



# 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.

## 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

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.

## 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.

