



Remote Inspections: past, present and future

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Overview

- *The past*
- *The present*
- *Process issues*
- *Deficiencies*
- *Some statistics*
- *The future*



The Past

Remote inspections performed in 2020

Regulators had to find alternatives to on-site inspections for assessing GMP compliance of pharmaceutical companies.

Many had implemented distant assessment processes using communication and information technology including real-time video streaming of facilities and activities

The remote inspection process was introduced in March 2020 for domestic inspections and August 2020 for overseas inspections performed by TGA.



The Past

Remote inspections performed in 2020

Domestic sites – PIC/S data in 2020

69% of responders were able to conduct on-site inspections

57% were using distant assessment with virtual components

57% were using hybrid inspections

Foreign sites – PIC/S data in 2020

Only 14% of responders were performing on-site inspections

38% were using Distant Assessment with virtual components



The Past

Remote Inspections

GMP clearances were extended

Some agencies used distant assessment to justify extensions and postponing inspections

Developed reflection paper on experiences



Future Plans When Pandemic Has Ended- future gazing in 2020- PIC/S data

28% of responders will continue to use distant assessment process for some activities

49% had not decided their post-pandemic plans yet

Strong support for the development of guidelines and tools to harmonise procedures for distant assessments to facilitate continued reliance between international partners

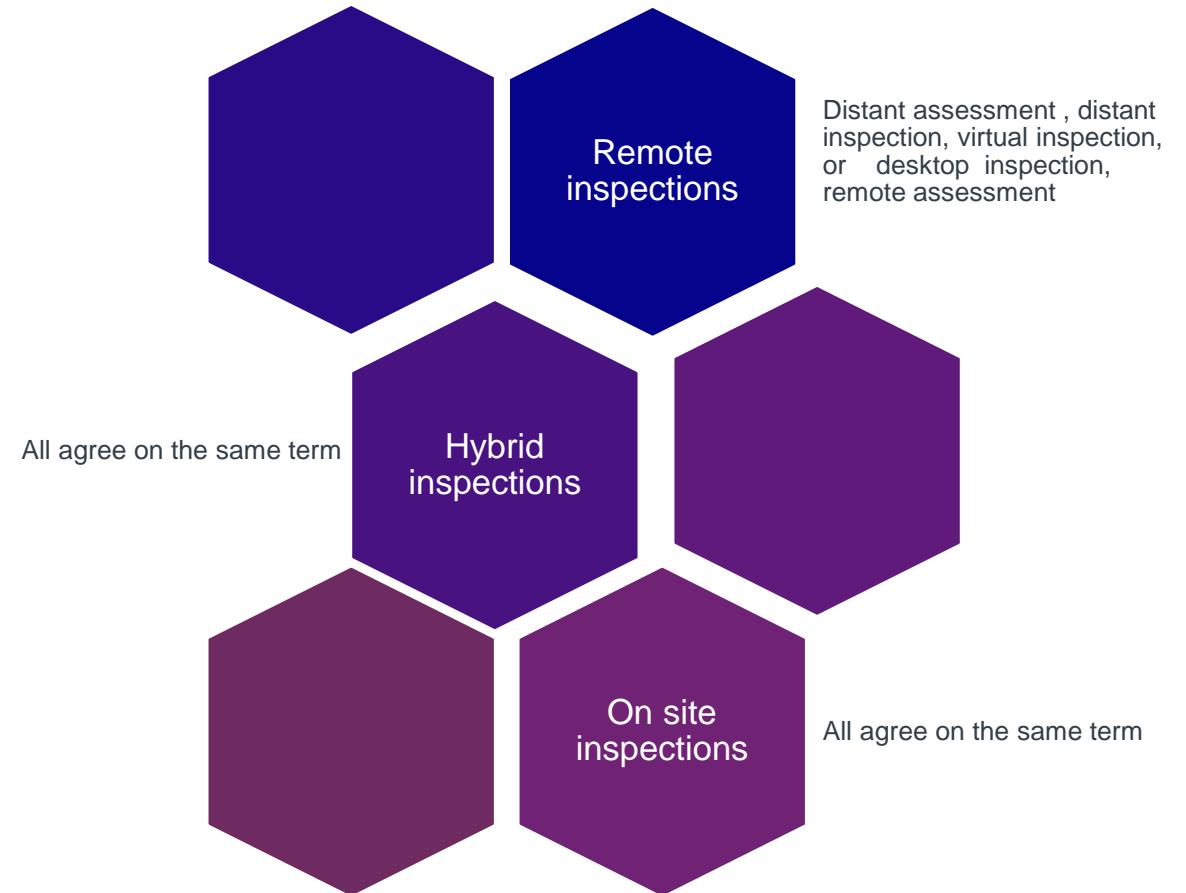
The Past

Inspection/assessment terminology

Each jurisdiction used a different term for inspections and assessments and this led to confusion and some impact on sharing of information.

