



**Australian Government**

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**Australian Pesticides and  
Veterinary Medicines Authority**



# **Good Manufacturing Practice Audit Procedure**

March 2025

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## Introduction

The purpose of this document is to provide detailed instructions on how routine (full or partial) Good Manufacturing Procedure (GMP) audits of veterinary chemical manufacturing premises are to be planned, conducted and reported to the Australian Pesticides and Veterinary Medicines Authority (APVMA).

This manual covers the procedure to be followed by [APVMA-authorised GMP auditors](#) when auditing an **Australian veterinary chemical manufacturing facility** for compliance with the [Agricultural and Veterinary Chemicals \(Manufacturing Principles\) Determination 2014](#) (Manufacturing Principles), the [Australian Code of Good Manufacturing Practice for Veterinary Chemical Products, 2007](#) (and relevant annexes – GMP Code), Part 8 of the [Agricultural and Veterinary Chemicals Code Act 1994](#) (AgVet Code) and Part 7 of the [Agricultural and Veterinary Chemicals Code Regulations 1995](#) (AgVet Code Regulations). It covers procedures to be followed for routine (full and partial) audits, and for verification (on-site) audits and desk reviews of corrective actions arising from routine audits. It also covers the procedures to be followed by Licence Holder when selecting an auditor, and when responding to and forwarding the GMP Audit Report to the APVMA.

The procedure should also be followed for audits of **overseas veterinary chemical manufacturing facilities** by APVMA-authorised GMP auditors, however some differences in processes, forms, etc may apply. These differences are summarised in Section 5. For a list of all forms and templates, refer to Appendix A (page **Error! Bookmark not defined.**).

The procedure also covers other recognised GMP accreditation from [Therapeutic Goods Administration \(TGA\)](#) and the [National Association of Testing Authorities, Australia \(NATA\)](#). The TGA will audit a veterinary chemical manufacturing facility against the [Pharmaceutical Inspection Co-operation Scheme \(PIC/S\)](#). Testing laboratories can be audited by NATA to [ISO17025 General Requirements for the Competence of Testing and Calibration Laboratories](#).

The APVMA may attend audits as an observer(s) or may periodically conduct announced and unannounced audits to assess day-to-day GMP compliance.

All GMP Audit Reports are reviewed by the APVMA to ensure that a veterinary chemical manufacturing facility is compliant with the Agricultural and Veterinary Chemicals (Manufacturing Principles) Determination 2014 (Manufacturing Principles) and the GMP Code for the purpose of licensing.

## 1. General principles

### Supplying manufactured goods to Australia

No batch of veterinary chemical product(s) manufactured prior to licensing or issuance of a GMP compliance letter can be sold or supplied within Australia, or exported from Australia, unless prior approval has been obtained.

Note that the manufacture of [excluded nutritional or digestive \(END\) products](#) can be exempted from this requirement. For a product to be classified as an END product, the product must be manufactured under one of the following Quality Assurance (QA) systems:

- Meet the requirements of the APVMA GMP Code of Practice and manufacturing principles
- An Australian animal feed industry code of practice (such as FeedSafe or the FIAAA CoP)
- An Australian Standard for animal feed manufacture (in particular, AS 5812-2011)
- An animal feed quality standard of the United States of America or the European Union (such as FAMI-QS).

The QA system must be appropriate for the product. For example, a stock feed QA system will not apply to pet food, and vice versa.



Do not commence manufacturing for validation or supply to Australia until a manufacturing licence or GMP compliance letter has been granted, unless prior approval has been obtained, or those chemical products are [listed](#), [reserved](#) or [exempt](#).

### Confidentiality

The APVMA treat information about applications and manufacturers as official information. Find out more about confidentiality of the [APVMA approach to disclosure of commercially confidential information](#) on our website.

The APVMA publishes a list of [licensed Australian manufacturers](#).

### Determining whether a licencing or GMP compliance letter is required

Under the AgVet Code and the AgVet Code Regulations, an APVMA manufacturing licence is required to manufacture veterinary chemical products for supply in, or export from, Australia, unless otherwise exempt.

GMP compliance is how the APVMA determines that veterinary chemical products manufactured overseas and intended for import and supply to Australia, or manufactured domestically, comply with Australia's GMP requirements.

### Independent advice

If a Licence Holder has no previous experience with manufacturing veterinary chemical products within Australia, they may seek the services of a GMP consultant or a regulatory affairs consultant. The APVMA also recommends that Licence Holders seek independent legal advice to ensure they comply with all relevant requirements.

## Responsibilities of key persons

The AgVet Code Regulations, the Manufacturing Principles and the GMP Code outline specific responsibilities for the key persons nominated by the Licence Holder and listed in the APVMA records as being responsible for controlling production and quality.

Under the AgVet Code Regulations, it is a condition of the licence that the key people maintain their control of production and quality. If a key person is replaced, the Licence Holder must advise the APVMA of the name, qualifications and experience of their replacement as soon as practicable.

## Variations to a licence or its conditions

Licence Holders are responsible for notifying the APVMA of any changes or variations that may affect their licence or its conditions. This can apply to changes in the product (types), the manufacturing site and processes, or to key persons.

Licence Holders must [submit an application](#) to vary their licence, in accordance with the requirements set out in the AgVet Code.

## Recalls

Licence Holders are responsible for having a system in place to recall a product after it has been supplied to the Australian market and for implementing that system when required.

Recall action can be instigated by the Licence Holder, registrant or by the APVMA when:

- A chemical product may not meet the safety criteria, the trade criteria, the efficacy criteria or the labelling criteria
- The constituents of stocks of a registered chemical product or of a particular batch of a registered chemical product differ by more than the prescribed extent from the constituents stated in relation to the product in the Register
- The concentration of the constituents of stocks of a registered chemical product, or of a particular batch of a registered chemical product, differs by more than the prescribed extent from the concentration of the constituents stated in relation to the product in the Register, or
- The composition or purity of any constituent of stocks of a registered chemical product, or of a particular batch of a registered chemical product, differs by more than the prescribed extent from the composition or purity of that constituent stated in relation to the product in the Register.

The APVMA has published [recall guidelines](#) to provide more details on the responsibilities of Licence Holders and other parties when undertaking recalls.

## 2. Audit pathways – Overview

Audits may be undertaken by the APVMA's authorised auditors, by the TGA or by NATA. The choice of which audit pathway a Licence Holder takes to ensure GMP accreditation is an individual business decision. Please note that there are different costs associated with the different audit pathways.

### 2.1. APVMA Audits

The APVMA-authorised auditors may undertake an audit of a Licence Holder's manufacturing facility for 4 key reasons:

- Routine GMP audit.
- Audit to add a manufacturing site(s).
- Audit to vary a licence.
- Verification audit (Section 3.3).

In addition to audits undertaken by APVMA-authorised auditors, the APVMA may utilise its own staff to conduct audits as needed. These may include routine GMP audits, unannounced GMP audits, variation to licence or verification audits. At the discretion of the APVMA, a fee for these audits may be requested from the Licence Holder.

#### Routine GMP audits

Prior to each APVMA audit, the APVMA will notify the Licence Holder at least 3 months before the audit due date of the required audit duration. The Licence Holder must arrange for an APVMA-authorised auditor to conduct the audit before the audit due date. The [pre-audit notification and information form](#) must be provided to the APVMA at least 6 weeks prior to the audit being conducted. The APVMA-authorised auditor will verify during the audit that all key aspects of veterinary chemical manufacture are carried out within the scope of the Licence Holder's APVMA licence. The Licence Holder must also provide the APVMA with signed APVMA forms within required timeframes i.e. GMP Audit Reports, responses to non-conformances, related to the conduct and closure of such audits, unless granted extensions by the APVMA.

It is important for a Licence Holder to advise the APVMA of any changes to site, key personnel or any variation of licence prior to related correspondence between the Licence Holder and APVMA-authorised auditor. This is to enable the APVMA to provide relevant correspondence to the APVMA-authorised auditors in a timely manner.



