**DEVICE EVENT**

https://api.fda.gov/device/event

API status and freshness API OK | Updated 2015-05-22 | Data current through 2015-04-30

The openFDA device adverse event API returns data from [Manufacturer and User Facility Device Experience (MAUDE)](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm), an FDA dataset that contains medical device adverse event reports submitted by mandatory reporters—manufacturers, importers and device user facilities—and voluntary reporters such as health care professionals, patients, and consumers. Currently, this data covers publically releasable records submitted to the FDA from about 1992 to the present. The data is updated weekly.

Each year, the FDA receives several hundred thousand medical device reports (MDRs) of suspected device-associated deaths, serious injuries and malfunctions. The FDA uses MDRs to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products.

Disclaimer

Although MDRs are a valuable source of information, this passive surveillance system has limitations, including the potential submission of incomplete, inaccurate, untimely, unverified, or biased data. In addition, the incidence or prevalence of an event cannot be determined from this reporting system alone due to potential under-reporting of events and lack of information about frequency of device use. Because of this, MDRs comprise only one of the FDA's several important postmarket surveillance data sources.

See the [MAUDE dataset page](https://open.fda.gov/data/maude/) for more details.

**How records are organized**

Device adverse event reports vary significantly, depending on who initially reported the event, what kind of event was reported, and whether there were follow-up reports. Some reports come directly from user facilities (like hospitals) or device importers (distributors), while others come directly from manufacturers. Some involve adverse reactions in patients, while others are reports of defects that did not result in such adverse reactions.

Records served by the openFDA device adverse events endpoint loosely reflect field organization found in the [forms used by manufacturers and members of the public](http://www.fda.gov/Safety/MedWatch/HowtoReport/DownloadForms/default.htm) to report these events. Since reports may come from manufacturers, user facilities, distributors, and voluntary sources (such as patients and physicians) who are subject to different reporting requirements, the collected data in the adverse event system may not always capture every field and should not be interpreted as incomplete.

**Patients and devices.**

Reports may involve more than one device, and more than one patient. *Each* device, and each patient, is identified in the report by a *sequence number*, beginning with 1.

* The device section in a result has one JSON object for each device.
* Each device is identified by a number in the field device.device\_sequence\_number.
* The other fields describe that device.
* The patient section in a result has one JSON object for each patient.
* Each patient identified by a number in the field patient.patient\_sequence\_number.
* The other fields describe outcomes and treatments for that patient.
* The mdr\_text section, which has narrative descriptions of the adverse event or problem report, links these descriptions to patient outcomes by way of the same patient sequence number
* Here the sequence number is in the field mdr\_text.patient\_sequence\_number.
* Even in reports that did not involve any patient, the general device problem description is still associated with a “patient” with patient\_sequence\_number 1.

**Data downloads**

Medical device adverse event reports in MAUDE are current as of the end of the previous month. OpenFDA uses these adverse event reports, but processes the data further before supplying them through the API. During our beta testing, we are investigating the best ways to offer direct downloads of data provided by the API.

There are no plans for the openFDA initiative to change the MAUDE data release protocols. OpenFDA is a research project to make access to these datasets easier, not replace the current process. The information available through openFDA is not for clinical or production use and is in beta testing. While FDA makes every effort to ensure the data is accurate, it should be assumed that all results are not validated.

**Anatomy of a response**

This is a simulated openFDA API return for a non-count query. It is divided into two high-level sections, meta and results.

{

"meta": {

"disclaimer": "openFDA is a beta research project and not for clinical use. While we make every effort to ensure that data is accurate, you should assume all results are unvalidated.",

"license": "http://open.fda.gov/license",

"last\_updated": "2014-08-01",

"results": {

"skip": 0,

"limit": 1,

"total": 1355

}

},

"results": [

{

...

}

]

}

**Meta**

For non-count queries, the meta section includes a disclaimer, a link to the openFDA data license, and information about the results that follow.

