Remote Audit for Medical Devices QMS Audit

Khwunsuda Anuan
Client manager – Regulatory Services - APAC Assessment Delivery Operations

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By Royal Charter

bsi.

Agenda:

- Remote audit under accredited rule and relevant requirement.
- Risk assessment to determine feasibility of remote audit
- Preparation for remote audit.
- Remote audit practicing on audit date.

Type of Audit and Remote Audit

On-site:

An audit where all auditors are at the auditee premises

Remote audit:

The facilitation of assessment of a Conformity Assessment Body from a location other than that being physically present.

- An audit performed off-site using ICT, such as meeting platforms or limited video streaming
- Desktop audit: Remote audit using documentation only, eg a audit of a file sent by email
- Partial remote: An audit performed with a mixture of remote audit and on-site.

Remote audit under accredited rule and relevant requirement.

IAF Informative Document

- **IAF ID 12:2015**

Principles on Remote Assessment

- **IAF ID 12:2015**

Extraordinary Events or Circumstances Affecting ABs, CABs and Certified Organizations

- **IAF MD 4:2018**

Mandatory Document for the use of information and communication technology for auditing/assessment purposes

UKAS Accredited document:

❑ **TPS 62**

Management of Extraordinary Events or Circumstances Affecting UKAS Accredited Certification Bodies and their Certified Organisations, Edition 2 August 2016)

❑**TPS 73**

UKAS Policy on Accreditation and Conformity Assessment During the COVID-19 Outbreak. Edition 1; April 2020

Remote audit under accredited rule and relevant requirement.

MDR

- MDCG 2020-4

  Guidance on temporary extraordinary measures related to medical device Notified Body audits during COVID-19 quarantine orders and travel restrictions

- MDCG 2020-17

  Questions and Answers related to MDCG 2020-4. Dec 2020

Risk assessment to determine feasibility of remote audit

Consideration of risk

- Certification required i.e.: ISO and EN ISO 13485, MDR, MDSAP
- Product under certification scope and risk classification of device
- Audit objective i.e.: IAV, CAV, RAV, Scope extension
- Ability to be audited via an electronic platform and internet connection

Risk assessment to determine feasibility of remote audit

Risk Assessment (BSI):

Low

- Manufacturer with 100% subcontracted processes
- Software only manufacturer
- Low risk processes e.g. Assembly of low risk devices, Warehousing processes etc

Medium

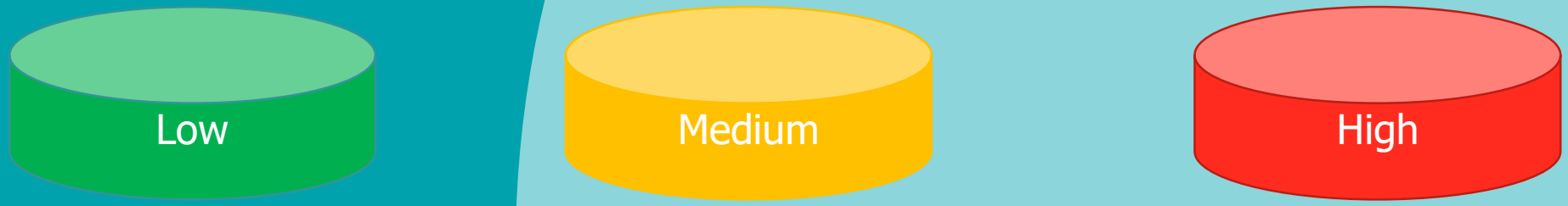
- Site has some manufacturing
- A good record of conformity (no majors or MDSAP gr 4-5)
- Devices are lower risk, e.g., CE Class I, Iia, IIb non-implantable, non Class D

High

- Site has no technology-based solutions for remote
- Site has noisy/challenging environments effect to remote
- Site performs on-site sterilization (Micro and QMS audits)
- •Legal manufacturer for high-risk device type

Risk assessment to determine feasibility of remote audit

Example 13485 Audit can be (BSI):



Stage 2	Remote	Remote/ Partial	Partial
CAV	Remote	Remote	Remote
RAV	Remote	Partial	Partial

Preparation for remote audit.