The APVMA will send an audit reminder 4 months before the audit due date requesting if the Licence Holder has had any major changes i.e. key personnel, new equipment, change to current facilities, new software and is wanting to change the scope of their licence i.e. new facilities, categories or steps of manufacture. Licence Holder will have 2 weeks from the reminder to advise the APVMA in writing with any major changes and changes to the scope of the licence. This may impact on the final audit duration determination.

An APVMA audit may be required for an overseas site if other acceptable evidence is not available for the purposes of APVMA product registration (see Section 5).



## Adding a new manufacturing site(s)

You may request [pre-application assistance](#) to discuss the application requirements for a new licence, or to vary a licence. There is a fee for this service. To be ready for an audit, the Licence Holder must have:

- Completed constructing or fabricating the premises.
- Taken functional control of the site (the APVMA may ask to see a certificate of occupancy or equivalent).
- Documented and implemented a quality system, in accordance with the requirements of the manufacturing principles and specifically tailored to the Licence Holder's proposed manufacturing operations, that includes procedures, records and instructions for the management of:
  - Quality Management Systems (QMS) such as deviation, change control, risk management, product quality review systems.
  - Documentation.
  - Materials.
  - Production operations, including master batch records.
  - Personnel matters including training, clothing and hygiene.
  - Validation and qualification.
  - Equipment assembly and calibration.
  - Maintenance, cleaning and sanitisation.
  - Environmental monitoring.
  - Pest control.
  - Complaints.
  - Recalls.
  - Returns.
  - Self-inspection.
  - Laboratory controls and operations.
  - Release for supply.
- Qualified all relevant facilities, utilities and equipment to at least the operational qualification (OQ) stage.
- Employed, nominated and trained all key staff responsible for controlling manufacturing operations and quality assurance.

## Varying a licence

To change details on a manufacturing licence – or to change its conditions – Licence Holders must apply to the APVMA for a licence variation. Changes can include:

- A change to the company name where the ACN / ABN remains the same (not a change to the legal entity).
- The change to a product type within an already licensed manufacturing category (and applicable steps).
- A change to steps of manufacture covered by the licence (addition / deletion).
- The inclusion of a subcontractor under the provisions of Regulation 59A (analysis and testing, packaging or labelling only).
- Any other change not already specified.

The requirement for a variation is because licences to manufacture chemical products in Australia are issued with certain details and licence conditions that are specific to each Licence Holder. The licence will specify, among other things, precisely what steps of manufacture, at which sites and what products can be manufactured as part of the licence. Any change to a licence or its conditions must be approved by the APVMA, meaning Licence Holders must submit an application well ahead of the audit.

The process for receiving, assessing and deciding the outcome of a variation application is similar to the process for new licence applicants, and is undertaken in accordance with APVMA legislation.

## Observing audits

APVMA staff will observe audits as part of quality assurance for both the auditing process and the individual APVMA-authorized auditors. TGA and NATA audits (below) may also be observed. Broadly, the reasons for observing audits may include:

- Auditor qualification and quality control.
- Auditor wishes to audit to a new category of manufacture.
- Complex audit history or new sites / steps of manufacture.
- Training staff.

If an audit is to be observed by APVMA staff, the Licence Holder and the auditor / inspector will be notified, and the role of the observer will be underscored. In particular, it will be explained that when an APVMA staff member is present as an observer, that person will not actively take part in, or otherwise influence, the audit. There will be no cost to the manufacturer for the APVMA staff to attend the audit as an observer.

## 2.2 TGA Audits

### APVMA-TGA memorandum of understanding

The TGA and the APVMA have a [Memorandum of Understanding \(MoU\)](#) on Good Manufacturing Practice Licensing and Inspection of Australian Manufacturers (APVMA-TGA MoU).

Manufacturers holding both TGA and APVMA licences may elect to have routine inspections conducted by the TGA only. The Licence Holder must notify the APVMA of this decision. If the purpose of the inspection is to underpin licence renewal or change (see also certification, below), then the TGA will not inspect a facility that is dedicated to the manufacture of veterinary products only.

### Mutual Recognition Agreements

The APVMA recognises authorities in Europe, including the United Kingdom, through [Mutual Recognition Agreements](#) (MRAs). The APVMA also recognises authorities in New Zealand, Canada and the United States as having requirements equivalent to the APVMA's GMP standards. On a case-by-case basis, the APVMA may recognise GMP evidence from a PIC/S participating authority / member.

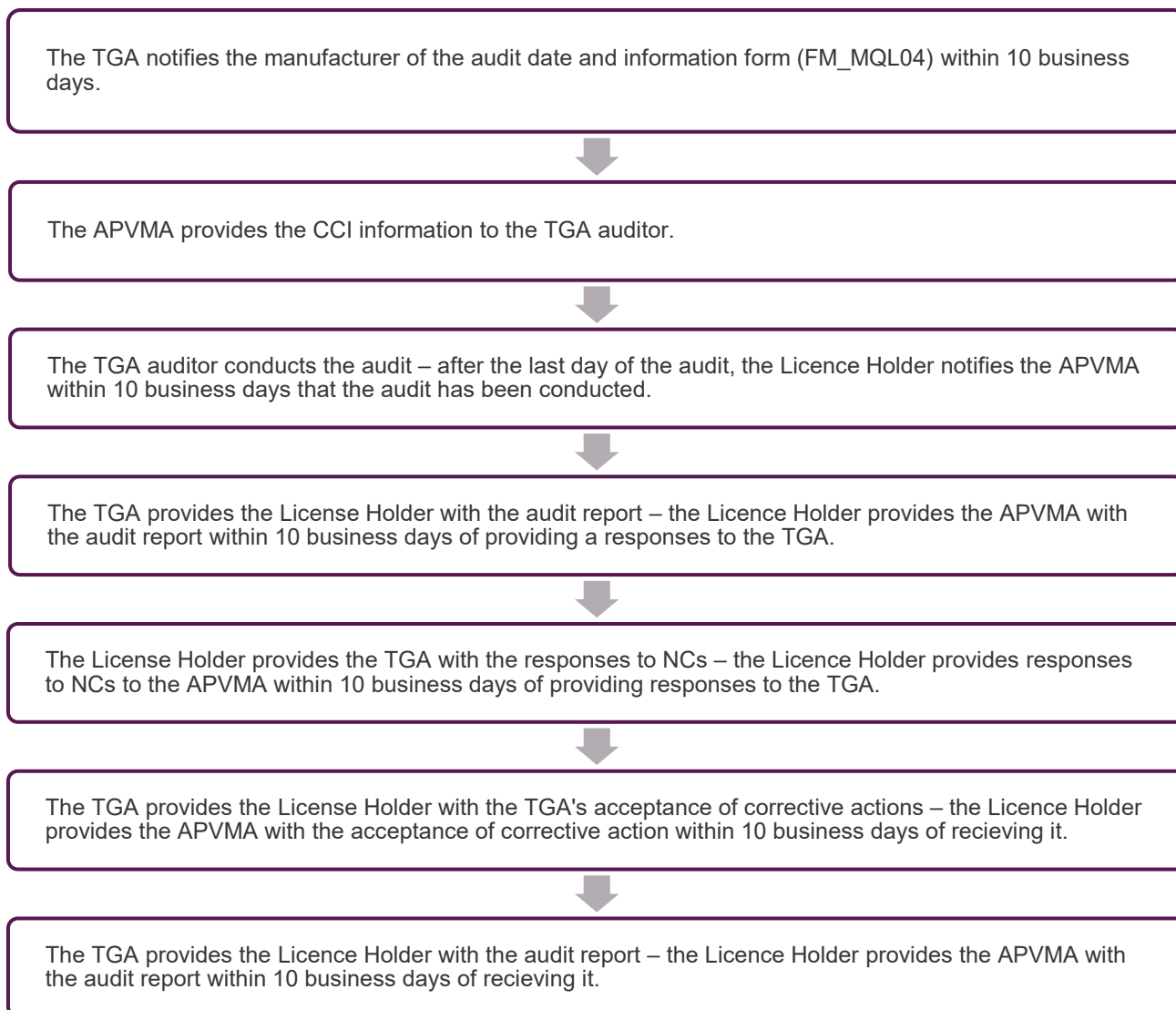
Manufacturers licensed by the APVMA, who wish to export veterinary chemical products to Europe or the UK, must be inspected by the TGA. APVMA-licensed manufacturer(s) requesting a Certificate of GMP Compliance under the provisions of the [Mutual Recognition Agreement between the EC and Australia \(EC-MRA\)](#) are required to submit form [FM\\_MQL39](#). This inspection must be requested by the APVMA, not by the manufacturer. The APVMA will assess the TGA inspection results and can then issue a GMP certificate to the manufacturer. Under the EU or UK MRAs, the authority in the recipient country recognises the TGA as the authority for inspecting veterinary premises in Australia and the APVMA as a certifying body. Note that in contrast to inspections undertaken for the purpose of licensing (above), the TGA will inspect a facility dedicated solely to the manufacture of veterinary products if the purpose of the inspection is to certify a product under an MRA.

