Guidance Document Title: Medical Device Regulatory Audit Report Form Guidelines
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Purpose

The purpose of this guidance document is to provide clarification on the information to record in the fields of the fillable Medical Device Regulatory Audit Report Form (MDSAP AU F0019.1).009 (i.e. rev. 9).

Preamble

The *Medical Device Regulatory Audit Report Form* (Document MDSAP AU F0019.1) must be used taking into account the requirements of the *MDSAP Quality Management System Audit Report Policy* (Document MDSAP AU P0019). The term "Audit Report" in the *MDSAP Quality Management System Audit Report Policy* and in the present document have a slightly different meaning. The requirements of the *MDSAP Quality Management System Audit Report Policy* actually apply to the "Audit Report Package" defined as follow:

The primary expected deliverables of an MDSAP audit that constitute the "Audit Report Package", are:

- The *Medical Device Regulatory Audit Report (Audit Report)*, including attachments (audit plan, and as applicable, list of critical suppliers, result of stage 1 audit, etc.)
- The *Nonconformity Grading and Exchange Form*,
- The *Nonconformity Reports.* It is not necessary for Nonconformity reports to be closed at the time they are shared with the Regulatory Authorities (see section 14 below). The Nonconformity Reports are to be documented on the Auditing Organization's corresponding form (until such time that there is a standard MDSAP form for documenting non-conformities, whereupon this form should be used).

The *Audit Report* summarizes the conditions and findings observed during the audit.

The *Nonconformity Grading and Exchange Form*:

- Is used as a tool to assist the auditor to identify all regulatory requirements related to a particular audit task (according to the MDSAP Audit Approach),

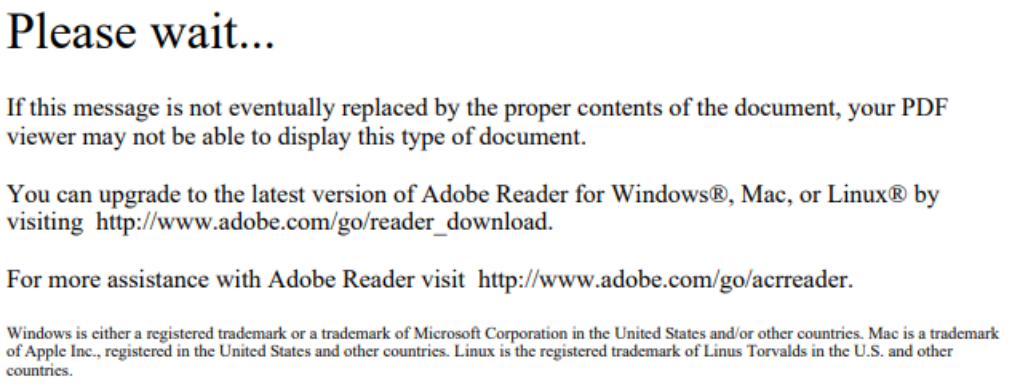
- Is used as the means to provide detailed information to the Regulatory Authorities on the nonconformities in a standard and aggregate way,
- Should contain the status of each listed nonconformity at the time of submission to the Regulatory Authorities,
- May include the response of the manufacturer to each nonconformity, and
- Is expected to be updated by the Auditing Organization to show the currency of the information each time it is submitted to the Regulatory Authorities.

Use of the Medical Device Regulatory Audit Report Form

A recorded presentation on how to use the MDSAP Regulatory Audit Report (AUR) Form was made available to the Auditing Organizations to train their auditors.

Compatibility

The form was developed using Adobe Experience Manager (AEM) Form Designer (formerly LiveCycle). This technology is incompatible with web browsers which often display the following picture when attempting to open the form.


Please wait...

If this message is not eventually replaced by the proper contents of the document, your PDF viewer may not be able to display this type of document.

You can upgrade to the latest version of Adobe Reader for Windows®, Mac, or Linux® by visiting http://www.adobe.com/go/reader_download.

For more assistance with Adobe Reader visit http://www.adobe.com/go/acrreader.

Windows is either a registered trademark or a trademark of Microsoft Corporation in the United States and/or other countries. Mac is a trademark of Apple Inc., registered in the United States and other countries. Linux is the registered trademark of Linus Torvalds in the U.S. and other countries.

Even if a browser is able to show the form correctly, the form won't function as expected.

The form must therefore be downloaded locally and must only be opened with Adobe Acrobat or Adobe Reader, version IX or higher. Adobe Reader can be obtained for free here. Other PDF processors can corrupt the form.

While some compatibility tests were successfully performed, some functions/features in the form may not be fully compatible with all systems. Please report any difficulty using this form by email to MDSAP@fda.hhs.gov.

Form protection
The form is password protected to prevent any modification in AEM or LiveCycle. However, no password is necessary to use the form in Adobe Acrobat or Adobe Reader. The technology does not ensure the protection of the recorded data unless the form is signed by the final reviewer.

