Global Medical Technology Alliance

Innovating for a Healthier World

Remote Audits

IMDRF Stakeholders Session

March 23, 2021

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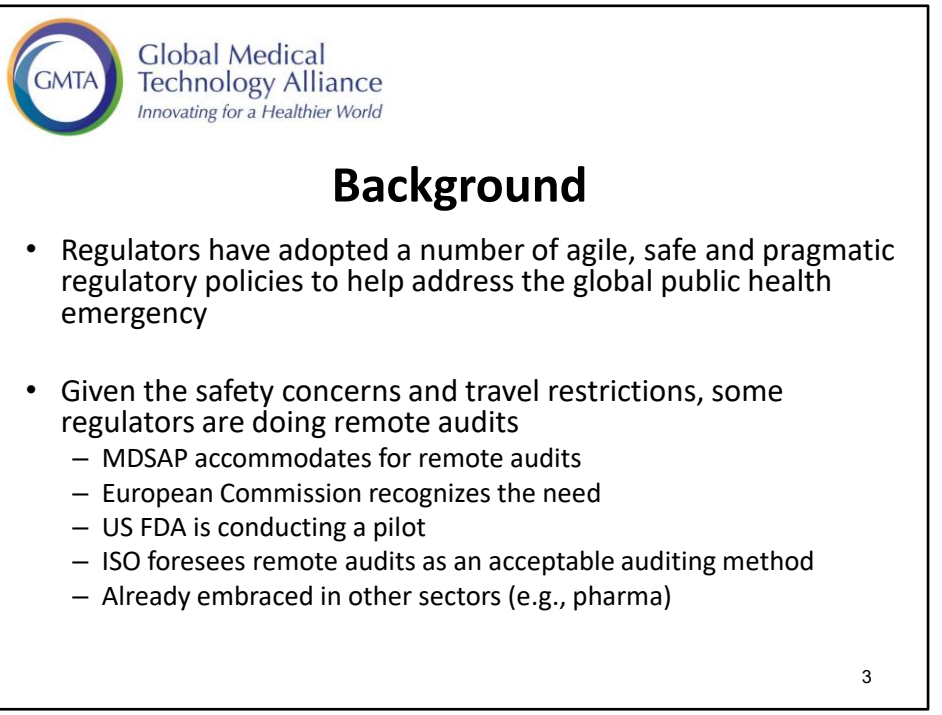
Outline

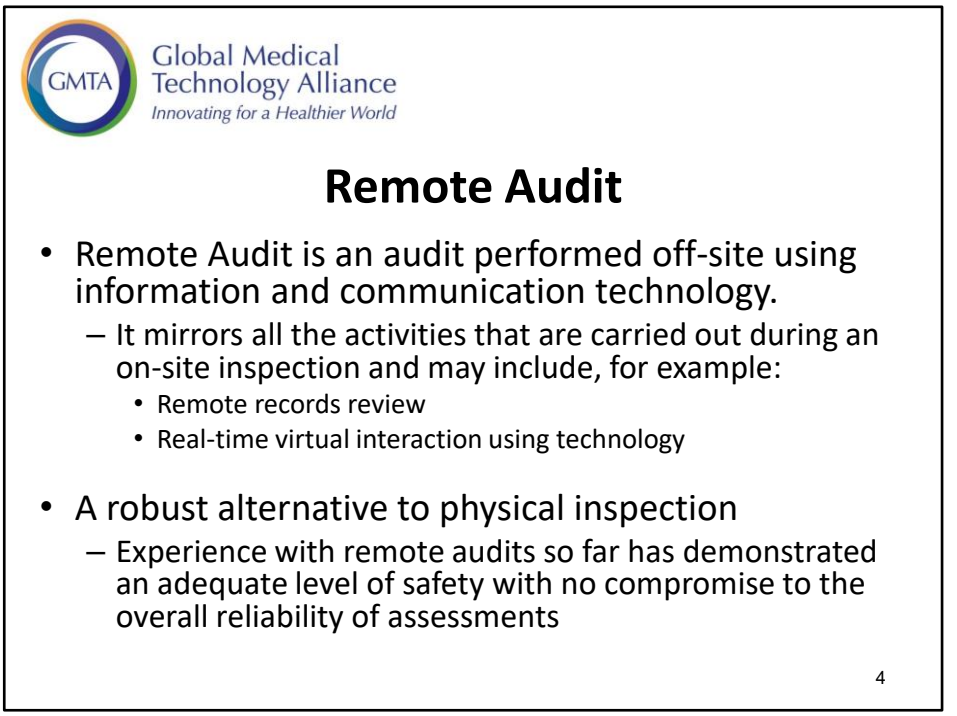
- Background
- Remote Audits
  - Basic Principles
  - Recommendations

2



References:

