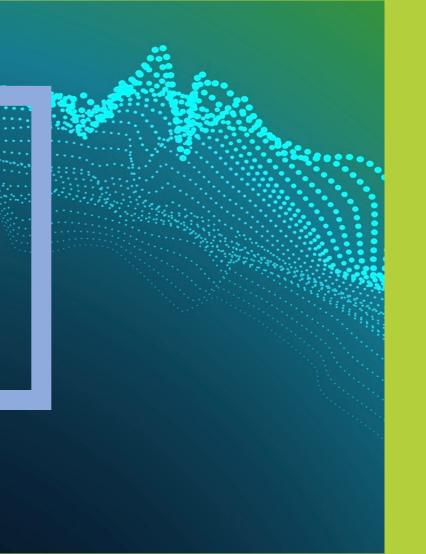
## **MDSAP** Audit Assessment

#### Amy Nelson, Chapter Lead QMS Quality Operations Roche Diagnostics





ANSI







## 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









