Hybrid audits – the new way of working post pandemic

Presented by Linda Moon, Global Quality & Accreditation Manager, Regulatory Services and Dr Yoann Buisson, GQA Technical Manager, Regulatory Services.

May 2022

Agenda

- Definitions
- Why hybrid?
- Lessons learnt from the Covid-19 pandemic
- Hybrid Unannounced audits – timescales and requirements
- Hybrid Unannounced audits – what to expect
- What's next?

What is a hybrid audit?

Hybrid audits are partially performed off-site using technology while at least one auditor is onsite during a portion of the audit. As a result, the audit will be delivered simultaneously on and off-site.

As an EU notified body and a UK approved body, we work with our Authorities in both the NL and the UK to ensure our actions are effective, efficient and legal. The mandatory requirement for onsite audits remains a critical part of the regulatory requirements in the EU and UK.

Other types of audits with a remote component

Surrogate audit:

An audit partially performed off-site using ICT while at least one auditor is simultaneously on-site during a portion of the audit, who does not need to be qualified for the respective certification scheme but shall have sufficient level of competence to be involved in the audit.

Split audits:

Split audits are audits that are hybrid however not all auditors are conducting the audit simultaneously and there could be a gap between the off-site and on-site audit.

Desktop audit:

Audit performed remotely by reviewing documentation.

Remote audit:

Audit performed off-site using information and communication technology (ICT).

bsi.

Why hybrid?

- Covid-19 pandemic has changed the ways of working across all businesses
- Solid learnings and evidence around the use of immersive technologies
- UN Sustainable Development Goals
- Work-life balance for our auditors
- Scheduling without geographical constraints
- Highly qualified experts provide specific expertise required

bsi.

BSI Sustainability commitment

Goal 3: Good health and wellbeing

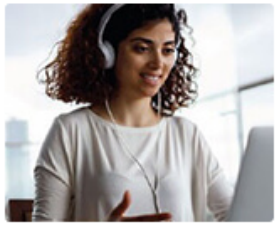
Goal 7: Affordable and clean energy

Goal 9: Industry innovation and infrastructure

Goal 12: Responsible consumption and production

BSI Sustainability commitment

Technologies in use by Regulatory Services – Medical Devices



Level 1: Live web streaming technology

Live streaming technology such as MS Teams, Webex and Adobe Connect to support:

- Document, record and procedure review
- Live interviews with your teams
- Connected learning live - our online training service

Secure sharing platforms may also be used to transfer documentation.

Level 2: Live streaming paired with mobile technology

Video applications on smart devices (phones and tablets) immerse our teams.

This technology enables virtual site tours. It allows us to observe the implementation of processes and activities in real time.

Technologies not yet in use for Regulatory Services – Medical Devices

Level 3: Live streaming paired with smartglass technology

Fully immerse in the audit by using hands-free technology such as smart-glasses and video headsets.

We provide immersive technology equipment in advance of the audit for your teams to use in action.

Live feeds communicate data to our augmented reality platform for verification by our experts.

Level 4: Drone and satellite aerial imaging and analytics

As part of our Immersive Technology Solutions, we are currently using drones, unmanned aerial vehicles (UAVs) or satellite imagery to bring our clients a safe, cost effective experience that brings superior levels of analytics, planning and lifetime digital remediation of corrective issues.

bsi.

Poll 1: What has been your biggest challenge during remote or hybrid audits conducted during the pandemic?

1. IT connection issues
2. Live streaming during manufacturing
3. Sharing documents
4. Building rapport and communication with the auditors

Lessons learnt:

- Feedback from the client and the auditors was positive overall
- File transfer platform was useful
- Audit was successful as QMS auditor was experienced/had suitable training
- Some technology issues
- Advance planning led to successful audits
- Clients could support two audit streams in the afternoon which made the audit efficient
- Possible motion sickness for remote auditor
- Manufacturer needed reassurance that there was no recording
- Hybrid approach uses live feed NOT recording
- Rapport not so easy to build remotely
- Study of remote vs on-site conducted

bsi.

Poll 2: What has been the key advantage to your organisation hosting remote audits conducted during the pandemic?

1. Reduced travel costs
2. Allowing SMEs / other staff to join and observe
3. Flexibility in booking/planning
4. Allows more people to look at the same audit stream and documents/evidence

Hybrid Unannounced audits – timescales and regulatory requirements

BSI Regulatory Services – hybrid audits are launched!

