2025 MDSAP AUDITING ORGANIZATION (AO) APPLICATIONS – QUESTION RESPONSES

NO.	QUESTION	RESPONSE
A- GENERAL APPLICATION QUESTIONS		
A1	When do applications open and close?	AO applications for recognition will reopen 1 July 2025 and close 29 September 2025. Please see Transmittal 2025-02 and Transmittal 2025-03 for further information on the application process.
A2	Why have prioritization criteria been introduced?	The criteria have been introduced to better match demand for MDSAP Regulatory Authority (RA) assessments with the available RA assessment resources, and to prioritize applicants with a higher likelihood of achieving recognition in a timely manner and participating in the MDSAP over the long term. Further information on eligibility and prioritization criteria is available here.
A3	What is meant by "Attestations"?	The application requires certain attestations whereby a senior official of the applicant commits to complying with MDSAP program requirements, declares that the applicant has not been convicted of an offense against medical device regulations, etc. These attestations take the form of a check box agreeing to a predetermined statement and the signature of an official. Notarization of these attestations is not necessary.

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A4	Is accreditation according to ISO 17021 mandatory?	Accreditation to ISO/IEC 17021-1:2015 is not mandatory. However, ISO/IEC 17021-1:2015 is part of the recognition criteria (with exception to certain requirements).
A5	Can candidates receive early advice if they are not likely to be eligible for recognition under the program?	Without access to the full application package for any candidate, MDSAP RAs cannot provide advice on the suitability of any organization to become an MDSAP AO. However, to be eligible, candidates must meet all criteria specified in IMDRF MDSAP WG N3 *Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition*. N3 are in addition to the normative requirements of ISO/IEC 17021-1:2015. From comprehensive review of this document, and its complementary document IMDRF MDSAP WG N4 *Competence and Training Requirements for Auditing Organizations*, each candidate can form an opinion as to their suitability for the program. Initial screening will not proceed if a candidate AO is not able to provide suitable documentation to demonstrate: - they fulfill the requirements of clause 5.1 of IMDRF/MDSAP WG/N3 2nd edition - financial stability over the past 3 years - available auditing resources (e.g. by the number of available auditor days) ≥ 150% of current demand
A6	Is there a fast recognition scheme for Notified Bodies (NBs) or Conformity Assessment Bodies (CABs)?	At present, there is no mechanism for the fast recognition of NBs or CABs.
A7	Do applicants require a local office in any MDSAP RA jurisdictions (e.g. Australia)?	There is no requirement to establish a local office in any of the MDSAP jurisdictions.

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A8	Are there any costs associated with submitting the application for recognition and for any subsequent phases of assessment and maintenance of the recognition?	There are no fees payable for submitting an application and undergoing the assessment process to become a recognized MDSAP AO. Commencing 1 January 2025, the MDSAP Regulatory Authority Council (RAC) has implemented an AO Contribution Scheme to ensure the ongoing sustainability, expansion, transparency and maintenance of the MDSAP. The contributions aim to assist with the costs associated with holding the annual MDSAP Forum, maintenance of the MDSAP website and training/education activities. The contribution amount is determined by the number of facilities an AO services - the more clients the AO has, the greater the contribution. The contribution scheme operates over a 3-year period so that existing AOs are aware of their contribution amount in advance. For 2025, the total contributed by all AOs combined is $133,330 USD. Some AOs contributed less than $10,000 while other AOs contributed more than $10,000. The RAC has agreed that contribution requirements for new AOs joining the program will commence the following calendar year after becoming authorized. As contribution amounts vary by AO, the amount payable for a potential AO cannot be confirmed prior to them applying.
A9	Is it possible to insert hyperlinks to the relevant documents in the Application Matrix, rather than references to them?	Hyperlinks are acceptable; however, IM/IT security policies of some participating RAs might disable or remove these. Consequently, please ensure that in such situations the matrix can still be used to perform assessment.

