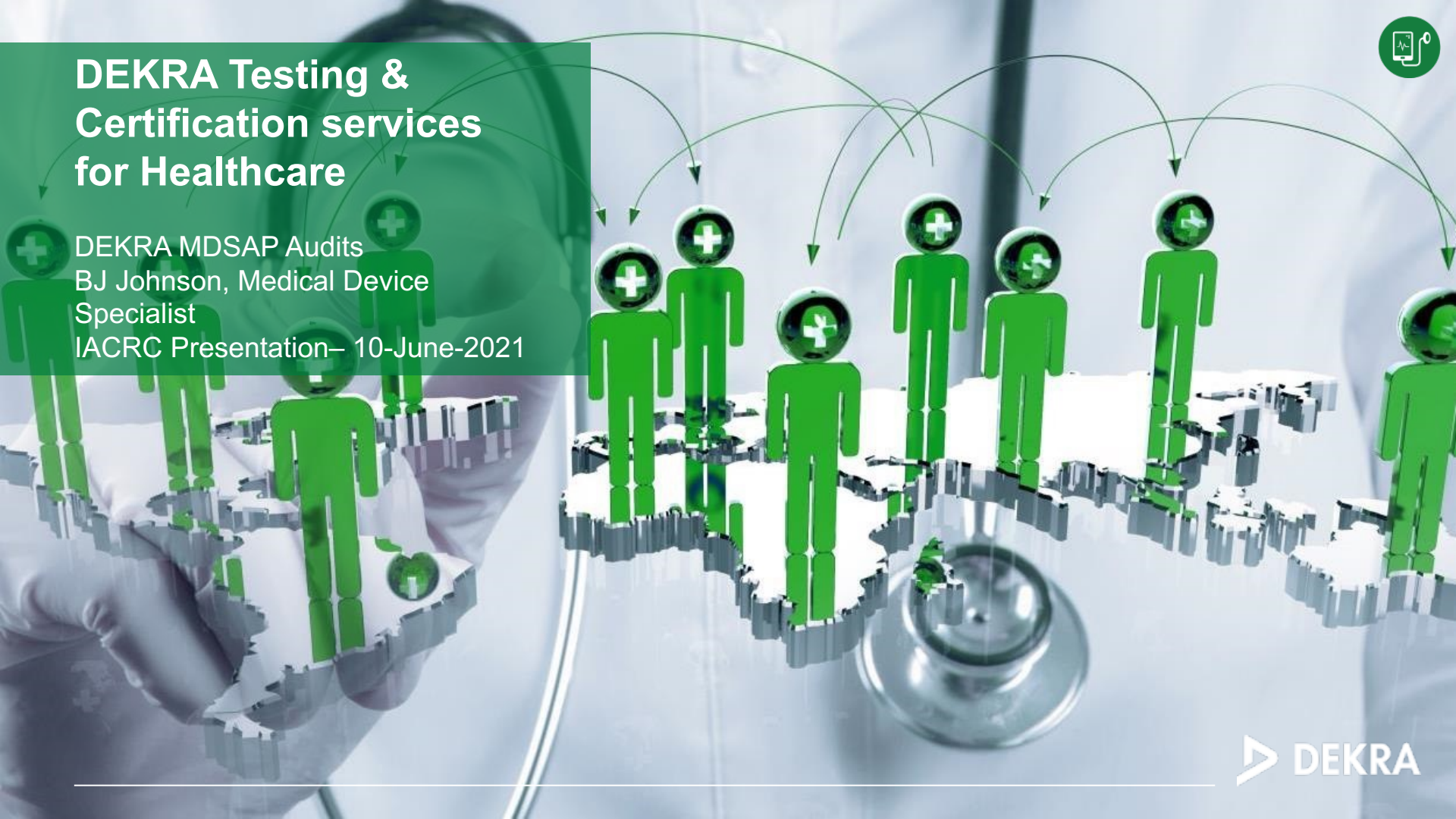

DEKRA Testing & Certification services for Healthcare

DEKRA MDSAP Audits
BJ Johnson, Medical Device Specialist
IACRC Presentation– 10-June-2021

DEKRA

Agenda

1. MDSAP Audits and Audit Cycle
2. MDSAP Audit Planning
3. MDSAP Audit Agenda
4. Conducting the Audit
5. MDSAP Audit Report
6. Recording of MDSAP Non-Conformities
7. Follow-up of MDSAP Non-Conformities
8. MDSAP Post Audit Processing
9. MDSAP Training and Auditors Code of Conduct

MDSAP Audits and Audit Cycle

Learning Objectives

- To see how an Auditing Organization (AO) conducts MDSAP Audits

MDSAP Audits and Audit Cycle

MDSAP Audit Cycle:

The Medical Device Single Audit Program is based on a three (3) year audit cycle.

