I.**Drug Discovery and Development**

II. Botanical Drug Development (Guidance for Industry) https://www.fda.gov/regulatory-information/search-fda-guidance-documents/botanical-drug-development-guidance-industry)

III. Guideline on the role of pharmacokinetics in the development of medicinal products in the paediatric population https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-role-pharmacokinetics-development-medicinal-products-paediatric-population_en.pdf

IV. Guideline on the investigation of drug interactions https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-investigation-drug-interactions-revision-1_en.pdf

V. Herbal medicinal products https://www.ema.europa.eu/en/human-regulatory/herbal-medicinal-products)

VI. Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products — Content and Format https://www.fda.gov/media/72142/download

VII. Quality by Design for ANDAs: An Example for Immediate-Release Dosage Forms https://www.fda.gov/files/drugs/published/quality-by-design-%28QbD%29-for-an-immediate-release.pdf

VIII. Guidance for Industry Bioavailability and Bioequivalence Studies Submitted in NDAs or INDs —General Considerations https://www.fda.gov/media/88254/download

IX. Guidance for Industry and FDA Staff Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data https://www.fda.gov/media/79922/download

X. Guidance for Industry and FDA Staff Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data https://www.fda.gov/media/79922/download

XI. Guidance for Industry Chronic Cutaneous Ulcer and Burn Wounds — Developing Products for Treatment https://www.fda.gov/media/71278/download

XII. Guidance for Industry Chronic Fatigue Syndrome/ Myalgic Encephalomyelitis: Developing Drug Products for Treatment https://www.fda.gov/media/87875/download

XIII. Guidance for Industry Clinical Pharmacogenomics: Premarket Evaluation in Early-Phase Clinical Studies and Recommendations for Labeling https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-pharmacogenomics-premarket-evaluation-early-phase-clinical-studies-and-recommendations

XIV. World Medical Association Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects https://www.wma.net/policies-

post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

XV. Ethical Guidelines For Biomedical Research On Human Subjects http://www.nitrd.nic.in/WriteReadData/userfiles/file/Ethical%20Guidelines.pdf

XVI. Ethical concerns in clinical trials in India: an investigation - http://environmentportal.in/files/Ethical_concerns_in_clinical_trials_in_India_An_investigation.pdf

XVII. International Ethical Guidelines for Biomedical Research Involving Human Subjects https://cioms.ch/publications/product/international-ethical-guidelines-for-biomedical-research-involving-human-subjects-2/

1. Guidance for Industry Diabetes Mellitus — Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes https://www.fda.gov/media/71297/download
2. Low Sexual Interest, Desire, and/or Arousal in Women: Developing Drugs for Treatment Guidance for Industry https://www.fda.gov/media/100833/download
3. Guidance for Industry and FDA Staff: Early Development Considerations for Innovative Combination Products https://www.fda.gov/media/75273/download
4. Guidance for Industry Exposure-Response Relationships — Study Design, Data Analysis, and Regulatory Applications https://www.fda.gov/media/71277/download
5. Guidance for Industry E7 Studies in Support of Special Populations: Geriatrics https://www.fda.gov/media/78220/download
6. Guidance for Industry Helicobacter pylori-Associated Duodenal Ulcer Disease in Adults: Developing Drugs for Treatment https://www.fda.gov/files/drugs/published/Helicobacter-pylori-Associated-Duodenal-Ulcer-Disease-in-Adults---Developing-Drugs-for-Treatment.pdf
7. Guidance for Clinical Investigators, Sponsors, and IRBs Investigational New Drug Applications (INDs) — Determining Whether Human Research Studies Can Be Conducted Without an IND https://www.fda.gov/media/79386/download
8. Guidance for Industry Integrated Summaries of Effectiveness and Safety: Location Within the Common Technical Document https://www.fda.gov/media/75783/download
9. Guidance for Industry Pharmacokinetics in Patients with Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling https://www.fda.gov/media/71311/download
10. Population Pharmacokinetics Guidance for Industry https://www.fda.gov/media/128793/download
11. Physiologically Based Pharmacokinetic Analyses — Format and Content Guidance for Industry https://www.fda.gov/media/101469/download