Audit date confirmed

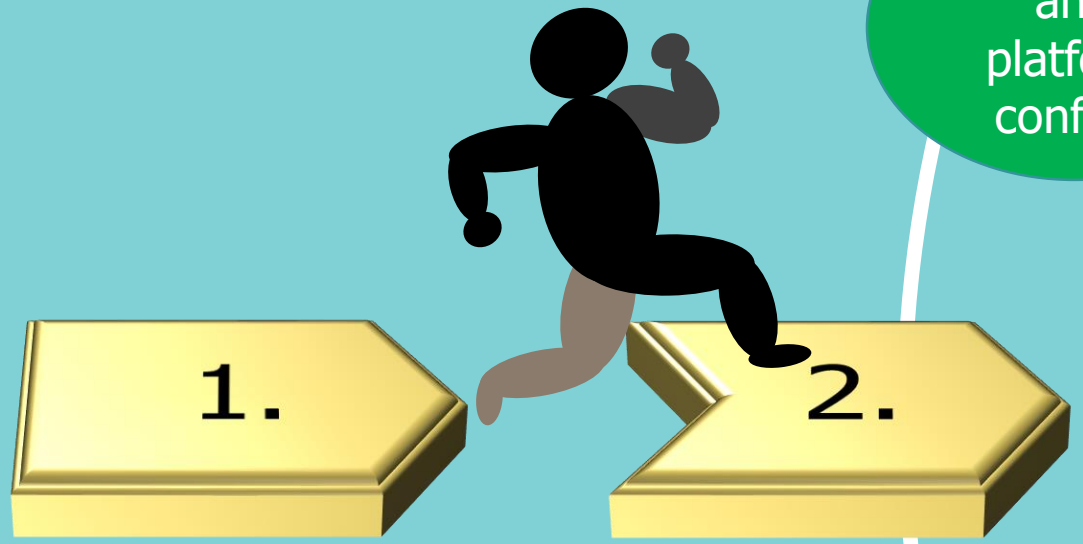
1. Audit date confirmation

2. Auditor send audit plan

3. Conduct ICT Test / Internet connection test

4. Document preparation

Preparation for remote audit.



Audit plan and platform confirm

- ❑ MS Teams
- ❑ WebEx
- ❑ Zoom
- ❑ Line
- ❑ Skype
- ❑ Google meet
- ❑ Other

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Preparation for remote audit.

GF035

Audit Plan

Revision 8 (April 2020)

Date	Time	Auditor / Auditee	Process (*ICT platform: MS Team for both desktop review and VDO live streaming)*	Clause
Sep 15, 2021	0900-0930	Auditor A	Opening meeting / Top Management interview / Review of Change include MDR product classification, product range	M: 4.1, 5.1
	0930-1030	Auditor A	Quality Manual, Q. Policy, Q. Objective, QMS planning, Management review meeting	M: 4.1, 4.2, 5.1-5.6, 8.4, 8.5 / MDR Article 10#9, Article VII and Annex XI Part A

Preparation for remote audit.

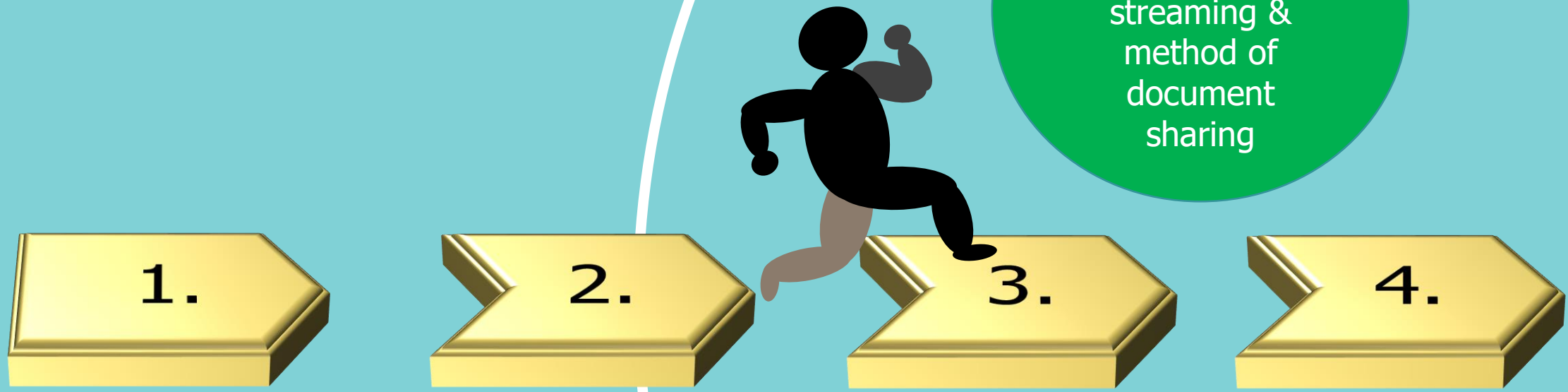
Is there a need?

Confidentiality and Regulators

Preparation for remote audit.

Preparation for remote audit.

Good connection for both desktop & VDO live streaming & method of document sharing



