References & Recommended Reading

Module 4 (Nonclinical Studies):

- ICH S9: Nonclinical Evaluation for Anticancer Pharmaceuticals
- ICH S6(R1): Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals
- ICH S8: Immunotoxicity Studies for Human Pharmaceuticals
- ICH S7A: Safety Pharmacology Studies for Human Pharmaceuticals
- ICH S7B: Nonclinical Evaluation of the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals
- ICH M3(R2): Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals
- FDA Guidance for Industry: Estimating the Maximum Safe Starting Dose in Initial Clinical Trials for Therapeutics in Adult Healthy Volunteers
- EMA Guideline on Strategies to Identify and Mitigate Risks for First-in-Human Clinical Trials with Investigational Medicinal Products
- OECD Principles of Good Laboratory Practice (GLP)

Module 5 (Clinical Studies):

- ICH E6(R2): Good Clinical Practice - Consolidated Guideline
- ICH E8(R1): General Considerations for Clinical Trials
- ICH E9(R1): Statistical Principles for Clinical Trials
- ICH E11: Clinical Investigation of Medicinal Products in the Pediatric Population
- FDA Guidance for Industry: E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1)
- EMA Guideline for Good Clinical Practice
- FDA Guidance for Industry: Adaptive Designs for Clinical Trials of Drugs and Biologics
- EMA Guideline on the Investigation of Bioequivalence
- WHO Handbook for Good Clinical Research Practice