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).

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

Caution

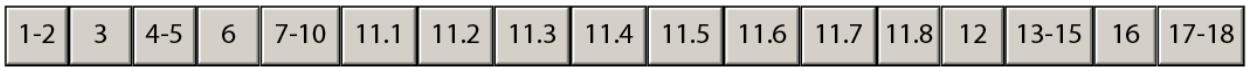
⚠ *This form is likely to lose functionalities or become corrupted if used with PDF processors other that **Adobe Acrobat** or **Adobe Reader**. The form was verified and validated using Adobe Acrobat XI Pro; different versions may exhibit slightly different behaviors".*

MDSAP vs. 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 other than those 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. See Appendix 1 for information on how to use the report for a non-MDSAP audit.

Navigation of the Form

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.



Content of the Report, Section by Section

Header

The header displays the following information:

- Audited facility
- Both the MDSAP and the Auditing Organization's audit report references

- The Audit start and end dates

Section 1 Audit Information

Auditing Organization	Select the name of the Auditing Organization from the dropdown list. See Annex 1 in case of non-MDSAP audit.
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
AO Audit Report Ref	This field is used by the Auditing Organization to uniquely identify the audit report in its information system.
Languages Used during the Audit	Language(s) used during the audit activities.
Audit Team	
Team Member	Full name
Role	Select any applicable box (may be multiple)
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

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 name under which it is registered with the Regulatory Authorities.
MDSAP Facility Identifier	Unique identifier (6 digit number) generated by the Regulatory Exchange Platform – secure (REPs).
Address, incl. *Street Address* *Address Details*	

City *Country* *State/Province* *Zip Code*	
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 site audited.
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. Additional jurisdictions and corresponding Facility identification numbers can be added in the Other Jurisdictions field.

Section 3 Certification Schemes, Scopes & Criteria, Audit Types

Certification Schemes *MDSAP* *CE Marking* *Other*	Check the applicable schemes.
For each Certification Scheme	
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 Initial (or Certification) audit to a Mock audit based on the outcome of the audit. For any type that does not appropriately fit any prior

	designation. When selected, a fillable field will appear describing the audit type.
Scope of certification	Statement of activities and range of devices to appear in a certification document (if issued). When the scope of certification is extensive, it may be included in a document attached to the report.(see section 17 below). If the manufacturer exports products to Brazil and/or Japan, the report must include a list with the name of the medical devices with their respective risk class and registration number at ANVISA and/or MHLW. This list may be included in a document attached to the report (see section 17 below).
Standards	For an MDSAP audit, ISO 13485 should always be selected. Other standards used for audit criteria may also be specified.
Jurisdictions and Medical Device Regulations	Select 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. Jurisdictions that are not pre-listed in the form may be added as an “Other Jurisdiction”. In such a case, the

	relevant Regulation(s) should also be specified.
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, or the manufacturer's quality management system's documentation.

Section 4 Certification Holder and Multi-site Organization

Certification Holder	Identify the certification holder. If the audited facility is not a certification holder, the certification holder should be specified.
Campus	Check 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.
Related sites audited as part of the scope of certification	Check if the scope of certification covers sites other than the Audited Facility. If yes, specify the related site name, address and MDSAP facility ID.
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.

Section 5 Audit Objectives

Audit Objectives	List all the audit objectives. <u>Note:</u> under MDSAP, typical cycle audits (i.e. excluding special audits) should always include the following

	objectives specified in MDSAP AU P0019 MDSAP Medical Device Audit Reports Policy: i. The review of the conformity of the organization's QMS with MDSAP requirements; ii. The review of the compliance with the applicable country specific requirements (recalls, adverse event reports, etc.) of the regulatory authorities participating in the MDSAP. The applicable regulatory requirements should be clearly identified in the objectives; iii. Aspects of product review, including: • Product/process related technologies (e.g. injection molding, the incorporation of a medicine or material of animal origin in a medical device, sterilization); and, • Assuring the availability and maintenance of the evidence of adequate product technical documentation in relation to relevant regulatory requirements.

Section 6 Audited Facility Description

Regulatory Roles played by the Audited Facility, considered in the scope of audit	
Europe	Select all regulatory roles played by the audited facility.
Other	Any additional useful information to understand the activities included in the scope of audit/certification at the audited facility.
Activities at the Audited Facility	
(List of Activities)	Select all activities implemented by the audited facility applicable to the products within the scope of the audit or 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.
Activities taking place at that address that are not included in the Scope of	Any additional useful information to understand the activities not included in the scope of the audit /certification at the auditing facility.

Certification	
Number of staff	Total number of staff affiliated to the audited facility and involved in the scope of the Audit Program, 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.
Number of staff working in shifts	Specify the number of staff working in shifts.

