99005023008000

Show qualified person according to § 14 German Medicines Act

Modul	Sachverhalt
Leistungsschlüssel	99005023008000
Leistungsbezeichnung I	Show qualified person according to § 14 German Medicines Act
Leistungsbezeichnung II	Show qualified person according to § 14 German Medicines Act
Typisierung	2a - Bundesauftragsverwaltung: Regelung, Land: Vollzug
Quellredaktion	Baden-Württemberg
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	
Leistungsgruppierung	
Verrichtungskennung	
SDG-Informationsbereich	
Lagen Portalverbund	

Modul	Sachverhalt
Einheitlicher Ansprechpartner	
Fachlich freigegeben am	
Fachlich freigegen durch	
Handlungsgrundlage	Arzneimittelgesetz (AMG) • § 14 Entscheidung über die Herstellungserlaubnis • § 15 Sachkenntnis • § 20 Anzeigepflichten
Teaser	The German Medicinal Products Act describes the requirements for various responsible persons (legal guarantors).
Volltext	The German Medicinal Products Act describes the requirements for various responsible persons (legal guarantors). It stipulates that you must notify the competent authority of a qualified person for the manufacturing authorisation.
Erforderliche Unterlagen	• Employment references (copy) • Proof of training (certified copy) • Curriculum vitae (in tabular form, relating to training and professional activity) • Certificate of good conduct (document type O for direct transmission from authority to authority) • Form "Declaration of nomination" • Declaration of commitment
Voraussetzungen	• Qualified persons must have the necessary expertise and reliability. • As a qualified person in accordance with Sections 14 and 15 of the German Medicines Act (AMG), you require a licence to practise as a pharmacist or alternatively a university degree in pharmacy, chemistry, biology, human or veterinary medicine and proof of successfully completed examinations in accordance with the catalogue of subjects listed in Section 15 AMG.
Kosten	There are no costs for the advert.

Modul	Sachverhalt
Verfahrensablauf	You can notify a qualified person in writing or online. • You notify the competent person by means of a written application or using the online service. • The notification is then received by the authority. • The authority checks the notification formally and for completeness. • If any documents are found to be missing during the check, you will be contacted and asked to provide the missing documents. • Once the missing documents have been submitted or the formal check has been passed, the competent authority will make a decision. • The notification can be confirmed or rejected. • The decision will be communicated to you as the person making the notification. • A statement of fees will then be drawn up and sent to you with a request for payment.
Bearbeitungsdauer	
Frist	Pursuant to Section 20 of the Medicinal Products Act, the holder of a manufacturing/import licence must notify the competent authority in advance of any change in connection with the qualified person, submitting the supporting documents. In the event of an unforeseen change of the qualified person in accordance with Section 14, the notification must be made immediately.
weiterführende Informationen	
Hinweise	You must report any changes immediately. A fine may be imposed in the event of an offence.
Rechtsbehelf	• Objection • Information on how to lodge an objection will be sent with the decision on your advert.
Kurztext	
Ansprechpunkt	
Zuständige Stelle	

Modul	Sachverhalt
Formulare	
Ursprungsportal	