Australian Government
Department of Health
Therapeutic Goods Administration

Remote Inspections from TGA Manufacturing Quality Perspective

Remote Auditing – Impact of Covid-19 Restrictions on Manufacturers and Test Laboratories

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TGA Health Safety Regulation

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Remote Inspection

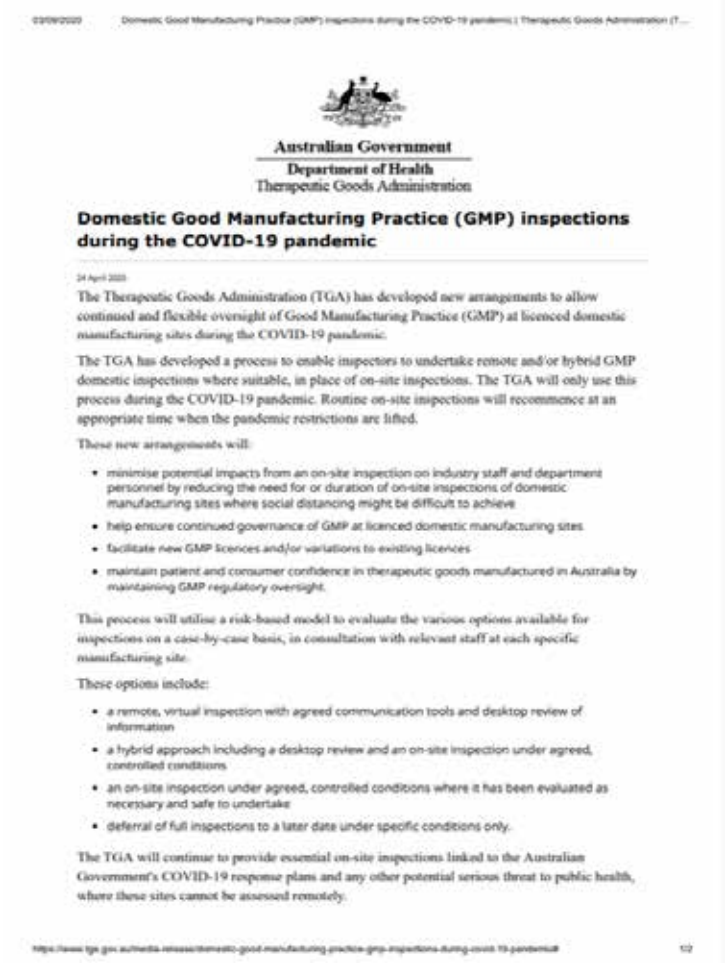
- Scope
- TGA GMP inspections during COVID-19 pandemic
- Remote inspections
- Tips
- Current status of inspection program
- Conclusion

Scope:

Includes inspections of manufacturers of therapeutic goods specifically medicines, blood and biologicals.

Excludes inspections of manufacturers of medical devices

TGA GMP inspections during COVID-19



Australian Government
Department of Health
Therapeutic Goods Administration

Domestic Good Manufacturing Practice (GMP) inspections during the COVID-19 pandemic

24 April 2020

The Therapeutic Goods Administration (TGA) has developed new arrangements to allow continued and flexible oversight of Good Manufacturing Practice (GMP) at licenced domestic manufacturing sites during the COVID-19 pandemic.

The TGA has developed a process to enable inspectors to undertake remote and/or hybrid GMP domestic inspections where suitable, in place of on-site inspections. The TGA will only use this process during the COVID-19 pandemic. Routine on-site inspections will recommence at an appropriate time when the pandemic restrictions are lifted.

These new arrangements will:

- minimise potential impacts from an on-site inspection on industry staff and department personnel by reducing the need for or duration of on-site inspections of domestic manufacturing sites where social distancing might be difficult to achieve
- help ensure continued governance of GMP at licenced domestic manufacturing sites
- facilitate new GMP licences and/or variations to existing licences
- maintain patient and consumer confidence in therapeutic goods manufactured in Australia by maintaining GMP regulatory oversight.

This process will utilise a risk-based model to evaluate the various options available for inspections on a case-by-case basis, in consultation with relevant staff at each specific manufacturing site.

