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 Packaging BOMs of Material modules keep track of all c their respective specifications, including workflow approvals, effectivity 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 approveeple approvte aoooove [illegible]