"meta": {

"disclaimer": "openFDA is a beta research project and not for clinical use. While we make every effort to ensure that data is accurate, you should assume all results are unvalidated.",

"license": "http://open.fda.gov/license",

"last\_updated": "2014-08-01",

"results": {

"skip": 0,

"limit": 1,

"total": 1355

}

meta.disclaimer

**string**

Important details about the openFDA beta and limitations of the dataset.

meta.license

**string**

Link to a web page with license terms that govern data within openFDA.

meta.last\_updated

**string**

The last date when openFDA was updated. Note that this does not correspond to the last report date in the system. Rather, it is the last time openFDA received a system or data update.

meta.results.skip

**integer**

Offset (page) of results, defined by the skip [query parameter](https://open.fda.gov/api/reference/#query-parameters).

meta.results.limit

**integer**

Number of records in this return, defined by the limit [query parameter](https://open.fda.gov/api/reference/#query-parameters). If there is no limit parameter, the API returns one result.

meta.results.total

**integer**

Total number of records matching the search criteria.

**Results**

For non-count queries, the results section includes matching device adverse event report records returned by the API.

**Field-by-field reference**

**Event**

These fields describe the general nature of the adverse event. For example, whether it was a device malfunction or defect, whether there were patients involved, who reported the event, and so on.

adverse\_event\_flag

**string**

Y = The report is about an incident where the use of the device is suspected to have resulted in an adverse outcome in a patient.

N = The report is not about an adverse outcome in a patient.

Empty if no data was available or entered.

product\_problem\_flag

**string**

Y = The report is about the quality, performance, or safety of a device—for example, defects or malfunctions. This flag is set when a device malfunction could lead to a death or serious injury if the malfunction were to recur.

N = The report is not about a defect or malfunction.

Empty if no data was available or entered.

date\_of\_event

**date string - *YYYYmmdd***

Actual or best estimate of the date of first onset of the adverse event. This field was added in 2006.

date\_report

**date string - *YYYYmmdd***

Date the initial reporter (whoever initially provided information to the user facility, manufacturer, or importer) provided the information about the event.

date\_received

**date string - *YYYYmmdd***

Date the report was received by the FDA.

number\_devices\_in\_event

**string**

Number of devices noted in the adverse event report. Almost always *1*. May be empty if report\_source\_code contains Voluntary report.

number\_patients\_in\_event

**string**

Number of patients noted in the adverse event report. Almost always *1*. May be empty if report\_source\_code contains Voluntary report.

report\_number

**string**

Identifying number for the adverse event report. The format varies, according to the source of the report. The field is empty when a user facility submits a report.

*For manufacturer reports.* Manufacturer Report Number. The report number consists of three components: The manufacturer’s FDA registration number for the manufacturing site of the reported device, the 4-digit calendar year, and a consecutive 5-digit number for each report filed during the year by the manufacturer (e.g. 1234567-2013-00001, 1234567-2013-00002).

*For user facility/importer (distributor) reports.* Distributor Report Number. Documentation forthcoming.

*For consumer reports.* This field is empty.

**Source**

These fields describe the source and initial reporter of the adverse event report.

report\_source\_code

**string**

Source of the adverse event report. Possible values:

Manufacturer report

Voluntary report

User facility report

Distributor report

health\_professional

**string**

Whether the initial reporter was a health professional (e.g. physician, pharmacist, nurse, etc.) or not.

Y = The initial reporter is a health professional.

N = The initial reporter is not a health professional.

reporter\_occupation\_code

**string**

Initial reporter occupation.

Other

Physician

Nurse

Health professional

Lay user/patient

Other health care professional

Audiologist

Dental hygienist

Dietician

Emergency medical technician

Medical technologist

Nuclear medicine technologist

Occupational therapist

Paramedic

Pharmacist

Phlebotomist

Physical therapist

Physician assistant

Radiologic technologist

Respiratory therapist

Speech therapist

Dentist

Other caregivers

Dental assistant

Home health aide

Medical assistant

Nursing assistant

Patient

Patient family member or friend

Personal care assistant

Service and testing personnel

Biomedical engineer

Hospital service technician

Medical equipment company technician/representative

Physicist

Service personnel

Device unattended

Risk manager

Attorney

Unknown

Not applicable

No information

Unknown

Invalid data

initial\_report\_to\_fda

**string**

Whether the initial reporter also notified or submitted a copy of this report to FDA.