- The Initial Audit
- Surveillance Audit
- Re-audit

MDSAP Audits and Audit Cycle

MDSAP Audit Cycle:

The Medical Device Single Audit Program is based on a three (3) year audit cycle.

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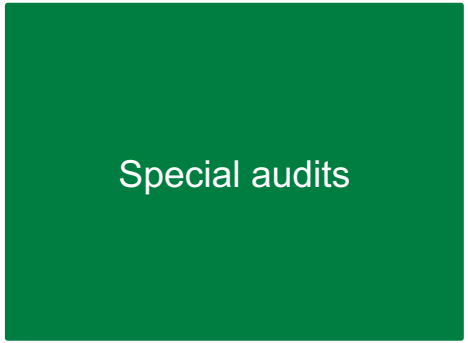
- Re-audit



MDSAP Audits and Audit Cycle

Initial Audit (Initial Certification Audit):

- Stage 1 – Documentation Review, Evaluation of Preparedness for Stage 2 Audit, etc.

Stage 2 – Evaluation of QMS Implementation and Effectiveness:

- A Stage 2 audit shall be conducted in accordance with ISO/IEC 17021 and all applicable MDSAP Audit process tasks.

Surveillance Audits:

- Surveillance Audits shall be conducted in accordance with ISO/IEC 17021 and all applicable MDSAP Audit Process tasks.

MDSAP Audits and Audit Cycle

Surveillance Audits (continued):

- *Surveillance audits do not need to cover all MDSAP requirements;* a surveillance audit must address the following (as applicable):
  - i) A review of changes to the manufacturer, QMS, or products since the previous audit (changes may necessitate regulatory submissions)
  - ii) MDSAP Audit Process tasks associated with the:
    - Management Process
    - Measurement, Analysis, and Improvement Process
    - Medical Device Adverse Event and Advisory Notice Reporting Process
    - Device Marketing Authorization and Facility Registration Process To include confirmation that marketing authorization of products remains in effect.
    - Design and Development Process

MDSAP Audits and Audit Cycle

Surveillance Audits (continued):

- If the first surveillance audit includes the Design and Development Process, the second surveillance should include the Production and Service Controls Process (or vice-versa) unless further indicators of existing or potential nonconformities dictate otherwise.
- The Purchasing Process should be audited as necessary during the audit of the other QMS processes.

Recertification Audits:

- A Recertification Audit shall be conducted in accordance with ISO/ IEC 17021 and all applicable MDSAP Audit Process tasks.

MDSAP Audits and Audit Cycle

Recertification Audits (continued):

- The purposes of a recertification audit are to
  1. evaluate the continued effectiveness and suitability of the organization's QMS (as a whole) to satisfy all applicable QMS requirements of ISO 13485 and all other applicable MDSAP requirements; and,
  2. confirm the continued relevance and applicability of the organization's QMS with respect to the scope of certification and/or MDSAP specific requirements.

- Recertification audits can be shorter than initial audits through more selective and focused sampling.

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MDSAP Audits and Audit Cycle

Recertification Audits (continued):

- Recertification audits will address the following (as applicable):
  - i) A review of the MDSAP audit reports for the current audit cycle (i.e. back to the last initial audit or re-audit)
  - ii) A review of changes to the manufacturer, QMS, or products since the previous surveillance audit
  - iii) A follow up of corrections and/or corrective actions stemming from findings of the previous surveillance audit (and/or other MDSAP audit conducted since the previous surveillance audit)
  - iv) A review of the effectiveness and suitability of the manufacturer's QMS over the current audit cycle
  - v) All applicable MDSAP Audit Process tasks. The audit of the processes and the sampling should focus on the following (based on risk):
    - a) Identified past potential and existing nonconformities
    - b) New/modified designs and new products
    - c) New/modified processes
    - d) Areas not sufficiently covered during the surveillance period

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MDSAP Audit Planning – Test Plan

The Test Plan includes:

MDSAP Audit Planning – Test Plan

The Test Plan includes:

Client identification and locations, Facility Identification #

MDSAP Audit Planning – Test Plan

The Test Plan includes:

Client identification and locations, Facility Identification #

Qualification of the product as a medical device and its classification

MDSAP Audit Planning – Test Plan

The Test Plan includes:

Client identification and locations, Facility Identification #

Qualification of the product as a medical device and its classification

Qualified audit team members *and* product review expertise necessary

MDSAP Audit Planning – Test Plan

The Test Plan includes:

