

**GLP REGISTRATION QUESTIONNAIRE**

**GLP COMPLIANCE MONITORING PROGRAMME**

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| **GENERAL INFORMATION** | |
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| **Note 1:** | Except where otherwise allowed for under the IANZ GLP Compliance Monitoring Programme (see the IANZ publication *Procedures and Conditions for GLP Registration*), the information requested by this Questionnaire shall be maintained in confidence by IANZ. Key exceptions to this general rule are / may be:   * Information published on the test facility’s Schedule to the Certificate of Registration, which is publically available on the IANZ Directory at [www.ianz.govt.nz](http://www.ianz.govt.nz); * Reproduction of some or all of this information for members or observers of IANZ inspection teams who may be external to IANZ (but only after the test facility has agreed to their membership / observation of the inspection team and have signed a declaration of confidentiality with IANZ); * Selected information that may be provided to (i) members of the OECD Working Group on Good Laboratory Practice, and/or (ii) regulatory (receiving) authorities reviewing Study Reports, under New Zealand’s obligations to OECD’s programme on the Mutual Acceptance of Data. |
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| **Note 2:** | This Questionnaire is usually completed and submitted to IANZ along with one or other of the following forms:   * Application for Registration, for applicant organisations seeking to enter the IANZ GLP Compliance Monitoring Programme, or; * Application for Re-inspection, for currently Registered (GLP Compliant) facilities in preparation for a scheduled re-inspection. |
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| **1.1** | Name of applicant or Registered organisation |
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| **1.2** | Please provide a brief summary of the primary function of the organisation and/or any changes in function during the past two years. |
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| **SCOPE OF GLP OPERATIONS** | | | | |
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| **2.1** | Please indicate the types of non-clinical health and environmental safety studies undertaken for which Registration is sought. Indicate all that apply. | | | |
|  | (Currently Registered facilities may also attach a copy their current Schedule to the Certificate of Registration with any deletions, corrections or alterations sought.) | | | |
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|  |  |  | **20.01** | **Physical – Chemical Testing** |
|  | | | | |
|  | |  | (a) | Characterisation of formulated test items |
|  | | | | |
|  | |  | (b) | Stability studies |
|  | | | | |
|  | |  | (c) | Active ingredient assay of formulated products |
|  | | | | |
|  | |  | Other: | Specify: |
|  | | | | ……………………………………………………………………………………….. |
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|  |  |  | **20.02** | **Toxicity Studies** |
|  | | | | Please specify the types of toxicity studies undertaken:  (e.g. acute, sub-acute, chronic, reproductive, etc. or by reference to OECD Test Guidelines) |
|  | | | | ……………………………………………………………………………………….. |
|  | | | | ……………………………………………………………………………………….. |
|  | | | | Please indicate the test systems typically used for these toxicity studies: |
|  | | | | ……………………………………………………………………………………..... |
|  | | | | ……………………………………………………………………………………….. |
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|  |  |  | **20.03** | **Mutagenicity Studies** |
|  | | | | Please indicate the test system(s) typically used for these studies:  (and/or reference OECD Test Guidelines) |
|  | | | | ……………………………………………………………………………………….. |
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|  |  |  | **20.04** | **Environmental Toxicity Studies on Aquatic or Terrestrial Organisms** |
|  | | | | Please indicate the test systems typically used for these toxicity studies:  (and/or reference OECD Test Guidelines) |
|  | | | | ……………………………………………………………………………………….. |
|  | | | | ……………………………………………………………………………………….. |
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|  |  |  | **20.05** | **Studies on Behaviour in Water, Soil and Air; Bioaccumulation** |
|  | | | | Please specify the types of studies undertaken:  (or by reference to any applicable OECD Test Guidelines) |
|  | | | | ……………………………………………………………………………………….. |
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|  |  |  | **20.06** | **Residue Studies** |
|  | | | | |
|  | |  | (a) | Field Studies (animals) – veterinary medicines |
|  | | | | |
|  | |  | (b) | Field Studies (plants) – agricultural chemicals |