In April the RS Hybrid Audit Programme was launched. The audits were all unannounced visits, and the teams all comprised a QMS Auditor on-site and a Technical Specialist working remotely via Microsoft Teams.

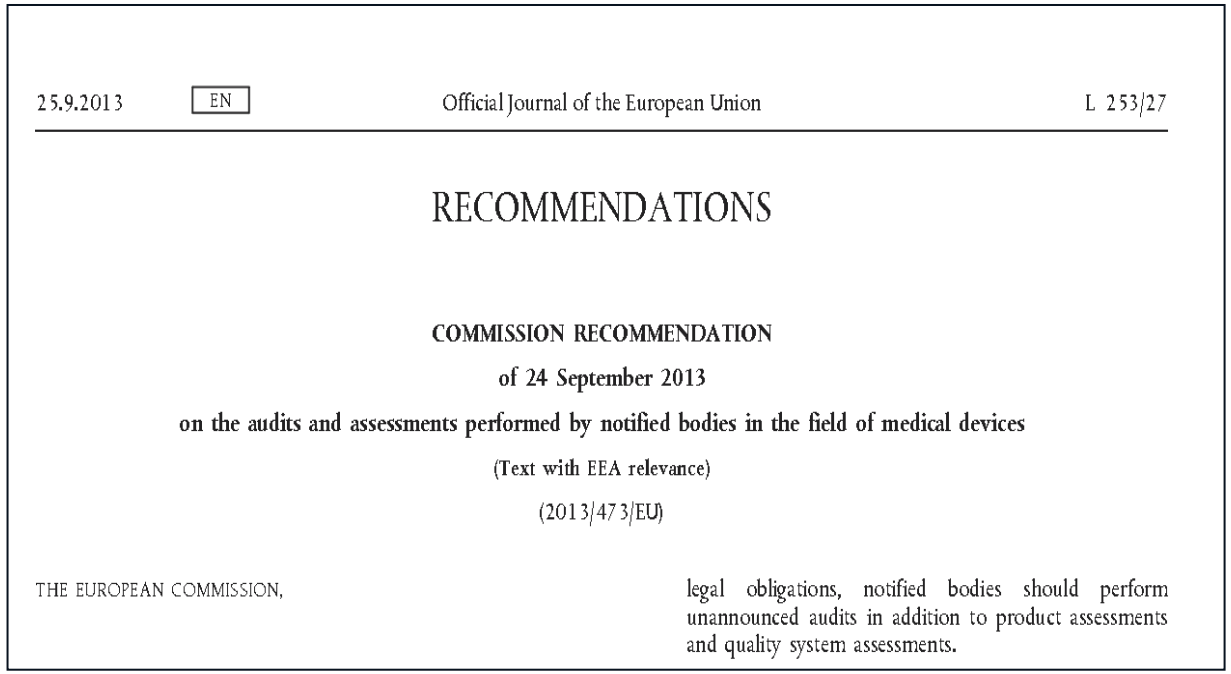
Unannounced audits

The PIP breast implant scandal made it clear that immediate improvements in the oversight of medical devices were needed. As a result, the European Commission embarked on a full regulatory overhaul of the medical device regulations with the goals of providing high levels of safety and restoring public confidence.

EU 2017-745 – Annex IX, 3.4:

The notified body shall randomly perform at least once every five years unannounced audits on the site of the manufacturer and, where appropriate, of the manufacturer's suppliers and/or subcontractors,

Commission Recommendation 2013/473/EU



25.9.2013 EN Official Journal of the European Union L 253/27

RECOMMENDATIONS

COMMISSION RECOMMENDATION

of 24 September 2013

on the audits and assessments performed by notified bodies in the field of medical devices

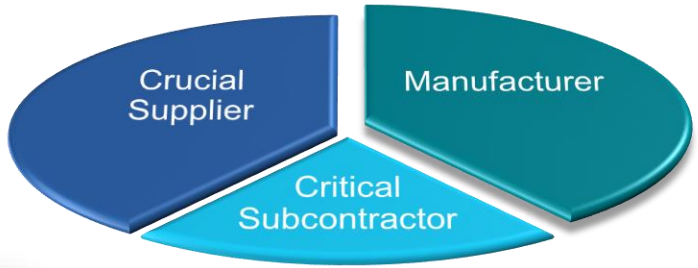
(Text with EEA relevance)

(2013/473/EU)

THE EUROPEAN COMMISSION,

legal obligations, notified bodies should perform unannounced audits in addition to product assessments and quality system assessments.