Yes = FDA was also notified by the initial reporter.

No = FDA was not notified by the initial reporter.

Unknown = Unknown whether FDA was also notified by the initial reporter.

No answer provided or empty = This information was not provided.

reprocessed\_and\_reused\_flag

**string**

Indicates whether the suspect device was a single-use device that was reprocessed and reused on a patient.

Y = Was a single-use device that was reprocessed and reused.

N = Was not a single-use device that was reprocessed and reused.

UNK = The original equipment manufacturer was unable to determine if their single-use device was reprocessed and reused.

**Device**

If there were devices listed in the adverse event report, there will be a device section, consisting of a list of devices. Each object in the device section may consist of many of the following fields.

"device": [

{

"…": "…"

}

]

The first field is a record-local index for the particular device; it is also used to link this device information to narrative (text) descriptions in the mdr\_text section.

device.device\_sequence\_number

**string**

Number identifying this particular device. For example, the first device object will have the value 1. This is an enumeration corresponding to the number of patients involved in an adverse event.

device.device\_event\_key

**string**

Documentation forthcoming.

device.date\_received

**string**

Documentation forthcoming.

**Identification**

Each device has fields that can be used to uniquely identify it.

device.brand\_name

**string**

The trade or proprietary name of the suspect medical device as used in product labeling or in the catalog (e.g. Flo-Easy Catheter, Reliable Heart Pacemaker, etc.). If the suspect device is a reprocessed single-use device, this field will contain NA.

device.generic\_name

**string**

The generic or common name of the suspect medical device or a generally descriptive name (e.g. urological catheter, heart pacemaker, patient restraint, etc.).

device.device\_report\_product\_code

**string**

Three-letter FDA Product Classification Code. Medical devices are classified under [21 CFR Parts 862-892](http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/classifyyourdevice/default.htm). The assigned FDA Product Classification Code (procode) can be identified using the [Product Classification Database](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm).

**Device model and catalog numbers**

If available, these values should be recorded exactly as they appear on the device or device labeling, including spaces, hyphens, etc.

device.model\_number

**string**

The exact model number found on the device label or accompanying packaging.

device.catalog\_number

**string**

The exact number as it appears in the manufacturer’s catalog, device labeling, or accompanying packaging.

device.lot\_number

**string**

If available, the lot number found on the label or packaging material.

device.other\_id\_number

**string**

Any other identifier that might be used to identify the device. Expect wide variability in the use of this field. It is commonly empty, or marked NA, N/A, \*, or UNK, if unknown or not applicable.

**Age and expiration date**

device.expiration\_date\_of\_device

**string**

If available; this date is often be found on the device itself or printed on the accompanying packaging.

device.device\_age\_text

**string**

Age of the device or a best estimate, often including the unit of time used. Contents vary widely, but common patterns include:

nn YR or n.n YR = Device age *nn* or *n.n* years.

nn MO or n.n MO = Device age *nn* or *n.n* months.

nn DA or nn DA or nn DAY = Device age *nn* or *n.n* days.

UNK or UNKNOWN = Device age unknown.

DA = Documentation forthcoming.

NO INFO = Documentation forthcoming.

\* or empty if information not provided.

**Evaluation by manufacturer**

device.device\_availability

**string**

Whether the device is available for evaluation by the manufacturer, or whether the device was returned to the manufacturer.

Yes

No

Device was returned to manufacturer

No answer provided

I = Documentation forthcoming.

May also be empty if no answer provided.

device.date\_returned\_to\_manufacturer

**date string - *YYYYmmdd***

Date the device was returned to the manufacturer, if applicable.

device.device\_evaluated\_by\_manufacturer

**string**

Whether the suspect device was evaluated by the manufacturer.

