الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Steps to Issue a Good Manufacturing Practice (GMP) Certificate for Blood Establishments / Banks

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Steps to Issue a Good Manufacturing Practice (GMP) Certificate for Blood Establishments / Banks

Drug Sector
Saudi Food and Drug Authority

For more information, please visit the website

www.sfda.gov.sa

For inquiries

Blood.inspection@sfda.gov.sa

For comments

Drug.Comments@sfda.gov.sa

Drug Sector
Vision and Mission

Vision

To be the leading regional Drug Regulatory Authority for pharmaceuticals and cosmetic products, with professional excellence and services that contribute to the protection and advancement of public health in the Kingdom of Saudi Arabia.

Mission

Protecting public health by ensuring safety, quality, efficacy and accessibility of human, veterinary drugs and biological products, and safety of cosmetics, through administration of a national regulatory system that is consistent with international best practice. Through our mission, we also provide accurate and scientific-based information to the public and healthcare professionals.

Documentation:

Version	Publisher	Date	Comments
1	Executive Department for Inspection and Enforcement of Regulations	12th September 2018	-

❖ **Terms:**

1. The site must be appropriate and compatible with the requirements of the relevant governmental entities.
2. A commercial register must be present.
3. The technical director has a license to practice the profession from the Saudi Commission for Health Specialties.
4. Adherence to the Good Manufacturing Principles (GMP) for blood banks published on the SFDA website.

❖ **Documents:**

1. A copy of the commercial register.
2. Copies of the establishment's license.
3. Copies of the license to practice the profession from the Saudi Commission for Health Specialties for the technical director.
4. A copy of the national ID of the person responsible for following up the application at the Authority.
5. A copy of the legitimate power of attorney or an authorization certified by the Chamber of Commerce for the person responsible for following up the application at the authority.
6. Attach a copy of the reference SADAD number to pay the fees for issuing the GMP certificate, (establishment's licensing department) with a value of five hundred (500) riyals in the SADAD system (Saudi Food and Drug Authority invoice number (109))

❖ Application Process:

1. Fill out the application form to obtain the GMP certificate to license blood bank.
2. Submit the form with the commitment to the Saudi Food and Drug Authority after completing the data and signing.
3. Submit the required documents mentioned above.

❖ Notes:

1. The application for GMP certification must be submitted 6 months before the license expires.
2. The Blood Bank must use the GMP Certification Application form from the SFDA official website, accompanied by the other required documents.
3. For further information, please contact via email at: Blood.inspection@sfda.gov.sa

❖ Templates:

An electronic copy is available on the forms page.

Request Type \

☐ New License	☐ Update	☐ Renew
License No.		
Expiry date of Licensing		

Blood Bank Information \

Blood Bank Name		
Classification		
Province		
City		
Area/ District		
Street		
Coordinates (GPS)	North	
	East	

Contact Information \

Phone	
Fax	
Email	
Mailing Address	

Blood Bank Director Information \

Mobile	
Educational Qualifications	
Nationality	
Email	

Owner Information \

□ Individual Establishment	□ Company
Name	
Commercial Record No.	

Delegated Person to Follow Up \

Name	
ID Number	
Expiry Date	
Mobile	

❖ **Commitment:**

An electronic copy is available on the forms page.

Owner Commitment

1. This form has been filled by my knowledge with complete and correct information. Also, all attached documents are stamped by company's stamp and considered as an official copy. I take the extreme responsibility for any forgery or incorrect information on these documents.
2. I promise to update any changes in the current information.
3. I have read all terms and conditions of the Private Health Institutions system and I promise to follow all its content and any regulations followed. In addition, I promise to follow any regulation issued by SFDA in future.

- Signature:

- Name:

- Date:

- Blood Bank Stamp: