Introduction

What are good clinical practices, really? The concept of GCPs covers a lot of ground, from how to apply for an Investigational New Drug authorization to what kinds of subject information you can collect, to how to handle—and sometimes discipline—investigators under your charge. The FDA provides all the GCP regulations and guidance you need to run a clinical trial, but even those documents can't answer every question you may have.

Fortunately, the agency offers another resource—the staff of its Office of Good Clinical Practices (OGCP). Every day, OGCP fields questions from investigators, sponsors, IRBs and other interested parties. Questions like:

- Must I register my trial with the ClinicalTrials.gov database?
- What kind of certification must our testing laboratory have?
- How should we make corrections on medical notes?
- How should study records be stored?
- What constitutes a protocol deviation?
- Can a physician whose medical license is on probation continue as the principle investigator on a study?

Many of the questions may be similar to issues you struggle with in your clinical trials. Others may help you handle unexpected problems when they occur. But all of the questions in this compilation share one important characteristic: clear and detailed answers directly from OGCP authorities. OGCP's responses interpret the FDA's position, offer advice on how to proceed and point out key documents and resources that provide more in-depth guidance.

In addition to queries and responses, *GCP Questions, FDA Answers* contains 38 FDA resources frequently referenced by OGCP, including:

- *ICH E6 – Good Clinical Practice;*
- *Investigator Responsibilities – Protecting the Rights, Safety and Welfare of Study Subjects;*
- *Adverse Event Reporting to IRBs – Improving Human Subject Protection; and*
- *Oversight of Clinical Investigations – A Risk-Based Approach to Monitoring.*

If the inquiries in this book spark new questions of your own, OGCP is ready to help you as well. As one response explains:

> *"FDA's Office of Good Clinical Practice (OGCP) … has a central public mailbox where we welcome GCP questions (gcp.questions@fda.hhs.gov). You can find information about OGCP and the public mailbox address at the following web location: http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm134476.htm. We find that it is best to send questions to the public mailbox because it is monitored and managed Monday through Friday each week. Sending a question directly to specific staff may result in a delay if that staff person is out of the office."*

GCP Questions, FDA Answers provides you with the information you need – and some you may not have known you needed – to ensure your trials are as compliant and effective as they can be.