Variation to a Prequalified Finished Pharmaceutical Product (FPP): Major, Minor or Immediate Notification

Please complete each section of this application form electronically as a Word document and as a scanned signed PDF file. Please ensure that the electronic and the printed versions of the completed form accompany your submission.

# Application details

## Variation type: (tick all applicable options)

[ ]  Immediate notification (IN) [ ]  Minor variation (Vmin) [ ]  Major variation (Vmaj)

## Grouping of variations

[ ]  Single variation [ ]  Grouped variations

## Associated finished pharmaceutical product (FPP) name /PQ ref. number(s):

*e.g. Isoniazid Tablets 100mg – TB 173*

## Applicant details

Please note that the contact listed in the table below will be the primary contact for communication for this specific application.

|  |  |
| --- | --- |
| Applicant |  |
|  |  |
| **Primary contact person responsible for this application** | Title:First name:Family name: |
| **Contact person's position** |  |
| **Contact person's postal address** |
| **Unit** |  |
| **Building/PO Box Number** |  |
| **Road/Street** |  |
| **Plant/Zone** |  |
| **Village/Suburb** |  |
| **Town/City** |  |
| **District/Mandal** |  |
| **Province/State** |  |
| **Postal code** |  |
| **Country** |  |
| **Contact person's email address** |  |
| **Contact person's phone number** |  |

If there are other contacts who should be routinely copied into correspondence for this application they should also be listed below.

|  |  |
| --- | --- |
| Additional contact person  | Title:First name:Family name: |
| **Contact person's position** |  |
| **Contact person's postal address** |
| **Unit** |  |
| **Building/PO Box Number** |  |
| **Road/Street** |  |
| **Plant/Zone** |  |
| **Village/Suburb** |  |
| **Town/City** |  |
| **District/Mandal** |  |
| **Province/State** |  |
| **Postal code** |  |
| **Country** |  |
| **Contact person's email address** |  |
| **Contact person's phone number** |  |

|  |  |
| --- | --- |
| Additional contact person  | Title:First name:Family name: |
| **Contact person's position** |  |
| **Contact person's postal address** |
| **Unit** |  |
| **Building/PO Box Number** |  |
| **Road/Street** |  |
| **Plant/Zone** |  |
| **Village/Suburb** |  |
| **Town/City** |  |
| **District/Mandal** |  |
| **Province/State** |  |
| **Postal code** |  |
| **Country** |  |
| **Contact person's email address** |  |
| **Contact person's phone number** |  |

# Summary of proposed changes

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

## Variation title and number:

*e.g. Minor variation # 30a:*

*Change in batch size of the finished product — up to and including a factor of ten (10) compared to the biobatch*

## Summary of current and proposed details:

|  |  |
| --- | --- |
| Current details | Proposed details |
|  |  |

## Reason for change:

## Date of implementation (for Immediate Notifications only):

## If relevant to the variation, list the supporting active pharmaceutical ingredient master file (APIMF) number:

# Documentation checklist

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

|  |  |
| --- | --- |
| Note: All documents must be provided for this application to be valid. |  |
| Quality Information Summary (QIS) *For FPPs that have an agreed upon QIS, the QIS should be revised and submitted with any revised sections highlighted. A QIS should be completed in its entirety (irrespective of the proposed change). It should include information on all strengths, with any changes highlighted (e.g. in red type).* | *[ ]  Yes**[ ]  No agreed QIS**[ ]  No change to QIS* |
| Supporting documentation*All supporting documents as stipulated for the change in the* [Guidelines on variations to a prequalified product](http://www.who.int/medicines/areas/quality_safety/quality_assurance/Annex3TRS-981.pdf?ua=1) *are included in this submission* | *[ ]  Yes* |

# Declaration

*Please check all declarations that apply.*

I declare that:

[ ]  For each change all conditions as stipulated in the *Guidance on Variations to a Prequalified Product* 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:\_\_\_\_\_\_\_\_\_\_\_\_\_