Where We Visit



…where it is likely to ensure more efficient control…

Legal Manufacturer?

YES *if all or some manufacturing , design or test activities performed onsite for all or some products*

Critical Subcontractor or Crucial Supplier?

YES, for virtual manufacturers

Unannounced Audit: Frequency

- Audit frequency is a minimum of one audit in 5 years for both Directive and Regulation certificates for all device classifications
- Additional audits may be scheduled if the Scheme Manager considers there is a specific reason to do so

What if a manufacturer is not placing devices on the market?

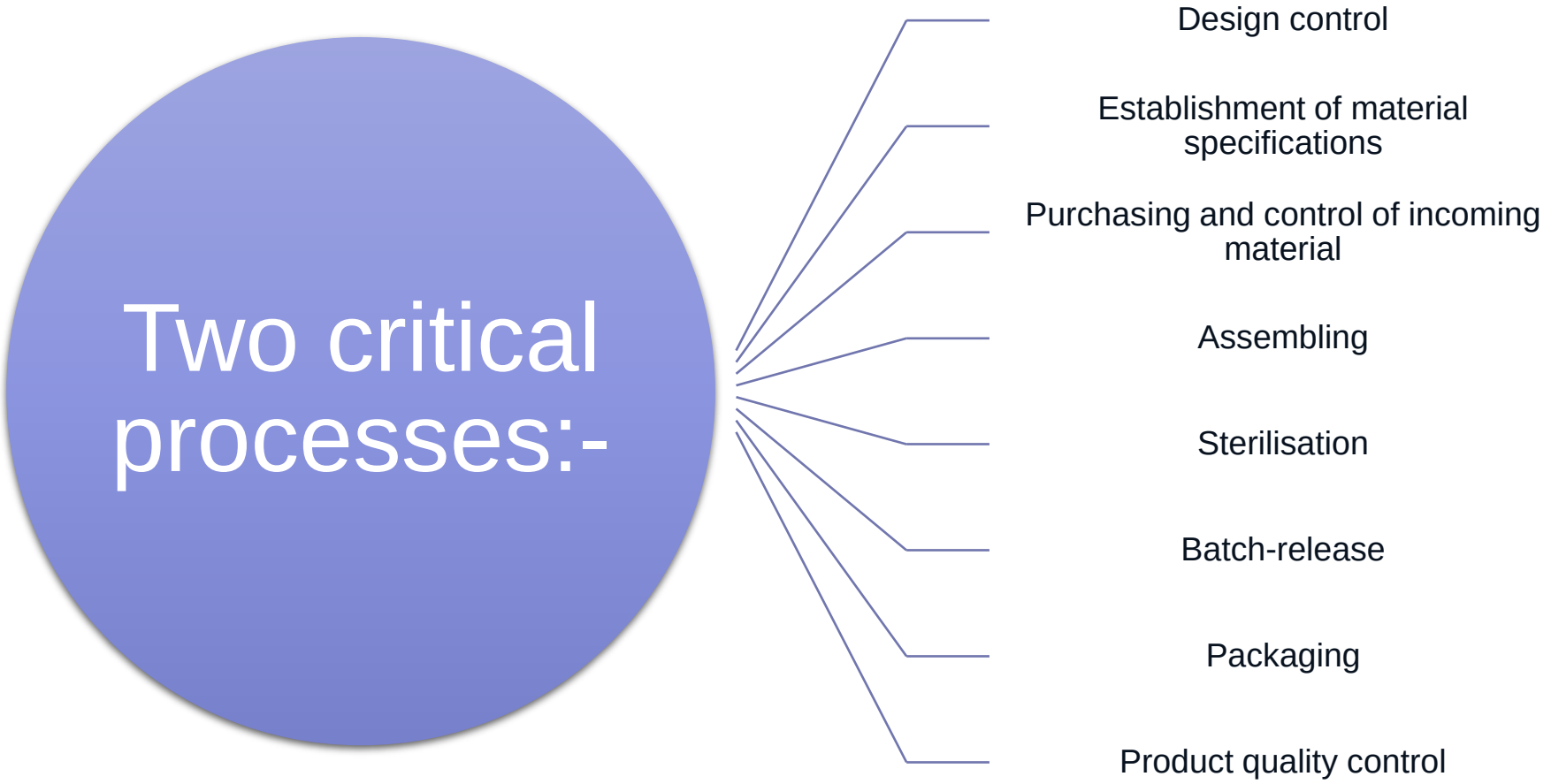
- At least one unannounced audit has to be delivered in the certification cycle irrespective of whether the Manufacturer has placed the CE marked product on the market or not
- If the manufacturer has any CE-marked devices on the market anywhere (even one limited device of a larger scope), an unannounced audit must be performed

bsi.