### TGA Audit process

Prior to each TGA audit, the Licence Holder must arrange for the TGA inspector to verify during the audit that all key aspects of veterinary chemical manufacture are carried out within the scope of that audit (European Community-Australian Mutual Recognition Agreement; EC-MRA) or TGA licence. The Licence Holder must maintain their TGA licence and advise the APVMA in writing, within 10 business days, of any changes in the scope of that licence. The Licence Holder must also provide the APVMA with copies of all TGA audit reports and correspondence i.e. responses to non-conformances, related to the conduct and closure of such inspections, within 10 business days of receipt of those reports or correspondence.

It is important for a manufacturer to advise the APVMA of any related correspondence between the manufacturer and TGA. This is to enable the APVMA to provide Commercially Confidential Information (CCI) to the TGA in a timely manner.

Figure 1: TGA audit process

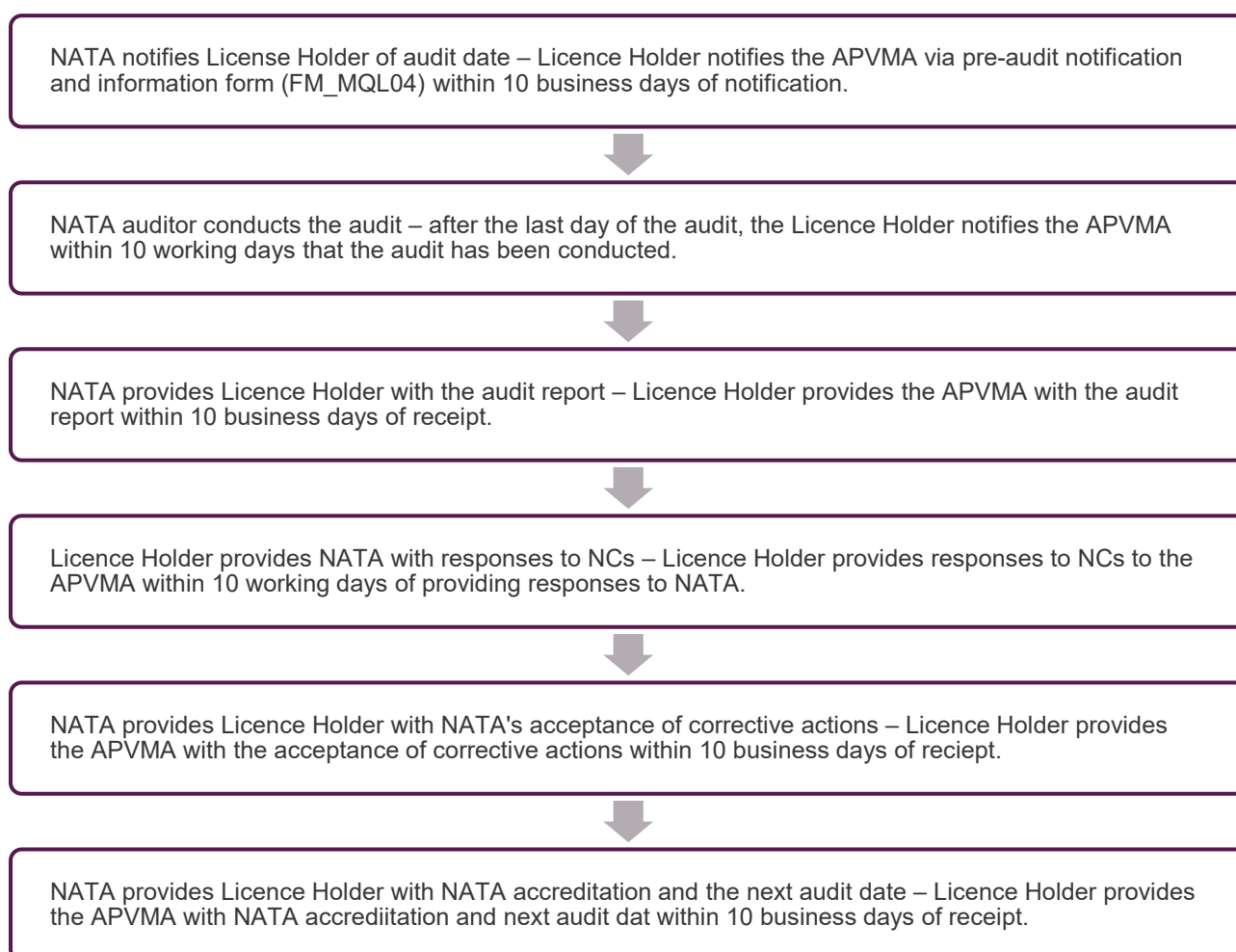


Advising the APVMA in writing within 10 business days of any changes in the scope of the licence and correspondence is a condition of a Licence. If this doesn't occur, regulatory action may be taken which may result in suspension or cancellation of the licence.

## 2.3 National Association of Testing Authorities Audits

The Licence Holder must maintain their NATA accreditation and advise the APVMA in writing, within 10 business days, of any changes in the scope of that accreditation that are likely to impact on the analysis or testing or both of veterinary chemical products. The Licence Holder must also provide the APVMA with copies of all NATA assessment reports and correspondence i.e. responses to non-conformances, related to the conduct and closure of such assessments, within 10 business days of receipt of those reports or correspondence. Providing this correspondence is important as the APVMA does not have an agreement with NATA and cannot retrieve or provide information to NATA.

