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Expert Advises Companies on Successful Risk Management

Effective site monitoring and quality assurance auditing are key to successfully managing risks in clinical studies, according to an industry expert.

Charma Konnor, senior manager and consultant at Phoenix Regulatory Associates, said such measures can significantly increase the likelihood of a successful submission to the FDA as well as successful clinical trial site audits.

Speaking at the FDANews Second Medical Device Quality Conference earlier this month, Konnor added that companies should have a good strategic plan in place to ensure clinical trial data quality and reliability.

“You can be very compliant on the QSR (quality system requirement) side, but if you fail with respect to the quality of your clinical trials, your application may not go anywhere,” she warned.

The FDA initiated current Good Manufacturing Practice (cGMP) requirements, defined in 21 CFR 820, to ensure good quality assurance practices are used for designing medical devices that are also consistent with QSRs worldwide.

The requirements also establish a framework that manufacturers must use when developing and implementing design controls.

Individuals selected to monitor performance measurements should make visits to clinical sites to verify that the requirements for ensuring the integrity of trial-related activities are being fulfilled, said Konnor.

Monitors should check for accurate, complete data entered in a timely manner. The FDA requires that sponsors monitor clinical studies and have written monitoring standard operating procedures, as defined in 21 CFR 812.

Monitoring helps assure the quality of the data gathered for the clinical study. Depending on the nature of the study, the number of sites included, and whether some sites present more risk than others, said Konnor, monitors should make visits pretty frequently.

“Maybe a site has staff that is constantly changing...that might be one you monitor more frequently and more closely than another site where you’ve got a stable staff — they’ve had no compliance issues in the past. You don’t have to monitor them as often,” Konnor explained.

Auditing Key for Quality Assurance

While monitoring concerns quality control, auditing applies to quality assurance. Konnor highly recommends internal audits. For example, she said, audits should begin with examining source records and comparing them to case report forms (CRFs) to ensure that data and other information are transcribed accurately.

The audit should record whether source data and CRF entries are entered in a timely manner, are accurate, and all data are traceable. Auditors should also check device accountability records, Konnor added. They should make notes on device shipment, receipt, implantation and whether any devices have been destroyed or returned.

If deficiencies aren't caught early, they could be overlooked throughout the clinical trial process and cause problems later.

Konnor affirmed that an internal auditor or monitor can easily correct a problem with a written explanation if it's caught early on.

Spending Money to Save Money

"What's important is documentation, document trail and traceability," said Konnor, referring to performance measures for which the FDA looks. Sometimes though, large and small companies alike may fall victim to sloppy risk management.

"Firms just don't want to take the extra time and spend the extra money to assure it has been done right," Konnor explained. "[Companies] don't want to spend the money on, say, a regulatory affairs manager involved from the get-go. They don't want to spend money on internal audits."

But Konnor warns that forgoing monitoring and auditing can be a costly mistake. Some companies may be overly confident that everything has been done correctly, or some could just be unfamiliar with the regulations and requirements that apply to their circumstances.

Konnor suggested that if a company doesn't have a full quality assurance audit department, it should hire a third-party auditor. She emphasized that companies should consider the importance of the quality design process and think before hurrying to get their applications and/or submissions into the FDA.

Audio recordings of Charma Konnor's presentation as well as other conference presentations are available from FDAnews. Contact Martin Heavner, conference director, at mheavner@fdanews.com.