A common approach (including shared definitions) on remote assessment was part of a mandate with a PICS working group to align terminology and foster some harmonisation in 2021.

The agreed approach was to define the types of remote inspections and align terms and show where terms could be used interchangeably.



The Present

Agreed terminology

Developed definitions of remote, hybrid inspections

Guidance on remote inspections developed to harmonise terms by PIC/S with TGA chair on the PIC/S Working Group on Remote Assessments.

A best practice approach to conducting remote inspections that covers logistics, feasibility, documentation

Remote Inspection

- Fully interactive distant or remote assessment
- Partially interactive distant or remote assessment
- Remote inspections is also called distant, remote assessment , virtual inspection, or desktop inspection

Hybrid Inspection

- Combination of on-site inspection and remote assessment

On site inspection

- No change

Remote Inspections past and present

The mechanics for a remote inspection performed by TGA

Meeting

- Meeting apps: MS Teams and WebEx only (secured document repository)
- Phone if no other options

Document review

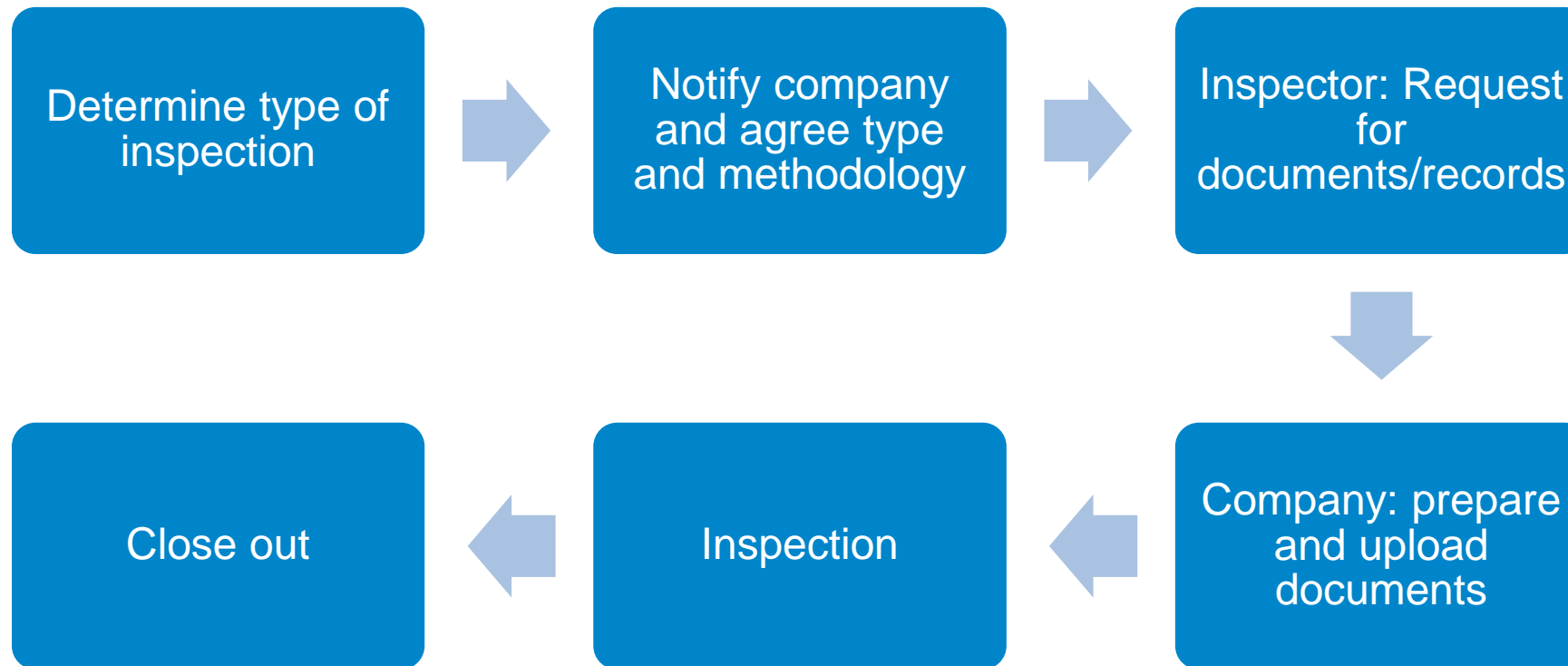
- Meeting apps for sharing of documents uploaded and documents on company's database
- Emails

