

GHTF

FINAL DOCUMENT

Title: Medical Device Postmarket Vigilance and Surveillance:
Universal Data Set for Manufacturer Adverse Event Reports

Authoring Group: Study Group 2

Endorsed by: The Global Harmonization Task Force

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The document herein was produced by the Global Harmonization Task Force, a voluntary group of representatives from medical device regulatory agencies and the regulated industry. The document is intended to provide non-binding guidance for use in the regulation of medical devices, and has been subject to consultation throughout its development.

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Preface

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1.0 Introduction

This guidance represents a follow-up to the identification of the elements necessary for a minimum data set defined in SG2 N7. This new effort, identified as SG2 N32 expands the minimum elements, and represents all elements that should be included in any report from the manufacturer or authorized representative to the National Competent Authority (NCA).

2.0 Scope

This document identifies the various distinct and essential elements to be included in a reported adverse event. This document does not represent a format, which might be otherwise defined by the national authority to whom the report is sent.

3.0 References

This guidance is intended for the device manufacturer, or authorized representative, in accordance with the requirements of SG2 N7 and SG2 N21.

4.0 General considerations

1. **Dates** should be formatted as follows: 2 digit day, 3 letter month, 4 digit year, e.g., 01 JAN 2001
2. **Age**, and other timeframes, should specify if counted in days, months or years.
3. A **reasonable effort** should be made to address all elements defined below, however failure or inability to do so is not justification for failing to submit a report within the established timeframes.
4. **Electronic addresses** are desired whenever available.
5. Each field must be completed with the requested information or “NA” if not applicable to the event or “unknown” when the data is not available.
6. Please use the **comments** section at the end to provide any additional details that are relevant and not requested elsewhere.
7. In order to avoid the connotation of blame, information identifying the Health Care Facility or the User may be considered optional in certain NCA systems.
8. Manufacturers and NCAs need to be aware that patient privacy requirements must be honored where applicable.
9. NCAs may designate some elements to be eliminated or made optional.

5.0 Data Set Elements and Guidance

I. Administrative Information

A. Report Control Number

1. Mfr’s Internal #
2. # assigned by NCA to whom sent

3. User Facility Report #
4. User Facility #

B. Report Type (select one)

1. Initial defined as the first information submitted by the manufacturer about a reportable event, but the information is incomplete and supplementary information will need to be submitted. This includes immediate notification
2. Follow-up defined as a report that provides supplemental information about a reportable event that was not previously available)
3. Final defined as the last report that the manufacturer expects to submit about the reportable event. A final report may also be the first report
4. Trend defined as information supplied as a result of trending in accordance with SG2 N36

C. Date of this report

D. Date the adverse event occurred

E. Classification of event: (ref N21, N33)

1. Unanticipated Death, unanticipated Serious Injury, or Serious Public Health Threat
2. All other reportable events

F. Mfr. awareness date defined as the date that a manufacturer first learned about a reportable event

G. Expected date of next report i.e., if this is not a “final” report, this represents the date when further information will be submitted to the NCA

H. Person, or authorized rep, submitting this report

1. Name of the contact person submitting the report
2. Company Name
3. Address
4. Phone
5. Fax
6. Electronic mail address

I. Identify to what other NCAs this report was *also* sent.

II. Clinical Event Information

- A. Event description narrative clarification: relevant information that might impact the understanding or evaluation of the adverse event AND that is not included elsewhere in this report. For example- “the patient was confused prior to becoming

trapped in the bedsides”; “the patient was a very low birth weight premature delivery and had a central line placed three days before onset of cardiac tamponade”; “the X-ray machine was over 20 years old and had been poorly maintained at the time of the adverse event”, etc.)

- B. Number of patients¹ involved
- C. Number of devices involved

III. Healthcare Facility Information

- A. Name
- B. Address
- C. Phone
- D. Fax
- E. Electronic mail address
- F. Contact Name at the Site of the Event

IV. Device Information (Repeat this section for each device involved)

- A. Device Information
 - 1. Mfr. Name
 - 2. Contact Name
 - 3. Address
 - 3. Phone
 - 5. Fax
 - 6. Electronic mail address
- B. Operator of device at the time of the event (select from list below)
 - 1. Healthcare professional
 - 2. Patient
 - 3. Other Caregiver
 - 4. None defined as: problem noted prior to use
- C. Usage of Device (select from list below)
 - 1. Initial Use
 - 2. Reuse of Single Use Device
 - 3. Reuse of Reusable Device
 - 4. Re-serviced/Refurbished
 - 5. Other, (Please Specify)
- D. Generic Device Information
 - 1. Nomenclature System
 - 2. Nomenclature Code
 - 3. Nomenclature Code Defined in Text
 - 4. Brand Name
 - 5. Model #

- 6. Catalogue #
- 7. Device identifiers e.g., serial #, batch #, software version #, etc.

E. Device Disposition/Current Location e.g., device has been destroyed, remains implanted in patient, was returned to the manufacturer, remains under investigation, etc.

F. Device approval information

- 1. Regulatory/National Competent Authority who approved device
- 2. Notified Body (NB) who approved device
- 3. Other 3rd party name who approved device
- 4. NB ID number
- 6. Document approval number

V. Results of Manufacturer’s Investigation

A. Manufacturers Device Analysis Results Specify, for this event, details of investigation methods, results, and conclusions

B. Remedial Action/Corrective Action/Preventive Action

Specify if action was taken by manufacturer for the reported specific event or for all similar type products. Include what action was taken by the manufacturer to prevent recurrence. Clarify the timeframes for completion of various action plans.)

VI. Patient¹ information (Repeat this section for each patient involved)

Provide individual patient information for each element as appropriate

A. Age of patient at time of event specify units of measure, i.e., days, months, or years

B. Gender

C. Weight in Kilograms (metric units will be assumed)

D. List of Devices involved with each patient, see Section IV

E. Patient-focused Resolution of Events and Outcomes

- 1. Corrective action taken relevant to the care of the patient
- 2. Patient outcome

¹ Includes any affected individual eg user, patient, or third party.

VII. Other Reporting Information (to be included in final reports only)

Is the mfr aware of similar events with this device with the same root cause?
Y/N

If yes, provide the number of the events- The "number" should be specified in terms of event per unit sold, or the number of event per unit sold / in use in a region, etc.

Providing this information is considered to be a burden to industry and NCA's should consider carefully in making this a national requirement (see item 9 under General Considerations).

VIII. Comments

IX. Manufacturer Disclaimer