# Application for Approval to Manufacture Veterinary Medicines and/or Vertebrate Toxic Agents and/or Exempt Products for Export

**ACVM 39 (August 2021)**

* This application from must be completed by each manufacturer in New Zealand applying for Good Manufacturing Practice approval to perform **any** step of manufacture of a veterinary medicine or vertebrate toxic agent registered under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997.
* Approvals are issued with a scope that defines the approved categories of manufacture. If a manufacturer wishes to manufacture products in categories other than those for which approval is currently held, a variation application must be made for the additional categories refer to <https://www.mpi.govt.nz/dmsdocument/45157>
* Email this signed, completed application form with all required documentation to the Ministry for Primary Industries at the above email address.
* Refer to the Privacy Act 2020 and Official Information Act 1982 notices at the end of this form regarding collection of information by the Ministry for Primary Industries.

# Part 1: Manufacturer Details

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| 1.1 Application is made for Approval as a Manufacturer of: | |
|  | Veterinary Medicines |
|  | Vertebrate Toxic Agents |
|  | Exempt products for export |

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| 1.2 Registered Company Name | New Zealand Business Number (NZBN) (if applicable) |
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| Trading Name *(if different from the registered company name listed in 1.3)* | |
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| 1.3 Manufacturer Address and Contact Details | |
| **Main Manufacturing Physical Site Address** *(including post code)* |  |
| **Postal Address** *(including post code)* |  |
| **Company Phone Number** |  |
| **Active Billing Details**  Provide the current accounts payable email address to which invoices should be emailed. |  |

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| 1.4 Secondary Sites of Manufacture  Specify any secondary sites of manufacture of the same company. Such as different sites where raw materials or finished product is stored, sites where QC testing and analysis are performed, packaging from bulk etc. | |
| **Address(es)** | **Activities** *(such as storage, Quality Control testing)* |
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| **1.5 Name of Designated Key Contact Person(s)** This will be the primary GMP contact, unless otherwise notified. *If more than one key contact person required, copy the table below.* | |
| **Name** |  |
| **Position** |  |
| **Direct Dial Phone Number** |  |
| **Email** |  |

