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*

JAF CONSULTING, INC. | PO BOX 15884 | WILMINGTON NC 28408 | WWW.JAFCONSULTING.COM
856.241.1900
INFO@JAFCONSULTING.COM

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.

JAF CONSULTING INCORPORATED

TRAINING & EDUCATION SERVICES

Quality & Compliance Solutions

WHAT WE DO!

JAF Consulting, Inc. provides proven, expert training programs that keep Pharmaceutical and Life Science Organizations ahead of critical technical and regulatory trends to strengthen a client's strategic advantage. Focused on quality and compliance-related activities, our instructors offer practical solutions in support of our theoretical recommendations. We provide hands-on implementation assistance that meet manufacturers' specific needs. By rigorously tracking global technical, regulatory, and legal trends, and by providing innovative programs that reach many levels of their clients' organizations, JAF training programs help clients sharpen their organizations' competitive edge.

CLIENT ADVANTAGES

- Rapid response to training needs
- Noted experts address clients' specific concerns
- Cost savings versus high in-house expenses
- Promote consistency from plant to plant
- Establish a firm understanding of current regulatory trends and impact on your business

JAF provides a full menu of training services, in the areas of needs assessment, program development, and current regulatory issues. Rather than a one size fits all approach, we partner with our clients and tailor the training program to meet their needs. We offer classroom training, train the trainer, and customized computer based interactive training modules.

PROGRAMS OFFERED (NOT ALL INCLUSIVE):

- Basic and Advanced topics in FDA: GLP, GCP, GMP, CSV
- Basic and Advanced topics in ISO: 17025, 14385
- 21 CFR Part 11, GDPR, Electronic Systems Compliance
- Vendor Management and Supplier Auditing

DESIGNING CUSTOMIZED TRAINING PLANS

The success of any organization operating in a regulated environment is determined largely by the knowledge and training provided to all levels of personnel. Each employee has the potential to unintentionally undermine the goals of a quality system by not recognizing the consequences of their actions. JAF Training Services will develop a training plan customized for our clients' industry and the various levels of staff within your organization. JAF can develop a routine training program that allows all employees to understand the importance of adopting a quality-oriented approach to every task.

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INTRODUCING EMPLOYEES TO REGULATORY REQUIREMENTS

In many instances, the lack of a true understanding of the regulatory requirements by personnel performing critical operations can be the biggest roadblock to executing a qualitative validation effort. While not every employee needs to possess a thorough understanding of regulations, it is important that all employees realize their importance. JAF Training Services provides a high-level overview of regulatory agencies and their practices and how to address questions that arise during inspections and audits. Actual case studies of regulatory noncompliance are presented to staff during training sessions. It is our experience that case studies are a valuable tool during training exercises. They help employees understand the importance of monitoring their actions and their environment. Training programs of this kind helps employees successfully handle audits and prepares them to assist in the execution of validation activities and other compliance practices. As standard practice, JAF Training Services evaluates the effectiveness of training courses by testing all students on course material.

PREPARING PERSONNEL FOR VALIDATION PROJECTS

JAF provides training for personnel to assist in the execution of validation projects. Training in this area is invaluable to an organization with limited validation resources. Furthermore, this allows a client to take advantage of core of personnel devoted to ensuring regulatory compliance and maintaining the ideals of the quality group.

NEXT STEPS

Have JAF educate your organization's personnel about regulatory requirements, their potential impact on operations, and methods of compliance by bringing JAF's staff of validation specialists to provide comprehensive onsite training.

MAINTAINING REGULATORY COMPLIANCE

JAF Training Services will customize training programs for all levels of personnel. JAF designs a training course for executive management that addresses the financial implications of noncompliance and provides justification for making decisions pertaining to validation. Alternatively, JAF designs a training program geared to maintenance and operations personnel. Our programs allow these groups to understand the importance of their activities in protecting the corporation's resources from unnecessary risks. Finally, JAF creates a comprehensive training program for those individuals executing validation studies to enable them to have a firm grasp of the complexities of validation and the details of a particular validation project. The flexibility to structure a specific type of training program required by an organization enables us to provide valuable educational material to your project team or departmental staff.

JAF CONSULTING INCORPORATED

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 form 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

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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.

JAF CONSULTING INCORPORATED

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.

