Over-the-Counter (OTC) Drug Manufacturer Qualification

Program Highlights

NSF®

Health Sciences

Introduction

NSF Health Sciences is a division of NSF International that for many years has provided expert consulting, auditing and training services to the pharmaceutical industry in the areas of current good manufacturing practices (cGMP) compliance and quality management.

Ongoing supply chain and manufacturing-related issues within the pharmaceutical sector are driving rapid changes to the regulatory environment and expectations for all sectors of the drug industry, both for prescription and over-the-counter (OTC) drug suppliers.

About This Program

Whether you're a manufacturer, packager or distributor of OTC drugs, our team of consultants can help you to demonstrate the compliance of your facility and its involvement in ensuring the quality of the drug products supplied to retailers. Our third-party OTC drug GMP program utilizes audit tools based on 21 CFR 210 & 211, ICH Q10 (Pharmaceutical Quality System) and a standardized grading scheme. We can help you verify that sufficient quality management systems are in place to assure regulatory compliance and product safety, as well as identify potential risks in your supply chain.

Audit Scope

Audits cover the following critical activities and include principles and guidance:

- Manufacturing procedures
- Production and process controls
- Personnel qualifications and responsibilities
- Cleaning procedures
- Building and facility maintenance
- Packaging and labeling procedures
- Equipment validation
- Holding and distribution
- Laboratory operations
- Recordkeeping
- Product traceability
- Identity testing
- International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) – ICH Q10: Pharmaceutical Quality System
- 21 CFR 210 & 211 and current good manufacturing practices (GMP) principles established through U.S. FDA enforcement activities

Audit Conclusions

Upon audit completion, NSF Health Sciences provides a non-conformity summary and detailed audit report that highlights where the company is in compliance with FDA's current GMP thinking and industry best practices, identifies areas of non-compliance and/or vulnerability and provides pragmatic recommendations for improvement.

The grading scheme includes pass/fail criteria based on the severity (critical, major or minor) of the identified non-conformities. A passing grade of A, B or C determines the frequency of future audits to verify compliance. This grading is intended to motivate companies to continually improve the quality of their manufacturing operations.

Benefits of This Program:

- Use a proven organization with demonstrated pharmaceutical experience
- Meet current expectations to stay ahead of your competition
- Protect your company's reputation
- Reduce the risk of FDA regulatory action
- Reduce the number and frequency of audits
- Ensure brand protection and integrity
- Gain a competitive advantage
- Level the playing field
- Avoid potential recalls
- Reduce risk to customers
- Improve quality of products sold to consumers
- Improve culture of quality in the organization and demonstrate a commitment to quality
- Improve supply chain management

Read About a Company's Experience with this Program

Customers and patients need to have complete trust in the safety of all medicine, whether prescription or over-the-counter," said Alain Turenne, director, product integrity, at Walgreen Co. *"If there are industry gaps of any kind in monitoring, standard setting and quality control, we need to fill them. We are proud to be working with NSF International to continuously elevate our already strong standards for product safety and integrity.*

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

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