# **Application Form**

# **ICMRA Pilot Program for Collaborative Hybrid Inspection**

This application form must be completed by an official contact person for the applicant for the regulatory submission submitted to at least one of the relevant jurisdictions as well as a contact person at the facility responsible for any inspection.

Ideally the submission of proposal for inspection should precede the regulatory submission by between 1 – 3 months to ensure co-ordination and alignment of inspection and assessment.

**Part 1. Applicant, Product and Application Details**

|  |  |
| --- | --- |
| Organisation or company name |  |
| Contact name |  |
| Function/Title |  |
| Contact email |  |
| Short title of the operations proposed in the regulatory submission (e.g., drug substance manufacturing, drug product manufacturing, post-approval change management protocol (PACMP), site transfer, or scale up, 20 words maximum) |  |
| Drug substance name |  |
| Drug product name |  |
| INN/USAN/Other product trade name |  |
| Product type | Chemical/small molecule  Biological molecule  Other - please specify: |
| Route of Administration |  |
| Dosage form |  |
| Therapeutic indication |  |
| Does the product have orphan drug designation? | Yes  No |
| Has the product been granted a designated status for early access patient treatment (e.g., Breakthrough, PRIME, Sakigake, Priority Review, or Fast Track Authorisation)? | Yes  No  If yes, please provide details: |
| Intended submission date if accepted into the pilot |  |
| Regions or countries where it is planned to file the regulatory submission and their associated application or dossier numbers |  |
| Description of the regulatory submission, including explanation of why assessment of the regulatory submission will benefit from the collaborative inspection under this pilot. |  |
| Does the regulatory submission involve a new facility site, suite, or area that was not previously inspected by the relevant jurisdictions? | Yes  No  If yes, please provide further details: |
| Do you anticipate any restrictions on sharing data or information among the regulatory authorities participating in the pilot? | Yes  No  If yes, please provide further details: |
| Do you anticipate any restrictions on publicly sharing high-level regulatory assessment outcomes of the pilot? | Yes  No  If yes, please provide further details: |

**Part 2. Facility Details**

**The following information should be completed for each facility that you are requesting to be considered for the ICMRA Collaborative Hybrid Inspection Pilot.**

|  |  |
| --- | --- |
| Organisation or company name |  |
| Address:  Street:  City:  Province:  Region:  Postal code:  Country: |  |
| Identify Relevant Areas (Buildings/Suites/Laboratories, etc.) that are under consideration for this Collaborative Hybrid Inspection. |  |
| Name of Manufacturer Point of Contact for the Inspection:  Job title:  Telephone number:  Email: |  |
| Description of Manufacturing/testing activities carried out at the facility relevant to the regulatory submission proposed for inclusion in the pilot. Please indicate which activities apply. | Manufacture of active substance  Manufacture of aseptically prepared dosage forms  Manufacture of terminally sterilised products  Manufacture of Non-Sterile Products  Manufacture of Biological Products  Primary Packaging  Secondary Packaging  Quality Control Testing  Other (specify) |
| Once the application or marketing authorisation is submitted to the relevant authorities, an inspection may take place at any time during the procedure and this inspection may be unannounced. It is for this reason that it is the responsibility of the applicant and the manufacturer to ensure that the facility is compliant with GMP and that the facility is ready for an inspection at the time of submission.  A lack of compliance and inspection preparation and readiness may lead to delays in the inspection processes and application assessment. | Please confirm that facility is in compliance with GMP and is inspection ready at time of submission.  Please attach a table summarising the inspection history of the site within the last 5 years (Annex A). |
| The person at the facility responsible for the inspection should confirm that the facility meets the Criteria for Participation in the Collaborative Hybrid Inspection Protocol.  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ NAME\***  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Function/Title**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **date (dd-mm-yyyy)** | The facility agrees the participating NRAs will share information to support the collaborative hybrid inspection;  The facility agrees to the application and availability of technology to enable remote facility tours;  The facility agrees to provide the platform for document sharing. This should include direct access to documentation, electronically or otherwise, by inspectors, and in formats which can be downloaded/printed as required and, if feasible, in ‘searchable’ form;  The facility agrees to safeguard the privacy and confidentiality of all parties; and  The facility agrees that the working language of the inspection will be in English and will, if requested provide competent translation services to support the timely availability of information and documentation to the inspection team. |
| National Regulatory Authorities being Requested to participate in the Collaborative Hybrid Inspection: |  |
| Preferred timeframe for Proposed Collaborative Hybrid Inspection (with reasoning): | Month and Year: |
| Applicant's signature | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  date (dd-mm-yyyy) |

**Annex A – Template for Facility Compliance History**

***Please provide in the below table the details of GMP inspections (either on-site or remote) carried out at the facility by any regulatory authority within the past 5 years****.* ***The following information should be completed for each facility that you are requesting to be considered for the ICMRA Collaborative Hybrid Inspection Pilot.***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Date & Duration of Inspection** | **Inspecting Authority** | **Scope of Inspection (i.e., Pre-Approval, Post-Approval, Surveillance, etc.)** | **Outcome of Inspection (Compliant/not Compliant/site with no inspection history (as communicated by inspecting authority)[[1]](#footnote-2)** | **Did inspection lead to regulatory action?** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

**If the site has been previously inspected by any regulatory authority within the past five years and found to be not in compliance with GMP, please outline any remediation measures that have been taken to bring the site into compliance.**

1. If site has been previously inspected by an authority that makes inspectional information public then please include reference in the table to the relevant information (e,g EUDRAGMDP). [↑](#footnote-ref-2)