ISO 13485 Certification Process/MDSAP

BJ Johnson, 8 September 2022

MDRC Presentation

Agenda

- Audits and Audit Cycle
- Audit Agenda
- Audit Process
- Audit Reports
- Post Audit Processing
- How Regulators use the Information
- Benefits of MDSAP for Regulators

Audits and Audit Cycle

Audit Cycle

- There is a three (3) year cycle
- Audits are conducted once per calendar year
- The Initial Audit
- Surveillance Audits
- Re-Certification Audit

Audits within the cycle will cover each section of the ISO 13485 standard.

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
  - 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.

Conducting the MDSAP Audit

Audit Process:

- Auditors will follow the MDSAP Audit Approach – MDSAP AU P0002.007
  - Audit Tasks will be completed by review of documents and viewing of personnel doing their work
- 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 Post Audit Processing

The post audit activities and timelines are as follows:

MDSAP Post Audit Processing

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- 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.

How Regulators use the Information

- Reports can be quickly reviewed to see that a manufacturer is in a state of control.
- If issues are found, quickly make determinations if additional actions are necessary.
- Can be used to aid in regulatory decisions in your jurisdiction.
  - Conformity Assessments
  - Quality Management System approvals
  - Pre-Market Approval

Benefits of MDSAP for Regulators

- More predictable audit as the same process is followed and same audit report template is used by each auditing organization.
- Be assured that country specific regulations are covered during each audit.
- Does not preclude you from conducting your own inspections/audits if deemed necessary.
- Promote more efficient and flexible use of regulatory resources through work sharing and mutual acceptance among regulators while respecting the sovereignty of each authority.
- The standardized audit report makes it easy to find the information that is relevant to your organization.

Thank **you!**