



White Paper:

Effective Nonconformance
Management Key to FDA and
ISO Compliance

The Power of an Integrated Quality Management System



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Introduction

A product's quality, reliability, and safety depend to a great extent on its conformance to specifications that have been tested, proven safe, and approved. This is particularly critical in products that have direct impact on public health and safety, such as medicines, medical devices, cars, household appliances, and other consumer goods.

For this reason, the proper handling of nonconforming products is incorporated in Food and Drug Administration (FDA) regulations covering drugs, medical devices, and biologics, and ISO international standards, which apply to manufacturers of a wide range of consumer goods.

FDA compliance is mandatory for life sciences manufacturers and related industries covered by the agency's jurisdiction. Non-life science manufacturers comply with other federal regulations, but most of them also adhere to ISO quality standards, either voluntarily, or as part of compliance with requirements of countries where they want to sell their products.

FDA Warning Letter

A Warning Letter sent by the FDA to Advanced Imaging Research Inc., a manufacturer of head and body coils for magnetic resonance imaging (MRI) systems, illustrates the importance of material conformance to product quality.

An FDA inspection had revealed that the company's neonatal MRI coil device history records reflected out-of-specification discrepancies that rendered the coils as nonconforming. "Your firm did not perform re-tests, did not document and trend the nonconformance, nor did you quarantine the products," according to the Warning Letter sent by the FDA in April 2006. The agency asked the company for a written response, as well as a status update on the corrective and preventive action (CAPA) that the company must perform to avoid recurrence of the nonconformance.

An FDA Warning Letter serves as a formal means of communication for pointing out violations that could lead to legal and/or administrative sanctions, if such violations are not corrected promptly. While the ISO sector does not have an equivalent of a Warning Letter, a nonconforming product that is not corrected properly could mean loss of ISO certification, and consequently, either loss of opportunities in overseas markets, and/or end of business contracts with customers that require ISO certification.

In both FDA and ISO environments, a nonconforming product that causes injury or death could also mean liability lawsuits for the manufacturer.

Regulations and Standards

FDA regulations and ISO standards exist primarily to protect consumers, but they also help manufacturers avoid the consequences of unsafe and poor-quality products by making them integrate quality into their operations.

The following are some of the FDA regulations and ISO standards that require appropriate nonconformance disposition:

- FDA's Quality System Regulation (QSR) requires medical device manufacturers to establish and maintain procedures to control product that does not conform to specified requirements. The disposition of the nonconforming product must be documented (21 CFR Part 820.90).
- FDA's Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals require the testing of components for conformity with all appropriate written specifications for purity, strength, and quality (21 CFR Part 211.84).

- ISO/TS 16949, which specifies the application of ISO 9001:2000 for automotive manufacturers and their suppliers, calls for the control of nonconforming products to prevent their unintended use or delivery (Clause 8.3).
- ISO 9001:2000 requires management reviews, including examination of product conformity data (Clause 5.6.2). Organizations also must ensure that any nonconforming product is identified and controlled to prevent its unintended use or delivery (Clause 8.3).
- ISO 13485: 2003 requires management reviews, including examination of product conformity data (Clause 5.6).
- ISO 14001:2004 requires establishment and maintenance of nonconformance management procedures (Clause 4.5.3).

Handling Nonconformance

In handling nonconforming materials, regulated companies typically go through this procedure: identification, documentation, evaluation/investigation, segregation, and disposition.

A manufacturer usually handles the nonconforming material by performing any of the following:

- Rework – The nonconformance is fixed to make the material, component, or product comply with approved specifications.
- Regrade – Nonconforming materials are reassigned for an alternative use or use category.
- Scrap – Nonconforming materials are thrown away.
- Return – Nonconforming parts/components are sent back to supplier.
- Use as is – A nonconformance may be minor (no significant impact on product’s form or function) and the material can be used as is.

Whatever the manufacturer decides to do, it must document the entire process of nonconformance disposition to show that the action was justified and performed properly.

Nonconformance and CAPA

A common way of handling nonconformance is by fixing the product or material. Increasingly, however, manufacturers realize that they must not only fix existing problems, but also avoid future recurrence of a similar nonconformance. In this sense, the nonconformance disposition process is closely related to the CAPA process.

In the case of FDA-regulated medical device, pharmaceutical, and biotech companies, certain regulations require them to implement CAPA as part of the resolution of material nonconformance issues. Under QSR (21 CFR Part 820.100), medical device manufacturers are required to establish a CAPA procedure that will investigate the cause of any product nonconformance and identify action that would prevent the recurrence of such nonconformance.

The CGMP regulations for finished pharmaceuticals similarly require that any failure of a batch, or any of its components, to meet specifications must be thoroughly investigated and documented, including the investigation’s follow-up and conclusion (21 CFR Part 211.192).

Common Challenges

Implementing an effective and efficient nonconformance disposition process is far from easy. The following are some of the common challenges faced by companies, especially those using manual systems, in handling material nonconformances:

Disconnected Processes: In manual or hybrid systems, the reporting of and response to a nonconformance are likely to be disconnected, which could result in delayed resolution. A nonconformance process that's not connected to the CAPA system could pose serious problems in terms of the timeliness and accuracy of data collection and the thoroughness of documentation, all of which are critical to compliance.