Unannounced audits

Unannounced Audit Focus

General Audit Requirements

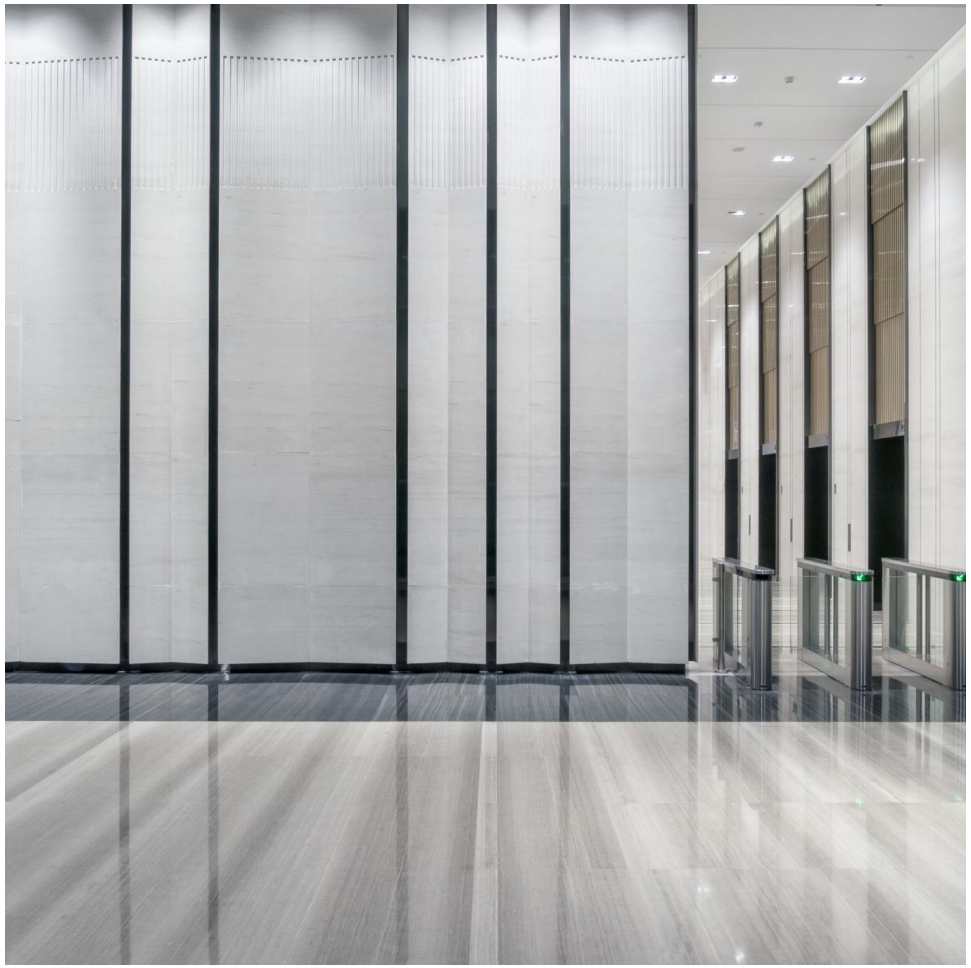


Hybrid Unannounced audits

– what to expect

Hybrid Unannounced audits – what to expect – arrival on-site

- Usually one day audit - may be two people on-site or one remote + one on-site
- On-site auditor will have the BSI regulatory services letter for the Unannounced audit – allowing for verification of both auditors
- On-site auditor will be holding the phone with the remote auditor live-streamed
- There is no RECORDING – it is live streamed

