

Introduction to the MDSAP

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In this training module, an Introduction to the Medical Device Single Audit (MDSAP) will be provided including an explanation and examples of the MDSAP audit approach and audit sequence

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In order to participate in the MDSAP, individual auditors must: be affiliated with an MDSAP-recognized auditing organization or be employed by one of the MDSAP participating regulatory authorities; demonstrate competence or be proficient in auditing to the International Organization for Standardization (ISO) 13485:2016: Medical devices — Quality management systems – Requirements for regulatory purposes document, (here in referred to as ISO 13485:2016); be familiar with or demonstrate knowledge of the specific regulatory requirements of the participating regulatory authorities; and successfully complete the MDSAP training program.

It is expected that the auditor is proficient in auditing to ISO 13485:2016 and is familiar with the specific requirements of the regulatory authorities participating in the Medical Device Single Audit Program or the MDSAP.

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In this training module, the learning objectives are to: give an overview of the MDSAP training; describe the MDSAP program; review the MDSAP Audit Approach; explain the sequence and planning of MDSAP audits; and explain how surveillance audits are planned and performed.

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We will begin with providing an overview of the MDSAP training.

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For simplicity and completeness, MDSAP training will primarily focus on the assessment of the organization's entire quality management system and additional country-specific requirements as required by the Medical Device Single Audit Program.

This type of complete assessment is described as a "certification" audit in ISO/IEC 17021-1:2015 Conformity assessment - Requirements for bodies providing audit and certification of management systems.

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The MDSAP training program is composed of the following modules: Introduction to the MDSAP, the current module; Overview of the MDSAP Process; Management Process; Measurement, Analysis and Improvement; Design and Development Process

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Production and Service Controls Process, Parts 1-3; Purchasing Process; Device Marketing Authorizations and Facility Registration; and Medical Device Adverse Events and Advisory Notices Reporting Process.

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Let's Describe the MDSAP.

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MDSAP is the acronym for Medical Device Single Audit Program (MDSAP). It is a regulatory audit program that was initially jointly developed by four jurisdictions.

MDSAP is unique because it allows a medical device manufacturer to have a single quality management system audit to satisfy the core requirements of all participating regulatory authorities. The MDSAP is also different from other harmonized programs in that it only requires a single audit report used by all participating jurisdictions.

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The current participating regulatory authorities (RAs) are Australia's Therapeutic Goods Administration, Brazil's Agencia Nacional de Vigilancia Sanitaria, Health Canada, Japan's Ministry of Health, Labour, and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA), and the United States Food and Drug Administration.

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As currently implemented, MDSAP allows any medical device manufacturer to contract with an MDSAP recognized Auditing Organization to have a single regulatory quality management system audit that meets the core requirements of all five Regulatory Authorities.

Each country defines how MDSAP outcomes are used within its jurisdiction in accordance with its legislation and regulatory framework. FDA's authorities set forth other applicable FDA device regulatory requirements, and the MDSAP program informs FDA's risk based approach to inspections.

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The Medical Device Single Audit Program was developed to jointly leverage regulatory resources to manage an efficient, effective, and sustainable single audit program focused on the oversight of medical device manufacturers' quality management systems.

The overall goal is to create an international coalition of countries dedicated to pooling technology, resources, and services to improve the safety and oversight of medical devices in a more efficient manner that is also less burdensome for industry. For example, rather than a manufacturer receiving five separate audits from Australia, Brazil, Canada, and the United States, the Medical Device Single Audit program allows a manufacturer to have one audit, performed by an MDSAP- recognized Auditing Organization, that satisfies the surveillance needs of all five regulatory authorities. This saves time and resources for both the manufacturer and the Regulatory Authorities.

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In developing the Medical Device Single Audit Program, the primary objectives were to operate a single audit program that provides confidence in program outcomes to enable the appropriate regulatory oversight of medical device manufacturers' quality management systems while minimizing regulatory burden on industry.

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Additional objectives are to promote more efficient and flexible use of regulatory resources through work-sharing and mutual acceptance among regulators while respecting the independence of each

authority, and to promote, in the longer term, greater alignment of regulatory approaches and technical requirements globally based on international standards and best practices.

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Let's discuss the MDSAP Audit Approach.

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The MDSAP Audit Approach has a total of seven processes, arranged in a set sequence, and built on a foundation of risk management. Each process is designed to address a set of related quality management system and other regulatory requirements comprehensively and logically.

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Let's take a closer look at the MDSAP audit sequence and the audit planning.

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The MDSAP audit sequence follows a process approach and has four primary processes - Management process, Measurement, Analysis and Improvement process, Design and Development process and a Production and Service Controls process with links to the supporting process for Purchasing.

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The MDSAP audit process has two additional supporting processes: Medical Device Adverse Events and Advisory Notices Reporting; and Device Marketing Authorization and Facility Registration. These processes are necessary to fulfill specific requirements of the participating MDSAP regulatory authorities that are not addressed elsewhere in MDSAP processes.

