By Definition

An “FDA Recordable Complaint” is any communication (written or oral) of dissatisfaction regarding the identity, quality, reliability, safety, effectiveness or performance of medical gas, drug, medical device or their container/closures.

An “Adverse Drug Event” is defined as any adverse drug experience occurring at any dose that results in any of the following outcomes: Death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

For more information on this subject, or any other medical gases compliance issue please contact Ron Ball at (317) 297-8518, or ron.ball@brcompliance.com.

What is a Recordable Complaint?

Examples of complaints - (Non-inclusive)

- Empty cylinders
- Valve not functioning properly
- Incorrect or damaged label
- No or Unreadable Lot Number
- Low purity to USP/NF specification
- High Impurities to USP/NF specification
- Incorrect mixture
- Improper or Incorrect CGA fitting

Documentation

Complaints, whether oral or in writing, must be investigated and brought to a conclusion. A complaint file must be maintained for FDA's review when they visit (even if no complaints have been registered). The Complaint file must contain the following information regarding any complaint:

- Customer Information (Name/Date/Contact Information)
- Product Information (Type/Lot Number/Filling & Distributing Location)
- Nature of complaint
- Investigation Information (Including any Testing & Results)
- Corrective Action (What will be done to prevent re-occurrence - person responsible for any follow-up)
- Reply to complainant
- Complaint Closure (Review of Completed Document Package by QC Unit)

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Adverse Event Reporting and Medical Device Reporting Requirements: Handling Product Complaints that qualifies for reporting under these regulations

Procedure/Guideline

1. When any information is received by the program member company regarding an adverse reaction (see definition on page 1) with the use of a program member's product, the Q/A Coordinator will be informed immediately.

2. When Information is received regarding an adverse reaction (see definition on page 1) with the use of a program member's product, the information will be reviewed by the Q/A Coordinator to determine if this event qualifies for reporting under the Adverse Event Reporting and Medical Device Reporting requirements.

3. Included in this responsibility is generating appropriate documentation of the decision to either report or not report the event.

4. The FDA links below will provide assistance and the necessary tools for the Q/A Coordinator to use in the reporting process:

    - Regulation: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=310.305

    - Guidance Document: http://www.fda.gov/cder/guidance/old037fn.pdf

    - Mandatory Reporting On Line: http://www.fda.gov/medwatch/REPORT/Mfg.htm

    - PDF Download of Form 3500A: http://www.fda.gov/medwatch/SAFETY/3500A.pdf

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