Australian Government
Department of Health
Therapeutic Goods Administration

GMP approach to overseas manufacturers of medicines and biologicals during the COVID-19 pandemic

Update - Additional information for sponsors

1 November 2021

In collaboration with the TGA-Industry Working Group on GMP (TIWGG) (//www.tga.gov.au/committee/tga-industry-working-group-good-manufacturing-practice-gmp-tiwgg), we are providing an update on certain temporary measures introduced last year for overseas manufacturers.

On-going use of Remote Inspections

We are currently working our way through a large number of Certification applications following the Suspension of overseas GMP inspections (//www.tga.gov.au/media-release/tga-suspends-overseas-gmp-inspections-and-qms-audits-until-further-notice). While international travel restrictions remain in place, we are continuing our remote GMP inspection program.

At the time of its introduction in mid-2020, we contacted sponsors with submitted applications for an inspection prior to including them in the program. **This will no longer occur** as remote inspections have become the only available option for certification applications during the pandemic.

> Prioritisation of remote GMP inspections of overseas manufacturers will be based on:
>
> - the ability to use the alternative GMP Clearance processes
> - current compliance information
> - applications for marketing authorisation

Sponsors and manufacturers should refer to the following guidance and educational material regarding remote inspections:

- TGA expectations for overseas manufacturers hosting remote inspections during the COVID-19 pandemic (//www.tga.gov.au/tga-expectations-overseas-manufacturing-sites-hosting-remote-inspections-during-covid-19-pandemic)
- GMP Forum presentation: Remote GMP Inspections: Current feedback and future considerations (//www.tga.gov.au/webinar-presentation-remote-gmp-inspections-current-

feedback-and-future-considerations)

GMP Clearance

We are liaising with our international regulatory partners to understand the range of approaches being taken regarding GMP inspections. This information is assessed and its effect on our GMP Clearance framework considered.

Compliance Verification (CV) pathway

Sponsors are reminded that the GMP Clearance questionnaire (//www.tga.gov.au/resource/gmp-clearance-questionnaire) remains in place as an option for manufacturers who had an on-site inspection in 2018/2019. The questionnaire has been widely used to renew GMP Clearances where no more recent inspections have taken place.

Since the introduction of the questionnaire, other regulatory agencies have introduced their own remote inspection programs. This has created alternative evidence types that may also meet the needs of a GMP Clearance assessment as a temporary measure during the pandemic.

> **For the CV pathway:**
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> We will accept an inspection report issued following a successful remote inspection or distant assessment in addition to or, in certain circumstances, in lieu of the GMP Clearance questionnaire.
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> In such circumstances, Sponsors should be able to justify why the report removes the need for the GMP Clearance questionnaire.
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> Sponsors should contact GMPclearance@health.gov.au (mailto:GMPclearance@health.gov.au) **prior to** submitting applications if there are doubts around the suitability of any evidence.

We do **not** accept inspection reports issued following a remote inspection or distant assessment as the **primary** evidence for a GMP Clearance i.e. it does not replace an inspection report from a physical on-site inspection.

Additionally, where applicants have already used the GMP Clearance questionnaire option, a TGA remote inspection will most likely be required for any subsequent application.

Mutual Recognition Agreement (MRA) pathway

The MRA pathway has not changed and the most current evidence issued by our MRA partners continues to be accepted for both new and renewal GMP Clearance applications.

However, by incorporating our MRA partners guidance and advice (for example, the EMA Guidance (https://www.ema.europa.eu/en/news/guidance-regulatory-requirements-context-covid-19-pandemic)), a large number of GMP Clearances now expire at the same time - on 31 December 2021. To avoid a repeat of this situation and the potential negative effects on both industry and regulatory agencies, we have developed a revised approach to reduce this risk and extend the

validity of our GMP Clearances. This approach, which incorporates the extended validity applied by our MRA partners, will be adopted for relevant new and renewal applications submitted and paid after 1 July 2021.

