Medical Device Single Audit Program

Frequently Asked Questions

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A. General Questions about MDSAP

1. What is the Medical Device Single Audit Program?

The Medical Device Single Audit Program (MDSAP) is a program that allows the conduct of a single regulatory audit of a medical device manufacturer's quality management system that satisfies the requirements of multiple regulatory jurisdictions. Audits are conducted by Auditing Organizations authorized and recognized by the participating Regulatory Authorities to audit under MDSAP requirements.

The MDSAP is a way that medical device manufacturers can be audited once for compliance with the standard and regulatory requirements of up to five different medical device markets: Australia, Brazil, Canada, Japan and the United States. The program's main mission is to "…jointly leverage regulatory resources to manage an efficient, effective, and sustainable single audit program focused on the oversight of medical device manufacturers."

2. Why was the MDSAP developed?

The MDSAP was developed to:

- Implement requirements that are defined in the IMDRF MDSAP Model;
- Enable appropriate regulatory oversight of medical device manufacturers' quality management systems while minimizing regulatory burden on industry;
- Promote more efficient and flexible use of regulatory resources through work-sharing and mutual acceptance among regulators while respecting the sovereignty of each authority;
- Promote globally, in the longer term, a greater alignment of regulatory approaches and technical requirements based on international standards and best practices;
- Promote consistency, predictability and transparency of regulatory programs by standardizing;
    - the practices and procedures of participating regulators for the oversight of third party auditing organizations,
    - the practices and procedures of participating third-party auditing organizations; and
    - Leverage, where appropriate, existing requirements and procedures for conformity assessment.

3. Which Regulatory Authorities are part of the MDSAP and what is the plan for expansion of the program?

The MDSAP was developed by representatives of the Australian Therapeutic Goods Administration (TGA), Brazil's Agência Nacional de Vigilância Sanitária (ANVISA), Health Canada, Japan's MHLW/PMDA, and the U.S. Food and Drug Administration (FDA). All regulatory authorities participating in the MDSAP are equal partners in the program.

Others Regulatory Authorities may eventually decide to participate in the MDSAP and to become active participants in the Program. For example, the World Health Organization (WHO) Prequalification of In Vitro Diagnostics (IVDs) Programme, the European Union (EU) and United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) are Official Observer to the MDSAP Regulatory Authority Council (RAC) and Subject Matter Expert (SME) Work Group.

4. What is the difference between a Regulatory Authority being a participant in MDSAP Subject Matter Expert (SME) Working Group (WG) versus being an observer to this working group?

The Regulatory Authority participants provide the resources to support the development, implementation, maintenance and expansion of MDSAP and participate actively in the process of recognizing, monitoring, and re-recognizing

Auditing Organizations under the framework of the IMDRF MDSAP. The participating Regulatory Authorities have committed to use the MDSAP deliverables. Each Regulatory Authority participant is also represented on the MDSAP Regulatory Authority Council (RAC); the MDSAP's governing board, by senior-level manager(s).

A Regulatory Authority who is an "observer" may attend MDSAP SME WG meetings, assessments, and other activities, but does not utilize MDSAP program deliverables to replace or supplement its regulatory scheme deliverables or portions of these deliverables. The observers are represented on the MDSAP RAC by one senior-level manager.

5. Is the list of medical device manufacturers participating in the MDSAP made publicly available?

No, this information is not made publicly available by the Regulatory Authorities.

6. Can industry provide input into MDSAP documents or the program in general?

Yes. There are two venues for the industry to contribute.
Following each MDSAP audit, Medical Device Firms participating in the MDSAP are invited to provide feedback through a survey that is available on the MDSAP FDA webpage.

Additionally, the MDSAP participating Regulatory have established and implemented an MDSAP Quality Management System. Feedback on MDSAP can be submitted to any of the participating Regulatory Authorities in written format, electronically, by telephone, or in person. Electronic feedback is preferred and may be submitted to one of the five email addresses listed below. MDSAP participating regulators will address the feedback in accordance with the procedure MDSAP QMS P0011 (Complaints and/or Customer Feedback Procedure.) Manufacturers are encouraged to provide feedback.

Contact emails:

MDSAP@tga.gov.au
MDSAP.ATENDIMENTO@anvisa.gov.br
qs.mdb@hs-sc.gc.ca
MDSAP@pmda.go.jp
MDSAP@fda.hhs.gov

7. **Have there been discussions with WHO regarding the use of MDSAP audits in the pre-clearance process for? Will medical devices assessed by the WHO be included in the program at a later stage?**

   WHO is participating as an observer to the MDSAP. WHO has indicated a willingness to adapt and integrate MDSAP processes as much as possible in their *Prequalification Program*. WHO intends to utilize MDSAP reports where possible if they are available for devices that are subject to their *Prequalification Program*.

8. **If an RA decides to change its GMP/QMS or Regulatory requirements, how will the changes be incorporated into MDSAP?**

   MDSAP Audit Approach documents can be periodically revised to reflect any changes in regulatory requirements. Accordingly, the impacted MDSAP training will be updated. The IMDRF MDSAP WG N3 document requires "The Auditing Organizations to participate in any regulatory coordination group established for the purpose of keeping the Auditing Organization's personnel current on medical device legislation, guidance documents, standards, and best practice documents adopted in the applicable regulatory systems." (N3 – Clause 6.1.3)

9. **How do I find out more specific information on the documents, policies, and procedures used in the MDSAP?**

   The MDSAP participating Regulatory Authorities and the candidate Auditing Organizations primarily utilize the IMDRF MDSAP WG documents that can be found at: IMDRF Documentation.

   In addition, there are many other MDSAP Regulatory Authority Council approved documents in order to implement the program, for example: an audit strategy for auditing medical device manufacturers, requirements for the audit reports, a method for audit time calculation, and the MDSAP Quality Management System procedures. For further information on the MDSAP and associated documents, please refer to the MDSAP Home Page or contact one of the participating Regulatory Authorities at:

   MDSAP@tga.gov.au
   MDSAP.ATENDIMENTO@anvisa.gov.br
   qs.mbd@hc-sc.gc.caMDSAP@pmda.go.jp
   MDSAP@fda.hhs.gov

B. Questions related to Assessments

10. Can Contract Research Organizations participate in MDSAP? What about Certified Quality Auditors?

The MDSAP includes the use of Auditing Organizations, also known as Certification Bodies or Registrars in other schemes. If an Auditing Organization also acts as a Contract Research Organization, the organization's management system must ensure the impartiality of the Auditing Organization.

An independent Certified Quality Auditor may not individually apply for recognition under the MDSAP. Should an auditor become permanently employed or work on a contract basis for an Auditing Organization, and meet the competency and other criteria for auditors as required under MDSAP, e.g. absence of conflict of interest, that auditor may be qualified to perform MDSAP audits as long as the AO is authorized or recognized under MDSAP.

11. How will an Auditing Organization pay regulators for the application and training?

There are currently no application fees or costs associated with the MDSAP Training. Training on the MDSAP Audit Approach and the requirements of the participating Regulatory Authorities is available on-line to Auditing Organizations candidate applicants (MDSAP Training Material).