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The five MDSAP audit sequence processes, Management, Measurement, Analysis and Improvement, Design and Development, Production and Service Controls, and Purchasing are built on a foundation of requirements for risk management and comprise the requirements of a quality management system for medical device manufacturers according to: ISO 13485:2016 - Medical devices - Quality management systems - Requirements for regulatory purposes; the Quality Management System requirements of the Conformity Assessment Procedures of the Australian Therapeutic Goods (Medical Devices) Regulations (TG(MD)R Sch3), Brazilian Good Manufacturing Practices (RDC ANVISA 665/2022), Japan Ordinance on Standards for Manufacturing Control and Quality Control of Medical Devices and In Vitro Diagnostic Reagents (MHLW Ministerial Ordinance No. 169), and the Quality Management System Regulation (21 CFR Part 820).

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The MDSAP Audit Approach was designed for the audit of the MDSAP processes in the following sequence: first, Management, then Measurement, Analysis and Improvement, followed by Design and Development, and finally Production and Service Controls.

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The Purchasing process can be audited as a supporting process to the Measurement, Analysis and Improvement process, the Design and Development process, or the Production and Service Controls process, depending on the audit evidence uncovered.

The Device Marketing Authorization and Facility Registration process is audited as a linkage to the Management process and from the Design and Development processes as needed.

The Medical Device Adverse Events and Advisory Notices Reporting process is audited as a linkage to the Measurement, Analysis and Improvement process since the input to this supporting process is normally captured by the Measurement, Analysis and Improvement process.

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The MDSAP audit sequence was designed and developed to allow for the audit to be conducted in a logical, focused, and efficient manner. Information learned during the audit of one process will be used to make decisions about what to select for audit during the next process.

The MDSAP audit sequence is designed to not only manage the flow of audit activities, but to also manage the flow of information between audit activities in order to maximize audit effectiveness.

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By using information learned during the audit of one process to make decisions as to what to select for audit in the next process, the audit team will be able to better assess the inter-relationship of processes and nonconformities and avoid following unproductive audit trails while focusing on higher-risk areas.

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When applicable, information regarding device or identified quality management system nonconformities observed during the audit of the Measurement, Analysis and Improvement process should be used to make decisions as to design projects or design changes to assess during audit of the Design and Development process, suppliers to evaluate during audit of the Purchasing process, and processes to review during audit of the Production and Service Controls process.

Let's discuss some examples of what we mean by interrelationship of processes and nonconformities. If during the audit of the Measurement, Analysis and Improvement process, a change was made to the design of a device to remedy nonconformities, consider selecting that design change for review during audit of the Design and Development process. If complaints were noted by the auditors during the audit of the Measurement, Analysis and Improvement process and the investigations of those complaints revealed quality problems with supplied product or services, consider selecting those supplier files for review during your audit of the Purchasing process. Likewise, if nonconformities were identified that were shown to be the result of a process problem, considering selecting that process for review during audit of Production and Service Controls.

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If the audit of the Measurement, Analysis and Improvement process reveals quality problems that have arisen that were found to be design-related, those designs, including design changes, should be considered when making decisions as to the design and development projects to be reviewed. The audit of this process, the Design and Development process, follows the audit of the Measurement Analysis and Improvement process per the MDSAP audit sequence.

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Audit of the Production and Service Controls process will follow audit of the Measurement, Analysis and Improvement process and the Design and Development process per the MDSAP audit sequence. Information the audit team has learned about device and quality management system nonconformities

during audit of the Measurement, Analysis and Improvement process, as well as higher risk elements and essential design outputs from the design projects reviewed during audit of the Design and Development process, should be used to make decisions as to the production processes to be reviewed during the audit of the Production and Service Controls process.

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Many auditors may not be accustomed to performing an audit in such a prescribed manner. The question inevitably comes up whether utilizing the MDSAP audit sequence will still allow the lead auditor to provide the organization with an audit plan, as described in ISO/IEC 17021-1:2015. The answer is yes. The audit plan will still contain the audit scope, objectives, roles and responsibilities of the audit team members, allocation of appropriate resources to the audit, and other information. The audit activities will follow the MDSAP audit sequence, and the audit plan will transpose the MDSAP audit sequence to the physical locations or areas of the manufacturer.

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Let's review an example of an audit to be conducted by one auditor over four days. For this scenario, a sample audit plan might look something like the plan on this slide and the next two slides. Please note that this example is simplified, it does not include all the information required by ISO 17021-1:2015.

The audit starts as normal with the opening meeting, followed by a plant/facility tour. The Management process is the first process to be audited. According to the MDSAP audit sequence, the Device Marketing Authorization and Facility Registration may be initially reviewed. A Daily Wrap-up is conducted at the end of the day.

