



AUDITING & ASSESSMENT SERVICES

Validation & Regulatory Services Practice

AUDIT & ASSESSMENT PROJECTS

Data Integrity
3rd Party (CRO, CMO)
GLP, GCP, GMP Audits
21 CFR Part 11 Compliance
Laboratory System Assessments
Systems and Periodic Review Audits
Vendor Selection /Qualification Audits

SUPPLIER AUDIT/ ASSESSMENT

DEFINING QUALITY STANDARDS

In a regulated environment, evaluating products and services provided by suppliers is not just good business practice; it is a requirement. JAF Compliance Audit Services will design a supplier assessment plan to assure that company's suppliers meet or exceed defines quality standards. A supplier assessment plan will help you evaluate the personnel, development practices and applicable supplier support and maintenance programs of a supplier firm. This type of analysis can help streamline development and validation efforts by identifying supplier methodologies and standard practices.

STRUCTURING SUPPLIER ASSESMENT METHODS

For many organizations in regulated industries, the overwhelming tasks involved in maintaining internal quality standards often require the use of all available resources. In many instances, thorough supplier assessment is neglected. As a result, organizations can become vulnerable to regulatory compliance issues and potential quality-related problems with suppliers. JAF Compliance Audit Services has developed supplier assessment plans to help organizations with limited resources ensure supplier conformance to quality standards.

By defining supplier assessment practices and acceptance criteria in a clear and comprehensive manner, the effort needed to obtain critical supplier information is assumed by the supplier not your quality group. This results in less administration effort needed on your part and an increased awareness of quality conformance requirements by your suppliers.

Let JAF help you prepare and execute a structured Compliance Audit and Assessment Program that will demonstrate regulatory compliance of your computerized systems and supporting practices.

JAF works as a partner with clients who are in need of Audit services in order to provide them with rapid unbiased solution to a particular product or organization.

JAF provides high quality Audit Services that embody a practical and cost-effective approach in assisting clients comply with today's regulatory requirements.

VALIDATION ASSESSMENT PROJECTS INCLUDE:

- *VENDOR/DEVELOPER QUALITY ASSURANCE PLAN*
- *VENDOR/DEVELOPER DEVELOPMENT METHODOLOGY*
- *VENDOR/DEVELOPER ESCROW AGREEMENT*
- *VENDOR/DEVELOPER AVAILABILITY OF SUPPORT*
- *VENDOR/DEVELOPER PERSONNEL QUALIFICATIONS*
- *VENDOR/DEVELOPER COMMERCIAL EVALUATION*

EXECUTING SUPPLIER ASSESSMENT PROGRAMS

In addition to developing supplier assessment programs, JAF Auditing and Assessment Services will perform in-depth evaluations of supplier qualifications through supplier quality questionnaires, supplier site audits, and initiatives designed to challenge supplier practices. Using JAF to perform these necessary tasks increases the level of quality conscientiousness of your suppliers, indicating to them that their practices are subject to third-party evaluations.

MONITORING ONGOING SUPPLIER CONFORMANCE

Monitoring Ongoing Supplier Conformance
JAF Auditing and Assessment Services will monitor the quality conformance of your suppliers through routine evaluations performed according to your quality standards. JAF will manage all computer-related supplier assessments in concordance with your organization's list of approved suppliers. The flexibility to design and execute supplier evaluations to the level required by your organization enables JAF to provide a valuable resource to your quality compliance group.

IT INFRASTRUCTURE AUDITS

Organizations of all types are recognizing the benefits of implementing sophisticated network application systems such as Document/Image management, Database Management, and Data Warehousing. These can be from software vendors such as Documentum and Oracle or custom built systems.

KNOWING YOUR VALIDATION NEEDS

By performing audits of your information systems, JAF will help prepare your organization for potential regulatory reviews.

Because of our experience in regulated industries and knowledge of regulatory trends, we will provide you with an expert and objective assessment of your compliance program to help you pinpoint deficiencies and recognize risks.

Satisfy your regulatory requirements for computerized systems by utilizing JAF's industry proven methodology and validation specialists to optimize your company's existing quality system.