JAF CONSULTING, INC. | PO BOX 15884 | WILMINGTON NC 28408 | WWW.JAFCONSULTING.COM
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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

JAF CONSULTING INCORPORATED

PROGRAM MANAGEMENT SERVICES

Validation and Regulatory Services Practice

EVALUATING QUALITY COMPLIANCE PROGRAMS

A compliance program is the best indicator of an organization's commitment to marketing quality products in a regulated industry. The challenges facing organizations in implementing a sound compliance program often stem from a lack of understanding of the ever-changing regulations that are imposed upon them. JAF Program Management Services performs in-depth evaluations of quality compliance strategies surrounding computer systems. By performing audits of your quality systems, we will address potential regulatory issues to help your organization develop a compliance structure that will reflect the ideals of your quality group.

STRUCTURING YOUR REGULATORY COMPLIANCE PROGRAM

JAF has developed and modified programs used by pharmaceutical, biotechnology, medical device and diagnostic companies to direct the necessary actions to maintain regulatory compliance. JAF's proven methodology ensures that all applicable regulatory requirements are addressed within an integrated quality system. JAF has the expertise to help you structure your program of quality compliance with a minimum of effort by building on to your existing quality systems rather than reinventing them.

- JAF Program Management Services provides our clients with the expertise to evaluate, structure, implement and maintain an effective approach to regulatory compliance.
- JAF will develop a comprehensive program for establishing and maintaining regulatory compliance by using JAF's thorough knowledge of current regulations industry standards and best practices.

"With our experience in various regulated industries and knowledge of regulatory trends, we will provide expert and objective assessments of your existing systems and quality program to identify deficiencies and potential risks and exposure."

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DEVELOPING STANDARDS

JAF has helped develop validation programs that can encompass all computer system validation projects for a given organization. A comprehensive program for computer systems validation reflects the high level of organization of the corporation and reduces initial time and effort that may be wasted on projects by defining and establishing the validation methodology for all projects.

SUPPORTING REGULATORY COMPLIANCE PROGRAMS

JAF Program Management Services offers support to implement compliance programs and develop specific validation project plans in accordance with corporate compliance programs. Adhering to your current programs, we will design project plans to demonstrate regulatory compliance of your computer system and supporting practices. JAF's team of validation specialists, quality assurance experts and technical writers will work together with your organization to prepare a presentation that is clear, concise and comprehensive.

MAINTAINING REGULATORY COMPLIANCE

JAF Program Management Services is dedicated to maintaining the regulatory compliance of our clients by informing them of the latest proposed and effective regulations and ensuring that established compliance programs comply with new regulations. JAF will provide services developed to routinely evaluate your internal practices and determine potential areas of non-compliance. These services have been invaluable to our clients as they provide independent evaluations of quality compliance programs and present possible options that may be adopted to prevent regulatory non-compliance.

COMPONENTS OF A COMPLIANCE PROGRAM

- Validation Methodology
- Validation Master Plan Standardization
- Software Quality Assurance Plan (SQAP)
- System Development Life Cycle Methodology (SDLC)
- Validation Protocol and Report Standardization
- Supplier/Vendor Assessment Plan

JAF CONSULTING INCORPORATED

PROJECT MANAGEMENT & EXECUTION

Validation and Regulatory Services Practice

ANALYZING PROJECT SCOPE AND APPROACH

Validation of a computerized system can often be difficult to manage without the proper objective analysis skills required to determine the scope of a project and the approach needed to complete the associated tasks that encompass the project. JAF validation services will examine your development strategy for a new or existing computerized system to allow for a comprehensive assessment of development, user, and operations practices supporting that system. JAF validation services will perform general assessments to identify the status of your organizations' information systems validation policies. JAF will build a plan of activities necessary to bring your system documentation and controls into total compliance.

CLIENT ADVANTAGES

A clear and comprehensive project plan is vital to streamline validation efforts. JAF has developed validation project plans used by pharmaceutical, biotechnology, medical device and diagnostic companies to structure validation of networks, document management systems, production planning systems, statistical analysis programs, process logic controllers, and other computerized systems. JAF will develop a validation plan to direct your organization's efforts and establish actions necessary to maintain regulatory compliance. JAF's proven methodology ensures that all applicable regulatory requirements are met with a minimum of effort by using your resources in the most efficient manner possible.

