



Australian Government
**Australian Pesticides and
Veterinary Medicines Authority**

LICENCE TO MANUFACTURE VETERINARY CHEMICAL PRODUCTS

Licence Holder: Asurequality Australia Pty Ltd
ACN 106 678 704

Licence No: 1085

The APVMA hereby issues a licence under section 123 of the Agricultural and Veterinary Chemicals Codes (Agvet Codes) to the above named person (the Licence Holder) to carry out the following step(s) of manufacture:

Quality assurance (QA) of raw materials, aseptic filling and sterilisation (heat).

This licence authorises the manufacture of the following type(s) of veterinary chemical products only:

Category 1 (Sterile and/or immunobiologicals products) - Immunobiologicals and aseptically-prepared subcutaneous implants

—at the following premises:

28 Mareno Road
TULLAMARINE VIC 3043

This licence is subject to the conditions set out in subsection 126(4) of the Agvet Codes, regulations 60–62 of the *Agricultural and Veterinary Chemicals Code Regulations 1995* (Agvet Code Regulations) and the **additional conditions in the attached Schedule(s)**.


For the purposes of paragraph 126 (4)(b) of the Agvet Codes and in accordance with regulation 60 of the Agvet Code Regulations, the following persons are nominated as the persons having control of production and quality respectively:

Production: Bruce Wentworth

Quality: Shelli Marklew

This licence comes into force on the date of issue and replaces the previous licence issued on 7 March 2008. This licence remains in force unless otherwise suspended or cancelled by the APVMA.

Dated this 7th day of September 2008


Kathryn Winterton
Acting Manager, GMP
Delegate of the Australian Pesticides and
Veterinary Medicines Authority

This licence remains the property of the APVMA and must be returned on request


SCHEDULE 1 OF ADDITIONAL LICENCE CONDITIONS


The following additional conditions apply to and form part of Licence No. **1085** issued to the Licence Holder:

Asurequality Australia Pty Ltd

ACN 106 678 704

- S1.1 This Licence authorises only those steps of manufacture, product type(s) and premises listed.
- S1.2 The Licence Holder must manufacture the veterinary chemical products that are the subject of this Licence, in accordance with the APVMA's Manufacturing Principles and associated Codes of Good Manufacturing Practice, and any standards that apply to the products.
- S1.3 At the direction of the APVMA, the Licence Holder must undergo an audit by an APVMA-authorized person of the manufacturing facilities, equipment, systems, processes, procedures and personnel used in the manufacture of veterinary chemical products and must demonstrate to the satisfaction of the APVMA that their operation and conduct is in compliance with the Agvet Codes, the APVMA's Manufacturing Principles, associated Codes of Good Manufacturing Practice and any standards that apply to the products.
- S1.4 The Licence Holder must provide to the APVMA within 25 working days of the completion date of every audit conducted by an APVMA-authorized person, the original signed copy of each audit report and associated audit checklists, together with details of all corrective actions that they propose to take with respect to the non-conformances identified therein and timeframes for their implementation. Where an audit conducted by an APVMA-authorized person identifies critical non-conformances, the Licence Holder must notify the APVMA of the critical non-conformances in writing within three (3) working days of the completion date of that audit.
- S1.5 The Licence Holder must implement all the corrective actions arising from audits within the timeframes agreed to or specified by the APVMA, and provide the APVMA with sufficient objective evidence to confirm that all the corrective actions have been implemented to the APVMA's satisfaction.
- S1.6 The Licence Holder must allow, for the purposes of an audit, an APVMA-authorized person ready access to all relevant facilities, equipment, systems, processes, procedures, personnel and information and must not knowingly conceal or withhold relevant information.
- S1.7 The licence holder may sub-contract work out only to Australian manufacturers or laboratories that are licensed by the APVMA or to overseas manufacturers or laboratories whose evidence of GMP compliance is recognised by the APVMA to carry out the contracted steps in the manufacture of veterinary chemical products.

Dated this  day of September 2008


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Kathryn Winterton
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