



# LAPSES IN COMPLIANCE – OVERCOMING THE RISKS OF COST CUTTING FOR OTC DRUG MANUFACTURERS

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Pharmaceutical retailers around the world are challenged with ensuring that the over-the-counter (OTC) products they sell meet regulatory requirements and continue to conform to Good Manufacturing Practices (GMPs). What's more, they are required to manage this risk across a broad range of product categories.

Though many retailers recognize that FDA oversight is good, there is general consensus that it can often be insufficient for OTCs. To combat this, OTC retailers typically conduct audits of the manufacturer supply network either themselves or through a third-party provider.

Because of this, OTC manufacturers are, in many cases, hosting and receiving audits from several retailers, often for the same product type and under the same quality system. Plus, these auditors often approach their inspections by focusing on the area in which they are most comfortable.

The result can be a significant amount of variability and inconsistency between audits and auditors, as well as variation in how the GMP requirements are interpreted. For manufacturers, there is an ongoing sense of audit fatigue, while retailers lack confidence that GMP audits are sufficiently able to mitigate risk, despite these ongoing efforts.

According to Maxine Fritz, Executive Vice President for NSF International's Pharmaceutical Services, "OTC manufacturers are held to the same standard as prescription drugs such as CAPA management, laboratory controls, validation, qualifications and equipment.

"But because OTCs are not typically considered high-risk drugs, the OTC industry has largely gone unregulated. The FDA can only investigate so many



companies and so, in time, GMPs have lapsed. A lot of manufacturers now need to ensure that they have good quality and are compliant with the regulations."

However, because the FDA doesn't have enough resources to investigate every organization, OTC manufacturers are expected to follow monographs to ensure they meet the established compendial requirements and that ongoing compliance and quality systems are in place. But this trust system doesn't always work and, over time, lapses in compliance have occurred.

In a lot of cases, these lapses occur as a direct result of manufacturer cost cutting.

"Most OTC manufacturers have competitors, and customers will have the choice between branded and non-branded options," explains Fritz. "In order to compete, many companies turn to cost cutting. In this process, compliance is often unknowingly reduced or eliminated and there can be unintended consequences."



To help OTC manufacturers avoid the pitfalls of cost cutting and ensure they meet all relevant regulatory requirements, NSF offers a number of expert solutions, including third-party drug audits to current GMPs. These GMP auditing services can be used by retailers for their private label programs or as part of their overall supplier/vendor qualification and monitoring programs.

“We can conduct gap assessments which identify gaps in regulatory and quality systems and highlight how they can be remediated in order to prepare for regulatory inspections from the FDA or a third-party recognized certification program,” says Fritz.

Through a hands-on collaborative approach, NSF also helps clients that have received an FDA Form 483 to develop their responses to the FDA, create a CAPA plan and remediate the situation by applying pragmatic solutions to correct any deficiencies.

For OTC manufacturers outside of the United States who are determined to be OAI (official action indicated) by the FDA, the FDA can detain products and prohibit manufacturers from importing them into the United States. In these instances, NSF can help international manufacturers with developing and implementing corrective and preventive actions. Fritz says, “It can be complex because often there are language issues, but we can certainly get them ready for their next regulatory inspection and ensure compliance so they can ship their product back into the U.S.”

For example, one Chinese OTC manufacturer turned to NSF when its products were placed on FDA import alert. NSF needed to identify compliance gaps and provide recommendations to meet FDA requirements under 21 CFR 210 and 211.

For more information, contact [healthsciences@nsf.org](mailto:healthsciences@nsf.org) or visit [www.nsfpharma.org](http://www.nsfpharma.org)

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To achieve this, NSF evaluated the FDA's findings and developed a four-phase approach for the company.

**Phase 1:** The first phase, completed by a team of expert NSF consultants, helped to establish a baseline and highlight all existing GMP deficiencies, as well as those identified by the FDA. NSF developed a risk-based corrective action plan that categorized and prioritized the findings and corrective actions based on risk.

**Phase 2:** NSF provided a team of expert consultants to help the manufacturer remediate based on the risk-based corrective action plan, working side-by-side coaching, mentoring and working collaboratively with the manufacturer's personnel.

**Phase 3:** The team performed final effectiveness checks through audits to confirm compliance and effectiveness of the implemented corrective actions and improvements.

**Phase 4:** NSF conducted a series of mock inspections to prepare the site for any future FDA re-inspections and ensure GMP compliance remained at a consistently high level.

According to NSF International: “Our staff and consultants has been in your shoes. We understand. We work with industry experts who have the appropriate range of skills and who constantly seek to fit the right person and the right solution, the first time, to every job.”