



Kingdom of Saudi Arabia
Saudi Food & Drug Authority



Guidance

**on Licensing Consulting
Services Establishments**



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1- Introduction

1.1 Purpose of the Guidance



The Saudi Food and Drug Authority (SFDA) issued these requirements based on Article 9 of Chapter 3 of the "Executive Regulations of the General Authority for Food and Drug" issued by Royal Decree No. M/6, dated 25/1/1428 AH, which stipulates that "The Authority shall determine the requirements for the licenses required for food and drug establishments, devices, medical products, feed factories, pesticides, laboratories, consultancy establishments, and all related to the work of the Authority."

This Guidance aims to define the conditions and requirements for licensing consulting service establishments under the supervision of the Saudi Food and Drug Authority (SFDA). Additionally, it clarifies the rights, obligations, and legal responsibilities of both the Authority and the establishments covered by the Guidance.

1.2 Applicability



These terms and conditions apply to consulting service establishments in the Kingdom that wish to engage in consulting services related to activities subject to the supervision of the Saudi Food and Drugs Authority (SFDA). The purpose is to assist the Authority's clients in implementing its conditions and requirements, provided that this Guidance does not conflict with any laws or regulations.

1.3 Terms and Definitions



The Kingdom: The Kingdom of Saudi Arabia

The Authority: The Saudi Food and Drugs Authority (SFDA)


Licensing: The process by which the Authority grants permission to engage in consulting activities in the field specified in the licensing document for commercial purposes in the Kingdom's market

Licensing area: The scope of work specified in the licensing document submitted by the consultancy entity to the beneficiary for implementing the Authority's conditions and requirements.

Consulting Service Establishments: Entities licensed by the Authority to provide general consulting services related to activities and fields related to the Authority work.

2 Licensing

2.1 Procedure for Submitting a License or Renewal Application

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- Create an account.
 - Submit a license or renewal application.
 - Pay the financial compensation.
 - The license is issued.
 - An inspection visit is conducted.

1- Create an account for the establishment in the electronic system (Ghad) and specify the required activity based on the commercial registration.

2- Submit a license application or renewal for the consulting office.

3- The Authority reviews the application, and, if there are no issues, issues the payment invoice.

4- Pay the financial compensation.

The Authority issues the license, which is valid for a period of 5 years.

6- The Authority conducts an inspection visit to the licensed establishment according to approved mechanisms.

2.2 Conditions



1-The owner shall be a Saudi national. If the owner is a foreign investor, they shall be licensed by the Saudi Arabian General Investment Authority (SAGIA).

2- If the establishment wishes to obtain a license for pharmaceutical consulting services, it shall comply with the conditions and requirements outlined in the Pharmaceutical Establishments and Preparations System issued by Royal Decree No. M/D, dated 22/08/1441 AH, as well as its executive regulations.

3- If the establishment wishes to obtain a license for food consulting services, it shall comply with the conditions and requirements outlined in the Food System issued by Royal Decree No. M/1, dated 06/01/1436 AH, as well as its executive regulations.

4- If the establishment wishes to obtain a license for veterinary pharmacovigilance consulting services, it shall comply with the requirements specified in the Guidance line on Pharmacovigilance for Veterinary Products published on the Authority's website. Additionally, the center shall provide evidence of its contract with the parent company of veterinary pharmaceuticals to carry out veterinary pharmacovigilance activities, either directly with the parent

company or with one of its registered factories in the Kingdom. In this case, the responsibility remains with the parent company in accordance with the Veterinary Pharmaceuticals System.

5- Attach the commercial registration and municipal license, provided that one of the activities listed below is included:

Type of establishment	Type of activity
Food Consulting	Activities of Food Consulting Services
Pharmaceutical Consulting	Pharmaceutical Consulting Centers
	Consulting Services in Bioequivalence and Bioavailability Studies
	Consulting Services in Providing Drug and Poison Information
	Pharmacovigilance Consulting Services
	Veterinary Pharmacovigilance Consultation Activities
Medical Devices and Products Consulting	Consulting Services in Regulating Medical Devices
	Consulting Services in Quality Assurance and Radiation Protection in the Field of Radiological Health
	Technical Consultation in Medical Equipment Maintenance
Cosmetic Consulting	Consulting Activities in Cosmetics
Feed Consulting	Consulting Activities in Feeds
Pesticide Consulting	Consulting Activities in Pesticides

6- The establishment's director shall be a full-time Saudi with at least a bachelor's degree.