Yes = An evaluation was made of the suspect or related medical device.

No = An evaluation of a returned suspect or related medical device was not conducted.

Device not returned to manufacturer = An evaluation could not be made because the device was not returned to, or made available to, the manufacturer.

No answer provided or empty = No answer was provided or this information was unavailable.

**Use of device**

The following fields describe who was operating the device, if applicable, and whether it was an implanted device.

device.device\_operator

**string**

The person using the medical device at the time of the adverse event. This may be a health professional, a lay person, or may not be applicable.

Physician

Nurse

Health professional

Lay user/patient

Other health care professional

Audiologist

Dental hygienist

Dietician

Emergency medical technician

Medical technologist

Nuclear medicine technologist

Occupational therapist

Paramedic

Pharmacist

Phlebotomist

Physical therapist

Physician assistant

Radiologic technologist

Respiratory therapist

Speech therapist

Dentist

Other caregivers

Dental assistant

Home health aide

Medical assistant

Nursing assistant

Patient

Patient family member or friend

Personal care assistant

Service and testing personnel

Biomedical engineer

Hospital service technician

Medical equipment company technician/representative

Physicist

Service personnel

Device unattended

Risk manager

Attorney

Other

Unknown

Not applicable

No information

Unknown

Invalid data

device.implant\_flag

**string**

Whether a device was implanted or not. May be either marked N or left empty if this was not applicable.

device.date\_removed\_flag

**string**

Whether an implanted device was removed from the patient, and if so, what kind of date was provided.

Month and year provided only day defaults to 01 = Only a year and month were provided. Day was set to 01.

Year provided only = Only a year was provided. Month was set to 01 (January) and day set to 01.

No information at this time = Documentation forthcoming.

Not available = Documentation forthcoming.

Unknown = Documentation forthcoming.

\* = Documentation forthcoming.

B = Documentation forthcoming.

V = Documentation forthcoming.

**Manufacturer**

Each device has its own fields for identification of the manufacturer.

**Device manufacturer name**

device.manufacturer\_d\_name

**string**

Device manufacturer name.

**Address**

device.manufacturer\_d\_address\_1

**string**

Device manufacturer address line 1.

device.manufacturer\_d\_address\_2

**string**

Device manufacturer address line 2.

device.manufacturer\_d\_city

**string**

Device manufacturer city.

device.manufacturer\_d\_state

**string**

Device manufacturer two-letter state code.

device.manufacturer\_d\_country

**string**

Device manufacturer two-letter country code. *Note: For medical device adverse event reports, comparing country codes with city names in the same record demonstrates widespread use of conflicting codes. Caution should be exercised when interpreting country code data in device records.*

device.manufacturer\_d\_zip\_code

**string**

Device manufacturer 5-digit zip code.

device.manufacturer\_d\_zip\_code\_ext

**string**

Device manufacturer 4-digit zip code extension (zip+4 code).

device.manufacturer\_d\_postal\_code

**string**

Device manufacturer postal code. May contain the zip code for addresses in the United States.

**Patient**

If there were patients noted in the adverse event report, there will be patient section, consisting of a list of patient treatment and outcomes. Each object in the patient section consists of the following fields.

"patient": {

"…": "…"

}

patient.patient\_sequence\_number

**string**

Number identifying this particular patient. For example, the first patient object will have the value 1. This is an enumeration corresponding to the number of patients involved in an adverse event.

patient.date\_received

**date string *YYYYmmdd***

Date the report about this patient was received.

patient.sequence\_number\_treatment

**list of strings**

Treatment the patient received.

patient.sequence\_number\_outcome

**list of strings**

Outcome associated with the adverse event for this patient. Expect wide variability in this field; each string in the list of strings may contain multiple outcomes, separated by commas, and with numbers, which may or may not be related to the patient\_sequence\_number.

Life Threatening

Hospitalization

Disability

Congenital Anomaly

Required Intervention

Other

Invalid Data

Unknown

No Information

Not Applicable

Death

**Report text**

The mdr\_text section contains narrative information about the adverse event or problem report. Text may be about the problem, about the device, or about the patient adverse event, depending on the nature of the report. Each narrative or text description has the following fields.

