

Untangling the Audit Trail: Tips for Effective Review

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Introduction

Electronic data integrity can only be assured if proper documentation exists within the audit trail for full reconstruction of study events. Some systems include so much or so little information that it can be difficult to determine when a problem or deviation has occurred. Quality assurance professionals can assist with ensuring proper data integrity in a Part 11-compliant system with an effective audit trail review. This poster will outline ways to improve audit trail review, starting with proper validation, progressing to consistent training, and concluding with suggestions of how to approach the review of an audit trail.