99031003022000, 99031003022000

Apply for a certificate of compliance with the principles of Good Laboratory Practice (GLP)

Modul	Sachverhalt
Leistungsschlüssel	99031003022000, 99031003022000
Leistungsbezeichnung I	Apply for a certificate of compliance with the principles of Good Laboratory Practice (GLP)
Leistungsbezeichnung II	
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Hessen
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	Chemikalien (031)
Verrichtungskennung	Bescheinigung (022)
SDG-Informationsbereich	

Modul	Sachverhalt
Lagen Portalverbund	Forschungs- und Entwicklungsnetzwerke (2100300)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	03.09.2012
Fachlich freigegen durch	Hessian Ministry for the Environment, Climate Protection, Agriculture and Consumer Protection
Handlungsgrundlage	https://www.gesetze-im-internet.de/chemg/__19b.html https://www.bfr.bund.de/de/gute_laborpraxis__glp_-258.html https://www.gesetze-im-internet.de/chemg/__19b.html https://www.bfr.bund.de/de/gute_laborpraxis__glp_-258.html
Teaser	
Volltext	'Good laboratory practice' means a quality assurance system that deals with the organisational process and framework under which non-clinical health and environmental safety studies, the results of which are intended to enable risk assessment in an official procedure, are planned, carried out and monitored. It also includes recording, archiving and reporting of the audit. As a test facility or test site, you can apply for a certificate of compliance with the principles of Good Laboratory Practice. You will receive this certificate after carrying out a so-called inspection procedure if you meet the requirements specified for this purpose. The inspection procedure shall be repeated after 3 years at the latest. The extensive requirements can be found in Annex 1 of the Act on Protection against Hazardous Substances (ChemG). NOTE: A legitimate interest exists, for example, if a GLP certificate is required for exportable products, although there is no inspection obligation according to § 19 a Abs. 1 ChemG. Order archives that offer the archiving of GLP-relevant documents are inspected as test sites and certified accordingly. https://www.gesetze-im-internet.de/chemg/anhang_1.html https://www.gesetze-im-internet.de/chemg/anhang_1.html

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Erforderliche Unterlagen	Application (original) including the following documents/information: • Organizational structures (organizational charts (company/GLP structure), functional descriptions, number of employees) • Description of the studies for which the GLP certificate is requested. • Rooms of the test facility/test site (building plans/floor plans, GLP area marked) • Testing • List of all standard operating procedures (SOP'n) • SOP on the general procedure for creating, approving, modifying, distributing and archiving SOPs
Voraussetzungen	The requirements for the issuance of a GLP certificate result from § 19 b ChemG. Afterwards • the tests to be carried out must be GLP-subject tests in accordance with § 19 a ChemG or a legitimate interest must be credibly demonstrated, • the test facility or site and the tests or phases of tests carried out there shall comply with the principles of good laboratory practice set out in Annex I ChemG.
Kosten	The costs of the procedure depend on the time required.
Verfahrensablauf	The GLP office checks the application documents and initiates the inspection procedure. It selects the GLP inspectors to carry out the inspection and determines the inspection management. The inspection is carried out in accordance with the guidelines listed in the annex to the General Administrative Regulation on the procedure for official supervision of compliance with the principles of Good Laboratory Practice (ChemVwV-GLP) and concluded by handing over a short protocol (list of deficiencies) during the final meeting. If necessary, further documents will be requested prior to the inspection. During an initial inspection, a preliminary inspection is usually carried out. In the case of repeat inspections, this is determined on a case-by-case basis. The inspection process is concluded with an inspection report describing the extent to which a test facility/site

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	adheres to GLP principles. This report shall also indicate the categories of tests from which tests are carried out in accordance with GLP principles. After completion of the inspection procedure, the Hessian Ministry for the Environment, Energy, Agriculture and Consumer Protection (HMUELV) issues the GLP certificate, provided that all requirements are met. If you have any questions about the inspection procedure, you can contact the GLP office.
Bearbeitungsdauer	
Frist	An application for a GLP certificate shall be decided within a period of 3 months after completion of the inspection procedure pursuant to § 19b paragraph 1 sentence 1.
weiterführende Informationen	
Hinweise	OtherFurther information on GLP can be found at:• Federal Institute for Risk Assessment (BfR)• Federal Working Group on Chemical Safety https://www.bfr.bund.de/de/start.html https://www.blac.de/servlet/is/2057/ https://www.bfr.bund.de/de/start.html https://www.blac.de/servlet/is/2057/
Rechtsbehelf	
Kurztext	
Ansprechpunkt	Regierungspräsidium Darmstadt, Office of the GLP Commission Hesse
Zuständige Stelle	
Formulare	
Ursprungsportal	Bescheinigung über die Einhaltung der Grundsätze der Guten Laborpraxis (GLP) beantragen, Apply for a certificate of compliance with the principles of Good Laboratory Practice (GLP)