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.
Workshop I

- In small groups, answer the following four questions.
- We will share answers.
1. How did you prepare for your MDSAP audit?

2. What do you wish you had done to prepare for your MDSAP audit?
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?
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
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)
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
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
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
- REP\(s\) 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