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.

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.

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