

# A Guide for Licensing Consulting Services Establishments

## Guideline

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## Establishments licensing management

### Operations sector

Disclaimer: The English version is a translation of the original in Arabic for information purposes only. In case of a discrepancy, the Arabic original will prevail.

## Table of Content

<b>1</b>	<b>Introduction</b>	
1.1	Purpose of this guide	<b>3</b>
1.2	Applicability	<b>3</b>
1.3	Terms and definitions	<b>3</b>
<b>2</b>	<b>License</b>	<b>4</b>
2.1	Procedure for submitting a license or renewal application	<b>4</b>
2.2	Conditions	<b>4</b>
2.3	Required Documents	<b>7</b>
2.4	Financial Compensation	<b>8</b>
2.5	Rights and obligations	<b>8</b>

## 1. Introduction

### 1.1 Purpose of this guide

SFDA issued these requirements based on Article 9 of Chapter three of the "executive regulations of the General Authority for food and Medicine" issued by Royal Decree No. (m/6) dated 25/1/1428 A.H, which stated that " the Authority shall specify the requirements for the necessary licenses for food and pharmaceutical establishment, equipment installations, medical products, feed and pesticide plants, laboratories and everything related to SFDA field of work.

This guide aims to define the terms and requirements of the licensing of the consulting services establishments under the supervision of the food and Drug Authority. In addition to clarifying the rights of the obligations of the authority and the establishments covered in the guide and their legal responsibility.

### 1.2 Applicability

These terms and conditions apply to the consulting services establishments in Saudi Arabia and those who wish to engage in the activity of consulting services related to the activities controlled by SFDA in order to assist SFDA customers to apply SFDA terms and requirements, unless this guide contradicts one of the regulations.

### 1.3 Terms and Definition

**Kingdom:** Saudi Arabia

**Authority:** Saudi Food and Drug Authority (SFDA)

**License:** A process whereby the Authority grants permission to engage in consulting activity in the field specified in the license document commercially in the Kingdom market.

**Licensing area:** Scope of work specified in the license document provided by the consultant to the beneficiary to apply the terms and requirements of the Authority.

**Consulting Services Establishments:** Bodies licensed by the authority to provide general advisory services for activities and areas related to the Authority work.

## 2. License

### 2.1 Procedure for Submitting a License or Renewal Application



1. Create an account for the establishment in the electronic system (GHAD) and determine the required activity according to the commercial register.
2. Submit a license application or renew a consulting office.
3. The Authority audits the application and when there are no notes, the Authority issues the payment invoice.
4. Payment of the financial compensation.
5. The Authority shall issue the license and be valid for (5) years.
6. The authority shall conduct an inspection visit to the licensed establishment according to the approved mechanisms.

### 2.2 Conditions

1. The owner shall be Saudi. If the owner is a foreign investor, s/he shall be licensed by the General Investment Authority.
2. If the establishment wishes to license the pharmaceutical advisory services, it shall comply with the terms and requirements of the regulations on pharmaceutical establishments issued by Royal Decree No. m/d dated 22/8/1441A. H and its executive regulations of conditions and requirements.
3. If the establishment wishes to license food advisory services, it shall comply with the terms and requirements of the food regulations issued by Royal Decree No. (1/M) dated 6/1/1436 A.H and its executive regulations of conditions and requirements.

4. Attach the commercial register and the municipal license, which shall include one of the activities described below:

Establishment Types	Activity Types
Food consulting	Activities of food consulting services.
Drugs consulting centers	Drugs consulting centers.
	Consulting services in equivalence and bioavailability studies.
	Consulting services in providing information of drugs and toxins.
	Consulting services in the field of Pharmacovigilance.
Consulting for medical devices and products	Activities of consulting services in the field of medical devices organization.
	Activities for providing consulting services, quality assurance and radiation protection in the field of Radiological Health.
	Technical consulting in the field of devices maintenance
Consulting in cosmetology	Consulting activities in the field of Cosmetology
Consulting in the feed	Consulting activities in the feed field
Consulting in pesticides	Consulting activities in the pesticides field

5. The director of the establishment shall be a full-time Saudi, with a minimum bachelor's degree.

6. A qualified Saudi Technical Officer shall be appointed for each activity, with a minimum bachelor's degree, according to the following requirements.

