

Workshop II

Improvement Ideas

Workshop II

- MDSAP is still a relatively young program.
- There are opportunities for improvement.

Workshop II

- In small groups, brainstorm on improvement ideas for the program.
- We will share answers.

Workshop II

- What could be improved in terms of:
 - Training
 - Communication
 - Access to information
 - Process
 - Audit flow
 - Other

Feedback

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

Feedback

- What could be improved in terms of:
 - Training
 - On regulations (publicly available training is only on the MDSAP audit model)
 - Webinars by Regulatory Authorities

Feedback

- What could be improved in terms of:
 - Communication
 - Positive comment: Transparency / responsiveness from Regulatory Authorities
 - Responsiveness of Auditing Organisations to enquiries
 - Direct communication from Regulatory Authorities to manufacturers by emails (or other means) after changes to the program
 - How to use REPs
 - Audit reports in French

Feedback

- What could be improved in terms of:
 - Access to Information
 - Regulations in multiple languages
 - Availability of MDSAP information from each Regulatory Authority's website

Feedback

- What could be improved in terms of:
 - Process
 - Benchmark with AS 9100 with regard to staging new scheme / revision – IAQG
 - More organized checklist – especially for stage 1
 - Clarification about post-audit timeline
 - Possibility to audit from a facility some activities taking place at a difference facility

Feedback

- What could be improved in terms of:
 - Audit Model / Audit Flow?
 - Clarify to auditors that the audit model is not inflexible in terms of:
 - Sequence of tasks
 - Allocation of time per task (not all tasks require the same time – the in the procedure to determine audit duration is based on averages)
 - Auditors should not issue NCs without first confirming the facts with the manufacturer

Feedback

- What could be improved in terms of:
 - Audit Model / Audit Flow?
 - Competence / consistency between auditors
 - Ensure that auditors only raise NCs directly relevant to the scope of audit /scope of certification
 - Interpretation vs. requirements
 - Audit Model Document:
 - Where an audit task includes several ideas, make them more visible (bullet points, paragraphs, etc.)
 - Provide understanding on multi-path audits to limit overlap (perceived or real)
 - Group tasks that are related

Feedback

- What could be improved in terms of:
 - Other?
 - Consistency between auditing organisations
 - Cost reductions

Feedback

- **Benefits:**
 - Cost savings
 - Avoidance of inspections