The MDSAP Consortium is developing a cost-recovery scheme to ensure the ongoing and stable financing of the program and its electronic platform REPs (Regulatory Exchange Platform – secure)

12. How are assessments of Auditing Organizations being conducted by RAs under the MDSAP?

The assessment program is defined in key documents for the planning and conduct of assessments by Regulatory Authority assessment teams; and, the follow-up and monitoring of assessment activities of Auditing Organizations. The sequence of all assessment activities follows a 4-year cycle. The cycle begins with an initial authorization, followed by annual surveillance assessments for three consecutive years. Assessments are performed per document MDSAP AS P0034: *Guidance for Regulatory Authority Assessors on the Method of Assessment for MDSAP Auditing Organizations* and associated MDSAP Documentation.

13. Must Auditing Organizations have all documentation in English to be assessed by the Regulatory Authorities?

Auditing Organizations must have at least the documents requested for the application submission and for Stage 1 Assessment in English. During the Stage 2 Assessment, the Auditing Organizations must have personnel with fluency in English to translate documents and records that are not in English. Additionally, records that are specific to the MDSAP program (including but not limited to the documents included in the audit report package) should be in English as well.

14. What is the best way to determine what is expected of the Auditing Organizations with regard to multiple jurisdictions during audits of manufacturers?

Medical device manufacturers will have to be audited according to the scope declared in their application for certification services. Based on the countries where the manufacturer sells (or intends to sell) or has devices registered, the AO will determine the regulatory requirements applicable to that manufacturer.

The AOs will have to refer to the MDSAP AU P0002 Audit Approach to make that determination. This document incorporates or references the regulatory requirements of each of the participating Regulatory Authorities.

15. What oversight do Regulatory Authorities have over the Auditing Organizations?

In accordance with best practices, the MDSAP incorporates a transparent assessment program by Regulatory Authorities who will oversee the compliance of the Auditing Organizations with MDSAP requirements. This program includes a robust plan and schedule for assessing the competence and compliance of MDSAP Auditing Organizations and includes assessments of their head office and critical locations, as well as witnessing the performance of Auditing Organization´s audits ("witnessed" audits), as part of an ongoing four year recognition cycle.

The Regulatory Authorities participating in MDSAP will base their recognition and assessment process on the IMDRF MDSAP WG and MDSAP documents in addition to other documents approved by the Regulatory Authority Council. IMDRF Documentation and MDSAP Documentation.

In particular, Regulatory Authorities will evaluate or "assess" an Auditing Organizations' compliance to the requirements of IMDRF MDSAP WG documents N3 and N4.

- IMDRF MDSAP WG N3 *Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition*
- IMDRF MDSAP WG N4 *Competence and Training Requirements for Auditing Organizations*

16. What is a witnessed audit?

A witnessed audit is performed to permit Regulatory Authorities to verify that an Auditing Organization adequately conducts their audits using the MDSAP Audit Approach and reports appropriately on the outcomes of audits. It is an essential assessment activity for building and maintaining confidence in the reliability of the third party Auditing Organization. During a witnessed audit, the Auditing Organization's audit team conducts the audit of the medical device manufacturer and the Regulatory Authorities' assessment team observes the AO without interfering in the audit process. The RA Assessment team does not assist or coach the AO auditors, nor does it provide additional information to the AO audit team or collect information on their behalf.

After the Auditing Organization has issued the audit report, the assessment team finalizes and shares their conclusions with the Auditing Organization.

The RA conclusions are not in relation to the compliance of the manufacturer to ISO 13485 and the relevant regulatory requirements. The RA's conclusions only relate to the ability of the Auditing Organization to audit against the requirements of the MDSAP.

17. Who performs witnessed audits and how are the assessors selected?

The witnessing of an audit being conducted by an Auditing Organization will be performed by qualified MDSAP Regulatory Authority Assessors. These assessors are experienced Regulatory Authority Assessors who have knowledge of the MDSAP requirements, the requirements of the participating Regulatory Authorities and the device and manufacturing technologies used by the medical device manufacturer that is being audited.

Regulatory Authority Assessors are qualified against the competency requirements as defined in the document IMDRF MDSAP WG N6 FINAL:2013, *Regulatory Authority Assessor Competence and Training Requirements.*

18. Can an Auditing Organization contest an unfavorable recognition decision or a nonconformity and its grading?

If an Auditing Organization disagrees with an unfavorable recognition decision or a nonconformity issued by the Regulatory Authorities, it may formally file for an appeal to the participating Regulatory Authorities. The process is defined in MDSAP AS P0021: Appeals Procedure.

19. If a current Notified Body applies for recognition to perform audits under the MDSAP, but does not pass the MDSAP assessment, could they also be de-notified to the EU Directive?

No. European Competent Authorities and Designating Authorities are not participants in the MDSAP. It is therefore unlikely that European Authorities would de-designate a Notified Body based on the outcome of an MDSAP Assessment. Nevertheless, European Authorities are likely to be informed if the reason for refusing the authorization was due to concerns that arose from a concurrent assessment of an Auditing Organization of the relevant European regulations. In such cases, the European Authorities may follow-up with the Auditing Organization and make their own assessment of the situation.

20. Who from the Auditing Organization or the Regulatory Authorities makes the final decision on the compliance of the medical device manufacturer?

The Auditing Organizations are fully responsible for making the decision on compliance to issue MDSAP certification documents under the program.

Independently, each MDSAP participant Regulatory Authority may use the report for different purposes, to support the regulatory decisions in their jurisdiction. If, based on the Auditing Organization's audit report, a Regulatory Authority concludes that the manufacturer is not in compliance with the regulations, the Regulatory Authority may engage in enforcement activities according to their policies, taking into account, if possible, the follow-up activities conducted by the Auditing Organization.

21. How does a regulatory authority inspectorate become an Auditing Organization?

Regulatory Authorities who are seeking recognition under MDSAP need to comply with the same requirements as a commercial Auditing Organization. The other participating Regulatory Authorities will conduct an assessment according to the international standard ISO/IEC 17021-1 and the additional requirements defined in IMDRF MDSAP WG N3 and IMDRF MDSAP WG N4, per the assessment methodology documented in MDSAP AS P0034.

22. How will MDSAP ensure that every RA has the same evaluation standards for the Auditing Organization?

Auditing Organizations are assessed for compliance with the requirements of IS0/IEC 17021-1 and the additional requirements of N3 and N4. An assessment program, assessment methodology for Auditing Organizations and guidance for RA Assessors is defined in MDSAP AS P0034. Regulatory Authority assessors execute assessment tasks for each process defined in the documents above and identify objective evidence of definition, implementation and effectiveness of each of the requirements. If nonconformities are identified, a grading system is used to assist in determining the timeline for any corrections or corrective actions and to support a predefined recognition and de-recognition process.

Regulatory Authority assessors are qualified against the requirements of IMDRF MDSAP WG N6, *Regulatory Authority Assessor Competence and Training Requirements* to perform the assessment of an Auditing Organization. Regulatory Authority assessors will participate in both face to face and distance training activities. The MDSAP Regulatory Authorities are committed to operating under a joint MDSAP Quality Management System to establish controls over the program and to facilitate continuous improvement. Applicable MDSAP Assessment Procedures and Forms are publically available.