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		Additionally, hyperlinks must lead to a document that each RA can access. Some RAs have access restrictions to outside document repositories.
A10	Will the MDSAP RAC/RAs meet with any applicant prior to applications opening or as part of the application process?	The MDSAP RAC is not intending to meet with any candidates prior to applications re-opening or as part of the application process.
A11	Are candidates required to attach the manual and the procedures mentioned in MDSAP AS F0010.6 AO Application Matrix and MDSAP AS F0010.4.001 Supplemental AO Application Matrix -IMDRF N4?	Once a candidate AO has been selected for assessment, the Assessment Program Manager (APM) assigned to the AO will contact the applicant to request the submission of required documentation. Although documents are not required on application, the relevant matrices must be completed with relevant references to documentation to pass initial screening. The complete documentation does not need to be submitted with the initial submission of the application forms.
A12	In regard to MDSAP AS F0010.8.001 Auditor and Technical Expert Competency Summary, do candidates attach to their application, for each person reported in the Matrix, the documents certifying the assigned qualification?	No, records will be verified during the Stage 1 and/or Stage 2 assessment(s). Initial screening must be able to establish that the relevant documentation will be available for Stage 1 and/or Stage 2 assessment(s)
A13	Can candidates start mandatory training required for some internal staff that need to qualify as auditors?	There is no guarantee that any organization will be prioritized for selection to undergo the assessment process to become recognized. Once a candidate is selected by the MDSAP RAC to move forward with the assessment phase, the process will take a few months before the Stage 2 assessment occurs, at which point the candidate AO would have to demonstrate their auditors' competence.

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A14	What are the approximate number of person-days required for the MDSAP application?	The number of person-days required depends on a range of factors and your capacity to undertake the application process needs to be considered as part of your response. You will be able to determine how many days after you have reviewed the documentation and requirements.
A15	Is it a mandatory requirement for applicants to obtain recognition from the International Medical Device Regulators Forum (IMDRF) prior to submitting an application for the MDSAP?	MDSAP AOs are not required to obtain recognition from IMDRF.
A16	Do applicants need to have in-house or affiliated laboratory for an MDSAP application?	No.

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A17	<u>Mandatory Requirement for Commercial Liability Insurance</u> Is the procurement of commercial liability insurance a default obligation for AOs under this clause, except in the two explicitly stated scenarios (government liability coverage or regulatory authority direct responsibility)? Are there any other exceptions or alternative financial mechanisms permitted by the IMDRF/MDSAP framework that are not explicitly listed here? Can an AO fulfill the liability financing requirement by maintaining a "self-insured risk fund" (i.e., a designated reserve fund set aside to cover	Yes. Commercial liability insurance is one of the requirements of IMDRF/MDSAP WG/N3 FINAL:2016 (Edition 2) – Clause 5.3.1 for recognition as an MDSAP Auditing Organisation. No. There are no known precedents where an exception or alternative to commercial liability insurance has been permitted.

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	potential liabilities) instead of commercial insurance?	
A18	Jurisdictional Consistency Across MDSAP Participants For AOs operating in multiple MDSAP jurisdictions (e.g., the U.S., Canada, Japan, Brazil, Australia), must the liability coverage comply with the specific laws of each country, or does a globally comprehensive insurance policy satisfy the clause? How should regional variations in legal exemptions (e.g., government-mandated liability schemes) be addressed in such cases?	AOs may provide certification in any country, not only in the jurisdictions of the participating MDSAP Regulators. MDSAP recognises that …" Country specific laws and regulations, outside the medical device Regulatory Authority's purview, may be applicable to the manufacturer for certain legal and financial responsibilities." IMDRF IMDRF/MDSAP WG/N3 FINAL:2016 (Edition 2) Clause 5.1 The provision of certification services to any manufacturer are usually in accordance with a contract between the Auditing Organisation and the client manufacturer. Contracts usually identify the legal jurisdiction within which non-compliance with a contract may be contested. If a manufacturer is successful in contesting a provision of a contract, then the provisions of liability insurance should allow for the AO or manufacturer to make a claim in the jurisdiction of the contract for services.
A19	Application expectations and preferred communication channels	All questions and applications are to be directed to the MDSAP.RAC.Secretariat@tga.gov.au All application content requirements are detailed on MDSAP.global and within the application documentation. Some further explanation of requirements are detailed in Q A5 above. Note that Section 1.0 - IMDRF MDSAP WG N3 clearly states that ISO/IEC 17021-1:2015 acts as the generic base requirements for MDSAP recognition. It is being used as a normative reference within the MDSAP. If you have a specific question that is not answered in these documents, please email the MDSAP.RAC.Secretariat@tga.gov.au