Reporting bugs
As any piece of software, the form may include bugs. Please report any bugs to the FDA's general MDSAP email address: mdsap@fda.hhs.gov

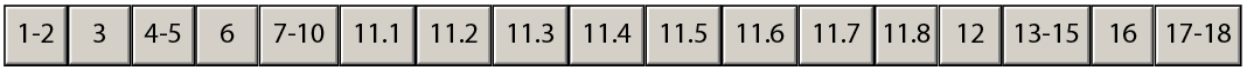
MDSAP and Non-MDSAP audits

The form was originally developed to record information relative to audits performed under MDSAP. However, it became clear that some Auditing Organization saw benefits in using the form for audits combining MDSAP with other schemes or even for other medical device audits not conducted under MDSAP, as well as by Auditing Organizations other than those recognized under MDSAP. Starting with revision 8 of the form, the form can be used for any medical device regulatory audit and revision 9 includes checkboxes to specify any applicable scheme (MDSAP, CE Marking, ISO 13485 or Other).

Note: if an auditing organization performs a combined audit under MDSAP and another scheme but decides to issue separate scheme-specific report, the MDSAP audit report would include all the information and findings from the audit that are relevant to MDSAP.

Navigation of the Form and Action Buttons

The form includes a series of buttons in the header, visible on every page, allowing to reach the various sections of the report in one click.



the footer of the form also includes several action buttons:

- "Save As" to save the form filled out (the record) under a new name.

- "Export Data" creates an email with attached to it, an XML data file of the entire data set contained in the form.
- "Refresh after Data Import" runs scripts to ensure that if data is being pushed into the form (other that Nonconformity information from an NGE form into Section 12 of the AUR form) the form appropriately displays the various fields in the form.

Content of the Report, Section by Section

Header

The header automatically displays the following information provided in other sections of the report:

- Audited facility
- Both the MDSAP and the Auditing Organization's audit report references, as well as the report's approval date, or the mention "[Unapproved]
- The Audit start and end dates

Section 1 Audit Information

In this table and the followings, an asterisk denotes a field that is required if MDSAP applies to the audit. The form will not allow the final reviewer to sign if any required field is left blank

Form field	Guidance
Certification Schemes covered by this report	Select all the audit or medical device certification schemes that apply to this report, with the following options: "MDSAP", "CE Marking" for any European directive or regulation relative to medical devices or In vitro diagnostic devices, "ISO 13485" for any ISO 13485 certification scheme other than MDSAP, and "Other" for any other applicable scheme applicable to the audit (e.g. UKCA, ISO 9001...); Note: at least one scheme must be selected
Did the audit cover any other schemes that are documented in a separate report ?	Indicate if the audit covered other schemes than those reported in the present report, for wich a separate report would be issued. For example, if the audit covered both MDSAP and European requirements and separate reports are issued for each scheme, then select "yes".

*MDSAP Auditing Organization**	If MDSAP applies, select the name of the Auditing Organization from the dropdown list.
Certification Body / Notified Body / Conformity Assessment Body	If any scheme other than MDSAP applies, specify the name of auditing organizations or notified bodies responsible for these schemes
*Audit Starting Date**	Date of the opening meeting. Format: YYYY-MM-DD
*Audit Ending Date**	Date of the closing meeting. Format: YYYY-MM-DD
Audit Duration (in Auditor-Day)	Planned duration from the opening meeting to the closing meeting, inclusive, in auditor-days. Note: In the context of a combined audit under multiple schemes, this corresponds to the overall audit duration – from the opening meeting to the closing meeting – spent auditing the organization's quality management system. This would not include the time spent on other non-auditing activities (e.g. assessment of a medical device technical documentation in the context of the European Regulations).
AO Audit Report Ref	This field is used by the Auditing Organization to uniquely identify the audit report in their information system.
Languages Used during the Audit	Language(s) used during the audit activities.
Auditing Modality	Specify the audit modality: - on-site: all audit team members on site - remote: all audit team members off-site - hybrid: some audit team members on site, other off-site If remote or hybrid, specify whether this was according to the Pilot described in MDSAP AU P0036 or as extraordinary measures necessary because of specific circumstances (e.g. COVID 19). Also check the box if the audit was performed in parts - i.e. split audit - that is when the audit stoped for a period of time greater than an overnight or weekend period and then recommenced to audit completion. In such a case, specify also whether the report is:

	- partial: summarizing the findings of only a part of the overall audit, or - final: compiling the findings of all parts of the audit.
--- Audit Team ---	not a field
Team Member	Full name

Role	Select any applicable box (may be multiple).
	