**Figure 2: NATA audit process**



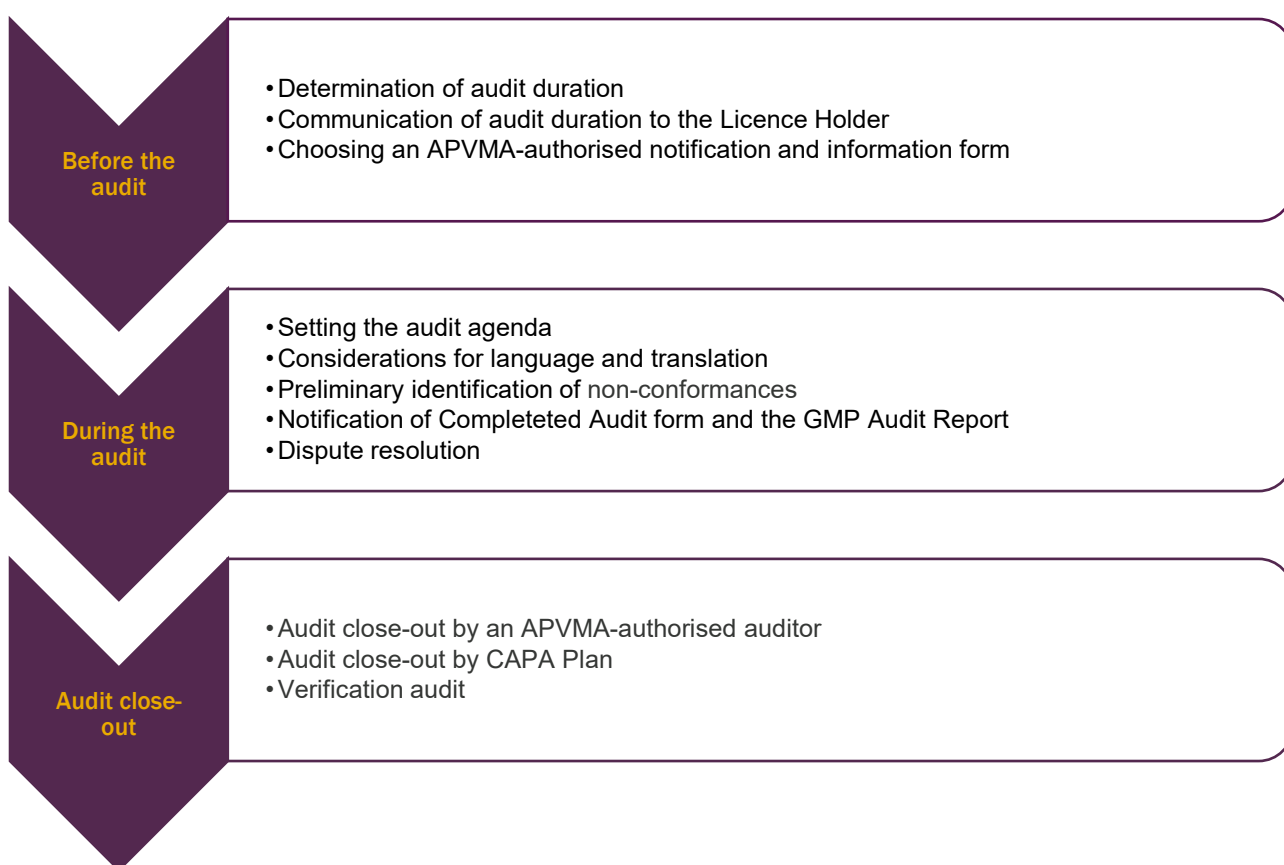
Advising the APVMA in writing within 10 business days of any changes in the scope of the licence and correspondence is a condition of a Licence. If this doesn't occur, regulatory action may be taken which may result in suspension or cancellation of the licence.

### 3. APVMA audits – Procedure

An overview of the audit and review procedure for the APVMA audits is given in Figure 3 below. Each of the items in this figure is discussed in the following 3 sections.

Figure 3: APVMA audit process

#### 3.1 Before the audit



#### APVMA determines audit duration

When determining audit duration, the APVMA will take into account the type of products manufactured, the complexity of the manufacturing process, the size of the manufacturing facility, the Licence Holder's audit history, and any manufacturing-related adverse experiences or recalls. In addition, the APVMA will consider any changes to key personnel (appointments or resignations), operations or to buildings, key equipment or product lines.

As a baseline, however, audit duration will be calculated as the sum of the following 3 parts:

- a) Risk-based audit duration, plus
- b) Non-conformity additional duration, plus
- c) Licence variation additional duration.

**Risk-based audit duration** ranges from Low (1 day) to High (3 days), as set out below:

### **High risk – minimum audit duration 3 days**

High risk products and processes include:

- Category 1 – Sterile products.
- Category 1 – Immunobiological products.
- Multi-category manufacturing.

### **Medium risk – minimum audit duration 2 days**

Medium risk products and processes include:

- Category 2 or 3, only non-sterile products
- Products containing antibiotics.

### **Low risk – minimum audit duration 1 day**

Low risk products and processes include:

- Category 4, Premix / supplements.
- Laboratories.
- Single step – labelling / packaging, release for supply, or storage.

One day will be added to this risk-based starting point for audit duration, if either of the following non-conformity scenarios applies:

- 10 or more total non-conformities, and/or
- 5 or more Major non-conformities from the previous audit.

A further one day will then be added to the calculated audit duration if the license is to be varied for either of the following reasons:

- A new facility is to be added to the license (i.e., a new building for storage, manufacturing or laboratory services).
- A new step of manufacture / product dosage form / category is to be added to the license, increasing the base risk (for example., the current licence covers non-sterile products, and a variation is sought to add a sterile step of manufacture).

The APVMA will use this 3-step formula to obtain a baseline estimate for audit duration. At the APVMA's discretion, this baseline calculation may then be modified on account of additional intelligence<sup>1</sup> about the Licence Holder, or manufacturing site.

## Communicating audit duration to the Licence Holder

At the close of the preceding audit (see below), the APVMA will issue an audit outcome letter that includes, amongst other things, the due date for the next audit and the first estimate of audit duration (as described above).

Four months prior to the date of the next audit, the APVMA will collate and review any relevant s161 notices, compliance issues, adverse experiences or recalls; relevant conditions attached to any new product registrations or permits; and relevant licence variation applications. An audit due reminder will be sent to the Licence Holder requesting if there have been any major changes i.e. key personnel, new equipment, change to current facilities, new software and is wanting to change the scope of their licence i.e. new facilities, categories or steps of manufacture. Then a [licence variation](#) application must be submitted. This licence variation application should be submitted within 2 weeks of the date of the audit due reminder. Based on this information, adjustments may be made to the first estimate for audit duration which was provided at the closure of previous audit, if conducted.

Three months before the audit due date, the APVMA will issue a final audit reminder notice to the Licence Holder. This reminder notice will cite the final audit duration.

## Choosing an APVMA-authorised auditor

At least 6 weeks prior to the audit due date or proposed date of audit, whichever is sooner, the Licence Holder must select an auditor from the current [list of APVMA-authorised GMP auditors](#). Then arrange for the audit to be conducted by the required time, and notify the APVMA on a signed '[Pre-audit notification and information form](#)'. Overseas sites should use the '[Pre-audit notification and information form—overseas sites](#)'. The form should be emailed to the APVMA. Unsigned forms will not be accepted by the APVMA.

If the APVMA has not received notification that an audit has been arranged prior to 6 weeks of the due date for audit, the APVMA will contact the Licence Holder to remind them that an audit is due and to ensure the audit schedule is maintained. Failure to arrange an audit, as directed by the APVMA, may result in suspension or cancellation of the licence for breach of licence condition.

The auditor must also submit a signed 'Confirmation of audit booking form' to the APVMA as soon as possible after the audit date is confirmed with the Licence Holder. The 'Auditor's declaration' at the foot of the document, confirming the auditor has no actual or perceived conflict of interest in performing the audit **MUST** be signed by the auditor. Unsigned forms will not be accepted by the APVMA. Submission of this form by email is acceptable provided the form contains an electronic signature in the 'Auditor's declaration' section, and the form does not contain any commercially sensitive information.

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<sup>1</sup> Intelligence refers to any information that is publicly available or has been confidentially provided to the APVMA. This includes, but not limited to, adverse experiences, recalls, compliance issues, conditions on product registration or permits and new information under section 161 of the Schedule to the AgVet Code.



The APVMA may reject the Licence Holder's choice of auditor if:

- The auditor has carried out the previous 2 consecutive routine full audits on the facility.
- The auditor has carried out consultancy services for the Licence Holder within the preceding 3 years or there is any other potential conflict of interest.
- The APVMA considers that the auditor is not suitably qualified to audit the nominated type of manufacturing facility or manufacture.
- The APVMA considers that a substantive conflict of interest may exist.
- The APVMA considers that under the circumstances, for whatever reason, another auditor is more appropriate.

In most cases, the APVMA will liaise with the Licence Holder and the auditor and advise the Licence Holder to select an alternative auditor. However, as indicated above, the APVMA reserves the right to appoint an auditor of its own choice if considered appropriate. This may include the appointment of a suitably qualified and experienced APVMA staff member.