# Part 2: Scope of activities to be included in approval

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| **2.1 Requested Category and Scope of Approval of Facility** | | |
| Select the categories of products/functions you are applying to manufacture. *If you are applying for a secondary site, include the categories that you are applying for at the secondary site.* | | **Applying for** |
| **1** | **Manufacturing Operations - Sterile Products** | |
| *1.1* | *Aseptically prepared (complete processing operations for the following dosage forms unless otherwise stipulated)* | |
|  | * + 1. Large volume liquids |  |
| * + 1. Lyophilisates |  |
| * + 1. Semi-solids |  |
| * + 1. Small volume liquids |  |
| * + 1. Solids and implants |  |
| * + 1. Powders |  |
| * + 1. Other aseptically prepared products - <***Specify details here>*** |  |
| *1.2* | *Terminally sterilised (complete processing operations for the following dosage forms unless otherwise stipulated)* | |
|  | * + 1. Large volume liquids |  |
| * + 1. Semi-solids |  |
| * + 1. Small volume liquids |  |
| * + 1. Solids and implants |  |
| * + 1. Powders |  |
| * + 1. Other terminally sterilised prepared products - <***Specify details here>*** |  |
| **1B** | **Manufacturing Operations - Biological Products** | |
| *1.3* | *Biological veterinary products* | |
|  | * + 1. Blood products |  |
| * + 1. Immunological products |  |
| * + 1. Biotechnology products |  |
| * + 1. Animal extracted products |  |
| * + 1. Tissue engineered products |  |
| * + 1. Other biological medicinal products - <***Specify details here>*** |  |
| **2** | **Manufacturing Operations - Non-sterile Products** | |
| *2.1* | *Non-sterile products (complete processing operations for the following dosage forms unless otherwise stipulated)* | |
|  | * + 1. Capsules, hard shell |  |
| * + 1. Capsules, soft shell |  |
| * + 1. Tablets |  |
| * + 1. Granules |  |
| * + 1. Pellets |  |
| * + 1. Other solid dosage forms - <***Specify details here>*** |  |
| * + 1. Semi-solids |  |
| * + 1. Powders |  |
| * + 1. Impregnated matrices |  |
| * + 1. Liquids for external use |  |
| * + 1. Liquids for internal use |  |
| * + 1. Medicinal gases |  |
| * + 1. Pressurised preparations, sprays, aerosols |  |
| * + 1. Transdermal patches |  |
| * + 1. Intraruminal preparations (including boluses) |  |
| * + 1. Intrauterine preparations |  |
| * + 1. Other non-sterile medicinal product - <***Specify details here>*** |  |
| **3** | **Manufacturing Operations - Ectoparasiticides** | |
| *3.1* | *Non-sterile ectoparasiticides for external use (complete processing operations for the following dosage forms unless otherwise stipulated)* | |
|  | * + 1. Aerosols |  |
| * + 1. Collars |  |
| * + 1. Ear Tags |  |
| * + 1. Liquids |  |
| * + 1. Pastes |  |
| * + 1. Powders |  |
| * + 1. Sprays |  |
| * + 1. Other dosage forms - <***Specify details here>*** |  |
| **4** | **Manufacturing of Active Substances** | |
| *4.1* | *Manufacture of Active Substance by Chemical Synthesis* | |
|  | * + 1. Manufacture of active substance intermediates |  |
| * + 1. Manufacture of crude active substance |  |
| * + 1. Salt formation / Purification steps e.g. crystallisation - <***Specify details here>*** |  |
| * + 1. Other - <***Specify details here>*** |  |
| *4.2* | *Extraction of Active Substance from Natural Sources* | |
|  | * + 1. Extraction of substance from plant source |  |
| * + 1. Extraction of substance from animal source |  |
| * + 1. Extraction of substance from mineral source |  |
| * + 1. Modification of extracted substance - <***Specify source here>*** |  |
| * + 1. Purification of extracted substance - <***Specify source here>*** |  |
| * + 1. Other - <***Specify details here>*** |  |
| *4.3* | *Manufacture of Active Substance using Biological Processes* | |
|  | * + 1. Fermentation |  |
| * + 1. Cell Culture - ***<Specify cell type here>*** |  |
| * + 1. Isolation / Purification |  |
| * + 1. Modification |  |
| * + 1. Other - <***Specify details here>*** |  |
| *4.4* | *Manufacture of sterile Active Substance (4.1, 4.2, 4.3 to be completed as applicable)* | |
|  | * + 1. Aseptically prepared |  |
| * + 1. Terminally sterilised |  |
| *4.5* | *General Finishing Steps* | |
|  | * + 1. Physical processing steps (e.g. drying, lyophilisation, milling, micronisation, sieving) - <***Specify details here>*** |  |
| * + 1. Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) |  |
| * + 1. Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) |  |
| * + 1. Other - <***Specify details here>*** (*for activities not described above*) |  |
| **5** | **Packaging Only** | |
| *5.1* | *Primary Packing (non-sterile products)* | |
|  | * + 1. Capsules, hard shell |  |
| * + 1. Capsules, soft shell |  |
| * + 1. Tablets |  |
| * + 1. Granules |  |
| * + 1. Pellets |  |
| * + 1. Other solid dosage forms - <***Specify details here>*** |  |
| * + 1. Semi-solids |  |
| * + 1. Powders |  |
| * + 1. Impregnated matrices |  |
| * + 1. Liquids for external use |  |
| * + 1. Liquids for internal use |  |