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|  | |  | Other: | Specify: |
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|  |  |  | **20.07** | | | **Studies on Effects on Mesocosms and Natural Ecosystems** | | | | | |
|  | | | | | | Please specify the types of studies undertaken:  (or by reference to any applicable OECD Test Guidelines) | | | | | |
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|  |  |  | | **20.08** | | **Analytical or Clinical Chemistry** | | | | | |
|  | | | | | | | | | | | |
|  | |  | | (a) | | Analysis of residues in agricultural samples and biological specimens | | | | | |
|  | | | | | | | | | | | |
|  | |  | | (b) | | Veterinary Clinical Pathology | | | | | |
|  | | | | | | | | | | | |
|  | |  | | Other: | | Specify: | | | | | |
|  | | | | | | ……………………………………………………………………………………….. | | | | | |
|  | | | | | | ……………………………………………………………………………………….. | | | | | |
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|  |  |  | | **20.09** | | **Other** | | | | | |
|  | | | | | | | | | | | |
|  | |  | | (a) | | Target Animal Safety | | | | | |
|  | | | | | | | | | | | |
|  | |  | | (b) | | Veterinary Histopathology | | | | | |
|  | | | | | | | | | | | |
|  | |  | | (c) | | Medical Devices | | | | | |
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|  | |  | | Other: | | Specify: | | | | | |
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| **2.2** | **Master Schedule of Studies** | | | | | | | | | | |
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|  |  |  | | Please enclose a copy of your test facility’s Master Schedule of studies (covering a | | | | | | | |
|  | | | | period of at least the last 3 years). | | | | | | | |
|  | | | | (Where it will assist the interpretation of the Master Schedule, please annotate or attached instructions, definitions, or similar.) | | | | | | | |
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| **2.3** | **Multi-Site Studies** | | | | | | | | | | |
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|  |  | | |  | Is your test facility involved in multi-site studies? | | | | | | |
|  | Yes/No | | |  |  | | | | | | |
|  | If Yes, please indicate your test facility’s role in multi-site studies. Indicate all that apply. | | | | | | | | | | |
|  | | | | | | | | | | | |
|  | |  | |  | As the Test Facility with Study Director | | | | | | |
|  | | | | | | | | | | | |
|  | | | | |  | |  | Routinely |  |  | Occasionally |
|  | | | | | | | | | | | |
|  | |  | |  | As an organisationally distinct Test Site with Principal Investigator | | | | | | |
|  | | | | | | | | | | | |
|  | | | | |  | |  | Routinely |  |  | Occasionally |
|  | | | | | | | | | | | |
|  | |  | |  | As the Test Facility (with Study Director), and with Test Site(s) with Principal | | | | | | |
|  | | | | | Investigator(s) as part of the one GLP organisation | | | | | | |
|  | | | | | | | | | | | |
|  | | | | |  | |  | Routinely |  |  | Occasionally |
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| **TESTING FACILITIES** | | | | | |
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| **3.1** | Please enclose a copy of a floor plan / map of your facility, indicating the areas for which | | | | |
|  | GLP compliance is claimed. | | | | |
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| **ORGANISATION & PERSONNEL** | | | | | |
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| **4.1** | **Organisation** | | | | |
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|  |  |  | Please enclose a current GLP staff organisation chart | | |
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|  |  |  |  |  | If your GLP staff organisation chart is a ‘special sub-set’ of your overall |
|  |  |  |  |  | organisation, please enclose a copy of your overall organisation chart. |
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|  |  |  |  |  | If your GLP staff organisation chart does not included named individuals, |
|  |  |  |  |  | please annotate or provide a list of individuals holding key GLP positions. |
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| **4.2** | **Personnel** | | | | |
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|  | Please indicate the approximate number of staff involved your GLP operations: | | | | |
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|  |  | |  | Full time | |
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|  |  | |  | Part time (permanent) | |
|  | | | | | |
|  |  | |  | Part time (contract) | |
|  | | | | | |
|  |  | |  | Study Directors / Principal Investigators (as included in the above numbers) | |
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|  | Please list any key GLP staff that has left your organisation in the last two years. | | | | |