7- A qualified Saudi technical supervisor shall be appointed for each activity. He should have at least a bachelor's degree. This should meet the following requirements:

Field		Additional requirements depending on the field
Food	Quality Assurance and Quality Management Systems	<ul style="list-style-type: none">• The technician shall hold at least a university degree in one of the specialties approved by the Authority.• He shall have practical experience in the same field for three years for bachelor's degree holders, two years for master's degree holders, or one year for Ph.D. holders.• One member of the technical staff shall have a certified quality systems certificate, such as Hazard Analysis Critical Control Point (HACCP), ISO 22000, or FSSC (Food Safety System Certification), from a recognized entity.
	Food Supply Chain Operations	<ul style="list-style-type: none">• The technician shall hold at least a university degree in one of the specialties approved by the Authority.• He shall have practical experience in the same field for three years for bachelor's degree holders, two years for master's degree holders, or one year for Ph.D. holders.
	Providing Food and Nutrition Studies and Research related to the Authority's work	<ul style="list-style-type: none">• The technician shall hold a valid professional registration and classification card from the Saudi Commission for Health Specialties as a clinical or remedial nutritionist.

Field		Additional requirements depending on the field
Drugs and cosmetics	Pharmaceutical Consulting Centers	<ul style="list-style-type: none"> One member of the technical staff shall hold at least a bachelor's degree in any field related to pharmaceutical and herbal products.
	Consulting Services in Bioequivalence and Bioavailability Studies	<ul style="list-style-type: none"> The responsible person shall have at least 3 years of experience in the same field. A training plan shall be provided to develop the skills of the staff in licensed areas.
	Consulting Services in Providing Drug and Poison Information	<ul style="list-style-type: none"> A copy of the professional registration card for the center's manager shall be provided. The pharmaceutical consulting center shall operate from an independent location if it includes the activity of conducting bioequivalence and bioavailability studies or a laboratory for analyzing pharmaceutical and herbal products.
	Consulting activities in the field of cosmetics	<ul style="list-style-type: none"> One member of the technical staff shall hold at least a bachelor's degree in any field related to cosmetics, along with providing relevant experience in the same field.
	Pharmacovigilance Consulting Services	<ul style="list-style-type: none"> The responsible person shall be a licensed pharmacist or a full-time medical doctor registered with the Saudi Commission for Health Specialties. He shall have a minimum of two years of experience in the same field or have completed a training program in the same field for Saudi nationals.
	Veterinary Pharmacovigilance Consultation Activities	<ul style="list-style-type: none"> The responsible person should be a full-time Saudi veterinarian or a full-time Saudi pharmacist registered with the Saudi Commission for Health Specialties and should have the ability to contact a qualified veterinarian. He shall have at least two years of experience in the same field or have completed a training program in the same field for Saudis.

Field		Additional requirements depending on the field
Medical devices	Consulting Services in Regulating Medical Devices	<ul style="list-style-type: none"> One of the technical staff members shall hold at least a bachelor's degree in any field related to medical devices.
	Consulting Services in Quality Assurance and Radiation Protection in the Field of Radiological Health	<p>The responsible person shall have a minimum of 3 years of experience in the same field.</p> <ul style="list-style-type: none"> A training plan shall be provided to develop the skills of the staff in licensed areas. A copy of the certificates from the Saudi Commission for Health Specialties for facility employees should be included.
	Technical Consultation in Medical Equipment Maintenance	<ul style="list-style-type: none"> Evidence of regular calibration and maintenance of devices from an accredited entity or laboratory shall be provided. A copy of the personal radiation dose records for practicing establishment employees shall be attached. If applicable, a copy of the license to handle radioactive materials should be included. A copy of the radiation protection officer's license shall be attached. A copy of the radiation protection and safety program, approved in both Arabic and English, shall be attached and certified by the establishment.

8- SFDA shall be provided with the organizational structure and a list of the technical and administrative staff, along with certified copies of their qualifications and training courses, as well as their job descriptions.

9- The establishment shall have a database for archiving all relevant data and documents to facilitate access and retrieval, with a retention period of no less than 5 years.

10- The establishment shall have a quality management system in place that outlines approved work procedures and the method for preserving technical reports for clients.

11- SFDA shall be provided with any other commercial activities of the establishment, in addition to updating this information whenever there is a change.

