Auditing, Remediation, and Staff Augmentation

THE FDA GROUP LLC

TABLE OF CONTENTS

3 Introduction

4 Auditing

- 5 GMP Auditing
- 6 GCP Auditing
- 7 GLP Auditing
- 8 Pharmacovigilance Auditing
- 9 Vendor/Supplier Auditing

10 Remediation

11 Staff Augmentation

12 Data Integrity & Computer System Validation

INTRODUCTION

Overview

The FDA Group is an organization that utilizes a proprietary talent selection process of former FDA & industry professionals, amplified by a corporate culture of responsiveness and execution. Headquartered in Westborough, Massachusetts, The FDA Group has 500+ specialists worldwide, 75+ of whom are former FDA.

Why is The FDA Group in business?

The FDA Group is in business to enhance the quality of people's lives. Whether it is our clients, employees, contractors, vendors, communities, or the patients who receive the products we touch, our purpose lies in discovering meaningful ways to apply our experience, expertise, and passion for quality in everything we do.

How does The FDA Group do it?

We are able to do this through our proprietary talent selection process and deep-rooted corporate culture built upon 5 Core Values. These Core Values are the heartbeat of our organization and focus on the following concepts:

1. **Respond with urgency.**
2. **Find a way to make it happen.**
3. **Communicate openly and honestly.**
4. **Be humbly confident.**
5. **Be easy to work with.**

What does The FDA Group do?

The FDA Group is a global leader in auditing, remediation support, staff augmentation, regulatory affairs, and expert witness services.

AUDITING

An increasing number of public health concerns and challenges have underscored regulators' proactive pursuit of compliance throughout all regulated industries. Our quality professionals perform detailed assessments of your existing quality system, identify current and potential problems, recommend corrective and preventive actions, and work closely with your staff to implement these improvements to your quality system. Our consultants analyze FDA's inspection history using predictive language to determine your risk for future inspections and can assist you with all aspects of compliance, including but not limited to, GMP, GCP, and GLP.

GMP AUDITING

Good Manufacturing Practices ensure products are produced and controlled to the appropriate quality standards while adhering to industry regulations. Resolving and preventing compliance issues for medical products requires expertise in planning, developing, and implementing Good Manufacturing Practice (GMP) quality systems.

Our quality professionals bring direct experience in pharmaceutical, biotechnology, combination, and medical device development and manufacturing to help you understand and address quality assurance needs at every stage of product development. Our team works closely with your staff to improve processes for manufacturing, distribution, and packaging facilities—taking the lead in planning, executing, and analyzing comprehensive audits to uncover potential deficiencies and make the necessary improvements, all while empowering your staff to maintain compliance well into the future.

GMP Auditing Services:

- Mock Pre-Approval Inspections (PAI) and mock FDA audits
- Mock Notified Body Inspections
- Vendor/supplier audits
- Formal risk assessments & risk mitigation strategies
- Quality system & corporate SOP gap analysis

Additionally, we help clients in:

- Compliance master planning and strategy
- Corrective actions and implementation plans
- Planning and execution of remediation projects
- Validation and qualification
- Quality system & corporate SOP guidance and development
- Training and development of training programs

GCP AUDITING

When conducting clinical trials on investigational medicinal products or devices, you are required to show the planning, study conduct, performance, monitoring, auditing, analysis, and reporting all meet the ethical and scientific standards for Good Clinical Practice (GCP). Failing to adequately meet GCP standards can threaten the data collected, the future of your products and your reputation within the industry.

Our quality professionals closely examine your particular study before planning and executing study-specific GCP audits of protocols, investigator sites, trial master files, pharmacovigilance, databases, and reports. With the help of experienced industry professionals, you can be confident knowing results are credible and accurate while maintaining quality practices throughout research.

GCP Auditing Services:

- Mock BIMO Inspections
- Auditing and document review for SOPs, clinical GCP protocols and reports
- Audits of submission for ethical approval for GCP clinical trials
- Audits of clinical sites
- Audits of Trial Master Files (TMFs)
- Audits of Contract Research Organizations (CROs) and other vendors
- Clinical trial audits are tailored to your particular compliance needs and stage of product development

GLP AUDITING

When using laboratories, whether research (non-GLP), preclinical (GLP), clinical (GCLP) or commercial product QC support (GMP), it's important to ensure that data is credible and in compliance with protocols, standard operating procedures (SOPs), and regulatory requirements.