Prior to the audit, the APVMA GMP Officer may send to the auditor:

- Relevant particulars of the Licence Holder, including the pre-audit notification and information form submitted by the Licence Holder.
- Copy of the completed application form (for new applicants for a licence or licence variation).
- Copy of the previous audit reports.
- Copy of the current APVMA licence and schedule of conditions (if an existing licensee).
- Copy of any documents relevant to an audit.
- Copy of other relevant correspondence from the Licence Holder's file.

The auditor should normally prepare an audit plan with a proposed timetable, which should be provided to and discussed with the Licence Holder prior to the audit, to verify whether it is suitable and whether relevant staff will be available and/or that the plant will be operating, etc.

### **Pre-audit notification and information form**

If a Licence Holder fails to provide the notification that an audit has been arranged, after the APVMA GMP officer has followed up with the Licence Holder to remind them that an audit is due, the APVMA may take action. This may result in suspension or cancellation of the licence.

## 3.2 During the audit

### Audit agenda

The agenda on the day of audit will be at the auditor's discretion, although should be consistent with [ISO 19011: 2018 Guidelines for Auditing Management Systems](#). Key elements should include:


- An initial meeting with the Licence Holder, staff and senior management for introductions, to confirm the scope of the audit, discuss the audit plan and how it will be conducted, and a brief introduction / familiarisation with the personnel, plant and procedures.
- The confirmation of the scope of manufacture to be inspected (categories, steps of manufacture, product types, licence conditions).
- A review of any changes in the company structure, quality management system, the facility and/or key personnel since the last audit.
- A review of previous audit outcomes and steps taken to address the required corrective actions.
- Inspection of the facilities, procedures, records, etc.
- Confirmation with the Licence Holder during the audit about the relevance and accuracy of observed non-conformances.
- Preparation of a draft report (if practical).
- An exit interview where all non-conformances are highlighted and options for corrective action(s) assessment are canvassed.

On completion of the audit, the auditor should hold an exit interview with the Licence Holder, staff and senior management to discuss the outcome of the audit. As part of the exit interview, the auditor must identify the **Critical non-conformances observed** and discuss with the manufacturer the various options, priorities and appropriate timelines for corrective action. **Major** and **Minor non-conformances**, as well as observations / areas for improvement, should also be highlighted to the Licence Holder. The auditor is encouraged to provide balanced (positive / negative) feedback regarding compliance, as well as identifying any non-conformances.

## Language and translation

Audits will be conducted in English. If the APVMA need to talk to people who cannot speak or understand English, the Licence Holder will need to:


- Provide a guide with some technical understanding who can act as a translator.
- Translate any documents that the APVMA requests into English.

	<p><b>The translator:</b></p> <p>Please ensure the translator can translate technical language. The translator needs to be able to translate a technical question asked by the auditor in English into the relevant language, as well as translate technical information into English. The auditor may terminate the audit if they cannot communicate effectively or if the provided documents are not in English. If the information cannot be properly translated to the auditor, this may adversely affect the inspection outcome.</p>
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The Licence Holder may also appoint observers.

## Preliminary identification of non-conformances

The auditor will inform the Licence Holder of all potential non-conformances that have been observed and will give the Licence Holder an opportunity to provide any additional relevant information.

	<p>If the auditor notifies the Licence Holder of an observed non-conformance, the Licence Holder can provide additional information for the auditor to review. However, if the Licence Holder has additional information, the APVMA preference is that this is provided to the auditor during the audit.</p>
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## Notification of completed Audit form and the GMP Audit Report

The auditor must use approved, current versions of audit documents, in the standardised format, as provided by the APVMA. Audit documents to be completed by the auditor include:

- The [Notification of Completed Audit form \(FM\\_MQL06\)](#), within 3 business days of audit completion (24 hours where Critical non-conformances are observed).
- The [GMP Audit Report \(FM\\_MQL05\)](#), within 10 business days of audit completion.
- The GMP Audit Report supplements for annexes 1 – 6 (as required), within 10 business days of audit completion.

The auditor must complete and forward a Notification of Completed Audit form to the APVMA within **3 business days of completion of the audit**. Where Critical non-conformances have been identified, this form must be submitted to the APVMA within 24 hours of the audit. If additional comments are warranted, they can be provided as a covering letter. The form should be uploaded to Objective Connect (preferred) or sent to the APVMA by email.

The auditor must provide the Licence Holder with the GMP Audit Report and any associated documents (e.g. report supplements for annexes, product audit checklists) within 10 business days of the last day of the audit. A

copy of the GMP Audit Report and associated documents are to be submitted to the APVMA by the auditor at the same time through Objective Connect (preferred) or sent to the APVMA by email.

Auditors should note that the GMP Audit Report has 4 sections:

- **Manufacturer and audit details**, details of the manufacturer, facility and key audit information.
- **Compliance report** should contain sufficient detail, based on the observations made, to allow the APVMA to make an informed licensing decision.
- **Non-conformances (NC) identified** lists Minor, Major and Critical non-conformances identified in detail and close-out requirements (desk or verification audit and due dates); estimate of audit rating from non-conformance score.
  - Non-conformances must be accurately classified and clearly written in a way which would allow the Licence Holder, the APVMA and/or another auditor identify what was non-compliant, and allow another auditor to review and confirm the corrective actions at a subsequent audit.
  - Each non-conformance must be assigned an identifying reference number, and the relevant GMP code clause or Manufacturing Principle must be cited. The most relevant one should be referenced (maximum 3) (refer Appendix B).
  - The agreed date for submission of corrective actions / plan for desk-review and/or date for verification audit should be included in this section.
  - Section C also includes the auditor's calculation of the NC score and audit rating/level. The rating or score may be subject to change once the APVMA have assessed the provided information. While the APVMA does not normally alter the NC score provided by an auditor, the APVMA may de-aggregate distinct non-conformances when determining a NC score. Similarly, if a NC score reported is not clearly expressed – or it is challenged by the Licence Holder – the APVMA may ask the auditor to provide further information to justify the score and rating assigned.
  - Where there is any disagreement, the Licence Holder will need to negotiate the matter with the APVMA (see below).
- **Auditor's summary**, auditors should comment on the Licence Holder's level of compliance with the Manufacturing Principles and GMP Code. The auditor must sign the form.

The GMP Audit Report should accurately reflect both the auditing activities undertaken and observations made as well as the compliance status of the facility. Terms such as '*assessed*', '*examined*', '*checked*', '*read*' and '*reviewed*' will be interpreted as indicating a more thorough assessment of the procedures and/or records, in this instance the relevant documents need to be individually cited. In contrast, terms such as '*scanned*', '*sighted*', and '*viewed*' will be interpreted as indicating a superficial assessment of the procedures and/or records, in this instance the documents do not need to be individually cited. Phrases such as '*sighted 6 raw material specifications*' would be acceptable. Due to the necessity for the auditor to pursue non-conformances, the extent to which individual requirements and guidelines are investigated will be left to the auditor's discretion.

Individual requirements and guidelines not examined should be left blank or marked '*not assessed*' and these areas can be followed up as a priority at the next audit. Any areas or sections of the GMP code that were not audited should be listed in **Section A, question 15** of the audit report. Any GMP requirements rated as being 'Non-Compliant' in **Section B** should be mirrored by non-conformances (Critical, Major, Minor) in **Section C**. For

clarity, auditors should provide reference numbers to non-compliant requirements in **Section B** and link them with the non-conformances in **Section C**.

The APVMA requires the auditor to securely retain copies of the GMP Audit Report and associated documents acquired in connection with, or produced in the performance of, the GMP Audit for at least 7 years post the audit as per document retention requirements. This will assist in the situation where later comment is sought by the APVMA.

The auditor is expected to meet all obligations with respect to the terms of their agreed contract with the Licence Holder, and in accordance with the requirements of this procedure and their deed of authorisation. The Licence Holder is expected to meet all obligations with respect to the terms of the agreed contract with the auditor. This includes payment for audit services rendered. Licence Holders should note that further payments may be required for verification audits or desk reviews of corrective actions.