2.3 Required documents

Type of establishment	Type of activity
License Application Form	The form is submitted through the (GHAD) platform. When creating an account in the system, adding the activity of a consulting entity is required.
Commercial Registration	The commercial registration shall be valid.
Municipality License for the Establishment or Government Entity Licensing the Location	The license shall be valid.
Organizational Structure	Documented with a letter from the owner of the establishment confirming the accuracy of the data and pledging to inform the Authority in case of changes in the technical staff.
List of Technical and Administrative Staff	Including their qualifications and job descriptions. Documented with a letter from the owner of the establishment confirming the accuracy of the data and pledging to inform the Authority in case of changes in the technical staff.
Technical Staff Data	Including national ID, curriculum vitae, academic certificates, and work experience. Required for the owner, the establishment manager, and the staff involved.

2.4 Financial compensation



Payment of the financial compensation for the license is required, with an amount of 1000 Saudi Riyals for each consulting field.

2.5 Rights and commitments



2.5.1 Rights and commitments of the Authority

1- In the event of proven negligence, explicit violation, or breaches of the Authority's regulations and/or its technical and administrative requirements related to this Guidance, the Authority has the right to take appropriate actions when any provision of this Guidance is violated, including but not limited to:

1.1. Suspension or curtailment of licensing activities

1.2. Revocation of the license

In addition to the penalties stipulated in the Authority's regulations.

2- The Authority is entitled to access all documents related to consultations and the information available at the consulting establishment.

3- SFDA shall the verify the accuracy of the information provided by the consulting establishment.

4- SFDA shall not be responsible for any errors that may occur from the consulting establishment.

5- The Authority is committed to reviewing any complaints submitted by beneficiaries of consulting establishment services, conducting a thorough examination, and providing a technical opinion.

6- The Authority is committed to ensuring the confidentiality of information.

7- The Authority is committed to publishing a list of licensed consulting establishments on its website and any other suitable means.

8- The Authority exercises regular supervision on the consulting establishment to ensure its compliance with the regulations and requirements of the Authority. This includes inspection visits based on the mechanisms approved by the Authority.

9- SFDA shall have the right to assess consulting services establishments based on its approved mechanisms and to publish the assessment results for the public.

2.5.2 Rights and Commitments of The Consulting Establishment

1- The consulting establishment is committed to following up on all regulations, rules, Guidance, requirements, circulars, and instructions issued by the Authority regarding its licensed activity upon their issuance. Any amendments or additions to these should be followed on the Authority's website, and beneficiaries should be notified accordingly.

2- The consulting office has the right to object to the Authority's decision not to grant a license and provide justifications for this objection within 60 days from the date of being informed of the decision. The objection shall be made in accordance with the regulatory procedures in place for such matters.

3- The consulting establishment is committed to maintaining the confidentiality of information accessed by its employees or contracted individuals during the licensing period and after the license has expired. It shall not disclose any information related to the services it has provided.

4- The consulting establishment is committed to independence, neutrality, and integrity, ensuring there is no conflict of interest in the services it provides in the case of multiple activities within the establishment. It ensures the independence of the technical staff participating in consultations from any supply or distribution activities of products in the same field of consultation.

5- The consulting establishment is committed to having sufficient expertise and knowledge in the field of the Authority's work and its regulations.

6- The consulting establishment shall immediately notify the Authority if it is unable to continue meeting the licensing requirements and obligations.

7- The consulting services provided shall be approved by the technical staff and the responsible technical person in the consulting establishment.

8- The consulting establishment is committed to providing an adequate number of technical and scientific competencies in accordance with the Authority's standards.

9- The consulting establishment is committed to not using the name of the Authority for advertising or promotional purposes or placing it on products or facilities benefiting from the services of the consulting establishment.

10- The consulting establishment is committed to reporting to the Authority any cases of suspicion or irregular practices related to its activities.

11- The licensed consulting establishment has the right, during the validity period of its license, to expand its licensed activities after obtaining the necessary approvals.

12- The consulting establishment is also entitled to submit a license renewal application before the current license expires, with a period not exceeding (6) months prior to expiration.

13- The consulting establishment is committed to notifying the Authority of any updates or changes to its consulting activities that are covered by the valid license within a period not exceeding 30 days from the date of the update or change.

14- The consulting establishment is committed to ensuring that the technical staff receives training courses in the licensed activity.

15- The consulting establishment shall comply with the regulatory requirements of other government agencies (if applicable).

