GCP Qualification Audits

Choosing Quality Contractors and Sites

Table of Contents

Introduction

The Need for Qualification Auditing 3

Establishing a GCP Qualification and Approval Program 4

Auditing Approach for a Qualification Audit 5

Qualifying a Contract Research Organization 7

Selecting a CRO 8

Qualifying a Central Laboratory 11

Regulations Governing Central Laboratories 11

Monitoring Clinical Sites 13

Regulations Governing Clinical Sites 14

Risk-Based Auditing 15

Necessary Audit Documentation 17

Vendor Audit Files 17

Audit Certificates 18

Post-Study CRO Assessment 19

Appendices 21

A. Sample SOPs

B. FDA Draft Guidance: *Investigator Responsibilities – Protecting the Rights, Safety and Welfare of Study Subjects*

C. FDA Draft Guidance: *Informed Consent Information Sheet*

D. FDA Draft Guidance: *Oversight of Clinical Investigations – A Risk-Based Approach to Monitoring*

E. ICH E3 – *Structure and Content of Clinical Study Reports*