

# Approach of Auditing Organizations to ISO 13485

Eamonn Hoxey

26 May 2022

# The Headlines

1. Accreditation of Auditing Organizations
2. Standards supporting conformity assessment
3. MDSAP assessment of Auditing Organizations

# Accreditation

- Ensure that conformity assessment bodies (e.g. laboratories, inspection or certification bodies) have the technical capacity to perform their duties
- Used in regulated sectors and voluntary areas
- Increases trust in conformity assessment
- Reinforces the mutual recognition of products, services, systems, and bodies

# Accreditation infrastructure

- Accreditation Body
- Sector-specific requirements
- Guidance

# Standards supporting conformity assessment

- **ISO COMMITTEE ON CONFORMITY ASSESSMENT (CASCO)**
  - Develops policy and publishes standards related to conformity assessment
- [ISO/IEC 17021-1:2015](#)
  - Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 1: Requirements
- [ISO/IEC 17021-3:2017](#)
  - Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 3: Competence requirements for auditing and certification of quality management systems

# MDSAP assessment of Auditing Organizations

- Initial assessment
  - Application review
  - Stage 1 Assessment including Documentation Review
  - On-site assessment (Head Office)
  - 3 Witnessed Audits
  - On-site Assessment of all critical locations
- Surveillance
  - Surveillance on-site assessment (Head Office)
  - 1 Witnessed Audit
  - 1 Witnessed Audit per critical location
- Re-recognition
  - Stage 1 Assessment including Documentation Review for changes
  - Re-recognition on-site assessment (Head Office)
  - 1 Witnessed Audit
  - On-site Assessment of all critical locations

# Conclusion

- Assessment and monitoring of Auditing Organizations
  - Ensures technical capacity
    - Resources
    - Expertise
    - Independence
    - Capacity