21 CFR PART 11- ELECTRONIC RECORDS & ELECTRONIC SIGNATURES

Quality & Compliance Solutions

WHAT IS 21 CFR PART 11?

21 CFR Part 11 was intended to be an umbrella regulation describing required controls for electronic record keeping and electronic signatures under all FDA predicate regulations. Although some predicate regulations require many of the same controls as Part 11, others are vague in what controls are required or expected. As the agency re-examines Part 11, the pharmaceutical and life science industries are asking many questions of what the predicate rules require and whether an umbrella regulation such as Part 11 helps clarify how electronic records and electronic signatures may be used in all regulated environments.
JAF offers services to clarify these issues and enable conformance to 21 CFR Part 11 and Predicate rule.

GLOBAL ASSESSMENT PROGRAMS FOR 21 CFR PART 11 COMPLIANCE

The key to implementation of 21 CFR Part 11 is the application of a standardized interpretation that mitigates variability and misunderstanding of electronic records and electronic signatures requirements. JAF's Quality and Regulatory Compliance Services provides expertise to help medical products companies evaluate or develop global policies and interpretations of 21 CFR Part 11 to ensure each interpretive statement of Part 11 is defensible and meets accepted FDA guidance documentation and industry best practices. JAF will identify potential areas of concern with 21 CFR Part 11 interpretations and suggest alternatives to minimize non-conformance. Assessing all critical systems prior to remediation is the preferred approach since the assessment effort may reveal similarities between like systems and may lead to evaluating potential remediation efforts for a common grouping of systems. This approach seems to be adopted most frequently since the information generated from a comprehensive assessment is used by clients as a basis to obtain funding for remediation and develop a global sense of urgency regarding compliance with Part 11. This approach also provides information to re-evaluate the assessment approach and assessment criteria.

ANALYSIS & REMEDIATION OF LEGACY ELECTRONIC RECORDS & ELECTRONIC SIGNATURE SYSTEMS

JAF's Quality and Regulatory Compliance Services will develop quantitative means to evaluate the entire inventory of computerized systems for nonconformance to 21 CFR Part 11. JAF will provide services to inventory systems into logical groupings, collect assessment data, provide options for remediation and develop a prioritized list of systems to bring into compliance. The basis of all evaluations is a sound understanding of 21 CFR Part 11, corporate policies and accepted industry practices. The result is a comprehensive plan for assessment and demonstrable remediation of legacy systems.

ANALYSIS & PLANNING FOR IMPLEMENTATION OF ELECTRONIC RECORDS & ELECTRONIC SIGNATURE SYSTEMS

JAF's Quality and Regulatory Compliance Services will work with users, administrators and developers to design functionality into electronic records and electronic signatures systems so that new systems meet the requirements of the regulation in conjunction with the corporate procedures. JAF will develop strategic planning documentation to map system functional specifications directly to 21 CFR Part 11 requirements or corporate policy requirements. A documented strategy for compliance provides a clear path for regulators to understand intentions and justifications for technical functionality and administrative controls of a system.

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21 CFR PART 11 TRAINING

As with any change, the key to success is knowledge and training. When introducing a new system that is 21 CFR Part 11 compliant, users must be aware of changes in the way that they must now conduct business. The best way to encourage user acceptance and ensure understanding is to make them aware of why the changes are necessary and how to successfully incorporate these changes into their policies and procedures. Training is essential in successfully implementing a Part 11 compliant system. JAF Validation and Regulatory Services will provide this training to educate your users about the newest regulation, 21 CFR Part 11.

VALIDATION OF ELECTRIC RECORDS & ELECTRONIC SIGNATURES REQUIREMENTS

Before beginning a project that involves a Part 11 compliant system, it is beneficial to perform an evaluation to access the current state of compliance of the company. JAF's Compliance Group will evaluate the infrastructure to ascertain the compliance of the support systems. This evaluation will identify necessary SOPs and procedures that will be necessary for the support and maintenance of a Part 11 compliant system. The process also includes the review of company standard operating procedures to evaluate if the system will meet the business requirements.

JAF ELECTRONIC RECORDS & ELECTRONIC SIGNATURES REQUIREMENTS

JAF Electronic Records and Electronic Signatures Services include:

- Evaluation of Interpretations of Electronic Records and Electronic Signatures Requirements
- 21 CFR Part 11 Training
- Global Assessment Programs for 21 CFR Part 11 Compliance
- Validation of Electronic Records and Electronic Signatures Systems
- Analysis and Remediation of Legacy Electronic Records and Electronic Signatures Systems

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