



Help Achieve Compliance Objectives

The demands placed on **Medical Device Manufacturer** executives to balance compliance requirements with speed to market and price rivalry from competitors has increased dramatically over the past few years. In the face of the laws, regulations and policies as set forth by the U.S. Food and Drug Administration (FDA), along with public company concerns such as Sarbanes-Oxley, manufacturers are challenged with the seemingly contradictory goals of compliance adoption and organizational agility.

Technology solutions have matured rapidly to support recently formed compliance requirements. These tools are now readily found and completely integrated within Microsoft Dynamics GP Enterprise Requirement Planning (ERP) systems. The following components within Dynamics GP are critical to managing compliance requirements:

- **Workflow** – For enforcing standard operating procedures where multiple people and complex interdependencies exist, Dynamics GP integrates with the highly configurable Microsoft Office SharePoint Services (MOSS) workflow engine.
- **Audit Trails** – Track the markings of all critical transactions including minute data changes and record details about the change. This can be applied to master data such as customer information and also important transactional processes, such as materials assigned to a manufacturing order.
- **Electronic Signatures** – A key factor in sustaining the separation of duties is having technology solutions that require two-deep sign-offs on critical data changes or transaction entries. This feature in collaboration with Audit Trails is imperative in conforming to the principles set forth in FDA Title 21 Part 11 (21CFR11) and ISO standards.

A More Efficient Manufacturing Process

In addition to the compliance requirements, **Medical Device Manufacturers and Distributors** are under mounting pressure from offshore competitive threats and increasing political demands to keep costs in check. The best prescription for managing costs is a streamlined manufacturing and distribution process. Along with the standard efficiency features applicable for all manufacturers and distributors, Dynamics GP offers

the following functionality that is on the front-burner for most Medical Device Manufacturers and Distributors:

- **Lot Tracking** – Transform time-consuming searches into quick, efficient processes by identifying all instances of an item with a single cradle-to-grave trace.
- **Contract Manufacturer Integration** – Generate purchase orders for outsourced services based on manufacturing orders. Track shipment details and outsourcing costs precisely.
- **Quality Assurance** – Implement tight control of the quality verification process, helping to ensure that products consistently meet or exceed customer expectations. Achieve high levels of loyalty by providing customers with detailed information on quality assurance.
- **Product Configuration** – Streamline your organization’s Bill of Materials (BOM) structure through utilization of a rules based configuration engine. Enable rapid quoting and order generation with improved item and pricing accuracy.

PLEASE CONTACT US FOR MORE INFORMATION:

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