- Client identification and locations, Facility Identification #
- Qualification of the product as a medical device and its classification
- Qualified audit team members *and* product review expertise necessary
- Should include assessment of completeness of the QMS documentation

MDSAP Audit Planning – Test Plan

The Test Plan includes:

- Client identification and locations, Facility Identification #
- Qualification of the product as a medical device and its classification
- Qualified audit team members *and* product review expertise necessary
- Should include assessment of completeness of the QMS documentation
- Language of the audit

MDSAP Audit Planning – Test Plan

The Test Plan includes:

- Client identification and locations, Facility Identification #
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- Should include assessment of completeness of the QMS documentation
- Language of the audit
- Terms of the agreement with the manufacturer

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MDSAP Audit Planning – Test Plan

The Test Plan includes:

- Client identification and locations, Facility Identification #
- Qualification of the product as a medical device and its classification
- Qualified audit team members *and* product review expertise necessary
- Should include assessment of completeness of the QMS documentation
- Language of the audit
- Terms of the agreement with the manufacturer
- Sites of the manufacturer or their supplier(s) that will be audited.

MDSAP Audit Planning – Test Plan

The Test Plan includes:

Client identification and locations, Facility Identification #	Qualification of the product as a medical device and its classification	Qualified audit team members *and* product review expertise necessary	Should include assessment of completeness of the QMS documentation
Language of the audit	Terms of the agreement with the manufacturer	Sites of the manufacturer or their supplier(s) that will be audited.	Audit days, justifications and MDSAP Audit time calculation spreadsheet

MDSAP Audit Planning – Test Plan

The Test Plan includes:

- Client identification and locations, Facility Identification #
- Qualification of the product as a medical device and its classification
- Qualified audit team members *and* product review expertise necessary
- Should include assessment of completeness of the QMS documentation
- Language of the audit
- Terms of the agreement with the manufacturer
- Sites of the manufacturer or their supplier(s) that will be audited.
- Audit days, justifications and MDSAP Audit time calculation spreadsheet
- Test plan peer reviewed and approval for MDSAP Audits

MDSAP Audit Planning – Audit Time Calculations

MDSAP audit time is based on the tasks to be performed for each audit process.

- The number of audit tasks accomplished during the audit of a medical device manufacturer will vary depending on the type of audit performed *and* the specific activities performed by the organization.
- Audit time can be adjusted based on:
  - Number of sites
  - Number of employees
  - Tasks that will not be performed, such as installation and servicing
  - Tasks that need duplication, such as Chapter 2 - Device Marketing Authorization and Facility Registration, when multiple countries are in scope
  - Complex operations such as on-site sterilization.

MDSAP Audit Planning – Audit Time Calculations

Adjustments based on Multiple Site Audits:

- When multiple site audits are conducted, the audit time necessary to conduct the audit of each individual site must be calculated separately.
- The total audit time is the cumulative audit time necessary to audit each individual site.
- Multiple site audits may require the duplication of audit tasks at each of the sites. Conversely, multiple sites may not have the same responsibilities and processes. Individual site audit time should be calculated based on the specific responsibilities and processes of that site.
- Sampling of design and manufacturing sites is not permitted. Sites must be audited for the activities being performed

MDSAP Audit Planning – Audit Time Calculations

Adjustments based on organization size:

- All considerations affecting audit time calculations should be described in the recorded justification supporting the audit time determination.
- DEKRA has to maintain documented evidence of the calculations (and other justifications) used to determine the audit time for each audit.

MDSAP Audit Planning – Audit Time Calculation example

MDSAP Audit Planning – Audit Time Calculation example

- IAF MD 9 indicates 7.5 days for recertification
- Adjustments (-15%, no production on-site) = 6.5 days.
- MDSAP audit time calculation 6.5 days represents 100% on-site audit time (for all tasks to be performed).

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MDSAP Audit Agenda

- Audit Agendas are created based on the type of audit (initial, surveillance, recertification) and the amount of time derived from the Audit Time Calculation Sheet
- The Agenda will notate what standards and regulations are applicable to the audit
  - CE, ISO, MDSAP
- Each applicable MDSAP country will be noted
- Task numbers will be noted on each item to assure tracking of the required tasks
- If the audit is completed for other country specific regulations, such as CE, the audit topics that are shared will be noted together on the agenda, if specific items are required, they will have a topic added to the agenda.