Field		Additional requirements by field
Food	Quality assurance and management systems	<ul style="list-style-type: none"> <li>-The technician shall have a minimum university degree in one of the disciplines approved by SFDA.</li> <li>- Practical experience in the same field for three years for holders of a bachelor's degree, two years for holders of a master's degree, one year for holders of a doctoral degree.</li> <li>- A member of the technical staff who holds an accredited certificate in quality systems, such as: - Control system Critical Points (HACCP), (ISO 22000) or (22000 FSSC ...), etc., from a recognized authority.</li> </ul>
	Food chain processes	<ul style="list-style-type: none"> <li>-The technician shall have a minimum university degree in one of the disciplines approved by SFDA.</li> <li>- Practical experience in the same field for three years for holders of a bachelor's degree, two years for holders of a master's degree, one year for holders of a doctoral degree.</li> </ul>
	Provide food and nutrition studies/research related to SFDA work.	<ul style="list-style-type: none"> <li>- The technician shall have a professional registration and classification card from the Saudi Commission For Health Specialties as a dietician or therapeutic dietitian in effect.</li> </ul>
Feed and pesticides	Consulting activities in the field of feed or pesticides.	<ul style="list-style-type: none"> <li>- A member of the technical staff shall be a minimum bachelor's degree holder in any field related to pesticides, chemistry, or agriculture.</li> </ul>
	Drug Counselling Center	<ul style="list-style-type: none"> <li>-A member of the technical cadre shall be a minimum bachelor's degree holder in any field related to pharmaceutical and herbal preparations.</li> <li>- The responsible person shall have experience in the same field at least of 3 years.</li> <li>- A training plan shall be provided to develop the center's employees in licensed fields.</li> <li>- A copy of the professional registration card of the center manager.</li> <li>- The drug consulting center shall occupy an independent place, if that the center's activity includes equivalence, bioavailability, or laboratory analysis of pharmaceutical and herbal preparations.</li> </ul>

Drugs and cosmetics	Consulting services in equivalence and bioavailability studies.	
	Consulting services in providing information of drugs and toxins.	
	Consulting activities in the field of Cosmetology	A member of the technical staff shall have a minimum bachelor's degree in any field related to cosmetology and provide experience in the same field.
	Consulting services in the field of Pharmacovigilance.	-The person in charge shall be a full-time pharmacist or doctor and classified with the Saudi Authority For Health Specialties. - Having experience in the same field of at least two years or having a training program in the same field for Saudis.
Medical devices	Activities of consulting services in the field of medical devices organization.	A member of the technical cadre shall be a minimum bachelor's degree holder in any field related to medical devices.
	Activities for providing consulting services, quality assurance and radiation protection in the field of Radiological Health.	-The responsible person shall have at least 3 years of experience in the same field. - A training plan shall be provided to develop the center's employees in licensed fields. - A copy of the certificate of the Saudi Commission for Health Specialties for the employees of the establishment.
	Technical Consulting in the field of devices maintenance.	-Provide a proof of calibration and maintenance work for devices periodically from certified body or laboratory. - A copy of the record of personal radiation dose readings for the establishment employees. - If there is a practice license for radioactive materials, attach a copy of it.

		- Attach a copy of the Radiological Protection and safety program in both languages (Arabic and English) and approved by the establishment.
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7. Provide the Authority with the organizational structure, list of technical and administrative cadres. Besides certified copies of their filling, training courses and job description.

8. The establishment has a database to archive all relevant data and documents. Thus, it is easy to obtain and retrieve for not less than (5) years.

9. Provide a quality Law within the establishment that shows the approved work procedures, and the means to save technical reports to customers.

10. Provide the Authority with other commercial activities of the establishment and update them at each change.

### 2.3 Required Documents:

Documents	Notes
License application form	- The License application form is submitted via GHAD platform. - When opening an account in the system, it is required to add a consultancy office activity.
Commercial register	-The commercial register shall be valid.
Municipal license for the establishment / or government body licensed to the site.	-The license shall be valid.
Organizational Structure	Shall be certified by a letter from the owner of the establishment pledging to correct the data and inform the Authority if the technical staff is changed.
List of technical and administrative staff	-Include their qualifications and job description. - Shall be certified by a letter from the owner of the establishment pledging to correct the data and inform the Authority if the technical staff is changed.
Data of technical staff	- Includes: national identity, resume, certificates of academic qualification and work experience. -Requests for the owner, establishment manager, and related employees.



