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* |
|  |
|  |