Where Critical non-conformances have been identified, the Licence Holder must notify the APVMA of those **within 24 hours**. This is a condition of the licence.

## Dispute resolution

If the Licence Holder does not accept one or more of the auditor's findings at the audit and is unable to reach an agreement with the auditor, the Licence Holder should state their reasons / justification in Part 1 of the Response to GMP Audit Report form (or a separate letter), offering alternative corrective actions or solutions and timeframes for correction (where applicable). If the Licence Holder is not satisfied or has concerns with the auditor's assessment of their corrective actions addressing non-conformances identified, the Licence Holder should write to the APVMA detailing their concerns and the reasons why they consider their corrective actions to be adequate.

In these and other cases of dispute, the APVMA will convene an APVMA Review Panel. This Panel will be chaired by the APVMA delegate for the issuance of licenses – the MQL Assistant Director or the MQL and Assurance Director in the A/Director's absence – and will include the Senior GMP Officer with oversight for the audit review. The Panel will discuss the matter at hand with both the manufacturer and the external authorised auditor and will make a decision that can then be taken forward in the audit review and close-out procedure.

## 3.3 Audit close-out

As noted above, auditors must provide the Licence Holder with the GMP Audit Report and any associated documents within 10 business days of the last day of the audit. Licence holders will then have 15 business days from receipt of the GMP Audit Report to respond to this in writing, and provide corrective action evidence and/or a plan for review. Plus, a further 15 business days for the auditor's assessment of this response results in an overall 8-calendar-week window for the immediate rectification of non-conformances.

- Where non-conformances can be corrected within this 8-week window, between the end of the audit and the APVMA-authorised auditor's assessment of the Licence Holder's response to the audit outcomes, the audit will be closed out by the auditor. As required, this may include a verification audit (see below).

- Where the correction of non-conformances cannot be completed within this 8-week window, a Corrective and Preventive Action (CAPA) Plan will be developed by the Licence Holder. Once the auditor and the APVMA have agreed to the CAPA Plan, audit close-out will then be transitioned to the APVMA. As required, this may include a verification audit (see below).

There are 2 pathways to audit close-out.

Where the Licence Holder and auditor require more than 8-week window to respond and assess non-conformances, timelines must be discussed and approved by the APVMA.

Note, however, that where **Critical** non-conformances have been identified, the APVMA and the auditor will work together with the Licence Holder to develop a CAPA Plan that can be implemented immediately and, thus, will immediately address any risk to animals, humans or environment.

### Audit close-out by an APVMA-authorised auditor

Within 15 business days of receipt of the GMP Audit Report – which should also be within 25 working days of the audit completion – Licence Holders must sign FM\_MQL05 confirming they have read and agree to the report, including any non-conformances noted. Licence Holders must then return a copy of the GMP Audit Report to both the APVMA [mls@apvma.gov.au](mailto:mls@apvma.gov.au) and to the auditor.

If no non-conformances are identified, the Licence Holder must complete only the GMP Audit Report (FM\_MQL05). Although not compulsory, the APVMA also requests that Licence Holders complete Part 2: Manufacturer's Feedback to the APVMA.

If non-conformances have been identified in the GMP Audit Report, the Licence Holder must also complete, sign and return to the auditor and the APVMA (as above) Part 1 of a [Response to GMP Audit Report form](#), providing a response and corrective action evidence for each and all of the non-conformances identified in the GMP Audit Report. This will include details of proposed corrective actions. If these corrective actions cannot be undertaken within the 8-week period following completion of the audit, Licence Holders should develop a CAPA Plan. This is discussed in more detail in the following section (Audit close-out by CAPA Plan).

- If the Licence Holder does not accept some or all the auditor's findings, they should raise these with the auditor in the first instance. If an agreement cannot be reached, the Licence Holder should then discuss their concerns with the APVMA – as discussed in Section 3.2.
- Licence Holders are encouraged to complete Part 2: '[Manufacturer's feedback to the APVMA](#)', on the APVMA website, –of the Response to GMP Audit Report form. Licence Holder should answer the questions in this section and provide comment on the auditor's conduct, preparation and any other relevant information. This section remains confidential and will be viewed by the APVMA only. Although, specific issues of concern may be discussed with the auditor. This will be at a level above the detail provided by the Licence Holder. Responses will be de-identified and de-aggregated for sharing with other internal and external stakeholders.

Once the APVMA has received the auditor's written confirmation that all corrective actions arising from the audit have been completed, an internal review of the audit will be undertaken. The APVMA will then send written advice to the Licence Holder of its decision with respect to audit closure, licensing and notification of the due date for the next audit, and the first estimate of audit duration (Section 3.1).

Once the audit is closed out, the auditor must notify the APVMA that audit materials are securely stored.



It is a condition of all licences that Licence Holders must sign and submit all audit reports and related documentation to the APVMA within 25 business days of the audit completion date. Failure to provide the documentation within the required timeframe may result in suspension or cancellation of the licence for breach of licence condition.

### Audit close-out by Corrective and Preventive Action Plan

Where the correction of non-conformances cannot be undertaken within the 8-week period between completion of the audit, and the auditor's review of the Licence Holder's Response to GMP Audit Report form (see above), a CAPA Plan will be developed by the Licence Holder.

For Critical and Major non-conformances, the CAPA Plan must include the following:

- An investigation of the root cause of all Critical and Major non-conformances.
- The details of the corrective action(s) to address the root cause(s) of non-conformances.
- The details of the preventative action(s) to address the root cause(s) of non-conformances.
- The corrections to address the non-conformances.
- The date by which all actions will be completed.

For Minor non-conformances that cannot be resolved within 8-weeks of the audit, the CAPA Plan must include the corrective actions to be taken and the date by which they will be completed. As relevant, and for all non-conformances, the CAPA Plan should also include a list of any documents and their reference numbers, and may include a requirement for a verification audit. Guidance for Licence Holders on the information that should be included in the CAPA Plan is given in Appendix C.

The CAPA Plan should be discussed with the auditor, finalised, and submitted to the APVMA by the Licence Holder within the stated 8-week period. The auditor must also provide the APVMA with a signed copy of the Plan, endorsing its corrective actions and timelines. The APVMA will then review the Plan and, if acceptable, audit close-out will, at this, point be transitioned to the APVMA. If changes to actions or timelines are required, these will be negotiated with the Licence Holder and auditor.

### Failure to submit an acceptable CAPA Plan

In the situation where the Licence Holder and auditor cannot agree to a CAPA Plan that is acceptable to both parties, the APVMA will form an APVMA Review Panel (Section 3.2). If a prolonged disagreement appears unavoidable, the APVMA will terminate the auditor's ongoing involvement and will take responsibility for development of the CAPA Plan. If a CAPA Plan cannot be developed to a standard that is acceptable to the APVMA within 16 calendar weeks (4 months) of completion of the audit, the facility will be considered non-compliant with Regulation 61 (3A) and will be managed accordingly.

### Audit close-out

Once transitioned to the APVMA, the APVMA will assume responsibility for monitoring completion of the tasks within the timelines detailed in the Licence Holder's CAPA Plan.

Note that Licence Holders are expected to observe these timelines unless written advice to the contrary is obtained from the APVMA.

Note also that failure to complete the tasks described within the timelines stated may result in regulatory action by the APVMA. This may include, as relevant, licensing action or adjustment of the Licence Holder's audit interval (Section 4).

Once the CAPA Plan has been completed to the satisfaction of the APVMA, the APVMA will review the audit and close it out. At this point, the APVMA will issue an audit outcome letter that includes, amongst other things, the due date for the next audit and the first estimate of audit duration (Section 3.1).

### Verification audits

Verification audits involve an on-site inspection or visit by the auditor. The verification audit differs from routine audits in that the scope of the audit will be restricted to confirming that non-conformances identified at the previous full audit have been satisfactorily addressed.

The procedure for a verification audit will be similar to a full audit, except that a product-specific evaluation will not usually be required and the APVMA will not usually provide the auditor with any further information unless it is specifically requested.