Our quality professionals plan and conduct comprehensive audits for all types of laboratories. We go beyond simply giving advice and guidance, taking an active role in solving laboratory quality issues, establishing a quality management system, preparing laboratory policies and SOPs, and planning routine monitoring and quality control test procedures.

GLP Auditing Services:

- Audits of safety or specialty laboratories
- Mock FDA inspections
- CLIA assessments
- Qualification of GLP facilities
- Gap analyses
- SOP development

PHARMACOVIGILANCE AUDITING

Pharmacovigilance (PV) auditing is essential when balancing the risks and benefits of a new drug, biologic, or medical device. As regulators step up pharmacovigilance and place greater scrutiny on pharmacovigilance Quality Management Systems, it's up to you to assess internal activities, vendor relationships, commercial partnerships and others that comprise the pharmacovigilance system.

Our professionals have firsthand experience in quality management for pharmacovigilance systems. We will help you audit current pharmacovigilance systems to ensure regulatory compliance while providing your internal team with the training it needs to maintain quality processes in the future.

VENDOR/SUPPLIER AUDITING

FDA's focus on vendor, supplier, and contract manufacturer compliance is tightening. Increased regulatory scrutiny has placed a greater emphasis on the importance of auditing the quality systems, practices, processes, products, and documentation of all third party providers. The supply chain is only as strong as its weakest point. To protect yourself and your stakeholders from the consequences of recalls, seizures, injunctions, and other enforcement actions, it is critically important to identify and remediate all compliance issues present in your outsourced operations through comprehensive audits and corrective actions conducted by experienced quality professionals.

Our certified, experienced auditors plan, schedule, and execute vendor/supplier quality management audits to identify areas of conformance and nonconformance with applicable global regulations. We provide a project manager free of charge to take the weight of a large auditing program off of your shoulders. These leaders allocate resources appropriately and ensure your deadlines are met throughout all phases of the project. Following assessment, our experts provide a detailed report including all observations, deficiencies, and a risk-based corrective action plan for improvement.

With an enhancement plan in place, our quality professionals will work closely with you to provide recommendations, resolve compliance issues, track corrective actions, and communicate the status of resolutions with company management. This comprehensive approach to vendor/supplier quality management strengthens your vendor/supplier relationships while ensuring your products are of the highest quality through a quality system that is compliant and efficient.

Vendor/supplier Auditing Services:

- Vendor/supplier audit plan strategy and creation
- Vendor/supplier audit execution and project management
- Vendor/supplier audit plan maintenance and support
- MDSAP strategies and audit implementation

REMEDIATION

Compliance remediation is the process of recognizing problems, creating a plan to correct and prevent them from occurring in the future, and executing to that plan. This often requires alignment with an experienced remediation partner capable of identifying the root causes of compliance issues, resolving them, and communicating those actions to the FDA.

We specialize in planning and conducting comprehensive remediation projects. Our team of former FDA and industry professionals work hand-in-hand with pharmaceutical, biologic, and medical device manufacturers to uncover the root cause of compliance issues, remediate them, and implement the necessary measures to safeguard your reputation for quality both now and in the future.

Failing to address concerns highlighted in FDA 483s and FDA warning letters can threaten your product pipeline, or worse, result in a recall, import ban, detention or product seizure—damaging your global supply chain, financial well-being, and reputation. If you have received Form 483 Inspectional Observations, warning letters, or any other enforcement action from regulating agencies, we have the resources, experience, and processes required to resolve those issues quickly and effectively.

Our Proven 4-Step Remediation Process

1. Analyze observations and choose the quality investigation model best suited to thoroughly understand the compliance issues at hand.
2. Launch an internal investigation with the assistance of key stakeholders to assess all affected processes and reveal the root causes of noncompliance.
3. Draft a comprehensive Corrective and Preventive Action (CAPA) plan and assure agreement by all stakeholders.
4. Implement agreed-upon corrective and preventive actions with the appropriate amount of supervision and monitoring.

