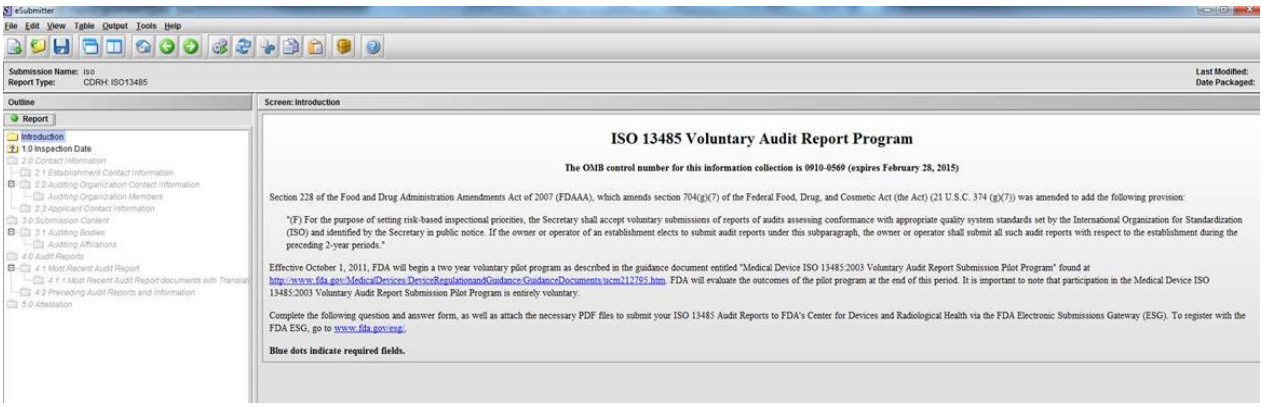
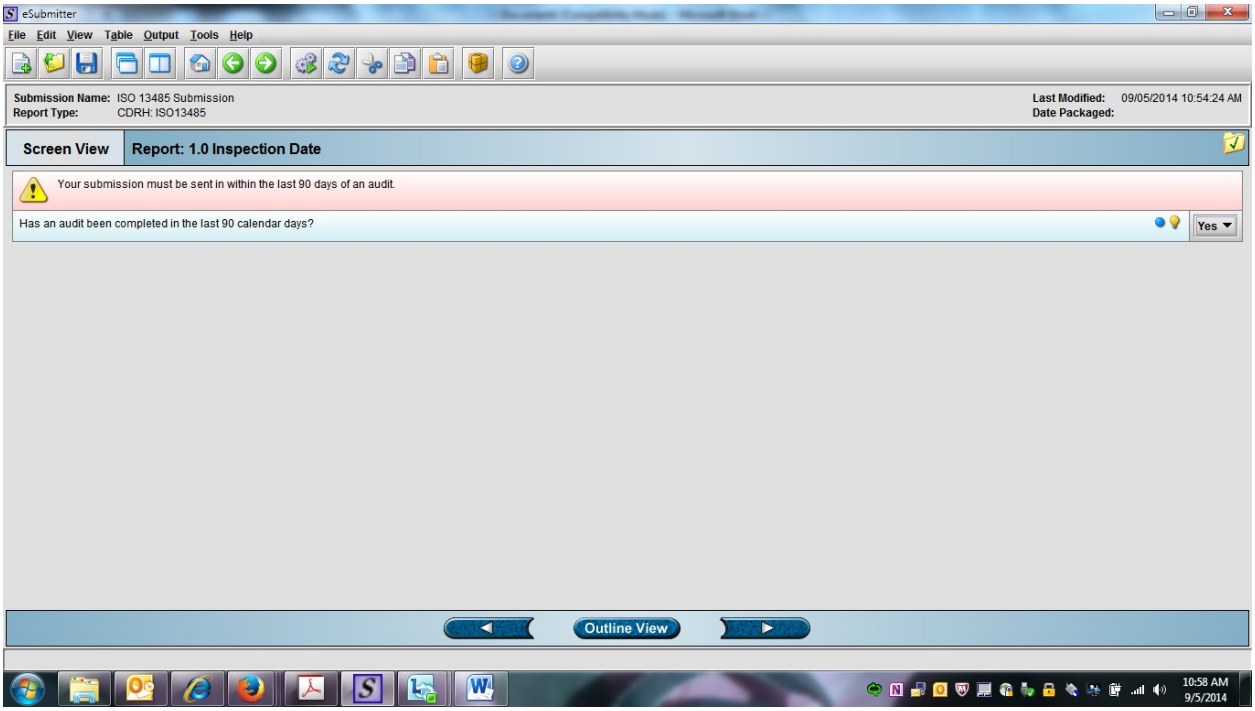