| * + 1. Medicinal gases |  |
| * + 1. Pressurised preparations, sprays, aerosols |  |
| * + 1. Transdermal patches |  |
| * + 1. Intraruminal preparations (including boluses) |  |
| * + 1. Intrauterine preparations |  |
| * + 1. Other non-sterile medicinal product - <***Specify details here>*** |  |
| *5.2* | *Labelling and* *Secondary Packing* |  |
| **6** | **Quality Control Testing (*of product manufactured on site*) –** *(if testing is performed by main site and secondary site, use a line for each site specifying which site is performing which testing)* | |
| *6.1* | *Microbiological: sterility* | |
|  | ***<Specify tests here>*** |  |
| ***<Specify tests here>*** |  |
| *6.2* | *Microbiological: non-sterility* | |
|  | ***<Specify tests here>*** |  |
| ***<Specify tests here>*** |  |
| *6.3* | *Chemical/Physical* | |
|  | ***<Specify tests here>*** |  |
| ***<Specify tests here>*** |  |
| *6.4* | *Biological* | |
|  | ***<Specify tests here>*** |  |
| ***<Specify tests here>*** |  |
| **6B** | **Contract Quality Control Testing/Analysis (*of product NOT manufactured on site*)** | |
| *6.5* | *Microbiological: sterility* | |
|  | ***<Specify tests here>*** |  |
| ***<Specify tests here>*** |  |
| *6.6* | *Microbiological: non-sterility* | |
|  | ***<Specify tests here>*** |  |
| ***<Specify tests here>*** |  |
| *6.7* | *Chemical/Physical* | |
|  | ***<Specify tests here>*** |  |
| ***<Specify tests here>*** |  |
| *6.8* | *Biological* | |
|  | ***<Specify tests here>*** |  |
| ***<Specify tests here>*** |  |
| **7** | **Contract Sterilisation of active substances/excipients/finished product** | |
| *7.1* | *Sterilisation of active substances/excipients/finished products* | |
|  | * + 1. Filtration |  |
| * + 1. Dry heat |  |
| * + 1. Moist heat |  |
| * + 1. Chemical |  |
| * + 1. Gamma irradiation |  |
| * + 1. Electron beam |  |
| **8** | **Manufacturing of Vertebrate Toxic Agents** | |
| *8.1* | *Manufacturing activities – Manufacturing and packing into primary packaging* | |
|  | 8.1.1 Granules <Full manufacture including packaging and labelling for sale> |  |
| 8.1.1 Granules <Manufacture of bulk for further processing/packing> |  |
| 8.1.1 Granules <Downpacking including packaging and labelling for sale> |  |
| 8.1.2 Pellets <Full manufacture including packaging and labelling for sale> |  |
| 8.1.2 Pellets <Manufacture of bulk for further processing/packing> |  |
| 8.1.2 Pellets <Downpacking including packaging and labelling for sale> |  |
| 8.1.3 Blocks <Full manufacture including packaging and labelling for sale> |  |
| 8.1.3 Blocks <Manufacture of bulk for further processing/packing> |  |
| 8.1.3 Blocks <Downpacking including packaging and labelling for sale> |  |
| 8.1.4 Pastes <Full manufacture including packaging and labelling for sale> |  |
| 8.1.4 Pastes <Manufacture of bulk for further processing/packing> |  |
| 8.1.4 Pastes <Downpacking including packaging and labelling for sale> |  |
| 8.1.5 Powders <Full manufacture including packaging and labelling for sale> |  |
| 8.1.5 Powders <Manufacture of bulk for further processing/packing> |  |
| 8.1.5 Powders <Downpacking including packaging and labelling for sale> |  |
| 8.1.6 Liquids <Full manufacture including packaging and labelling for sale> |  |
| 8.1.6 Liquids <Manufacture of bulk for further processing/packing> |  |
| 8.1.6 Liquids <Downpacking including packaging and labelling for sale> |  |
| 8.1.7 Pressurised sprays, aerosols, gases <Full manufacture including packaging and labelling for sale> |  |
| 8.1.7 Pressurised sprays, aerosols, gases <Manufacture of bulk for further processing/packing> |  |
| 8.1.7 Pressurised sprays, aerosols, gases <Downpacking including packaging and labelling for sale> |  |
| 8.1.8 Other dosage forms/activities - <***Specify product type and/or activities performed>*** |  |
| **8B** | **Repacking/Relabelling of Vertebrate Toxic Agents** | |
| *8.2* | *Relabelling or secondary packaging activities only* |  |
| **8C** | **Quality Control Testing of Vertebrate Toxic Agents** | |
| *8.3* | *Testing of Vertebrate Toxic Agents* | |
|  | ***<Specify tests here>*** |  |
| ***<Specify tests here>*** |  |
| **9** | **Other –** *(e.g. exempt products for export)* | |
| *9.1* | *Other product types or manufacturing steps not listed -* <***Specify details here>*** |  |
| **10** | **Release for Supply** | |
| *10.1* | *Finished product release activities for supply in New Zealand* |  |
| *10.2* | *Finished product release activities for export* |  |
| **10B** | **Release for Supply – Vertebrate Toxic Agents** | |
| *10.3* | *Finished product release activities for supply* |  |
| **Comments/Clarifying Remarks in relation to scope of activities performed** | | |
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| **2.2 Are any of the products intending to be manufactured (or tested) any of the following:** | | |
| **Β-Lactam Antibiotics** | Yes | No |
| **Other highly sensitising antibiotics** | Yes | No |
| **Live Cells** | Yes | No |
| **Pathogenic Organisms** | Yes | No |
| **Radiopharmaceuticals** | Yes | No |

# Part 3: Details of products and manufacturing performed

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| **3.1 Manufacturer as the Registrant.**  **Are you applying for approval to manufacture veterinary medicines or vertebrate toxic agents for which you are or will be the REGISTRANT?** *If YES, complete below including details of the steps of manufacturing conducted e.g. bulk manufacturing, downpacking, labelling and secondary re-packing, QC testing, release for supply etc. If full manufacturing is to be conducted, enter ‘full manufacturing’. Add more rows as required. If NO, proceed with section 3.2.* | | | | | | | | | Yes  No | |
| **ACVM Registration Number** | **ACVM Registered trade name** | **Product Type** | **Formulation Type** | **Manufacturing steps performed at this site** | **QC Testing/ Analysis conducted at this site** *(specify tests e.g. HPLC, sterility)* | **QC Testing/ Analysis conducted by contract lab** *(specify contract laboratory & tests performed)* | | **Market**  **NZ only or NZ & exported**  *(list exported markets if known)* | **Entity responsible for release for supply** | |
| **Lab Name** | **Testing** | **For NZ** | **For Export** |
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| **3.2 Contract Manufacturing.**  **Are you applying to manufacture any veterinary medicines or vertebrate toxic agents for which another organisation is the registrant?** *If YES, complete below including the steps of manufacturing conducted e.g. bulk manufacturing, downpacking, labelling and secondary re-packing, QC testing, release for supply etc. If full manufacturing is to be conducted, enter ‘full manufacturing’. Add more rows as required. If NO, proceed with section 3.3.* | Yes  No |

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| **ACVM Registration Number** | **ACVM Registered trade name** | **Product Type** | **Formulation Type** | **Manufacturing steps performed at this site** | **QC Testing/ Analysis conducted at this site**  *(specify tests e.g. HPLC, sterility)* | **QC Testing/ Analysis conducted by contract laboratory** | | **Market**  **NZ only or NZ & exported**  *(list exported markets if known)* | **Entity responsible for release for supply** | |
| **Lab Name** | **Testing** | **For NZ** | **For Export** |
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| **3.3 Manufacture for Export Only – Veterinary Medicines NOT registered in New Zealand but to be included in the scope of audit and approval for export purposes.** | | | | | | | | |
| **Are you applying to manufacture or to perform a step of manufacture of any products that are for export only (products that would require registration if they were sold in New Zealand)?** *If YES,**list details below. Add more rows as required. If NO, proceed with section 3.4.* | | | | | | | | Yes  No |
| **Name of Product manufactured for export only**  *(not registered or sold in NZ)* | **Product Type** | **Formulation Type** | **Manufacturing steps performed at this site**  *(full manufacture or partial manufacture with details)* | **QC Testing/Analysis conducted at this site** | **QC Testing/Analysis conducted by contract laboratory** | | **Market**  *(list exported countries)* | **Entity responsible for release for supply** |
| **Lab Name** | **Testing** |
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| **3.4 Veterinary products exempt from registration in NZ; to be included in scope of audit approval for export purposes.** | | | | | | | | |
| **Are you applying to manufacture any products that are exempt from registration in New Zealand that need to be included in the scope of approval for export purposes?** *If YES,**list details below. Add more rows as required. If NO, proceed with section 3.5.* | | | | | | | | Yes  No |
| **Name of Product manufactured for export**  *(exempt from registration in NZ)* | **Product Type** | **Formulation Type** | **Manufacturing steps performed at this site** | **QC Testing/Analysis conducted at this site** | **Testing/Analysis conducted by contract laboratory** | | **Market**  *(list exported countries)* | **Entity responsible for release for supply** |
| **Lab Name** | **Testing** |
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| 3.5 Other Products Manufactured on Site. | | | | | |
| **Are there any other products (e.g. human pharmaceuticals pesticides, agricultural chemicals) manufactured on the premises** *If YES,**list details below. If NO, proceed with part 4.* | | | | | Yes  No |
| Name of Product | **Product Type** | **Formulation Type** | **Manufacturing steps performed at this site** | **Details** *(Specify briefly how cross contamination is managed e.g. dedicated equipment/different facilities)* | |
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# Part 4: Approval by Other Authorities

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| **4.1 Is the manufacturing premises GMP licensed, certified or registered by any other domestic or international regulatory authority?** | | Yes  No |
| *If YES, specify authority and attach appropriate current evidence. If NO, specify N/A and proceed with section 4.2.* | <***Specify authority here>***  Certificate Attached | N/A |
| **4.2 Does the manufacturing premises have any other quality accreditation (ISO, IANZ)?** | | Yes  No |
| *If YES, specify authority and attach appropriate current evidence. If NO, specify N/A and proceed with part 5.* | <***Specify authority here>***  Certificate Attached | N/A |

# Part 5: Details of Manufacturing Premises and Operations

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| 5.1 Site Master File  Append to this application a Site Master File (or equivalent) to illustrate the quality system used in manufacturing. MPI has adopted the *PIC/S explanatory notes for industry on the preparation of a Site Master File*. This can be found at the link: <https://picscheme.org/docview/3463> | Attached |

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| 5.2 Site Plan  Append to this application a diagram showing the location of all buildings and their functions and activity. This diagram should also indicate the activities carried out on adjacent properties. | Attached |

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| * 1. Building plans   Append to this application line diagrams of the layout of all buildings used for storage, manufacture, filling, packing, labelling and quality control. The major plant items and equipment should be identified. The use and activities carried out in each room should be indicated with all entrances and exits.  Where controlled air systems are installed provide a plan that indicates the positions of inlet and outlet grills and ducts, the filters installed and their specifications. In aseptic rooms the number of air changes per hour and the pressure gradients between controlled rooms should be included. | Attached |

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| * 1. Process Flow   Append to this application flow diagrams that show the complete production process from the raw material stage to the finished product stage for each veterinary medicine, vertebrate toxic agent or exempt product for export manufactured, down-packed, repacked/relabelled or tested for product types or activities that are applicable to the scope you are applying for. Where several products are manufactured on site it may be necessary to use more than one diagram. Step-by-step descriptions of each stage of manufacture should be provided, including steps where contractors are used. If you perform a specific step only, specify at what stage the product is received and the actions performed on your site. | Attached |

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| * 1. Cleaning   Attach a description or copy of the cleaning methods used on product contact surfaces/ equipment used in the manufacturing process. Include a description and/or justification verifying that cross-contamination has been mitigated where products are manufactured using non-dedicated equipment or in rooms/areas where other products are manufactured. Provide details of cleaning validation planned and/or performed. For further information and guidance refer to the following link: [Microsoft Word - PI 006-3 Recommendation on Validation Master Plan.doc (picscheme.org)](https://picscheme.org/docview/3447) | Attached |

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| * 1. Batch Records   Append to this application the batch records / batch documents that are used to record the manufacturing particulars of each batch of veterinary medicine, vertebrate toxic agent or exempt product for export produced on site in relation to the activities performed in this application. For example, the document that is used to trace the raw materials used in each batch, the date the manufacturing steps are performed and the operator(s) performing the key steps. | Attached |

