Workshop I
How to prepare for an MDSAP Audit

Date: 2018/05/09

Workshop I

- Most industry attendees to the stakeholder day have already undergone an MDSAP audit.

Workshop I

- Your experience with MDSAP can help others to prepare for their upcoming audits.

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Workshop I

- In small groups, answer the following four questions.
- We will share answers.

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Workshop I

1. How did you prepare for your MDSAP audit?

2. What do you wish you had done to prepare for your MDSAP audit?

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Workshop I

3. What types of information/communication should be exchanged between AOs and manufacturers to streamline the preparation for an MDSAP audit?

4. What could the regulatory authorities do?

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Feedback

- The following slides collate the comments received from the Stakeholder participants.

Feedback

- General Comment:

  New audit = some level of fear

Feedback

1. How did you prepare for your MDSAP Audit?

- Use of companion document
- Identify SMEs/procedures/pull out records that will be requested
- Organize procedures/records to facilitate the availability
- Provide all documents electronically
- Mock audits / internal audits
- There are resources available on the Internet
- Inputs to management review

Feedback

1. How did you prepare for your MDSAP Audit?

- Educating / training / communication internally
- Give some time for people to realise that they already comply with MDSAP requirements
- Revisit CAPAs (from last 2 years) especially external NCs
- Exchange information with other firms (internal/external to corporation) about MDSAP audit experience
- Understand grading of NCs to be prepared to challenge auditors if necessary

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Feedback

2. What do you wish you had done to prepare for your MDSAP audit?

- Training to be at the same level as the auditors
- Keep in mind that the program is new to the auditors as well and they may not be as familiar with all the regulations as they are with ISO 13485
- Competency analysis
- Supplier analysis
- Plan better interfacing with functions done outside the audited facility (multi-site)

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Feedback

2. What do you wish you had done to prepare for your MDSAP audit?

- Be prepared to adjust to the vocabulary in the audit model (avoids misunderstandings)
- Plan stage 1 ahead of stage 2 with enough time to address issues

Feedback

3. What type of information/communication should be exchanged between Auditing Organisations and manufacturers to streamline the preparation for an MDSAP audit?

- Stage 1 not completely meaningful
- Responsiveness to request for scheduling
- Training material

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Feedback

3. What type of information/communication should be exchanged between Auditing Organisations and manufacturers to streamline the preparation for an MDSAP audit?

- Description of activities at each site / interfaces
- Provide information for stage 1 early

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Feedback

4. What could Regulatory Authorities do?

- Feedback after the audit has taken place → no certificate issued yet but how did Regulatory Authorities look at report
- REPs with some publicly available information on performance (analytics)
- Difficulty identifying the risk classification of devices under all the different regulations
- Availability of regulations in English