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| PRE-AUDIT NOTIFICATION and INFORMATION FORM**(Australian Sites)**Form: FM\_MQL04 |

**IMPORTANT: To be completed and signed by the MANUFACTURER and submitted to the APVMA at least 4 weeks prior to the scheduled audit date. Undergoing an audit is a requirement under Section 61(8) of the Agricultural and Veterinary Chemicals Code Regulations 1995.**

**BOTH Parts A & B are to be completed. If the information required for Part B is available in a Plant Master File (PMF) that may be submitted with references provided on this form.** This information, and any other relevant APVMA information, will be provided to the Auditor to assist with their preparation for the audit.

***Email:*** ***MLS@apvma.gov.au*** ***(preferred, if no commercially confidential content):***

***Or mail to: Director MQL, APVMA, GPO Box 3262, SYDNEY NSW 2001***

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**PART A: Audit Notification**

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| 1. Name of manufacturer to be audited.
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| 1. Street Address of Manufacturer to be audited
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| 1. ACN of Manufacturer
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| 1. **Licence/File No.**
 |  | 1. **Date/s of audit.**
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| 1. Type of Audit: *(Tick appropriate*)
 | [ ]  **FULL - Initial**[ ]  **FULL - Subsequent**[ ]  **PARTIAL *(please explain in Comments)*** | 1. **Category of manufacture to be audited.**
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| 1. **Auditor/s *(for this audit)***
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| 1. **Other sub-contractors and/or facilities to be audited *(if listed in Schedule 2 or in conditions of licence)***
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| 1. **Comments:**
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**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.**

**The APVMA will provide personal information collected in relation to this form to the nominated auditor for the purposes of the audit.**

**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**

**Manufacturer’s Declaration:** In signing this form I am authorising the APVMA to release relevant information to the Auditor for the purposes of this audit.

**Signature of Representative:** …………………………………………... **Date:** ……………………..

**Name of Representative:** ……………………………………………

##### Part B: Information for Audit

If the information required for Part B is available in a Plant Master File (PMF) that may be submitted, with references provided for each question on this form.

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| **Please highlight areas where significant changes have occurred since the last audit (or for new applicants, since the application form was submitted).** |

1. **PRODUCTS MANUFACTURED:**

 List all veterinary chemical products manufactured, or partly manufactured (eg packaged only) on site, under the various product types described in Attachment 1. **Highlight which products will be in production during this audit**.  *(attach list if preferred)*

Include products that are:

* Registered
* registration pending (application submitted to APVMA but not yet finalised)
* subject to permit
* manufactured under contract
* for export only

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| **Product** | **APVMA No. (or Permit No.)** | **Category (1, 2, 3 4)** | **Dosage form *(if sterile, aseptic or terminally sterilised)*** | **Steps of manufacture *(full, packaging only, release only etc)*** |
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1. For biological products, list all viable organisms used in the production areas.

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| **Product** | Organism/s |
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1. List the typical number of batches of product manufactured per day. If products are manufactured infrequently/ seasonally, please indicate how often per year and/or which months products are manufactured.

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1. Please state whether any veterinary chemical products manufactured on site contain any of the following materials:

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| penicillins |[ ]
| cephalosporins |[ ]
| other antibiotics |[ ]
| cytotoxic medicines |[ ]
| hormones |[ ]
| steroids |[ ]
| chemicals to which any schedule of the SUSDP applies |[ ]
| Genetically modified organisms |[ ]
| Radioactive |[ ]
| Actives/ingredients containing nano material (less than 100 nanometres) |[ ]

If you ticked any of the above, please provide details below:

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1. List any other non-veterinary chemical products manufactured on site (group as appropriate).

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1. List any other non-manufacturing activities performed on site (e.g. warehousing, marketing, R&D etc.)

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1. **PERSONNEL:**

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| **a) Contact person:** |
| Name: |  | Title *(Mr, Ms, Dr etc)* |  |
| Position: |  |
| Telephone number: |  |
| Facsimile number: |  |
| Mobile number: |  |
| Email address:  |  |

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| **b) Person responsible for PRODUCTION:** |
| Name: |  | Title *(Mr, Ms, Dr etc)* |  |
| Position: |  |
| Telephone number: |  |
| Facsimile number: |  |
| Mobile number: |  |
| Email address:  |  |

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| **c) Person responsible for QUALITY (QA/QC):** |
| Name: |  | Title *(Mr, Ms, Dr etc)* |  |
| Position: |  |
| Telephone number: |  |
| Facsimile number: |  |
| Mobile number: |  |
| Email address:  |  |

