FACT SHEET

Responding to FDA Enforcement

Being prepared for actions

Without the right attention to core quality principles, pharmaceutical, biotechnology and medical device companies can be vulnerable to compliance lapses and regulatory enforcement actions. This can be costly, prompting key stakeholder concerns, damage to a company's reputation and bottom line, and interruption of critical drug or device supplies. An organization's ability to quickly adapt to meet increasing regulatory enforcement is paramount to its success — and demands a focus on the global, cultural and regulatory elements of change. In this heavily scrutinized regulatory environment, staying ahead of the curve on quality and regulatory compliance requires a focused, integrated, proactive approach, with the right partner to help you navigate this increasingly complex landscape.

Optimize your regulatory and quality performance with IQVIA

As the FDA and other regulatory agencies increase their surveillance and enforcement actions, biopharma and medical device companies are turning to IQVIA. Our team of industry experts, including some who have worked at the FDA, helps customers respond with distinct and effective strategies to restore customer credibility with the FDA — as well as strengthen their quality processes with cost-effective approaches.

HERE'S WHAT WE OFFER OUR CUSTOMERS:

- Focus on resolving FDA enforcement actions, using our extensive knowledge of quality systems and management consulting expertise.
- Track record of successful remediation, resolving Warning Letters and establishing both organizational and cultural foundations for sustained compliance.
- Experience working with virtually every major biopharma and medical device company across the globe.
- Development and implementation of sustainable, compliant quality systems and processes — as well as attention to cultural transformation/organizational change to help mitigate risk and prevent future problems.
- Global Quality System remediation programs to meet FDA requirements and ensure that other international regulations/standards are improved, and not compromised.
- Knowledgeable team comprised of former FDA officials, industry experts and management consultants.
- Robust insight into the changing global regulatory landscape, to ensure that any remediation changes to quality systems meet the current and future needs of the business.

IDENTIFY THE RIGHT PARTNER TO SUPPORT YOUR QUALITY AND GMP REGULATORY REQUIREMENTS

The Quality & Compliance practice at IQVIA is comprised of former FDA experts — including industry and management consulting experts — led by seasoned professionals who believe that the optimal compliance pathway is an integrated approach including preventive solutions to proactively strengthen processes and quality systems.

When manufacturers undertake quality system remediation in response to enforcement, they must identify the underlying factors that contribute to non-compliance. Our experience has shown that successful and sustainable organizational change rests on individuals embracing and adopting the change.

OUR GLOBAL EXPERTS CAN HELP YOUR TEAMS:

- Provide strategic consultation on quality systems and GMP/QSR compliance
- Conduct GMP/QSR assessments and training
- Perform mock FDA inspections and FDA preparedness training
- Undertake internal and supplier audits
- Provide strategic direction for effectively managing organizational changes to quality systems, processes and cultural transitions
- Develop and implement quality systems
- Develop and execute validation programs
- Create and implement corrective action plans
- Investigate suspected fraud and scientific misconduct

Organizational change

IQVIA offers an integrated approach to assessing and maximizing the effects of change on individuals and organizations. Putting the right processes, tools and techniques in place can help you manage the cognitive, emotional and intellectual transitions people experience — helping you ensure the adoption of change.

OUR APPROACH TO CULTURAL TRANSFORMATION

Our pragmatic approach reflects years of real-world experience in implementing projects with customers. We customize our project plans based on the customer culture and project needs.

Understand change impacts and provide employees with the tools and training they will need in the new environment

