MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Online course
Interpretation and application of ICH E6(R2) Good Clinical Practice

This online course is directed at educating and training government regulators (reviewers and inspectors) as well as other stakeholders on key concepts of International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) E6(R2). Using case studies and quizzes to reinforce understanding, this course can be taken in its entirety or as needed. Certificates will be given for full completion of the course.

Modules:

- What is ICH E6(R2) and how does it apply to regulators?
- The 13 Principles of ICH GCP
- IRB Responsibilities
- Investigator Qualifications and Responsibilities
- Sponsor Responsibilities
- Protocol and Investigator's Brochure
- Key Documents of ICH E6(R2)-Essential Documents
- GCP in Practice for Reviewers
- GCP in Practice for Inspectors