These options include:

- a remote, virtual inspection with agreed communication tools and desktop review of information
- a hybrid approach including a desktop review and an on-site inspection under agreed, controlled conditions
- an on-site inspection under agreed, controlled conditions where it has been evaluated as necessary and safe to undertake
- deferral of full inspections to a later date under specific conditions only.

The TGA will continue to provide essential on-site inspections linked to the Australian Government's COVID-19 response plans and any other potential serious threat to public health, where these sites cannot be assessed remotely.

These new arrangements *(of remote and hybrid inspections)* will:

- ***minimise potential impacts from an on-site inspection*** on industry staff and department personnel by reducing the need for or duration of on-site inspections of domestic manufacturing sites where social distancing might be difficult to achieve
- help ensure ***continued governance of GMP*** at licenced domestic manufacturing sites
- facilitate ***new GMP licences and/or variations*** to existing licences
- ***maintain patient and consumer confidence*** in therapeutic goods manufactured in Australia by maintaining GMP regulatory oversight.

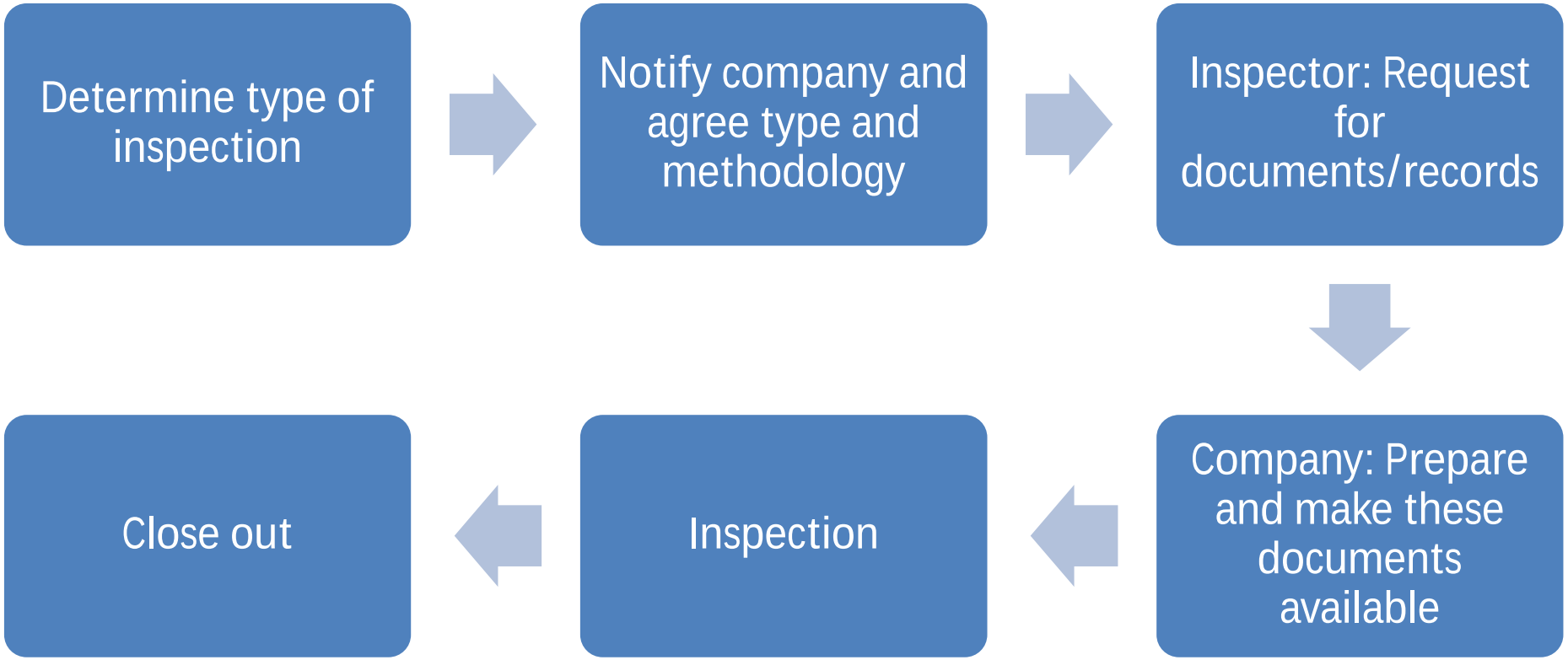
This process will utilise a ***risk-based model to evaluate the various options*** available for inspections on a case-by-case basis, in ***consultation with relevant staff at each specific manufacturing site***.