eSubmitter
File Edit View Table Output Tools Help
Submission Name: iso
Report Type: CDRH: ISO13485
Last Modified:
Date Packaged:
Outline
Report
Introduction
1.0 Inspection Date
2.0 Contact Information
2.1 Establishment Contact Information
2.2 Auditing Organization Contact Information
Auditing Organization Members
2.3 Applicant Contact Information
3.0 Submission Content
3.1 Auditing Bodies
Auditing Affiliations
4.0 Audit Reports
4.1 Most Recent Audit Report
4.1.1 Most Recent Audit Report documents with Translation
4.2 Preceding Audit Reports and Information
5.0 Attestation
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/ucm212795.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/esg/.
Blue dots indicate required fields.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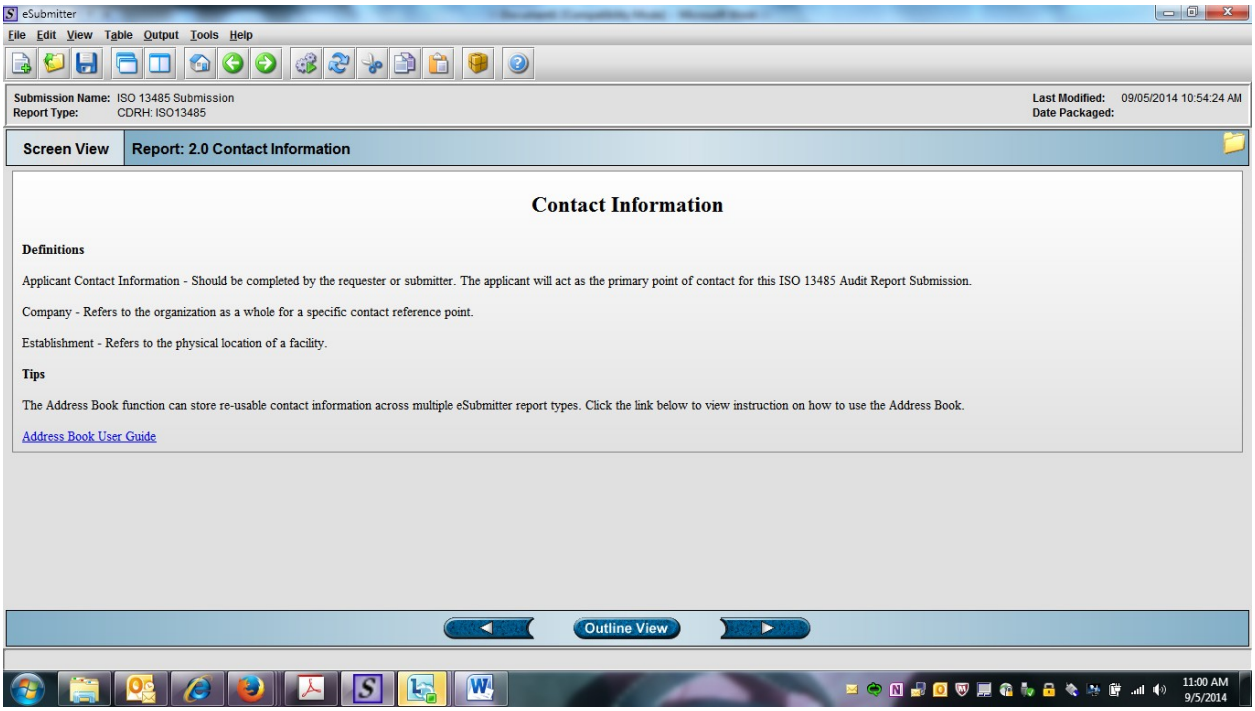
