Australian Government
Department of Health
Therapeutic Goods Administration

TGA Remote Domestic and International Inspections Approach

Referred for GMP clearance if inspection reliance possible

Inspection scheduling and assignment

IT platform assessment with manufacturers

Decision to inspect virtually or on-site

PIL issued

CAPA accepted

GMP Licences and Certificates issued

GMP Clearance issued

Pre-Inspection

Licencing and Certification Section

Application receipt, compliance signal or re-inspection activates a review process.

Application review and pre-inspection questionnaire informs whether to undertake a GMP clearance or remote inspection.

Scheduling and assignment of inspection to Inspector following conflict of interest check.

Costing estimate determined and agreed with Australian sponsor and initial invoice sent.

Desktop Evaluation

Inspection Section

Inspector undertakes preliminary review and develops Inspection Plan.

Desktop evaluation only for reinspections where GMP Clearances have previously been granted.

Evaluation of evidence including electronic documents through secure platforms; live sharing of screens displaying computerised systems; teleconference and videoconferences with manufacturer personnel and SMEs. Video recordings supplied by manufacturer may be reviewed. Translation may be required.

Live Virtual or On-site Inspection

Inspection Section

Live virtual inspection required at high risk or new international sites where there has been no or unreliable prior visits from other regulators. These may be undertaken by manufacturer personnel or third parties.

On-site limited time domestic inspection undertaken for all domestic sites unless WHS risks exist, travel restrictions apply or when manufacturers cannot accommodate inspection of COVID-19 reasons.

Live video (via smart glasses, mobile cameras, drones or cameras) meetings to review manufacturing operations, equipment, facilities and relevant documentation. Translators may be required.

Overseas regulator assistance may be sought as a last resort to undertake onsite components of international inspections. Existing MOUs will be used (if possible) to facilitate arrangements or re/developed if required.

PIL prepared and issued to manufacturer.

CAPA received then liaison with manufacturer prior to finalisation of Inspection Report and close out of inspection.

Review Panel may be convened when serious compliance issues identified.

Post-Inspection

All Sections

Invoicing of inspection reconciled.

GMP Certificates are issued only when a full desktop and virtual inspection process is undertaken or if an inspection by another regulator if deemed relevant and reliable.

GMP Clearance issued to Australian Sponsor for international inspections.

Licences may be issued with conditions.

Acronyms

CAPA – Corrective and Preventative Action
GMP – Good Manufacturing Practice
MQB – Manufacturing Quality Branch
PIL – Post Inspection Report
SME – Subject Matter Expert