Where the non-conformances are of a Critical nature, or where the Licence Holder disputes the auditor's findings, the Licence Holder is advised to use the dispute resolution process (Section 3.2).

Each time a verification audit or desk review is performed to review corrective actions or plan, the auditor must complete a '[Corrective Action Review form](#)' (MQL\_24) noting the non-conformance number, specific evidence reviewed, and its acceptability. If further corrective action is required, the auditor should note the new due date for resubmission of evidence on the form. In most cases, the maximum period allowed should be 15 business days. The auditor will send the form to the Licence Holder and a copy to the APVMA within 15 business days of receipt of submissions for desk review.

Once all non-conformances are closed out to the auditor's satisfaction (by evidence or plan), this should be indicated on the Corrective Action Review form by ticking the 'Yes' box.

If a verification audit or desk-review is delayed, or submissions are not received by the due date, the auditor should advise the APVMA of the status of the arrangements for closure. The APVMA will follow-up with the Licence Holder where necessary.



## 4. Audit interval and scheduling

Audit intervals will be allocated to Licence Holders based on the scheme outlined in Table 1: Risk-based audit interval calculation below. This scheme classifies Licence Holders according to the following 4 audit levels:

1. Audit level 1: assigned when the audit has reported no Major non-conformances and the non-conformance score is less than 7. When a manufacturing site is assigned an audit level 1, the high levels of compliance with the manufacturing standards provide a basis for allocating longer audit intervals.
2. Audit level 2: assigned when an audit has reported no more than 5 Major non-conformances and their non-conformance score is between 7 and 20. This means the APVMA considers manufacturing sites with an audit level 2 rating to have a functioning quality management system, although with some identifiable weaknesses to address.
3. Audit level 3: assigned when non-conformance scores total 21 to 40, with no more than 10 Major non-conformances.
4. Audit level 4: assigned when the audit reports more than 10 Major non-conformances and/or a non-conformance score greater than 40.

### Exception for Critical non-conformance

In situations when an audit identifies a Critical non-conformance the Licence Holder must implement immediate corrective actions, irrespective of their established audit rating or category. The schedule anticipates that other compliance and enforcement tools may be used to support auditing where appropriate.

### Rescheduling audits

In exceptional circumstances, Licence Holders can formally request to reschedule an audit. A written request should be submitted to the MLS email address at [mls@apvma.gov.au](mailto:mls@apvma.gov.au) 14 days prior to the audit due date. Requests may be based on:

- Recent major changes to management and/or staffing.
- Factory fires or other unscheduled asset crises and any associated maintenance or repair activities.
- Other circumstances, such as voluntary licence suspension where cessation of manufacture may mitigate many of the risks associated with the postponement of an audit.

Table 1: Risk-based audit interval calculation

Category	Low (< 7) Level 1	Medium (7-20) Level 2	High (21-40) Level 3	Very High (> 40) Level 4
1	30 months	24 months	12 months	≤12 months
Multiple	30 months	24 months	12 months	≤12 months
2	36 months	30 months	12 months	≤12 months
3 or 4 or 6	36 months	30 months	18 months	≤12 months

## 5. APVMA audits of overseas sites

Registrants of intermediate or finished products manufactured overseas are required to provide acceptable evidence of overseas GMP compliance to the APVMA. Conditions of registration require the registrant to ensure all sites involved in any step of manufacture – whether in Australia or overseas– maintain compliance with GMP. Product applicants / registrants must ensure appropriate evidence of compliance is kept and submitted to the APVMA on request.

If a product applicant or registrant is unable to provide existing acceptable evidence of GMP compliance for an overseas manufacturing site used, then an audit by an APVMA-authorized auditor may be required.

For overseas audits, the majority of the audit processes and procedures described above apply, with the following differences:

- The audit may be arranged and/or paid for by the product applicant / registrant rather than the manufacturer.
- The auditor may require additional notice for overseas audits, to allow for travel arrangements to be made.
- The pre-audit notification and information form for overseas sites should be used (fm\_mql45).
- The audit will usually focus on the products to be imported to Australia, rather than the full range of products manufactured at the site.
- Additional time may be required for the audit if interpreters or translation of documents are required.
- The APVMA cannot issue a licence for overseas sites; instead, the APVMA provides a letter of confirmation of GMP compliance for the site, to whoever commissioned the audit.

Information on APVMA audits of overseas sites can be found on the APVMA [website](#).

## 6. Summary – Key responsibilities

The **Licence Holder / manufacturer** is responsible for:

- Arranging the audit well in advance of the due date advised by the APVMA.
- Sending a signed and completed Pre-audit Notification and Information form to the APVMA promptly, at least 6 weeks ahead of the audit date.
- Reviewing the final 'GMP Audit Report' and signing the last page within 25 business days of the audit date. By signing the report, the Licence Holder is agreeing to the list and level of non-conformances observed during the audit.
- Advising the APVMA as soon as possible in the case of disagreement or dispute with the auditor's findings, or assessment of corrective actions.
- Advising the APVMA in writing, and within 24 hours of the audit completion date, of any Critical non-conformances identified and detailing root cause and proposed corrective actions.
- Completing Part 1 of the Response to GMP Audit Report form (compulsory) and Part 2 (encouraged but not mandatory) within 25 business days of the audit date, and submitting both to the APVMA.
- Sending a copy of the completed Part 1 of the Response to GMP Audit Report form to the auditor within 25 business days of audit completion.
- Signing and sending the original version of the completed GMP Audit Report and all associated documents (e.g. report supplements for annexes, if used) to the APVMA within 25 business days of audit completion.
- Paying the auditor for the primary audit and all desk and/or verification audits required to close the audit.

The **APVMA-authorised GMP auditor** is responsible for:

- Completing correct, current versions of all audit documents, using only standard authorised formats, as supplied by the APVMA.
- Sending a signed Confirmation of Audit Booking form to the APVMA when audits are booked.
- Conducting the audit in a thorough, professional manner in accordance with this procedure.
- Sending a Notification of Completed Audit form to the APVMA within 3 business days (24 hours where Critical non-conformances are observed) of completion of the audit.
- Providing the Licence Holder with the original version of the completed GMP Audit Report plus all associated documents (e.g. report supplements for annexes, if used) within 10 business days of the audit, and providing copies to the APVMA.
- Reviewing corrective actions by either desk-review (objective evidence or CAPA plan) or verification audit and completing and submitting a Corrective Action Review form, to the Licence Holder and the APVMA, within 15 business days of receipt of the evidence / CAPA plan.
- Notifying the APVMA when they are satisfied that all non-conformances have been satisfactorily addressed, by review of objective evidence or satisfactory plan.

- Advising the APVMA if a verification audit is postponed, or corrective action submissions are not received within the agreed timeframes.
- Returning confidential Licence Holder and product information to the APVMA, or providing written confirmation to the APVMA that all information has been securely stored, once the audit is closed out.

The **APVMA GMP officer / reviewer** is responsible for:

- Monitoring audit timeframes and initiating regulatory action as appropriate.
- Reminding Licence Holders when audits are due or overdue.
- Vetting the suitability of the auditor.
- Collating audit information in consultation with any other relevant APVMA sections, where necessary.
- Forwarding information on the Licence Holder to the auditor prior to the audit.
- Monitoring the progress of the audit and close-out processes, and intervening where necessary.
- Providing confirmation of whether an audit can be closed based on an agreed CAPA plan.
- Recommending whether licences should be issued, continued, suspended or cancelled, conditions imposed / removed.
- Facilitating early resolution of disputes between the Licence Holder and auditor regarding non-conformances and/or corrective actions.
- Attending the APVMA Review Panel if a dispute resolution is required.
- Recommending when the next audit is due and advising the Licence Holder of the next due date upon close-out of the current audit.

The **APVMA Assistant Director / Director, MQL** is responsible for:

- Reviewing recommendations on licensing, audit duration and re-audit timeframes, as necessary.
- Chairing the APVMA Review Panel if a dispute resolution is required.
- Approval of closure of non-conformance by CAPA plan.