> **For the MRA pathway:**
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> An additional period of validity, beyond that recommended by our MRA partners, will be applied to a GMP Clearance where possible and will be determined by:
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> - the type of manufacturing steps being performed at the facility
> - the length of time since the last physical inspection by the national authority
> - the level of oversight applied by the national authority such as remote inspections and distant assessments

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3 July 2021

The COVID-19 pandemic has created many challenges to the ongoing Good Manufacturing Practice (GMP) regulation of medicine and biological manufacturers.

Following the suspension of overseas GMP inspections and QMS audits (//www.tga.gov.au/media-release/tga-suspends-overseas-gmp-inspections-and-qms-audits-until-further-notice), a significant amount of consideration was given to the appropriate level of regulatory oversight required to maintain an assurance of product quality without requiring wholesale changes to existing processes.

These considerations needed to be agile yet sustainable as the length of time that international travel restrictions remain in place is difficult to predict.

Remote GMP Inspections

Manufacturers of medicines and biologicals are routinely inspected using a risk-based approach (//www.tga.gov.au/manufacturer-inspections-risk-based-approach-frequency) against the appropriate Manufacturing Principles (//www.tga.gov.au/good-manufacturing-practice-overview).

Following the suspension of on-site inspections, we developed new arrangements to allow continued and flexible oversight of licenced domestic manufacturers by performing remote GMP inspections (//www.tga.gov.au/media-release/domestic-good-manufacturing-practice-gmp-inspections-during-covid-19-pandemic).

The domestic program demonstrated that it would be possible to replicate this approach for overseas medicine and biological manufacturers. However, it is recognised that broadening this program may bring additional challenges and the same number of manufacturers cannot be inspected using this approach.

From July 2020, we will begin the remote GMP inspections program for some overseas manufacturers.

Sponsors who have submitted Certification (CE) applications or whose manufacturer has been identified as requiring a remote GMP inspection will be contacted to register their interest in participating.

We have published additional guidance on the Expectations for overseas manufacturing sites hosting remote inspections during the COVID-19 pandemic (//www.tga.gov.au/tga-expectations-overseas-manufacturing-sites-hosting-remote-inspections-during-covid-19-pandemic).

As travel restrictions begin to ease, we may still conduct on-site components of GMP inspections of manufacturers who have had a remote inspection performed.

GMP clearance

We are conscious that a number of our overseas regulatory partners have also faced disruptions to their on-site inspection programs for both domestic and overseas manufacturers. This has created additional challenges for our existing reliance mechanisms requiring similar flexibility in our regulatory oversight.

In order to support industry, we have implemented a temporary change to our documentation requirements for GMP Clearance applications submitted through the Compliance Verification (CV) pathway during the COVID-19 pandemic.

In order to support your GMP Clearance application, Sponsors may provide:

- A recently expired inspection report from a recognised regulator, and
- a GMP Clearance questionnaire (//www.tga.gov.au/resource/gmp-clearance-questionnaire) as well as any additional documents identified during the completion of the questionnaire

GMP Clearance applications will be assessed using our risk-based approach and as per our existing process, outcomes will be dependent on the quality of the application and information provided. Assessments that identify certain risk criteria may still require a remote GMP inspection.

There are no changes to GMP Clearance where current evidence is available. There is also no change to the existing MRA pathway and sponsors are encouraged to continue to submit their renewal applications using the existing evidence available.

Fees

The fees (including inspection hourly rates) outlined in the fees and charges summary (//www.tga.gov.au/schedule-fees-and-charges) will continue to be charged for the above inspection and GMP Clearance processes in line with our cost recovery requirements.

Contact us

The TGA is committed to working with Australian sponsors during this time. Our staff are available to assist via the contact information below:

- For domestic and overseas inspections and general GMP enquiries, contact the Licensing and Certification Section: GMP@health.gov.au (mailto:GMP@health.gov.au)
- For overseas GMP Clearance desk-top assessments and extensions to GMP Clearances, contact the GMP Clearance section: GMPClearance@health.gov.au (mailto:GMPClearance@health.gov.au)

Additional information about the TGA's response to coronavirus (COVID-19) (//www.tga.gov.au/collection/covid-19) is available on our website.

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Tags: manufacturing
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