23. Would an Auditing Organization receive independent recognition by each participating Regulatory Authority?

No. Recognition is a joint exercise and hence recognition of an AO by the MDSAP Regulatory Authority Council (RAC) means recognition by each participating Regulatory Authority. It may be possible that some jurisdictions have to internalize MDSAP Recognition in their national regulatory framework. For example, Anvisa publishes a Resolution in "*The Brazilian National Gazette*" for each AO that is authorized or recognized in the MDSAP. It has the same effective and expiration date as the MDSAP recognition letter.

24. Will Auditing Organizations be informed when there is a complaint against them so that improvements can be made?

Yes. MDSAP QMS P0011 Complaints and/or Customer Feedback Procedure include in its scope complaints related to the Auditing Organizations and to Medical Device Manufacturer participating in MDSAP.

C. Questions related to Audits

25. Which manufacturers are eligible to undergo an MDSAP audit?

All manufacturers of medical devices are eligible to undergo an audit under the MDSAP. However, each regulatory authority may establish exclusion criteria for manufacturers meeting certain conditions if deemed necessary or when limited by legislation. It is important to note that manufacturers that participate in the MDSAP program are responsible for securing and maintaining a contract with an MDSAP recognized AO. AOs operate as fee-for-service organizations. In other words, medical device manufacturers are responsible for paying for MDSAP audits conducted by an AO. The Regulatory Authorities participating in MDSAP are not involved in contractual arrangements / the contract negotiation process between manufacturers and AOs.

26. How can a medical device manufacturer participate in the MDSAP?

All medical device manufacturers interested in participating in MDSAP can contact any of the Auditing Organizations authorized or recognized to perform MDSAP audits. The list of *Auditing Organization Availability to Conduct MDSAP Audits* is available online.

Medical device manufacturers do not apply to a Regulatory Authority for an audit under MDSAP.

27. Does the MDSAP add requirements for the manufacturer?

No. The MDSAP Audit Approach was developed to cover existing requirements from the Regulatory Authorities participating in the MDSAP. The program does not add any new requirements to existing requirements from ISO 13485 or other country-specific requirements of the participating Regulatory Authorities.

28. What are the potential benefits of a manufacturer participating in the MDSAP?

The MDSAP offers many benefits to medical device manufacturers including the following:

- A single audit is used in lieu of multiple separate audits or inspections by participating regulatory authorities or their representatives. Therefore, for

many medical device manufacturers, the MDSAP reduces the overall number of audits or inspections and optimizes the time and resources expended on audit activities.

- Additionally, as a longer term goal, it is expected that the program will enhance confidence in the reliability of third-party audits, that more Regulatory Authorities will join the program, and that other Regulatory Authorities will use information made available through the program to limit the need for additional audits.
- Some participating regulatory authorities will use MDSAP audit outcomes as an alternative to their own inspections to process applications for medical device marketing authorization.
- Like in any third party auditing program, the medical device manufacturer is free to choose among all authorized auditing organizations to perform the audits. Routine audits are announced and planned with the manufacturer.
- The MDSAP is expected to improve the predictability of audit outcomes through:
    - enhanced auditing organization recognition criteria,
    - monitoring of auditing organizations by the participating Regulatory Authorities,
    - the use of a standard MDSAP audit approach,
    - the grading of any nonconformity using objective criteria to characterize the significance of the finding,
    - the reporting of the audit outcomes using a standard report template.
- Enrolling in the MDSAP may be seen as evidence of a medical device manufacturer's commitment to quality management systems for product quality and regulatory compliance.

29. What are the potential benefits to the manufacturer participating, specific to each jurisdiction?

Australia: The Therapeutic Goods Administration – TGA

- The TGA currently uses MDSAP audit reports and certificates as part of the evidence that is assessed for compliance with medical device conformity assessment procedures and market authorization requirements, unless the medical device is otherwise excluded or exempt from these requirements or if current policies restrict the use of MDSAP audit reports. Further details are provided in the '*Use of market authorisation evidence from comparable overseas regulators / assessment bodies for medical devices (including IVDs)*' guidance.
- For MDSAP certificates and audit reports to be considered by the TGA, the Australian regulatory requirements must have been covered in the audit(s), and certificates must show that the manufacturer has been assessed and found to comply with the relevant aspects of the Therapeutic Goods (Medical Devices) Regulations 2002.

Brazil: The Brazilian National Health Surveillance Agency – ANVISA utilizes the outcomes of the program, including the reports, to constitute an important input on ANVISA's pre-market and post-market assessment procedures, providing, when applicable, key information that are expected to support regulatory technical evaluation on these issues.

As defined in RDC 15/2014 and RE 2.347/2015, ANVISA may use MDSAP audits in lieu of a premarket inspection by ANVISA to grant ANVISA's GMP Certificate to manufacturers intending to put medical devices of class III or IV on the Brazilian market. Undergoing an MDSAP audit may accelerate ANVISA´s GMP certification process, which is a pre-requisite to the marketing authorization.

ANVISA can also use MDSAP audits to renew ANVISA's GMP Certificate bi-annually, as an alternative to an ANVISA comprehensive inspection.

Note: ANVISA do not use MDSAP audit reports from manufacturers where the result of ANVISA's previous inspection was considered unsatisfactory and therefore the manufacturer had the certification submission denied. In such cases ANVISA will start using the MDSAP reports only after a new ANVISA inspection with a satisfactory result.

Canada: MDSAP certification is required to obtain a new (or maintaining or amend an existing) Class II, III or IV medical device license, pursuant to section 32 of the Regulations.

Japan: When an MDSAP audit report is submitted at the timing of premarket or periodical post-market QMS inspection application, Japan's Ministry of Health,

Labour and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA) will use the report:

1) To exempt a manufacturing site etc.* from on-site inspection, and/or
2) To allow a Marketing Authorization Holder (MAH) to substitute considerable part of documents required for the inspection with the report.

Note: PMDA may perform on-site inspection or request additional QMS documents, when it is determined necessary after a review of the MDSAP audit report package.

*Exceptions:

a) A Registered Manufacturing Site (RMS) which manufactures medical devices made of human/animal tissues,
b) A RMS which manufactures radioactive IVDs, and
c) An establishment of a MAH.

United States: U.S. Food and Drug Administration's (FDA) Center for Devices and Radiological Health, will accept the MDSAP audit reports as a substitute for FDA routine inspections. Additional benefits include:

- MDSAP routine audits are announced, scheduled by the Auditing Organization with the manufacturer, with a pre-established duration;
- The FDA will review MDSAP audit reports with a level of scrutiny commensurate to the significance of audit findings, taking into account the review and follow-up performed by the Auditing Organization;
- Firms have one month to provide their full response to critical nonconformities (grade 4 and 5) to the Auditing Organization (as opposed to 15 working days following and FDA inspection);
- Certification documents issued by the Auditing Organization state compliance with applicable US regulations, which may provide a marketing advantage.

Note: Inspections conducted "For Cause" or "Compliance Follow-up" by FDA will not be affected by this program. Special inspections, such as the annual Risk Based Workplan inspection program may also not be affected by MDSAP. Moreover, this MDSAP program would **not** apply to any necessary pre-approval or post approval inspections for Premarket Approval (PMA) applications or to decisions under section 513(f)(5) of the Act (21 U.S.C. 360c(f)(5)) concerning the classification of a device.