- Allow JAF help you prepare and execute a structured validation project that will demonstrate regulatory compliance of your computerized systems and supporting practices.
- JAF works as a partner with clients who are in need of computer validation services in order to provide them with rapid turnkey computer system validation. From designing test protocols and establishing the right level of validation, to training on computer validation issues, our firm provides its customers with CSV services specifically suited to their needs.
- JAF provides high quality CSV services that embody a practical and cost effective approach in assisting clients comply with today's regulatory requirements.

EXECUTING VALIDATION PROJECT PLANS

JAF will develop any level of support required to assist a client in the execution of computerized systems validation projects. JAF personnel in validation, systems development, and software quality assurance departments can perform any function of a validation project. JAF will also provide the expertise to evaluate a client's available resources and prepare a realistic schedule for completion.

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DOCUMENTING SUCCESS

JAF Validation Services provides the expertise necessary to document the results of a validation project in a clear, concise and comprehensive manner. Our team of validation specialists and technical writers will work with your personnel to document results which will demonstrate that all functional requirements of a given system are satisfied and all specifications comply with regulatory requirements.

MAINTAINING REGULATORY COMPLIANCE

JAF Validation Services offers ongoing audits of validated systems to ensure that an objective evaluation is routinely performed. JAF monitors the operations surrounding a validated system to verify adherence to supporting policies and procedures. We will evaluate any proposed changes to a validated system to determine the impact on the validation status and help client's continue to maintain regulatory compliance.

MANAGING RESOURCES

Whether it's a new product implementation or retrospective compliance effort of an existing system or facility, a significant project is likely to require the addition of several resources, possibly working at multiple sites with multiple disciplines. JAF's project management background gives us a solid grounding in the skills needed to manage large projects effectively. Our expert project managers, validation consultants, documentation specialists, and testers guarantee the fastest possible response to any resource requirement your project requires. With over 20 years of combined experience in mobilizing, training, and managing highly skilled professionals, ensures not only the optimal approach, but timely efficiencies for your compliance projects.

STAFF AUGMENTATION

In today's busy IT environment, successful project development and implementation is often a challenge. Business conditions may require more aggressive design and implementation schedules than your staff will handle. Corporate missions can arise that are too complex or too time consuming for your staff to undertake. At other times you may experience difficulty in launching new solutions, face unexpected staff turnover, or come to an impasse with the latest technology. When these situations occur, you need top quality help and you need it fast. That's where JAF will make a real difference in your success. With our Staff Augmentation Services, you can draw from our Professional Services staff to get expert assistance with project management, custom application design, quality assurance, system administration, or validation documentation preparation and execution assistance. JAF's Staff Augmentation Services is ready to help with the expertise you need to reach your goals.

JAF CONSULTING INCORPORATED

QUALITY ASSURANCE AS A SERVICE QAAAS

Quality & Compliance Solutions

WHAT WE CAN DO FOR YOU!

JAF Consulting, Inc. is pleased to announce their new service offering, Quality Assurance as a Service (QAaaS). This service is based on the Functional Service Provider (FSP) model, which will benefit organizations by providing increased productivity, flexibility and scalability of staff, and significant cost savings.

JAF's team can seamlessly integrate into any organizations programs as a QAaaS provider. Our team has worked with many different organizations and understands the types of projects we will be called to produce in. We have our own internal procedures in which we are trained, or we could utilize your procedures and processes. Our consultants have no less than 10 years of experience as Quality Assurance professionals, we understand compliance and we are able to hit the ground running with any program we are integrated with.

We can provide the flexibility and scalability of workforce as needed. Within this model we are able to provide dedicated resources for you to utilize across multiple sites or therapeutic programs. As resource requirements can fluctuate during the implementation of a program, JAF's QAaaS model can add qualified resources quickly with our full-time staff, or network of quality assurance professionals, and when programs wind down, we are able to reduce resources effectively without the burden of contract or HR issues.

Our principals have been in the pharmaceutical and life science industry for over 30 years, and in the capacity of JAF Consulting, Inc. for the past 16 years. Although the technologies and delivery methods of drug products have changed, the need for quality has not. JAF will make the complex world of regulatory interpretation, simple, by working with you to develop a solid and sustainable compliance program. JAF is a smart and agile consulting strategic partner to life science companies who need a quality and regulatory compliance program that addresses the immediate needs of today, while providing the confidence and peace of mind for tomorrow.