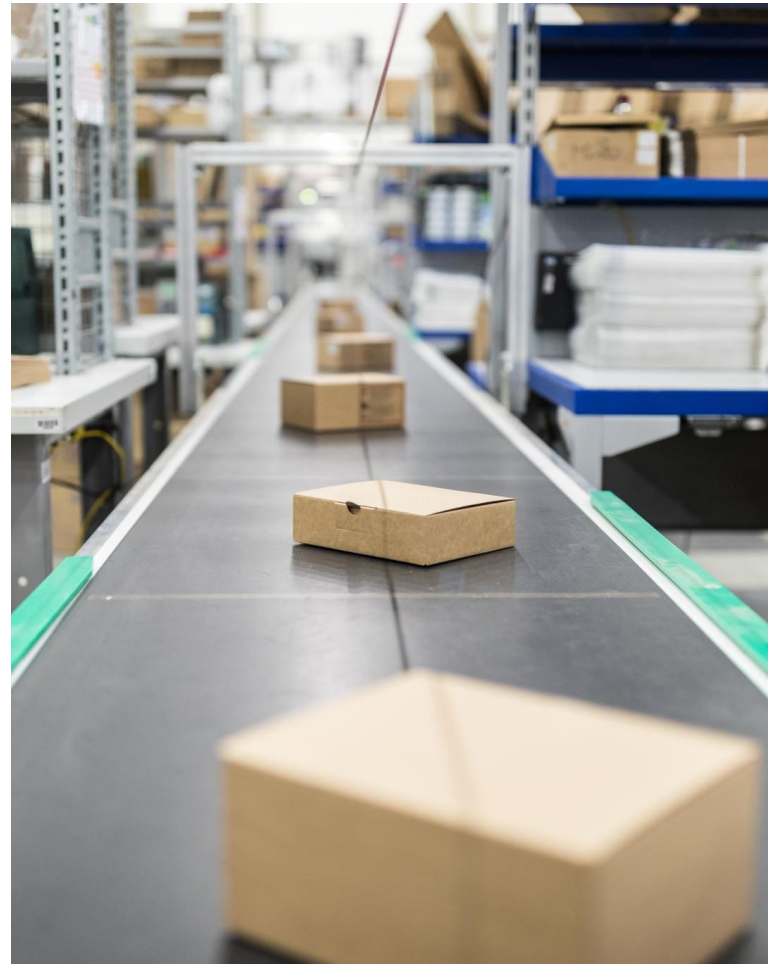


bsi.

Hybrid Unannounced audits – tour of manufacturing

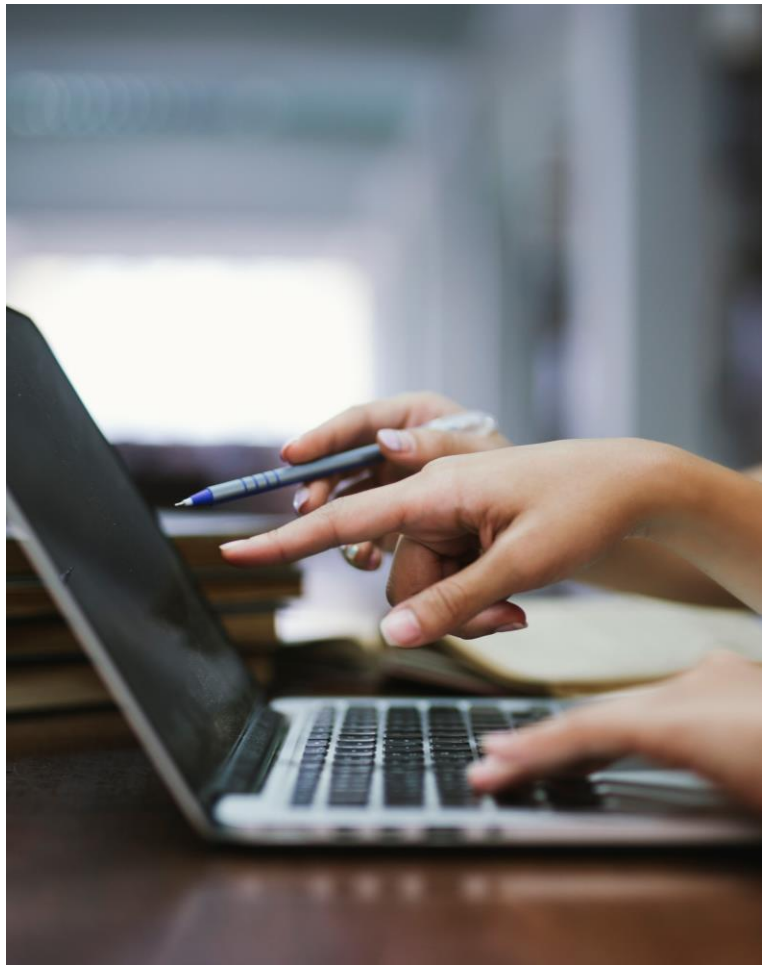
- Brief introduction / opening meeting
- Straight to manufacturing – aim within 15 minutes of arrival otherwise can be considered an obstacle
- Company Wifi code
- On-site auditor will lead tour with remote auditor on their phone on MS Teams

