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| Application form for a GLP Inspection |
| Form no. NABAF01G |



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| Logo Small | **NATIONAL ACCREDITATION BOARD - MALTA**  |
| **Application for Good Laboratory Practice (GLP) Inspection** |
| Instructions1. This application should be completed in detail and returned duly signed to:

**The Director,****National Accreditation Board Malta,****Mizzi House,****National Road,****Blata l-Bajda HMR9010,****Malta**1. This application shall be submitted in digital format.
2. This application, except for original signatures, **shall be typed** and shall be submitted in WORD format either via email or in any other digital format. Handwritten applications shall not be accepted. A scanned copy of the application form with original signatures shall also be submitted.
3. All information provided will be treated in confidence.
4. Additional information may be obtained by contacting the NAB-MALTA at the above address or Tel: (+356) 23952510, e-mail: info@nabmalta.org.mt
5. Incomplete applications will result in a delay in process, therefore, ensure that all the information required is available before submitting to the NAB-MALTA.
6. As regards GLP Inspections, the NAB-MALTA has a co-operation agreement with Sciensano, Belgium with which it will co-ordinate the inspection and other related activities.
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| SECTION A |

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| 1. Basic details regarding the Test Facility subject of this application |
| Company Name  |  |
| Address  |  |
| Company registration number |  |
| VAT Number (for invoicing purposes) |  |
| Website  |  |
| Are there premises at another address that form part of this test facility? If so, please give details. |
| Please provide details concerning the legal entity (i.e. name as registered at MBR or sole traders applicable) ownership, management and organisation of the test facility;e.g. is it a private company, a wholly owned subsidiary, a department of a larger organisation etc*.* |

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| 2. Basic details regarding the Test Facility management (This person will have legal responsibility for ensuring that the GLP Regulations are complied with. Please note that to avoid a conflict of interests, this person should not act as a study director or principal investigator for GLP studies.)  |
| Test Facility Manager  |  |
| Position |  |
| Contact Number  |  |
| Email address  |  |

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| 4. Person to contact about this application *(if different from above)* |
| Name  |  |
| Position |  |
| Contact Number  |  |
| Email address  |  |

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| SECTION B |

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| 5. What type of product will you be testing? *(Please tick one or more boxes below to indicate which activities will take place within the test facility for which GLP compliance will be claimed)* |

| **Type of study**  | **Identity of chemicals (categories)** |
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| Physical-chemical testing  | [ ]  Industrial chemicals[ ]  Pharmaceuticals[ ]  Veterinary Medicinal Products[ ]  Food/Feed Additives[ ]  Cosmetics [ ]  Biocides[ ]  Detergents[ ]  Novel Food[ ]  Genetically Modified Organisms[ ]  Medical Devices[ ]  Other products (Please specify) |
| Toxicity Studies | [ ]  Industrial chemicals[ ]  Pharmaceuticals[ ]  Veterinary Medicinal Products[ ]  Food/Feed Additives[ ]  Cosmetics [ ]  Biocides[ ]  Detergents[ ]  Novel Food[ ]  Genetically Modified Organisms[ ]  Medical Devices[ ]  Other products (Please specify) |
| Mutagenicity Studies | [ ]  Industrial chemicals[ ]  Pharmaceuticals[ ]  Veterinary Medicinal Products[ ]  Food/Feed Additives[ ]  Cosmetics [ ]  Biocides[ ]  Detergents[ ]  Novel Food[ ]  Genetically Modified Organisms[ ]  Medical Devices[ ]  Other products (Please specify) |
| Environmental toxicity studies on aquatic and terrestrial organisms | [ ]  Industrial chemicals[ ]  Pharmaceuticals[ ]  Veterinary Medicinal Products[ ]  Food/Feed Additives[ ]  Cosmetics [ ]  Biocides[ ]  Detergents[ ]  Novel Food[ ]  Genetically Modified Organisms[ ]  Medical Devices[ ]  Other products (Please specify) |
| Studies on behaviour in water, soil and air; bioaccumulation  | [ ]  Industrial chemicals[ ]  Pharmaceuticals[ ]  Veterinary Medicinal Products[ ]  Food/Feed Additives[ ]  Cosmetics [ ]  Biocides[ ]  Detergents[ ]  Novel Food[ ]  Genetically Modified Organisms[ ]  Medical Devices[ ]  Other products (Please specify) |
| Residue studies  | [ ]  Industrial chemicals[ ]  Pharmaceuticals[ ]  Veterinary Medicinal Products[ ]  Food/Feed Additives[ ]  Cosmetics [ ]  Biocides[ ]  Detergents[ ]  Novel Food[ ]  Genetically Modified Organisms[ ]  Medical Devices[ ]  Other products (Please specify) |
| Studies on effects of mesocosms and natural ecosystems | [ ]  Industrial chemicals[ ]  Pharmaceuticals[ ]  Veterinary Medicinal Products[ ]  Food/Feed Additives[ ]  Cosmetics [ ]  Biocides[ ]  Detergents[ ]  Novel Food[ ]  Genetically Modified Organisms[ ]  Medical Devices[ ]  Other products (Please specify |
| Analytical and clinical chemistry testing  | [ ]  Industrial chemicals[ ]  Pharmaceuticals[ ]  Veterinary Medicinal Products[ ]  Food/Feed Additives[ ]  Cosmetics [ ]  Biocides[ ]  Detergents[ ]  Novel Food[ ]  Genetically Modified Organisms[ ]  Medical Devices[ ]  Other products (Please specify): |
| Other studies (please specify)*Pharmacodynamic, pharmacokinetic, pharmacogenomic, bio distribution, toxicokinetic, safety pharmacology, validation studies for virus deactivation or removal, histopathology* |  |
| Other GLP linked activities (please specify)*Contract archiving, animal breeding and mating house, electronic data management, computer program validation, clinical analysis, bioanalytical part of bioequivalence trials* |  |

