

A background image showing laboratory glassware. In the foreground, there is a conical flask containing a bright green liquid, a graduated cylinder with a blue liquid, and another conical flask with an orange liquid. The background is slightly blurred, showing more lab equipment and a clean, professional setting.

VALIDATION CONSULTING SERVICES

Quality & Compliance Solutions

WHAT WE DO

JAF works as a partner with companies needing computer validation services in order to attain rapid turnkey computer system validation. Our firm provides its customers with many Quality Assurance services specifically suited to their needs. From the design of test protocols, establishing the right level of validation, and training on computer validation issues, JAF will provide specific services tailored to your organization.

COMPLIANCE PROGRAM PLANNING & DEVELOPMENT

In The challenges facing organizations in the implementation of a sound compliance program often stem from a lack of understanding of the constant changing of regulatory expectation that are imposed upon them. JAF will address all of those regulations and identify potential regulatory issues to help your organization develop a compliance structure and quality system that will reflect the values and requirements of your business.

JAF Program Services include:

- Quality System Assessment and Remediation
- Validation Policy and Standards Development
- Systems Assessment, Categorization and Prioritization (Validation Site Master plan)
- Vendor Qualification / Audit Process Development
- System Life Cycle Documentation
- Validation Maintenance Programs
- Change and Configuration Management

- JAF Consulting, Inc. is a full service, Quality and Regulatory Services consulting firm specializing in the Quality Assurance services and management and execution of Computer System Validation Projects in the Pharmaceutical and Life Science Industries.
- JAF's services include validation master planning to protocol development and execution. Our consultants are renowned for their practical understanding and implementation of regulatory requirements. Our expertise has demonstrated that the key to successfully satisfying regulatory agencies is a well-planned, logical approach in all phases of a project from initiation to implementation to use.
- JAF is dedicated to providing the pharmaceutical, life science, biotechnology, and medical device industries with leading computer validation services.
- JAF provides high quality CSV services that have earned a reputation for being a practical, cost effective approach to assisting our clients in complying with today's regulatory requirements.

COMPLIANCE TRAINING & WORKSHOPS

Each individual within an organization has the potential to unintentionally undermine the goals of a quality system by not recognizing the consequences of their actions. JAF's services will develop training plans customized for our clients' industry and the various levels of staff within your organization.

JAF offers the following to help meet your Training needs:

- Validation and Compliance Training
- Basic Computer Validation
- Advanced Topics
- 21 CFR Part 11 Training

21 CFR PART 11

The Food and Drug Administration is aggressively moving toward an electronic regulatory submissions environment. 21 CFR Part 11- Electronic Records; Electronic Signatures, is the most recent addition to the FDA's regulations. 21 CFR Part 11 applies to any records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted under any FDA agency records requirement. It also applies to any electronic records submitted to the agency.

JAF offers the following to help meet your 21 CFR Part 11 needs:

- Policy Development
- Planning and Remediation
- Training

COMPLIANCE PROJECT MANAGEMENT & EXECUTION

JAF will examine your development, implementation and support strategies for new or existing systems and processes. We provide a comprehensive assessment and a structured remediation plan for development, user, and operations practices.

AUDITING & ASSESSMENT SERVICES

JAF designs audit or assessment plans to assure that systems operating in your organization adhere to your internal quality standards as well as those of the regulatory authorities. A vendor qualification program will assist you in evaluating the personnel, development practices, and applicable vendor support and maintenance programs of a vendor firm.

JAF offers the following Auditing and Assessment services to help meet your needs:

- Vendor Qualification Programs
- Compliance Audits
- Third Part Site Audits - Laboratories, CROs, Clinical
- Vendor & Supplier Audits
- Computer System Validation Audits
- SOP & Process Audits

JAF Project Services include:

- Baseline Assessment / GAP Analysis
- Specifications Development
- Validation Planning
- Standard Operating Procedure Development
- Qualification (IQ, OQ, PQ) Protocols and Scripts
- Validation Summary Reports

