

# How MISys Manufacturing Related to Regulatory Standards

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## 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