MDSAP Audit Agenda

MDSAP Agenda:

Agenda:

Process Activities	Auditor	Auditor	Time planning
Day 1: June 7, 2021			
Opening meeting, introduction, finalize agenda	#1	#2	09:00
Certification update/Management System Dynamics • Changes in the organization; • Changes to quality management system documents; • Changes to subcontractors, certification status; • Changes to products, additions/deletions to products offered; • Use of Certification Marks and other references to certification • Updates to CN (including latest DoC's) • Status of the audit matrix; • Future projects/products/changes;	#1		09:30
Management Processes (Tasks 1 - 6)		#2	09:30
Management Processes (Tasks 7 - 8)	#1		10:30
Lunch			12:00
Management Processes (Tasks 9 & 11)		#2	12:30

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Conducting the MDSAP Audit

Audit Process:

- Auditors will follow the MDSAP Audit Approach – MDSAP AU P0005 002
  - Audit Tasks will be completed by review of documents and viewing of personnel doing their work
  - Tasks are not required to be in order of their number
- Questions may be used directly from the document or asked in a different way by the auditor
- All tasks required by the agenda will be completed by the end of the audit
- If there are 2 auditors, there are some tasks that may be completed concurrently rather than in order
- Country Specific regulations will be covered under the task in which it is located.
  - Example, Management Task 8 – Documents and Records Control, has an addition for Brazil to verify that change records include a description of the change, identification of the affected documents, the signature of the approving individual(s), the approval date, and when the change becomes effective [RDC ANVISA 16/2013: 3.1.5].

MDSAP Audit Report

- MDSAP Audit reports are prepared using an online MDSAP Audit report form with form fields.
- Audit report fulfills requirements of GD211.
- 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.

MDSAP Audit Report

- For multi-sites, an audit report for each site audited shall be generated.
- The audit of separate buildings within the same physical campus is not considered a multi-site audit.
- The Audit Report contains 18 Sections:

MDSAP Audit Report

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Medical Device Regulatory Audit Report

My Medical Device Company
2021-06-07-AUR-DEKR-00-000-0000 / 1234567
From 2021-06-07 To 2021-06-09

1-2	3	4-5	6	7-10	11.1	11.2	11.3	11.4	11.5	11.6	11.7	11.8	12	13-15	16	17-18

Section 1. Audit Information

Auditing Organization DEKRA Certification B.V.

Audit Starting Date 2021-06-07 **Audit Ending Date** 2021-06-09 **Duration of Audit** (in auditor-days) 2.5

AO Audit Report Ref 1234567 **Languages used during the audit** English

Audit Team

Team Member BJ Johnson

Role ☒ Lead Auditor ☐ Auditor ☐ Technical Expert ☐ Auditor in training ☐ Observer ☐ Interpreter

Affiliation ◉ AO Employee ○ External Resource:

Section 2. Audited Facility

Name of the Audited Facility **MDSAP Facility Identifier**

My Medical Device Company **00-000-0000**

Street Address

222 Main Street

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MDSAP Audit Report

- The Audit Report contains 18 Sections:
  - Section 1 – Audit Information
  - Section 2 – Audited
  - Section 3 – Certification Schemes, Scopes & Criteria, Audit Types
  - Section 4 – Certification Holder and Multi-site Organization
  - Section 5 – Audit Objectives
  - Section 6 – Audited Facility Description
  - Section 7 – Critical Suppliers
  - Section 8 – Audit History
  - Section 9 – Exclusions and Non-Applications of Requirements in the QMS
  - Section 10 – Outcome of Pre-Audit Activities
  - Section 11 – Audit Findings (This is the main body of the report)
  - Section 12 – Nonconformities
  - Section 13 – Significant Deviations from the Audit Plan
  - Section 14 – Follow-up of Past Nonconformities
  - Section 15 – Summary of Major Changes to Audited Facility
  - Section 16 – Conclusions
  - Section 17 – Attachments
  - Section 18 – Audit Report Approval

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Recording of MDSAP Non-Conformities

- Nonconformities are identified in a separate form within the MDSAP process and then copied into the audit report.
- This form contains an area where the manufacturer can fill in their corrective action plan and another area for documenting the completion of that plan.
- If the audit team identifies a nonconformity previously identified by the manufacturer, that is under an appropriate process of remediation, an NC need not to be issued, information about this finding should be provided and preceded by the words:”NC previously identified by the manufacturer:” in the audit report.
- In addition this should be identified on the Grading and Exchange form and check the box for “The organization detected and properly addressed the NC prior to the audit.”

