

 MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM Responsible Office/Division	Document No.: MDSAP AU WI0006.1.002	Page: 1 of 3
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WORK INSTRUCTIONS

Auditor Training

The purpose of this work instruction is to inform MDSAP-recognized auditing organizations and their auditors as to the method by which auditing organizations will submit the names of auditors to MDSAP for the creation of learner accounts and the method by which computer-based MDSAP training is accessed.

Training has been created regarding the MDSAP audit model. This training is required of each auditor who will be performing MDSAP audits. The training is computer-based and is located at <http://MDSAP.articulate-online.com>.

System Requirements

Software Operating System

Windows 2000, 2003, XP, Vista, Windows 7, Windows 8

Viewing Content

Flash Player 6.0.79 or later (<http://www.adobe.com/go/getflash>), and one of the following browsers:

Windows: Internet Explorer 6, Firefox 1, Google Chrome, Safari 3, Opera 9.5, Netscape 7, AOL 8, CompuServe 7

Mac: Safari 3 and later, Firefox 1.x and later, Google Chrome

Linux: Firefox 1, Opera 9.5, Konqueror 3.3.1

HTML5: Google Chrome 14 or later on Windows or Mac

Safari 5.1 or later on Windows or Mac

Mobile Safari on Apple iOS 5.0 or later on iPad (downloading of an app that will allow your iPad to view Flash content, such as iSwifter, Puffer, or Photon is required)

Creating Learner Accounts

Each auditor will require an account in Articulate Online to access the training. A request for an account should be sent to MDSAP.Training@fda.hhs.gov by the auditing organization. The request must contain the e-mail addresses of the auditors separated by commas. For example:

Jane.Doe@AO.com, Bob.Smith@AO.com, John.Public@AO.com.

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Within ten (10) business days of submitting the list of auditor e-mail addresses to MDSAP.Training@fda.hhs.gov, auditors will receive an e-mail notification such as:

Below is your login information for MDSAP Training. You can use this information to login to MDSAP Training and view content.
Account URL: <http://MDSAP.articulate-online.com>
E-mail Address: Jane.Doe@AO.com
Password: XYZ123

Accessing the Training

Learners will access the computer based training at <http://MDSAP.articulate-online.com> using the e-mail address and password provided. Successful completion of the MDSAP Training will be tracked by the participating regulatory authorities. It is important that the auditors access the training using their e-mail address and password.

After a learner logs on to <http://MDSAP.articulate-online.com> using the e-mail address and password provided, the following screen should display:

Welcome to MDSAP Training
Select the content you would like to view.

The required MDSAP training on the audit model is intended to be performed in the following order:

- (1) Introduction to MDSAP
- (2) MDSAP Management
- (3) MDSAP Device Marketing Authorization and Facility Registration
- (4) MDSAP Measurement, Analysis and Improvement
- (5) MDSAP Medical Device Adverse Events and Advisory Notices Reporting
- (6) MDSAP Design and Development
- (7) MDSAP Production and Service Controls, part 1
- (8) MDSAP Production and Service Controls, part 2
- (9) MDSAP Production and Service Controls, part 3
- (10) MDSAP Purchasing

Learners must score 70% or better on each of the Final Quizzes for successful completion of the training.

At the conclusion of each successfully completed Final Quiz, the learner should capture a copy of their training record using a screen-capture program such as Print Screen or Snagit.

In addition to the required training on the MDSAP audit model, there are additional training modules regarding topics such as the regulatory framework of

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the various regulatory authorities participating in the MDSAP, and country-specific pre-market and post-market information. These training modules are recommended, but not mandatory. Training modules that are not mandatory are identified in MDSAP.articulate-online as “Optional” or “Recommended”.

Accessibility for Learners with Disabilities

MDSAP training is available to learners who require electronic media that is accessible via assistive technology, such as screen readers. If a learner requires accessible content, a request for the accessible version should be sent to MDSAP.Training@fda.hhs.gov. The request must include the learner’s complete e-mail address. Within ten (10) business days, the accessible version will be e-mailed to the learner.

Changing e-mail or password

Learners can change their e-mail or password from the “Settings” button in MDSAP.articulate-online. Passwords can also be changed from the log-in screen.

In the event a learner has lost or forgotten their password, an e-mail should be sent to MDSAP.Training@fda.hhs.gov requesting that the password be reset, accompanied by the learner’s e-mail address. Within ten (10) business days, an e-mail will be sent to the learner with their new password.

Technical Difficulties

Learners may occasionally encounter technical issues such as dropped audio or program “freezing”. If these issues do not resolve, close the Articulate Online session and close the web browser. In some cases, the technical issue will resolve if the learner re-opens Articulate Online using a different web browser. For example, if a learner experiences dropped audio when accessing a particular training course using Internet Explorer, close the Articulate Online program and Internet Explorer, then re-open Articulate Online using Firefox or Google Chrome.

Questions

Questions regarding accessing the training may be sent to MDSAP.Training@fda.hhs.gov. A response will be sent within ten (10) business days.