

MDSAP Audit Assessment

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• Audit Assessment



- Audit Organization evaluated – Auditing organization assessment

Medical Device Mfr evaluated – Audit Approach
Initial assessment (Stage 1, 2), Surveillance 1, 2,
Re-recognition assessment

Audit reports shared with participating Health Authorities

• Audit Assessment Experience

- Auditing Organization – Witnessed audit
 - Interaction between Assessor and Auditing Organization
 - Minimal to no interaction between Assessor and Medical Device Manufacturer
- Medical Device Manufacturer MDSAP Audits
 - Reduction in Health Authority routine Agency inspections as a result of MDSAP certificate
 - Transparency between Health Authority and Medical Device Manufacturers
 - Utilization of Remote audits where possible





• Question & Answers



•THANK YOU

