

# 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