99031003022000

Apply for a certificate of compliance with the principles of good laboratory practice (GLP)

Modul	Sachverhalt
Leistungsschlüssel	99031003022000
Leistungsbezeichnung I	Apply for a certificate of compliance with the principles of good laboratory practice (GLP)
Leistungsbezeichnung II	Apply for a certificate of compliance with the principles of good laboratory practice (GLP)
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Sachsen
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	
Leistungsgruppierung	
Verrichtungskennung	

Modul	Sachverhalt
SDG-Informationsbereich	
Lagen Portalverbund	
Einheitlicher Ansprechpartner	
Fachlich freigegeben am	
Fachlich freigegen durch	
Handlungsgrundlage	• § 19b [Gesetz zum Schutz vor gefährlichen Stoffen (ChemG)](http://www.gesetze-im-internet.de/chemg/) • [Allgemeine Verwaltungsvorschrift zum Verfahren der behördlichen Überwachung der Einhaltung der Grundsätze der Guten Laborpraxis (ChemVwV-GLP)](http://dipbt.bundestag.de/dip21/brd/2011/0529-11.pdf) • Laufende Nummer 24 Tarifstelle 1 [Sächsisches Kostenverzeichnis (SächsKVZ)](https://www.revosax.sachsen.de/vorschrift/19330-Zehntes-Saechsisches-Kostenverzeichnis)
Teaser	"Good laboratory practice" is a quality assurance system that deals with the organisational procedure and the framework conditions under which non-clinical health and environmental safety tests, the results of which are intended to enable a risk assessment in an official procedure, are planned, carried out and monitored. It also includes the recording, archiving and reporting of the test
Volltext	#### Certificate in accordance with Section 19b of the Act on Protection against Hazardous Substances (ChemG) "Good laboratory practice" is a quality assurance system that deals with the organisational procedure and the framework conditions under which non-clinical health and environmental safety tests, the results of which are intended to enable a risk assessment in an official procedure, are planned, carried out and monitored. It also includes the recording, archiving and reporting of the test As a test facility or test site, you can apply for a

Modul	Sachverhalt
	certificate of compliance with the principles of good laboratory practice. You will receive this certificate after carrying out a so-called inspection procedure and fulfilling the specified requirements. The extensive requirements can be found in Annex 1 of the Act on Protection against Hazardous Substances (ChemG). ### Single point of contact You can utilise the service of the Single Point of Contact for this procedure. They will guide you through the procedure, take care of correspondence with all the authorities responsible for your concerns and provide you with expert advice. • [Single point of contact](https://amt24.sachsen.de/zufi/cms/einheitlicher-ansprechpartner) Amt24 information
Erforderliche Unterlagen	Application (original) including the documents requested therein
Voraussetzungen	For the issue of a GLP certificate • the tests to be performed must be tests subject to GLP according to § 19 a ChemG or a legitimate interest must be substantiated. • the test facility or test site and the tests or phases of tests performed there must comply with the principles of good laboratory practice according to Annex I ChemG. **Note:** A legitimate interest exists, for example, if a GLP certificate is required for exportable products, although there is no obligation to test in accordance with Section 19 a (1) ChemG.
Kosten	EUR 1,109 to EUR 16,169
Verfahrensablauf	The body that issues the certificate checks the application documents and initiates the inspection

Modul	Sachverhalt
	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 of the General Administrative Regulation on Good Laboratory Practice (more precisely: ChemVwV-GLP). • The inspection ends with the presentation of a short report (list of defects) at the final meeting. • If necessary, further documents will be requested prior to the inspection. • In the case of an initial inspection, a pre-inspection is usually carried out; in the case of repeat inspections, this is determined on a case-by-case basis. • The inspection procedure is concluded with an inspection report. This describes the extent to which a test facility/test site complies with the GLP principles and from which test categories tests are carried out in accordance with the GLP principles. • If all requirements are met after completion of the inspection procedure, the competent body issues the GLP certificate. **Note:** If you have any questions about the inspection procedure, you can contact the body responsible for issuing the GLP certificate.
Bearbeitungsdauer	Once the inspection procedure has been completed, a decision on the application for a GLP certificate will be made within three months.
Frist	not specified
weiterführende Informationen	
Hinweise	
Rechtsbehelf	More details in the notice
Kurztext	
Ansprechpunkt	

Modul	Sachverhalt
Zuständige Stelle	
Formulare	
Ursprungsportal	