Recording of MDSAP Non-Conformities

Form optional functionality: inclusion of the audited facility's response to nonconformities ◉ Enabled ○ Disabled

2. Nonconformity Summary

	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Total
Number of NC	**1**	**0**	**1**	**1**	**0**	**3**

NC Ref.	Statement on Nonconformity	ISO 13485 Clause	MDSAP Grade	Status*
[1] AR01/ Major01	Release of product into inventory was not always done after planned arrangements had been completed. Production lot# B20200512 was released into inventory on May 13th, 2020 prior to the release of sterility and LAL test data. The LAL test was dated June 1, 2020 an sterility test report was dated June 5, 2020. SOP 10 requires all test results to be received and passed prior to release of product into inventory. It was verified that results all passed and product was not shipped until August 1, 2020.	8.2.6	4 Major	Not responded
[2] AR01-Minor01	The information gathered in the feedback process does not always serve as potential input into risk management for monitoring and maintaining the product requirements as well as the product realization or improvement processes. Procedure SOP 8.2.2, Rev A, Complaint Handling does not contain a link from complaints to risk management. In addition, complaint files reviewed did not show if risk management documentation was checked for either of those items. Files reviewed include: Complaint 20-22, 20-23, 20-24, 20-25, 21-01, 21-02.	8.2.1	3 Minor	Not responded

x 11.00 in

Follow-up of MDSAP Non-Conformities

NC grade 1 to 3	• Follow up begins at 6 months from the end of the audit.
NC grade 4 and 5	• Nonconformity Reports must be actively updated until the effectiveness of the corrections and corrective actions proposed by the audited facility or organization has been verified.
Initial audit	• There shall be no conclusion that the manufacturer complies with regulatory requirements if there is one or more Grade 5 NCs or more than 2 Grade 4 NCs.

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Follow-up of MDSAP Non-Conformities

An unannounced audit shall occur following any audit that results in:

- One or more nonconformity(s) graded as a “5”; or,
- More than two nonconformities graded as a “4.”

The timing of the unannounced audits should be unpredictable and in addition to the normally scheduled audits.

As a general principle an unannounced audit should be executed by at least two auditors and not take less than one day.

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MDSAP Post Audit Processing

The post audit activities and timelines are as follows:

MDSAP Post Audit Processing

The post audit activities and timelines are as follows:

- D0 + 5 working days
- D0+15 calendar days
- D0+30 calendar days
- D0+45 calendar days
- D0+90 calendar days

MDSAP Post Audit Processing

The Audit Report Package to be shared with the Regulatory Authorities includes:

- The documented Medical Device Regulatory Audit Report form MDSAP AU F0019.1. The audit report provided must be the final version after its technical review by the Auditing Organization;
- Audit Agenda as provided to the client;
- List of critical suppliers (if this information could not be included in the audit report)
- If any nonconformity was issued during the audit, the Nonconformity Grading and Exchange form MDSAP AU F0019.2;

MDSAP Post Audit Processing

The Audit Report Package to be shared with the Regulatory Authorities includes:

- If any nonconformity was issued, or left open during the audit, the Nonconformity Reports issued by AO on their corresponding forms, including the remediation plan developed by the manufacturer and the results of the review of this remediation plan by AO.
- The evidence of implementation of corrections and/or corrective actions provided by the manufacturer to remedy any nonconformity grade 4 or 5.
- Upon request from an MDSAP Regulatory Authority, AO is expected to provide updated nonconformity reports within 10 calendar days.
- It is not necessary for Nonconformity reports to be closed at the time they are shared with the Regulatory Authorities.

MDSAP Auditor Training

- DEKRA has a specific training module for MDSAP
- All auditors complete the MDSAP training on the FDA Learning Portal
- Auditors are monitored during training audits and receive feedback on improvements needed.
- A final monitored qualification audit is conducted once all planned training audits are completed.
- Annual training to MDSAP as well as updated upon changes to the systems made by the MDSAP Group.

MDSAP Auditor Code of Conduct

All MDSAP Auditors must sign and abide by the Code of Conduct.

Code of Conduct for MDSAP Auditors / Technical Experts – Main Points

By participating in or acting in any capacity for regulatory audits under the MDSAP, the undersigned person declares the following:

- To act in a professional and ethical manner at all times.
- To faithfully represent the interests of the recognizing Regulatory Authority(s).
- To record and report truthfully and accurately audit evidence in an impartial and unbiased way.
- Not to use information obtained in the course of audits for any personal gain.
- To disclose any relationship, or financial interest, past or present, that may create a conflict of interest, or the appearance of a conflict of interest, and to notify management of any new conflicts of interest or potential conflicts of interest as soon as the case may arise.
- Not to disclose, verbally or written, any information obtained in the course of audits to any third party, not including the recognizing Regulatory Authority(s), unless authorized in writing or required by law.
- Observe professional secrecy with regard to information obtained during any audit or technical assessment.

Questions

Thank you