THE OTC DRUG MANUFACTURER'S GUIDE TO CGMP COMPLIANCE & QUALITY MANAGEMENT

Critical Questions and Considerations for Compliance Within the Key Areas of Regulatory Focus

THE FDA GROUP LLC

TABLE OF CONTENTS

SUMMARY

The U.S. FDA and other regulating bodies are increasingly inspecting and citing manufacturers of nonprescription drug and health products for current Good Manufacturing Practice (CGMP) violations. Many of these deficiencies underscore widespread underlying inadequacies in implementing and maintaining a robust Quality Management System (QMS). Given the nature of the observed deficiencies and their potential to affect consumer safety, regulators are recommending many of these firms engage outside consultants qualified to assist in performing comprehensive CGMP audits and lead subsequent remediation activities. This guide offers an actionable analysis of common CGMP compliance and QMS problems along with key questions for assessing compliance accordingly.

Contact us today to get qualified expert assistance backed by a Total Quality Guarantee.

US Toll-Free: 1-833-FDA-GROUP
International: +001 508 926 8330

INTRODUCTION

Recently, a number of significant quality and compliance deficiencies observed during routine regulatory audits have prompted the FDA and other regulatory bodies to dramatically step up inspection and enforcement of over-the-counter (OTC) drug, cosmetic, and supplement manufacturers. Increased inspections have led to numerous enforcement actions including warning letters, import alerts, and recalls.

The issues observed at these facilities have a few common themes and patterns, all of which indicate an underlying inadequacy within the Quality Management System (QMS). These include microbiological contamination control and detection due to poorly managed controls and a lack of suitable and validated testing, flaws in manufacturing operations and quality assurance, poor nonconformance management, and issues related to the establishment, responsibilities, and authority of organizational departments, namely the Quality Unit (QU).

Repeated occurrences of these deficiencies have led regulators to highlight what they see as an industry-wide lack of understanding and implementation of current Good Manufacturing Practices (CGMPs) and inadequate systems for supporting quality system management more generally. As is required under Title 21 of the Code of Federal Regulations, drugs manufactured in the U.S.—prescription and nonprescription alike—must conform to CGMPs. To achieve quality policies and objectives, regulators expect to see a formalized, robust QMS in place for documenting processes, procedures, and responsibilities for maintaining CGMP compliance.

This guide offers actionable summaries of the compliance problems these firms are experiencing while connecting them to the underlying problem related to the existence and proper implementation of a QMS. To assist firms in assessing their own risk levels and taking appropriate action, we've presented these issues as a series of questions that firms should ask of themselves when determining the need for CGMP auditing and subsequent remediation.

A BRIEF WORD ON CONTEXT

Before we dive into the specifics, it's important to be aware of the statement the FDA includes at the bottom of virtually every warning letter as it offers critical context:

> *"Violations cited in this letter are not intended as an all-inclusive list. You are responsible for investigating these violations, for determining the causes, for preventing their recurrence, and for preventing other violations."*

The message is simple and meaningful: Don't miss the forest for the trees. Read between the lines. Warning letters and inspection observations are intended to be both specific calls-to-action as well as indirect indicators of larger systemic problems. Don't isolate your actions to only what's been called out. Address the whole system.

"CGMP CONSULTANT RECOMMENDED"

In many of its recent warning letters to OTC and related firms, the FDA has "strongly recommended" engaging a third-party consultant qualified in the relevant regulations to assist in meeting CGMP requirements. The excerpt below offers the specific areas in which regulators suggest firms receive expert CGMP assistance:

> *"[We recommend] that the qualified consultant perform a comprehensive audit of your entire operation for CGMP compliance, and evaluate the completion and effectiveness of your corrective actions and preventive actions."*

If you are in need of a qualified CGMP consultant with extensive experience in quality and compliance, contact us today to learn more about our comprehensive auditing and remediation services. Our consultants have direct experience bringing firms into compliance with regulatory expectations and all of our services are backed by a Total Quality Guarantee.

GET QUALIFIED QMS/CGMP ASSISTANCE NOW »

1. DO YOU HAVE A FUNCTIONAL UNDERSTANDING OF RELEVANT REGULATIONS & STANDARDS?

Understanding the regulatory expectations and standards regulating bodies expect manufacturers to know and follow is a critical fundamental. For firms manufacturing drug and health products, 21 CFR Parts 210 and 211 as well as any relevant USP standards governing specific types of products and the systems used to produce them are central.

