

# Vigilance System

REU Associates, Mentor, OH 44060  
www.reuassociates.com T: 440-953-9789

## Practical Hints to MEDDEV 2.12-1 rev 5 Vigilance System Compliance

Medical Device Vigilance Guidance MEDDEV 2.12 rev 5 is well in force.

Medical device manufacturers, distributors and authorized representatives have made significant changes to vigilance system policies and practices to incorporate the new guidance by the January 2008 deadline. While not legally binding, there is an expected adoption of the guidance. Notified Bodies are evaluating policy, procedures and practices during their conformity assessments.

The MEDDEV 2.12-1 rev 5 Guidelines on a Medical Device Vigilance System has expands in scope, outlines more strict timing for reporting of incidents, introduces new terminology and concepts, and provides more detailed guidance on handling of field safety corrective actions.

### KEY POINTS

- 1 Revise Vigilance Policies
- 2 Revise Clinical Investigation Procedures
- 3 Understand new terminology
- 4 Create a guide for making incident reporting decisions
- 5 Update key documents
- 6 Know Reporting Timelines

## Revise Corporate Vigilance Policies

The revision to the scope of MEDDEV brings into its purview previously excluded devices. Devices that were placed on the market before the medical device directive became effective are now subject to vigilance system reporting. Similarly included are devices that do not carry the CE-mark but fall under the Directives scope, such as custom devices. Revise Vigilance System policies to include custom and "grandfathered" devices. This should also be stated in the Quality Manual.

## Revise Clinical Investigation Procedures

Companies conducting clinical investigations in the U.S.A. have long been aware of the need to report adverse events occurring during the clinical investigations to the F.D.A. The expansion to the scope of the MEDDEV guidance now similarly includes "devices that do not carry the CE mark, but fall under the Directives scope" such as devices used in clinical investigations.

## Understand new terminology

Understanding these terms and concepts are vital to good decision making for reporting obligations. Incorporate these terms into your documents and understand their meaning.

---

*Create a decision tree to consistently evaluate all complaints and other events for incident reporting*

---

## Use an Incident Reporting Decision Tree

The new guidance outlines the criteria for determining when a report is required but also includes guidance for when it is not. Terminology further helps to clarify intentions for incident reporting. However, it is expected that organizations clearly document their decisions, particularly for decisions not to report. Using a well communicated, consistent logic based on a thorough understanding of the guidance can help demonstrate compliance. Use a pre-defined decision tree to evaluate all complaints and other events for incident reporting. Incorporate document justifications for each decision not to report an incident.

## Update Key Documents

The guidance has implications on numerous processes within the quality system. Your quality system must reflect these changes and be communicated throughout the organization, starting with the policies outlined in your quality manual.

Suggested documents to consider for revision:

1. Quality Manual
2. Complaint Handling Procedure
3. Adverse Event or Incident Reporting Procedures
4. Recall and Advisory Notice Procedures
5. Clinical Investigation Procedures
6. Trend Analysis Procedures



## Know Reporting Timelines

Reports are now to be submitted immediately unless otherwise justified. Previous timelines of 10 and 30 days for incident reports are now the maximum time periods for reporting. This makes it critical for manufacturers and distributors to have an effective internal communication system and clearly understand the events which could be considered a reportable incident. In the case of doubt, it is expected that a report will be submitted.

---

*“Timescale for reporting is stricter.”*

---

---

*“In case of doubt, there should be a predisposition to report.”*

---



**REU Associates, Inc.**

Mentor, Oh 44060  
www.REUassociates.com

**Phone:**  
440-953-9789 or 440-897-5675

**E-mail:**  
Reuassociates.com

REU Associates, Inc are regulatory affairs and quality system professionals specializing in assisting medical device companies achieve world-wide regulatory and quality compliance and meet product submission & registration objectives.