Submission Report

Section: Report

Introduction

ISO 13485 Voluntary Audit Report Program

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 [web address]. 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/esg/.

Blue dots indicate required fields.

1.0 Inspection Date

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

Has an audit been performed in the last 90 calendar days?	*	Yes

2.0 Contact Information

Contact Information

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.

Definitions

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

2.1 Establishment Contact Information

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

Warning:	*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 Information:	
Contact Name	
Occupation Title	
Email Address	
Address	

Establishment Name	
Division Name	
Address	
Telephone Number	
FDA Establishment Identifier (FEI)	

Verify that your FEI and Facility Address are up to date. Any inconsistencies may cause the submission to be rejected. Establishment Registration & Device Listing

Please select the associated FDA District Office *	

2.2 Auditing Organization Contact Information

Please enter Auditing Organization contact information *	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Address	
Establishment Name	
Address	
Telephone Number	

Auditing Organization Members

Team Member Name	
Is this team member an employee or a contractor to the auditing organization?	

Team Member Name	
Is this team member an employee or a contractor to the auditing organization?	

Team Member Name	
Is this team member an employee or a contractor to the auditing organization?	

Team Member Name	
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Team Member Name	
Is this team member an employee or a contractor to the auditing organization?	

2.3 Applicant Contact Information

Information:	*Contact name should be the submitter of this submission.*

Please enter your contact information *	
Contact Information:	
Contact Name	
Occupation Title	
Email Address	
Address	
Establishment Name	
Address	
Telephone Number	

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 *				
Item	Product Code	Device Class	Classification Panel	C.F.R. Section

Audit Type *	

3.1 Auditing Bodies

Select all that apply.	*	[ ] Australia [ ] Canada [ ] European Union [ ] Japan

Auditing Affiliations

Select an auditing body affiliated with Australia.
Select an auditing body affiliated with Canada.
Select an auditing body affiliated with the European Union.
Select an auditing body affiliated with Japan.

4.0 Audit Reports

Information:	*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)). Section 228 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.*

4.1 Most Recent Audit Report

Information:	*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.	*	
Attach the original Audit Report.		*

Attach the original ISO 13485 certificate *	

Attach any associated correspondence for this Audit Report period. *	
Are all of the above original documents in English? *	

4.2 Preceding Audit Reports and Information

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? *	Yes

Section: Previous Audit Reports

1.0 Preceding Audit Reports and Information

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?	*	5

1.1 First Preceding Audit Report

Attach your Previous Audit Reports	*
If the ISO 13485 certificate is different for this Audit Report, please attach the relevant ISO 13485 certificate.	*
Attach any associated correspondence for this Audit Report.	*

Are all of the above original documents in English?	*	

1.2 Second Preceding Audit Report

Attach your Previous Audit Reports	*
If the ISO 13485 certificate is different for this Audit Report, please attach the relevant ISO 13485 certificate.	*
Attach any associated correspondence for this Audit Report.	*

Are all of the above original documents in English?	*	

1.3 Third Preceding Audit Report

Attach your Previous Audit Reports	*

If the ISO 13485 certificate is different for this Audit Report, please attach the relevant ISO 13485 certificate. *	
Attach any associated correspondence for this Audit Report period. *	
Are all of the above documents in English? *	

1.4 Fourth Preceding Audit Report

Attach your Previous Audit Reports. *	
If the ISO 13485 certificate is different for this Audit Report, please attach the relevant ISO 13485 certificate. *	
Attach any associated correspondence for this Audit Report period. *	
Are all of the above documents in English? *	

1.5 Fifth Preceding Audit Report documents

Attach your Previous Audit Reports *	
If the ISO 13485 certificate is different for this Audit Report, please attach the relevant ISO 13485 certificate. *	
Attach any associated correspondence for this Audit Report period. *	
Are all of the above documents in English? *	

Attestation

Stop:	*Any submissions submitted after 90 days from the last day of the Audit will be rejected.*
Information:	*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 *	