

# Application for Active Pharmaceutical Ingredient Master File (APIMF) eCTD Baseline Amendment

Please complete each section of this application form and provide as a signed text selectable Pdf file.

## 1. APPLICATION DETAILS

<b>Applicant Organisation Name</b>	
<b>Applicant Organisation's ePQS Account UID<sup>1</sup></b>	<i>If the Account does not yet exist in ePQS, please complete the New Account form appended it to this application form. Repeat as necessary.</i>
<b>Applicant Contact's Name</b>	
<b>Applicant Contact's ePQS Contact UID<sup>1</sup></b>	<i>If this Contact does not yet exist in ePQS please complete the New Contact form appended it to this application form. Repeat as necessary.</i>
<b>Application Subtype</b>	eCTD Baseline
<b>WHO APIMF Number(s)</b>	
<b>API name (INN)</b>	
<b>APIMF Version number</b>	

## 2. AMENDMENT CHANGE TYPE: 1C (AMIN)

### 2.1 Conditions and documents

The APIMF is already accepted by PQT and there are no on-going applications associated with this APIMF. No changes are made, whether editorial or otherwise, to the details of the currently accepted APIMF.

YES

**3. DECLARATION (PLEASE CHECK ALL DECLARATIONS THAT APPLY)**

I declare that:

- The submitted APIMF is compiled in compliance with WHO PQT's eCTD documentation requirements.
- There are no changes to accepted APIMF information.
- There are no changes to the currently agreed upon API-QIS.
- The information submitted is true and correct.
- I understand that if unauthorized changes have been submitted this may result in suspension of the APIMF.

Name: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**4. APPLICATION CHECKLIST**

***To ensure a complete application, please use this checklist to verify that all required information has been prepared for submission.***

Item	Submitted (Yes / Not applicable)
1. A cover letter	
2. A signed APIMF application form (PDF)	
3. The APIMF correctly formatted	
4. A copy of the API-QIS	

Please file this application via the ePQS Portal (<https://who.my.site.com/ePQS/s/login>).

Further information regarding the portal and its use can be located on the PQT website at this address:  
<https://extranet.who.int/prequal/epqs/epqs-portal>.

REPEAT AS NECESSARY

**New Account record**

Account Information	Format
Organisation's Legal Name	
Organisation description	
Email	
Phone	
Primary Contact	First Name, Last name, email address
<b>Physical Location</b>	
Address (Unit, Street No., Industrial Zone, Building)	
City	
Province/State	
Zip/Postal Code	
Country	
Latitude (Decimal) to a precision of 1/10 <sup>th</sup> of a second	If available
Longitude (Decimal) to a precision of 1/10 <sup>th</sup> of a second	If available
DUNS#	If applicable
EMA (IRIS) ORG-ID <sup>1</sup>	If applicable
EMA (IRIS) LOC-ID <sup>1</sup>	If applicable
<b>Mailing Address</b>	
Same as above? (if no, complete following fields)	Yes / No
Address (Unit, Street No., Industrial Zone, Building)	
City	
Province/State	
Zip/Postal Code	
Country	
Organization type	
<b>Other information</b>	
Area of interest	<i>e.g. IVD Lab testing, Medicine Prequalification, Inspections etc</i>
Is the proposed Account part of a hierarchy of accounts already in ePQS	Yes / No
Is there a superior Account record in the hierarchy this Account should be linked to?	Yes / No
Parent Account Name	
Parent Account, Organization UID	<i>Please include the Organization UID, if this is known.<sup>2</sup></i>

<sup>1</sup> see <https://iris.ema.europa.eu/locations/>

**New Contact record**

<b>Contact Details</b>	
<b>Salutation</b>	<i>Mr, Miss, Ms, Mrs, Dr, Prof.</i>
<b>First Name</b>	
<b>Family Name</b>	
<b>Full Name</b>	
<b>Job Title</b>	
<b>Phone</b>	
<b>Mobile</b>	
<b>Email</b>	
<b>Fax</b>	
<b>Mail Address</b>	
<b>Address (Unit, Street No., Industrial Zone, Building)</b>	
<b>City</b>	
<b>Province/State</b>	
<b>Zip/Postal Code</b>	
<b>Country</b>	
<b>Job Function</b>	
<b>PQT Area of interest</b>	<i>What aspect of ePQS will you be involved in e.g. IVD Lab testing, Medicine Prequalification, Inspections etc</i>