International Manufacturing Site Registration Procedure

National Health Regulatory Authority (NHRA)

Kingdom of Bahrain

July 2019

Version 1.0

1. Introduction

This document is meant to provide assistance to industry and professionals on how to comply with governing statutes and regulations. The document also provide assistance to staff on how NHRA mandates and objectives should be implemented in a manner that is fair, consistent and effective.

Manufacturing site registration is mandatory with NHRA prior to submission of application for new product registration or variation application pertaining to relevant site transfer.

It should be noted that the NHRA has the right to request any information and data within the context of this procedure.

This document should be read in conjunction with other applicable guideline documents.

2. General notes:

The objective of this document is to define the procedure for registration of international manufacturing site.

Listed below are few of the instruction vital for registration process:

1. It is the responsibility of the applicant to ensure that all of the information given in the approval checklist and supporting documents are true and valid.
2. Applicant must ensure that the submitted application form is signed and stamped.
3. Applicant in the application form refers to the marketing authorization holder (company).
4. Application should clearly indicate activity at the site (bulk manufacturing, batch release).
5. Bulk manufacturer in addition to batch releaser of sterile formulation should be registered with NHRA prior to submission of application for sterile product registration.
6. Batch releaser, technical release site should be registered with NHRA prior to submission of application for product registration or variation application pertain to relevant site transfer
7. Respond to NHRA queries or requests for more data for review, with in the timelines to avoid closure/rejection of the application.

Failure to comply with the above shall render the issued license cancelled.

3. Submission & Documentation

In order to submit new application, the applicant must request an appointment to the concerned staff in PPR department by email. Appointments are assigned on a first-come basis.

On the appointment day NHRA staff will check the file to make sure all the requested documents are available only valid applications will be accepted.

4. Assessment and Queries

Each application is assessed in accordance with relevant International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) quality guidelines. In cases where queries arise, a request for further information will be sent to the applicant. The applicant is requested to respond to such requests in a timely manner and in accordance with any decided timeline.

NHRA will not be held responsible for the delay of registration process, if the applicant fails to respond to NHRA request in a timely manner.

Failure to respond to NHRA request for information will result in rejection of the application.

5. Licensing

The license is valid for 5 years.

NHRA reserves the right to cancel or withdraw the license, if found non- compliant during its lifecycle after registration.

Registration of the manufacturing site with NHRA, do not circumvent the need for finished product registration. As per the Bahrain Pharmacy law 18 of 1997, pharmaceutical product must be registered with NHRA prior to its export, sale and distribution in Kingdom of Bahrain.

6. Renewal

The renewal procedure will follow the same registration procedure, however the documents required are highlighted in the manufacturing site check list annex1.

Applicant must ensure to submit a list of relevant variation submitted in last 5 years. If not applicable, a declaration letter for the same must be submitted.

7. Application fees

As per resolution 17 of 2016, application fees and service fees is chargeable for each application submitted to NHRA. The applicant must refer to the latest fee structure from NHRA website

Annex I

International Manufacturing Site Registration/Renewal Check List

Agent name:		
Manufacturing site name:		
Type of application:	Registration ☐	Re-registration ☐

1	Covering letter from the local agent in Bahrain signed.	☐
2	Letter from the company indicating the name and address of the manufacturing site and clarifying the relation between them (***Company letter head, signed & stamped***).	☐
3	Manufacturing site registration/renewal form signed and stamped.	☐
4	Company profile (***SMF or other document to inform us about the company activities and responsibilities.***)[#]	☐
5	Copy of legalized contract between the company and the local agent (***pharmacy***)[#] including product list.	☐
6	Contact details for responsible persons at the company[#]	☐
7	Appointment Letter of the agent from the Company. [#]	☐
8	Copy of signed and stamped Certificate of registration of the company from the Ministry of Industry & Commerce.[#] (hard copy)	☐
9	Letter from the company declaring the name of medicine (s) released from this site (***Registered or to be submitted for registration***).	☐
10	Letter from the company declaring the activities performed at the site including batch release or bulk manufacturing.	☐
11	Copy of variations done since last 5 years relevant to the site's name and address only. (Applicable to renewal only), if no variation has been submitted a declaration must be submitted.	☐
12	Copy of Bahrain registration license (applicable for renewal only)	☐
13	Copy of valid GCC Central or SFDA manufacturing site registration certificate. (***If the applicant cannot comply with this requirement then valid GMP certificate is required from one competent authorities*)***	☐
14	GMP certificate from health authority in the country of origin. (hard copy) (***if the country of origin is not one of the competent authority listed below the GMP must be legalized***)	☐
15	Copy of valid Manufacturing License	☐
16	Proof of payment of the application fee (not refundable in case of rejection) [#]	☐
17	All documents to be submitted on CD	☐

*** Competent authorities (EMA, UK MHRA,USFDA, Health Canada, TGA, New Zealand Medsafe, Swiss medic, Japanese Ministry of Health)**
 # required for registration of a new entity.

For Internal Use Only:

I declare that I have received the documents and materials confirmed in the above Checklist

Name :
Signature :_____ **Date :**
Comments :