Facility review

- Live streaming using meeting apps, phone, tablet
- Uploaded photos and pre-recorded videos

Remote Inspections past and present

Overview of the remote inspection process



This the overall process used from 2020 until now

TGA decision making process for type of inspection

Criticality

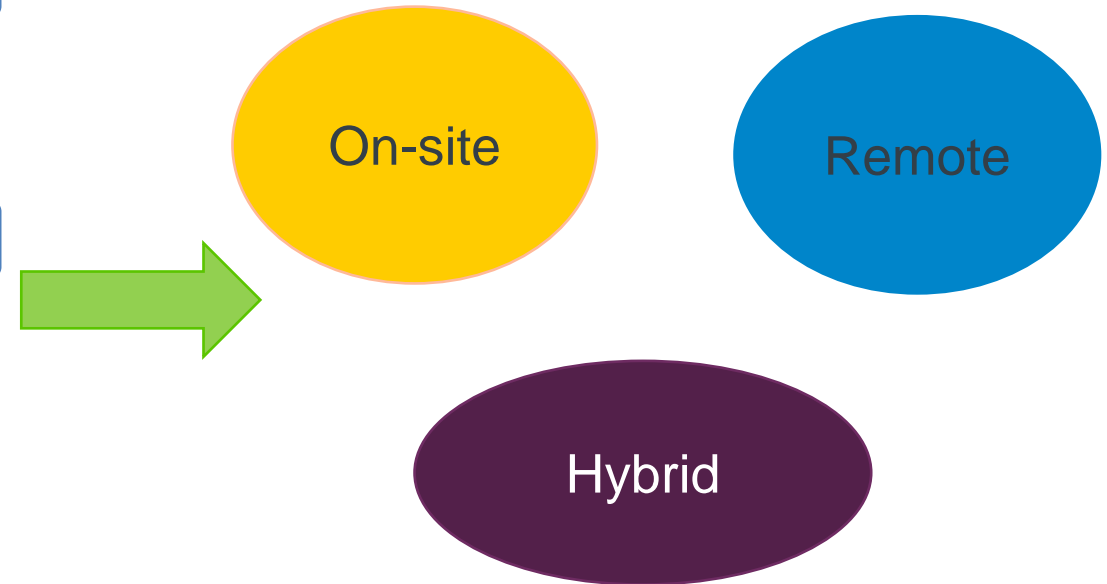
- Manufacturing type (risk)
- Manufacturer's compliance history

Protection of products and personnel

- Manufacturer's internal restriction requirements for protection of staff and products
- Manufacturer's corporate restriction requirements for protection of staff and products
- Manufacturer's procedures for protection of inspectors

Technology

- Manufacturer's technological capability to support remote inspection



Remote inspections

Common issues with remote overseas inspections

Logistics

Resources, time zone, inspection duration, translation, documents requested, soft skills, facility review limitation

Technology

Connection issues, document sharing, data privacy, file size

Regulatory

Flexibility with inspection, travel costs, useful for follow up inspections

Remote Inspections

The benefits of the remote inspection for Industry as mentioned by Industry

The flexibility of remote inspections as it was less rigid and pressured than onsite.

Reduces/eliminates the travel costs associated with onsite inspections for the industry.

A remote evaluation may also warrant delaying an on-site inspection, or justifying a reduction in depth and scope of an on-site inspections

