MHRA Remote Inspection Strategies
6th India Pharmaceutical Forum

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MHRA inspection strategy

Majority of MHRA inspections on-site:

- GMP, GDP & GLP not routinely done remotely
- GPvP & GCP inspections 'Day 1' office-based assessments
- Office based assessments for IAG cases

March 2020 Pandemic halted routine on-site in UK:

- Transformation of inspection model to remote
- High-risk or Covid-19 support inspections prioritised

https://www.gov.uk/guidance/guidance-for-industry-on-mhras-expectations-for-return-to-uk-on-site-inspections

Pre-pandemic remote inspection approaches

- Prior to pandemic, increasing levels of pre-inspection requests across GxPs:

  – Pre-inspection compliance reports

  – Procedures

  – Safety listings

  – Deviations and CAPA review etc.

- Enabled most efficient use of inspector time on site

Lockdown revised remote inspections

- From Q1 2020 routine GxP inspections moved to remote model:
  - Inspection model refined, defined, & embedded into MHRA quality system

- Pragmatic approach implemented, reducing burden wherever possible
- Accommodates 'inspectees' working remotely as well as inspectors

- Inspection Reports still issued:
  - For GMP certificate denotes inspection conducted remotely
  - Inspection statements cover only those areas reviewed
- Critical inspection findings raised across GxPs demonstrating effective remote approach

Risk-Based Approach

Continued

- Prioritised inspections for Critical finding follow-up, licensing need or Covid-19 support
- Emergency approvals & conditional MAs
- Refined inspection scope to ensure risk-based need met:

Cross-divisional support from CTU, VRMM and Licensing Divisions

Paused

- Routine overseas inspections

- NHS-sites currently not inspected unless critical, to enable essential Covid-19 work to continue

- Routine investigator sites paused; now being incorporated into remote working

Remote Inspections Conducted 1st Apr 20- 31st Jan 21 Total 670 inspections

INSPECTION TYPE

Inspection Type	Count
GCP	27
GLP	30
GMP	267
GPVP	25
GDP	321
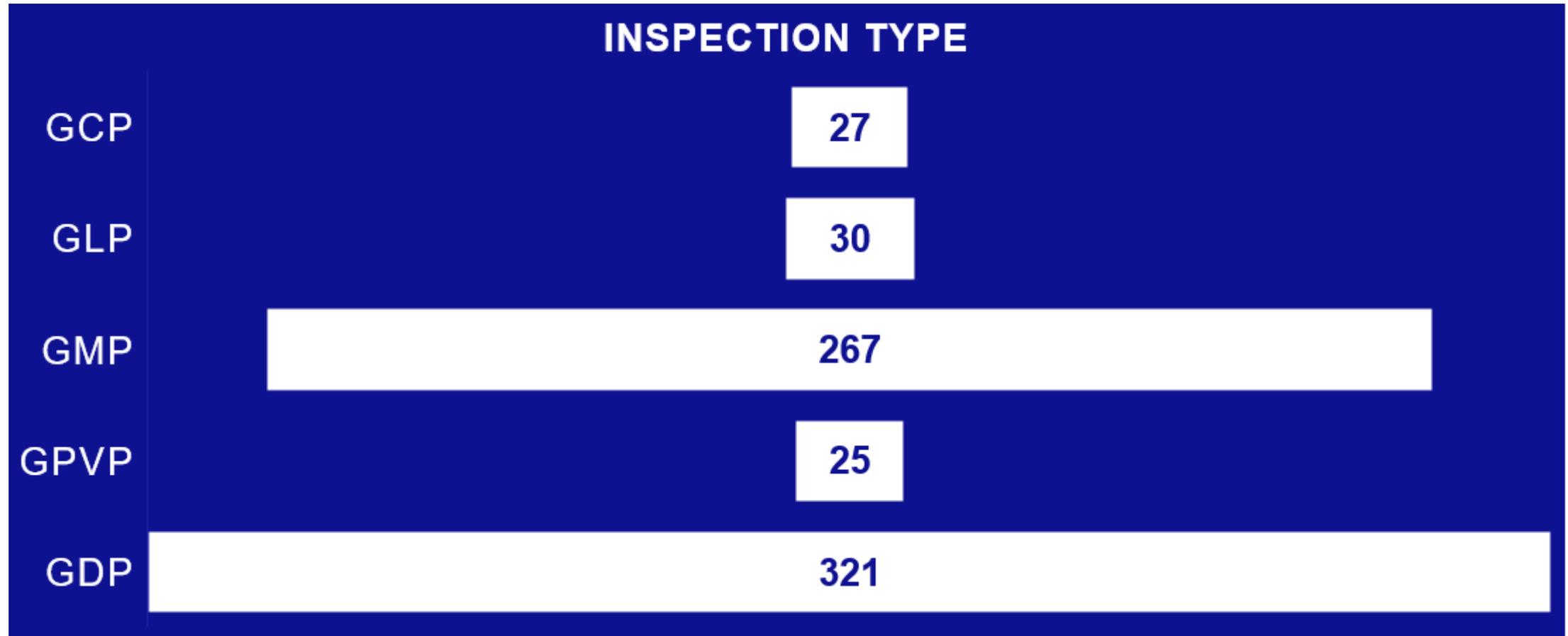
Practical considerations