	Example:
	if an auditor-in-training is not actively auditing or only under the direct supervision of the audit's lead auditor or qualified auditor, then
	- the auditor-in-training must me listed as "auditor-in-training" only;
	- the auditor or lead auditor must be listed accordingly, and not as observer.
	If the auditor-in-training is acting as auditor or lead auditor as part of their qualifying witnessed audit then
	- that person auditor-in-training must be listed as both "auditor" or "lead auditor" as applicable, and "auditor-in-training";
	- the observer (who must be qualified to take over the role of the auditor-in-training if necessary) is to be listed as "Observer".

Affiliation	*AO Employee* if a permanent employee. (may be part time or full time) *External Resource* if an independent auditor or technical expert, or an employee from an external organization, employed on an ad-hoc basis to perform the assigned audit. Specify the name of the external organization or "self-employed" as applicable.

Section 2 – Audited Facility

Form field	Guidance
*Name of the Audited Facility**	Specify first the name of the organization as it would appear on any certification document, and if different, the name under which it is incorporated, or if applicable, other trade name under which it is registered with the Regulatory Authorities.

*MDSAP Facility ID**	Unique identifier (“F” followed by a 6-digit number).
Address, incl. *Street Address* *Address Details* *City* *Country* *State/Province* *Zip Code*	Complete physical address of the audited facility. In case the facility is a campus, specify the primary address. If the facility is the certification holder, this is the address that appears on the certification document. Note: Selecting the country in the dropdown list activates the State/Province field, which is a dropdown list if the selected country is Australia, Brazil, Canada, Japan or the United States. For other countries, type in the State or province, as applicable.
Contact Person, incl. *Title* *Email* *Telephone*	Identify the individual of the audited organization responsible for interacting with the Auditing Organization for audit planning and associated follow-up activities. This individual’s normal work location may or may not be the audited facility.
Senior Management of Audited Facility (Name and Title)	At a minimum, this must list the name and title of the individual ultimately responsible for the audited facility. If the facility is part of a broader corporation, this individual should be one of the registered officers of this facility.
Facility Identification Numbers, including for *Australia, TGA* *Brazil, Anvisa* *Canada, Health Canada* *Japan, PMDA* *USA, FDA* *Other Jurisdictions*	Where applicable, specify the set of jurisdiction-specific identifiers issued by the MDSAP Regulatory Authorities to the audited facility. There may be more than one identifiers listed for a single jurisdiction, for example in the case of a campus. This is however not the list of device marketing authorizations. If the information is not available or not applicable, indicate “NA”. Additional jurisdictions (e.g. MDSAP official observers or affiliate members, or non-MDSAP-related countries) and corresponding Facility identification numbers can be added in the Other Jurisdictions field.

Section 3 Certification Schemes, Scopes & Criteria, Audit Types

For each Certification Scheme selected in section 1, specify the following information, as applicable to the scheme.

Form field	Guidance
Audit Type: - *Initial* - *Surveillance* - *Recertification* - *Special* - *Unannounced* - *Mock* - *Specify*	Select the appropriate button. While "Unannounced audits" are a subset of "Special audits", only select "Unannounced" when applicable. For any other special audit, select "Special". A Mock audit cannot lead to a certification decision. Note an audit cannot be downgraded from Initial (or Certification) audit to a Mock audit based on the outcome of the audit. Specify when the radio button incompletely described the audit type. For example: - If a special audit, specify succinctly the reason or trigger of the audit; - for an unannounced audit triggered by the outcome of a previous audit, specify the ref. of the audit that triggered the unannounced audit; - if a surveillance or recertification audit included a scope extension or modification in the jurisdictions covered by the audit, mention it.
Scope of certification	Statement of activities and range of devices to appear in a certification document (if issued). In case of a multi-facility organization, the sub-scope specific to the audited facility can also be specified. Check the box if the audit plan takes into account any change to the scope of certification that would require the issuance of a new certificate, in term of type of activities, categories of devices, facilities or MDSAP jurisdictions.

Applicable Audit Criteria (depending on scheme)	<u>If MDSAP applies</u>: ISO 13485 always applies. Select the year of revision. Other standards used as audit criteria may also be specified. Check the box corresponding to the countries where the manufacturer commercializes or intends to commercialize medical devices, and to which regulations the manufacturer claims compliance. This shows the considered regulations. As required, specify the applicable regulatory documents considered and against which the manufacturer claims compliance. For example, US 21 CFR 821 only applies if the manufactured devices are subject to device tracking. See the MDSAP Certification Document Requirements MDSAP AU P0026 – section 9 – for specific considerations on the inclusion or exclusion of 21 CFR Part 820 as audit criterion. <u>If CE Marking applies</u>: Check the boxes specifying the applicable directives or regulations: - MDD: Medical Device Directive 93/42/EEC - AIMD: Active Implantable Medical Device Directive 90/385/EEC - IVDD: In Vitro Diagnostic Directive 98/79/EC - MDR: Medical Device Regulation (EU) 2017/745 - IVDR: Vitro Diagnostic Regulation (EU) 2017/746 For any of these, select the Annex(es) against which the audit was performed. <u>If ISO 13485 applies</u>: Select the version of the international standard

	If Other scheme applies: List the certification criteria (e.g. ISO 9001:2015)
Other reference doc.	Specify documents that are not considered as "Audit Criteria", i.e. a non-opposable document that may not be directly referenced in a nonconformity. These may include guidance documents or other interpretative documents, recognized standards, scheme certification rules or the manufacturer's quality management system's documentation.