https://www.tga.gov.au/media-release/domestic-good-manufacturing-practice-gmp-inspections-during-covid-19-pandemic

TGA GMP inspections during COVID-19

The TGA will only use this process during the COVID-19 pandemic. Routine on-site inspections will recommence at an appropriate time when the pandemic restrictions are lifted.

Process


Determine type of inspection
Notify company and agree type and methodology
Inspector: Request for documents/records
Company: Prepare and make these documents available
Inspection
Close out

Determine type of inspection

Federal, state and territory government restrictions and requirements where the manufacturer is located and where the inspectors are based

Criticality

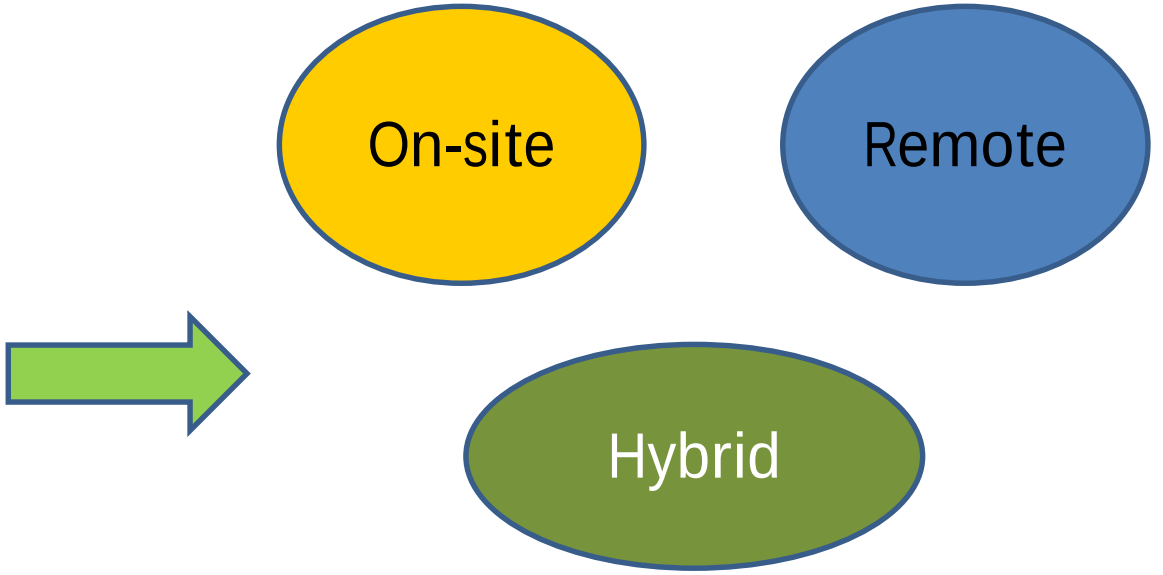
- Manufacturing type (risk)
- Manufacturer's compliance history

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



If deemed critical to be on-site, may delay that component until restrictions are lifted.

Remote inspection

Technology and limitations

Meeting

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

Document review

- Meeting apps for sharing of documents
- Emails

Facility review

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

Availability of internet and size of bandwidth

Inspection process (1)

Scope

Default – same as if on-site

To be determined on a case by case basis

Inspection Methodology

Same as if on-site

Read documents, followed by Q&A

Length of Inspection

May take more days, but cumulative hours will be as if on-site

If major/critical non-compliance observed – duration may be more than originally planned or may include an on-site component at a later date.

Inspection process (2)

Response to deficiencies observed

No change to the process

Compliance level achieved

Will not be better than the previous (on-site) inspection

Can be lower than the previous (on-site) inspection

Tips (1)

Trial runs:
Test every individual device that will be used during the inspection

Trial runs:
Test every activity; send invitation, accept invitation, join the meeting, uploading/downloading of materials

IT support to troubleshoot problems during trial runs and remote inspection

Essential

Tips (2)

Documents/records for review:

- Sharing of uploaded documents
- Sharing of documents/records from company's database
- Scanning of hard copy documents may be required
- Use of accessorised **camera** for sharing documents
- Photos and videos may be required if live streaming is not available.