- TC and Video conference for opening/ closing meetings; interviews and screen share

- Use of file sharing technology

- Email

- Livestreaming of documents

- Remote access to eSystems such as eTMF, eCRF etc.
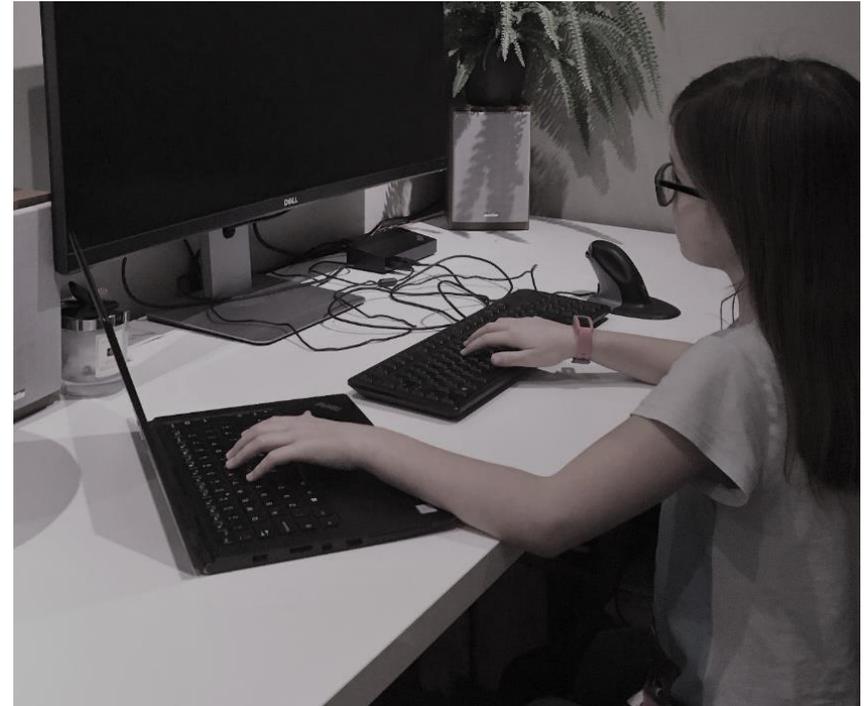
Logistical Approaches & Challenges

- Organisations notified as normal (unless triggered short-notice)

- Any pre-inspection documents requested & reviewed as normal

- Modified requests & dossiers ensuring needs of inspection scope are met

- Inspection scope often narrower than on-site, but directed by risk

- Inspections take longer (often)
- Delays in receipt of requested documents

- Inability to ask 'real-time' Qs
- Facial expressions/ Body language!

- Rapport building

- Inability to easily assess state of premises/ equipment/ facilities

Technological challenges

- Ability to access all eSystems – accounts / passwords!
- Hybrid systems
- Technical capability of sites impacts remote interactions
- Data protection considerations
- Size of e-files and time to download
- Camera restrictions in some areas/ countries
- Connection issues….!

Visuals subject to technology on site:

- CCTV
- Webcam pointed at live CCTV
- Remote access to live CCTV
- Mobile connected to video call
- Head camera with live voice interaction connected to video call

Other Remote Challenges

?   Data integrity difficult to "virtually" inspect

⚠   Increased risk of 'disreputable' companies editing information

👤   Handling of CAPA

📉   Reduction of onsite training opportunities

👀   Eye strain!

Successes – MHRA Perspective

Regulator oversight maintained ensuring public health protection

Potentially allows more documents to be reviewed!

Facilitates 'theory' training of new inspectors

Useful approach for follow up inspections

Protects the health and safety of inspectors & companies during times of risk

Allows for more flexibility

Industry Views

Diverse views on flexibility – some sites appreciated; others felt it extended on-site approach

Supports health & safety of the company staff

Allows for greater flexibility with work schedule of inspectees

Potentially remote inspections may warrant delaying an on-site inspection, or reduced scope of on-site – seen as positive

Motivation to continue standards of compliance even in extreme change

Public Health Benefits

- Regulator oversight of patient safety and data integrity upheld

- Facilitates maintenance of pharmaceutical supply chain

- Enables oversight of COVID-19 vaccine development and has accelerated the approval process

- Continues to promote access to promising innovative therapies

Increased trust and confidence of the public in regulators and regulated parties' capacity to adjust and continue working towards patient safety

Hybrid Inspections & the Future

- For the foreseeable…MHRA operating 'Critical' and 'Covid-19 support' required inspections on-site only

- Hybrid approaches continue

- Inspection areas previously considered impossible remotely, have been challenged with successful outcomes…

- Remote BE inspections taken forward into current 'routine' ways of working

- Data sharing electronically/ shared desk top vs. data that requires analysis

Focus remains on risk

ICMRA Covid-19 Digital Transformation Working Group

- ICMRA Digital Transformation of GCP & GMP Inspections:

  - 'Deep-dive' presentation to ICMRA Policy Group in Oct 2020

  - MHRA Chair, membership includes:
    - WHO, US FDA, HC
    - HSA, TGA, PMDA
    - HPRA, ANSM, AEMPS
    - PEI, SwissMedic, Saudi FDA

  - Reflection paper in development on remote inspection approaches

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