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| **GLP QUALITY SYSTEM DOCUMENTATION** | | | | | |
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| **5.1** | Please enclose a full list of all standard operating procedures (SOPs) describing your GLP operation, and particularly those relevant to the scope of GLP studies undertaken (Section 2.1 above) | | | | |
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| **5.2** | Please enclose copies of the following SOPs: | | | | |
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|  |  |  | SOP(s) describing the organisation, test facility management responsibilities, Study | | |
|  |  |  | Director/Principal Investigator responsibilities, etc. | | |
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|  |  |  | Personnel training SOP(s) | | |
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|  |  |  | Quality assurance SOP(s), describing the QA operation | | |
|  | | | | | |
|  |  |  | Document control SOP(s) | | |
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|  |  |  | Test and reference item management SOP(s) | | |
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|  |  |  | SOP(s) on Study Plan requirements, amendments and deviations | | |
|  | | | | | |
|  |  |  | SOP(s) on raw data recording and record maintenance | | |
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|  |  |  | SOP(s) on Study Report requirements | | |
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|  |  |  | Archiving SOP(s), including describing the operation of the archive | | |
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| **NEXT STEPS** | | | | | | |
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| **6.1** | | Please ensure all sections of this Questionnaire have been completed appropriately. | | | | |
|  | | For assistance or further information, please contact the IANZ Programme Manager – GLP Compliance Monitoring at International Accreditation New Zealand: | | | | |
| **Telephone: (09) 525 6655** | | | | | | |
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| **6.2** | **CHECKLIST** | | | | | | |
|  | Please check that the copies of the following documents, as requested elsewhere in this Questionnaire, are enclosed: | | | | | | |
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|  |  | |  | Current GLP staff organisation chart | | | |
|  | | | | | | | |
|  |  | |  | Floor plan / map of your facility, indicating the areas for which GLP compliance is | | | |
|  |  | |  | claimed | | | |
|  | | | | | | | |
|  |  | |  | Master schedule of studies (covering at least the last 3 years) | | | |
|  | | | | | | | |
|  |  | |  | A full list of all standard operating procedures (SOPs) and particularly those relevant | | | |
|  |  | |  | to the scope of GLP studies undertaken. | | | |
|  | | | | | | | |
|  |  | |  | SOP(s) describing the organisation, test facility management responsibilities, Study | | | |
|  |  | |  | Director/Principal Investigator responsibilities, etc. | | | |
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|  |  | |  | Personnel training SOP(s) | | | |
|  | | | | | | | |
|  |  | |  | Quality assurance SOP(s), describing the QA operation | | | |
|  | | | | | | | |
|  |  | |  | Document control SOP(s) | | | |
|  | | | | | | | |
|  |  | |  | Test and reference item management SOP(s) | | | |
|  | | | | | | | |
|  |  | |  | SOP(s) on Study Plan requirements, amendments and deviations | | | |
|  | | | | | | | |
|  |  | |  | SOP(s) on raw data recording and record maintenance | | | |
|  | | | | | | | |
|  |  | |  | SOP(s) on Study Report requirements | | | |
|  | | | | | | | |
|  |  | |  | Archiving SOP(s), including describing the operation of the archive | | | |
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| **6.3** | Please identify the person who completed this Questionnaire / submission: | | | | | | |
|  | | | | | | | |
|  | Name: | | | | ……………………………………………………………………………………………... | | |
|  | Title: | | | | ……………………………………………………………………………………………... | | |
|  | Date: | | | | ………………………………………….. | | |
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| **6.4** | | Please forward this completed Questionnaire and the documents listed above to: | | | | |
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|  | | | | | | **International Accreditation New Zealand** |
|  | | Postal: | | | | **Private Bag 28908**  **Remuera**  **Auckland 1541** |
|  | | Physical: | | | | **Level 1, 626 Great South Road**  **Ellerslie**  **Auckland 1051** |
|  | | Attention: | | | | Programme Manager – GLP Compliance Monitoring |
|  | | | | | | |
|  | | *Please keep at least one copy of the completed Questionnaire for your files and for reference during the inspection.* | | | | |