Part 210	Part 211
An outline of the minimum GMP requirements covering manufacturing, facilities, and controls for the manufacture, processing, packing, and holding of all drugs in such a way that meets the guidelines for safety, quality, and purity.	An outline of the minimum GMP requirements for finished drug products. This also covers various other areas, including personnel, facilities and equipment, production processes, stability testing, and labeling.

Because the rules in the entire 21 CFR 200 series explicitly address handling, storage, labeling, processing, donor selection and a host of other elements relevant to the pharmaceutical marketing process, they impact both manufacturers and the firms they partner with to produce and market products, including suppliers and contract manufacturers.

Companies that want to sell their products in FDA-regulated markets must be willing to apply compliance and quality assurance efforts to every part of their supply, manufacturing, and distribution chains. Specific to many OTC manufacturers (and other firms that may not have previously focused so heavily on FDA regulatory practices), a review of current systems and processes will often reveal significant deficiencies.

While prior regulatory encounters are obvious indicators that systems require improvement, all firms should take it upon themselves to assess their functional understanding and adherence to 21 CFR 200 series regulations and make any necessary improvements as a proactive compliance initiative. This is especially pertinent given the increased regulatory oversight being placed on these manufacturers.

Whether addressing observations from regulators or working proactively to assess and address compliance gaps, auditing and remediation projects are not only time

and energy-intensive, but rarely have a convenient starting or ending point. How and where do you start improving when you don't know what your deficiencies are or how far they stretch into your systems?

Given the difficulty in broadly assessing system compliance, this is one area in particular, firms rely heavily on outside experts for guidance. Working with consultants who understand how the best compliance systems are structured helps you reassess your own quality management practices from a more insightful, objective perspective that aligns with regulators' expectations.

A SAMPLE OF RELEVANT 21 CFR PARTS 210 AND 211 REQUIREMENTS

Document Control:

Subpart F, Section 211.100 – There shall be written procedures for production and process control, assuring that drug products have the intended identity, strength, quality, and purity. Written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units.

Quality Control Unit:

Subpart B, Section 21.22 – There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company.

Control of Microbiological Contamination:

Subpart F, Section 211.113 – Appropriate written procedures, designed to prevent objectionable microorganisms in drug products not required to be sterile, shall be established and followed. Appropriate written procedures, designed to prevent microbiological contamination of drug products purporting to be sterile, shall be established and followed. Such procedures shall include validation of all aseptic and sterilization processes.

Training:

Subpart B, Section 211.25 – Each person engaged in the manufacture, processing, packing, and holding of a drug product shall have the necessary education, training, and experience to perform the assigned functions.

Corrective and Preventive Action (CAPA):

Subpart J, Section 211.192 – Any unexplained discrepancy or the failure of a batch or any of its components to meet any of its specifications shall be thoroughly investigated. A written record of the investigation shall be made and shall include the conclusions and follow-up actions.

Audits:

Subpart J, Section 211.180 – All records, or copies of records, shall be readily available for authorized inspection. Records shall be subject to photocopying or other means of reproduction as part of such inspection. Records that can be immediately retrieved from another location by computer or other electronic means shall be considered as meeting this requirement.

Nonconformance:

Subpart E, Section 211.84 – Each component shall be tested for conformity with all appropriate written specifications for purity, strength, and quality. Any lot of components that does not meet the specifications shall be rejected.

Resources:

- 21 e-CFR Part 210
- 21 e-CFR Part 211
- FDA Over-the-Counter Guidance Listings
- FDA Inspection Technical Guide: Reverse Osmosis
- United States Pharmacopeial Convention
- FDA Quality Systems Approach to Pharmaceutical CGMP Regulations

2. ARE YOU AT RISK FOR COMMONLY-CITED CGMP/ QMS PROBLEMS?

The increased inspection activity at OTC and similar manufacturing sites is driven primarily by deficiencies that are being observed over and over again. Nearly all of these problems point to a QMS in need of improvement.

When considering the health of your own QMS and where certain vulnerabilities may lie, existing warning letters can serve as helpful resources for assessing your own susceptibility to deficiencies regulators have observed at similar firms and are likely targeting during inspections.

In this section and the others throughout this guide, we've included excerpts from relevant warning letters that offer a few examples of specific CGMP/QMS-related deficiencies commonly observed at OTC and similar manufacturing sites.