## 2.4 Financial Compensation

Paying the financial compensation for a license in the amount of (1000 Riyals) for each consulting field.

## 2.5 Rights and Obligations

### 2.5.1 SFDA Rights and Obligations

1. If a negligence, an explicit violation, or violation of the Authority's regulations and / or its technical and/or administrative requirements are proven herein, the Authority has the right to take appropriate measures when any of the provisions of this guide are violated, including but not limited to:
  - 1.1 Suspension or curtailment of licensing activity.
  - 1.2 License revocation.In addition to the penalties stipulated in the Authority's regulations,
2. The Authority has the right to review all the consultancy documents and information available at the consulting establishment.
3. The Authority has the right to verify the information provided by the consulting establishment.
4. The Authority is not responsible for any mistakes that may occur from the consulting establishment.
5. The Authority is obliged to consider and study any complaint submitted by the beneficiaries of the services of the consulting establishment beside reporting the technical opinion.
6. The Authority is obliged to ensure the confidentiality of information.
7. The Authority is obliged to publish the list of consulting establishments licensed by the Authority on its website or any means it deems appropriate.
8. The Authority periodically monitors the consulting establishment to ensure its compliance with SFDA regulations, conditions and requirements, which include inspection visits as per the approved mechanisms.
9. The Authority has the right to evaluate consulting services establishments based on the mechanisms approved by it beside publishing the evaluation results to the public.

## 2.5.2 Consulting Establishment Rights and Obligations

1. The consulting establishment is obligated to follow up all the regulations, guidelines, requirements, conditions, circulars, and instructions related to its licensing activity, as soon as it issued by the Authority, and any amendments or additions made on SFDA website and notify the beneficiaries thereof.
2. The consulting office has the right to object to the Authority's decision not to license and to provide the justifications for that within (60) days from the date of knowledge of the legal procedures followed for that.
3. The consulting establishment has the right to seek the assistance of collaborators from faculty members in universities, specialized colleges and employees of health institutions. As well as foreign experts, according to the regulations in force in Saudi Arabia. Considering the approval of their reference on this and provided the Authority with a resume to obtain the approval.
4. Full commitment to cooperate and facilitate the work of SFDA officials during inspection visits. In addition to implementation of SFDA recommendations after the inspection visits.
5. The consulting establishment is obligated to maintain the confidentiality of the information that the establishment, its employees or who have been contracted with accesses to. And that is during the period of its license and after the expiry of the license. Besides, any information related to the services you have provided shall not be disclosed.
6. The consulting establishment is committed to independence, impartiality, integrity and to ensure that there is no conflict of interest in the services provided if there is more than one activity with the establishment. Beside ensuring the independence of the technical personnel participating in the consultations on any activity supplying or distributing products in the same field of consulting.
7. The consulting establishment shall have sufficient experience and knowledge in the field of SFDA work and regulations.
8. Inform the Authority immediately if the consulting establishment is unable to continue achieving the requirements and conditions of the license.
9. Commitment that the consulting services provided are approved by the technical staff and the technical officer in the consulting establishment.
10. The obligation to provide enough technical and scientific competencies in accordance with SFDA standards.
11. The obligation to not use the Authority name or any logos for the purposes of advertising and place them on products/establishments that benefit from the consulting establishment services.

12. The obligation to inform the Authority of related suspicious cases or illegal practices.
13. The licensed consulting establishment has the right, during the validity period of the license, to increase the licensing activity after obtaining the necessary approvals.
14. An establishment has the right to submit a renewal application for a license for no more than six months before the expiry of the valid license.
15. The obligation to notify the Authority of any update or change that occurs to the valid consulting establishment's activities for not exceeding (30) days from the date of the update or change.
16. The obligation to obtaining training courses for the technical staff in the licensed activity.
17. The obligation to fulfil the statutory requirements of other government agencies (when applicable).