Firms with activities related to the Electronic Product Radiation Control (EPRC) provisions of the Act will continue to be subject to FDA inspections for the EPRC activities. Manufacturers of products that are not subject to device inspections, i.e. drugs, biologics, etc., may also require an FDA inspection (see question #39).

World Health Organization (WHO): In the framework of the *Prequalification Program* for diagnostic devices, the WHO may recognize successful MDSAP -

audits as acceptable evidence of QMS compliance with international regulations. This may result in either abbreviated or waived WHO inspection depending on the scope of audit.

30. What are the costs associated with MDSAP audits?

The cost of conducting an MDSAP audit is dictated by the commercial arrangement between the medical device manufacturer and the authorized or recognized MDSAP Auditing Organization.

31. Where can industry find out which jurisdictions an AO is recognized for?

An Auditing Organization authorized or recognized to perform MDSAP audits must have demonstrated competence in each jurisdiction's regulations. Therefore, the recognition is not restricted in terms of a Regulatory Authority's jurisdiction and covers all jurisdictions participating in MDSAP. The letter of recognition to conduct medical device regulatory audits under MDSAP is standardized.

32. How does the MDSAP ensure that medical devices are being manufactured in accordance with the regulations of multiple jurisdictions?

The MDSAP relies on:

- Annual audits of manufacturers according to an audit approach specific to the program. This audit approach was developed to review the compliance of a manufacturer's quality management system to the international standard ISO 13485 and additional regulatory requirements applicable to the countries where the devices are sold; and
- Annual assessments of the Auditing Organizations' management system compliance to the international standard ISO/IEC 17021-1 and MDSAP specific requirements as defined in IMDRF MDSAP WG documents.

33. How do Auditing Organizations ensure that duplicate efforts are not performed during an audit of a manufacturer that sells in multiple jurisdictions?

The MDSAP audit process was designed and developed not only to prevent duplication, but also to ensure that the program provides efficient and thorough coverage of the requirements of; Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485: 2016) and any corresponding section(s) of the Australian Therapeutic Goods (Medical Devices) Regulations (SR

236, 2002), the Brazilian Good Manufacturing Practices (RDC ANVISA 16/2013), the Canadian Medical Device Regulations (CMDR, Part 1), the Japanese QMS ordinance (MHLW MO 169), the Quality System Regulation (21CFR 820), and other country-specific requirements.

The MDSAP audit sequence follows a process approach and was designed and developed to allow the audit to be conducted in a logical, focused, and efficient manner.

MDSAP AOs are required to create a facility profile in the online portal (REPs) for each facility audited. The profile is kept updated by the AOs. This allows for timely notification to RAs of a manufacturer's participation or withdrawal from MDSAP.

Timely notification of MDSAP initial audit schedules by AOs will prevent the duplication of inspection/audit of Medical Device Manufacturers participating in MDSAP. Additionally, adequate notification of situations where a Medical Device Manufacturer no longer elects to participate in MDSAP will ensure that continued regulatory oversight is maintained by all participating RA's.

34. How are regional regulatory differences addressed in the program?

The regulatory requirements of the participating Regulatory Authorities have been incorporated into the MDSAP Audit Approach. An auditing organization will perform audits using this approach and record findings in relation to the regulations of the participating Regulatory Authorities.

Each Regulatory Authority independently utilizes the MDSAP audit deliverables (audit reports, certification documents) according to their regulations and policies.

35. How are audits of medical device manufacturers conducted under the MDSAP?

Authorized and recognized Auditing Organizations perform MDSAP audits according to documents developed by the participating Regulatory Authorities. Some relevant policies and procedures introduced by the program to ensure consistency across Auditing Organizations and/or auditor teams include:

- The sequence of processes specified in the Audit Approach MDSAP AU P0002 must be followed; the audit duration is based on planned audit tasks MDSAP AU P0008 *Audit Time Determination - Procedure*, ensuring consistency across Auditing Organizations. In general, the duration of MDSAP audits will not exceed the accumulated time of audits and inspections

performed currently by each participating Regulatory Authority according to their governing regulatory frameworks.

- An audit report is issued with each audit, using a standard fillable template specifically designed for medical device regulatory audits.
- Nonconformities identified during an audit are graded on a scale from 1 (least critical) to 5 (most critical), and are managed according to criteria defined in the document GHTF/SG3/N19:2012, *Quality management system – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange*).
- Audited manufacturer are responsible for the timely development and implementation of action plans to address non-conformities identified during audits MDSAP AU P0027 Post Audit Activities and Timeline Policy.
- Auditing Organizations share the audit outcomes with the participating Regulatory Authorities to support their pre-market or post-market programs. Upon successful certification or recertification audits, Auditing Organizations issue MDSAP-specific certification documents stating compliance to ISO 13485:- and applicable regulatory requirements. MDSAP AU P0026 Certificate Document Requirements.

36. What is the difference between a Stage 1 and a Stage 2 Audit? (Initial Audit?)

The "Initial" audit also known as an "Initial Certification" audit consists of a Stage 1 and a Stage 2 audit.

- Stage 1 – A first Stage 1 audit consists of a documentation review and the evaluation of the readiness of the manufacturer to undergo a Stage 2 audit.
- Stage 2 – The purpose of a Stage 2 audit is to determine if all applicable QMS requirements of ISO 13485 and all other applicable regulatory requirements from participating regulatory authorities have been effectively implemented.

37. How is the audit duration determined?

The method and the criteria to be used by the Auditing Organizations to calculate the time necessary to conduct an MDSAP audit of a medical device manufacturer is defined in the procedure MDSAP AU P0008 entitled *Audit Time Determination*.

The MDSAP audit approach defines the activities and tasks that are to be performed in an MDSAP Audit Cycle including; the activities and tasks for an Initial (Stage 1 and 2) Audit (a.k.a. Certification Audit), Surveillance, Re-audit (a.k.a. Recertification Audit), and for Special Audits. The appropriate audit tasks defined within the MDSAP Audit Cycle must be used when calculating audit times. When applicable,

the appropriateness of the audit duration for subsequent activities should be confirmed during the Stage 1 audit.

There are varying numbers of audit tasks depending on the process being audited. Audit time is calculated based on the number of applicable audit tasks associated with the type of audit to be conducted (as defined in the MDSAP Audit Cycle) and the specific activities of the organization to be audited.

38. At what frequency do MDSAP audits occur?

Medical device manufacturers that participate in the MDSAP are audited annually, according to a three-year certification cycle. The Initial Audit, also referred to as the *"Initial Certification Audit"* is a complete audit of a medical device manufacturer's quality management system (QMS). The initial Audit is followed by partial Surveillance Audits conducted once per year for two consecutive years. The cycle re-commences with a complete Re-audit, also referred to as a "Recertification Audit" in the third (3rd) year.

Special Audits, Audits Conducted by Regulatory Authorities, and Unannounced Audits are potential extraordinary audits that may occur at any time within the audit cycle.

39. Can the scope of an MDSAP audit include combination products?

The implementation of the MDSAP is intended to allow for a single audit to satisfy the regulatory requirements of the participants.

Medical Devices that include; drugs (medicinal substances) or biologics (e.g. materials of animal origin that have been rendered non-viable, or tissues, cells or substances of microbial or recombinant origin, human blood or extracts of human blood or blood products, etc.) (a.k.a. "combination products") may be included in the scope of an MDSAP audit.