Section 7 Critical Suppliers

Not Applicable	Select the box if no critical supplier applies in the context of the audit.
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	

Section 8 Audit History

Not Applicable (no prior audit)	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. 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.
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

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

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

Introduction This section will record the information specified in section 2.3.3 of the document MDSAP AU P0019 MDSAP Medical Device Regulatory Audit Reports.	
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	
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: - Detailed information providing the context of a nonconformity should be preceded by “NC:”; - When the audit team identifies a nonconformity previously identified by the manufacturer, that is under

	an appropriate process of remediation, and an NC is not to be issued, information about this finding should be provided and preceded by the words: "NC previously identified by the manufacturer:". - Observations should be preceded by "Observation:"; - Information on changes should be preceded by "Change:"
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
Section 11.2 – Process: Device marketing Authorization and Facility Registration	
Technical Documentation sampled and outcome of their evaluation	Self-explanatory
Check if evaluation document attached	
Section 11.5 – Process: Design and development	
Selected design file and rationale for the selection	Refer to MDSAP AU P0002 Audit Approach, Task 2
Section 11.6 – Process: Production and Service Controls	
Selected Production and	Refer to MDSAP AU P0002 Audit Approach, Task 2

Service Processes and Rationale for their selection	
Section 11.7 – Process: Purchasing	
Selected Supplier File and Rationale for the selection	Refer to MDSAP AU P0002 Audit Approach, Task 2
Section 11.8 – Other Findings	
Findings relative to requirements specific to certification schemes other than MDSAP	Self-explanatory

Section 12 Nonconformities

NC Ref #	This may be either the full nonconformity record identifier, or the order number of the nonconformity, or a combination of both. The nonconformity reference # should be unambiguous.
Statement of Nonconformity/Supporting Evidence	This may duplicate or summarize the detailed statement of nonconformity from the nonconformity report. Any nonconformity in the audit report must also be documented in the MDSAP Nonconformity Grading and Exchange Form (MDSAP AU F0019.2) and on the AO's nonconformity report form, unless it is not raised against any MDSAP audit criterion.
ISO 13485	The clause of ISO13485 against which the nonconformity is raised.
Grade	The grade is determined using the MDSAP Nonconformity Grading and Exchange Form (MDSAP AU F0019.2)

Section 13 Significant Deviations from the Audit Plan

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	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

Not Applicable	Select if: - there were no open nonconformities from prior audits requiring follow-up during this audit; - there were no 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 (i.e. the manufacturer properly identified and recorded nonconformity, there was an appropriate process of remediation and they were grade 4, or grade 5, NC); - there were no records of audit finding requiring future verification of implementation and effectiveness in the report from a prior audit requiring follow-up during this audit (i.e. even though the manufacturer properly identified and recorded the nonconformity, there was an appropriate process of remediation, and it was graded as 1, 2, or 3).

	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 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. 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.
Additional Comments	May include a rationale for the status of past nonconformities.

Section 15 Summary of Major Changes to Audited Facility

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

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 re-issued nonconformities when the planned remediation actions against a nonconformity from a past audit have not been implemented or are not effective (recurring nonconformity). 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. <u>Note:</u> any recommendation should be substantiated by information in the audit report.

Section 17 Attachments

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). Note: It may not be feasible to generate a single file combining the audit report and the attachments but a pdf "portfolio" can associate several files together. 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

Approver 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.
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. In case a change is necessary after approval, 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.

Reference Documents

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

Document History

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. Appendix 1 How to use the report for a non-MDSAP audit was added.	Hiromi Kumada, PMDA
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

Appendix 1 How to use the report for a non-MDSAP audit

1. The form includes 2 fields to designate the Auditing Organization, only one being visible at a time. By default, the visible field is the dropdown list of MDSAP AOs. For a non-MDSAP audit, select the last option in the dropdown list: “Not an MDSAP Auditing Organization, or not an MDSAP Audit”. The field is replaced by a new editable dropdown list in which the user can either type the name of the Auditing Organization, or “select from the list of MDSAP Auditing Organizations” if the audit is performed under MDSAP.
   Note: The user must type the name of the Auditing Organization in any case of non-MDSAP audit, regardless whether the Auditing Organization is recognized under MDSAP.
2. When the option “Not an MDSAP Auditing Organization, or not an MDSAP Audit” is selected, the following happens:
   a. The form displays an orange message prominently indicating that “The audit report uses a form developed for MDSAP, however the audit was not performed under MDSAP”
   b. The header only shows the Auditing Organization’s Audit Report Reference
   c. In section 3 – *Certification Schemes, Scopes and Criteria, Audit Types* – the subsection on MDSAP is hidden

Note: in section 3, checking the MDSAP Not Applicable check box has the same effect as selecting “Not an MDSAP Auditing Organization, or not an MDSAP Audit” as described above, and places the cursor on the Auditing Organization field.