File Edit View Table Output Tools Help
Submission Name: ISO 13485 Submission
Report Type: CDRH: ISO13485
Last Modified: 09/05/2014 10:54:24 AM
Date Packaged:
Screen View
Report: 1.0 Inspection Date
Your submission must be sent in within the last 90 days of an audit.
Has an audit been completed in the last 90 calendar days?
Yes
Outline View
10:58 AM
9/5/2014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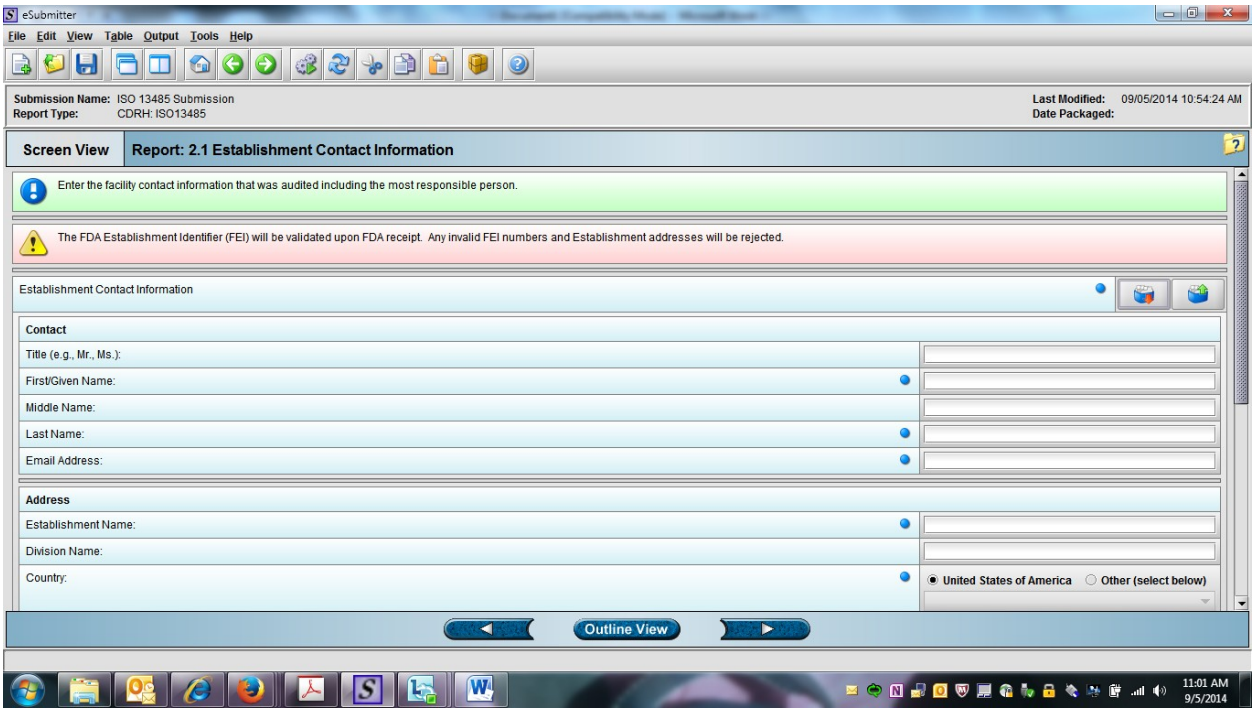
File Edit View Table Output Tools Help
Submission Name: ISO 13485 Submission
Report Type: CDRH: ISO13485
Last Modified: 09/05/2014 10:54:24 AM
Date Packaged:
Screen View
Report: 2.0 Contact Information
Contact Information
Definitions
