Overview of the MDSAP

An excerpt from Compliance Navigator's MDSAP guidance
The Medical Device Single Audit Program (MDSAP) was developed by the International Medical Device Regulators Forum (IMDRF) to conduct regulatory audits of the quality management systems (QMS) used by manufacturers of medical devices.

The MDSAP audit is based on BS EN ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes with the applicable regulatory requirements of the participating jurisdictions - Australia, Brazil, Canada, Japan and the USA – included as areas of focus. The MDSAP Companion Document (2017) originally identified the audit tasks that have to be covered and the links to the applicable regulatory requirements for participating jurisdictions. In September 2020, the Companion Document was combined with the description of the MDSAP audit approach into a single document. This updated, combined MDSAP Audit Approach document did not make fundamental changes to the audit process. The updated document does, however, provide clarification on some of the audit tasks, particularly in relation to some of the regulatory requirements from MDSAP-participating jurisdictions. The training material for MDSAP audits is available on the US Food and Drug Administration (FDA) website under CDRH (Center for Devices and Radiological Health) Learn (click on the ‘Postmarket Activities’ drop-down menu, then scroll down to the Inspections - Global Harmonization subheading). MDSAP documents are also publicly available.
Audits conducted to the MDSAP follow a closely prescribed process of defined tasks. An MDSAP audit uses a process approach, based on a foundation of risk management, to select samples of procedures and records to examine. The audit process is described in the MDSAP Audit Approach. The audit focus is on how risks are identified and addressed. This is investigated using four primary processes and three supporting processes, in the following sequence:

1. Management is the first primary process to be examined, to assess the commitment of the organization’s top management to planning and implementing the QMS;
   • The supporting process of Device marketing authorization and facility registration examines the maintenance of the necessary approvals, clearances and registrations. The relationship between the organization and the entity acting on its behalf in each jurisdiction is reviewed;

2. Measurement, analysis and improvement is the next primary process, in which the processes for preventing and correcting nonconformities are assessed. Processes associated with nonconformance events are highlighted for further evaluation;
   • The supporting process of Medical device adverse events and advisory notices reporting is considered;

3. The primary process for Design and development is then examined, focusing on recently introduced or changed devices and devices associated with nonconformance events. The application of risk management and the transfer of the output of design and development into production are areas of focus;

4. Production and service controls is the final primary process to be reviewed, looking at how controls on production are planned and implemented;
   • The Purchasing supporting process supports all the primary processes and focuses on examples of the purchase of both goods and services identified as associated with highest risk activities, new product introductions or design changes. This also includes review of the adequacy of controls on processes outsourced to external parties.

There is a set formula to calculate the time allotted for an audit, based on the number of processes that are carried out.

Nonconformities are classified with a numerical classification from 1 to 5 using the grading system developed by the Global Harmonization Task Force (GHTF).
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