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master™ CONTROL

White Paper:

Complaint Handling as an Integral Part of FDA and ISO Compliance

Introduction
Organizations, especially businesses, exist because of their customers. There are two types of customers — external (i.e., paying clients, general public) and internal (people within the organization). Both are important.

In the broadest sense, customer complaints are a form of communication, and companies can benefit from communicating with their customers. In the FDA and ISO environments, where quality is foremost, complaints have a deeper implication. They may indicate serious safety and quality issues. In this context, effective complaint handling is not just a matter of good business practice but compliance.

To illustrate the critical role of complaints, consider the global recall of ReNu MoistureLoc, a Bausch & Lomb contact lens solution, suspected to have caused serious corneal infection in 109 people. Called fungal keratitis, the infection could potentially lead to blindness. Consumer complaints, first in Asia, and then in the United States, alerted the FDA and Bausch & Lomb to the problem. As a result, the company recalled the product in April 2006 and the FDA launched an investigation.

Regulations and Standards
As the example above showed, customer complaints serve as an important alert system for the FDA, which regulates consumer products amounting to more than $1.4 trillion a year. Industries such as medical device, drugs and biologics, and blood/blood components are mandated to report to FDA any consumer complaints concerning death, serious injury, or adverse reaction.

Complaints are just as critical to ISO-certified companies. Although adherence to ISO standards is largely voluntary, ISO-certified organizations know that business is not just about selling products and services. They must assume responsibility for product quality and safety to earn customers' trust. In certain countries, ISO standards have been incorporated into law, making ISO conformance a regulatory requirement in those jurisdictions.

FDA regulations and ISO standards that require a formal complaint-handling process include the following:

- FDA's Quality System Regulation requires medical device manufacturers to establish and maintain procedures for receiving, evaluating, and investigating complaints by a formally designated unit (21 CFR Part 820.198). "This [complaint-handling system] should be the beginning point of every inspection to determine whether the firm has received complaints of possible or potentially defective devices," according to the regulation.

- FDA's Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals require establishment of a procedure for reviewing and evaluating complaints about drug products (21 CFR Part 211.198).

- FDA's CGMP requirements for blood and blood components require maintenance of records of complaints of adverse reactions, a thorough investigation of each adverse reaction, and a written report of the investigation (21 CFR Part 606.170).

- ISO 9001: 2000 (Clause 5.6) requires management reviews, including examination of customer feedback.

- ISO 13485: 2003 (Clause 8) requires medical device manufacturers to create a procedure for gathering feedback from customers and a feedback system for monitoring emerging problems.

Challenges

The importance of customer-complaint management in attaining regulatory compliance is clear, but implementing an effective and efficient system is far from easy. Consider the following challenges commonly encountered by regulated companies.

- **Lack of Standard Procedure** – Customer complaints come from different sources (e-mail, phone, fax, letters, corporate Web site, sales reps, etc.) and are often addressed by different people within an organization. Without a standard mechanism to gather and process data from different sources, complaints may languish in someone's "in" box or voice mail. Worse, complaints may get lost.

- **Inadequate Documentation** – Without a formal record-keeping system and an effective tool for capturing data from complaints, documentation may be inadequate for the purpose of compliance or in responding to a product liability lawsuit. Poor documentation of steps taken by management to resolve the complaint could also serve as ammunition for the opposing party in case of litigation.

- **Inefficiency** – Paper-based or partially electronic complaint-handling processes tend to be inefficient. Typical problems include misplaced or overlooked complaints coming from disparate sources, incomplete information, lack of follow up, and inadequate response. All of these can result in delayed and ineffective complaint resolution.

- **Lack of Customer Access** – A customer may have to talk to different departments before reaching the person with the appropriate authority to act on a complaint. This is frustrating to customers, whose information may help prevent future complaints. FDA-regulated companies are likely to hear from the agency itself since consumers and health care professionals may report product-safety and quality-related complaints directly to the agency.

- **Lack of Management Strategy** – Without the ability to track complaints and monitor resolutions, it is practically impossible for an organization to formulate an effective strategy for future complaint resolution. Managers who are unable to see the "big picture" are simply not equipped to fully understand customer concerns and prevent the issues that led to the complaints.

Complaint Handling and Compliance

A company should develop a philosophy and strategy for customer-complaint handling as part of its overall compliance initiative. Instead of taking a defensive posture, it should learn how to turn complaints into opportunities. While this is easier said than done, the following steps can help an organization move toward that direction.

