Quality Control Document:

Calibration of Balances

# Purpose

All equipment used to analyse and process human biomaterial samples from Clinical Trials of Investigational Medicinal Products must be regularly calibrated to ensure integrity of samples and reliability of data.

This document provides a balance calibration record for documenting balance calibration checks, instructions on how to perform a balance calibration check and how to document the calibration check using this record.

Where balance calibration is being performed in house the contents of the Balance Calibration Record is mandatory, however the design is optional.

# Instructions

1. Remove this first instruction page.
2. Update the header to include the trial ID.
3. Update the footer, retaining the document reference information relating to this quality control document (QCD).
4. Record a description, the Equipment Unique ID number, the balance location and the working range of the balance.
5. Document action to be taken if a balance fails its calibration check.
6. Source certified weights:

* certified weights have to be directly traceable to national standards
* certified weights have to be sent to be recertified to national standards every two years
* use three different weights which reflect the upper, lower and middle of the ‘working’ range of the balance.

1. Record the weight, serial number and acceptable ranges of the weights. The table below shows the reference weights available and the range of acceptable readings.
2. To calibrate the balance, weigh each of the reference weights once and record the weight. If all three of the reference weights are within range then the balance has passed the calibration check.

* Do not handle weights directly. For larger weights wear cotton or similar non-powdered gloves and use forceps for small weights.

1. Document on the balance calibration record each time a balance calibration is performed.
2. If the balance fails the calibration check, ensure the action to be followed if the calibration check is failed is adhered to.
3. Store the balance calibration record safely and securely in the Laboratory Master File throughout the trial and archive with the other trial records upon closure. Refer to the Archiving SOP (UoB-ARC-SOP-001).

|  |  |
| --- | --- |
| **Reference weight (g)** | **Acceptable range (g)** |
| 0.001 | 0.00095 - 0.00105 |
| 0.05 | 0.0495 - 0.0505 |
| 1 | 0.99 - 1.01 |
| 10 | 9.9 - 10.1 |
| 100 | 99 - 101 |
| 500 | 498 - 502 |
| 1000 | 999-1001 |
| 2000 | 1998 - 2002 |

# Related documents

* UoB-ARC-SOP-001 Archiving
* UoB-CRL-SOP-001 Laboratory Set-up and Management
* UoB-CRL-SOP-002 Laboratory Facilities
* UoB-CRL-SOP-003 Sample Management
* UoB-CRL-SOP-004 Laboratory Analysis
* UoB-CRL-SOP-005 Reportable Issues

UoB QMS documents can be found on the [CRCT website](https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/index.aspx). Internal work instructions can be obtained from the CRCT ([crct@contacts.bham.ac.uk](mailto:crct@contacts.bham.ac.uk)) and/or from the RGT ([researchgovernance@contacts.bham.ac.uk](mailto:researchgovernance@contacts.bham.ac.uk)).

# Balance Description:

# Equipment Unique ID Number:

# Balance Location:

# Working Range:

|  |  |
| --- | --- |
| **Action to be followed if calibration check fails:** |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Reference weights to be used (g):** | **Serial number of reference weights:** | **Acceptable ranges (g):** |
| **1st weight:** |  |  |  |
| **2nd weight:** |  |  |  |
| **3rd weight:** |  |  |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Date**  **(dd-mmm-yyyy)** | **Weight displayed by balance (g)** | | | **Pass or Fail** | **Initials** |
| **1st weight** | **2nd weight** | **3rd weight** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |