



BORANG PERMOHONAN
PENDAFTARAN KILANG VAKSIN VETERINAR DI MALAYSIA
APPLICATION FORM FOR
REGISTRATION OF VETERINARY VACCINE PLANT IN MALAYSIA
(SUBMISSION OF DOSSIER IN TWO (2) HARDCOPIES)

MAKLUMAT TEKNIKAL DAN DOKUMENTASI DI DALAM DOSIR <i>Technical Information and Documentation Provided in The Dossier</i>	MUKA SURAT <i>Page Number</i>	CATATAN <i>Remarks</i>
A. MAKLUMAT AM / GENERAL INFORMATION		
1. Nama syarikat /Name of company		Sila Nyatakan / Please state
2. Alamat Syarikat / Company address		Sila Nyatakan / Please state
3. Nama Penuh Pemohon / Full Name of Applicant		Sila Nyatakan / Please state
4. Jawatan pemohon di syarikat Company Position		Sila Nyatakan / Please state
5. No telefon / Phone. No.:		Sila Nyatakan / Please state
6. Emel / Email address		Sila Nyatakan / Please state
SEKSYEN 1 / SECTION 1 : MAKLUMAT KILANG VAKSIN VETERINAR <i>INFORMATION ON VETERINARY VACCINE PLANT</i>		
1. Profil Syarikat dan Latar Belakang / Company Profile and background i. Butiran aktiviti pengilangan / Details of manufacturing activities		Sila Nyatakan / Please State
2. Carta Organisasi / Organisation chart		Sila lampirkan <i>Please attach</i>
3. Senarai kakitangan utama / List of key personnel i. Kelayakan dan tanggungjawab mereka / qualifications & their responsibilities		Sila Senarai dan Lampirkan <i>Please list and attach</i>

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<p>4. Pelan Tanah, Pelan Bangunan, Dan Legenda/ <i>Plot plans, blueprints and legends</i></p> <ul style="list-style-type: none"> i. Pelan tanah/ <i>Plot plans</i> ii. Pelan bangunan/ <i>Blueprints</i> iii. Legenda/ <i>Legends</i> iv. Gambar-gambar/ <i>Photographs</i> <p>5. Spesifikasi Bangunan/ <i>Building specification</i></p> <ul style="list-style-type: none"> i. Bahan Lantai, Dinding, Siling, Partisi, Dan Pintu Serta Semua Bahagian Lain Fasiliti Yang Digunakan Untuk Penyediaan Vaksin/ <i>Materials of floors, walls, ceilings, partitions and doors and all other parts of facilities used for the preparations of vaccines</i> ii. Sistem Saliran dan Paip/ <i>Drainage and plumbing system</i> iii. Pelan Kawasan Tertutup - Sistem Pengudaraan, Inlets Dan Outlets, Penapis, Jumlah pertukaran udara dan Perbezaan Tekanan/ <i>Plan of contained areas – ventilation system, inlets and outlets, filters and number of air changes & pressure differentials</i> <p>6. Senarai Peralatan Di Setiap Bilik/ <i>List of equipment in each room</i></p> <p>7. Gambaran proses pengeluaran dan rekod/ <i>Production process diagram and records</i></p> <p>8. Langkah-langkah pencegahan pencemaran/ <i>Contamination precaution</i></p> <ul style="list-style-type: none"> i. Pembinaan bilik yang digunakan untuk penyediaan vaksin/ <i>Construction of rooms used for preparation of vaccines</i> ii. Pelan Pergerakan Personel/ <i>Plan of personnel movement</i> iii. Pelan Pergerakan Peralatan & Bahan/ <i>Plan of equipments & materials movement</i> 		<p>Sila lampirkan <i>Please attach</i></p> <p>Sila Lampirkan <i>Please Attach</i></p> <p>Sila Lampirkan <i>Please Attach</i></p> <p>Sila Senarai dan Lampirkan <i>Please list and attach</i></p> <p>Sila Lampirkan <i>Please Attach</i></p> <p>Sila Lampirkan <i>Please Attach</i></p> <p>Sila Lampirkan <i>Please Attach</i></p> <p>Sila Lampirkan <i>Please Attach</i></p>