- International:
  - ISO 9001 Auditing Practices Group – Guidance on remote audits
  - ISO 19011:2018 Guidelines for Auditing Management Systems
  - MDSAP Transmittal Number: AO 2020-10 [Superseding MDSAP Transmittal Number 2020-07]; Transmittal Date: 2020/12/31
    Title: Further Extension and Expansion of Temporary Extraordinary Measures related to MDSAP audits during covid-19 quarantine orders and travel restrictions – alternative audit arrangements
- Europe:
  - MDCG 2020-4 *Guidance on temporary extraordinary measures related to medical device Notified Body audits during COVID-19 quarantine orders and travel restrictions*, April 2020
    - MDCG 2020-17 Questions and Answers related to MDCG 2020-4, December 2020
  - Commission Notice on the application of Sections 2.3 and 3.3 of Annex IX to Regulation (EU) 2017/745 and Regulation (EU) 2017/746 with regard to notified bodies' audits performed in the context of quality management system assessment (Text with EEA relevance) 2021/C 8/01; C/2021/119



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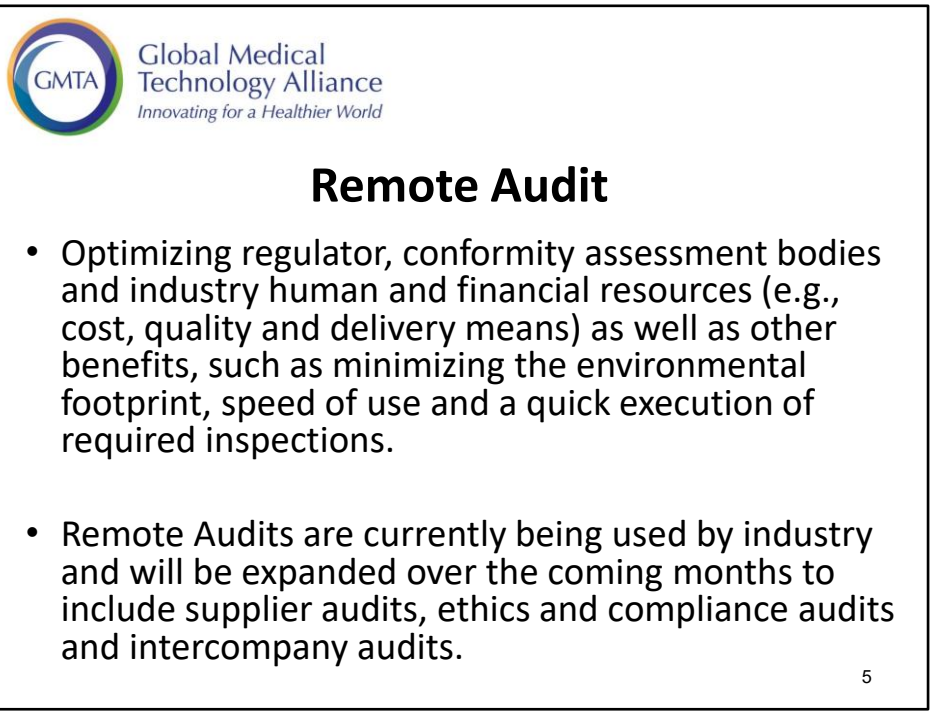

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Basic Principles

- Use available technology
- Replacement for physical inspection
- Same or similar scope as physical inspection
- Should be included as an overall part of audit plan that also includes recognition and reliance of existing audits (e.g., MDSAP)
- A lesson learned from the COVID-19 pandemic – Remote audits are beneficial during a public health emergency

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Recommendations

- GMTA supports further development of concepts and principles for remote audits
- GMTA encourages regulators to consider the use of remote audits as a viable alternative to physical inspections (on-site audits) under specified circumstances

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Early Lessons Learned During a Global Pandemic

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Presentation Outline

- Background
- Challenge
- Early Lessons Learned
- Recommendations

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Background

- Need for rapid review and approval mechanisms to meet specific needs during COVID-19 pandemic
- Access to COVID diagnostic tests, personal protective equipment, ventilators in high demand
- Required close collaboration with regulators, developers and healthcare providers

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Challenge

- Clinical and Regulatory
  - Access to virus samples
  - Accuracy of, and access to, comparator test
  - Changing and moving targets
  - Lack of clarity in regulation
  - Lack of harmonization in regulations to enable marketing authority at pace with urgent need to scale
- Scaling production in a short period of time
- Access to Real World Data

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Early Lessons Learned

- Leverage regulatory decisions from other regulators
- Regulatory agility during pandemic has been critical
  - Remote audits in place of on-site
  - Leverage regulatory reliance
  - Use of alternative sources for clinical evidence

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Recommendations

- Ensure that current IMDRF documents acknowledge the need to ensure rapid review and approval
- Utilize reliance mechanisms to promote rapid review and approval
- Consider the development of specific IMDRF guidance to promote the use of rapid review and approval mechanisms during a global pandemic
- Ensure adequate training and communication for regulators
- Regulatory agility should be leveraged beyond pandemic