The present - Common Deficiencies from TGA inspections

Remote

Poor Investigations

Validation

Documentation

Data Integrity

On site

Poor investigations

Validation

Data Integrity

Training

Domestic Inspections

The present - Common Deficiencies from TGA inspections

Remote

Poor Investigations, CAPA and deviation handling

Validation and qualification

Documentation

Data Integrity

On site

Poor investigations

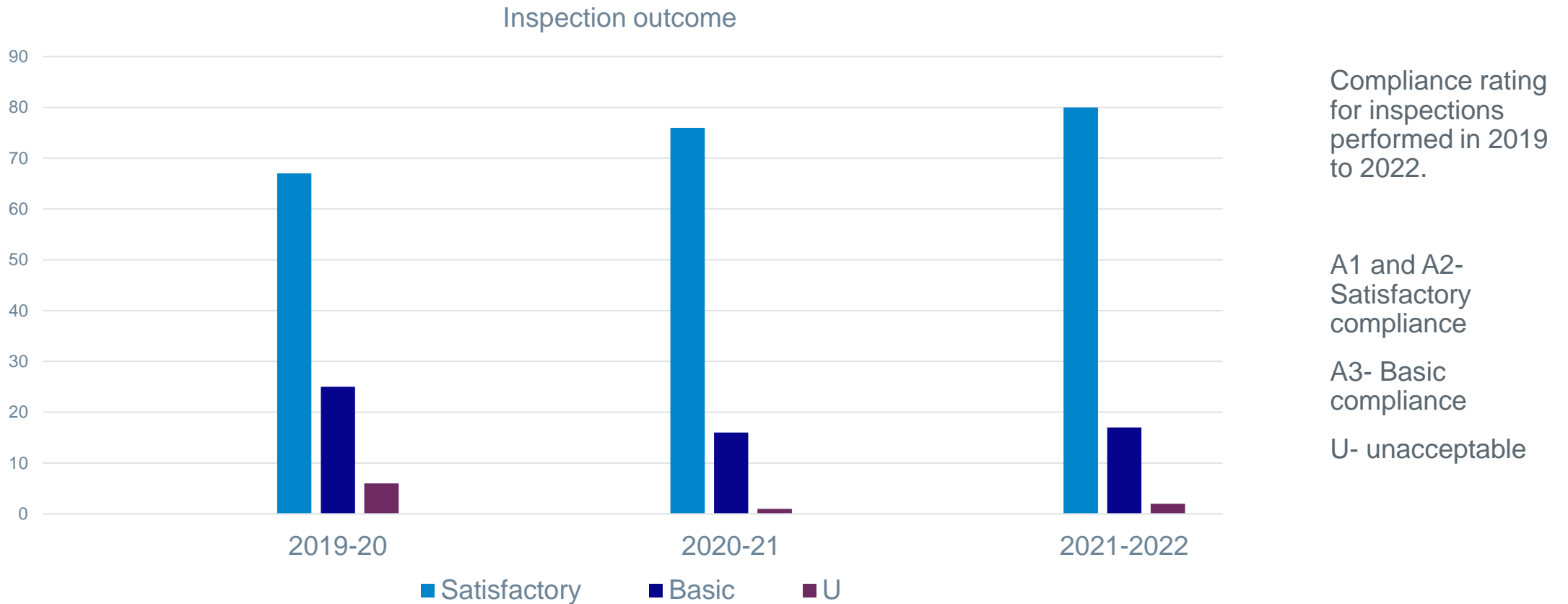
Validation

Quality Risk Management

Training

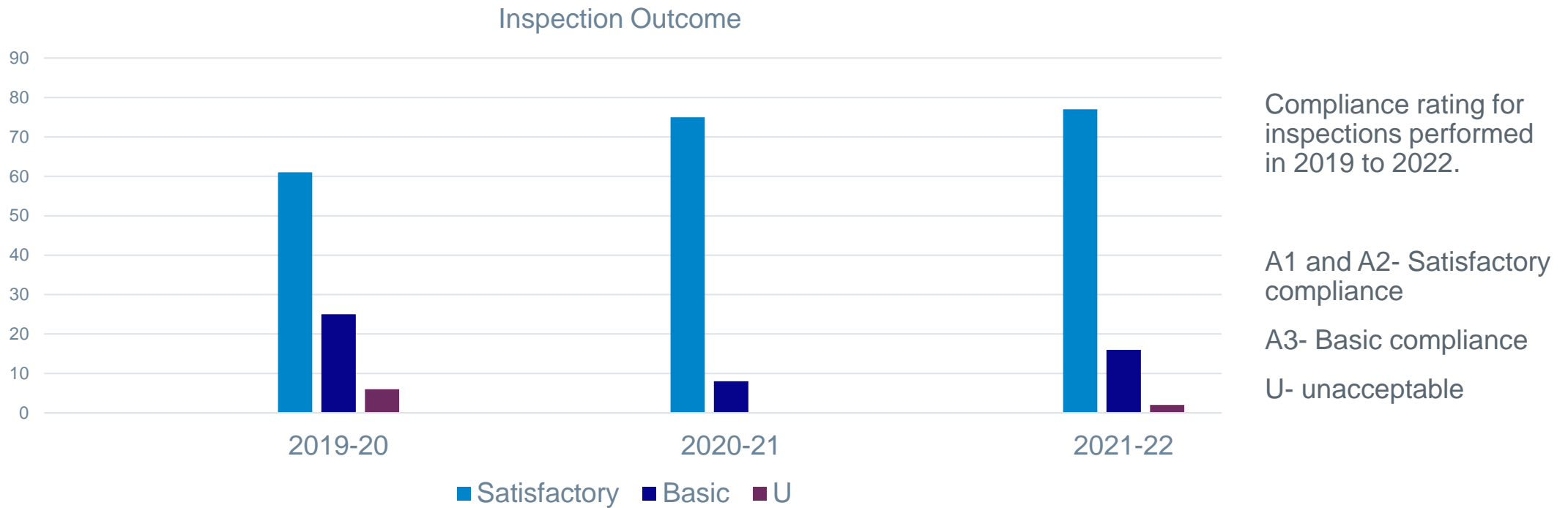
Compliance outcomes from all inspections performed

