

FDA Invites Industry to Participate in Medical Device Single Audit Program (MDSAP) and Announces New MDSAP Educational Modules

The Food and Drug Administration (FDA) joins the [Medical Device Single Audit Program’s Regulatory Authority Council](#) in encouraging medical device manufacturers to participate in the Medical Device Single Audit Program (MDSAP) Pilot. The Medical Device Single Audit Program is expected to begin transition to full implementation on January 1, 2017.

What is Medical Device Single Audit Program (MDSAP)?

As envisioned by the [International Medical Device Regulators Forum \(IMDRF\)](#), the FDA developed MDSAP in collaboration with regulatory authorities from Australia, Brazil, Canada, and Japan. IMDRF recognizes that a global approach to auditing and monitoring the manufacturing of medical devices could improve their safety and oversight on an international scale.

MDSAP enables medical device manufacturers to contract with an MDSAP-authorized Auditing Organization (AO) to conduct a single audit against the relevant medical device regulatory requirements of all fully participating regulatory authorities. For more information about the Medical Device Single Audit Program, please visit the [FDA MDSAP Pilot Webpage](#).

In an effort to help inform the medical device manufacturing community about MDSAP, the FDA posted ten new medical device education modules to the [CDRH Learn](#) Program website.

What is CDRH Learn?

CDRH Learn is a multimedia catalog of online educational modules intended to provide information about medical device laws, regulations, and policies that is comprehensive, interactive, and easily accessible. The format for each topic is chosen to present the information in the most effective way possible.

New MDSAP Modules

Ten new modules can be found in the “Postmarket Activities” section of CDRH Learn.

CDRH Learn Module Title	Key Learning Objective(s)
1. Introduction to MDSAP	<ul style="list-style-type: none"> • Understand the purpose of the MDSAP program. • Learn about the MDSAP audit model, sequence and process. • Understand the requirements for writing nonconformity statements and the final report.
2. MDSAP Management	<ul style="list-style-type: none"> • Understand the purpose, audit tasks, expected audit outcomes and assessment of conformity for management. • Learn about the links to other MDSAP processes. • Recognize country specific requirements for management.
3. MDSAP Device Marketing Authorization and Facility	<ul style="list-style-type: none"> • Understand the purpose, audit tasks, expected audit outcomes for device marketing authorization and facility registration and links

Registration	<p>to other MDSAP processes.</p> <ul style="list-style-type: none"> • Recognize country specific requirements. • Learn the assessment of conformity for the audit tasks.
4. MDSAP Measurement, Analysis and Improvement	<ul style="list-style-type: none"> • Understand the purpose, audit tasks, expected audit outcomes and assessment of conformity for Measurement, Analysis and Improvement. • Learn about the links to other MDSAP processes. • Recognize country specific requirements.
5. MDSAP Medical Device Adverse Events and Advisory Notices Reporting	<ul style="list-style-type: none"> • Understand the purpose, audit tasks and expected outcomes and links for Adverse Events and Advisory Notices Reporting. • Recognize country specific requirements. • Learn the assessment of conformity for the audit tasks
6. MDSAP Design and Development	<ul style="list-style-type: none"> • Understand the purpose and expected audit outcomes for the Design and Development process and the links to other MDSAP processes. • Learn the audit tasks and the assessment of conformity for the audit tasks. • Recognize country specific requirements.
7. MDSAP Production and Service Controls, part 1	<ul style="list-style-type: none"> • Understand the purpose of the Production and Service Control process. • Know the expected outcomes from the audit of the Production and Service Controls process. • Learn the audit tasks and links to other MDSAP processes. • Recognize country specific requirements for Production and Service Controls. • Review the assessment of conformity for the audit tasks.
8. MDSAP Production and Service Controls, part 2	
9. MDSAP Production and Service Controls, part 3	
10. MDSAP Purchasing	<ul style="list-style-type: none"> • Understand the purpose, audit tasks, expected audit outcomes and conformity assessment for purchasing. • Learn about the links to other MDSAP processes. • Recognize country specific requirements for purchasing.

Disclaimer

These CDRH Learn Modules are available for informational purposes only. They are not intended for use by auditing organizations or as official MDSAP auditor training or as part of the MDSAP assessment criteria.

For More Information about Medical Devices

If you have any questions about CDRH Learn, or medical devices in general, contact the Division of Industry and Consumer Education (DICE):

- Phone: (800) 638-2041 or 301-796-7100; 9 am - 4:30 pm Eastern Time
- Email: DICE@fda.hhs.gov

Please visit us at [our website](#) for more information about how we may help you.

Thank You,

Food and Drug Administration
Center for Device and Radiological Health