JAF Consulting, Inc. is a global quality and regulatory compliance services consulting firm specializing in the auditing, management and execution of computer system validation projects. JAF's services are GLP, GCP, GMP QA (QAaaS), quality management systems, SOP writing, computer system implementation and validation, GxP auditing and assessment, training and education.

When you partner with JAF you receive high-quality services that have earned a reputation for being practical and cost effective to assist our clients in complying with today's regulatory requirements.

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856.241.1900
INFO@JAFCONSULTING.COM

SOFTWARE SELECTION & IMPLEMENTATION SERVICES

Quality & Compliance Solutions

WHAT WE CAN DO FOR YOU!

Selecting a new enterprise solution to power your enterprise can be a challenging situation. JAF understands. We are by your side to help you remain confident when evaluating and selecting a new software solution. JAF employs a proven strategy to help evaluate your needs, determine any gaps in your existing process or software, and develop a plan of action to move forward. We will then work with your key stakeholders and staff to evaluate and implement new software solutions.

As a vendor-neutral firm, JAF Consulting, Inc. has experience selecting and implementing many different types of software packages. Our consultants understand the complex challenges faced by regulated industries in designing, building and maintaining systems to support operations and compliance. We leverage our deep industry and regulatory expertise to help our clients maximize revenue, optimize pricing and ensure compliance with changing regulation.

Software selection is a critical step in this process. Depending on the type of software needed, there can be dozens of choices. We start with a deep understanding of your critical processes that will be supported by the new technology. We work with you to evaluate and help you understand the potential software matches -- either through onsite software review or more formal vendor demonstrations.

"We provide Software Selection and Implementation services for life science clients looking for new software solutions."

We will help you navigate and understand the regulatory expectations for the implementation of these software systems. We'll even assist with software pricing and vendor negotiations to get you the right software at the lowest possible price.

During software implementation our project managers and process consultants work with the software vendor and your IT and functional staff to install, configure, and prepare your new software for launch. We focus on ensuring the software is configured according to your specifications, your staff is adequately trained, and there is minimal impact to your current operations. If the system is governed by regulated authorities, JAF will also prepare all deliverables to support the intended use of the system.

We have a simple definition for a successful project: one that begins and ends on time and on budget and meets management expectations for its efficiency and operation.

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856.241.1900
INFO@JAFCONSULTING.COM

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.

JAF CONSULTING, INC. I PO BOX 15884 I WILMINGTON NC 28408 I WWW.JAFCONSULTING.COM
856.241.1900
INFO@JAFCONSULTING.COM

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

JAF CONSULTING INCORPORATED

VALIDATION PROGRAM & PROJECT MANAGEMENT SERVICES

Quality & Compliance Solutions

EVALUATING QUALITY COMPLIANCE PROGRAMS

JAF compliance program is the best indicator of an organization's commitment to marketing quality products in a regulated industry. The challenges facing organizations in implementing a sound compliance program often stem from a lack of understanding of the ever-changing regulations that are imposed upon them. JAF Program Management Services performs in-depth evaluations of quality compliance strategies surrounding computer systems. By performing audits of your quality systems, we will address potential regulatory issues to help your organization develop a compliance structure that will reflect the ideals of your quality group.

With our experience in various regulated industries and knowledge of regulatory trends, we will provide expert and objective assessments of your existing systems and quality program to identify deficiencies and potential risks and exposure.

STRUCTURING YOUR REGULATORY COMPLIANCE PROGRAM

JAF has developed and modified programs used by pharmaceutical, biotechnology, medical device and diagnostic companies to direct the necessary actions to maintain regulatory compliance. JAF's proven methodology ensures that all applicable regulatory requirements are addressed within an integrated quality system. JAF has the expertise to help you structure your program of quality compliance with a minimum of effort by building on to your existing quality systems rather than reinventing them.

ABOUT US

- JAF Validation Program and Project Management Services provides our clients with the expertise to evaluate, structure, implement and maintain an effective approach to regulatory compliance.
- JAF will develop a comprehensive program for establishing and maintaining regulatory compliance by using JAF's thorough knowledge of current regulations industry standards and best practices.
- JAF will help you prepare and execute a structured validation project that will demonstrate regulatory compliance of your computerized systems and supporting practices.
- JAF works as a partner with clients who are in need of computer validation services in order to provide them with rapid turnkey computer system validation. From designing test protocols and establishing the right level of validation, to training on computer validation issues, our firm provides its customers with CSV services specifically suited to their needs.
- JAF provides high quality CSV services that embody a practical and cost-effective approach in assisting clients comply with today's regulatory requirements.