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	Estimated timelines for the evaluation and approval of AO applications	Applications close 29 September 2025; however, as applications are received, they will be reviewed for completeness and the candidate advised if any required information is missing. In line with advice provided in MDSAP Transmittal Number: 2025-02, applicants will be informed whether their application is selected once the application window closes and all submitted applications have been screened. It is anticipated that candidates will be advised whether they have been prioritized to undergo full assessment for MDSAP AO recognition by late 2025. Candidates will also be advised if their application has not been selected and may reapply during subsequent application windows
	Whether Türkiye-based applicants have been previously evaluated, and if so, any specific considerations relevant to such applicants,	Information on any other applicant, current or past, is confidential; however, there are no specific considerations applying to Türkiye-based applicants Applicants will be screened for eligibility based on existing eligibility criteria in ISO/IEC 17021-1:2015 and IMDRF/MDSAP WG/N3 2nd Edition – Clause 5.1, demonstrated financial stability, and access to sufficient auditing and certification resources. Applicants that meet the existing screening criteria will be scored and ranked using criteria targeting a number of areas of interest as listed in MDSAP Transmittal Number: 2025-02.
	Whether the completed AO application form must be submitted along with the full set of supporting QMS documentation, or if only the forms are	It is sufficient to submit an AO application form and other forms referenced in the application. In particular, the completion of the Application Matrix and the Supplemental Application Form for the requirements of N4 will be used to indicated the extent of documentation available to demonstrate compliance with ISO/IEC17021-1:2015 and the

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	initially required, then QMS documentation to follow later, Any additional advice, procedural recommendations, or references you may suggest for applicants located outside of the IMDRF member countries.	extent of documentation to be developed or modified to demonstrate compliance with N3, N4 and MDSAP QS Audit Procedures. QMS documentation will be requested if the AO undergoes a Stage 1 assessment. There is no requirement for a candidate AO to be located in an IMDRF member country.
A20	Could you please confirm whether the document titled MDSAP AS F0010.8 – Auditor and Technical Expert Competency Summary (7 December 2019), which is included in the application package and published on the mdsap.global website, is up to date? We have noted that the technical areas listed in this document differ from those specified in the MDSAP AS F0010.1 – AO Application for Recognition Form (17 May 2025), and we would appreciate clarification on this matter.	Please complete each form as available. Thank you for bringing this to our attention. We note that MDSAP AS F0010.1 (Application Form) does not include the following categories: - General non-active, non-implantable medical devices - Non-active medical devices for disinfecting cleaning, rinsing - Active Implantable Medical Devices - Radioactive seeds for interstitial radiotherapy - IVD Instruments and Software - Devices for home use - IVD Instruments and Software - Near patient use other than home use - Medical Devices Incorporating / Utilizing Specific Substances / Technologies - Medical devices incorporating medicinal or biologically active substances - Medical Devices Incorporating / Utilizing Specific Substances / Technologies - Medical devices containing or manufactured using tissues of animal origin