Applicant Contact Information - Should be completed by the requester 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
Outline View
11:00 AM
9/5/2014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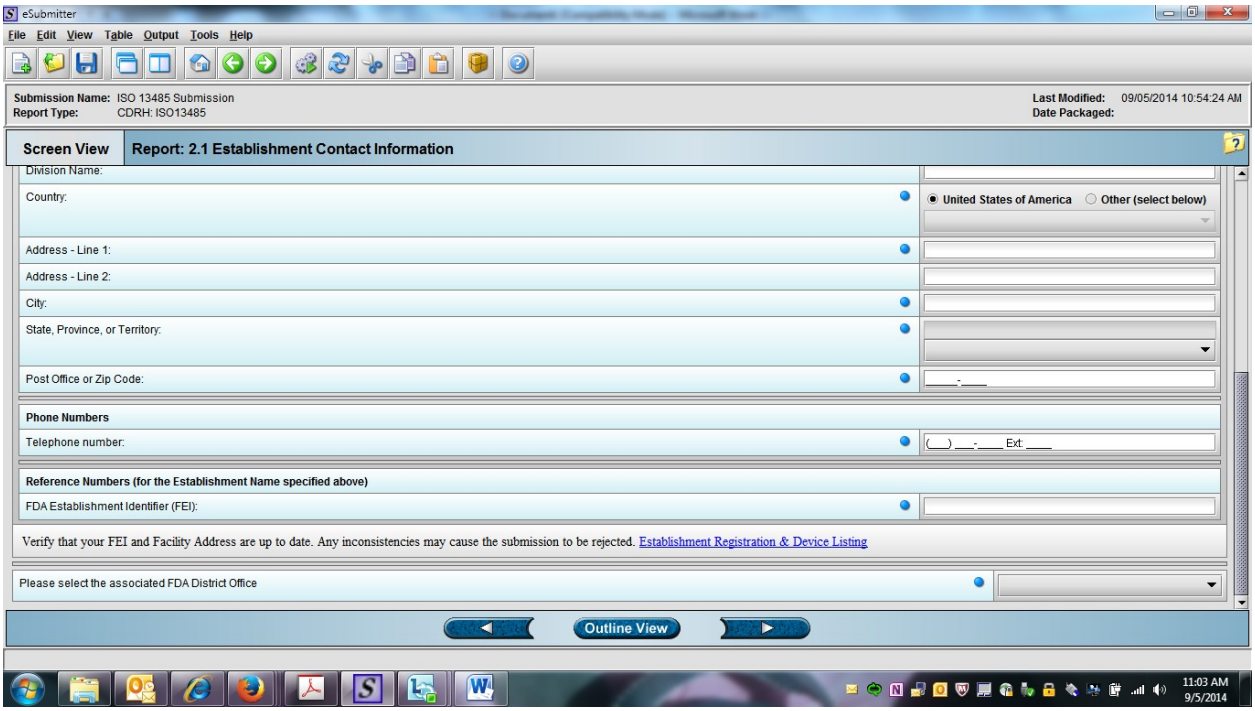
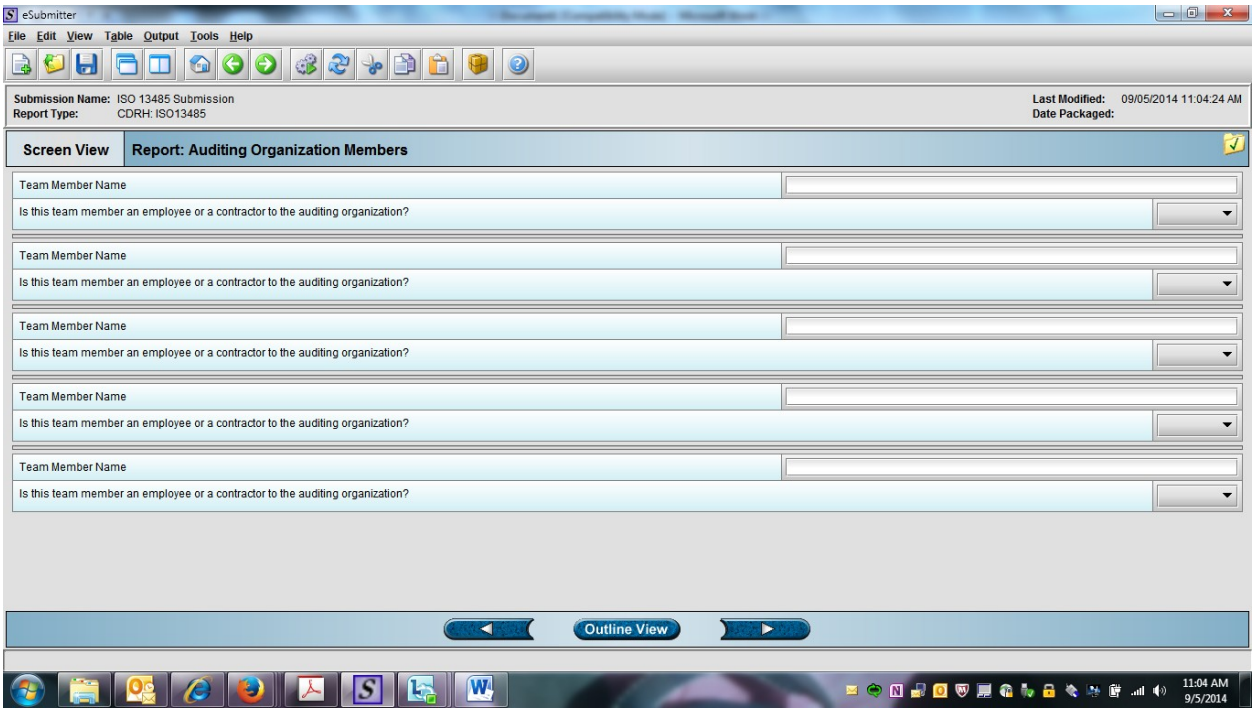
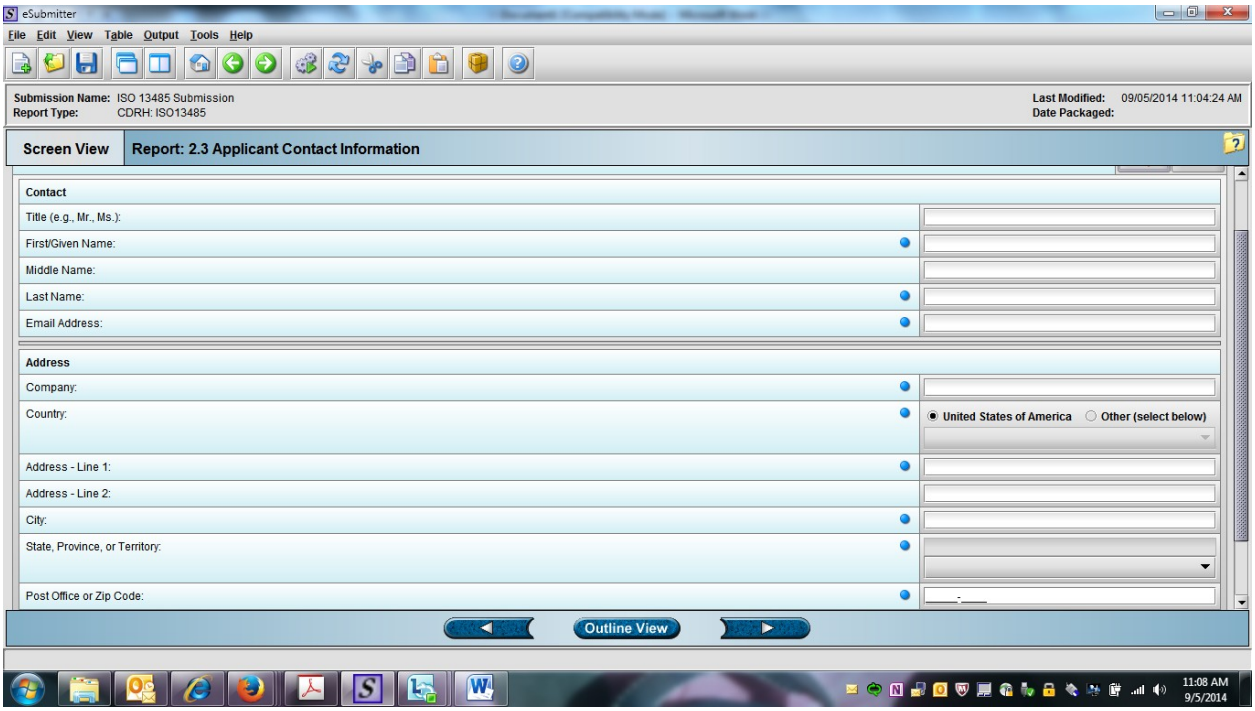
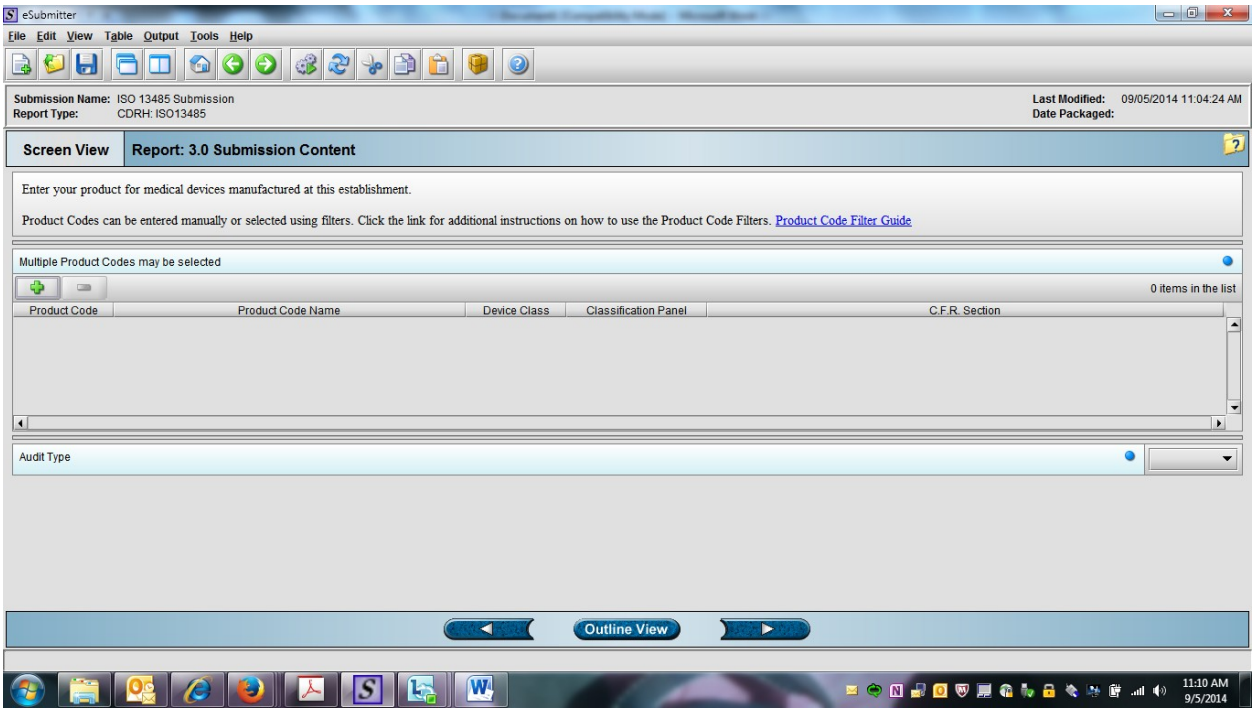
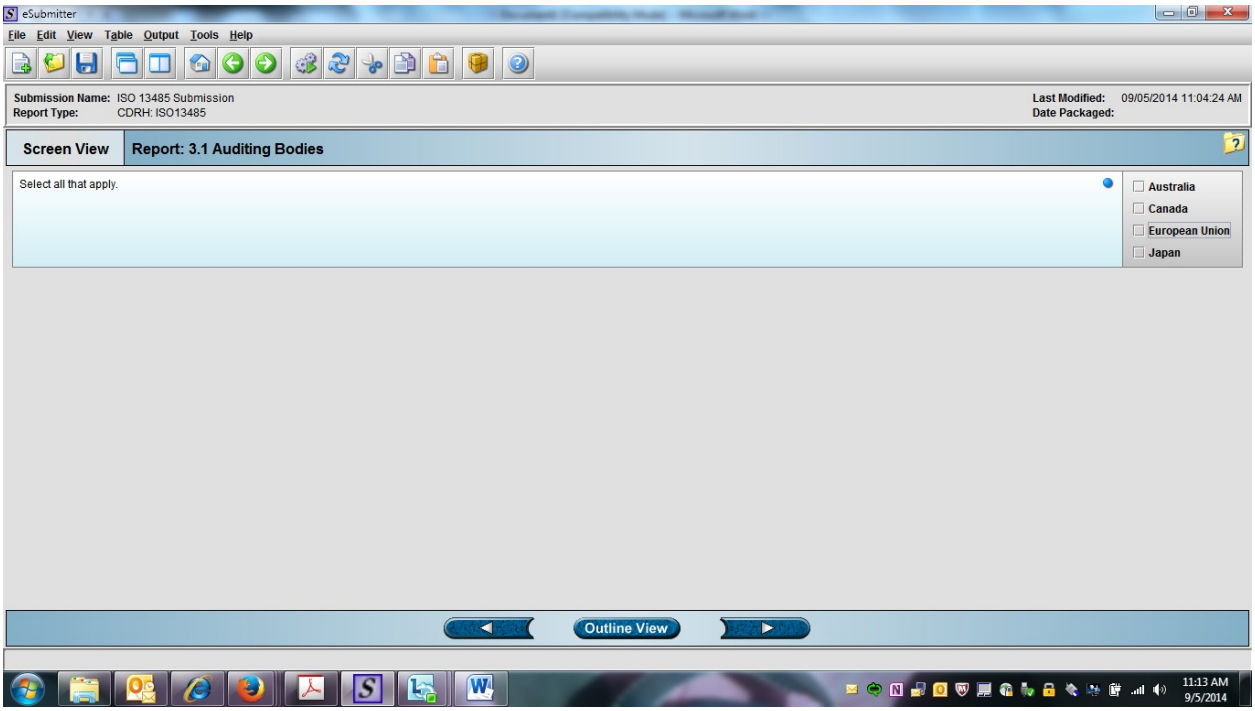
File Edit View Table Output Tools Help
Submission Name: ISO 13485 Submission
Report Type: CDRH: ISO13485
Last Modified: 09/05/2014 10:54:24 AM
Date Packaged:
Screen View
Report: 2.1 Establishment Contact Information
Enter the facility contact information that was audited including the most responsible 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)
Outline View
11:01 AM
9/5/2014