12. Guidance for Industry Pharmacokinetics in Pregnancy — Study Design, Data Analysis, and Impact on Dosing and Labeling https://www.fda.gov/media/71353/download
13. Clinical Drug Interaction Studies — Cytochrome P450 Enzyme- and Transporter-Mediated Drug Interactions Guidance for Industry https://www.fda.gov/media/134581/download
14. Clinical Trials Guidance Documents (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-trials-guidance-documents)
15. Guidance for industry: estimating the maximum safe starting dose in initial clinical trials for therapeutics in adult healthy volunteers. https://www.fda.gov/media/72309/download
16. The National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017 (https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf)
17. Guideline on the pharmacokinetic and clinical evaluation of modified release dosage forms https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-pharmacokinetic-clinical-evaluation-modified-release-dosage-forms_en.pdf
18. Estimating the Maximum Safe Starting Dose in Initial Clinical Trials for Therapeutics in Adult Healthy Volunteers https://www.fda.gov/media/72309/download
19. Guidance for Industry Pharmacokinetics in Patients with Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling https://www.fda.gov/media/71311/download
20. General Guidelines for Drug Development of Ayurvedic Formulations (http://ccras.nic.in/sites/default/files/viewpdf/Publication/CCRAS_Guideline%20of%20Drug%20Development.pdf)
21. General Guidelines for Safety/Toxicity Evaluation of Ayurvedic Formulations (http://ccras.nic.in/sites/default/files/viewpdf/Publication/CCRAS_Guideline%20of%20Safety_Toxicity.pdf)
22. General Guidelines for Clinical Evaluation of Ayurvedic Interventions (https://www.ayush.gov.in/docs/clinical_evaluation.pdf)
23. Exposure-Response Relationships — Study Design, Data Analysis, and Regulatory Applications https://www.fda.gov/media/71277/download
24. Drug-Drug Interaction Assessment for Therapeutic Proteins Guidance for Industry https://www.fda.gov/media/140909/download
25. Clinical Drug Interaction Studies With Combined Oral Contraceptives Guidance for Industry https://www.fda.gov/media/143849/download
26. Evaluation of Gastric Dependent Drug Interactions With Acid-Reducing Agents: Study Design, Data Analysis, and Clinical Implications Guidance for Industry https://www.fda.gov/media/144026/download

27. Guidance for Industry Irritable Bowel Syndrome — Clinical Evaluation of Drugs for Treatment https://www.fda.gov/media/78622/download
28. Guidance for Industry Considerations for Plasmid DNA Vaccines for Infectious Disease Indications https://www.fda.gov/files/vaccines,%20blood%20&%20biologics/published/Guidance-for-Industry--Considerations-for-Plasmid-DNA-Vaccines-for-Infectious-Disease-Indications.pdf
29. Use of Electronic Informed Consent https://www.fda.gov/media/116850/download
30. Division of Pharmacometrics https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/division-pharmacometrics#FDAPharmacometrics2020StrategicGoals
31. Selected Pharmacometric Reviews, Guidances, and Presentations https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/selected-pharmacometric-reviews-guidances-and-presentations
32. Safety issues in the preparation of homeopathic medicines (https://www.who.int/medicines/areas/traditional/prephomeopathic/en/)
33. WHO-Quality of Life User Manual (https://www.who.int/tools/whoqol)
34. WHO guidelines for assessing quality of herbal medicines with reference to contaminants and residues (https://apps.who.int/iris/handle/10665/43510)
35. WHO guidelines on good herbal processing practices for herbal medicines (https://www.gmp-compliance.org/guidelines/gmp-guideline/who-guidelines-on-good-herbal-processing-practices-for-herbal-medicines)
36. Q7 *Good Manufacturing Guide for Active Pharmaceutical Ingredients* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-q7a-good-manufacturing-practice-guidance-active-pharmaceutical-ingredients
37. Q8 (R2) – *Pharmaceutical Development* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q8r2-pharmaceutical-development
38. Q11 – *Development and Manufacture of Drug Substances (Chemical Entities Biotechnological/Biological Entities)* https://www.fda.gov/files/drugs/published/Q11-Development-and-Manufacture-of-Drug-Substances--Questions-and-Answers-%28Chemical-Entities-and-Biotechnological-Biological-Entities%29.pdf
39. Standard Protocol Items: Recommendations for Interventional Trials https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5114123/pdf/nihms6040.pdf
40. Schedule M - Good manufacturing practices and requirements of premises, plant and equipment for pharmaceutical products. https://ipapharma.org/wp-content/uploads/2019/02/schedule-m-1.pdf

1. Ayurvedic Pharmacopeial Publications: This includes Ayurvedic Pharmacopoeia, Ayurvedic Formulary of India, and other supporting pharmacopoeial publications.

(https://pcimh.gov.in/show_content.php?lang=1&level=1&ls_id=56&lid=54

1.National Formulary of India 4th Edition 2011 https://main.mohfw.gov.in/sites/default/files/7966072180.pdf

2.Essential Drug List Ayurveda https://arogya.maharashtra.gov.in/Site/PDFs/EDL_Ayurveda.pdf

1.The Drug and Cosmetic Act 1940 https://legislative.gov.in/sites/default/files/A1940-23.pdf

2.Reviewing Clinical Trials: A Guide for the Ethics Committee https://cdn.pfizer.com/pfizercom/research/research_clinical_trials/ethics_committee_guide.pdf