Uploaded documents:

- Logical file structure
- Logical naming convention for documents and files

Tips (3)

Presenters/SME's should:

- Know technology options to present
- Be conversant with the technology/app used – how to share documents from various sources

Please be aware of:

- Audio – mute/unmute, use of loud speaker (can cause echo)
- Video – on/off, background

Current status of inspection programs

Domestic Inspection Program

- No stoppage of inspections
- Reasonably up to date
- We have been conducting on-site, hybrid and remote inspections since March 2020

Overseas Inspection Program

- Inspection program interrupted since March 2020
- Just recommenced – the first overseas inspection was carried out in August 2020
- Current backlog which is being addressed
- More challenges than domestic inspections; language, culture, time zone,
- Remote inspection only, no option of a hybrid or on-site inspection for the foreseeable future
- In the process of working with PIC/S member health authorities for their assistance if an on-site inspection component is required

Finally…

APVMA inspections	• No change. TGA continues to inspect on behalf of APVMA when required.

Licence vs GMP Certificate for Australian manufacturers	• Licence
	  • TGA issues a GMP licence to domestic manufacturer following a satisfactory initial inspection.
	  • Licence has no expiry date, and remains valid so long as the company accepts the TGA inspection when due and continues to be compliant.
	• GMP Certificate
	  • TGA issues a GMP certificate to domestic manufacturer based on the licence.
	  • GMP Certificate is valid for 3 years from the date of the last inspection.

Recognition of TGA remote inspections by other regulators	• GMP Certificate issued for domestic manufacturer includes a statement that the inspection was conducted remotely. • The destination country authority determines whether the inspection (and Certificate) is acceptable.

Conclusion

Remote inspection has limitations and cannot replace on-site inspection

More work is required to support a remote inspection (company and inspector). TGA will work flexibly with companies to enable inspections to be conducted as best the situation allows.

TGA has adopted the PIC/S Guide to GMP PE009-14 since 1 July 2020

Website and link references

Domestic Good Manufacturing Practice (GMP) inspections during the COVID-19 pandemic
https://www.tga.gov.au/media-release/domestic-good-manufacturing-practice-gmp-inspections-during-covid-19-pandemic

Overseas inspection | TGA expectations for overseas manufacturing sites hosting remote inspections during the COVID-19 pandemic
https://www.tga.gov.au/tga-expectations-overseas-manufacturing-sites-hosting-remote-inspections-during-covid-19-pandemic

GMP Clearance questionnaire
https://www.tga.gov.au/resource/gmp-clearance-questionnaire

A notice about the implications of adopting the PIC/S Guide to GMP PE009-14

Transition to new GMP requirements for medicinal products https://search.tga.gov.au/s/redirect?collection=tga-websites-web&url=https%3A%2F%2Fwww.tga.gov.au%2Fresource%2Ftransition-new-gmp-requirements-medicinal-products&auth=gY9yTOTeejVYAJ2yDGyX3Q&profile=_default&rank=4&query=GMP+-archive%3AArchived

TGA interpretation and expectations for demonstrating compliance
https://www.tga.gov.au/resource/pe009-pics-guide-gmp-medicinal-products

More information – Media channels

TGA website	www.tga.gov.au
TGA Facebook	https://www.facebook.com/TGAgovau/
TGA Twitter	https://twitter.com/TGAgovau
TGA YouTube	https://www.youtube.com/channel/UCem9INJbMSOeW1Ry9cNbucw
TGA topics blog	https://www.tga.gov.au/blogs/tga-topics
TGA Linkedin	https://www.linkedin.com/company/therapeutic-goods-administration/
TGA Instagram	https://www.instagram.com/tgagovau/?hl=en

Contact us

General & Australian manufacturing enquiries:
gmp@health.gov.au

Overseas manufacturing enquiries:
gmpclearance@health.gov.au

Thank you!

Australian Government

Department of Health

Therapeutic Goods Administration