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		Similarly, for MDSAP AS F0010.8 (Competence Summary), we note that the form doesn't include the section on Devices for which technologies or processes are used.
B- WITNESSED AUDITS		
B1	Requirement for Simulated On-site Audit during the Second Stage In the second stage of the on-site audit, is it required that MDSAP auditors conduct a simulated on-site audit as part of the assessment process? If necessary, are there any specific instructions, guidelines or best practices related to mock auditing?	No. The results of a simulated / mock audits are not used as part of the assessment of a candidate Auditing Organisation. Actual audits of manufacturers are witnessed. Stage 2 of the Assessment of a candidate Auditing Organisation requires a team from the participating MDSAP Regulatory Authorities to observe (witness) the practices of the candidate for the conduct of actual MDSAP audits. The results of three witness audits must be used to support a decision on whether, or not, to recognise a candidate as an MDSAP Auditing Organisation.
B2	Prepare the review cases for the on-site audit in the second stage. Is it necessary to pre-prepare audit cases for the on-site audit in the second stage? If so, a specific number of review cases should be prepared. Could you please provide detailed guidelines, standardized templates, or key elements to ensure that these cases fully align with the MDSAP requirements?	A team from participating MDSAP Regulatory Authorities will conduct witness audits using MDSAP AS P0012.003. The assessment program and relevant procedures require: - The provision of information to the MDSAP RAs about the first three audits that are proposed to be conducted under an MDSAP Certification program. - The Assessment Program Manager (APM) to agree on the suitability of proposed audits for their use as witnessed audits. Assessments are performed in four steps: - Pre-audit meeting - Audit observation - Audit report review

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		- Closing meeting including the provision of nonconformity reports, as applicable Prior to an audit the AO will be requested to provide related information as indicated in the Assessment Team's Audit Reporting template - Section 6 of MDSAP AS F0012.3.005
B3	Is there a correlation between the scope of recognition and the number of witnesses? The relationship between the number of witness audits and the business scope of the application: Does the term "three-time witness audits" imply that it refers to a fixed three-instance witness audits irrespective of the business scope of the application?	No, the number of witness audits is fixed at three and irrespective of the application scope. If the initial three witness audits are not successful and effective, additional audits may be witnessed. Witnessed audits are to verify the application by the candidate AO of the MDSAP Audit Approach, the MDSAP QMS Audit Procedures, and the effectiveness of an AO's management of competence. Audits to be selected for witnessing should be selected for different manufacturers using different audit teams. The Assessment Program Manager may discuss the suitability of an audit to be witnessed.
B4	Are witnessed audits required for the initial recognition?	The recognition process requires three (3) MDSAP witnessed audits before initial recognition is granted. However, a decision whether to grant a temporary authorization to perform MDSAP audits will be made after a successful Stage 2 assessment.
B5	Requirements for audit projects for three witness audits: What specific requirements exist for audit projects during three witness audits? Do these audit items need to be prepared in accordance with the scope of business of the application?	The Regulators will request documents to prepare for the witness audit. For example, the audit plan, documents provided by the manufacturer, internal AO documents such as the basis for audit time calculation and auditor competence records. The documents requested are standard and not related to the application scope.

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	Requirements for witness auditors and language: Can the same auditor be used for all three witness audits? Are there any specific language requirements for on-site witness audits?	No.The Regulators need to witness different auditors to evaluate the Auditing Organisation processes and the effectiveness of the AO's training in the use of the Audit Approach and application of regulatory requirements. A language translator may be necessary if the assessor team member(s) does not speak the language used in the audit. The AO is to provide the language translator if it is necessary. Note that the audit reporting policy (MDSAP AU P0019.005 Clause 5.2) requires "the language of the report is subject to the operating language of the auditing organization and should be understandable by the manufacturer; however, all audit reports must also be available in English."
C- AUDITOR QUALIFICATIONS		
C1	Which audits count for the auditor qualification criteria: We interpretated any ISO 13485, combination ISO 13485+ISO 9001, MDR and IVDR could count for the requested audit amount. Is our interpretation correct?	1. Audits conducted in accordance with the requirements of any medical device regulatory audit scheme (audits specifically conducted in accordance with the requirements of a regulator) can be considered to justify the required number of audits. 2. However, some MDSAP audits should be included to justify the familiarity of the auditor with the MDSAP audit approach (see MDSAP AU P0002). 3. In cases where audits in accordance with (1) and (2) above are insufficient to meet the criteria set in IMDRF document N4, the AO would be expected to record a rationale justifying the competence of the auditor to audit according to the MDSAP Audit Approach. Considering non-regulatory ISO 13485 audits as part of the expected

