

TITLE/TOPIC OF GUIDANCE	CONTACT
Patient Reported Outcomes	Do
Promotion of Combination Oral Contraceptive Products	Do
CATEGORY—BIOPHARMACEUTICS	
Clozapine Tablets—In Vivo Bioequivalence and In Vitro Dissolution Testing	Do
CATEGORY—CHEMISTRY	
Documentation for Antibiotics and Other Cellular Metabolites Produced by Microorganisms Modified Using Recombinant DNA Technology	Do
Drug Products: Chemistry, Manufacturing, and Control Documentation	Do
Drug Substance: Chemistry, Manufacturing, and Control Documentation	Do
CATEGORY—CLINICAL/MEDICAL	
Acne Vulgaris	Do
Analgesics	Do
Clinical Development Programs for Metered Dose Inhaler and Dry Powder Inhalers Products—Revised	Do
Clinical Evaluation of Drugs for the Treatment of Acute Coronary Syndrome	Do
Clinical Evaluation of Combination Estrogen/Progestin-Containing Drug Products Used for Hormone Replacement Therapy in Postmenopausal Women—Revised	Do
Clinical Evaluation of Drugs for Neuropathic Pain	Do
Clinical Evaluation of Drugs for the Treatment of Heart Failure	Do
Collection and Use of Race and Ethnicity Data in Clinical Trials for FDA Regulated Products	Do
Development of New Opiate Formulations	Do
Developing Antiviral Drug for the Mitigation of Complication Associated Vaccine Immunization	Do
Developing Antiviral Drugs for the Treatment of Smallpox	Do
Drug-Coated Cardiovascular Stents	Do
Evaluation of New Treatments for Diabetes Mellitus	Do
Gingivitis	Do
Safety Review of Clinical Data	Do
CATEGORY—CLINICAL/PHARMACOLOGY	Do
Content and Format of the Clinical Pharmacology Section	Do
Content and Format of the Warnings and Precautions, Contradictions and Boxed Warning Sections of Prescription Drugs	Do
Immediate Release to Modified Release Dosage Forms	Do
In Vitro Drug Metabolism/Drug Interaction—Guidance for Reviewers	Do
CATEGORY—COMPLIANCE	
Current Good Manufacturing Practices for Compressed Medical Gases—Revised	Do
Maintaining Adequate and Accurate Records During Clinical Investigations	Do