



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."

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

