WHO Prequalification Team: medicines

Collaborative Procedure Between World Health Organization (WHO) and Selected National Medicines Regulatory Authorities (NMRAs) in Inspection Activities

Form for Nomination of an Observer or Co-inspector in Inspections

|  |  |
| --- | --- |
| Country: |  |
| Name of Drug Regulatory Authority: |  |
| Postal address: |  |
| Telephone number: (Include codes) |  |
| Fax number: |  |
| **Details of the person being nominated** |
| Title (indicate Mr, Miss or Mrs): |  |
| First name (and Initials): |  |
| Surname / Family name: |  |
| Position in DRA and area of work / responsibility: |  |
| Passport number: |  |
| Nationality: |  |
| Date of issue: |  |
| Date of expiry: |  |
| Contact details: E-mail: |  |
| Phone: |  |
| Fax: |  |
| Number of years of experience as inspector: |  |
| Qualifications: |  |
| Understanding of the English language (spoken): | Excellent / Good / Average / Little  |
| Understanding of the English language (written): | Excellent / Good / Average / Little  |
| Knowledge of GMP, GCP, GLP (specify for each): |  |

|  |  |  |
| --- | --- | --- |
| Areas inspected previously, and average number of inspections (rough indication) | **Areas** | **Number** |
| **Active Pharmaceutical Ingredient (API)** |  |
| * Chemical synthesis
 |  |
| * Extracted from plants
 |  |
| * Fermentation/cell culture
 |  |
| * Derived from animals
 |  |
| **Contract Research Organization (CRO)** |  |
| * Clinical part of the study
 |  |
| * Bioanalytical part of the study
 |  |
| * Statistical analysis of the study
 |  |
| **Finished Pharmaceutical Product (FPP)** |  |
| * Solid Oral Dosage forms
 |  |
| * Liquid Oral Dosage forms
 |  |
| * Sterile products
 |  |
| **Quality control laboratory** |  |
| * Chemistry and general
 |  |
| * Instrumentation
 |  |
| * Microbiology
 |  |
| Describe the objective of joining as an observer in the inspections: |  |
| Describe plans for implementation and/or improvement of inspection activities after this joint inspection: |  |
| **Details of person responsible for nominating the participant** |
| Title (indicate Mr, Miss or Mrs): |  |
| Name: |  |
| Position in the DRA: |  |
| E mail address: |  |
| Signature: |  |
| Date: |  |