The Regulatory Authorities that take into account MDSAP audit reports for combination products expect that the Auditing Organization, when conducting an audit for these products, will:

- undertake, to the extent possible during on-site audits, an assessment of the product / process related technologies in accordance with the requirements of N3 Clauses 9.2.4, 9.3.2 and 9.4.1, and the requirements of the MDSAP audit approach for compliance with the country specific requirements;

- assign relevant technical competence to the audit team that is assessing the product / process related technologies and relevant controls for the handling, testing and manufacture of these types of devices; and
- record their findings in accordance with the requirements of MDSAP AU P0019 MDSAP Medical Device Regulatory Audit Reports.

However, due to differences in the way that these products are regulated in the jurisdictions of the participating Regulatory Authorities, MDSAP audit reports and certification documents will not be considered an alternative to the inspection and assessment requirements in some jurisdictions, as described below:

Australia: Manufacturers of some medical devices, other than IVD medical devices, that contain tissues of animal origin or microbial origin, or incorporating stable derivatives of human blood or human plasma, or incorporate, or are intended to incorporate a substance that, if used separately, might be considered to be a medicine, are 'specified medical devices' defined under s.4 Definitions of the Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018. MDSAP Audit Reports can be used to support a TGA application for Conformity Assessment for 'specified medical devices'.

Brazil: According to Brazilian regulations there are no specific requirements for combination products regarding the Quality Management System, and for that, all the requirements already disposed on the MDSAP Audit Approach promotes adequate coverage for the needs established in the Brazilian legislation and regulation for those products. Therefore, combination products that are considered medical devices in Brazil are included in MDSAP –

Canada: The MDSAP Audit Approach covers the requirements for combination products that are regulated as medical devices.

Japan: There are no Japanese characteristic requirements for combination products which are categorized as devices. Therefore, MDSAP Audit results will be considered as alternatives to confirm the compliance of Quality Management System (QMS) requirements for such products.

United States: The MDSAP Audit Approach only covers the requirements of the US medical device regulations. As additional requirements of the US regulations apply to devices incorporating drugs or biologics, the FDA cannot consider MDSAP - audits of combination product manufacturers as an alternative to FDA inspections. Consequently, such products are still subject to FDA inspections regardless of the participation of the manufacturer in the program. Nevertheless, the FDA may take into account the outcome of an MDSAP audit covering combination products to optimize the scope of the FDA inspection to be performed.

NOTE: When a combination product manufacturer also manufactures non-combination products, it is expected that during the initial certification audit and at least once during the subsequent certification cycle the audit team includes the technical competence to audit combination products; and, when applicable, the audit plan includes the quality management system processes and activities associated with the combination product. MDSAP audit plans and reports of combination product manufacturers must consider, where applicable:

1) Supplier Controls and acceptance activities (including testing) associated with the starting material that is to be used in the manufacture of the drug or biologic component (in particular Active Pharmaceutical Ingredients);
2) Controls of the manufacturing processes for the drug or biologic component;
3) Final acceptance and testing activities, including those associated with the drug or biologic component in the finished product; and
4) Stability programs that consider the drug or biologic component in the finished product.

40. Is there a checklist available for industry that compares the ISO 13485 requirements with each participating country's regulations?

The *Audit Approach* MDSAP AU P0002 contains specific instructions on the MDSAP audit process. It incorporates an audit sequence and instructions for auditing each specific process. The audit process tasks incorporate references to the applicable ISO 13485: 2016 clause(s) and any corresponding section(s) of the Australian Therapeutic Goods (Medical Devices) Regulations (SR 236, 2002), the Brazilian Good Manufacturing Practices (RDC ANVISA 16/2013), the Canadian Medical Device Regulations (CMDR, Part 1), the Japanese QMS ordinance (MHLW MO 169), and the Quality System Regulation (21CFR 820).

41. Is MDSAP a top down inspection, as with the Quality System Inspection Technique employed by FDA?

The MDSAP Audit Approach, which was inspired by the FDA's Quality System Inspection Technique document, is based on a "top-down" auditing approach.

42. Does the audit process include a daily review of areas of concern?

Yes. Auditing Organizations must be in compliance with the requirements of IMDRF MDSAP WG N3, and N4, including the requirements of ISO/IEC 17021-1 and all other related MDSAP documents. ISO/IEC 17021-1, Sub-Clause 9.4.3.1-

Conducting the opening meeting, requires that "during the audit, the client will be kept informed of the audit progress and any concerns."

43. Are MDSAP audits conducted by single or multiple auditors?

Procedure MDSAP AU P0008 Audit Time Determination specifies how to determine the on-site audit duration in man-days. Auditing Organizations decide how many auditors will compose the audit team. For instance, a 6 man-day audit could be completed in 3 days by a 2-auditor team. Auditing Organisations are also required to take into account the competency of the audit team for the type of audit and the scope of products that are produced under the control of the manufacturer's QMS.

44. Who assigns a particular auditor? The Auditing Organization or Regulatory Authority?

It is the AOs' responsibility to assign auditors for individual audits of medical device manufacturers, taking into account their competence, impartiality and availability.

Unlike other certification programs, a manufacturer may not oppose the choice of the auditor under the MDSAP (IMDRF MDSAP WG N3 *Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition* exception to ISO /IEC 17021-1, section 9.2).

45. If MDSAP becomes mandatory for one or more participating countries will manufacturers be expected to be compliant with regulations in a jurisdiction that it does not market?

The manufacturers are expected to be compliant only with the regulations for the jurisdictions where their products are marketed or manufactured for distribution.

46. Can RA's discredit/void any audits that were conducted by an AO due to inadequate audit method/technique? If so, will manufacturers have to go through re-audits for audits they believed to have passed?

The MDSAP does not include mechanisms for requiring an audit to be re-done. Nevertheless, if an audit report appears to be unreliable, does not include a participating MDSAP jurisdiction in which the products are distributed, or does not include all the appropriate devices in the audit scope a participating Regulatory Authority may not be able to utilize the certificate or report as part of their process to grant a marketing authorization. A misleading audit report may also present a risk to

public health and could lead the Regulatory Authorities to conduct its own follow-up inspection. Alternatively, an RA may request that an AO conduct a special audit to follow up on an issue. (IMDRF MDSAP WG N3 – clause 9.6.6.)
Manufacturers may forward a complaint with the participating Regulatory Authorities in relation to an audit performed by an Auditing Organization. The complaint will be processed using the procedure described in MDSAP QMS P0011.

47. If an AO issues a negative final report, does this mean the manufacturer can no longer supply to/sell in all of the regulatory jurisdictions that are participating in the Program?

MDSAP audit reports records the recommendation of the audit team for initial, continuing certification, or re-certification of the audited medical device manufacturer. When the AO determines that the audited manufacturer does not meet QMS or other regulatory requirements, each of the Regulatory Authorities concerned would determine appropriate actions relative to the identified nonconformities. The nonconformities may or may not be associated with regulatory requirements of all participating regulatory authorities.

48. What happens if significant non-conformities are identified by an Auditing Organization and subsequently shared with the Regulatory Authorities?