1. Please indicate the numbers of employees engaged in following work areas and the numbers of shifts of staff per day:

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| --- | --- | --- |
| **Work Area** | **Permanent** | **Casual** |
|  | **No. Staff** | **No. Shifts per day** | **No. Staff** | **No. Shifts per day** |
| Production |  |  |  |  |
| Quality Control |  |  |  |  |
| Storage and Distribution |  |  |  |  |
| Technical and engineering support services |  |  |  |  |
| TOTAL |  |  |  |  |

1. Please provide an organisational chart showing the persons responsible for production, quality control and quality assurance*. (attach if preferred).*

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1. **CERTIFICATION:**

**Is the company licensed or certified under any other GMP/quality scheme?**

[ ]  YES (please provide a copy of the licence or accreditation)

[ ]  NO

**SITE DESCRIPTION (brief)** *(the location and immediate environment; the size of the site, types of buildings (construction materials, ages, floor size area).*

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1. **OTHER AUDITS/INSPECTIONS**

**Has the site been audited or inspected by another regulatory authority (Australian or Overseas) since the last APVMA audit?**

[ ]  YES

[ ]  NO

**Was the outcome of this audit**

[ ]  SATISFACTORY

[ ]  UNSATISFACTORY (unable to be closed or regulatory action taken)

**If the outcome of the audit was unsatisfactory, please provide comment:**

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1. **PLANS:** Please provide outline plans of the site to be audited, highlighting production areas. If possible, provide very brief notes to indicate the activities carried out on the site. Please do not reduce so far as to make words difficult to read.

(a) For sterile products areas, indicate room and area classification, pressure differentials and air change rate *(category 1 manufacturers only).*

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(b) Are there any segregated storage areas available and if so for what purpose?

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(c) Where applicable, are the categories of manufacture segregated from each other?

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1. **VENTILATION SYSTEMS** Please provide a brief description of ventilation systems (if applicable). eg extraction and air supply: if supply is filtered, grade of filter and air classification if any.

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1. **WATER SYSTEMS** - Please provide a brief description of water purification systems. If Purified Water, BP or the equivalent is made, include/attach a full diagram of the system.

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1. **MAJOR PRODUCTION EQUIPMENT AND QUALITY CONTROL INSTRUMENTATION**

Please provide a list of major production equipment but only sufficient to allow the auditor to gain an overall appreciation of the processes. Include a list of laboratory instrumentation.

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1. **CONTRACT MANUFACTURING**

**a)** Please provide details of any contract manufacturing of veterinary chemical products carried out on the site **for other manufacturers or registrants**. Please provide company names and addresses. *(attach list if preferred).*

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| **Client (name and address)** | **Product/s** | **Steps performed (ie full, packaging only)** |
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**b)** List all laboratories/manufacturers involved in **analysing or testing** of any of the veterinary chemical products (or intermediates) produced.

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| **Name of Manufacturer** | **Address** | **APVMA Lic. No.** | **Product** | **Test/s performed** |
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**c)** Are any other steps of your manufacture (such as packaging, sterilising etc, but *excluding* provision of raw materials) contracted out to **other manufacturers**?

 Yes [ ]  *complete details below* No [ ]  🡪 go to Question 26

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| --- | --- | --- | --- | --- |
| **Name of Manufacturer** | **Address** | **APVMA Lic. No.** | **Product** | **Step(s) of Manufacture** |
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**d).** If you do not perform **release for supply** of the products manufactured, who does perform this step?

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| **Name of Manufacturer** | **Address** | **APVMA Lic. No.** | **Product** |
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1. **DOCUMENTATION / PROCEDURES**

a) Please provide a list of the Standard Operating Procedures (SOPs) and methods used on the site*. (attach list if preferred)*

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b) Please attach copy of Master Validation Plan, if any.

1. **COMPUTERS**

a) Are computers used for:

[ ]  monitoring status of raw materials, intermediates, finished product?

[ ]  controlling stock levels?

[ ]  calculating formulation quantities?

[ ]  other?

*Please explain below.*

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b) If any aspect is ticked in 26 a), is the computer system validated? *Please explain below.*

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1. **OTHER INFORMATION**

Please provide brief details of any further information that may be relevant to the audit, such as changes to key staff, equipment or processes since the previous APVMA audit.

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**ATTACHMENT 1:**

**Types of Products Manufactured**

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| **Category** | **Type of Manufacture** | **Dosage Form/Formulation Type*****(examples - not necessarily complete list)*** |
| Category 1 | Sterile and/or immunobiological products | sterile productsimmunobiological productssubcutaneous implants |
| Category 2 | Non-sterile veterinary preparations other than Categories 3 and 4 | tabletscapsulespelletscreamsointmentspastesliquids (including liquid oral supplements)powdersgranulesgelssuspensionssprays |
| Category 3 | Ectoparasiticides (externally applied) | liquidspastespowdersear-tags |
| Category 4 | Premix/supplements | premixessupplements (which require registration) |