Over-the-Counter (OTC) Drug Vendor Qualification Program

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Health Sciences

Introduction

Audits are essential to evaluate capabilities, adequacy of production and control procedures, suitability of equipment and facilities, current good manufacturing practice (cGMP) compliance and effectiveness of the quality management system (QMS). Our third-party auditing program helps manufacturers understand which requirements must be met in order to produce over-the-counter (OTC) drugs, including pain relievers, nasal decongestant sprays, cough syrups, antacids, allergy medications, toothpaste, sunscreen, medicated powder and homeopathics.

About This Program

The NSF OTC program focuses on quality management. It provides retail pharmacies a dependable and unbiased means to help them qualify their vendors and suppliers when they outsource the manufacturing of their drug products. The U.S. FDA and other regulators are clear that while manufacture may be outsourced, the accountability for drug product quality cannot be outsourced and resides firmly with the firm ultimately placing the drug product on the market. Our long-standing experience in the drugs sector can help you understand and satisfy these expectations.

Drivers for OTC Drug Manufacturers

Rapid globalization of pharmaceutical supply chains and an increased use of contract manufacturers is a reality in the pharma sector today. With increased public health issues relating to these two areas, regulators are making it very clear that the firm marketing and selling the product must be able to demonstrate its accountability for the quality of the product – this cannot be demonstrated by testing alone, and requires a demonstrable knowledge of what GMP controls and quality systems are being applied during product manufacture and supply.

The FDA recognizes that there are a lot of retailers and U.S. manufacturers who do not quite understand the issues and regulations surrounding supply chain management and the use of contractors. Retailers have final responsibility of their supply chain and they need to have a clear understanding of their contract manufacturer's state of compliance.

GMPs Are Not New for OTC Drug Manufacturers

The cGMP regulations apply to all drug products, whether OTC or prescription.

"Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act requires drugs to be manufactured in conformance with current good manufacturing practice. This section does not differentiate between OTC and Rx products and it was not intended by Congress to do so." CPG Sec. 450.100 cGMP Enforcement Policy – OTC vs. Rx Drugs.

'Low Risk' of OTC Drug Products Can Be Misleading

Medicines with a long history of use give us confidence in the safety and efficacy of the active substance molecule itself, and are allowed to be sold over the counter at certain doses without a prescription. The safety and efficacy are well known and hence often judged 'low risk'. This 'low risk' does not take into account the conditions and standards under which the OTC drug is made or the security and quality of the supply chain used for their active ingredient(s) and excipients.

From a public health and patient safety perspective, an adulterated OTC drug could potentially impact a larger population than a prescription medicine. Consumers are at risk and it is the responsibility of each manufacturer to minimize this risk.

The Law

In the U.S., **OTC drug manufacturers must meet 21 CFR 210/211 and cGMP requirements.**

> *Quality is the underpinning of everything we do, and it is imperative that we have a drug quality program as robust as those programs we presently have for drug efficacy and drug safety. Further, we must be strategic and have systems in place to identify and respond to quality issues before they become problems. This is especially criticial due to the global nature of drug manufacturing and the sourcing of raw materials outside the U.S.*
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> **Janet Woodcock, MD**
> **CDER Director**
> ***PDA Letter – Jan 2013***

To ensure your company's compliance, contact NSF about its OTC Drug Third-Party Vendor Qualification Program.

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