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| * 1. Release Procedure   Append to this application a detailed description or copy of the release procedure and associated checks performed as part of the release for each batch. | Attached |

# Part 6: Contract Manufacturing

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| **6.1 Specify below all your contract manufacturing sites including those that perform partial manufacture, sterilisation, repacking/relabelling, QC testing etc.** *Copy this table below if there are more than one contract manufacturing site. If you do not contract any manufacturing functions to other sites proceed with Part 7.* | | | | |
| **Company Name** |  | | | |
| **Site Address** |  | | | |
| **Company Contact Name** |  | **Position** |  | |
| **Company Contact Email** |  | **Phone number** |  | |
| **Manufacturing Function(s)** |  | | | |
| I confirm that this site holds a current GMP Certificate or ISO accreditation and/or understands that they may be subject to a GMP Inspection | | | | Yes |
| I confirm that this site is aware they are named in this application | | | | Yes |
| I confirm that there is a written quality/technical agreement in place with this site | | | | Yes |

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| **6.2 I confirm GMP certificates or evidence of ISO accreditation are attached for the contract manufacturing sites listed above.** | Yes |

# Part 7: Staff Responsibilities

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| **7.1 Person Responsible for Production** | |
| **Name** |  |
| **Position in Company** |  |

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| **7.2 Person Responsible for Quality** For companies responsible for ‘release for supply’, this includes the person with the responsibility of formally releasing the product to market. | |
| **Name** |  |
| **Position in Company** |  |

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| 7.3 Organisational Chart Append a staff organisational chart to this application. | Attached |

# Part 7: Payment Details

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| Invoicing/Payment | | |
| **Payment details are the same as the main manufacturing site details** *(proceed to Part 8)* | |  |
| **Payment details are different to the manufacturing site details and are specified below:** | |  |
| **Company Name** |  | |
| **Address** |  | |
| **Postal Address** |  | |
| **Attention to** |  | |
| **Any other details** |  | |

# Part 8: Applicant Statement

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| Applicant Statement  This section should be completed by a senior member of staff (such as CEO, Director, person responsible for Quality). | | | | |
| I confirm that:   * I am authorised to make this application as the applicant OR a person with legal authority to act on behalf of the applicant noted in Part 1; and * the information supplied in and with this application is truthful and accurate to the best of my knowledge; and * I understand that if there are future, ongoing levies or charges for business activity, MPI will send me an invoice for these charges. Any late or non-payment may result in a penalty fee, lodgment with a credit collection agent and/or withdrawal of service. | | | | |
| I confirm that I and other key staff are conversant with the ACVM Standard and Guideline for Good Manufacturing Practice | | | |  |
| I confirm the site is ready for an inspection, or will be after this date (*if ready now select today’s date*): | | | | Select date |
| I confirm that the relevant records, procedures and signed technical agreements (quality agreements) will be available for the inspection | | | |  |
| **Name** |  | **Telephone** |  | |
| **Signature** |  | **Email** |  | |
| **Date** | Select date | |

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| Collection of Information |
| **Collection of Personal Information**  Pursuant to Principle 3 of the Privacy Act 2020, we advise that:   * This information is being collected for the purpose of approving a manufacturer of veterinary medicines or vertebrate toxic agents or exempt products for export under the ACVM Act; and * The recipient of this information, which is the agency that will collect and hold the information, is the Ministry for Primary Industries, PO Box 2526, Wellington 6140; and * Some of the information being collected will be displayed on a public register; and * The collection of information is authorised under section 10 of the ACVM Act; and * The provision of this information is necessary in order to process this application; and * The supply of this information is voluntary; and * Failure to provide the requested information is likely to result in a return of the application form to the applicant, and may ultimately result in a refusal to approve the manufacturer; and * Under Principles 6 and 7 of the Privacy Act 2020, you have the right of access to, and correction of, any personal information which you have provided.   **Collection of Official Information**  All information provided to the Ministry for Primary Industries is official information and may be subject to a request made under the Official Information Act 1982.  If a request is made under that Act for information you have provided in this application, the Ministry for Primary Industries will consider any such request, taking into account its obligations under the Official Information Act 1982 and any other applicable legislation. |