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		number of audits should in no case represent more than (25%) of the expected number of audits. 4. Before an initial qualification as auditor, a candidate auditor should participate in MDSAP audit as auditor-in-training. 5. Before an initial qualification as MDSAP lead auditor, a candidate lead auditor should be witnessed as lead auditor of an MDSAP audit. 6. Pre-existing qualifications by a recognized MDSAP AO can help justify a deviation from (4), but the AO should still record their rationale for trusting the ability of the candidate to lead MDSAP audits without performing a witness audit of the auditor. The auditor should be witnessed leading an MDSAP audit within 12 months following the granting of the qualification to audit under MDSAP. 7. In the case of a candidate lead auditor who is already qualified by the AO as a lead auditor under another medical device regulatory scheme, the AO may deviate from (5), with a recorded rationale for trusting the ability of the candidate to lead MDSAP audits, provided the auditor is witnessed leading an MDSAP audit within 3 years. 8. The qualification of an auditor or lead auditor who – after being initially qualified - would not participate in any MDSAP audit over a sliding 3-year period should be downgraded back to auditor-in-training and undergo a witnessed MDSAP audit prior to renewing their qualification. Deviations from the expected number of annual audits is permissible providing there are appropriate conditions to enable that auditor to fulfil the expected number of audits in the following year (e.g. an auditor taking parental leave and reducing their travels for a few months but expected to return to a more usual auditing activity afterwards).

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C2	For the initial qualification / maintenance of competence, is it possible to count also audits carried out in a different CB / Notified Body?	See also C4. Auditors must be qualified for MDSAP audits, hence audits carried out by an auditor under the control of any recognized MDSAP AO may be included to satisfy initial and ongoing competence requirements. Pre-existing qualifications by a recognized MDSAP AO can help justify a deviation from IMDRF/MDSAP WG/N4(2nd Ed) – Clause 8.1.3 [witnessing before being qualified as a lead auditor], but the AO should still record their rationale for trusting the ability of the candidate to lead MDSAP audits without audits without performing a witness audit of the auditor. The auditor should be witnessed leading an MDSAP audit within 12 months following the granting of the qualification to audit under MDSAP.
C3	Please elaborate on the precise process and specific requirements for obtaining MDSAP auditor qualifications. This includes details on the mandatory prerequisites, a comprehensive breakdown of the application procedures from start to finish, and the exact assessment criteria employed to determine a candidate's eligibility.	A comprehensive response is not possible in the context of this Q&A. For auditor qualifications, the precise process and the specific requirements for the qualification of an MDSAP Auditor are determined by the AO through the application of ISO/IEC 17021-1:2015 Clause 7 – Resource Requirements. In brief, and as an example, a summary of Clause 7.1 - Competence of personnel, for AOs … - Have processes to ensure that personnel have appropriate knowledge and skills relevant to the MDSAP and that the knowledge and skills can be applied in the context of audit. - Have a process to determine and document competence criteria (required knowledge and skills) having regard to the requirements of the MDSAP - Have an effective process to apply the competence criteria for initial competence evaluation and the ongoing monitoring of competence and performance.