Our Approach to Compliance Remediation

Our active remediation model goes beyond consulting to solve a variety of compliance problems while offering ongoing project management and training services each step of the way. Once remediation is complete, we plan, implement, and audit your quality system to ensure regulatory compliance is maintained well into the future.

STAFF AUGMENTATION

Staff augmentation provides exclusive access to a diverse talent pool of professionals capable of addressing virtually any need pertaining to quality within the pharmaceutical, biotechnology, and medical device industries.

Managing quality effectively in an FDA-regulated environment requires a system to control, monitor, and verify all activities and processes related to product safety. Our staff augmentation services pair you with the right professionals to enhance your quality system through a customized evaluation and improvement program tailored to your specific needs.

Our large staff of 520 specialists worldwide, 65 of whom are former FDA, bring firsthand experience and a thorough understanding of FDA and global compliance requirements to assess your current quality system, identify gaps, and implement the improvements necessary to maintain compliance within the increasingly complex, global regulatory environment.

We recognize the challenges of developing and managing an effective quality system under the watchful eye of regulators. Our professionals draw on years of experience and highly specialized skills to ensure objective, accurate, and actionable recommendations are made each step of the way.

Staff Augmentation Services:

- Preparing policies, quality standards, and SOPs
- Reviewing batch records
- Planning, conducting, and/or managing remediation projects
- Performing root cause investigations, progressing Corrective and Preventive Actions (CAPA)
- Performing audits
- Planning and conducting mock FDA inspections
- Performing global supplier and vendor audits
- Identifying and closing data integrity gaps in a GxP environment
- Reviewing and improving management controls
- Identifying and assuring the “c” in cGMP: melding industry standards with ever-changing regulations
- Enhancing management controls
- Conducting oversight programs for senior leadership
- Reviewing and improving training resources
- Executing site-wide organizational improvement plans

DATA INTEGRITY & COMPUTER SYSTEM VALIDATION

Compliance with cGMP requires companies record, track, manage, store, and easily access documents such as Standard Operating Procedures (SOPs), Batch Records, Test Data, and log books. Current regulations also require manufacturers to review Electronic Batch Records (EBRs) of manufactured batches and resolve all discrepancies prior to batch release. EBRs consisting of electronic records should be reliable, trustworthy, traceable, and verifiable to conform with US FDA's 21 Code of Federal Regulations (CFR) Part 11 and European Union's Annex 11.

Our data integrity, validation, and quality experts perform comprehensive computer systems and data assessments to ensure your system requirements are fully met and adequately documented.

Data governance and management practices are evaluated using risk-based validation strategies to protect the integrity of your data and strengthen your quality system in the process. Compliance gaps identified during the assessment are addressed through comprehensive remediation.

Thorough computer system validation (CSV) ensures your system stands up to scrutiny, leaving you secure in the knowledge that your data is safe, reliable, and available. Our CSV experts implement systems and obtain "fit for use" certification in the areas of computer and cloud systems validation and data integrity.

Our framework for CSV and data integrity assessment can be applied to both proprietary and commercially available software. Projects are planned and executed by leading computer system validation experts with intimate knowledge of current regulatory requirements and years of experience enhancing IT operations, control systems, and data integrity for pharmaceutical, medical device, and biotechnology companies.

Our comprehensive data integrity and computer systems validation services include, but are not limited to:

- Computerized and Cloud System Validation (CCSV) and qualification
- Establishing data integrity infrastructures
- Third party CMO audits
- Vendor audits
- Mock Pre-Approval Inspection (PAI) audits of data integrity
- Formal risk assessments and risk mitigation strategies

Additionally, we assist clients in:

- Planning and remediation assistance for data integrity gaps
- Guidance and development of Data Governance and Data Management Programs
- FDA-483 and warning letter responses for data integrity
- Pre-audit preparation and support during audits
- Training and development of training programs in data integrity and CSV

info@thefdagroup.com 1-833-FDA-GROUP

CONTACT THE FDA GROUP FOR EXPERT ASSISTANCE »