Poor Turnaround: A manual system is inherently inefficient. Paperwork may languish in someone's desk, and for a sequential process such as nonconformance, it could mean a delay in resolution of the incident.

Poor Tracking: It is time-consuming to physically track paperwork. A manual system makes it almost impossible to identify and avoid bottlenecks.

MasterControl Solution

MasterControl Nonconformance™ is a configurable and easy-to-use solution designed to automate, manage, and streamline the process for identifying, evaluating, reviewing, and handling of nonconforming materials, components, parts, and finished products. This solution can handle nonconformances in new materials, in-process materials, parts, and finished products.



MasterControl Nonconformance™ is integrated with the MasterControl™ quality management suite. It is designed to automate, manage, and streamline paper-based processes for identifying, evaluating, reviewing, and handling of nonconforming materials, components, parts, and finished products.

Compliant: MasterControl is designed not only to help attain FDA and ISO compliance but to allow continuous compliance by optimizing the nonconformance disposition process, speeding up turnaround from initiation to approval, and keeping the overall quality system always ready for inspections and audits.

- **Best-Practice Form:** A pre-configured, multi-page form simplifies the process and accelerates evaluation and disposition of nonconforming materials by prompting the appropriate departments to collect and track all relevant data. The form is automatically routed to responsible personnel and escalates accordingly if the case is not processed promptly.
- **Best-Practice Process:** This solution incorporates a five-step process that will help the quality unit make timely and appropriate decisions. The process will guide the team from initiation through investigation, recommendation, disposition, and management approval.
- **Analytics Reporting Tool:** The solution includes a standard set of pre-configured reports that can be customized by end users. Nonconformances can be trended, and incidents analyzed by material, shift, machine, supplier, etc. These “data-mining” capabilities can give important insight into systemic quality issues and serve as another starting point for CAPA.
- **Audit Trail, Electronic Signatures:** MasterControl provides time-stamped audit trail, reporting, and electronic signature capabilities that fully satisfy FDA’s 21 CFR Part 11 requirements. The e-signature can be configured to include a user name’s title and the route step name in the manifest. This will help distinguish the different kinds of approval that a document or packet receives, a critical factor in the FDA environment.

Connected: MasterControl connects the nonconformance process with other quality processes for a holistic approach to quality management.

- **Web-based Platform:** MasterControl is Web-based so it can connect employees, customers, suppliers, and others involved in nonconformance disposition regardless of location.
- **Flexible Process:** MasterControl can be used as a stand-alone process for the purpose of small-scale, localized disposition of nonconforming materials. But the system is flexible and it allows integration with the CAPA process if the situation warrants a separate CAPA handling while the initial nonconformance is independently processed and closed.
- **Form-to-Form Launching:** A CAPA form can be launched directly from a nonconformance form, connecting one process to the next. Not only does MasterControl streamline this process, but it also maintains the links so one can review a completed process and easily see what triggered the CAPA. Relevant information from the nonconformance form will be automatically entered into the CAPA form, reducing data entry and increasing accuracy.

Complete: MasterControl offers a robust integrated quality management solution — plus the appropriate tools and services for successful implementation and validation.

- **Validation:** For FDA-regulated companies, MasterControl offers a continuum of innovative validation products and services designed to allow “continuous validation” by making future upgrades easier, faster, and more cost-effective. This product line addresses different levels of validation needs based on individual risk assessment. MasterControl’s strategic approach dramatically cuts the time involved in validating a system and reduces the risks of project implementation, both of which help lower validation cost.

- **Product Training:** MasterControl's Professional Services team, consisting of former ISO auditors and system administrators, has developed a comprehensive training program that serves as a foundation for successful project implementation and helps companies realize software ROI faster. The team conducts training at MasterControl's state-of-the-art Training Center in Salt Lake City and also at customers' facilities.
- **Technical Support:** Choosing MasterControl means getting the necessary technical support to ensure project success. MasterControl offers the expertise, infrastructure, and flexibility to meet every customer's needs, from initial installation to routine troubleshooting.

Conclusion

Material nonconformance is usually unexpected, and always unwanted. But with proper handling, a manufacturer can turn the situation around, and find ways to prevent future nonconformances and to further improve product quality. Technology has a lot to offer to ease the burden of nonconformance disposition, and it would be wise for any forward-looking company to take advantage of it.

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About MasterControl Inc.

MasterControl Inc. produces software solutions that enable regulated companies to get their products to market faster, while reducing overall costs and increasing internal efficiency. MasterControl securely manages a company's critical information throughout the entire product lifecycle. Our software is known for being easy to implement, easy to validate and easy to use. MasterControl solutions include quality management, document management/document control, product lifecycle management, audit management, training management, bill of materials, supplier management, submissions management, and more. Supported by a comprehensive array of services based on industry best practices, MasterControl provides our customers with a complete information management solution across the entire enterprise. For more information about MasterControl, visit www.mastercontrol.com, or call: 800-825-9117 (U.S.); +44 1256 325 949 (Europe); or 03-6801-6147 (Japan).



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