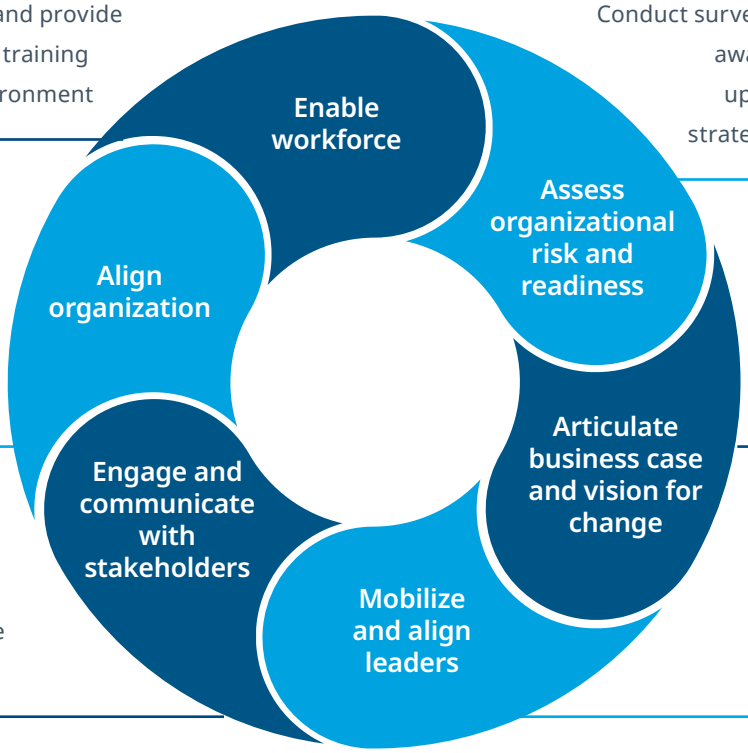
Conduct surveys and interviews to understand awareness and buy-in related to the upcoming change. Develop change strategy based on degree of readiness

Adjust organization design and HR/performance management systems to drive new behaviors and reinforce change

Position change within the organization and create a compelling vision for future success

Identify stakeholders whose support is critical to program success, and develop/execute plans to engage and influence stakeholders

Help leaders align values to the vision and prepare them to drive change cohesively as a team



Case Studies

Case study: FDA warning letter response — third-party verification

Company

Multi-national pharma manufacturer

Challenge

Provide third-party verification of batch records and investigations process for certain products to restore FDA confidence in the customer's ability to release product, and investigate lab and manufacturing deviations adequately. Because of the Warning Letter, the customer had stopped production of a key product group on the FDA Drug Shortage List.

IQVIA response

Leveraging experience across many disciplines, IQVIA experts helped determine the root cause of key manufacturing deficiencies and established new, efficient processes to help plant management restore compliance.

Impact

The root cause of the problem was resolved and validated, and the product supply was renewed. With new CAPA processes in place, the fully optimized system eliminated the backlog of investigations — and was rolled out on a corporate level to assure global consistency and control.

Case study: quality system remediation

Company

Global medical device company

Challenge

Third-party certification of the company's quality system was required to resume distribution of one of its primary product lines following issuance of a consent decree.

IQVIA response

IQVIA's Core Team Process helped to systematically evaluate and improve all subsystems of the company's quality system. The team provided project oversight and partnered with each of the subsystem teams to provide the guidance and regulatory expertise needed to address the compliance challenges.

Impact

The company achieved third-party certification in accordance with the consent decree. The improvements resulted in a global quality system that is compliant, sustainable and adaptable to each of the company's many medical device divisions.

Case study: cultural transformation/organizational change

Company

Global medical device company

Challenge

Ongoing quality issues resulted in several regulatory findings and a Warning Letter. During remediation efforts, the company identified the need for cultural transformation to ensure the success of quality improvement initiatives.

IQVIA response

IQVIA performed a global organizational assessment to identify barriers to success at all levels of the organization. Our team provided recommendations for an organizational restructuring to ensure greater alignment and worked with customer stakeholders to define and launch a global PMO. Efforts included creating a change agent network to facilitate and drive the cultural change; designing and launching a robust communications program; and revising the performance management system.

Impact

Successful organizational cultural transformation ensured that remediation efforts and quality improvement initiatives were successful — and have resulted in reduced findings on audits and regulatory agency inspections. Improved relations across global sites and business areas, through the elimination of internal silos, have increased the flow of information and transparency throughout the organization.

For more information on how IQVIA can help you avoid the high cost of non-compliance, contact us.

CONTACT US

4820 Emperor Boulevard | Durham | NC 27703 | United States

regulatory_quality_compliance@iqvia.com

iqvia.com/smartsolve

IQVIA TECHNOLOGIES