FDA Compliance

Adapt to changing customer demands and ever more stringent regulatory mandates

Features

- Control formula access and maintain change history log
- Design and print Nutritional Labels and Supplemental Information Panels
- Generate bi-directional lot traceability reports against suspect finished goods, ingredients and packaging materials
- Design and produce Lot Recall Letters
- Support FDA, 21 CFR Part 11, GFSI and cGMP requirements

Benefits

- Facilitates the acquisition and retention of an advanced Food Safety Certification
- Comply with external auditor requirements
- Meets customer and industry labeling requirements

Introduction

Compliance capabilities across BatchMaster software modules ensure that federal and industry specific regulatory mandates, as well as customer specific requirements. BatchMaster Software keeps current with best practice processes for many process industries, including the Food, Beverage, and Nutraceutical industries.

With BatchMaster ERP, you will be compliant in terms of generating industry specific product labeling and industry standard compliance reports. In addition, BatchMaster screen security and transactional audit trails meet both corporate and regulatory governance requirements.

Key features

Version Control

Formulation and Packaging Bills of Material modules keep track of all changes to their respective specifications, including workflow approvals, effectivity dates and other relevant version data in a history log.

Transactional Audit Trails

Audit trails capture and report on key manufacturing related transactions, from receiving thru production to shipping. Production activities captured include batch job creations, releases, adjustments and closures.

Recipe Target Characteristics

Recipes are dynamically adjusted to meet physical and nutritional target specifications during laboratory formulation and batch production. Ingredient values are taken from either the integrated Genesis or USDA database, or a user defined table of values.

To ensure compliance, the Formulation screen visually notifies the user of any physical and nutritional value that exceeds established percentages or recommended daily intake levels.

SOP Instructions Library

A library of standard operating procedures or special instruction templates can be established, where each template can contain one or more steps. Product developers would select one or more templates from the library to a formula or packaging bill of materials, including intermediates, and sub-assemblies. These instructions are either printed out on the batch ticket or on a separate document, or displayed on a mobile device. Online execution offers the advantage of mandating the confirmation of each instruction before processing to the next step in the process.

QC Test Library

A library of QC tests can be established, where each test has defined acceptable values, tolerances, sample and retest values. Product developers would select one or more QC tests from the library to a formula or packaging bill of materials, including intermediates, and sub-assemblies. These QC test are either printed out on the batch ticket or on a separate document, or displayed on a mobile device. Online execution offers the advantage of mandating the confirmation of each QC test before processing to the next step in the process.

Nutritional and Supplemental Labeling

BatchMaster Software maintains multiple approved Nutritional Label and Supplemental Label formats within the Production module. Labels address ingredients, nutritional values, serving size and other required values. All labels can be further customized to meet each customer's international market and individual product labeling requirements.

Certificate Of Analysis

Users can personalize COA documents for their customers. These COA documents report on those QC tests applied and the results obtained for a specific finished good, intermediate or assembly.

Lot Traceability

From receiving through production to shipping, all inventory movements of lot controlled items is captured and tracked. In receiving, lot numbers are either captured or generated for lot controlled items. In production, lot numbers of consumed ingredients and packaging materials are captured. Lot numbers are auto-generated for both intermediates and finished goods. Executing warehousing tasks with mobile devices ensures that lot information is accurately captured.

GFSI traceability and recall mandates can be satisfied in minutes rather than hours thanks to the system's bi-directional lot tracing capabilities. Suspect ingredients, raw materials, intermediates, finished goods can be tracked from shipping to receiving, receiving to shipping or anywhere within manufacturing. As a next step, recall letters for the suspect items can be produced for both customers and suppliers, including purchase order, customer order, batch job and lot number information.

FDA Master Batch and Batch Manufacturing Record Management

To facilitate the accurate capture and reporting of transactional information, the system provides built-in document management, automated workflows, audit trails, electronic signatures, versioning control, and archiving.

About BatchMaster Software

BatchMaster Software offers a set of comprehensive, modular financial and manufacturing ERP solutions for formula-based process manufacturers.
For more information, Please visit www.batchmaster.com or email your request to sales@batchmaster.com