1. *Complete and sign this form as per instructions below (please note completion of Part 1 is compulsory if NCs are identified, Part 2 is encouraged)*
2. *Return the completed response form with the signed GMP Audit Report (FM\_MQL05), signed by the Manufacturer, to the APVMA* ***within 25 working days*** *of the audit date.*

***Email:*** ***mls@apvma.gov.au*** ***(preferred)*** ***Mail to****: Director, MQL, APVMA*

 *GPO Box 3262, SYDNEY NSW 2001*

1. *Send a copy of PART 1 of this form to the Auditor at the same time, along with evidence/plan as required.* ***Part 2 should only be sent to the APVMA****.*
2. *If NO non-conformances were identified, please consider completing and returning Part 2 to the APVMA as above.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Manufacturer** |  | **Licence No.** |  |
| **Street Address of Facility Audited** |  |
| **Date/s of Audit** |  | **Auditor’s Name** |  |

The Manufacturer should select the appropriate option based on the [assessed score](http://apvma.gov.au/node/19676) received and [Audit Level](http://apvma.gov.au/node/19676) indicated in the audit report.

**Audit to be closed based on** *(select one):*

1. [ ]  Submission of Objective Evidence of Corrective Actions to the Auditor (Audit Levels 1, 2, 3 or 4)
2. [ ]  Detailed Plan of Corrective Actions ([Audit Level 1 and 2 only](http://apvma.gov.au/node/19676)) – see guidance on next page

[ ]  Detailed plan attached

[ ]  Detailed plan to be provided by *(date)………………..*

1. [ ]  Combination of Detailed Plan and Objective Evidence (Audit Level 1 and 2 only)

**Comment:**

| Non-Conformance Number*(from Section C of Audit Report)* | Manufacturer’s response including ROOT CAUSE and proposed CORRECTIVE ACTIONS*Please provide details on what* ***specific actions*** *will be takento address each non-conformances, including identification of the root cause.*  | Documents to be amended/created(Name and reference/document number) | Timeframe for completion of corrective actions |
| --- | --- | --- | --- |
|  | **Root Cause:** |  |  |
| **Corrective action:** |
|  | **Root Cause:** |  |  |
| **Corrective action:** |
|  | **Root Cause:** |  |  |
| **Corrective action:** |
|  | **Root Cause:** |  |  |
| **Corrective action:** |
| **Comments:** |  |  |  |

**Privacy**

*The collection of personal information by the Australian Pesticides and Veterinary Medicines Authority (APVMA) in relation to this form is for the purpose of assisting the APVMA to perform its functions under the Agricultural and Veterinary Chemicals (Administration) Act 1992 and related legislation, including for the purpose of processing audits and audit outcomes.*

*Personal information collected by the APVMA will be managed in accordance with the Privacy Act 1988.*

*More information about the way in which the APVMA manages personal information, including its Privacy Statement, is available at* [*https://apvma.gov.au/node/3207*](https://apvma.gov.au/node/3207)

**Representative’s Name:** ………….………….. **Signature:**……………………………………

**Position:** ………………………………………  **Date:** …………………………

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Guidance for Preparing Plans for Audit Closure** [**(Audit Levels 1 and 2 only):**](http://apvma.gov.au/node/19676)

* The plan should include a detailed description of any changes to be made. Consideration should be given to the root cause, where applicable. Where documents are to be amended, a description of the change to be made, the names of the documents affected and their document reference numbers should be recorded. An indication of expected dates associated with completion of drafts, review of documents and publishing of final documents should also be included.
* Details of when training will be undertaken and what the training will include should also be provided along with the people to be included within the training (position titles).
* If validation activities are to be undertaken then a detailed description of what the validation will cover and the timeframes to be met should be provided.
* If building works are to be undertaken then a description of the key events and target completion dates should be included.
* Please also refer to **Appendix C** of the[**GMP Audit Procedure**](http://apvma.gov.au/node/19871)

Please note the following questions are intended to provide valuable confidential feedback to the APVMA on the quality and rigour of GMP audits conducted. **This form should only be sent to the APVMA and not to the auditor.** Your responses will assist us in our Quality Assurance Program for GMP Auditors.

You may send it directly to the MQL Section of the APVMA by email (preferred) to mls@apvma.gov.au or post to MQL Section, APVMA GPO Box 3262, Sydney NSW 2001.

|  |  |  |  |
| --- | --- | --- | --- |
| **Manufacturer** |  | **Licence No.** |  |
| **Street Address** |  |
| **Date of Audit** |  | **Auditor’s Name** |  |

***Please circle ONE rating or tick ONE box for each question and provide comments:***

|  |
| --- |
| 1. **Did the auditor provide an audit plan and/or explanation of the audit process?**
 |
| Yes [ ]  No [ ]  *If NO, please provide comment****Comments:*** |
| 1. **How systematic was the audit? Please comment on any problems.**
 |
| 1 2 3 4 5 6 7 8 9 10 Poor Average Excellent***Comments:*** |
| 1. **How would you rate the auditor’s preparation for the audit?**
 |
| 1 2 3 4 5 6 7 8 9 10 *Poor* *Average* *Excellent****Comments:*** |

|  |
| --- |
| 1. **Was sufficient time allocated by the auditor for the audit?**
 |
| Yes [ ]  No [ ]  *If NO, please provide comment****Comments:*** |
| 1. **Were all non-conformances listed in the audit report clearly identified to you during the audit and/or at the exit meeting?**
 |
| Yes [ ]  No [ ]  *If NO, please provide comment****Comments:*** |
| 1. **How thorough was the audit?**
 |
| 1 2 3 4 5 6 7 8 9 10 Too easy About right Too harsh/too “picky”***Comments:*** |
| 1. **How would you describe the auditor’s manner/attitude during the audit?**
 |
| ***Comments:*** |
| 1. **Do you feel there were any conflict of interest issues or instances of inappropriate behaviour by the auditor?**
 |
| Yes [ ]  *If YES, please provide comment* No [ ] ***Comments:*** |
| 1. **How valuable did you find the audit for your company in terms of identifying areas of weakness or potential weakness?**
 |
| 1 2 3 4 5 6 7 8 9 10Not at all Some use Extremely useful***Comments:*** |
| 1. **How long did it take to receive the audit report from the auditor?** *(please insert the number of working days from the date of the audit)****.***
 |
| …………. Working days |
| 1. **Any other comments?**
 |
|  |

***Name:*** *………………….……..……………* ***Signature:*** *……….…………………………*

***Position:*** *……………………………………………..* ***Date:*** *……………………………..*

***Thank you for taking the time to complete the questionnaire.***