Are you at risk of the following deficiencies or similar ones?

- **Issued on 3/20/19**

  "Your firm lacked adequate investigations into failing drug products, poor water quality, and customer complaints. More specifically, in numerous instances, your quality unit failed to investigate out-of-limit microbial results from your purified water system used to manufacture water containing drugs. Failures of finished product testing and retention samples also lacked meaningful and effective investigations. In addition to these total count failures, you identified objectionable microorganisms (such as Burkholderia multivorans) in multiple drug products but lacked investigations." **(21 CFR 211.22(a))**

- **Issued on 1/12/18**

  "[You failed] to investigate the frequent, excessive levels of microorganisms in your water system. You did not explain how you will ensure adequate and effective investigation of out-of-limit test results moving forward." **(21 CFR 211.192)**

- **Issued on 2/20/19**

  "Our inspection indicated that your water quality is not suitable for its intended use. Your firm also lacked water system validation and did not demonstrate that it can consistently produce water that is suitable for pharmaceutical use. You routinely use "deionized water" for drug manufacturing and equipment cleaning. The use of deionized water for

pharmaceutical manufacturing does not assure that the drugs produced will have the quality and purity they purport or are represented to possess. You lack sufficient chemical testing for this water system, including total organic carbon. You also infrequently performed microbial monitoring of this system. In addition, your acceptance limits for chemical and microbial quality were inadequate. **(21 CFR 211.100 (a) and (b))**

- **Issued on 2/20/19**

  "Our findings indicate that your water system is not designed to consistently produce high purity water for use in drug products, in part because the procedures for the water system do not adequately address the control and maintenance of the water system. Your firm also failed to perform water system validation studies. You only had a brief vendor operational qualification report regarding an obsolete version of your water system." **(21 CFR 211.100 (a) and (b))**

As many firms have discovered firsthand, QMS failures that reveal themselves in areas like water system management are susceptible to problems that can be incredibly serious while being frustratingly difficult to detect without proper quality assurance measures. Take, for example, a situation where personnel may be inadvertently contaminating water system samples during testing without a process in place to identify the specific contaminants. If investigators detect a water system failure only to discover a firm isn't identifying the microbiological contaminants, it's likely that upon pulling and testing their own sample, they could identify a highly dangerous contaminant that could compromise consumer safety, thereby revealing a major QMS gap.

In a situation like this, a robust QMS would have provided documented processes and procedures for providing the data needed to not only detect the specific contaminant but correct and prevent the problem when it was discovered. Without it, firms are forced to jump directly into correction mode without the information they need to be successful (in this case, a proper root cause analysis and appropriate remediation plan). As time goes on, failing to accurately capture the nature of the problem at the outset only makes matters worse when responses are rejected citing inadequate problem-solving methods.

Sample Questions for Assessment

- Is your water system compliant?
- Have you experienced failures?
- Do you have the means of properly investigating failures?
- How often are you monitoring your system?
- Does your system's design lend itself to control issues?

3. ARE YOUR ANALYTICAL AND MICROBIAL TESTING AND VALIDATION METHODS ESTABLISHED AND SUITABLE FOR DETECTING CONTAMINATION?

As detailed in recent warning letter citations, microbiological method development (method suitability and validation in particular) is often mishandled or overlooked entirely. These vital processes are complex, often involving wide specifications, broad parameters, and the inherent variation that comes from working with living organisms.

Method suitability testing is used to evaluate residual antimicrobial activity of a product under testing to ensure that the results achieved in recovery test media are representative. Regulating bodies like the FDA expect firms to produce a method of testing that effectively neutralizes any antimicrobial effect and will allow control organisms to grow in expected numbers. Products likely to have this type of effect may contain preservative agents, anti-microbial or bacterial or fungistatic compounds.

Conducting these activities properly requires strict adherence to criteria set out in USP guideline. It is absolutely critical to have the appropriate comparison controls in place to ensure method development is properly carried out and the optimal technique is used.

Are you at risk of the following deficiencies or similar ones?

