3.7 Pediatric Rare Disease Voucher Application

1.3.8 Fast-Track Designation Application

1.3.9 FDA Priority Review Application

1.3.10 United States Prescribing Information (USPI)

1.4 EMA applications

1.4.1 CHMP Scientific Advice Briefing Books

1.4.2 PRIME Application (PRIority MEdicines)

1.4.3 Pediatric Investigational Study Plan Application

2 CLINICAL SCIENCE

2.1 Clinical Study Synopsis, Full Protocol, and Protocol Lay Version

2.2 Clinical Study Report Core and Appendices, Lay Version

3 SCIENTIFIC PUBLICATIONS/MANUSCRIPTS

3.1 Full manuscripts

3.2 Conference abstracts and posters