Non-conformities identified by an Auditing Organization are to be graded in accordance with the document GHTF/SG3/N19:2012 – Quality management system – Medical devices – Nonconformity Grading System for Regulatory Purposes and Information Exchange. Nonconformities are to be recorded and graded by the Auditing Organization using MDSAP AU F0019.2 NC Grading and Exchange Form.

IMDRF MDSAP WG N3 defines that the Auditing Organization shall provide information to the recognizing Regulatory Authority(s) about the audits and decision on conformity to quality management system requirements. The procedure MDSAP AU P0027 Post-Audit Activities and Timeline Policy defined that if the audit identified one or more grade 5 nonconformities, or more than two grade 4 nonconformities, or a public health threat, or any fraudulent activity or counterfeit product, the Auditing Organization shall inform the Regulatory Authorities within 5 working days. For Grade 4 or 5 nonconformities, manufacturers are expected to provide evidence to the Auditing Organization of implementation of the remediation actions addressing any grade 4 or 5 nonconformity within 30 days of the audit end date. Auditing Organizations are subsequently expected to provide the audit package, which includes the NC Grading and Exchange form, to a recognizing Regulatory Authority within 45 days of the end of audit. Post-audit actions timelines for a manufacturer and an Auditing Organization are further described in MDSAP AU P0027 Post-Audit Activities and Timeline Policy.

On receipt of the 5 days' notice the participating Regulatory Authorities will undertake actions that are appropriate for their jurisdictions and willnotify the other participating Regulatory Authorities of the actions that should be taken in relation to the manufacturer.

49. How are nonconformities that are identified during an MDSAP audit managed? What is the timeline for a manufacturer to respond to nonconformities?

The document MDSAP AU P0027 Post-Audit Activities and Timeline Policy defines the activities to be completed and timeline that a medical device manufacturer must follow to address the nonconformities identified during an MDSAP audit.

The manufacturer must provide a remediation plan for each nonconformity within 15 calendar days from the date the non-conformity report was issued. The plan must include:

- the outcome of the investigation of the nonconformity and its cause(s),
- the planned correction(s), and
- the planned corrective action(s) to prevent recurrence.

The evidence of implementation of the remediation actions addressing any grade 4 or 5 nonconformity must be provided within 30 calendar days after the audit end date. (Page 1-section 2 Timeline)

50. Who would conduct follow-up visits to close the non-conformities?

An Auditing Organization would normally conduct close-out activities for all non-conformities in accordance with their procedures.

A participating Regulatory Authority may request that an Auditing Organization carry out a Special Audit to further investigate, follow-up or to close an audit under the direction of the requesting Regulatory Authority.

A recognizing Regulatory Authority may conduct its own Special Audit at any time it deems necessary and within the purview of its jurisdiction. (IMDRF MDSAP WG N3 – clause 9.6.6.)

51. Do Auditing Organizations collect evidence of nonconformities, or other evidence usually collected during Regulatory Authorities' inspections?

Under the MDSAP, Auditing Organizations are not required to collect any evidence, but the audit report must substantiate any audit finding by reference to audit evidence. Due to this restriction, the US FDA will limit enforcement actions based on MDSAP audit reports to advisory actions only.

This waiver also applies to other evidence usually collected during Regulatory Authorities' inspections, such as evidence of interstate commerce by the FDA.

For example, what does the FD&C Act mean by "Interstate Commerce". *Section 201(b) of the FD&C Act [21 U.S.C. 321(b)] tells what circumstances place a product in interstate commerce:*

(1) Commerce between any State or Territory and any place outside thereof, and
(2) Commerce within the District of Columbia or within any other Territory not organized with a legislative body.

"Interstate commerce" applies to all steps in a product's manufacture, packaging, and distribution. It is very rare that a cosmetic product on the market is not in "interstate commerce" under the law. For example, at least some of your ingredients or packaging most likely originates from out of state, or even out of the country. Likewise, it is foreseeable that your products will leave the state. Although there are certain exemptions [21 CFR 701.9], factors such as these generally cause the requirements of the FD&C Act to apply to your products."

52. During witnessed audits, will Regulatory Authorities prompt AO's in identifying nonconformities?

The RAs will not interfere in the way an AO conducts its audit. The MDSAP is intended to allow competent auditors from MDSAP recognized AOs to conduct a single audit of a medical device manufacturer's quality management system in compliance with the requirements of the RAs participating in the MDSAP program. For this purpose, the RA's will ensure, by periodical assessment, including the witnessing of audits of manufacturers conducted by AOs, that AOs are applying the MDSAP audit approach and assigning adequate competence to the task.

53. As a manufacturer, how do I show that I was successfully audited under the MDSAP?

Upon successful completion of an initial audit or re-audit, an Auditing Organization will issue certification documents including a reference to the MDSAP that will state compliance to ISO 13485 and the applicable Medical Device Regulations from each jurisdiction that were used as audit criteria.

54. If a manufacturing site is already under regulatory action with a participating Regulatory Authority, can they participate in the MDSAP?

If a manufacturer is currently subject to regulatory action from one of the participating Regulatory Authorities, then the manufacturer should consult with the RA about their eligibility for an MDSAP audit prior to resolution of the action. There are no exclusion criteria regardless of the past audit/inspection history, and regardless of the type of medical devices manufactured by the organization. Nevertheless, if a manufacturer had a previously unfavorable inspection by a participating Regulatory Authority, this Regulatory Authority may still choose to conduct a follow-up inspection. For example, this is the case with inspections conducted by the U.S. FDA. ANVISA will not use MDSAP audit reports from manufacturers where the result of ANVISA's previous inspection was considered unsatisfactory and therefore the manufacturer had the certification submission denied. In such cases ANVISA will start using the MDSAP reports only after a new ANVISA inspection with a satisfactory result.

55. What happens to a Manufacturer when the AO recognition is revoked?

The impact of a cessation of recognition or the revocation of the authorization to audit, under the MDSAP may affect a large number of manufacturers. The event should not directly affect any existing marketing authorization. Nevertheless, Regulatory Authorities may need to consider individual or collective transitional arrangements to assure existing or potential public health risks are mitigated.

To stay in the program, a manufacturer would need to contract another Auditing Organization to resume the audit cycle at the point of departure of the de-recognized Auditing Organization.

56. Will industry auditors have access (for a fee) to the AO auditor training? [Will training be available for manufacturers to ensure that its QMS will meet the MDSAP criteria?]

Computer-based on-line training modules have been created describing the MDSAP Audit Approach that is to be used by Auditing Organizations to conduct audits of Medical Device manufacturers. This training is a requirement for each Auditing Organization auditor who will be conducting MDSAP audits. Due to limited availability of licenses agreement the training is not being made available to non-Auditing Organization certification bodies or to medical device manufacturers. However some of the MDSAP training modules are available on the MDSAP webpage - CDRH Learn (Postmarket Activities Section/ Inspections – Global Harmonization); scroll down to "Postmarket Activities ".

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57. Why aren't MDSAP audit reports used by the FDA as substitutes for inspections for Premarket Approval (PMA) applications?

The FDA explicitly excludes PMA pre-approval and post-approval inspections for Premarket Approval (PMA) due to the lack of regulatory convergence in the following:

1. the premarket device assessment processes performed under the various regulations (e.g. US Premarket Application, Australian Design Dossier or Design Examination, Canadian Device License Application); and,
2. where the responsibilities for final decisions of safety and performance/effectiveness of a medical device are placed (regulatory authority vs. third party organization).

