



LABORATORY COMPLIANCE SERVICES

Quality & Compliance Solutions

WHAT WE DO

JAF Consulting, Inc. is your one stop solution – we will be your interface between instrument vendors and your compliance program. JAF is committed to helping laboratories achieve their compliance goals by providing services that are standardized, harmonized, flexible, and cover most systems within your laboratory environment, regardless of the manufacturer or regulated industry that you are part of.

Laboratories that are seeking methods to streamline the compliance approach can rely on JAF's Laboratory Compliance Solutions

EXPERTISE & QUALITY

JAF's extensive knowledge in instrument qualification and validation is complemented perfectly by proficiency in instruments, systems, and validation. We can offer qualification processes that are totally independent of both the equipment manufacturer and software provider. Data systems are validated according to your methodologies or, JAF will develop a laboratory qualification program for your organization. JAF will ensure compliance with the applicable predicate rule as well as 21 CFR Part 11 requirements. All documentation is customized to meet your standards and expectations.

HARMONIZATION & FLEXIBILITY

With our unique technologies and processes, we will standardize the approach to qualification across the laboratory, site, and company. These processes give uniform protocols for all brands of instruments and provide a consistent approach to delivery. Ultimately, you receive standardized documentation for consistent results and higher quality documentation. This standard methodology eliminates many of the complexities when it comes to regulatory audits. It also allows you to qualify and validate your instruments with a visit from a single source, JAF Consulting, Inc.

Every lab is different. When it comes to compliance, rigorous protocols don't have to mean inflexible methodologies. We have the customized solutions to fit the requirements of your organization.

LABORATORY QUALIFICATION & VALIDATION DOCUMENTATION

JAF will provide complete compliance documentation to support your laboratory qualification/ validation program.

- Master Validation Plan
- Laboratory Inventory and Assessments
- Laboratory Compliance Requirements
- System Requirements
- Qualification Protocols
- Summary Reports

LABORATORY DATA INTEGRITY AUDITS

JAF's experts have conducted numerous data integrity reviews and audits, identifying data integrity issues and providing practical remediation solutions. We have helped companies lift import restrictions associated with data integrity observations and have assisted companies with data integrity reviews under the FDA's Application Integrity Policy (AIP) and other international regulatory agency expectations.

Our audits review all aspects of your records and data recording practices including laboratory systems and electronic storage. We also verify the accuracy and reliability of data submitted in drug and biologic marketing authorization applications.

Services we provide:

- Data integrity focused audits: Conducted by JAF's experts, these audits provide findings and recommendations for closing gaps.
- Third-party data integrity audits: Audits of CMOs, CTOs, CROs and other service providers or prospective suppliers.
- Mock inspections with data integrity focus: Our staff helps your company prepare for the real thing.
- Data integrity assessments: A collaborative approach to identify system weaknesses and find solutions by utilizing our team's expertise to your advantage.

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

IS YOUR LAB MOVING? WE CAN HELP!

JAF Laboratory Compliance Services will assist you if you are planning or involved in a laboratory move. JAF will design a laboratory qualification program that will allow the move to happen without major implications, by developing all of the necessary protocols and test cases to keep you in compliance during and after the move.

There is no longer a need to call a different vendor to qualify every piece of equipment in your laboratory. JAF is your single source. No matter the manufacturer, we have the expertise and methods to ensure accurate, professional qualification of most laboratory equipment.