Section 4 Certification Holder and Multi-site Organization

Form field	Guidance
Certification Holder	Identify the certification holder. If the audited facility is not a certification holder, enter the certification holder information.
Campus	Indicate if the audited facility is part of a campus including buildings at different addresses that were also visited during the audit. If yes, specify the campus building names and addresses. Note: in case the audited facility is listed as a campus in REPs but the audit team did not audit the activities at all the campus addresses, then only specify the campus addresses whose activities were audited.
Related facilities included in the scope of certification	Indicate if the scope of certification covers facilities other than the Audited Facility. If yes, specify the related facility name, address and MDSAP facility ID as follows: - If the audited facility is the certification holder, list all the other facilities in the scope of certification. - If the audited facility is not the certification holder, only list the other facilities included in the scope of certification. See example below*

Corporate Information	Organization information should be clarified in cases where a manufacturer has multiple names or identities. This clarification also extends to relevant relationships with sister, parent, and daughter companies, including subsidiaries, acquisitions, business units, and joint ventures under the scope of the QMS, audit program, or certification. When preparing this section, auditors should be mindful to frame the explanation in the context of the QMS being audited and its associated scope of activities and devices. Note: refrain from copying the promotional language from the organization's website.

* For example, if a certified organization includes 3 facilities A (certification holder), B (a campus with 2 addresses B1 – main campus address - and B2) and C, then the audit reports would list the facilities as follows:

Audited facility	A	B	C
Section 2:	A	B1	C
Certification Holder	Yes	No: A	No: A
Campus	No	Yes: B1 + B2	No
Related facilities	Yes: B1+C	Yes: C	Yes: B1

Section 5 Audit Objectives

Form field	Guidance
Audit Objectives	List all the objectives applicable to the audit. The field in the audit report form includes some template language based on baseline objectives of initial, surveillance or recertification audits from MDSAP AU P0019. That language should be adapted to the specifics of the audit. Additional objectives could include, for example, the follow-up of past nonconformities, if applicable.

Section 6 Audited Facility Description

1. Fields relative to Regulatory Roles played by the Audited Facility, considered in the scope of the audit

Form field	Guidance
MDSAP jurisdictions	Select all regulatory roles assumed by the audited facility in the context of each jurisdiction. This information should be coherent with the publicly available information from each Regulatory Authority related to the facility's device marketing authorizations and registration. Note: the definition of these terms vary depending on the jurisdiction. The form displays these definition when hovering each term. Note: if the audit reveals inconsistencies between the roles assumed by the audited facility and what the device marketing authorizations and facility registration suggest, this should be documented in section 11.2 of the audit report.
Europe	Select all regulatory roles played by the audited facility.
Other	Specify any regulatory roles assumed under other audit scheme and, as deemed necessary, any additional useful information to understand the other regulatory roles assumed in the context of MDSAP. For instance, an audited facility located in Canada could be the manufacturer of some medical devices and act as regulatory correspondent for other devices manufactured by another organization.

2. Activities at the Audited Facility (at each address of a campus, as applicable)

Form field	Guidance

(List of Activities)	Select all activities implemented at the audited facility and relevant to the scope of the scope of certification.
Other, specify	Any additional useful information to understand the activities included in the scope of the audit /certification at the auditing facility.
Medical device activities taking place at the audited facility's address that are not included in the Scope of Certification	Select whether there are any such activities, and if so, specify what they are and any additional useful information to understand why they are not included in the scope of certification.
Number of staff	Total number of staff affiliated to the audited facility and involved in the scope of certification, regardless whether usually working at the audited facility or at a remote location.
Number of shifts	Total number of shifts applies to the audited facility.
Attach the list of medical devices relevant to each address, including for each jurisdiction the class and the marketing authorization number	For any MDSAP audit including Brazil or Japan jurisdictions, the report must include a list with the name of the medical devices with their respective risk class and registration number at ANVISA and MHLW. This list may be included in a document attached to the report (see section 17 below). In the context of a multi-facility organization or a campus, that list should specify which facility or address are involved in the design and manufacture of the listed devices.