Domestic inspections performed by TGA



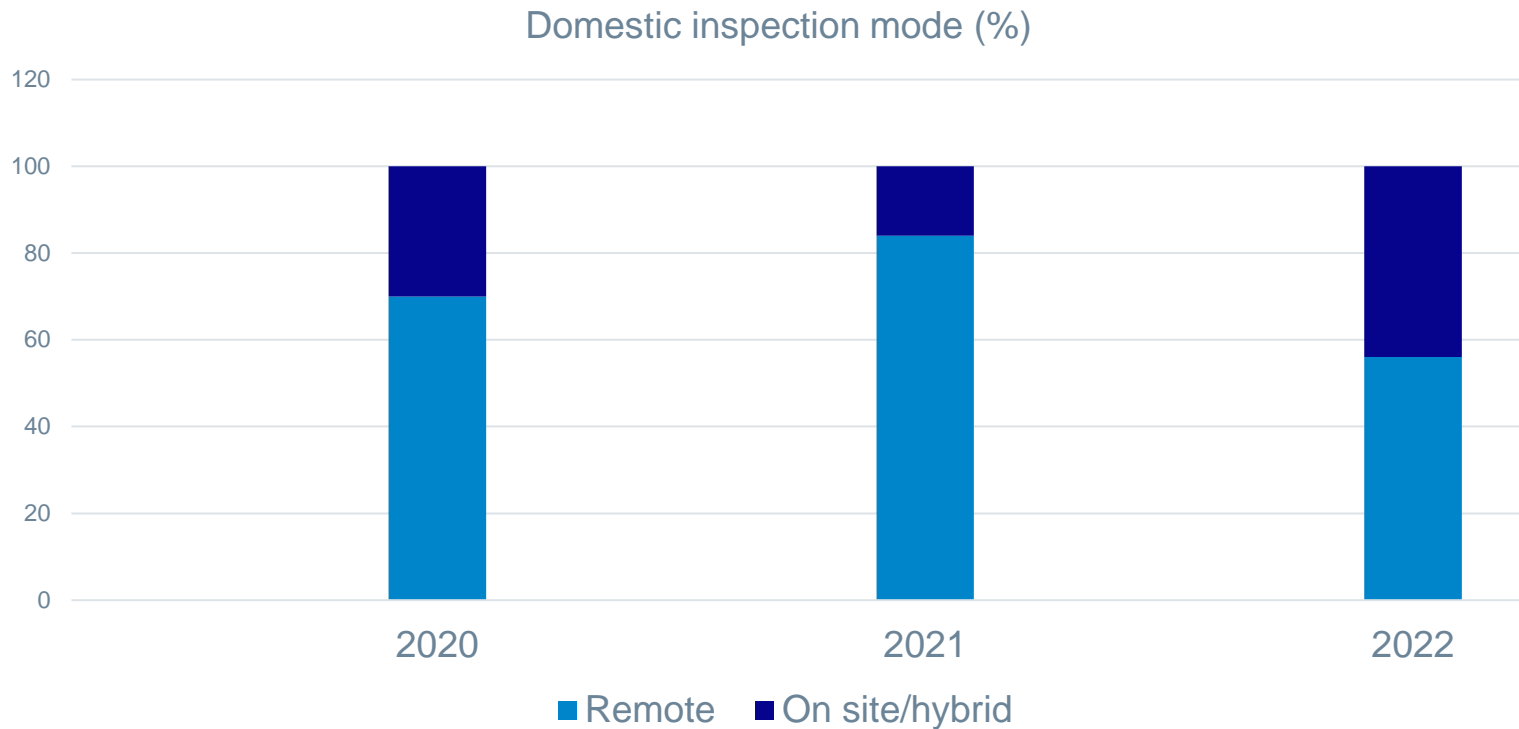
Compliance outcomes for all inspections performed