58. Which country specific regulatory requirements are included in the MDSAP audit criteria?

The Medical Device Single Audit Program (MDSAP) audit process was designed and developed to ensure a single audit will provide efficient yet through coverage of the relevant requirements of; Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485: 2016), the Australian Therapeutic Goods (Medical Devices) Regulations (SR 236, 2002), the Brazilian Good Manufacturing Practices (RDC ANVISA 16/2013), the Canadian Medical Devices Regulations (Part 1), the Japanese QMS ordinance (MHLW MO 169), the Quality System Regulation (21 CFR Part 820), and other specific requirements of medical device regulatory authorities participating in the MDSAP program including 21 CFR Part 803 and 21 CFR Part 806.

59. How will the determination be made on whether an audit report supports an FDA advisory action without the supporting evidence?

The determination will be made following existing FDA criteria for situation 1 as described in the applicable Compliance Program, Part V. The evidence will be described in the narrative descriptions of nonconformities contained in the audit report. The auditor competency (including ability to identify existing nonconformities) is something the regulatory authorities review extensively during Auditing

Organization assessment activities. An independent inspection by the FDA would be necessary to support judicial actions.

60. How will Nationally Recognized Testing Laboratory (NRTL) Program audits be accepted?

NRTL tests and MDSAP audit are completely separate programs, evaluating compliance to distinct criteria. NRTL tests are required by the US Occupational Safety and Health Administration.

61. Can Regulatory Authorities not participating in MDSAP have access to audit reports? If so, what amount of information will be made available and at what cost?

Regulatory Authorities not participating in the MDSAP will not have full access to audit reports. Nevertheless, if a Regulatory Authority has a confidentiality agreement with a participating Regulatory Authority, a request may be made to obtain a copy of a particular report.

However, non-participating Regulatory Authorities may request audit reports and certificates from the medical device manufacturer.

Regulatory Authorities participating in the MDSAP Affiliate Program may request the MDSAP Audit Report from the medical device manufacturer. A list of MDSAP Affiliates and information regarding the MDSAP Affiliate Program is listed on the MDSAP webpage.

62. Do the IMDRF or the Regulatory Authorities participating in the MDSAP plan to influence/revise the International Accreditation Forum (IAF) mandatory document MD9 on the audit of medical device manufacturers to ISO 13485?

No. The document IMDRF MDSAP WG N3 states that “IMDRF Regulatory Authorities have no official status within groups such as the IAF, or any voice in IAF governance or IAF mutual recognition agreements, that would allow the Regulatory Authorities to revise IAF documents to meet the needs of the regulators. It was also determined that the standard most commonly utilized is the ISO (the International Organization for Standardization) and IEC (the International Electro-Technical Commission) standard ISO/IEC 17021-1 entitled, “Conformity assessment – Requirements for bodies providing audit and certification of management systems.” Medical device Regulatory Authorities also have little influence in the standards

organization that produces this standard and cannot simply change the standard for medical device regulatory purposes."

63. Is the CE certification included in the outcome of a successful MDSAP audit?

The MDSAP Audit Approach MDSAP AU P0002 does not incorporate the requirements from the European regulations. Nevertheless, the medical device regulatory Audit Report form MDSAP AU F0019. 1 may be used for multipurpose audits and an Auditing Organization may incorporate the European requirements into the MDSAP audit criteria to eliminate duplicate reporting.

64. Can the RAs consider if one report can represent a multi-site audit?

The Regulatory Authorities agreed that a separate report is necessary for each audited site unless the manufacturer meets the definition of a campus, as stated in Communication by AOs with RA on Organizations participating in MDSAP.

65. Do audit tasks have to be repeated during a multi-site audit?

- The implementation of applicable QMS process elements should be audited at each site.
- Content of common procedures does not have to be audited again. However, the implementation of applicable QMS process elements should be audited at all applicable sites.
- The non-implementation of applicable QMS process elements may lead to nonconformities relating to document control (current, approved procedure not available at all sites); or failure to effectively train users of the procedure; or failure to effectively implement the procedure, among others.

66. What additional guidance can RAs provide AOs on the application of the MDSAP audit approach to multi-site audits and for suppliers?

- The AO should determine the applicable QMS activities and corresponding audit tasks at each site included in the audit program.
- Content of common procedures does not have to be audited again. However, the implementation of applicable QMS process elements should be audited at all applicable sites.
- The audit team should pay attention to the interaction and coordination of activities between sites.

- MDSAP audit could be extended to a supplier facility if the manufacturer cannot demonstrate effective controls.

67. How should an AO handle companies that have a legal address with no association to the company's daily operations?

- Per IMDRF MDSAP WG N3, the AO shall audit all sites that will be recorded on the certificate.
- AOs can initially visit the site to confirm its activities and relationship to the QMS.
- Describe relationships/activities and site omissions in the audit report.
- Auditors should confirm if changes result in additions of sites to audit program.
- Non-operations/functional sites should not be audited/certified.

68. Should a remote-audited facility be included on the certificate?

According to MDSAP AU P0026, section 7,"The certification document shall record all sites of the manufacturer's quality management system that have been audited on-site. "

69. How should AOs handle "virtual" manufacturers?

Virtual Manufacturers shall be treated as manufacturers and shall be audited accordingly for all activities applicable to the devices designed or manufactured.

70. Manufacturers indicated that the grading system was too complex to understand. Is there any plan to review it?

- The grading system is based on GHTF/SG3/N19:2012. A guidelines document was developed to account for the change from the 2003 to the 2016 version of ISO 13485 and to clarify situations for escalation that are described in GHTF/SG3/N19:2012. The guidelines document is MDSAP AS P0037: *Guidelines on the use of GHTF/SG/N19:2012 for MDSAP purposes.*

71. Can RAs provide additional guidance on how to distribute the audit activities among the audit team, using the audit approach?

- Audits require effective pre-audit planning.

- While one auditor is reviewing a primary process of the audit approach (e.g., Management), another auditor can cover a supporting process. (e.g., Facility Registration)
- Auditors covering the same process can cover different audit tasks.
- Maintaining audit team communication is essential.

72. How should an AO apply the audit approach when sites are not responsible for all QMS activities?

- AO should determine the applicable QMS activities and corresponding audit tasks at each site included in the audit program. This can be done in Stage 1 of the audit.
- The audit time calculation procedure, MDSAP AU P0008, and associated spreadsheet MDSAP AU F0008.2 (Audit Model 2017) can assist in identifying/planning audit tasks.

73. When should an AO employ a Technical Expert during an MDSAP audit?

ISO/IEC 17021-1 states: “The criteria for the selection of technical experts are determined on a case-by-case basis by the needs of the audit team and the scope of the audit.”

74. Can audit tasks be accomplished prior to on-site audit activities?

Yes. RAs encourage AOs to use pre-audit planning, communications and other activities as a mechanism to complete or assist in the completion of audit tasks when appropriate.

75. Under what circumstances would an MDSAP audit be followed by an RA inspection?

A RA inspection may be required if:

- An MDSAP audit report failed to provide evidence required to support market authorization decisions.
- An audit reveals public health safety concerns or fraudulent activity.
- Combination product device manufacturers may still require RA audits/inspections. See question #39 of the MDSAP Q&A document for additional guidance on combination products.
- Some situations when the manufacturer is currently subject to regulatory action (see question #54)

76. When should multi-site audit reports be submitted?

Audit reports must be submitted following the audit of each site, as stated in MDSAP AU P0027, Post-Audit Activities and Timeline Policy.