"mdr\_text": {

"…": "…"

}

mdr\_text.patient\_sequence\_number

**string**

Patient which the narrative text or problem description is about. For reports that did not involve a patient adverse event, this field will still often contain 1 even if the problem description is just about the suspect medical device.

mdr\_text.text\_type\_code

**string**

Description of Event or Problem = The problem (quality, performance, or safety concern) in sufficient detail so that the circumstances surrounding the defect or malfunction of the medical product can be understood. For patient adverse events, may include a description of the event in detail using the reporter’s own words, including a description of what happened and a summary of all relevant clinical information (medical status prior to the event; signs and/or symptoms; differential diagnosis for the event in question; clinical course; treatment; outcome, etc.). If available and if relevant, may include synopses of any office visit notes or the hospital discharge summary. This section may also contain information about surgical procedures and laboratory tests.

Manufacturer Evaluation Summary = If available, the results of any evaluation of a malfunctioning device and, if known, any relevant maintenance/service information should be included in this section.

Additional Manufacturer Narrative = Documentation forthcoming.

mdr\_text.text

**string**

Narrative text or problem description.

mdr\_text.mdr\_text\_key

**string**

Documentation forthcoming.

mdr\_text.date\_received

**string date - *YYYYmmdd***

Documentation forthcoming.

**Reporter-dependent fields**

**By user facility/importer**

For reports submitted by user facilities, importers, or distributors, the following information is available.

type\_of\_report

**list of strings**

The type of report.

Initial submission = Initial report of an event.

Followup = Additional or corrected information.

Extra copy received = Documentation forthcoming.

Other information submitted = Documentation forthcoming.

date\_facility\_aware

**date string - *YYYYmmdd***

Date the user facility’s medical personnel or the importer (distributor) became aware that the device has or may have caused or contributed to the reported event.

report\_date

**date string - *YYYYmmdd***

Date of the report, or the date that the report was forwarded to the manufacturer and/or the FDA.

report\_to\_fda

**string**

Whether the report was sent to the FDA by a user facility or importer (distributor). User facilities are required to send reports of device-related deaths. Importers are required to send reports of device-related deaths and serious injuries.

Y = The report was sent to the FDA by a user facility or importer.

N = The report was not sent to the FDA by a user facility or importer.

Empty if this information was not provided.

date\_report\_to\_fda

**date string - *YYYYmmdd***

Date the user facility/importer (distributor) sent the report to the FDA, if applicable.

report\_to\_manufacturer

**string**

Whether the report was sent to the manufacturer by a user facility or importer (distributor). User facilities are required to send reports of device-related deaths and serious injuries to manufacturers. Importers are required to send reports to manufacturers of device-related deaths, device-related serious injuries, and device-related malfunctions that could cause or contribute to a death or serious injury.

Y = The report was sent to the manufacturer by a user facility or importer.

N = The report was not sent to the manufacturer by a user facility or importer.

Empty if this information was not provided.

date\_report\_to\_manufacturer

**date string - *YYYYmmdd***

Date the user facility/importer (distributor) sent the report to the manufacturer, if applicable.

event\_location

**string**

Where the event occurred.

Other

Hospital

Home

Nursing home

Outpatient treatment facility

Outpatient diagnostic facility

Ambulatory surgical facility

Hospital

Catheterization suite

Critical care unit

Dialysis unit

Emergency room

Examination room

Laboratory/pathology department

Maternity ward - nursery

Operating room

Outpatient clinic/surgery

Patient's room or ward

Radiology department

Ambulatory health care facility

Ambulatory surgical center

Blood bank

Bloodmobile

Catheterization lab - free standing

Chemotherapy center

Clinic - walk in, other

Dialysis center

Drug clinic

Imaging center - mobile

Imaging center - stationary

Laboratory

Mobile health unit

Mri centers

Psychiatric center - walk in, other

Tuberculosis clinic

Urgent care center

Outpatient diagnostic facility

Long-term care facility

Hospice

Nursing home

Psychiatric facility

Rehabilitation center

Retirement home

Patient's home

In transit to user/medical facility

Public venue

Outdoors

Park

Playground

Public building

School

Street

Unknown

Not applicable

No information

Unknown

Invalid data

**Name and address**

distributor\_name

**string**

User facility or importer (distributor) name.

