99031003022000

Compliance with the principles of Good Laboratory Practice Certification

Modul	Sachverhalt
Leistungsschlüssel	99031003022000
Leistungsbezeichnung I	Compliance with the principles of Good Laboratory Practice Certification
Leistungsbezeichnung II	Apply for a certificate of compliance with the principles of Good Laboratory Practice
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Hamburg
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	Laboratory according to GLP , Standards for laboratories , GLP certificate , GLP certificate
Leistungstyp	

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Leistungsgruppierung	
Verrichtungskennung	
SDG-Informationsbereich	
Lagen Portalverbund	
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	14.03.2024
Fachlich freigegen durch	
Handlungsgrundlage	§§ 19a ff. ChemG State Ordinance on Administrative Fees (General Fee Tariff), Tariff Item 2.3.1 - VwGebV.
Teaser	"Good Laboratory Practice" (GLP) is a quality assurance system under which non-clinical safety tests are planned, carried out and monitored. To have the tests recognized as GLP-compliant, facilities require a GLP certificate.
Volltext	According to the Chemicals Act, non-clinical facilities require health and environmental safety tests for the approval or authorization of substances and preparations. These security checks must also be carried out for registration, login or notification procedures. They must be carried out in compliance with the principles of Good Laboratory Practice (GLP) and assess potential hazards to humans and the environment. The principles of Good Laboratory Practice provide precisely defined standards for organization, personnel, premises, test and reference substances, work instructions, result reports and archiving. To obtain GLP certification, test facilities and test sites must demonstrate that they meet the GLP requirements. Good Laboratory Practice aims to ensure that test results are internationally recognized and that animal testing is restricted.
Erforderliche Unterlagen	Please submit the documents requested by the GLP Commission with your informal application: Organizational structures, organizational plans (company/GLP structure) job descriptions, number of

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	employees Description of the investigations for which the GLP certificate is requested Documents relating to the premises of the test facility or test site, for example building plans or floor plans, GLP area marked test systems List of GLP studies already conducted list of standard operating procedures organizational charts List of all standard operating procedures (SOPs) Directory of Computer-Aided Systems SOP on the general procedure for creating, approving, amending, distributing and archiving the SOPs (Agreement after preliminary discussion)
Voraussetzungen	As a test facility or test site, you must demonstrate that you comply with the GLP principles. These provide precisely defined standards for organization staff Premises Test and reference substances The use of computer-aided systems Work instructions Result reports Archiving
Kosten	Fees apply. The amount of the fees depends on the time required for the preliminary and main inspection and the preparation of the report, if necessary with the involvement of other experts and assessors. You will receive a cost assessment notice, which will also show any expenses incurred.
Verfahrensablauf	You submit an informal application and submit it to the responsible authority. When you apply for the GLP certificate for the first time, your eligibility will be checked. Preliminary discussions and, if necessary, a preliminary inspection will take place. They provide the inspectors with all necessary documents to prepare for the inspection. During an inspection, the competent authority checks whether you comply with the principles of Good Laboratory Practice. You will receive an inspection report. If you do not yet comply with all the principles of Good Laboratory Practice, you will be given the opportunity to correct the deficiencies. You submit proof that the defect has been remedied. The responsible authority will decide on your application. You will receive the GLP certificate.
Bearbeitungsdauer	A decision on an application for a GLP certificate will be taken within 3 months after completion of the inspection procedure.

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Frist	In order to remain in the monitoring program, an application for a new GLP certificate must be submitted regularly. The deadlines are agreed individually in the inspection reports.
weiterführende Informationen	https://www.bfr.bund.de/de/gute_laborpraxis__glp_-258.html https://www.bfr.bund.de/de/gute_laborpraxis__glp_-258.html
Hinweise	On the website of the GLP Federal Office at the Federal Institute for Risk Assessment you will find all national GLP documents, OECD documents and EU documents on Good Laboratory Practice.
Rechtsbehelf	Contradiction
Kurztext	Certificate of compliance with the principles of Good Laboratory Practice Compliance with the principles of Good Laboratory Practice: Application for a certificate Institutions and laboratories that wish to conduct tests under Good Laboratory Practice (GLP) conditions require a GLP certificate. To obtain the certificate, an application must be submitted and a subsequent inspection by the responsible authority. To remain in the GLP monitoring program, both the application and the inspection must be repeated regularly.
Ansprechpunkt	If you want to find out exactly who is responsible for your request, please follow the link to Hamburg Service
Zuständige Stelle	Justice and Consumer Protection Authority
Formulare	
Ursprungsportal	Hamburg Service, Hamburg Service (Currently this link is only available in german)