

Adverse Event Reporting

Advancing Your Operations
Toward Audit *Compliance*
with *Merit Solutions*



Overview

For Microsoft Dynamics GP customers that are required to track Adverse Events and to file FDA Form 3500A. Merit Adverse Event Reporting tracks all Adverse Events within Dynamics GP, maintains a database of those Events including disposition information, and produces Form 3500A.

Features You Need

Increase Control

- Provides a central, controlled system for tracking, analyzing and reporting Adverse Events.
- Produces and records submission of MedWatch 3500A.
- Tracks standardized information such as details related to MeDRA, National Drug Code (NDC) and Manufacturing Protocol Number.

See the Big Picture

- Enables examination of information for all Adverse Events.
- Supports the case capture, management, reporting and analysis of adverse event cases for all medical products from all sources.

Maintain Compliance

- All changes to Merit Adverse Event records are tracked, recorded and maintained in Microsoft Dynamics GP Audit Trails in accordance with FDA 21 CFR Part 11 requirements.



AER Form

Save | New | Clear | Submit

AER # 5

Mfr Report # 1234567-2003-00007

UF/Dist Report #

Created By sa

Created Date 10/1/2003

Last Change By sa

Last Change On 10/1/2003

AER #	Mfg Report #	UF Report #	Cre
2	1234567-2003-00004	1234567890-2003-00001	
3	1234567-2003-00005	1234567890-2003-00002	sa
4	1234567-2003-00006	1234567890-2003-00003	sa
5	1234567-2003-00007		sa

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A - Patient

B - Event

C - Meds

D - Devices

E - Reporter

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F - Facility

G - All Mfg

H - Dvc mfg

Adverse Event Reporting tracks information required for MedWatch Form 3500A. The information is captured within the Microsoft Dynamics GP database for easy access and analysis of all Adverse Events. In the AER start screen, access each section of the 3500A form by clicking the corresponding form section.

Other Products of Interest

- Advanced Lot Management
- Advanced Serial Management
- Enhanced Security
- Validation Templates
- Sales Controls
- Sarbanes-Oxley Solution
- Production Workbench
- Quick Planner
- Microsoft Dynamics GP Audit Trails
- Microsoft Dynamics GP Electronic Signatures

Contact Us

Merit Solutions, Inc.

1749 S. Naperville Rd., Suite 200

Wheaton, IL 60187

www.meritsolutions.com

Phone: 630-614-7133

Fax: 630-614-7141

Email: info@meritsolutions.com