- **Issued on 3/20/19**

  "Over multiple years, your firm obtained recurring test results for water used as a component of your drugs, as well as results for finished homeopathic drug products, outside of microbiological limits. This testing revealed extremely high levels of microbiological contamination, including results that were Too Numerous to Count (TNTC), and identified the presence of significant opportunistic pathogens in your drugs. Furthermore, your tests of retained samples and customer complaint bottles found objectionable microbiological contamination in already distributed lots. FDA laboratory testing also revealed exceedingly high levels of microbiological contamination in multiple homeopathic drugs produced by your drug company." **(21 CFR 211.22(a))**

- **Issued on 3/20/19**

  "You failed to adequately demonstrate antimicrobial effectiveness of your preservative systems. For example, you attempted to evaluate

antimicrobial effectiveness of one of your liquid drugs and consider it suitable for its intended use in over several hundred other drugs with varying formulations. You lacked adequate studies to demonstrate the adequacy of your preservative systems and your firm has continued to identify very hazardous contamination levels in your products." **(21 CFR 211.100(a))**

- **Issued on 1/12/18**

  "Your firm failed to investigate test results showing that your water exceeds the allowable limit for microorganisms. Your tests on samples from your water system indicated that microorganism levels were too numerous to count (TNTC) on 25 out of 96 days. You use this water as a major component in manufacturing over-the-counter (OTC) drug products. Your failure to investigate violated your written procedures which require an investigation when results are above colony-forming units/milliliter (cfu/mL). This system is fundamentally flawed as it is not capable of producing water that is suitable for use in pharmaceutical manufacture." **(21 CFR 211.192)**

- **Issued on 1/12/18**

  "Our investigator found that your microbiological test methods are not adequately verified. Specifically, you did not show that these methods can recover microorganisms in the presence of the antimicrobial agents that are present in your drug products. In response to this letter, provide supporting documentation demonstrating the suitability of your microbiological test methods for your drug products. If your review reveals that a method is deficient, provide your CAPA plan. In addition, provide a comprehensive assessment of your laboratory operations and specify all CAPA activities to be undertaken to ensure your laboratory operations are robust." **(21 CFR 211.160(b))**

- **Issued on 1/12/18**

  "In your response, you state that you "indirectly verified" your method suitability. You also state that you will be using [method] in the future to 'neutralize preservative systems.' Your response is inadequate because you did not provide any test results to demonstrate that your microbiological test methods are suitable for their intended use." **(21 CFR 211.160(b))**

- **Issued on 2/20/19**

  "You used a raw material lot with a too-numerous-to-count result for total aerobic microbial count." **(21 CFR 211.192)**

- **Issued on 2/20/19**

  "You did not identify the microorganisms to determine whether any were potentially pathogenic and failed to evaluate the consumer hazard posed by this microbial contamination. You decided that this ingredient batch did not need to conform to a microbial specification because it is from a natural mineral source." **(21 CFR 211.192)**

- **Issued on 2/20/19**

  "Your firm failed to adequately validate the test methods you use with your microanalyzer to analyze the microbiological properties of your deionized water, raw materials, and finished drug products. You attempted to validate your test methods, but you failed to evaluate: whether your media can promote microbial growth; your ability to detect specific microorganisms; your system's limits and accuracy; your method's suitability to detect microorganisms in a sample; and, your method's reproducibility." **(21 CFR 211.165(e))**

- **Issued on 3/20/19**

  "You released multiple batches of drug products without conducting tests to ensure they were free from objectionable microorganisms. It is essential that your drug products are produced in a manner that is suitable for their intended uses and that each batch is tested for conformance to appropriate microbial quality specifications." **(21 CFR 211.165(b))**

- **Issued on 3/20/19**

  "Your response is inadequate because you did not provide your verification studies including data to show the suitability of the compendial method being used. Your response also failed to provide data to show that all previously released products, that remain on the U.S. market, were tested and found to meet your newly implemented USP microbial release specifications." **(21 CFR 211.165(b))**

Sample Questions for Assessment:

- Are you compliant with relevant USP (and other) standards for testing products?
- Are your sample handling procedures complaint with relevant regulatory expectations?
- Are you outsourcing sample testing?
- Are testing samples bring labeled and shipped appropriately?
- How can you demonstrate that you're maintaining the integrity of your samples if/when they're shipped?
- Have you conducted method suitability to ensure your testing methods are appropriate and effective?