distributor\_address\_1

**string**

User facility or importer (distributor) address line 1.

distributor\_address\_2

**string**

User facility or importer (distributor) address line 2.

distributor\_city

**string**

User facility or importer (distributor) city.

distributor\_state

**string**

User facility or importer (distributor) two-digit state code.

distributor\_zip\_code

**string**

User facility or importer (distributor) 5-digit zip code.

distributor\_zip\_code\_ext

**string**

User facility or importer (distributor) 4-digit zip code extension (zip+4 code).

**Suspect device manufacturer**

User facilities/importers (distributors) include the suspect device manufacturer name and address in their reports.

manufacturer\_name

**string**

Suspect medical device manufacturer name.

manufacturer\_address\_1

**string**

Suspect medical device manufacturer address line 1.

manufacturer\_address\_2

**string**

Suspect medical device manufacturer address line 2.

manufacturer\_city

**string**

Suspect medical device manufacturer city.

manufacturer\_state

**string**

Suspect medical device manufacturer two-letter state code.

manufacturer\_zip\_code

**string**

Suspect medical device manufacturer 5-digit zip code.

manufacturer\_zip\_code\_ext

**string**

Suspect medical device manufacturer 4-digit zip code extension (zip+4 code).

manufacturer\_country

**string**

Suspect medical device manufacturer two-letter country code. *Note: For medical device adverse event reports, comparing country codes with city names in the same record demonstrates widespread use of conflicting codes. Caution should be exercised when interpreting country code data in device records.*

manufacturer\_postal\_code

**string**

Suspect medical device manufacturer postal code. May contain the zip code for addresses in the United States.

**By device manufacturer**

These fields are for reports submitted by device manufacturers.

event\_type

**list of strings**

Outcomes associated with the adverse event.

Death = Death, either caused by or associated with the adverse event.

Injury (IN) = Documentation forthcoming.

Injury (IL) = Documentation forthcoming.

Injury (IJ) = Documentation forthcoming.

Malfunction = Product malfunction.

Other = Other serious/important medical event.

No answer provided = No information was provided.

device\_date\_of\_manufacture

**date string - *YYYYmmdd***

Date of manufacture of the suspect medical device.

U = Unknown.

single\_use\_flag

**string**

Whether the device was labeled for single use or not.

Yes = The device was labeled for single use.

No = The device was not labeled for single use, or this is irrelevant to the device being reported (e.g. an X-ray machine).

Empty = This information was not provided.

previous\_use\_code

**string**

Whether the use of the suspect medical device was the initial use, reuse, or unknown.

I = Initial use.

R = Reuse.

U = Unknown.

\* or empty = Invalid data or this information was not provided.

**Corrective or remedial action**

These fields describe the nature of corrective actions taken by the time the report was filed, if applicable.

remedial\_action

**list of strings**

Follow-up actions taken by the device manufacturer at the time of the report submission, if applicable.

Recall

Repair

Replace

Relabeling

Other

Notification

Inspection

Patient Monitoring

Modification/Adjustment

Invalid Data

removal\_correction\_number

**string**

If a corrective action was reported to FDA under [21 USC 360i(f)](http://www.law.cornell.edu/uscode/text/21/360i), the correction or removal reporting number (according to the format directed by [21 CFR 807](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=807)). If a firm has not submitted a correction or removal report to the FDA, but the FDA has assigned a recall number to the corrective action, the recall number may be used.

**Contact**

For reports submitted by a device manufacturer, these fields contain identification and contact information (including for the manufacturing site).

