

Life Sciences

Advancing your operations toward FDA compliance with *complete* enterprise-wide business software solutions



Overview

Merit Solutions provides complete business software solutions for Life Sciences companies requiring FDA 21 CFR Part 11 and cGMP compliance. A software development and consulting company, Merit software compliments and extends *Microsoft Dynamics™ GP* software.

Merit Solutions Life Sciences

Merit software, in conjunction with Microsoft Dynamics GP Audit Trails and Electronic Signatures, allows companies to adhere to the stringent data validation, security and process integrity requirements mandated by the FDA while leveraging the power of Microsoft's integrated business systems. Merit Solutions provides complete, enterprise-wide systems solutions, including:

- Enhanced Security
- Advanced Lot Management
- Advanced Serial Management
- Adverse Event Reporting Management
- Quality Management
- Sales Controls
- Product Life-Cycle Management
- Production Management
- Sales Management
- Financial Management
- Customer Sales Order Management
- Relationship Management
- Customer Service Management
- Project Management
- Microsoft Dynamics GP Audit Trails
- Microsoft Dynamics GP Electronic Signatures

Manufacturing Minded

Awarded the 2001 and 2004 *Microsoft Excellence Partner of the Year*, Merit continues to be a leader in addressing the needs of manufacturing and life sciences businesses.



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Features you need

Microsoft Dynamics GP Audit Trails

Microsoft Dynamics GP Audit Trails and Electronic Signatures and Merit Solutions Enhanced Security Modules enable compliance with FDA 21 CFR Part 11 regulations. *Microsoft Dynamics GP Audit Trails* tracks any changes associated with significant data activity in Dynamics GP. This includes the capture of information such as time, date, user, and 'before/after' data values. The flexible search-based report viewing and creation functionality utilizes SmartView, a Dynamics GP SmartList-like user interface to the audit database.

Microsoft Dynamics GP Electronic Signatures

Microsoft Dynamics GP Electronic Signatures enforces dual signature authorization, the use of reason codes and text comments on data changes related to your critical business processes. The *Microsoft Dynamics GP Electronic Signature* solution automatically activates to enforce the attachment of authorized identity information to any Dynamics GP key business documents.

Adverse Event Reporting

The Merit Solutions *Adverse Event Reporting* (AER) Module tracks the information required by the FDA for mandatory adverse event reporting on FDA Form 3500A. It includes the complete event data capture, retrieval, analysis and reporting environment for FDA regulated companies. *Adverse Event Reporting* provides full backwards tracking and look up into product lot information related to the event, allows for user selection of required codes and categories, such as Route of Administration Codes and Event Problem Codes, and produces the FDA Form 3500A.

Material Lot Control

Advanced Lot Management from Merit Solutions expands Dynamics GP with the ability to enforce material use limits through Expiration Dates and Lot Status standards. Lot status assignments enable management of inventory transaction movements by only authorized users and safeguard against erroneous use of unapproved materials in manufacturing and distribution.

Sales Controls

Sales Controls by Merit Solutions enforce sales process restrictions for Dynamics GP users allowing only customer orders within the strict licensing or credentials conditions to be processed. The *Sales Controls* module provides a central point for setting up and maintaining License or Authorization Types, as well specific customer – product combinations.

Validation Templates

Standardized, prewritten templates provide validation scripts for documenting and executing tests to meet company specific Dynamics GP Installation Qualification (IQ), Operational Qualification (OQ) and Production Qualification (PQ). The flexible Merit Solutions *Validation Templates* support necessary changes to SOPs and are updated with each new release of Dynamics GP providing accelerated adoption of new system releases in accordance with cGMP standards.

Relationship Management

Merit Life Sciences incorporates Microsoft solutions for digital management of sales activities, FDA relationship activities, capturing, coordination and follow through on sales orders, customer service, product distribution activities and performing marketing programs and campaigns.

Extensibility

The Microsoft Dynamics GP system provides pre-built applications software and the tools and objects to extend the software to meet unique requirements of a business.

Benefits

Businesses can automate key processes, increasing productivity and reducing cost, while maintaining compliance with FDA cGMP requirements. Merit and Microsoft Dynamics GP are highly scalable and can be implemented in a modular approach. Merit *Life Science* solutions are rapidly implemented and can be deployed in a hosted or onsite environment.

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