United States Jobs Expertini®

Regulatory Affairs and Quality Assurance Specialist

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Company: Albanese Confectionery Group, Inc

Location: Merrillville

Category: other-general

UNDERSTANDING

[redacted] and Quality Assurance Specialist plays a critical role, ensuring in-market regulatory compliance of new and existing products and supports the Quality Management System. An experienced regulatory or quality professional, this person has a strong understanding of applicable regulations, guidance and industry best practice pertaining to food and/or dietary supplement products.

This person will work independently with a high level of responsibility. In addition to label content management, they will take ownership of quality functions and successfully deliver smaller projects and specific regulatory and quality elements within larger projects.

CORE VALUES

[redacted] are more than just words, they're a way of life. We know that [redacted] strong culture & a higher purpose perform better in the long run.

Own It

Love People

Act for the Greater Good

Find a Way

Hustle and Refuse to Settle

RESPONSIBILITIES

[redacted]

Reviews, maintains, and creates label records for food and dietary supplement products by interpreting and applying applicable FDA regulations and guidance.

Compiles and interprets substantiation documentation for accurate and compliant labeling.

As directed, takes ownership of, and delivers successfully smaller projects and specific regulatory elements within larger projects such as innovation, implementation of new regulations, portfolio assessment and change control.

Supports review of product ideations, raw material assessments, formulation assessment, new claims, labels, advertising materials, third party products and related brand activities.

Performs evaluations to substantiate compliant labeling: formula, percent daily values, nutritional claim support, structure/function claims.

Creates formal assessment documents for customer records.

Develop and maintain accurate and compliant label content for dietary supplements and foods, as applicable.

Create and/or revise Standard Operating Procedures (SOPs) to improve the quality management system.

Participate in process qualifications. Create supporting documents.

Identify guidance documents, regulations, and international standards to provide interpretive assistance.

Perform CAPA investigations, implement corrective actions, and perform effectiveness checks.

Coordinate and maintain sampling and testing procedures. Facilitate lot release testing.

Review and maintain statistical sampling plans for quality inspections.

Demonstrates a high level of understanding of applicable regulations and implements

process improvements when required to ensure quality systems are maintained at a high level.

Support and improve Quality Systems by providing ongoing education on regulatory compliance.

Performs other duties as assigned.

WORKING RELATIONSHIP

Reports to the Quality Assurance Manager.

Communicates regularly and has a strong relationship with team members in multiple departments.

Communicates and meets periodically with other departmental leaders.

QUALIFICATIONS REQUIRED

Thorough understanding of FDA labeling, 21 CFR Part 111, and 21 CFR Part 117 compliance requirements.

Good judgement, decisiveness, and strong interpersonal skills.

Strong written and verbal communication skills

A self-starter with willingness to learn and develop new processes or procedures.

Demonstrates strong teamwork, collaboration, attention to detail, analytical skills, and organization.

Previous exposure to and application of regulations pertaining to food and/or dietary supplement manufacturing and labeling.

Basic computer skills, including Microsoft Outlook, Excel, Word, and PowerPoint

Capable of managing tasks while rapidly adapting to changing priorities.

Able to work independently with minimal supervision.

EDUCATION

[redacted]

Functional experience: 3 to 5 years of relevant prior business experience preferred. 1 to 2 years of experience in regulatory affairs or quality preferred.

Knowledge of international regulations (e.g. Health Canada, EU) a plus.

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