## Appendix

## Appendix A – Forms and templates

Shortened term	Full term
<a href="#">FM_MQL04</a>	Pre-audit notification and information form – Australian sites
<a href="#">FM_MQL45</a>	Pre-audit notification and information form – overseas sites
<a href="#">FM_MQL05</a>	GMP Audit Report form
<a href="#">FM_MQL06</a>	Notification of completed audit form
<a href="#">FM_MQL23</a>	Confirmation of audit booking form
<a href="#">FM_MQL24</a>	Corrective action review form
<a href="#">FM_MQL26</a>	Response to GMP Audit Report form
<a href="#">FM_MQL27</a>	GMP Audit Report supplement annex 1
<a href="#">FM_MQL28</a>	GMP Audit Report supplement annex 2
<a href="#">FM_MQL29</a>	GMP Audit Report supplement annex 3
<a href="#">FM_MQL30</a>	GMP Audit Report supplement annex 4
<a href="#">FM_MQL31</a>	GMP Audit Report supplement annex 5
<a href="#">FM_MQL32</a>	GMP Audit Report supplement annex 6
<a href="#">FM_MQL39</a>	Request for a Certificate of GMP Compliance under the Australia-EC MRA

## Appendix B – Guidance on writing non-conformances (for auditors)

The following guidance outlines the APVMA's expectations of auditors when reporting non-conformances from GMP audits.

Non-conformances are considered as signs of weakness in a quality system and may be identified during APVMA audits where Licence Holders are not able to demonstrate compliance with the Manufacturing Principles and GMP Code.

	<p>The role of the auditor is to systematically and objectively collect and analyse sufficient relevant evidence to allow them to make an assessment of the Licence Holders compliance with the APVMA's GMP requirements.</p> <p>The auditor must clearly differentiate between identifying a non-conformance with the requirements of the Manufacturing Principles and/or GMP Code, and making suggestions for improvement.</p>
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Non-conformances are identified and reported during the auditing process. They are important for communicating what the problem is so that it can be corrected and should be written in a clear and concise manner, ensuring that they are not misinterpreted or ambiguous. In some cases additional details to support the non-conformance may be recorded in the body of the GMP Audit Report, e.g. a description of evidence viewed.

Careful attention should be given to identifying the manufacturing principle or clause of the GMP Code to which the non-conformance relates. While there may be a number of references that could be related to one non-conformance, the most relevant one should be referenced (maximum 3).

### Writing up non-conformances

- Ensure the Licence Holder understands *why* the issue is non-compliant:
  - What is the problem / issue?
  - What was observed / how was this identified? What is the objective evidence to substantiate the non-conformance?
  - Consider– will the Licence Holder understand what the problem / issue is that needs to be corrected?
- Check the non-conformance – will the next auditor understand the non-conformance?

Other auditors will be receiving a copy of the GMP Audit Report in the audit information packs provided by the APVMA. It is important to consider:

- Does the non-conformance make sense, would you understand what was reviewed and what was non-compliant with the Manufacturing Principles / Code?
- Would you understand what needs to be implemented as the corrective action?
- Would you be able to check that the corrective actions have been implemented and are appropriate to address the non-conformance?



Remember, is the non-conformance clear enough to be understood by someone who was not at the audit when it was raised / identified?

- Identify the appropriate manufacturing principle / GMP code clause(s) (maximum of 3).

There may be a number of clauses / Manufacturing Principles that may be applicable to the non-conformances identified, however it is not necessary to list each reference, but to identify the most relevant one (max 3).

- If the cause of the non-conformances are related, for example, the non-conformance will be closed through the provision of a single standard operating procedure (SOP), i.e. if they link back to a problem with the SOP then they should be grouped as one.
- If the cause of the non-conformances are diverse and will result in different corrective actions being undertaken then they should be reported separately.
- Identify the classification (Minor, Major or Critical and/or repeat).

## Classifications of non-conformances

- **MINOR non-conformance** – Minor or less serious non-conformance which is unlikely to pose a risk to product quality.
  - May be less serious but not trivial.
  - Depends on the type of product, and context in which the issue is identified.
  - If significant numbers of Minor non-conformances are identified in one system area, it could be indicative of a system breakdown and may be more appropriately classified as Major.
- **MAJOR non-conformance** – failure to satisfy a key or mandatory requirement and/or one which **may pose** a risk to product quality.
  - Major deviation from the manufacturing principles and/or GMP Code.
  - May consist of several Minor non-conformances, which on their own may not be Major, but together may represent a Major non-conformance—should be explained and reported as such.
- **CRITICAL non-conformance** – a Major non-conformance which **poses** a risk to treated animals or users and must be corrected immediately.
  - Need to identify a clear link to use this classification.
  - Notify APVMA immediately (within 24 hrs).
  - May result in regulatory action being considered by the APVMA.



Although the auditor may discuss various options for corrective action, it is the responsibility of the Licence Holder to determine the most appropriate course of action to address identified non-conformances.

## Appendix C – Guidance on preparing a CAPA plan (for licence holders)

The following guidance should be considered when preparing a plan for assessment.

Licence Holders will have a maximum of 3 opportunities to submit a satisfactory plan to the auditor for assessment. If no agreement is reached, the APVMA will take over the process to implement the plan or require submission of objective evidence, to close the audit. This may also result in the Licence Holder's audit interval schedule to be reduced.

It is therefore in the Licence Holder's best interests to provide as much detail and relevant information as possible in their plan to allow the auditor to make an effective assessment.

- The plan should include a detailed and clearly cross-referenced description of the specific corrective actions in response to each of the non-conformances identified. The plan must include:
  - an investigation of the root cause of all Critical and Major non-conformances
  - the details of the corrective action(s) to address the root cause
  - the details of the preventative action(s) to address the root cause
  - the corrections to address the non-conformances
  - the date all actions will be complete.

The APVMA expects that where documents are to be amended, a detailed description of the change to be made, the names of the documents affected and their document reference and revision numbers should be recorded (preferably using a change control process). The description of the change should advise which point / clause / section is to be amended. For example:

“...point 1 will be amended to include a reference to the positions which may undertake this role, specifically the Quality Assurance Manager and their delegate, being the Quality Assurance team leader for powder products”.

Further details to include:

- An indication of proposed dates associated with completion of drafts, review of documents and publishing of final documents.
- Details of when training will be undertaken and what the training will include, along with the people included in the training (position titles).
- If validation activities are to be undertaken then a detailed description of what the validation will cover (i.e. validation protocol) and the timeframes to be met.
- If building works are to be undertaken, include a description of the key events and target completion dates.
- There may also be situations where a risk assessment should be undertaken to support the proposed activities.

## Appendix D – Guidance on assessing CAPA plans (for auditors)

The following guidance outlines the APVMA's expectations of auditors when undertaking an assessment of and approving a CAPA plan for the closure of non-conformances for Licence Holders.

### Expectations

Auditors should:

- Use the Corrective Action Review (CAR) form to record their assessment and attach a copy of the final version of the plan provided by the Licence Holder.
  - The documents should be sent to the APVMA within 8 weeks of the audit being completed.
- Assess and confirm that the Licence Holder has identified the 'root cause' where applicable.
- Ensure that timeframes have been stipulated, are reasonable and practical.
- Confirm that there is sufficient detail provided to allow the next auditor to understand what was agreed to for the closure.
  - Think about how you would interpret the response and what you would expect to see if you were provided with only the CAR form for the plan 3 years after the last audit—would you be able to understand what has been assessed and accepted? Will it result in the NC being closed?
- Provide a clear description of what has been agreed to in the CAR form to allow the APVMA and the next auditor to clearly identify what has been considered and why the response is accepted.
- Avoid ambiguous information or comments included within CAR reports.



If the auditor is not satisfied that an acceptable plan has been provided after 3 attempts by the Licence Holder (within the stated allowable timeframe), this should be noted accordingly on the CAR form.