Clinrex Munich
Dr. Dagmar Chase

GCP Basis:

ICH-GCP inkl. Addendum

EU Gesetzgebung zur klinischen Prüfung am Menschen inkl. EU Clinical Trials Regulation (536/2014)

Einblick in FDA-Vorgaben

Referent: Dr. Dagmar Chase

Introduction

- History of GCP
- International Council for Harmonisation – The ICH Process
- The Principles of ICH-GCP
- Declaration of Helsinki

ICH-GCP (including Addendum)

- Responsibilities of IRBs/IECs
- Responsibilities of Investigators (including typical inspection findings)
- Responsibilities of Sponsors (including typical inspection findings)
- Essential Documents, Filing and Archiving

EU Clinical Trial Directive 2001/20/EC

- A brief overview
- Eudralex Volume 10 / EudraCT Database / EU Clinical Trials Register

EU Clinical Trial Regulation 536/2014

- An Overview
- Transitional Provisions
- New Transparency Rules

FDA requirements: Particularities to watch out for if the trial is planned to be part of an US NDA

- FDA “black lists”
- FDA Form 1572
- Financial Disclosure Form