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| SECTION C |

| **6. Other details**  |
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| a) What is the objective of the work/studies you intend to perform?  |
| b) Is the study/work required to be conducted in compliance with GLP? Is this requirement specifically laid down in national legislation? If yes, please provide a reference to the applicable legislation below  |
| c) If there is no legislative requirement for this work to be conducted to GLP, has a national regulatory authority specifically requested that the study/work is to be conducted in compliance with GLP? If yes, please give details (including a named contact) and identify which regulatory authority has made this request.  |
| d) Why does this work need to be conducted to GLP? (Only applicable if you have answered “No” to both questions (b) and (c) above)  |
| e) Do you intend to conduct work that does not constitute a full GLP study, but will constitute a phase of, or be used to support a full GLP study? |
| f) If you will be conducting complete GLP compliant studies (under the control of your own study director), is there the possibility that some study phases would be conducted by another party, including the study sponsor? |
| g) How many staff are employed by the test facility? How many of these staff will be directly engaged in, or support the work for which GLP compliance will be claimed? |
| h) Have staff received recent (within the last year) training in GLP? Please provide details. |
| i) Are any areas shared with non-GLP compliant activities? If so, please give details. |
| j) Are there any other independently verified quality systems maintained in the areas claiming compliance? (e.g. GMP, ISO17025, ISO 9001) If yes, please give details. |
| k) What are the provisions for Quality Assurance monitoring of the test facility and the work conducted therein?  |
| l) Are QA staff independent of the conduct of GLP studies? |
| m) What constitutes the archive facilities? If utilising an off-site contract archive facility please give details. |
| n) Who is the appointed archivist and are they independent of GLP study conduct? If they have other functions within the GLP structure please describe these roles. |
| o) Will computerised systems be used in GLP studies? *A computerised system is defined as a group of hardware components and associated software designed to perform a specific function. Computerised systems may be used to capture, manipulate or store raw data. Common examples include HPLC systems, spreadsheets for data manipulation and statistical analysis packages.* If yes, please provide an overview of the types of systems and whether they are bespoke custom built systems or proprietary packages. |
| p) Are there documented procedures in place to ensure that computerised systems are installed, validated, operated and maintained to ensure that the GLP principles are complied with? If yes, please provide a copy with this application. |

| **SECTION D** |
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| **7. Documents and records to be submitted** |
| **Notes:***(1) The following documents must be submitted in electronic format with the application in the provided folder structure. NAB-MALTA will not process the application until all the items listed below have been received.**(2) If any of the documents are included as part of a quality management system manual or other documentation, please quote either the manual section or document reference number in the space provide next to the tick box.* |
|  |  | In the box below, tick as necessary and write any necessary references. If not applicable, explain why. |
|  | An index and numbered list of the attachments *(use the folder structure provided)* | [ ]  |
| 1.
 | Master list of Standard Operating Procedures in use | [ ]  |
|  | Master schedule of finished and on-going studies | [ ]  |
|  | Documented procedure for the production, control and revision of formal documentation (e.g. standard operating procedures and policy documents) | [ ]  |
|  | Documented procedures that described how QA activities will be planned, performed and reported. | [ ]  |
|  | Documented procedure to describe the placement into, and removal of items from, the archive. | [ ]  |
|  | Up-to-date GLP organisation chart with list of key personnel, their function and starting/end day in this function | [ ]  |
|  | List of computer systems in place, and validated Excel sheets | [ ]  |
|  | List of equipment | [ ]  |

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| **SECTION E** |
| **8. Statement by Applicant**The Organisation identified below (details of which are set out on paragraphs 1 and 2 of Section A of this application form) hereby applies to the NAB-MALTA to undergo an inspection for Good Laboratory Practice in line with the OECD guidelines and any other applicable and normative documents. The Organisation undertakes to pay all fees due to the NAB-MALTA. The Organisation declares that it has the necessary resources to undertake the GLP studies being requested. Submission of this form indicates that the systems described are fully operational and that the proposed facility considers that it is operating in accordance with the Principles of Good Laboratory Practice. The Organisation hereby confirms that it has a right to supply the data and information contained in this application or which it otherwise gives to the NAB-MALTA, and gives its own consent and confirms that it has obtained all properly informed consents from any individuals in respect of whom the Organisation is giving data or information to the NAB-MALTA to enable the NAB-MALTA to lawfully receive such data and information and make use thereof for the purposes of its functions (having particular regard to, but not limited to, applicable data protection legislation) and also confirms that all such data and information is complete, accurate and correct and that it will promptly provide any such further information and data as may be required by the NAB-MALTA to process this application. All communication related to a specific inspection shall be copied to the NAB-MALTA Officer appointed The Organisation also accepts that the NAB-MALTA might need to consult with the appropriate regulators. The Organisation also accepts that the NAB-MALTA teams may be accompanied by representatives from specific regulators or competent authorities.  |
| **9. Data Protection Declaration**The NAB-MALTA ("the Controller") will process your personal data in accordance with the relevant provisions of the General Data Protection Regulation (GDPR), the Data Protection Act (Chapter 586 of the Laws of Malta) and other regulations made thereunder. The Controller will process your personal data for assessment and administrative purposes and to comply with its legal obligations. For further information on how your personal data will be processed refer to the Controller’s privacy policy. I, the data subject, hereby consent to having the NAB-MALTA collect and process my personal information from this application. |
| **Signed for and on behalf of** *(enter name of organisation and preferably a rubber stamp)* |
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| **Company Representative** |
| **Position:** |
| **Signature:** | **Date:** |