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		- Maintain records of competence evaluation. - Ensure that personnel do not undertake audit and certification activities for the MDSAP before they are appropriately qualified. In addition to the requirements of ISO17021-1, the following two documents are complementary documents focused on requirements for an AO and individuals performing regulatory audits and other related functions under the respective medical device legislation, regulations, and procedures required in its regulatory jurisdiction. • IMDRF/MDSAP WG/N3 FINAL: 2016 (Edition 2) Requirement for Medical Device Auditing Organizations for Regulatory Authority Recognition • IMDRF/MDSAP WG/N4 FINAL:2021 (Edition 2) Competence and Training Requirements for Auditing Organizations. The information provided in IMDRF/MDSAP WG/N4 is supplemented by procedures describing the training required for each auditor who is to perform MDSAP audits, and a summary of competencies expected of auditors and technical support officers involved in the audit process. • Auditor Training - MDSAP AS G0010.1.001 • Auditor and Tech Support Expert Competency Summary - MDSAP AS F0010.8.002.
C4	According to *IMDRF/MDSAP WG/N4 FINAL:2021 (Edition 2), Clause 8.1*, an Auditor in Training is required to participate in at least 20 audit days within a 12-month period. Would these audit days need to be conducted exclusively under MDSAP, or can audits	The requirement is intended to ensure that auditors are practiced in the application of the MDSAP audit approach, however it is recognised that initially, an AO may not have sufficient demand for MDSAP audits to consistently meet the requirement by using MDSAP audits exclusively. Refer to question C1 above.

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	performed under ISO 13485, CE MDD, or CE MDR also be considered? Clause 8.0 also mentions that "alternative evidence of equivalent experience" may be accepted if it is appropriately justified and documented. Are there any examples available of what may be considered as equivalent experience? For example, would experience in CE MDD, CE MDR, or ISO 13485 audits qualify?	Yes, for the requirements for initial mandatory training outlined in clause 7.1, and where applicable, records of training or experience in CE MDD, CE MDR, or ISO 13485 audits may be used as acceptable alternative evidence.
C5	<u>Requirements for personnel competence and conditions for maintaining qualifications</u> Auditor Competency Requirements: Regarding the competency requirements for auditors, is it necessary to possess a relevant work background, or can auditing experience alone also fulfill these requirements? Conditions for Maintaining Auditor Qualifications: With respect to maintaining auditor qualifications, is it compulsory to complete six witnessing audits annually?	The Auditing Organisation shall establish measurable criteria for determining auditor competence based on the needs to assess QMS, manufacturing technologies and the regulatory requirements identified in the MDSAP Audit Approach (MDSAP AU P0002). See Q25 The extent to which an auditor demonstrates the established criteria must be evaluated by a competence qualifier (See N4) using evidence from relevant work experience and auditing experience. It is unlikely that one type of experience alone will be sufficient to demonstrate all relevant criteria. Auditors need to undergo a witness audit once every 3 years as per IMDRF N4 Cl 9.3.

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C6	For auditors who already have the ISO 13485 audit qualification, after completing the MDSAP special training, do they still need to intern for 20 person-days first before they can be converted to formal MDSAP auditors? If so, could you provide some guidance on the nature and scope of the internship? Can an ISO 13485 auditor conduct the audit activities after receiving the MDSAP auditors training and passing the exams?	Auditors who are candidates for qualification as an MDSAP auditor (Potential Auditor) must be able to demonstrate sufficient experience to have acquired the requisite knowledge and skills to successfully perform assigned tasks for the MDSAP. Auditors already qualified for ISO13485 using criteria determined under ISO/IEC 17021-1 Clause 7 are likely to satisfy the requirements for pre-requisite experience in N4-Clause 6.2. Potential auditors are required to demonstrate technical competence including "Knowledge of the regulatory requirements of the recognizing Regulatory Authority(ies) published in legislation and best practice documents, and the medical device business sector, to enable an assessment of the applicability and compliance with such laws, regulations, and standards." N4 Clause 6.3.3. MDSAP provides material to assist AOs to partially meet the mandatory training requirements for potential auditors N4 – Clause 7.1. The materials primarily relate to the MDSAP audit approach (MDSAP AU P0002) and the relevant regulatory requirements contained or referenced within the document. However, other documents from the MDSAP QMS including, for example, the MDSAP report and nonconformity writing policy and related forms should be included in an Auditor's training program. Prior to performing independent work for the MDSAP, N4-Clause 7.1 also requires AO's to provide auditors; training in QMS, the regulatory requirements of participating RAs, and risk management. Having completed the mandatory training that is specific for the MDSAP, auditors-in-training must practice the application of the MDSAP requirements under supervision. N4 – Clause 8.1.1.