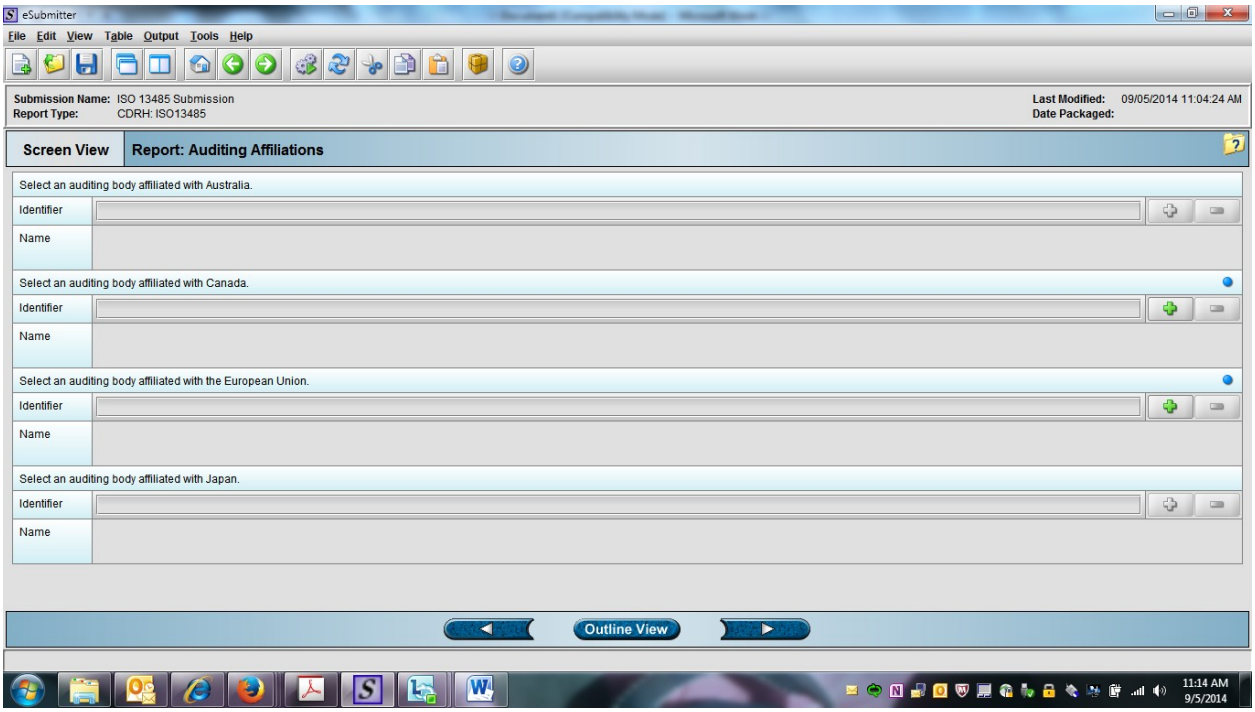

eSubmitter
File Edit View Table Output Tools Help
Submission Name: ISO 13485 Submission
Report Type: CDRH: ISO13485
Last Modified: 09/05/2014 10:54:24 AM
Date Packaged:
Screen View
Report: 2.1 Establishment Contact Information
Division Name:
Country:
United States of America
Other (select below)
Address - Line 1:
Address - Line 2:
City:
State, Province, or Territory:
Post Office or Zip Code:
Phone Numbers
Telephone number:
(___) ___-____ Ext: ____
Reference Numbers (for the Establishment Name specified above)
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
Outline View
11:03 AM
9/5/2014

