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Compliance with the principles of Good Laboratory Practice: Applying for a certificate

Heruntergeladen am 24.06.2025

<https://fimportal.de/xzufi-services/304398780/L100040>

Modul	Sachverhalt
Leistungsschlüssel	99031003022000, 99031003022000
Leistungsbezeichnung I	Compliance with the principles of Good Laboratory Practice: Applying for a certificate
Leistungsbezeichnung II	
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Niedersachsen
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	10.02.2022
Fachlich freigegeben durch	Lower Saxony Ministry for the Environment, Energy, Building and Climate Protection
Handlungsgrundlage	https://www.gesetze-im-internet.de/chemg/_19b.html https://voris.wolterskluwer-online.de/browse/document/cite/ac34a2c5-a703-3052-8dbc-04c8c6a518ff https://www.gesetze-im-internet.de/chemg/_19b.html https://voris.wolterskluwer-online.de/browse/document/cite/ac34a2c5-a703-3052-8dbc-04c8c6a518ff
Teaser	Facilities and laboratories that want to carry out tests or phases of tests under the conditions of Good Laboratory Practice (GLP conditions) require a GLP certificate.
Volltext	<p>Facilities and laboratories that want to carry out tests or phases of tests under the conditions of Good Laboratory Practice (GLP conditions) require a GLP certificate. In order to obtain the GLP certification, the test facilities or test sites must demonstrate that compliance with the GLP principles is guaranteed. An application must be submitted to obtain the certificate.</p> <p>The competent body shall receive the application and carry out a GLP inspection at the test facilities or test sites. If the test facility or site complies with GLP principles, the competent body shall issue a GLP certificate.</p>
Erforderliche Unterlagen	Documents are required. These depend on the subject matter of the application. Please contact the competent authority.
Voraussetzungen	<p>Test facilities or test sites must demonstrably comply with GLP principles.</p> <p>These provide for precisely defined standards for</p> <ul style="list-style-type: none"> • Organization

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	<ul style="list-style-type: none"> • Staff • Premises • test and reference substances, • Operating instructions • Reports on results and • Archiving
Kosten	<p>For the issuance of a GLP certificate:</p> <ul style="list-style-type: none"> • The amount of the fees is determined - according to Annex 1 to § 1 paragraph 1 of the General Fee Schedule of the State of Lower Saxony No. 21.1.1 - depending on the time spent. However, a minimum of EUR 300.00 will be charged. <p>For GLP inspection:</p> <ul style="list-style-type: none"> • The amount of the fees is determined - according to Annex 1 to § 1 paragraph 1 of the General Fee Schedule of the State of Lower Saxony No. 21.1.2 - depending on the time spent. However, at least EUR 900.00 will be charged. <p>Any expenses incurred will be shown in the cost assessment notice.</p>
Verfahrensablauf	<ul style="list-style-type: none"> • Application • Checking the completeness of the application documents • Inspection preparations, including the provision of documents by the applicant to the inspectors • Inspection • Decision with notice
Bearbeitungsdauer	<p>A decision on an application for a GLP certificate will be taken within a period of 3 months after the completion of the inspection procedure.</p>
Frist	<p>There are no legally prescribed deadlines to be observed.</p>
weiterführende Informationen	
Hinweise	<p>All national GLP publications, OECD documents and EU documents on Good Laboratory Practice are available</p>

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	<p>on the website of the GLP Federal Office at the Federal Institute for Risk Assessment. https://www.bfr.bund.de/de/gute_laborpraxis__glp_-258.html https://www.bfr.bund.de/de/gute_laborpraxis__glp_-258.html</p>
Rechtsbehelf	Objection - see information in the notices
Kurztext	<ul style="list-style-type: none"> • Compliance with the principles of Good Laboratory Practice: Applying for a certificate • Facilities and laboratories that want to carry out tests under the conditions of Good Laboratory Practice (GLP conditions) require a GLP certificate. • In order to obtain the certificate, an application must be submitted and then inspected by the competent authority. • The responsibility lies with the GLP control centre of the Central Support Centre for Air Pollution Control, Noise, Hazardous Substances and Major Accident Prevention (ZUS LLGS) in the State Trade Inspectorate Hildesheim.
Ansprechpunkt	<p>https://service.niedersachsen.de/dlp/ea https://service.niedersachsen.de/dlp/ea</p>
Zuständige Stelle	<p>The responsibility lies with the GLP control centre of the Central Support Centre for Air Pollution Control, Noise, Hazardous Substances and Major Accident Prevention (ZUS LLGS) in the State Trade Inspectorate Hildesheim.</p> <p>This procedure can also be handled by a "Point of Single Contact". The "Point of Single Contact" is a special service offered by the municipalities and the state for service providers.</p>
Formulare	<p>Ursprungsportal</p> <p>Einhaltung der Grundsätze der Guten Laborpraxis: Antragstellung zum Erlangen einer Bescheinigung, Compliance with the principles of Good Laboratory Practice: Applying for a certificate</p>