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	D- MDSAP TRAINING MATERIALS	
D1	Can you provide further information on auditor training resources?	MDSAP provides some resources for Auditing Organisations to assist in the training of auditors of a few aspects of the MDSAP; for example, the method to be applied for the conduct of an MDSAP audit and key regulatory requirements of the participating RAs, as described in the Audit Approach – MDSAP AU P0002. The participating MDSAP Regulatory Authorities expect that AO's use the resources provided as part of the evidence of training, however AOs are required to ensure that the training is effective to achieve intended results. The MDSAP training resources on the MDSAP Audit Approach are available at MDSAP Education Modules (CDRH Learn) | Medical Device Single Audit Program (MDSAP). These modules are intended to be performed in the following order: (1) Introduction to MDSAP (2) MDSAP Management (3) MDSAP Device Marketing Authorization and Facility Registration (4) MDSAP Measurement, Analysis and Improvement (5) MDSAP Medical Device Adverse Events and Advisory Notices Reporting (6) MDSAP Design and Development (7) MDSAP Production and Service Controls, part 1 (8) MDSAP Production and Service Controls, part 2 (9) MDSAP Production and Service Controls, part 3 (10) MDSAP Purchasing. Training modules foro each MDSAP country's regulatory framework are also available to provide auditors with the most basic / baseline knowledge for those who would not have that knowledge as part of their

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		previous competences. However, auditing organization are encourage to provide their auditors with more in-depth knowledge through other means. In a secure area, the MDSAP also maintains a suite of other resources that support the program, including training modules for MDSAP AOs that have already been recognized. Further training opportunities are provided at the MDSAP Annual Forum and other convened meetings scheduled on an ad hoc basis. There are currently no application fees or costs directly associated with the MDSAP training.
D2	Is it enough for auditors to study only the open online training materials when attending the training, or if it is mandatory to complete the specialized training modules stipulated by MDSAP? So the candidates only need self-study the training materials in CDRH Learn Module? There in no Final Quizzes for successful completion of the training?	The Audit Approach training modules are provided by the MDSAP RAs as a resource for training however AOs should not assume that completion of the modules, as presented, and on their own, provides sufficient evidence of an effective implementation of the MDSAP that will achieve intended results. MDSAP requires, in part, knowledge of the MDSAP Audit Approach, the MDSAP RA's regulatory requirements, and the MDSAP QMS procedures related to audit. The specialized training modules, whilst not mandatory, provide an overview of the regulatory requirements of the participating RAs "Successful" completion of training is a responsibility on an MDSAP AO. They are required by 17021-1 Clause 7.1.2 to have; a process for determining competence criteria for the performance of MDSAP audits, a process for competence evaluation using the determined competence criteria, methods for the evaluation of competence and records to support a claim of competence. Processes and methods are to be effective and