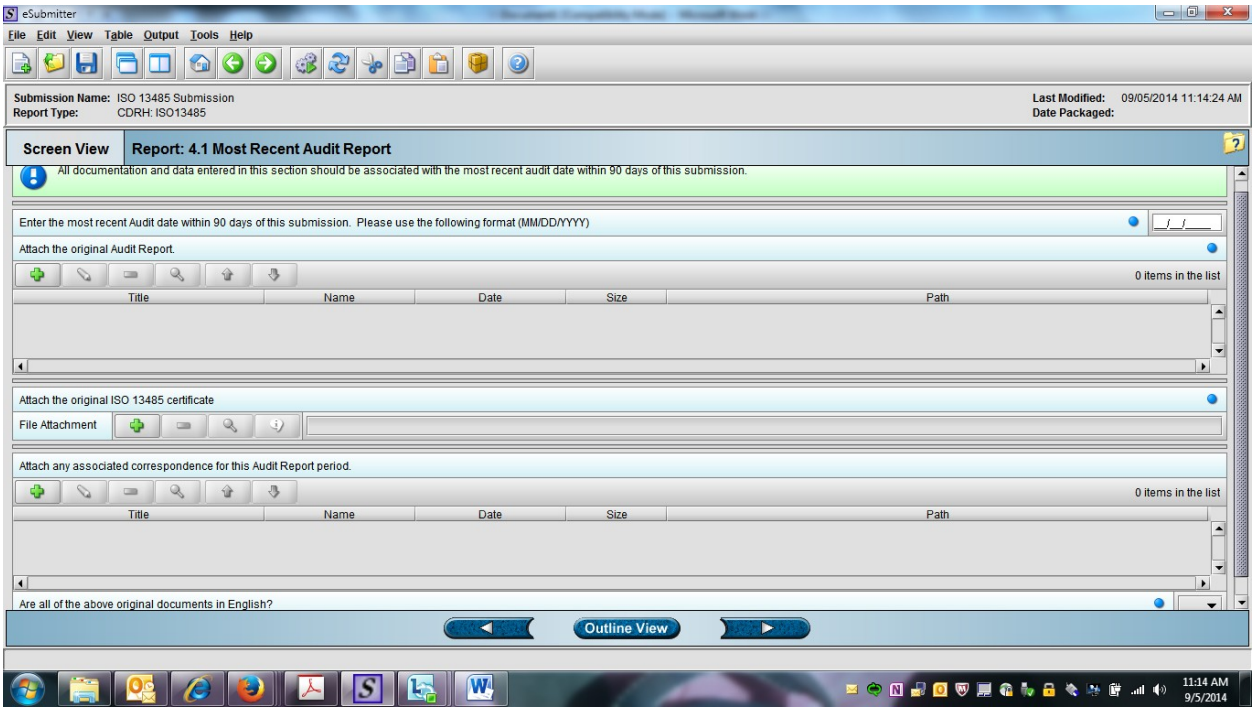

eSubmitter
File Edit View Table Output Tools Help
Submission Name: ISO 13485 Submission
Report Type: CDRH: ISO13485
Last Modified: 09/05/2014 11:04:24 AM
Date Packaged:
Screen View
Report: Auditing Organization Members
Team Member Name
Is this team member an employee or a contractor to the auditing organization?
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
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?
Outline View
11:04 AM
9/5/2014

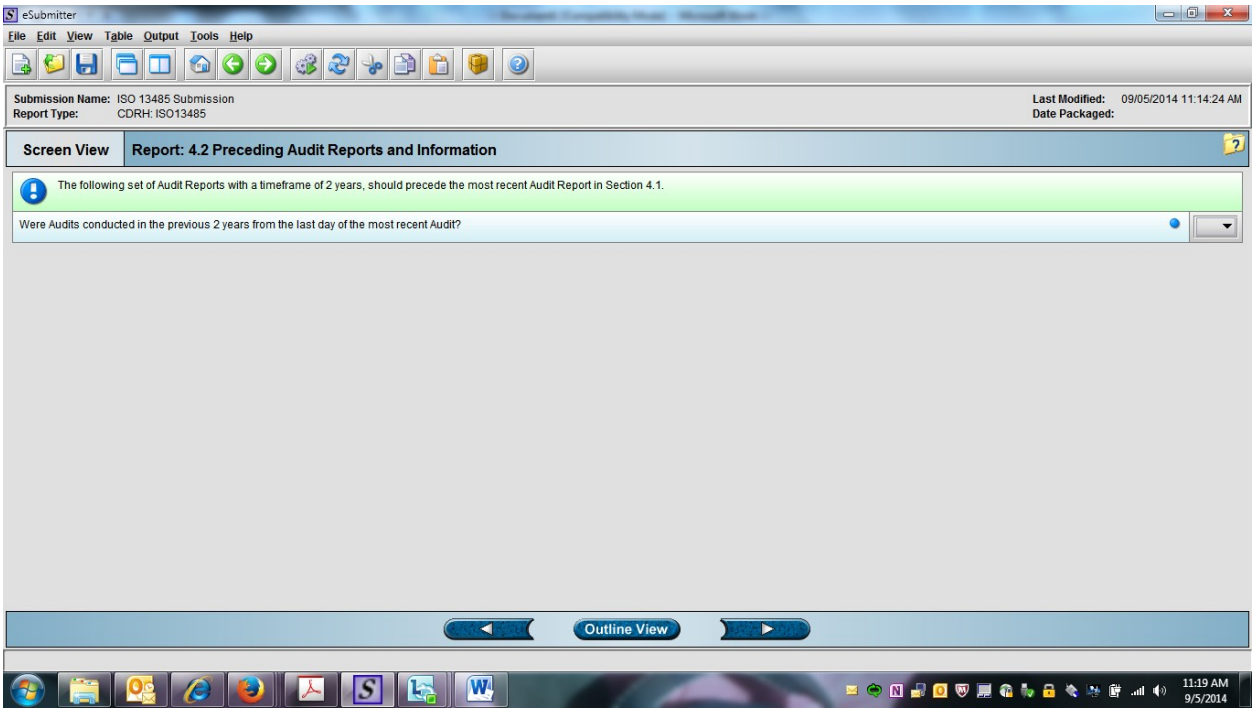

eSubmitter
File Edit View Table Output Tools Help
Submission Name: ISO 13485 Submission
Report Type: CDRH: ISO13485
Last Modified: 09/05/2014 11:04:24 AM
Date Packaged:
Screen View
Report: 2.3 Applicant Contact Information
Contact
Title (e.g., Mr., Ms.):
First/Given Name:
Middle Name:
Last Name:
Email 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:
Outline View
11:08 AM
9/5/2014