4. ARE YOU PROPERLY MANAGING NONCONFORMANCES AND CAPA?

Many of the regulatory actions taken by the FDA and other regulating bodies are linked to inadequate CAPA systems. As demonstrated by the large share of these citations issued specifically for "inadequate, incomplete, and undocumented investigations," there's a tendency throughout the industry to focus on immediate nonconformance correction rather than investigating and executing the corrective and preventive actions within the CAPA system.

Regulators expect firms to understand and use CAPAs as improvements to processes and procedures that eliminate nonconformances based on the results of root cause investigations. Once the root cause is determined, a corrective action is identified and implemented into the process. The change is then monitored to determine if the proper root cause was identified and if the corrective action was effective. Sometimes, the root cause analysis may reveal a potential for situations that may result in a compromised product. The solutions implemented to prevent predicted nonconformances are preventive actions.

While there are many perspectives on what makes for a successful CAPA system, just about everyone agrees that one of the most critical points is the initial investigation into the nonconformance to determine the root cause, or root cause analysis.

To conduct a thorough root cause analysis, teams should be qualified to use analysis tools that enable them to examine the impact of process inputs and their effect on the nonconformance. Once the investigation logically hones in on the true root cause, a CAPA can begin.

Further Reading: The Guide to CAPA & Root Cause Analysis in FDA-Regulated Industries

Are you at risk of the following deficiencies or similar ones?

- **Issued on 3/20/19**

  "You did not take effective actions to investigate root causes, and correct flaws, in your manufacturing operations and quality management systems to prevent recurrence of serious quality failures. Ultimately, you did not ensure timely and effective corrective and preventative actions to prevent exposure of consumers to contaminated product. While you continued to obtain microbiological test results outside of acceptable limits on a recurring

basis, you did not initiate recalls until the FDA identified these serious issues in our inspection and relayed safety concerns to you." **(21 CFR 211.22(a))**

- **Issued on 2/20/19**

  "You failed to thoroughly investigate the excessive microbial contamination. You distributed finished product made with the highly contaminated raw material. You released the failed lot of raw material, which was used in the manufacture of the finished drug product and failed to provide adequate corrective actions and preventive actions (CAPA)." **(21 CFR 211.192)**

- **Issued on 2/20/19**

  "We were unable to evaluate the adequacy of your responses because it lacked sufficient relevant information for FDA to evaluate the root cause of the microbial contamination or whether you conducted a thorough investigation. When an investigation lacks conclusive evidence of laboratory error, a thorough investigation would turn to potential manufacturing causes. We were not able to evaluate your interim OOS procedure or timelines for completion of your retroactive laboratory investigation because you did not provide them." **(21 CFR 211.192)**

- **Issued on 3/20/19**

  "Your firm failed to properly investigate and take appropriate corrective actions when an out-of-limit (OOL) result for the purified water system was reported from your testing laboratory." **(21 CFR 211.192)**

- **Issued on 3/20/19**

  "In your responses, you focused on the lack of proper documentation of the sanitization of your water system and indicated that subsequent testing showed the system was producing acceptable water. However, your response failed to adequately address potential risks to your drug products posed by objectionable microbiological contamination in your water system." **(21 CFR 211.192)**

Sample Questions for Assessment:

- How does your nonconformance/CAPA management system conform to regulatory expectations?
- Who performs nonconformance investigations?
- Are they properly trained on root cause analysis tools?
- Who review and approves deviations?
- Are they qualified to do so?

5. DO YOU HAVE A QUALITY UNIT AND DOES IT HAVE THE PROPER RESPONSIBILITIES AND AUTHORITY?

The pharmaceutical Quality Unit (QU) has been the target of many warning letters to OTC manufacturers and similar firms as an underlying cause of product quality and CGMP compliance problems.

Multiple OTC firms have been cited for having an inadequate QU, sometimes lacking one at all. Similarly, regulators have also cited firms for a lack of written procedures that govern the responsibilities and functions of the QU, whether they have one or not. 21 CFR Part 211 is clear about the need to establish a "quality control unit" with the documented responsibility and authority to make critical decisions.

The lack of a QU or inadequacies within an existing unit typically come attached with a direct recommendation to engage third-party experts.

Are you at risk of the following deficiencies or similar ones?