77. How should AOs handle sharing of audit reports with RAs that are not participating in MDSAP?

This should be worked out between the AO and its clients and spelled out in contracts when necessary.

78. Have the RAs defined the term "Public Health Threat"?

Public Health Threat is synonymous to the GHTF/SG2/N54R8:2006 term, Serious Public Health Threat – *Any event type, which results in imminent risk of death, serious injury, or serious illness that requires prompt remedial action*.

79. How should AO auditors structure nonconformity statements?

Nonconformities should be written in accordance with GHTF/SG3/N19:2012, section 4.1; and section 5.0 Appendix A.

80. Why have the RAs imposed an initial response period of fifteen (15) calendar days?

RAs operate under time constraints that require an awareness of audit outcomes within a specified number of days. In order to make informed decisions about audit outcomes, the RAs must assess the manufacturer's response.

81. For a consistent interpretation, could the RAs define the term "implementation" in MDSAP AU P0027 and AS F0015.1?

- NCs cited by AOs after an MDSAP audit of a manufacturer: In the context of a manufacturer replying to nonconformities identified during an MDSAP audit, the term "implement" relates to the implementation of the actions specified in the manufacturer's correction and corrective action plan.
    - Please refer to MDSAP AU P0027, sections 2 and 3.

- NCs cited by RAs following and assessment of an AO: In the context of an auditing organization replying to nonconformities identified during an RA assessment, the term “implementation” relates to the implementation, and confirmation of the effectiveness of corrections and corrective actions, subsequent to the review and acceptance by the RAs of the AO’s correction and corrective action plan.
    - Please refer to MDSAP AS F0015.1 AO Nonconformity Process Flowchart.

82. What does the MDSAP certificate represent?

- The MDSAP certificate is an attestation by the AO that the facilities listed in the certificate have been audited against the listed criteria for the listed scope and found to conform to those requirements, including the regulatory requirements for the specified jurisdictions of the RAs.
- It does not represent a marketing authorization nor does it oblige participating Regulatory Authorities to issue any such marketing authorization or endorsement of the manufacturer or its devices.

83. Can the RAs provide additional guidance on what should be recorded if the minimum N4 requirements cannot be fulfilled by an initial start-up AO?

- The RAs recognize that not all AOs will have the initial client participation to fulfill prerequisite annual experience requirements.
- AOs should document the circumstances and justify why requirements were not met in accordance with the principles for pre-requisite experience described in N4 Clause 6.2.
- RAs will consider each justification on a case-by-case basis.

84. Can the RAs clarify the requirements for the transfer of certification for participating manufacturers?

Transfer guidelines are detailed in ISO 17021-1:2015 Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 1: Requirements.

85. Can the RAs develop a single dispute resolution to minimize inconsistency if a manufacturer uses multiple AOs?

MDSAP P0031 – Documenting Differing Professional Opinion and Dispute Resolution Policy sets out a single mechanism for resolving disputes within the MDSAP program.

86. How long will RAs allow an MDSAP certificate to reference a jurisdiction where no product is distributed?

- MDSAP AOs can issue certificates referencing jurisdictions where the manufacturer does not yet have market authorization.
- Recognizing that market entry can take time, such certifications can be extended for a full three years.
- If at the end of three years, the manufacturer has not obtained or applied for market authorization, it is recommended that the requirements for the affected jurisdiction should be removed from the certificate until such time as the manufacturer can demonstrate implementation and effectiveness.

87. Can the manufacturer exclude a jurisdiction or products from the scope of an MDSAP audit?

A manufacturer may exclude the requirements of a jurisdiction where the organization does not intend to supply medical devices. In other words, audit criteria under the MDSAP include at a minimum ISO 13485 and the medical device regulations that are applicable in any of the participating regulatory authority's jurisdiction where the organization supplies medical devices. The MDSAP audit scope is expected to include all products that are supplied to a participating MDSAP jurisdiction.

88. What constitutes a counterfeit medical device or a fraudulent activity requiring notification of Regulatory Authorities?

For all practical purpose:

- A counterfeit medical device is a medical device that is represented as, and likely to be mistaken for, an authentic medical device with a valid marketing

authorization, or whose identity, nature and/or source are fraudulently misrepresented, or that is otherwise intended to defraud.

- A fraudulent activity is an intentional, reckless, dishonest and recurrent, or systematic, activity resulting, for example, in the production of a counterfeit product, or in the creation of fake records, false representations, or the alteration of genuine records to imply compliance. The unintentional failure to comply with requirements, despite due diligence, does not qualify as fraudulent activity.

89. What is the expectation for Class 1 medical device manufacturers participating in MDSAP?

The activities/processes, products or facilities that are eligible for exclusion from an MDSAP Program are outlined in the following table.

Jurisdiction	Consideration	Comments
Australia	Class I medical devices (non sterile, no measuring function) are not required to have a certified quality management system.	TG(MD)R Schedule 3 Part 6 establishes obligations / requirements for manufacturers of Class I medical devices (non sterile, no measuring function) that includes process definition, adverse event and recall reporting. By default, a certified QMS is not required by legislation for Class I medical devices (non sterile, no measuring function). However, a manufacturer may: - voluntarily choose to apply a more onerous conformity assessment procedure (e.g. Schedule 3 Part 1 or Part 4); OR - request an Auditing Organization to include Class I medical devices (non sterile, no measuring function) within the scope of an MDSAP ISO13458 certification. In these circumstances, the Auditing

		Organization should treat the requirements of the relevant Conformity Assessment Procedure (Part 1, 4 or 6) as regulatory requirements when establishing audit criteria.
Brazil	Class I and Class II medical devices are not subject to GMP Certification*. * However, ANVISA Resolution RDC 15/2014 still require that the manufacturer of the finished device have an effective QMS in place.	If all devices in the scope of certification are class I or II, or if the audited facility's contribution to the scope of certification only applies to class I or class II medical devices, the audit at that facility may disregard the requirements of the Brazilian regulation for registration purposes.
Canada	Class I medical devices are not required to have a certified quality management system.	If all devices in the scope of certification are class I or if the audited facility's contribution to the scope of certification only applies to class I medical devices, the audit at that facility may disregard the requirements of the Canadian regulation.
Japan	Class I medical devices are not required to have a certified quality management system.	If all devices in the scope of certification are class I or if the audited facility's contribution to the scope of certification only applies to class I medical devices, the audit at that facility may disregard the requirements of the Japanese regulation.
United States	Some Class 1 medical devices are "GMP-exempt", i.e. not subject to the US quality system regulation.	If all devices in the scope of certification are GMP-exempt or if the audited facility's contribution to the scope of certification only applies to GMP-exempt medical devices, the audit at that facility may disregard the requirements of the US Quality System regulation (21 CFR 820), with the exception of the requirements for

		maintaining complaint files and recordkeeping. Additionally, requirements still apply for compliance to Medical Device Reporting (21 CFR 803), Medical Devices; Reports of Corrections and Removals (21 CFR 806), and Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices (21 CFR 807).