

99005001005000

# Manufacture of medicines permit

Heruntergeladen am 19.06.2025

<https://fimportal.de/xzufi-services/S1000020010000012000/S100002>

Modul	Sachverhalt
Leistungsschlüssel	99005001005000
Leistungsbezeichnung I	Manufacture of medicines permit
Leistungsbezeichnung II	Permission to manufacture medicines
Typisierung	2a - Bundesauftragsverwaltung: Regelung, Land: Vollzug
Quellredaktion	Hamburg
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	<div lang="en-x-mtfrom-de">Medicines manufacturing license</div>, <div lang="en-x-mtfrom-de">Medicines Permission to manufacture</div>, <div lang="en-x-mtfrom-de">Manufacturing authorisation for medicinal products</div>
Leistungstyp	
Leistungsgruppierung	
Verrichtungskennung	
SDG-Informationsbereich	
Lagen Portalverbund	

Modul	Sachverhalt
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	08.07.2022
Fachlich freigegeben durch	
Handlungsgrundlage	•
Teaser	You need a permit from the responsible authority if you want to manufacture medicinal products and are based in Hamburg.
Volltext	<ul style="list-style-type: none"> <li>• The classic pharmaceutical drug manufacturers</li> <li>• Manufacturer of blood products</li> <li>• Pharmaceutical entrepreneurs</li> <li>• Active ingredient manufacturer</li> <li>• Exporters</li> <li>• Importers</li> <li>• External testing laboratories for pharmaceuticals</li> </ul> <p>If you want to commercially or professionally manufacture medicinal products (human medicinal products, including clinical trial medicinal products), test sera or test antigens, active substances that are of human, animal or microbial origin or that are produced by genetic engineering or other substances of human origin intended for the manufacture of medicinal products, you require a permit to do so.</p>
Erforderliche Unterlagen	<ul style="list-style-type: none"> <li>• Informal application with exact name of the applicant and information on the legal form, if applicable, extract from the commercial register</li> <li>• Organizational chart of officials</li> <li>• Name of the establishment (name, street, place),</li> <li>• Site plans of the operational buildings and operating rooms for production, testing and storage including the flow of materials and personnel</li> <li>• if available, information on external warehouses (including addresses and site plans),</li> <li>• Proof of availability of the rooms (e.g. rental agreement)</li> <li>• Designation of a qualified person according to Section 14 of the Medicines Act, including telephone number <ul style="list-style-type: none"> <li>• officially certified copy of the license certificate</li> <li>• Employment certificate to prove professional experience</li> </ul> </li> </ul>

## Modul

## Sachverhalt

- CV
- Proof of the required expertise of the persons according to Section 15 AMG
- Proof of the reliability of the competent person and the reporting person from the management by means of a certificate of good conduct of document type O
- Declarations of commitment for appointment as a qualified person or as a graduated plan representative or as an information representative
- Declaration on the designation that no professional or public prosecutorial proceedings are pending against the competent person or graduated plan representative or information officer or managing director
- Information on manufacturing activities (products, processes, volume per year)
- Human medicinal products or clinical investigational medicinal products
- Name of the medicinal product and dosage form, scope of manufacture and, where applicable, the process
- if applicable, information on the companies commissioned to carry out tests under the Medicines Act
- current "Site Master File" or description of the facility
- Quality Assurance Manual
- List of manufacturing activities including process overviews

## Voraussetzungen

- the presence of a person with the necessary expertise, reliability and availability (competent person)
- the availability of suitable operating rooms and facilities
- Proof that manufacturing and testing are carried out in accordance with the state of the art in science and technology and that the requirements of the EU Guide to Good Manufacturing Practice (GMP) are met.
- As part of the procedure, an acceptance inspection is carried out by the competent authority

## Kosten

Fees apply. The amount of the fees is calculated according to state law.

## Verfahrensablauf

- Organizational chart with functionaries
- exact name of the applicant and information on the

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	<p>legal form</p> <ul style="list-style-type: none"> <li>• Floor plan including planned material and personnel flows</li> <li>• Name of the establishment (name, street, place)</li> <li>• Information on external warehouses (including address)               <ul style="list-style-type: none"> <li>• a qualified person according to Section 15 of the Medicines Act,</li> <li>• a head of production and</li> <li>• a head of quality control, including telephone and fax number</li> </ul> </li> <li>• Name, telephone and fax number</li> <li>• Information on manufacturing activities (products, processes, volume per year)</li> <li>• Information on whether you are applying for authorisation for authorised human medicinal products or clinical investigational medicinal products</li> <li>• Name of medicinal products and dosage forms, scope of manufacture and process</li> <li>• Information on the companies commissioned to carry out tests under the Medicines Act, if applicable</li> </ul> <p>You can apply for permission informally to the responsible authority. Your application must contain the following information:</p>
Bearbeitungsdauer	The processing time is at least 4 weeks. If all the necessary documents are submitted to the responsible authority, the processing takes a maximum of 3 months.
Frist	Submit your application in such a way that all required documents are available at least three months before the planned start of production operations.
weiterführende Informationen	<a href="https://www.hamburg.de/politik-und-verwaltung/behoerden/bjv/themen/verbraucherschutz/pharmaziewesen/arzneimittelhersteller-88988">https://www.hamburg.de/politik-und-verwaltung/behoerden/bjv/themen/verbraucherschutz/pharmaziewesen/arzneimittelhersteller-88988</a> <a href="https://www.hamburg.de/pharmaziewesen/2131596/arzneimittelhersteller/">https://www.hamburg.de/pharmaziewesen/2131596/arzneimittelhersteller/</a>
Hinweise	No.
Rechtsbehelf	Contradiction
Kurztext	<ul style="list-style-type: none"> <li>• Permission to manufacture medicinal products</li> <li>• Manufacture of medicinal products permit</li> </ul>

Modul	Sachverhalt
	<ul style="list-style-type: none"> <li>• Medicinal products (human medicinal products, including clinical trial medicinal products)</li> <li>• Test serum or test antigens</li> <li>• Active substances of human, animal or microbial origin or produced by genetic engineering</li> <li>• Other substances of human origin intended for use in the manufacture of medicinal products</li> </ul>
Ansprechpunkt	
Zuständige Stelle	Justice and Consumer Protection Authority
Formulare	
Ursprungsportal	Hamburg Service, Hamburg Service (Currently this link is only available in german)