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iv. Kemudahan Penyahkuman, Penyuci, dan Biopelampauan/ <i>Disinfection, decontaminant & bio- containment facilities</i> v. Sistem Pengudaraan/ <i>Ventilation system</i> vi. Kualiti Air/ <i>Water quality</i>		Sila Lampirkan <i>Please Attach</i> Sila Lampirkan <i>Please Attach</i> Sila Lampirkan <i>Please Attach</i>
9. Bilik Penukaran dan Kemudahan Lain/ <i>Dressing rooms and other facilities</i> i. Pelan bilik penukaran/ <i>Plan of changing rooms</i> ii. Kemudahan bilik penukaran/ <i>Changing room facilities</i>		Sila Senarai dan Lampirkan <i>Please list and attach</i> Sila Senarai dan Lampirkan <i>Please list and attach</i> Sila Lampirkan <i>Please attach</i>
10. Kemudahan Kawalan Kualiti/ <i>Quality control facilities</i> i. Senarai peralatan/ <i>List of equipments</i> ii. Ujian yang dilakukan/ <i>Tests performed</i> iii. Dokumentasi kalibrasi peralatan/ <i>Documentation of equipment's calibrations</i>		Sila Lampirkan <i>Please attach</i> Sila Lampirkan <i>Please attach</i> Sila Lampirkan <i>Please attach</i>
11. Kemudahan Animal House/ <i>Animal House facilities</i> i. Sistem pengudaraan/ <i>Ventilation system</i> ii. Sistem saliran/ <i>Drainage system</i> iii. Pengurusan makhluk perosak/ <i>Pest management</i>		Sila Lampirkan <i>Please attach</i> Sila Lampirkan <i>Please Attach</i> Sila Lampirkan <i>Please Attach</i>

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<p>vii. Pengurusan sisa dan air buangan/ <i>Waste and effluent management</i></p> <p>12. Salinan lesen pengilangan atau sijil pendaftaran/ <i>Copy of manufacturing license or registration certificate</i></p> <p>13. Salinan Lesen Penubuhan Vaksin/ <i>Copy of license of establishment for vaccine</i></p> <p>14. Salinan sijil pemeriksaan kilang yang memuaskan atau sijil GMP/GQC/HSST/HACCP oleh pihak berkuasa kerajaan atau pemeriksa antarabangsa yang diakreditasi/ <i>Copy of certificate of satisfactory plant inspection or GMP/ GQC/ HSST/ HACCP certificate by government authorities or accredited international inspectors</i></p>		<p>Sila Lampirkan <i>Please Attach</i></p> <p>Sila Lampirkan <i>Please Attach</i></p> <p>Sila Lampirkan <i>Please Attach</i></p> <p>Sila Lampirkan <i>Please Attach</i></p>

(Catatan: Mesti dilengkapkan, ditandatangani, dan disahkan oleh doktor haiwan berdaftar syarikat/agen tempatan/ *Must be completed, signed and endorsed by the registered veterinarian of the company / local agent*)

Pengesahan/ Declaration:

Saya..... doktor haiwan berdaftar di Syarikat/Agen tempatan dengan ini mengesahkan bahawa maklumat teknikal dan dokumen yang disediakan dalam dosier adalah lengkap mengikut keperluan DVS untuk pendaftaran kilang vaksin veterinar di Malaysia.

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.

Permohonan ini diserahkan pada:.....

Submitted on:

.....
 (Tandatangan/Signature)

Nama / name:

Nombor pendaftaran MVC/ MVC
 Registration No:

(Cop Syarikat)
 (Company Stamp)