Section 7 Critical Suppliers

Form field	Guidance
Not Applicable	Select the box if no critical supplier applies in the context of the audit, considering the devices and processes taking place at the audited facility
Check if Critical Supplier List is Attached	As an alternative to entering data for every critical supplier, the audit team may attach a list of critical suppliers to the report. Such a list must include at least the information required by section 7.

Organization, Address	Specify the legal name and the physical address of the Critical Supplier. If the Critical Supplier operates several facilities, the information included in this section should correspond to the facility directly involved in the provision of the purchased products or services to the audited facility.
Products or Services used in Audited Processes	Specify the products or services obtained from the external source relevant in the context of the audit.
Check if the supplier was visited jointly with the Audited Facility	If checked, record the outcome of the audit of the activities at the supplier in section 11.7A. Note: if the critical supplier is audited at a distant time from the audit of the manufacturer, then the report needs to identify the manufacturer in section 2, the audit type as Special in section 3, the audit objectives specific to the audit at the supplier in section 5, the visited supplier in section 7, and the outcome of the audit in section 11.7A. Sections 4, 6, 8, 9 and 10 may be left blank, as well as all parts of section 11 other than 11.7A. Other sections are to be completed as usual and as relevant to the specifics of the audit.

Section 8 Audit History

IMDRF/MDSAP WG/N3 (2nd Edition specifies in section 9.4.3 that findings from any audit, (“mock audits,” “gap audits,” or “pre-assessment audits” outside of the scope of Stage 1/Stage 2 audits), shall be documented and taken into consideration when grading nonconformities identified at a subsequent regulatory audit. This includes any audit performed under a different medical device certification scheme. If a manufacturer is audited for the first time under the MDSAP but was already audited under the CMDCAS program or other ISO 13485 or regulatory program, then this should be included.

In case of the initial audit under a particular scheme of a facility that was already audited under other schemes before, specify the audit history under these other scheme.

In the case of an audit following the transfer from one auditing organization to another, include the history of audits performed by the previous auditing organization.

After the initial MDSAP audit, the audit history should include the audits of the on-going audit cycle, as well as external medical device audits of the audited facility since the last MDSAP audit.

Form field	Guidance
Not Applicable (no prior audit)	Self explanatory
Audit Date, Report Reference and Type	Specify information necessary to identify and locate the corresponding audit reports.
Summary of Findings from Prior Audits Listed Above	Summarizes the conclusions and nonconformities of all prior audits.

Section 9 Exclusion and Non-Applications of requirements in the QMS

Form field	Guidance
Exclusion and Non-Applications	Exclusions are the requirements from ISO 13485 – in particular relative to the design of the medical device – that are applicable to the product but may be excluded as authorized by the applicable regulations. <u>Note:</u> the Brazilian regulations do not authorize the exclusion of “design and development” from the scope of the quality management system. Non-Applications are the requirements from ISO 13485 that are irrelevant to the products in the scope of the audit program at the facility. <u>Note:</u> It is not necessary to mention non-applicable regulatory requirements. By definition, regulatory requirements may not be excluded.

Section 10 Outcome of Pre-Audit Activities

Form field	Guidance
Check if Documentation of Pre-Audit Activities is Attached	As an alternative to duplication of information from a separate report, the Pre-Audit report may be attached to this audit report. This especially applies to Stage 1 reports.
Outcome of Pre-Audit Activities	Pre-Audit activities include off-site documentation review. Indicate when this off-site documentation review took place and summarize any identified concerns. Reports of initial audits should include the results of the Stage 1 audit (e.g. documented findings, audit report, etc.). When elements of Stage 1 and Stage 2 audits are combined during a single on-site audit of the manufacturer, the report should include a statement that all Stage 1 and Stage 2 requirements were audited.

Section 11 Audit Findings

This section will record the information specified in section 2.3.3 of the document MDSAP AU P0019 MDSAP Medical Device Regulatory Audit Reports.

1. Fields applicable to every MDSAP audit approach processes

   Section 11.1 – Process: Management
   Section 11.2 – Process: Device Marketing Authorization and Facility Registration
   Section 11.3 – Process: Measurement, Analysis and Improvement
   Section 11.4 – Process: Medical Device Adverse Events and Advisory Notices Reporting
   Section 11.5 – Process: Design and Development
   Section 11.6 – Process: Production and Service Controls
   Section 11.7 – Process: Purchasing

Form field	Guidance
Completed Audit Tasks	Select one, several or all audit tasks from the selected process.

