



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.

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.