**Contact person**

manufacturer\_contact\_t\_name

**string**

Manufacturer contact person title (Mr., Mrs., Ms., Dr., etc.)

manufacturer\_contact\_f\_name

**string**

Manufacturer contact person first name.

manufacturer\_contact\_l\_name

**string**

Manufacturer contact person last name.

**Contact person address**

manufacturer\_contact\_street\_1

**string**

Manufacturer contact person street address line 1.

manufacturer\_contact\_street\_2

**string**

Manufacturer contact person street address line 2.

manufacturer\_contact\_city

**string**

Manufacturer contact person city.

manufacturer\_contact\_state

**string**

Manufacturer contact person two-letter state code.

manufacturer\_contact\_zip\_code

**string**

Manufacturer contact person 5-digit zip code.

manufacturer\_contact\_zip\_ext

**string**

Manufacturer contact person 4-digit zip code extension (zip+4 code).

manufacturer\_contact\_postal

**string**

Manufacturer contact person postal code. May contain the zip code for addresses in the United States.

manufacturer\_contact\_country

**string**

Manufacturer contact person two-letter country code. *Note: For medical device adverse event reports, comparing country codes with city names in the same record demonstrates widespread use of conflicting codes. Caution should be exercised when interpreting country code data in device records.*

**Contact person phone number**

manufacturer\_contact\_pcountry

**string**

Manufacturer contact person phone number country code. *Note: For medical device adverse event reports, comparing country codes with city names in the same record demonstrates widespread use of conflicting codes. Caution should be exercised when interpreting country code data in device records.*

manufacturer\_contact\_area\_code

**string**

Manufacturer contact person phone number area code.

manufacturer\_contact\_exchange

**string**

Manufacturer contact person phone number exchange.

manufacturer\_contact\_extension

**string**

Manufacturer contact person phone number extension.

manufacturer\_contact\_pcity

**string**

Manufacturer contact person phone number city code.

manufacturer\_contact\_phone\_number

**string**

Manufacturer contact person phone number.

manufacturer\_contact\_plocal

**string**

Manufacturer contact person local phone number.

**Manufacturer name and address**

manufacturer\_g1\_name

**string**

Manufacturer name.

manufacturer\_g1\_street\_1

**string**

Manufacturer street address line 1.

manufacturer\_g1\_street\_2

**string**

Manufacturer street address line 2.

manufacturer\_g1\_city

**string**

Manufacturer city.

manufacturer\_g1\_state

**string**

Manufacturer two-letter state code.

manufacturer\_g1\_zip\_code

**string**

Manufacturer 5-digit zip code.

manufacturer\_g1\_zip\_ext

**string**

Manufacturer 4-digit zip code extension (zip+4 code).

manufacturer\_g1\_postal\_code

**string**

Manufacturer postal code. May contain the zip code for addresses in the United States.

manufacturer\_g1\_country

**string**

Manufacturer two-letter country code. *Note: For medical device adverse event reports, comparing country codes with city names in the same record demonstrates widespread use of conflicting codes. Caution should be exercised when interpreting country code data in device records.*

**By any manufacturer**

This information is ordinarily provided by all manufacturers.

date\_manufacturer\_received

**date string - *YYYYmmdd***

Date when the applicant, manufacturer, corporate affiliate, etc. receives information that an adverse event or medical device malfunction has occurred. This would apply to a report received anywhere in the world. For follow-up reports, the date that the follow-up information was received.

source\_type

**list of strings**

The manufacturer-reported source of the adverse event report.

Other

Foreign

Study

Literature

Consumer

Health Professional

User facility

Company representation

Distributor

Unknown

Invalid data

**Keys and flags**

event\_key

**string**

Documentation forthcoming.

mdr\_report\_key

**string**

Documentation forthcoming.

manufacturer\_link\_flag\_

**string**

Indicates whether a user facility/importer-submitted (distributor-submitted) report has had subsequent manufacturer-submitted reports. If so, the distributor information (address, etc.) will also be present and this field will contain Y.

Y = There are subsequent manufacturer-submitted reports.

N = There are no subsequent manufacturer-submitted reports.