WHO Prequalified Quality Control Laboratory (QCL) Annual Report on Activities

|  |  |  |
| --- | --- | --- |
| Laboratory Name: |  |  |
| Country: |  |  |

1. ***Summary of services provided:***
   1. ***To UN agencies and other public health organizations procuring medicines***

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | Name of customer |  | Total number  of samples  analysed |  | Number of  compliant  samples | Number of non-compliant samples |  | Analytical  techniques  /methods  used |
| 1 |  |  |  |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |  |  |  |
|  |  | *Add more rows if*  *required* |  |  |  |  |  |  |  |

* 1. ***Other customers***

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Name of customer | Total number of samples analysed |  | Number of  compliant  samples |  | Number of  non-compliant  samples | Analytical techniques/  methods used |
| 1 |  |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |  |
|  | *Add more rows if required* |  |  |  |  |  |  |

1. ***List of External Inspections and/or Audits in the past 12 months (report year)***

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Inspection or audit party/authority** | **Scope of audit** | **Outcome(s)** |
| **1** |  |  |  |
| **2** |  |  |  |
| **3** |  |  |  |
|  | *Add more rows if required* |  |  |

1. ***Details of any proficiency testing schemes the laboratory participated in for the past 12 months (report year)***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Organizing party** | **Dates of participation** | **Methods involved** | **Outcomes** | **Adopted corrective measures**  **(if applicable)** |
| **1** |  |  |  |  |  |
| **2** |  |  |  |  |  |
| **3** |  |  |  |  |  |
|  | *Add more rows if required* |  |  |  |  |

1. ***Summary of customer complaints concerning results of analysis performed by the laboratory***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Customer/ organization name** | **Date complaint received** | **Nature of complaint** | **Corrective action taken**  **(if any)** |
| **1** |  |  |  |  |
| **2** |  |  |  |  |
| **3** |  |  |  |  |
|  | *Add more rows if required* |  |  |  |

1. ***Changes that have been implemented that may impact on the content of the laboratory information file (LIF) e.g. changes to facility, equipment, key personnel, new tests or techniques introduced***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Nature of change |  | Effective date | Included in revised LIF (Yes or No) |
| 1 |  |  |  |  |
| 2 |  |  |  |  |
| 3 |  |  |  |  |
|  | *Add more rows if required* |  |  |  |

1. ***Revised/updated LIF attached …….…YES/NO***

**If “YES”, reference number and version of LIF \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Prepared by (full name)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Title \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

***Designation:***

|  |
| --- |
| *Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*  *Format - DD/MM/YYYY* |
|  |
|  |