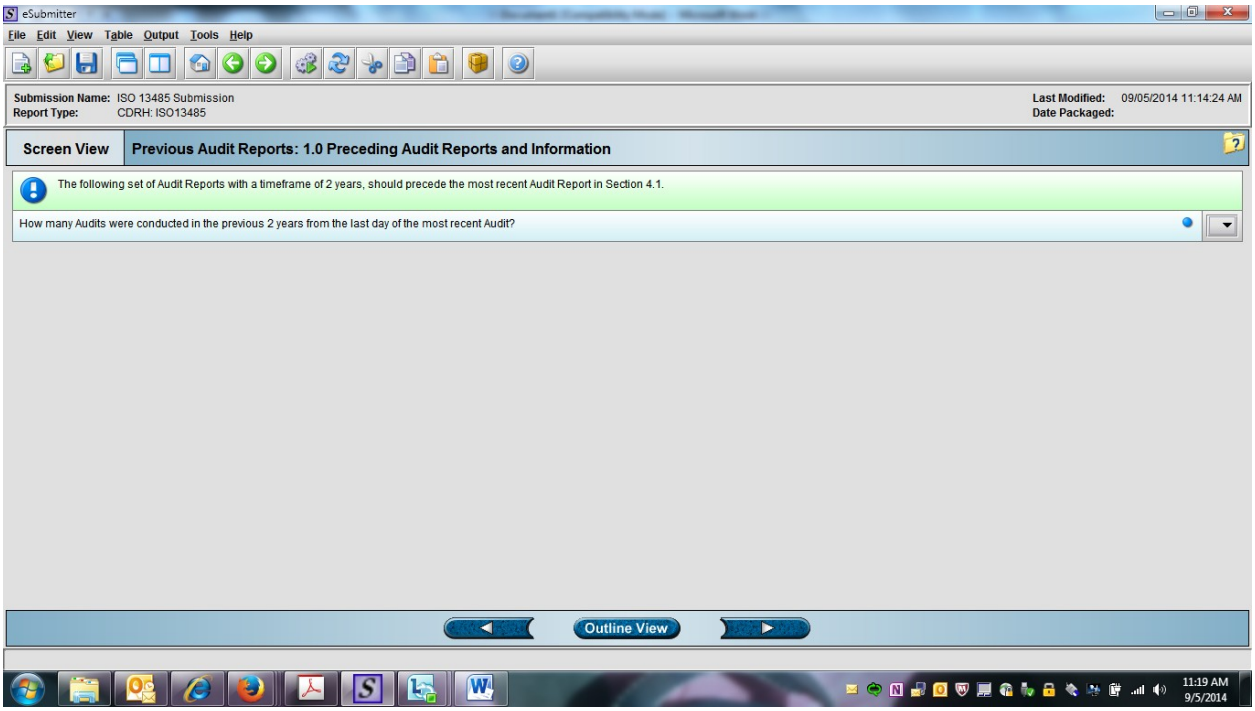

eSubmitter
File Edit View Table Output Tools Help
Submission Name: ISO 13485 Submission
Report Type: CDRH: ISO13485
Last Modified: 09/05/2014 11:04:24 AM
Date Packaged:
Screen View
Report: 3.0 Submission Content
Enter your product for medical devices manufactured at this establishment.
Product Codes 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
Outline View
11:10 AM
9/5/2014

