Desktop Audit Questionnaire – Veterinary Vaccines

Manufacturers are required to provide a response against each of the items below.

Manufacturers are encouraged to provide a copy of a site master file for the manufacturing site and augment their responses below with references to the relevant section of the site master file.

1. Preliminary questions

1.1 Have Australian biosecurity officers (or third-party auditors auditing on behalf of an Australian importer) previously audited the manufacturing site?

Yes (continue to question 1.2)

No (continue to question 2)

1.2 Have any of the following changes been made at the manufacturing site since this last audit?

- Changes to infrastructure at the manufacturing site that impact production lines

- Changes to company ownership at the manufacturing site

- Changes to the status of quality management at the manufacturing site.

Yes – Provide more information on the change below:

_____
_____
_____
_____

No (continue to question 2)

2. General information requirements

2.1 Name and address of importer

2.2 Name and address of exporter

2.3 Name and address of manufacturing facility

Name of contact person:

2.4 Provide a full description of the supply chain for the goods exported to Australia, including the details of off-site storage warehouses for raw materials, intermediate, and finished product.

2.5 Provide an organisation chart for key personnel at manufacturing facility.

2.6 Number of days worked per week:

2.7 Number of shifts worked per day:

2.8 Number of employees

3. Production

A complete response to the items listed below will include reference to the facility site maps or

other site plans.

3.1 Provide names and type of all products manufactured for export to Australia.

3.2 Provide a description of the layout of the buildings on the manufacturing site such that the designation and conditions of use of all rooms are correctly identified as well as the biological agents handled within them.

3.3 Provide a broad description of each stage of the manufacturing process for veterinary vaccines, including equipment used, at each stage of production.

3.4 Provide a description of the air handling and ventilation systems for contained and/or clean area premises, including pressure gradients and rates of air change. Describe the system for monitoring pressure gradients and responses to air pressure changes.

3.5 Provide a detailed description of the system for ensuring employee competency including training required to be deemed proficient.

3.6 Describe processes and systems in place for managing the risk of cross contamination between manufacture of different antigen lots. Manufacturers should reference all relevant factors including:

- Cleaning and sterilisation of equipment, cell culture laboratories and production suites

- Maintenance of employee hygiene

- Trafficking restrictions for equipment and personnel

- The use of equipment or areas within the manufacturing plant that are dedicated to production of specific antigens

- Restrictions on the order of production of different antigens

3.7 Describe procedures to prevent cross contamination in storage/warehousing areas. How are warehouses designed and organised to manage the storage and movement of raw materials, packaging/labelling materials, intermediate/finished product?

3.8 Describe how product flow and personnel movement are designed to minimise risk of cross contamination within the manufacturing plant.

3.9 Describe the system designed to prevent contamination through vermin/pest infestation.

3.10 Describe how storage areas are restricted to authorised personnel only and how entry/egress is monitored.

4. Materials of animal origin.

4.1 Describe how the quality management system ensures separation of materials of animal origin and manages the risk of cross contamination.

4.2 Describe the systems and processes designed to identify, separate, trace and monitor consumption of materials of animal origin. Include detailed information relevant to the traceability and identification system for raw materials used in manufacture through sourcing, manufacture, and dispatch of final product.

4.3 Outline how a clear audit trail is maintained from the original supplier of raw materials to final quality release and dispatch of finished product?

4.4 Provide a list of all materials of animal, microbial and viral origin that are held at the facility. This includes but is not limited to:

i) All antigens that are stored on site (whether they are manufactured at the facility or not), and

ii) All microbial and viral cultures that are contained in research and development laboratories on site.

For materials of animal origin please include information on the supplier and country of origin of the animals from which the material is sourced.

5. Quality assurance, quality control

5.1 Provide a detailed description of the company system for quality assurance. The response should reference the procedure for accrediting new suppliers and the ongoing management of all supplier data. The response should clearly demonstrate how commercial and regulatory specifications are maintained. The response should address the continual identification and traceability of raw materials against specifications.

5.2 Describe the elements of quality control that are built into the system to ensure product is manufactured to meet company and client specifications and the requirements of regulatory agencies. Include the frequency of product quality review.

5.3 Explain the system for company review of the quality management system. How does this review process feed into ongoing process improvement?

The response should reference all relevant internal review processes including internal audits, senior management reviews, periodic product reviews, mock product recalls, traceability exercises and the complaints review process.

5.4 Describe the system for change control. This system ensures that a formal evaluation and impact assessment is done before changes, which affect production, quality, and/or regulatory compliance, are implemented. The response should explain the procedure for responding to changes that impact information supplied in support of an import permit application.

5.5 Provide details of current regulatory authority approvals for the facility. Provide copies of certificates of approval/registration. How often is the facility subject to audit by the regulatory authority?

Provide the dates of the most recent audits/inspections carried out by the regulatory authority.

6. Documentation

6.1 Provide details of the company's document control system within the manufacturing facility. How does the document control system ensure all documents are accurate and up to date?

6.2 Are approved and dated specifications available for all products, including raw materials, packaging/labelling materials?

Describe the process for creation of new specifications for raw materials that have been qualified and approved for use in manufacture.

Explain how the system ensures established specifications are reviewed for content accuracy.

6.3 Describe the process for creation of new documents, including standard operating procedures (SOPs). Who is responsible for identifying the need for new documents? Who creates the document and what is the process for approval of new documents?

6.4 Describe the system for review of documents, including SOPs. How often are documents reviewed and who is responsible for the review?

6.5 How are employees made aware of the release of new documentation/SOPs? How does the facility ensure employees incorporate new processes, outlined in new or amended documents, into their work program?

6.6 How are rescinded documents removed from the document control system?

6.7 How long are batch/serial specific records kept after the expiry date of final products?

6.8 Provide a list of all current SOPs in use within the facility.

6.9 Provide copies of the SOPs that describe the following:

- Maintenance/repair program for manufacturing operations i.e., planned and unplanned maintenance events
- Pest control program
- Employee hygiene programs
- Sanitation and cleaning of production suites
- Cleaning of production equipment
- Receipt into the facility of all starting materials for use in production, including packaging materials
- Labelling and storage of starting materials
- Quarantine storage procedure for incoming raw materials, particularly animal derived materials
- Release procedure for raw materials to be used in production
- Sampling procedures for raw materials, intermediate and final product
- QA rejection of raw materials, intermediate and final product
- Quarantine procedure for final product pending final QA release
- QA release of final product for commercial distribution
- Batch traceability for product recall purposes

7. QA Manager's declaration

I declare that the information provided in this document and in supporting dossiers is accurate and that the Department of Agriculture, Fisheries and Forestry will be notified of any changes to the production process which affect the content of these documents.

Signature:	
Name:	
Date:	
Position:	
Company name and address:	

7. Fees for desktop audits

Category	Description	Unit	Cost per unit
Audit – in office	Desktop audit of production manuals etc.	¼ hour (or part thereof)	$ 37.00 (AUD)