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For day two, the Measurement, Analysis and Improvement process is the next primary process to be audited. According to the MDSAP audit sequence, the Medical Device Adverse Events and Advisory Notice Reporting process is audited as a linkage from the Measurement, Analysis and Improvement process. The day ends with the daily Wrap-up being conducted.

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On day three, Design and Development process is audited, followed by audit of the Purchasing process. Purchasing may be audited as a linkage from Measurement, Analysis and Improvement, Design and Development, and Production and Service Controls. A Daily Wrap-up is again conducted.

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On the last day, Day 4, Production and Service Controls is audited, followed by writing of nonconformities and conducting the closing meeting.

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Let's review an example of an audit being conducted by two auditors over two days. Again, this is a simplified version of an audit plan.

The audit starts as it normally would: an opening meeting, followed by a plant/facility tour. The first process to be audited per the MDSAP audit sequence is Management. Since the initial review of Device Marketing Authorization and Facility Registration may be performed as a linkage from the Management process, the second auditor can be addressing the audit tasks in the Device Marketing Authorization and

Facility Registration process while the first auditor is addressing the audit tasks in the Management process.

The Measurement, Analysis and Improvement process is the second process to be audited per the MDSAP audit sequence. Since the Medical Device Adverse Events and Advisory Notice Reporting process may be audited as linkage from the Measurement, Analysis and Improvement process, the second auditor can be completing the tasks in the Medical Device Adverse Events and Advisory Notice Reporting process while the first auditor completes the audit tasks in the Measurement, Analysis and Improvement process. Day 1 concludes with a Daily Wrap-up.

It is essential to maintain communication between the members of the audit team when auditing linked processes. For example, if the first auditor notes several complaints that appear to be reportable events, the second auditor should be made aware of these in order to confirm that the appropriate reports were filed for those complaints with the applicable regulatory authority.

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Day two of the two auditor, two-day audit starts with one auditor reviewing Design and Development, while the second auditor is reviewing Purchasing.

Since there are quite a few audit tasks in the Production and Service Controls process, in our example, both auditors are covering the audit tasks.

The audit will conclude with the audit team meeting, including writing the nonconformities, followed by the closing meeting with the organization's management.

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The MDSAP audit cycle consists of a three-year cycle as described in ISO/IEC 17021-1:2015. The cycle is: A full or 'certification' audit initially, a partial or surveillance audit the following two years, and a full 're-certification' or 're-audit' in the third year.

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Finally, let's explain how surveillance audits are planned and performed.

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Surveillance audits are not complete audits and do not cover all the MDSAP processes.

Surveillance audits have a number of fixed tasks to be covered as well as a variable component dictated by the circumstances of the audit.

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All surveillance audits must cover at least the following: a review of changes to the manufacturer, QMS, or products since the last audit, and the items described in MDSAP AU P0008: Audit Time Determination Procedure, Appendix 1.

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When the audit evidence collected during the fixed tasks indicates existing or potential nonconformity, the auditor follows audit trails into the Design and Development Process and the Production and Service Controls Process as appropriate. Audit tasks should be completed as applicable to the audit trails.

For example, if a review of complaints shows a trend with packaging failures for a sterile device, the auditor could audit the design and development process to see what risks and parameters were considered for the packaging. This could be followed by auditing the process validation and monitoring of sealing and handling activities. The auditor might also need to audit the purchasing process if there is an indication that purchased packaging material is nonconforming.

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If the audit evidence collected during the fixed tasks does not indicate particular audit trails to follow, the auditor will complete either the Design and Development Process or the Production and Service Controls Process.

So, if in the first surveillance year there were no particular trails to follow and the auditor audited the Design and Development process, the following surveillance audit should focus on the Production and Service Controls process to ensure complete coverage.

The Purchasing process can be audited as needed at any point during a surveillance audit.

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This slide and the next several slides in this presentation contain references to the standards and regulations.

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The MDSAP global website contains all the procedures and forms that Auditing Organizations will utilize regarding the MDSAP. This slide lists some of the most frequently used forms and procedures for audit time calculation, the non-conformity grading and exchange form, and the MDSAP fillable audit report form.

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This slide lists References for regulatory requirements for Australia and Brazil.

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This slides lists References for regulatory requirements for Canada and Japan.

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The next two slides contain a table that list some of the regulatory requirements for U.S. FDA and links to those requirements as resources for implementing the QMSR.

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Here are a few more listings that will provide greater details and the specific requirements for the U.S. FDA.

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In summary, MDSAP training focuses on the assessment of the organization's entire quality management system and the assessment of additional participating country-specific requirements. MDSAP Audits allows a medical device manufacturer to have a single quality management system audit. MDSAP Audit approach has a total of seven processes arranged in a set sequence. MDSAP audits have a number of fixed tasks to be covered.

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Thank you for your attention to this module "Introduction to the MDSAP".