	Note: if a planned task could not be completed, this task should not be selected (see also section 13 – Significant deviation from the audit plan – below).
Description of the Audited Process or Activity, and Area (physical or organizational)	Refer to MDSAP AU P0019 Medical Device Regulatory Audit Reports Policy, section 2.3.3– for details. The information in this field should be organized in order to facilitate review. In particular it is recommended to use the following [makers] that serve both as visual cue and facilitate the word search: - **[NC]**: for information relative to an identified nonconformity; - **[NC previously identified by the manufacturer]**: when the audit team identifies a nonconformity previously identified by the manufacturer, that is under an appropriate process of remediation, but should be reviewed during a future audit (and an NC is not to be issued); - **[Note]**: for any finding of significance, that was not a nonconformity but is worth considering. This could include areas that would necessitate further investigation during a subsequent audit; - [Change]: to provide details on observed changes. Note: The details of nonconformities, including their Context and Significance must be recorded in the NGE form and is duplicated in section 12 of the audit report, Therefore the reference of the nonconformity can suffice in this section.
Major Changes Observed?	Indicate if the selected process and tasks were subject to major changes since the last audit. If there was no prior audit history, the report should not identify any process as changed.

Key Documents Reviewed related to this Specific Process or Task	Including procedures, work instructions, etc.
Names and Titles of Persons Interviewed	Self-explanatory
Nonconformity?	Indicates whether the completion of the selected process and task(s) triggered the identification of nonconformities. If "yes", reference field become visible.
Concluding Statement regarding whether the Activity or Process under Audit is in Conformity with the Audit Criteria	Self-explanatory

2. Additional fields applicable to Section 11.2 – Process: Device marketing Authorization and Facility Registration

Form field	Guidance
Technical Documentation sampled and outcome of their evaluation	Self-explanatory
Check if evaluation document attached	As an alternative to recording the outcome of the evaluation of technical documentations in the form, a separate record may be attached to the audit report.

3. Additional fields applicable to Section 11.5 – Process: Design and development

Form field	Guidance
Selected design file and rationale for the selection	Refer to MDSAP AU P0002 Audit Approach, Task 2

4. Additional fields applicable to Section 11.6 – Process: Production and Service Controls

Form field	Guidance

Selected Production and Service Processes and Rationale for their selection	Refer to MDSAP AU P0002 Audit Approach, Task 2

5. Additional fields applicable to Section 11.7 – Process: Purchasing

Form field	Guidance
Selected Supplier File and Rationale for the selection	Refer to MDSAP AU P0002 Audit Approach, Task 2

6. Section 11A - Process: Purchasing - Annex: Findings at suppliers audited as part of this audit

   This is specifically to record the findings from the part of the audit performed at a supplier of the activities performed by that supplier as part of the scope of certification of the audited facility. (See additional also the information related to Section 7 above).

7. Section 11.8 – Other Findings

Form field	Guidance
Findings relative to requirements specific to certification schemes other than MDSAP	Refer to requirements from those certification schemes, as applicable

Section 12 Nonconformities

This section of the report duplicates the information on nonconformities from the present audit. It must be imported from the nonconformity grading and exchange (NGE) form by clicking the button [Import Nonconformity Information] and selecting the XML data file generated from within the completed NGE form.
Note : The follow-up of past nonconformities it=s to be recorded in section 14 of the audit report form, Even in the context of a special audit to follow-up on nonconformities.

Section 13 Significant Deviations from the Audit Plan, Obstacles and Unresolved Diverging Opinions

Form field	Guidance
Significant Deviations	State any significant deviations between planned and actual audit activities (e.g. in the order or duration of the audited topics). This includes any change agreed upon during the opening meeting or thereafter. Note: the audit plan must be attached to the audit report. This attachment must be the plan that was provided to the organization prior to the audit. The audit plan may be annotated though to reflect the changes, as appropriate.
Duration of the Audit (in auditor-days) Planned	Planned on-site duration in man-days of the audit.
Duration of the Audit (in auditor-days) Actual	Actual on-site duration in man-days of the audit. The man-day count must only take into account the on-site audit time of auditors (including lead auditor) and technical experts on the audit team.
Obstacles, including any unresolved diverging opinion between the audit team and the audited facility's representatives	Record all situations encountered that have the potential to impact the validity of the audit conclusions. Such as, instances where the audited organization refused to provide auditor-requested information, or the audited organization refused to grant the auditor(s) access to premises to conduct the audit.

Section 14 Follow-up of Past Nonconformities

This section is applicable when any nonconformities identified under the current audit scheme during a previous audit by the auditing organization - or in the context of a transfer of certification, by the previous auditing organization - and for which the verification of effectiveness of the corrective actions had not been verified during the last audit. This would include any nonconformity from the last audit and any nonconformities from an earlier audit that had been left open. That would also include any records of NC previously identified by the manufacturer in the MDSAP AU F0019.2 NC Grading and Exchange Form from prior audits, and requiring follow-up during this

audit (Note: in the form, such an NC would have a grade between parentheses and a status as “Monitoring”).