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	We want to explain how candidates can prove that they have finished the training materials of CDRH learning module through self-study. Is there an evaluation mechanism or other forms of compliance certification for the training? Please provide specific proof.	must be applied, and records available, before individuals take on the responsibility for the performance of their MDSAP activities. The form of records for the completion of training material, an evaluation mechanism or a form of compliance certification are all determined by a certification body that has been accredited against the requirements of ISO/IEC 17021-1. The publicly available on-line training modules are available on MDSAP.global – other modules are available only to AOs already participating in the MDSAP. Documents providing guidance or pertaining to MDSAP competence and training produced by the International Medical Device Regulators Forum (IMDRF), and the procedures describing the training required of each auditor who is to perform MDSAP audits, is also available at Other Resources | Medical Device Single Audit Program (MDSAP).
D3	I would like to clarify regarding the MDSAP Auditor Training requirements. Based on the Training requirements it was mentioned that all Final Tests/Quizzes for every MDSAP Chapter (from Chapter 1 to Chapter 7), the auditors are required to obtain a score of 80% and above. Instead of obtaining 80% in each chapter module, is it also possible if the auditors attend training regarding the MDSAP requirements covering all the chapter and pass a final exam comprising of mix of questions related to all 7 chapter and achieve a	An MDSAP AO is to determine effective processes and criteria under Clause 7 of 17021-1 The quizzes provided with the training material on the MDSAP Audit Approach require an 80% pass criteria for each separate stage of the Audit Approach. See also D2

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	score of 80% above instead. Will this suffice or it is mandatory to obtain individual scores for each MDSAP chapter?	
D4	In order for our auditors to participate in the *MDSAP Online Auditor Training*, is it required that our AO application has already been submitted?	There are no restrictions to access the material provided on CDRH Learn. Additional training modules that summarise RA pre and post market regulatory requirements will be provided for successful applicants.
E- AUTHORISED AND RECOGNISED		
E1	Can certification bodies conduct MDSAP audits and issue certificates in compliance with the MDSAP requirements prior to receiving official recognition from the MDSAP program?	As part of the assessment process, it is necessary for candidate AOs to perform at least three audits in accordance with the requirements of the MDSAP. These audits are to be witnessed by a team representing the participating MDSAP RAs before a decision can be made regarding formal recognition of the candidate. If Stage 1, documentation review, and Stage 2, head office assessment, is successfully completed, a candidate AO is “Authorised” by the RAs to conduct the three witness audits. If supported by the findings of the AO’s audit team, and NC closeout, a candidate AO may issue Certification for the AO’s first client for MDSAP Certification. If the findings of the MDSAP Assessors for the witnessed audits do not raise significant concerns, Authorised AOs may continue performing MDSAP audits and issuing MDSAP certificates.. AO’s do not need to wait for a formal recognition decision. If satisfied with the performance of the candidate AO after three witnessed audits, the MDSAP RAs will formally “Recognise” the candidate and issue a Recognition Letter, with any conditions, if necessary.

NO.	QUESTION	RESPONSE
		Once Recognised, an annual witnessed audit and head office assessment will be performed by the MDSAP RAs to monitor the performance of an AO.
		F- ONGOING TRAINING
F1	We seek clarification on whether establishing a regulatory intelligence system is necessary to comply with MDSAP requirements regarding: 1. Regulatory change management ("updating laws and regulations"); 2. Post-market surveillance activities for medical devices; and 3. Quality management system updates. "Regulatory intelligence system" refers specifically to a mechanism for systematically tracking, assessing, and implementing changes to relevant regulations, standards, and MDSAP procedural documents (e.g., amendments to participating countries' regulations, updates to ISO 13485). Could you please clarify: • Whether such a system is mandatory under MDSAP or recommended for maintaining ongoing compliance? • Where possible, provide relevant documentary references to facilitate our accurate implementation?	It is a requirement of ISO/IEC 17021-1:2015 that AOs need to ensure auditors are made aware and trained to any regulatory, technical or QMS changes. The RAs will provide regulatory updates to the AOs, through updates to the Audit Approach, Technical and Forum meetings, Transmittals and other training material to support regulatory and program changes. The RAs will provide a transition period when making changes to the Audit Approach or if sending a transmittal detailing program or regulatory changes. RAs do not generally provide training material relating to updates to technical standards.