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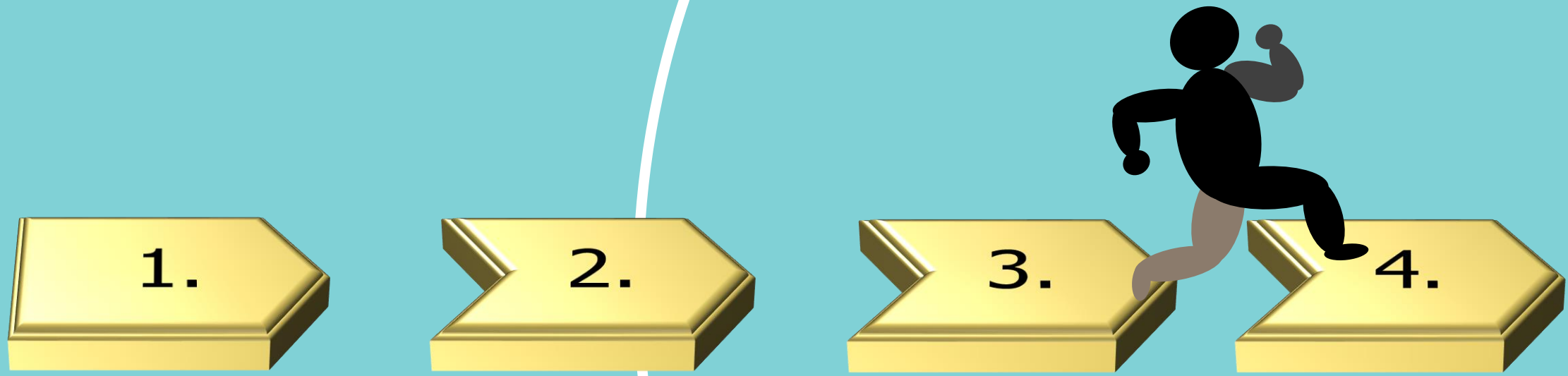

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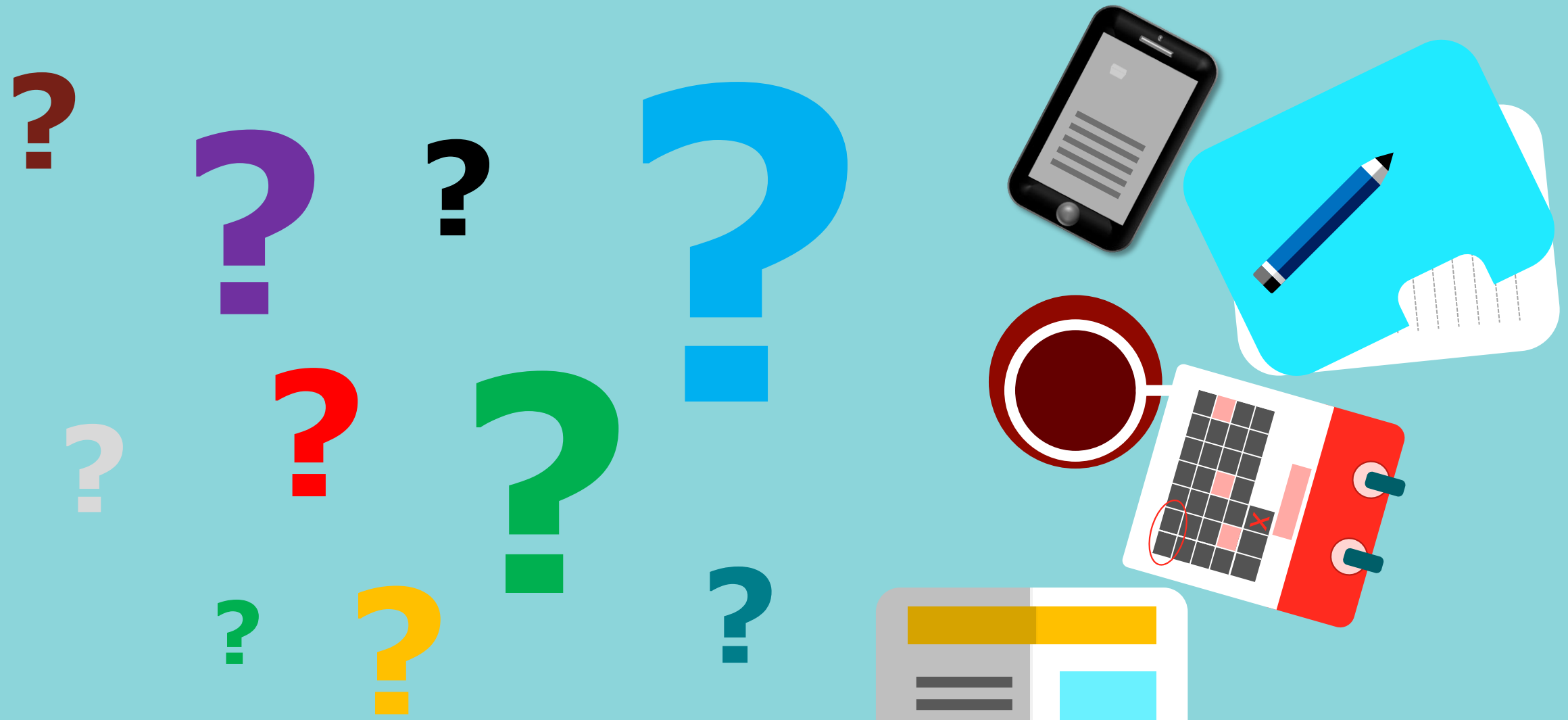
Remote audit practicing on audit date.

- ❑ Opening meeting via confirmed platform
- ❑ Audit as per audit plan
  - Separate invitation / meeting by auditor
  - In case audit in operation area, may need to have earpiece.
- ❑ Auditor meeting
- ❑ Closing meeting via confirmed platform

Reflective quiz



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