Form field	Guidance
Not Applicable	- Select if none of the conditions above apply Note: any nonconformity for which the remediation action effectiveness has not been verified is an open nonconformity.
Reference of the Nonconformity	Specify the unique nonconformity report identifier or the information necessary to uniquely identify the nonconformity. (e.g., Audit Report number + NC #) For nonconformities previously identified by the manufacturer, and not recorded in the *MDSAP AU F0019.2 NC Grading and Exchange (NGE) Form*, create a reference using the Audit Report number + report page where the audit finding was described.
Status of the Nonconformity	As an outcome of a follow-up audit (i.e. next surveillance, recertification, special or unannounced audit), a *Nonconformity Report* from a prior audit may either be: - *Closed*, meaning that the effectiveness of the remediation plan was verified; or - *Left open*, when the correction and corrective actions have been implemented as planned but the effectiveness of these actions could not be verified for a legitimate reason, provided no new occurrences of the same nonconformity have been experienced; or - *Superseded* by a *new Nonconformity Report*, in all other situations. A nonconformity left open should not be copied into the current audit’s Nonconformity Grading and Exchange (NGE) form.

	As a result, the auditing organization must keep track of the NGE forms that include nonconformities that were not closed as more than one could need their review. For nonconformities previously identified by the manufacturer, where NC was not identified in the previous audit, use the status “Superseded by a new Nonconformity Report”, if a NC was issued because the NC is still present at the following audit.
Reference of New Superseding Nonconformity, if Applicable	Specify the unique report identifier or the information necessary to uniquely identify the new nonconformity issued when a past nonconformity can neither be closed nor left open. A nonconformity superseding a previous one must be listed in the current audit’s NGE form.
Check if any record of the follow-up of past nonconformities is attached (using NGE form or any other form)	In particular, if the NGE form had been used during the previous audits, it is recommended to update it to reflect the current status of the nonconformities and attach it to the report
Additional Comments	May include a rationale for the status of past nonconformities.

Section 15 Summary of Major Changes to Audited Facility

Form field	Guidance
Summary of Major Changes	Includes major changes to products or processes, changes to the organizational structure or ownership, changes to key personnel and facilities and to the QMS as a whole. The description of these changes should include an assessment of whether regulatory requirements have been satisfied, or continue to be satisfied, and whether required regulatory submissions were made when necessary.

	Changes commented in Section 11 do not need to be duplicated in this section.

Section 16 Conclusions

Form field	Guidance
Total # of Open Nonconformities (NC)	Sum of the following two fields (# of NCs from Past Audits Left Open and # of NC Issued During this Audit).
Including # of NCs from Past Audits Left Open	Number of nonconformities identified during prior audit for which the remediation plan actions were implemented but their effectiveness could not be verified for a legitimate reason; and there has been no recurrence of the nonconformity since these actions' implementation.
# of NC Issued During this Audit	Number of new nonconformities, including nonconformities superseding a nonconformity from a previous audit. This number of new nonconformities equals the number of nonconformities listed in the nonconformity grading and exchange form and in section 12 of the report, minus any nonconformities marked as previously identified by the manufacturer (whose grade in displayed between parentheses). Note: the grading of such a re-issued nonconformity must consider it as a "repeat" nonconformity.
Conformity with Audit Criteria	Statement on the level of confidence in the ability of the Quality Management System to meet all the requirements from the audit criteria. (including ISO 13485 and the applicable regulations)
Effectiveness of the QMS in meeting Quality Objectives	Statement on the level of confidence in the ability of the Quality Management System to meet the set quality objectives.
Achievement of Audit Objectives	Statement on whether the audit team completed the specified objectives, regardless of whether the two preceding statements are favorable or unfavorable.

Factors Encountered that may affect the Audit Reliability	Any situational element that may not have enabled the auditor to investigate as deeply as intended.
Recommendations on *- Certification Status,* *- Follow-up Actions,* *- Audit Program,* *- Audit Team Competence, and* *- Audit Duration*	Such recommendations may be provisional, pending the review of the remediation plan. In such case, the statement should mention the provisional status and rationale. *Recommendations on Certification Status* may indicate, according to the audit team certification documents to be issued, withheld, renewed, amended, extended, restricted, suspended, or revoked. *Recommendations on Follow-up Actions* may indicate if actions should take place prior to the next audit, beyond the normal post-audit procedure, or appropriate modalities to address concerns identified during the audit. When the audit team identifies a requirement that is not fulfilled and is not recorded in the *MDSAP AU F0019.2 NC Grading and Exchange Form* (i.e. the manufacturer properly identified and recorded the nonconformity, it is under a process of an appropriate remediation and it was graded as 1, 2, or 3), a brief description about this audit finding is recommended to be included under this topic, at audit team discretion. *Recommendations on Audit Program* may indicate if the amendments should be considered for example in term of scope. (For example, are additional facilities to be included?) *Recommendations on Audit Team Competence* may indicate if future audit teams should possess some specific competency to investigate further in some areas and the rationale supporting this recommendation. *Recommendations on Audit Duration* may indicate if future audit durations should be increased or shortened and the rationale supporting this recommendation.

