Introduction

The ultimate success of a clinical trial depends in large part on the independent contractors brought on by the sponsor company. But how can a sponsor ensure it's hiring the best vendors for the job? Just as importantly, how can a sponsor make certain that its contractors are complying with all the relevant regulations governing clinical trials, whether they're conducted in the U.S. or abroad — or, in plenty of cases, both?

Ultimately, it's the sponsor's responsibility to ensure that a study is conducted in line with good clinical practice (GCP) regulations. That means it's the sponsor's responsibility to ensure its vendors are following those regulations. A sponsor can farm out some of the work of a clinical study, but it can't farm out its responsibility for regulatory compliance.

This report will walk readers through the steps for evaluating contractors prior to hiring them, as well as how to effectively monitor those contractors over the course of a study to ensure their continued GCP compliance.

The report begins with qualification audits—why you should conduct them before hiring a contractor, and how to make sure they're measuring the most important variables. You'll learn the principles of qualification auditing, and how to apply these principles to the different kinds of firms involved in a clinical study: CROs, clinical sites, and central testing labs.

You'll also learn how to best monitor clinical sites over the course of a study, how to apply risk-based strategies to those audits, and the kind of documentation you'll need to keep on vendors—including internal assessments that can help you determine whether to hire a given vendor again in the future.

This report is based on a Good Clinical Practices workshops conducted on behalf of FDAnews by Michelle Sceppa, principal and founder of MSceppa Consulting. Sceppa has more than 25 years of experience in quality assurance and regulatory compliance in the pharmaceutical and medical device industries. As a lead auditor, she has conducted and managed more than 300 internal and external audits for drug, biologics and medical device firms in the U.S. and Europe.