

How MISys Manufacturing Related to Regulatory Standards

Prepared by Darryl Bernstein, MISys Sales, March 20th, 2012.

Abridged by C. Kimbell, 2014

Introduction

Though MISys Manufacturing is not itself an ISO Certified application, the software can play a critical role in compliance with international and industry specific standards such as:

ISO 9000/9001 General Industry

ISO 13485 Medical Devices

Some of the tools that speak to compliance and certification requirements:

- Comprehensive inventory controls track on-hand inventory. Physical inventories done on a net change or cycle count basis do not disrupt operations.
- Transaction Audits provide full traceability for all transactions, the accounts affected and the individuals who performed them.
- Centralization of Data (items, BOMs, supplies, locations and related transactions) provides one database of all information.
- Accounting Integration is fully documented and tested.
- Custom Fields record data/metrics needed for quality procedures and other requirements.
- Customizable Alerts identify non-conforming conditions and notify the appropriate person to take corrective action.
- Security Measures, through user permissions, can be managed at the granular .
- Planning Tools
- Physical Inventory with Net Change Calculations and Cycle Counting
- Supplier Performance/Tracking - measure supplier's delivery performance, price competitiveness and quality performance (volume and value of returns).
- Automatic PO Generation and Status Tracking to eliminate errors and track delivery.
- Serial/Lot tracking for full traceability from raw material to finished good, with established procedures for assigning numbers. Drill-down interface provides quick access to the component serial/lot numbers on every level of a complex, finished good.
- Shop Floor Control establishes process definition and tracking, as well as accurate WIP through the manufacturing process.
- Manage tools to ensure proper maintenance and tolerance guidelines.
- Capacity Planning tools identify production bottlenecks and allow for easy schedule changes.
- Materials Requirement Planning – Time phased view allows you to manage inventory so you have it on hand when you need it and not before. Reduces inventory on hand.
- Forecast Cash Needs