- **Management Commitment** – A commitment from senior management through appropriate policies and procedures will signal to all employees that the organization is serious about customer satisfaction.

- **Accessibility of Complaint-Handling System** – A company must make it as easy as possible for customers to log in complaints, either through a corporate Web site or a toll-free telephone number. Inform customers about the complaint-handling system through the Web site, account mailings, product packaging, advertising, etc. FDA-regulated companies must be able to determine which complaints need to be reported to the agency as adverse events.

- **Complaint-Resolution Team** – Having a department or a team specialize on complaint handling will help ensure that complaints are resolved promptly. Under the FDA's Quality System Regulation, medical device manufacturers must designate a complaint-handling unit and employees who review complaints must have thorough knowledge of the product line to make an informed decision as to the severity and significance of a complaint and whether it requires investigation.

- **Complete Record-Keeping System** – For FDA-regulated companies, a thorough documentation of consumer complaints and adverse events and ensuing investigation (or corrective and preventive action) is a requirement. Records must include customer information, origin and details of the complaint, product information, details of investigation, and CAPA.

- **Optimization through Automation** – Paper-based or partially electronic complaint-handling processes are likely to bog down the complaint resolution lifecycle. Tracking complaints manually from unconnected sources is likely to be time-consuming. Monitoring complaints that could potentially result in a CAPA may be next to impossible in a manual system. Automating the complaint-handling system will streamline the process and increase efficiency and effectiveness.

The MasterControl Solution

Hundreds of companies worldwide use MasterControl to automate and effectively manage quality processes critical to compliance with FDA regulations and ISO quality standards.

MasterControl Customer Complaints™, an integrated part of the MasterControl™ quality management suite, helps companies attain and sustain compliance by optimizing the complaint-handling process, speeding up complaint resolution, and keeping the overall quality system always ready for FDA inspections and ISO audits. Here is how MasterControl addresses the challenges mentioned above.

- **Increased Efficiency Through Automation and Standardization** – MasterControl automates all tasks pertaining to customer complaints, including data collection, notification, follow-up, and escalation. Standardization allows for:

    - proper logging of complaints;

    - capture of complete information from across the enterprise, regardless of who gets the complaint;

    - timely investigation;

    - coordinated resolution; and

    - shorter complaint (submission-to-resolution) lifecycle.

- **Effective Documentation** – MasterControl offers a pre-configured, multi-page electronic form that ensures accurate capture of information from customer complaints. The best-practice form incorporates a simple three-step process that starts with the processing of a customer complaint, automatically moving to the internal investigation step, and culminating with a resolution of the issue as approved by the appropriate manager. Every step of the process will be documented.

- **Customer Access** – MasterControl's Web-based platform can connect employees, customers, suppliers, and others involved in complaint handling regardless of location. Via an external link on a company Web site or within a CRM application (or any application that supports URL links), customers can easily initiate a customer complaint. MasterControl can integrate complaint management to the rest of the quality system, providing links to corrective actions and adverse-event handling.

- **Effective Management Strategy** – MasterControl's advanced analytics and reporting capability increases management oversight and demonstrates appropriate control to regulatory agencies. A real-time view of the quality system allows management to develop a more proactive strategy for improvement. The solution includes the following customizable reports:

    - complaint summary;

    - in-process complaints;

    - complaints categorized by type, product, and department;

    - trending categorized by complaint type, product, and department.

Conclusion:
The ability to resolve customer complaints successfully is a key differentiator between successful and unsuccessful businesses. For FDA-regulated and ISO-certified companies, effective complaint handling is more than a good business practice — it's necessary for compliance. Choosing an appropriate software solution for automating and effectively managing the complaint-handling process should be integral to a company's strategy for sustaining compliance and a part of its commitment for improving customer satisfaction.

About MasterControl
MasterControl Inc. has been at the forefront of providing innovative software solutions since 1993. The MasterControl™ quality management suite is a configurable, easy-to-use, and integrated solution that automates and effectively manages document control, change control, training control, audits, corrective/preventive action (CAPA), customer complaints, and other forms-based quality processes under a single Web-based platform. The company offers comprehensive technical and customer support, including product training, implementation, and validation services.

For more information or additional white papers, visit www.mastercontrol.com,or call 800-825-9117.

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