

External User Guide

Renewal of the Certificate of Compliance with Good Manufacturing Practices

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1. Brief Overview

This manual is prepared to help applicants Apply for granting a GMP Issuance.

After completing this manual, the applicant should be able to perform all activities related to GMP Issuance on EDE Portal.

Please note: This service is only available to the **Local Manufacturers** Applicants.

2. Apply for Service

Portal users who have logged in successfully to EDE portal will be directed to Dashboard screen where they can apply to EDE's e-services.

For applicants to apply to their available services, they must go through the following process:

1. Create a new application
2. Complete application
3. Review application

The sections below will help user through the step-by-step process of applying to an application.

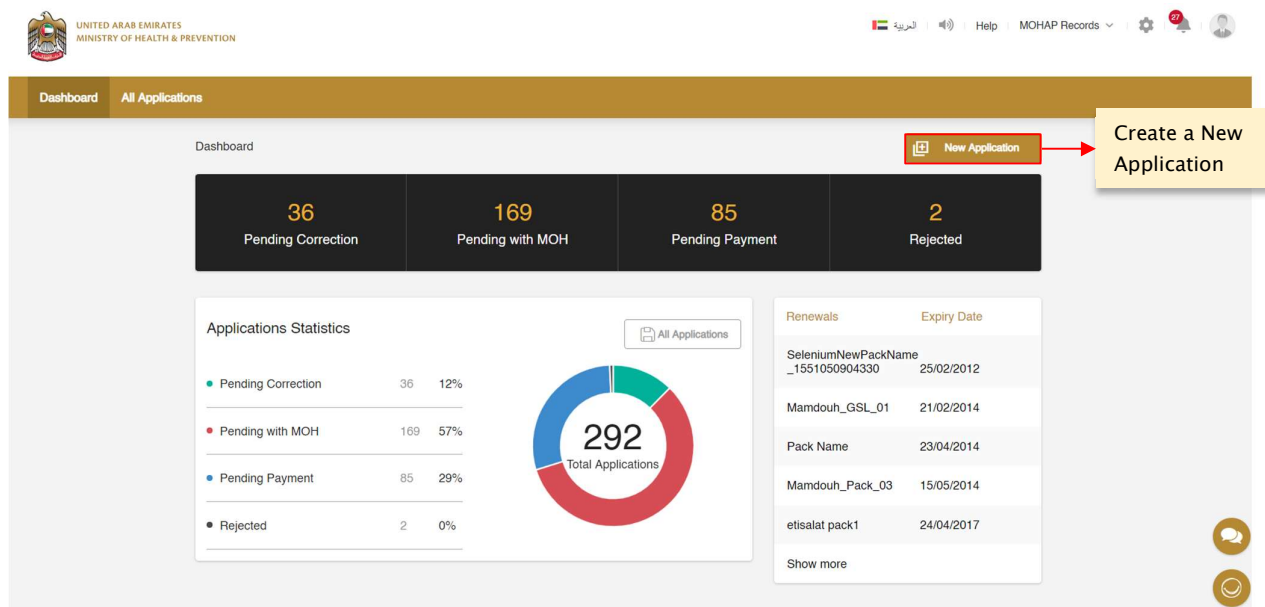


FIGURE A: DASHBOARD SCREEN

2.1 Create a New Application

To create a new application from the Applicant Portal, the user must do the following:

- Click on the **New Application**
- Select **Local Medical Factory** ⇒ **Registration** ⇒ **GMP Issuance**.
- Click Create Application button

