

## CASE STUDIES

### ELECTRONIC DATA CAPTURE VENDOR AUDITS

#### BACKGROUND

The Food and Drug Administration (FDA) requires that biopharmaceutical and medical device companies *“establish documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes.”* Computer systems that collect clinical trial information must conform to this definition of validation.

When using a vendor supplied system, the foundation for validation is an audit of the quality assurance used to develop the system. The American National Standards Institute (ANSI) defines this as *“conducting an independent review and examination of system records and activities in order to test the adequacy and effectiveness of data security and data integrity procedures, to ensure compliance with established policy and operational procedures, and to recommend any necessary changes.”*

Explore Consulting has skills and experience to help companies meet the requirements of software quality assurance and validation.

#### SITUATION 1

A small biotechnology company was preparing a pivotal phase III trial and wanted to use an Electronic Data Capture (EDC) system built by a Contract Research Organization (CRO). The biotech company had limited staff and lacked experience managing technology projects. The CRO was experienced with NIH studies but new to FDA regulated clinical trials.

#### SOLUTION

Explore Consulting performed a software quality assurance audit of the CRO

to assess the status of controlled and documented software development practices. Based on findings from the audit, Explore Consulting recommended strategies to reduce risk for the biotech company, provided project management for addressing remediation activities, mentored the CRO on validation, and delivered documented evidence for use by regulatory auditors.

#### SITUATION 2

A rapidly growing biopharmaceutical company was using a mid-size EDC vendor for its phase II clinical trials. A new Quality Assurance Manager discovered that previous audits of the vendor did not provide adequate information for evaluating vendor software quality. Also, the existing QA staff did not have experience in technology validation.

#### SOLUTION

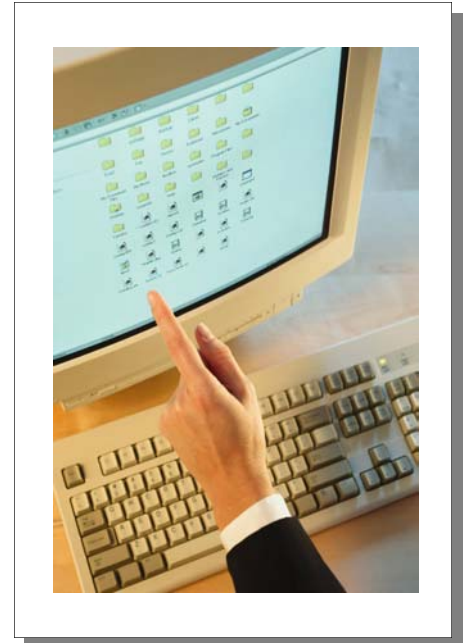
Explore Consulting audited the EDC vendor to provide a more thorough and independent perspective. Additionally, Explore mentored the existing QA staff through providing audit planning, checklist, and report templates to verify technology development artifacts.

#### SITUATION 3

A mid-size biotechnology company was using an industry leading EDC vendor and wanted to bring study set-up in house when the vendor released a new version of the product.

#### SOLUTION

Explore Consulting joined the team during one of the periodic vendor audits and assessed the new release validation. Also, Explore Consulting added weight to the company’s ongoing vendor quality concerns by directly addressing the vendor executive management with audit findings.



Explore Consulting can deliver quick, thorough quality assessments.

#### SUMMARY

Whether your software quality needs are small or comprehensive, Explore Consulting can deliver quick, thorough quality assessments. We have experience using industry standard audit practices like Good Automated Manufacturing Practices version 4 (GAMP4). We can help you raise the quality bar for both your company and the vendors on which you rely.

#### FOR MORE INFORMATION

Contact Explore Consulting to discover how we can help raise the bar for software quality assurance and better prepare for a regulatory audit.

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