JAF CONSULTING, INC. | PO BOX 15884 | WILMINGTON NC 28408 | WWW.JAFCONSULTING.COM
856.241.1900
INFO@JAFCONSULTING.COM

DEVELOPING STANDARDS

JAF has helped develop validation programs that can encompass all computer system validation projects for a given organization. A comprehensive program for computer systems validation reflects the high level of organization of the corporation and reduces initial time and effort that may be wasted on projects by defining and establishing the validation methodology for all projects.

SUPPORTING REGULATORY COMPLIANCE PROGRAMS

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.

MAINTAINING REGULATORY COMPLIANCE

JAF Program Management Services is dedicated to maintaining the regulatory compliance of our clients by informing them of the latest proposed and effective regulations and ensuring that established compliance programs comply with new regulations. JAF will provide services developed to routinely evaluate your internal practices and determine potential areas of non-compliance. These services have been invaluable to our clients as they provide independent evaluations of quality compliance programs and present possible options that may be adopted to prevent regulatory non-compliance.

JAF ELECTRONIC RECORDS & ELECTRONIC SIGNATURES REQUIREMENTS

Components of a Compliance Program:

- Computer System Validation Methodology
- Validation Master Plan Standardization
- Software Quality Assurance Plan (SQAP)
- System Development Life Cycle Methodology (SDLC)
- Validation Protocol and Report Standardization
- Supplier/Vendor Assessment Plan

ANALYZING PROJECT SCOPE & APPROACH

Validation of a computerized system can often be difficult to manage without the proper objective analysis skills required to determine the scope of a project and the approach needed to complete the associated tasks that encompass the project. JAF validation services will examine your development strategy for a new or existing computerized system to allow for a comprehensive assessment of development, user, and operations practices supporting that system. JAF validation services will perform general assessments to identify the status of your organizations' information systems validation policies. JAF will build a plan of activities necessary to bring your system documentation and controls into total compliance.

ORGANIZING YOUR VALIDATION PROJECT

A clear and comprehensive project plan is vital to streamline validation efforts. JAF has developed validation project plans used by pharmaceutical, biotechnology, medical device and diagnostic companies to structure validation of networks, document management systems, production planning systems, statistical analysis programs, process logic controllers, and other computerized systems. JAF will develop a validation plan to direct your organization's efforts and establish actions necessary to maintain regulatory compliance. JAF's proven methodology ensures that all applicable regulatory requirements are met with a minimum of effort by using your resources in the most efficient manner possible.

EXECUTING VALIDATION PROJECT PLANS

JAF will develop any level of support required to assist a client in the execution of computerized systems validation projects. JAF personnel in validation, systems development, and software quality assurance departments can perform any function of a validation project. JAF will also provide the expertise to evaluate a client's available resources and prepare a realistic schedule for completion.

DOCUMENTING SUCCESS

JAF Validation Services provides the expertise necessary to document the results of a validation project in a clear, concise and comprehensive manner. Our team of validation specialists and technical writers will work with your personnel to document results which will demonstrate that all functional requirements of a given system are satisfied and all specifications comply with regulatory requirements.

MAINTAINING REGULATORY COMPLIANCE

JAF Validation Services offers ongoing audits of validated systems to ensure that an objective evaluation is routinely performed. JAF monitors the operations surrounding a validated system to verify adherence to supporting policies and procedures. We will evaluate any proposed changes to a validated system to determine the impact on the validation status and help clients continue to maintain regulatory compliance.

MANAGING RESOURCES

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STAFF AUGMENTATION

In today's busy IT environment, successful project development and implementation is often a challenge. Business conditions may require more aggressive design and implementation schedules than your staff will handle. Corporate missions can arise that are too complex or too time consuming for your staff to undertake. At other times you may experience difficulty in launching new solutions, face unexpected staff turnover, or come to an impasse with the latest technology. When these situations occur, you need top quality help and you need it fast. That's where JAF will make a real difference in your success. With our Staff Augmentation Services, you can draw from our Professional Services staff to get expert assistance with project management, custom application design, quality assurance, system administration, or validation documentation preparation and execution assistance. JAF's Staff Augmentation Services is ready to help with the expertise you need to reach your goals.

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