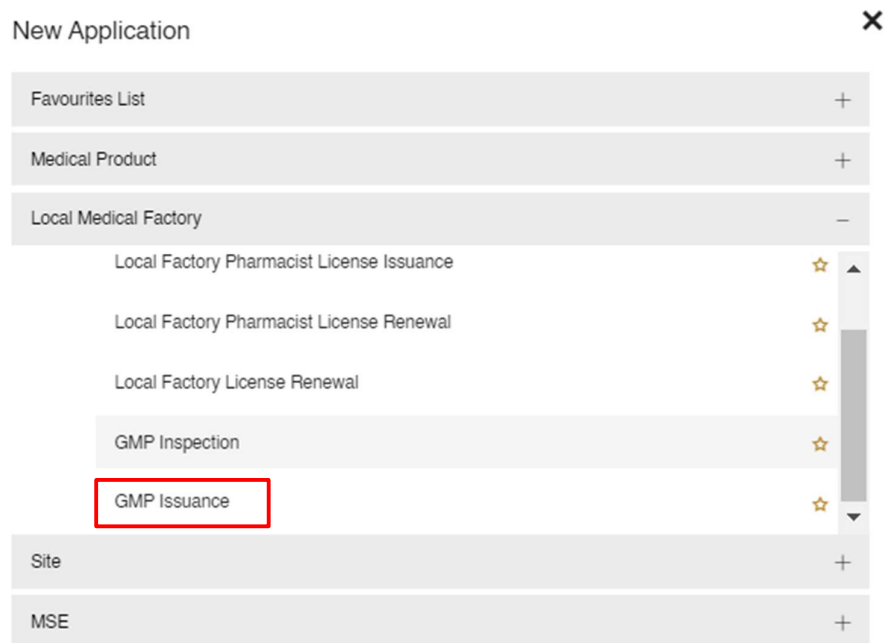


FIGURE B: NEW APPLICATION SCREEN

To complete a GMP Inspection application, the applicant must fill the following sections:

- Search by GMP Inspection Application Number
- Attachments.



FIGURE C: PROGRESS BAR

2.1.1 Search by GMP Inspection Application Number

Applicants should search by the by GMP Inspection Application Number.

0% Completed

1 Factory 2 Production Line 3 MOHAP Documents 4 Attachments

GMP Inspection Application Number (Optional)

GMPINS-2022-000034

FIGURE D: SEARCH GMP INSPECTION SCREEN

The below Local Factory details will be auto-populated:

- Inspection Reason
- Issue Date
- Expiry Date
- Factory Name(English)
- Factory Name(Arabic)
- Emirate
- City(English)
- City(Arabic)
- Address / Location(English)
- Address / Location(Arabic)
- Building/Location Owned By
- P.O.Box (Optional)
- Telephone (Optional)
- Fax (Optional)
- Website (Optional)
- Remarks (Optional)

Inspection Reason

Reason 1

Factory License Number (Optional)

Issue Date (Optional) ExpiryDate (Optional)

Factory Name(English) (Optional)

TEST_PAY_27

Factory Name(Arabic) (Optional)

TEST_PAY_27

Emirate

Dubai

City(English) (Optional)

Dubai

City(Arabic) (Optional)

Dubai

Address / Location(English) (Optional)

Dubai

Address / Location(Arabic) (Optional)

Dubai

Building/Location Owned By (Optional)

Dubai

P.O.Box (Optional) Telephone (Optional)

01234567890

Fax (Optional) Website (Optional)

Remarks (Optional) (🗨️)

REMARKS

Production Lines >

FIGURE E: FACTORY DETAILS SCREEN

2.1.2 Production Line

The Approved Production Lines will be auto-populated:

33% Completed

1 Factory 2 Production Line 3 MOHAP Documents 4 Attachments

1 Production Line

Production Category (Optional)

Manufacturing Activities

Activity
☞ Quality

Activities Lines

Line	Sub Line
☞ Steril Products	Capsule
☞ Steril Products	Powder

Discard < Factory Details Documents >

FIGURE F: PRODUCTION LINE SCREEN

Applicants can move to the next section by clicking Documents button.

2.1.3 EDE Documents

It is not required from the applicant to take any action on this screen, EDE Documents will be uploaded by EDE officers.

67% Completed

1 Factory 2 Production Line 3 MOHAP Documents 4 Attachments

MOHAP Documents

Table has no records.

Discard < Production Lines Attachments >

FIGURE G: EDE DOCUMENTS SCREEN

Applicants can move to the next section by clicking Attachments button.

2.1.4 Attachments Screen

Below are the attachments the applicant must submit before moving to the next section.

- Site Master File (Optional)
- List Of Production Lines & Manufactured Products (Optional)
- QC & QA Organogram (Optional)
- Production Manager Appointment Letter
- List Of The Factory Equipment (Optional)

FIGURE H: ATTACHMENTS SCREEN

2.1.5 Review Application

Review Application After the applicant completes filling all application details, they must click on the Review button to proceed with application submission. Once the applicant clicks the Review button, they will be redirected to Review screen where they are able to perform the following actions:

- Edit Application
- Discard Application
- Read & Accept General Terms & Conditions
- Submit Application

The screenshot shows a web interface for reviewing an application. At the top, there is a breadcrumb trail 'All applications / GMP Inspection' and two buttons: 'Required Documents' and 'Help'. Below this is a 'Review' section with a '< Back' button. A message states: 'Please take a moment to check that everything is correct. You can edit anything that's not right.' There are four expandable sections: 'Factory Details', 'Production Line', 'MOHAP Documents', and 'Attachments', each with a right-pointing arrow and an edit icon. Below these sections is a checkbox labeled 'I Accept The General Terms And Conditions' which is checked. At the bottom, there are two buttons: 'Discard' and 'Submit'.

FIGURE H: REVIEW APPLICATION SCREEN

2.2 Checkout

After an application has been submitted, EDE officer will be able to review the application and return it back for payment:

- Application Fees: AED 2000 per Application