Manufacturing summary sheet

This form should be completed for each new site master file (SMF) revision submitted. Revised versions of the SMF should be submitted in PDF format with the changes tracked.

Applicant details

|  |  |
| --- | --- |
| 1. Name and address of authorisation/licence holder, including Eircode
 |       |
| 1. Companies registration office number
 |       |
| 1. EMA LOC-ID for manufacturing site
 |       |
| 1. Licence/authorisation number
 |       |
| 1. Current site master file revision number
 |       |
| 1. Copy provided to the HPRA
 | [ ]  Yes [ ]  No |
| 1. Any other relevant information
 |       |

Manufacturer’s licence/authorisation details

Please indicate if each of the following parts of your manufacturer’s licence/authorisation are currently up to date:

|  |  |
| --- | --- |
| 1. Address of authorisation holder
 | [ ]  Yes[ ]  No If ‘no’, please give brief details:       |
| 1. Address of manufacturing site(s)
 | [ ]  Yes[ ]  No If ‘no’, please give brief details:       |
| 1. Manufacturing operations (see Annex 1) to this document.)
 | [ ]  Yes[ ]  No If ‘no’, please give brief details:       |
| 1. Product categories (see Annex 1)
 | [ ]  Yes[ ]  No If ‘no’, please give brief details:       |
| 1. List of imported products (see Annex 1)
 | [ ]  Yes[ ]  No If ‘no’, please give brief details:       |
| 1. Contract manufacturers/storage sites
 | [ ]  Yes[ ]  No If ‘no’, please give brief details:       |
| 1. Contract laboratories
 | [ ]  Yes[ ]  No If ‘no’, please give brief details:       |
| 1. Named personnel
 | [ ]  Yes[ ]  No If ‘no’, please give brief details:       |

Qualified Person details

|  |  |
| --- | --- |
| 1. Name
 |       |
| 1. Telephone number
 |       |
| 1. Email
 |       |

Number of Personnel working at the Authorised Site

1. Please confirm the size of your site for the total number of personnel for Production, Quality Control/Assurance and Engineering departments only.

If additional space is required, please complete on a separate sheet.

|  |  |
| --- | --- |
| Department | No. of personnel |
| [ ]  Small site (Less than 50 employees |       |
| [ ]  Medium Site (50-149) |       |
| [ ]  Large site (150-250) |       |
| [ ]  Major site (more than 250) |       |
| [ ]  Homeopathic manufacturing |       |

Annex 1

Please include a full list of product names and dosage form for the following activities.

|  |  |  |
| --- | --- | --- |
|  | PRODUCT NAME(S) | DOSAGE FORM |
| 1. Bulk manufactured on site
 |       |       |
| 1. Primary packaged on site
 |       |       |
| 1. Secondary packaged on site
 |       |       |
| 1. QC tested on site
 |       |       |
| 1. Batch released to market
 |       |       |
| 1. Site of importation only
 |       |       |

declaration

I hereby declare that, to the best of my knowledge and belief, all the particulars given in this site master file reflect the facilities, operations and organisational structures at the site.

Signature (primary QP):

Print name:

Title/position:

Date:

*Notes:*

Applications must bear the signature of the applicant. Where the application is on behalf of a limited company, the declaration must be signed by a director or the secretary and, in the case of a partnership, by a partner.

return address

Send to:

Licensing Section

Compliance Department

Health Products Regulatory Authority

Kevin O’Malley House

Earlsfort Centre

Earlsfort Terrace

Dublin 2

Tel: + 353 1 676 4971

Email: compliance@hpra.ie