- **Issued on 3/20/19**

  "Executive management must support a quality unit that assures product quality and patient safety, and not undermine the steps needed to prevent production and distribution of hazardous products. Our inspection findings indicate that your quality unit was not able to fully exercise its authority or responsibilities. In at least one instance, your Quality Assurance Manager recommended a drug product recall due to microbial contamination, but your firm failed to remove the adulterated drug product from the market. In addition, while the "OOS Log" includes certain laboratory results, it did not appear to ensure prompt and consistent reporting of every OOS (Out of Specification) laboratory result to quality assurance (QA) for appropriate review. The quality unit must be empowered to make final quality decisions. It is essential that the quality unit be enabled to provide timely oversight of all laboratory and manufacturing (including utilities) data that could impact product quality, whether or not lots have already been distributed." **(21 CFR 211.22(a))**

- **Issued on 3/20/19**

  "When making batch disposition decisions, the quality unit must be provided with all batch production and control records, including all deviations and test data, to enable a fully informed and appropriate decision regarding suitability for distribution." **(21 CFR 211.22(a))**

- **Issued on 2/20/19**

  "Your firm's quality unit approved a deviation report, despite minimal investigation and unacceptable justification." **(21 CFR 211.192)**

- **Issued on 2/20/19**

  "Your quality unit released OOS drug products for distribution without conducting a thorough investigation." **(21 CFR 211.192)**

- **Issued on 3/20/19**

  "You lack quality oversight for the manufacture of your finished homeopathic drug product and you released drug product without an established Quality Unit (QU)." **(21 CFR 211.22(a))**

- **Issued on 3/20/19**

  "Your management confirmed the lack of a QU and acknowledged that you lack written procedures, including, but not limited to, those procedures governing the responsibilities and functions of the QU. Without an adequate QU, you lack the ability to ensure the safety, identity, strength, quality, and purity of your drug product." **(21 CFR 211.22(c))**

- **Issued on 3/20/19**

  "You failed to establish, review, and approve all procedures, including those which may impact the safety, identity, strength, quality, and purity of your drug product. For example, in response to our investigators' request during the inspection for your established standard operating procedure (SOP), you wrote Procedures for Incoming Bioven Handling, Storage, and Shipping. This procedure was not signed as being reviewed and approved by quality personnel. In addition, you confirmed you did not have any other approved SOPs." **(21 CFR 211.22(c))**

Sample Questions for Assessment:

- Do you have a properly established, staffed, and managed Quality Unit?
- Does your Quality Unit have appropriate responsibilities and authority?
- Does your Quality Unit have access to the data it needs to make informed decisions?
- Have any and all relevant SOPs been reviewed and approved by quality personnel?

6. WHAT IS YOUR INSPECTION HISTORY?

As briefly mentioned before, a firm's prior inspection history can provide a general guide for managing expectations and inferring regulatory interest in areas that may have required attention in the past.

If a firm received inspectional observations in the past, it's imperative to review what actions have been taken to remediate and resolve those issues and ensure everything is thoroughly documented.

Similarly, firms that have received repeated observations should pay extremely close attention to the underlying quality system failures that led to them.

Sample Questions for Assessment:

- Have you received prior inspectional observations?
- What have you done to remediate these inspectional observations?
- If you are receiving repeated observations, where do you think the failure is?
- Why do you think you failed to meet regulatory expectations?

The Advantages of Working with an Experienced Compliance Consulting Firm

- Access to former FDA staff
- Strong relationships with the FDA
- Objective, unbiased perspective
- Ability to plan and write effective CAPA Plans
- Ability to identify additional gaps in compliance
- Knowledge of ever-changing regulatory environment

BE PROACTIVE AND PREVENT COMPLIANCE ISSUES

While we help many companies resolve FDA 483s and Warning Letters, we also help prevent them from being issued in the first place. At The FDA Group, we plan and conduct effective internal quality audits to ensure your Standard Operating Procedures (SOPs) are completely aligned with all documentation and operations—the critical part of any internal audit. More broadly, we assess your current systems and make the necessary improvements for ensuring regulatory expectations are met across all functions of your organization.

While European regulators monitor this process with SOPs in-hand, FDA in particular relies heavily on documentation to hold companies accountable for their actions. Our team of former FDA and industry experts can evaluate your procedures, personnel, and closely look at all documentation to ensure consistency throughout your organization.

Are you in need of expert assistance with responding to a Form FDA 483, Warning Letter or preventative action? The FDA Group offers world-class regulatory, GxP auditing, remediation, and staff augmentation services to all FDA-regulated industries.

CONTACT THE FDA GROUP FOR EXPERT ASSISTANCE »