	Note: any recommendation should be substantiated by information in the audit report.

Section 17 Attachments

Form field	Guidance
List of Audit Report Attachments	Attachments may include information generated by the audit team (e.g. audit plan, list of medical devices, MDSAP Nonconformity Grading and Exchange Form, Nonconformity Reports, including Past Nonconformities reviewed during this audit), by the manufacturer (e.g. list of critical suppliers). It may include appendices to record specific information necessary under an applicable certification scheme (e.g. product's technical documentation review checklist). It may also include evidence supporting nonconformity. (Not an exhaustive list). The + and – buttons add or remove rows, when the report includes additional attachments. Important: some rows become visible based on checked boxed in the body of the audit report (e.g. list of medical devices, list of critical suppliers, etc.). Make sure not to reassign these for to specify a different kind of attachment as this may affect the ability to upload the report in REPs. Note: It may not be feasible to generate a single file combining the audit report and the attachments. Even combining the files as a pdf "portfolio" would not enable to submit them in REPs. Each separate attachment file should be explicitly identifiable as pertaining to the audit report (for example, the file name could include the

	reference of the audit report and the attachment number).

Section 18 Audit Report Approval

Form field	Guidance
Lead Auditor Signature	the final version of the audit report should be signed by the lead auditor, as a confirmation that the content of the report accurately records the audit. Note: the lead auditor's signature does not lock the report and can be applied after the report is signed by the approver.
Report Approver Name and Title	The final version of the report should be approved by the Auditing Organization, by an individual independent from the authors of the report.
Report Approver Signature	This button disables all the fields and time-stamps the approval so that the report may not be modified after it is approved. Reports shared with the Regulatory Authorities must be approved. The same version of the report must be provided to the manufacturer. If the report must be revised after it was signed, the signature field must be cleared by the individual who approved it. In case a change is necessary after its submission in REPs, the Auditing Organization should issue an “Amending memorandum” amending the report. Any amending memorandum relative to a report previously shared with the Regulatory Authorities must be provided to the Regulatory Authorities along with the revised audit report. See additional details in MDSAP AU P0029.

Reference Documents

MDSAP AU P0019 MDSAP Medical Device Regulatory Audit Reports Policy
MDSAP AU F0019.1 Medical Device Regulatory Audit Report Form

Document History

Guidance Document Title: Medical Device Regulatory Audit Report Form Guidelines
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VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/ PROJECT MANAGER
001	2014-06-04	Initial Release	Marc-Henri Winter, FDA
002	2015-01-09	Clarification that the form must be used with Adobe Acrobat or Adobe Reader	Marc-Henri Winter, FDA
003	2015-09-22	On page 5; Japan was added to the countries that need a list with the name of the medical devices with their respective risk class and registration number. The following sections were updated to clarify how to report on nonconformity independently identified by the audit team, but previously identified by the manufacturer: Pages 11-12 – Section 11. Audit findings – *Description of the Audited Process or Activity, and Area (physical or organizational)* Pages 14-15 – Section 14 Follow-up of Past Nonconformities - *Not Applicable / Reference of the Nonconformity / Status of the Nonconformity* Pages 16-17 – Section 16 Conclusions - *Recommendations (…)*	Liliane Brown, FDA
004	2016-06-07	Page 2: replaced “YYYY-MM-DD is the Audit Ending Date” by “YYYY-MM-DD is the Audit Starting Date”	Marc-Henri Winter, FDA
005	2016-08-15	Page 9: added:…” IMDRF/MDSAP WG/N3 specifies in Edition 1(section 9.2.5) and Edition 2 (section 9.4.3) that findings from any audit, (“mock audits,” “gap audits,” or “pre-assessment.…”	Liliane Brown, FDA
006	2018-10-16	Changes were made throughout the document to be aligned with revision 8 of MDSAP AU F0019.1 Medical Device Regulatory Audit Report Form.	Hiromi Kumada, PMDA

VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/ PROJECT MANAGER
		Appendix 1 How to use the report for a non-MDSAP audit was added.	
007	2021-02-08	Section 2 – Audited Facility MDSAP Facility Identifier: DUNS # was replaced with unique identifier generated by REPs. Removed reference to MDSAP AU P0002 Audit Model and MDSAP AU G Companion Document and replaced with MDSAP AU P0002 Audit Approach throughout the document.	Hiromi Kumada, PMDA
008	2024-04-26	Updated to reflect MDSAP AU F0019.1.009, especially with clarifications on: - Functionalities of the form - The use of the form when an audit covers several schemes (i.e. MDSAP and non-MDSAP schemes). - Expectations related to most of the form's fields Removal of Appendix 1 Update formatting for improved accessibility	Marc-Henri Winter, FDA