International Inspections performed by TGA



Inspection mode –Remote vs Onsite/hybrid

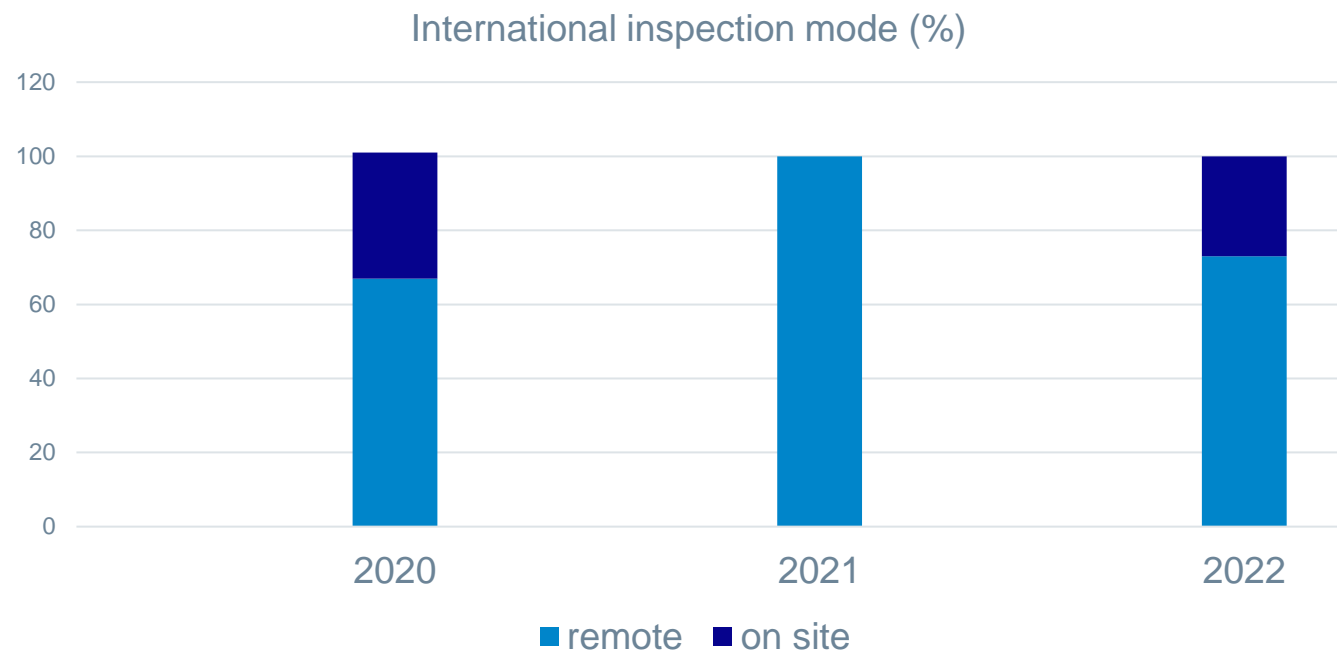
Domestic Inspections performed by TGA



The data shows the proportion of remote to onsite inspections for the periods 2020 to 2022 in Australia

Inspection mode

International Inspections performed by TGA



The data shows the proportion of remote to onsite inspections for the periods 2020 to 2022 internationally

The Future

Remote Inspections- settings – Feedback internationally

Will perform under these settings

Travel difficulties

Certain close out inspections

Will not be performing under these settings

For cause inspections

Initial inspections

Poorly compliant sites



Participate in the Q&A

Verbal questions:

Raise your hand to ask a verbal question. A member of the GMP Forum staff will provide a roaming microphone.

Written questions:

Scan the QR code below or click the link in your calendar to access Slido via your mobile device. You can submit your question, and vote on other questions submitted.





Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Coming up next in this room



Emmett Broderick

GMP Inspector

Manufacturing Quality Branch

Common Inspection deficiencies and trends