

**TECHNICAL AND ADVISORY COMMITTEE ON BIOLOGIC
DEPARTMENT OF VETERINARY SERVICES
MINISTRY OF AGRICULTURE AND AGRO-BASED INDUSTRY
WISMA TANI, PODIUM BLOCK 4G1, PRECINT 4
FEDERAL GOVERNMENT ADMINISTRATIVE CENTRE
62630 PUTRAJAYA
MALAYSIA
(Tel : 03-88702000 & Fax : 03-88886472)**

**OFFICIAL FORM FOR SUBMISSION OF DOSSIER / DOSSIER CHECK LIST
FOR REGISTRATION OF VETERINARY VACCINE PLANT IN MALAYSIA**

TECHNICAL INFORMATION AND DOCUMENTATION PROVIDED IN THE DOSSIER	PAGE REFERENCE NUMBER	REMARKS
<p>Submission of Dossier in two (2) copies :</p> <ol style="list-style-type: none">1. Company Profile and background<ul style="list-style-type: none">- Details of manufacturing activities2. Organisation chart3. List of key personnel – qualifications & their responsibilities4. Plot plans, blueprints and legends<ul style="list-style-type: none">- Plot plans- Blueprints- Legends- Photographs5. Building specification<ul style="list-style-type: none">- Materials of floors, walls, ceilings, partitions and doors and all other parts of facilities used for the preparations of vaccines- Drainage and plumbing system- Plan of contained areas – ventilation system, inlets and outlets, filters and number of air changes & pressure differentials6. List of equipment in each room7. Production process diagram and records8. Contamination precaution<ul style="list-style-type: none">- Construction of rooms used for preparation of vaccines		

TECHNICAL INFORMATION AND DOCUMENTATION PROVIDED IN THE DOSSIER	PAGE REFERENCE NUMBER	REMARKS
<ul style="list-style-type: none"> - Plan of personnel movement - Plan of equipments & materials movement - Disinfection, decontaminant & bio-containment facilities - Ventilation system - Water quality <p>9. Dressing rooms and other facilities</p> <ul style="list-style-type: none"> - Plan of changing rooms - Changing room facilities <p>10. Quality control facilities</p> <ul style="list-style-type: none"> - List of equipments - Tests performed - Documentation of equipment's calibrations <p>11. Animal House facilities</p> <ul style="list-style-type: none"> - Ventilation system - Drainage system - Pest management - Waste and effluent management <p>12. Copy of manufacturing license or registration certificate</p> <p>13. Copy of license of establishment for vaccine</p> <p>14. Copy of certificate of satisfactory plant inspection or GMP/ GQC/ HSST/ HACCP certificate by government authorities or accredited international inspectors</p>		

(Note : Must be completed, signed and endorsed by the registered veterinarian of the company / local agent)

I, _____ the registered veterinarian of company/local agent
 _____ hereby certify that the technical information and
 Documentation provided in the dossier is complete in accordance with the DVS requirements for
 Registration of veterinary vaccine plant in Malaysia.

Submitted on : _____ by :

Company Stamp :

 (Signature)

 (Name of Veterinarian)

 (Registration Number)