APPLICATION FORM FOR GOOD MANUFACTURING PRACTICES (GMP) VARIATION

TO BE SUBMITTED AS ELECTRONIC COPIES

CONFIDENTIAL

Variation to a Registered Finished Medicinal Product Facility Application form

Please complete each section of this application form electronically as a Word Document and as a scanned signed Pdf file. Ensure that the electronic and the printed versions of the completed form accompany your submission. Consult the Guideline on Licensing of Drug Manufacturing Facilities (FDA/MFD/GDL-02/03) for variation types and supporting documents to be submitted

1.0 Administrative Information

1.1 Application Name and address:

1.2 Location Address

1.3 Dosage forms manufactured on site

1.4 Licence/Certificate Number for site

1.5 Variation type: (tick all applicable options)

- ☐ Minor variation – notification
- ☐ Minor variation – prior approval
- ☐ Major variation

1.6 Variation Description:

1.7 Reason for variation:

1.8 Associated Finished Pharmaceutical Product (FPP) Name (if applicable)

2.0 Variation Details

2.1 Variation Description

☐ Single variation ☐ Grouped variations

2.2 Summary of proposed changes:

Current details	Proposed details

2.3 Reason for change:

2.4 Date of implementation (for Notifications only)

2.5 Impact on product quality, safety and efficacy:

2.6 Relevant documentation (protocols, reports etc.):

The following documents have been submitted together with this application form:

Note: All documents must be provided for this application to be valid.	
Supporting documentation *All supporting documents as stipulated for the change in the should be included in this submission*	☐ *Yes*

(For multiple variations (grouped variations), reproduce this section 2 and provide separate summaries for each proposed variation.)

3.0 Declaration

Please check all declarations that apply.

I declare that:

☐ For each change, all conditions *for* the change requested are fulfilled.

☐ There are no changes being made other than those applied for in this submission, except for possible editorial changes. Any other changes will be applied for separately.

☐ The information submitted is true and correct.

Name: _____

Signature: _____ Date:_____