- Witness testing will need to be observed by both auditors during the day
- There is no RECORDING – it is live streamed
- Both auditors can ask questions



Hybrid Unannounced audits – the remainder of the audit

- After manufacturing tour, the two auditors will decide on audit trails
- Audit will split into two streams (as normal but the manufacturer will need to be able to host one of these on MS Teams)
- Encrypted / secure file sharing technology will be used for safe transfer of technical file

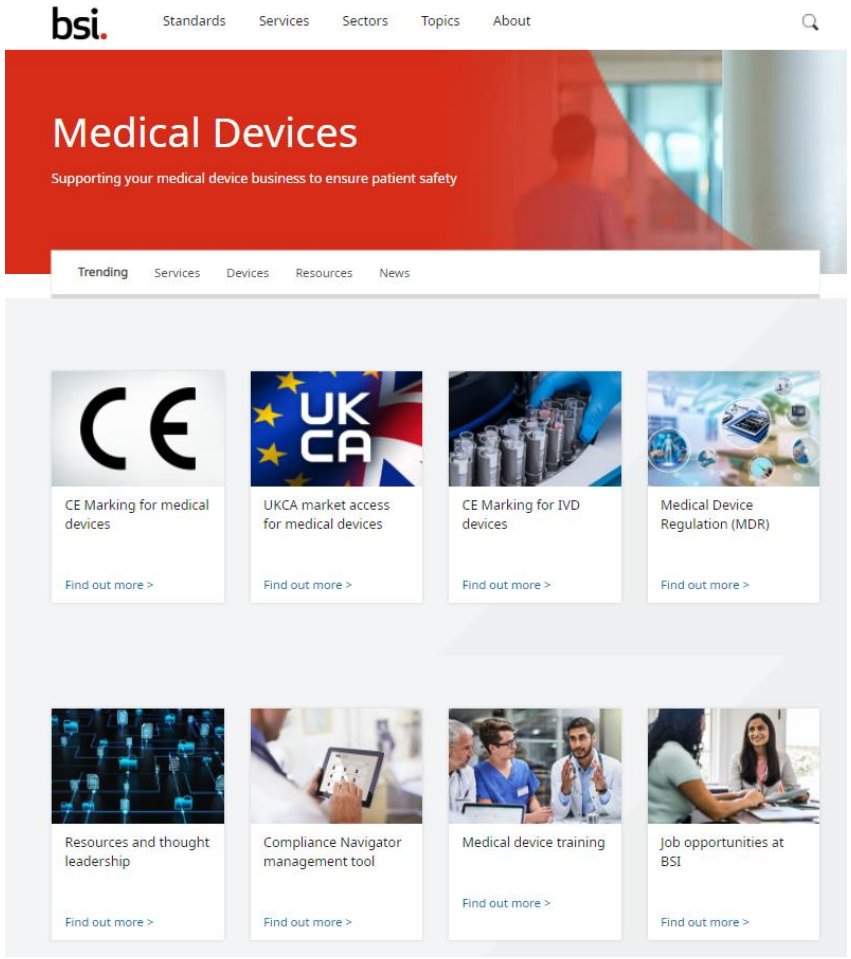


- Progress and any findings identified during the audit will be discussed
- Major and minor non-conformities raised
- Auditor briefing/ closing meeting
- Follow-up actions - obstacles

Lessons learnt from hybrid unannounced audits

- Positive feedback from manufacturers on the standardised process
- Positive feedback from manufacturers on innovative approach
- Effective audits delivered
- Manufacturers provided Wifi with suitable bandwidth for streaming which helped enable audit
- Manufacturers supported two audit streams which enabled effective audit

What's next?



BSI Regulatory Services is focused on establishing global standard practices in delivering remote engagement

https://www.bsigroup.com/en-GB/medical-devices/

What do manufacturers need to consider?

- Do you need to review your procedures to allow hybrid audits – particularly UAVs
- Do you need to train your team on hybrid UAVs?
- Critical sub-contractors – make sure they are aware and review your contracts

bsi.

Poll 3: What do you see as the key benefit of hybrid audits to your organisation?

1. Reduced travel costs for your organisation
2. Allowing SMEs / other staff to join and observe
3. Flexibility in booking/planning
4. Allows more people to look at the same audit stream and documents/evidence
5. Meeting sustainability targets

Questions?

Thank you for listening