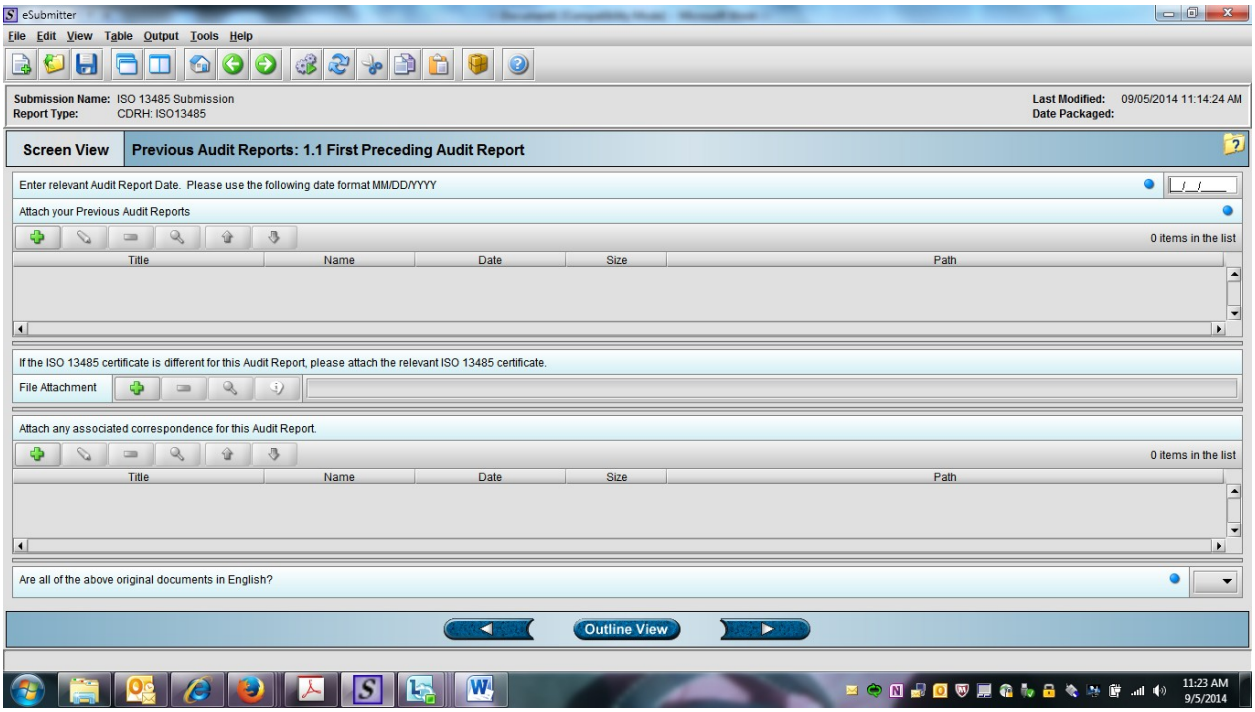

eSubmitter
File Edit View Table Output Tools Help
Submission Name: ISO 13485 Submission
Report Type: CDRH: ISO13485
Last Modified: 09/05/2014 11:04:24 AM
Date Packaged:
Screen View
Report: 3.1 Auditing Bodies
Select all that apply.
Australia
Canada
European Union
Japan
Outline View
11:13 AM
9/5/2014

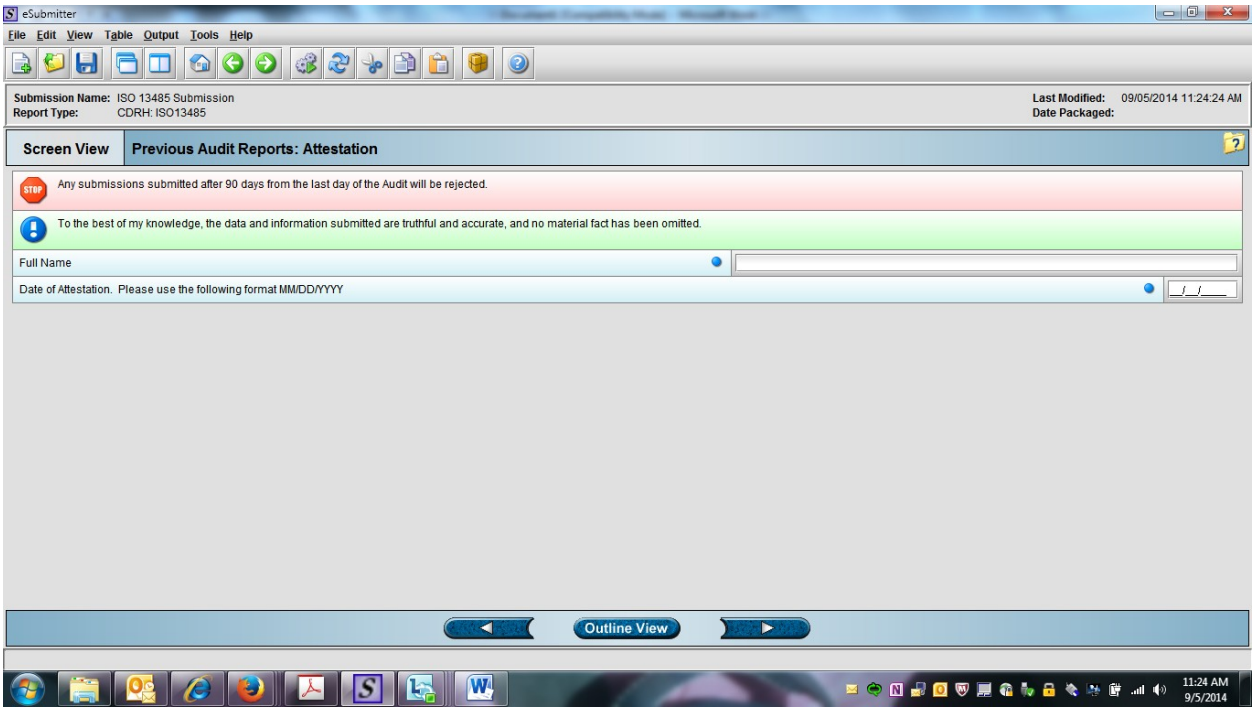

eSubmitter
File Edit View Table Output Tools Help
Submission Name: ISO 13485 Submission
Report Type: CDRH: ISO13485
Last Modified: 09/05/2014 11:04:24 AM
Date Packaged:
Screen View
Report: Auditing Affiliations
Select an auditing body affiliated with Australia.
Identifier
Name
Select an auditing body 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
Outline View
11:14 AM
9/5/2014


eSubmitter
File Edit View Table Output Tools Help
Submission Name: ISO 13485 Submission
Report Type: CDRH: ISO13485
Last Modified: 09/05/2014 11:14:24 AM
Date Packaged:
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.
0 items in the list
Title
Name
Date
Size
Path
Attach the original ISO 13485 certificate
File Attachment
Attach any associated correspondence for this Audit Report period.
0 items in the list
Title
Name
Date
Size
Path
Are all of the above original documents in English?
Outline View
11:14 AM
9/5/2014


eSubmitter
File Edit View Table Output Tools Help
Submission Name: ISO 13485 Submission
Report Type: CDRH: ISO13485
Last Modified: 09/05/2014 11:14:24 AM
Date Packaged:
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?
Outline View
11:19 AM
9/5/2014


eSubmitter
File Edit View Table Output Tools Help
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?
Outline View
11:19 AM
9/5/2014


eSubmitter
File Edit View Table Output Tools Help
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: 1.1 First Preceding Audit Report
Enter relevant Audit Report Date. Please use the following date format MM/DD/YYYY
Attach your Previous Audit Reports
0 items in the list
Title
Name
Date
Size
Path
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.
0 items in the list
Title
Name
Date
Size
Path
Are all of the above original documents in English?
Outline View
11:23 AM
9/5/2014


eSubmitter
File Edit View Table Output Tools Help
Submission Name: ISO 13485 Submission
Report Type: CDRH: ISO13485
Last Modified: 09/05/2014 11:24:24 AM
Date Packaged:
Screen View
Previous Audit Reports: Attestation
Any submissions submitted after 90 days from the last day of the Audit will be rejected.
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
__/__/____
Outline View
11:24 AM
9/5/2014