

eSubmitter

File Edit View Table Output Tools Help

Submission Name: ISO
Report Type: CDRH: ISO13485

Last Modified:
Date Packaged:

Outline

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Screen: Introduction

ISO 13485 Voluntary Audit Report Program

The OMB control number for this information collection is 0910-0569 (expires February 28, 2015)

Section 228 of the Food and Drug Administration Amendments Act of 2007 (FDAAA), which amends section 704(g)(7) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 374 (g)(7)) was amended to add the following provision:

"(F) For the purpose of setting risk-based inspectional priorities, the Secretary shall accept voluntary submissions of reports of audits assessing conformance with appropriate quality system standards set by the International Organization for Standardization (ISO) and identified by the Secretary in public notice. If the owner or operator of an establishment elects to submit audit reports under this subparagraph, the owner or operator shall submit all such audit reports with respect to the establishment during the preceding 2-year periods."

Effective October 1, 2011, FDA will begin a two year voluntary pilot program as described in the guidance document entitled "Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program" found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/cdm212755.htm>. FDA will evaluate the outcomes of the pilot program at the end of this period. It is important to note that participation in the Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program is entirely voluntary.

Complete the following question and answer form, as well as attach the necessary PDF files to submit your ISO 13485 Audit Reports to FDA's Center for Devices and Radiological Health via the FDA Electronic Submissions Gateway (ESG). To register with the FDA ESG, go to www.fda.gov/escg.

Blue dots indicate required fields.

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Submission Name: ISO 13485 Submission
Report Type: CDRH: ISO13485

Last Modified: 09/05/2014 10:54:24 AM
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Screen View Report: 1.0 Inspection Date

Your submission must be sent in within the last 90 days of an audit.

Has an audit been completed in the last 90 calendar days? No Yes

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Screen View Report: 2.0 Contact Information

Contact Information

Definitions

Applicant Contact Information - Should be completed by the requester or submitter. The applicant will act as the primary point of contact for this ISO 13485 Audit Report Submission.

Company - Refers to the organization as a whole for a specific contact reference point.

Establishment - Refers to the physical location of a facility.

Tips

The Address Book function can store re-usable contact information across multiple eSubmitter report types. Click the link below to view instruction on how to use the Address Book.

[Address Book User Guide](#)

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Screen View Report: 2.1 Establishment Contact Information

Enter the facility contact information that was audited including the most responsible person.

The FDA Establishment Identifier (FEI) will be validated upon FDA receipt. Any invalid FEI numbers and Establishment addresses will be rejected.

Establishment Contact Information

Contact

Title (e.g., Mr., Ms.):

First/Given Name:

Middle Name:

Last Name:

Email Address:

Address

Establishment Name:

Division Name:

Country: United States of America Other (select below)

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Screen View Report: 2.3 Applicant Contact Information

Contact

Title (e.g., Mr., Ms.):

First/Given Name:

Middle Name:

Last Name:

Email Address:

Address

Company:

Country: United States of America Other (select below)

Address - Line 1:

Address - Line 2:

City:

State, Province, or Territory:

Post Office or Zip Code:

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Screen View Report: 3.0 Submission Content

Enter your product for medical devices manufactured at this establishment.

Product Codes can be entered manually or selected using filters. Click the link for additional instructions on how to use the Product Code Filters. [Product Code Filter Guide](#)

Multiple Product Codes may be selected

0 items in the list

Product Code	Product Code Name	Device Class	Classification Panel	C.F.R. Section

Audit Type:

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Screen View Report: 3.1 Auditing Bodies

Select all that apply.

- Australia
- Canada
- European Union
- Japan

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Report Type: CDRH: ISO13485

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Screen View Report: Auditing Affiliations

Select an auditing body affiliated with Australia.

Identifier

Name

Select an auditing body affiliated with Canada.

Identifier

Name

Select an auditing body affiliated with the European Union.

Identifier

Name

Select an auditing body affiliated with Japan.

Identifier

Name

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Submission Name: ISO 13485 Submission
Report Type: CDRH: ISO13485

Last Modified: 09/05/2014 11:14:24 AM
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Screen View Report: 4.1 Most Recent Audit Report

All documentation and data entered in this section should be associated with the most recent audit date within 90 days of this submission.

Enter the most recent Audit date within 90 days of this submission. Please use the following format (MM/DD/YYYY)

Attach the original Audit Report.

Title	Name	Date	Size	Path
0 Items in the list				

Attach the original ISO 13485 certificate

File Attachment

Attach any associated correspondence for this Audit Report period.

Title	Name	Date	Size	Path
0 Items in the list				

Are all of the above original documents in English?

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Report Type: CDRH: ISO13485

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Screen View Report: 4.2 Preceding Audit Reports and Information

The following set of Audit Reports with a timeframe of 2 years, should precede the most recent Audit Report in Section 4.1.

Were Audits conducted in the previous 2 years from the last day of the most recent Audit?

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Submission Name: ISO 13485 Submission
Report Type: CDRH: ISO13485

Last Modified: 09/05/2014 11:14:24 AM
Date Packaged:

Screen View Previous Audit Reports: 1.0 Preceding Audit Reports and Information

The following set of Audit Reports with a timeframe of 2 years, should precede the most recent Audit Report in Section 4.1.

How many Audits were conducted in the previous 2 years from the last day of the most recent Audit?

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Last Modified: 09/05/2014 11:14:24 AM
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Screen View Previous Audit Reports: 1.1 First Preceding Audit Report

Enter relevant Audit Report Date. Please use the following date format MM/DD/YYYY

Attach your Previous Audit Reports

Title	Name	Date	Size	Path
0 items in the list				

If the ISO 13485 certificate is different for this Audit Report, please attach the relevant ISO 13485 certificate.

File Attachment

Attach any associated correspondence for this Audit Report

Title	Name	Date	Size	Path
0 items in the list				

Are all of the above original documents in English?

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Date Packaged:

Screen View Previous Audit Reports: Attestation

STOP Any submissions submitted after 90 days from the last day of the Audit will be rejected.

i To the best of my knowledge, the data and information submitted are truthful and accurate, and no material fact has been omitted.

Full Name

Date of Attestation. Please use the following format MM/DD/YYYY

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