Quality Control Document:

Calibration of Single-Channel and Multi-Channel Pipettes

# 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. Pipettes require calibration checks to ensure that the volumes dispensed are accurate.

Therefore, pipettes require calibration checks by pipette specialists. In addition, calibration checks may need to be performed ‘in house’, for example in the interim between calibrations by pipette specialists. This document gives further instructions of how to organise calibration checks by pipette specialists. It also provides a pipette calibration record for documenting ‘in house’ pipette calibration checks, instructions on how to perform pipette calibration for both single and multi-channel pipettes and how to document pipette calibration checks using this record.

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

# Instructions

## Organising calibration check by pipette specialists

1. Ensure pipette calibration checks are carried out at a regular interval, and as detailed on the trial’s Equipment Maintenance Schedule.
2. Use a pipette specialist, e.g. STARLABS to perform the pipette calibration.
3. Request an enhanced service that includes both pre and post calibration checks.
4. Review the pre-calibration report, if the report identifies the pipette was out of range perform a risk assessment to determine if this is likely to have affected data quality and whether this constitutes a Reportable Issue. Refer to the Reportable Issues SOP (UoB-CRL-SOP-005).
5. Ensure records/certificates are kept in the Laboratory Master File.

## In-house pipette check and calibration check

### Set up calibration record

1. Remove this first instruction page.
2. Set up a separate pipette calibration record for each pipette.
3. Update the trial/study ID in the header.
4. Update the footer, retaining the document reference information relating to this quality control document (QCD).
5. Record the action to be followed if a pipette fails its calibration check on the bottom of the form.
6. Record the pipette ID.

### Perform pipette check

1. Check the pipette for damage and/or poor function prior to performing the calibration check. If the pipette is damaged or not functioning correctly, document this on the pipette calibration record and follow the action to be followed if the pipette fails a calibration check.
2. Check the seal of the pipette and record details of the seal check on the pipette calibration record. Check the seal by securely attaching a clean tip to the pipette, draw the maximum volume of liquid handled by the pipette into the tip and suspending the pipette vertically, tip down for one minute. If a droplet of liquid forms on the end of the pipette tip then the pipette seals should be replaced.
3. Ensure the balance used to perform the pipette calibration check is within calibration. See the quality control document Calibration of Balances (UoB-CRL-QCD-011).
4. Ensure that all calibration records are stored safely and securely in the Laboratory Master File throughout the trial and archived with other trial documents when the trial closes. Refer to the Archiving SOP (UoB-ARC-SOP-001).

### Perform calibration check for single-channel pipettes

1. To perform a calibration check of a single-channel pipette, set the volume on the pipette according to the pipette size, as shown in Table 1.
2. Firmly attach a clean tip to the pipette.
3. Pipette and discard two volumes to wet the pipette tip.
4. Pipette distilled or deionised water (at ambient temperature) into a tared weighing boat on the balance. Record the weight of the volume and repeat until 10 volumes have been dispensed (zero the balance between each volume). Work as quickly as accuracy allows to reduce the evaporative loss of water.
5. Reject any dispensing operation where water is seen to be retained in the tip (i.e. pipetting error) and replace with an additional weight.
6. Calculate and record the mean dispensing weight. This should be within the range specified in Table 1 below; see also point 24.
7. Each individual accepted weight should be in the range of ± 10% of the mean dispensing weight.
8. If the mean dispensing weight and the individual weights are inside the specified range, the pipette is acceptable for use.
9. If the mean dispensing weight and any individual weight are outside the specified range, the pipette should be re-checked up to a total of three times; the pipette is acceptable if the individual and mean weights obtained from two out of three checks are within the specified ranges, the pipette is unacceptable if the individual and mean weights obtained from two out of three checks are outside the specified range.
10. Each time a single-channel pipette fails a calibration check the information must be recorded on the calibration record together with details of repairs. Ensure the action to be followed if a pipette fails a calibration check is also adhered to.
11. Each time a pipette is repaired it should be calibrated again to ensure it is within it acceptable range.
12. If the pipette is acceptable, re-label it with the next ‘calibration check due’ date.

### Multi-channel pipettes

1. To perform a calibration check of a multi-channel pipette, set the volume according to Table 1.
2. Place a fresh tip firmly on each channel of the pipette.
3. Draw the liquid up into the tips, hold the pipette vertically and observe the level of the liquid in the tips. If the liquid level is uniform across the tips proceed to the next section. If the level is different between tips then the pipette requires repair.
4. Pipette distilled or deionised water (at ambient temperature) from all channels simultaneously into a tared vessel. Record the weight of the volume and repeat until 10 volumes have been dispensed (zero the balance between each volume).
5. Record the volume dispensed from each channel by using the following calculation:

|  |  |
| --- | --- |
| Mean weight of water per channel (mg) = | Total weight of water (mg) |
| 10 x number of channels |

1. The mean weight should be in the range specified in Table 1.
2. If the mean weight is outside the specification range the pipette should be rechecked up to a total of three times; if two means are within specification the pipette is acceptable, if two means are outside specification then the pipette is unacceptable.
3. Each time a multi-channel pipette fails a calibration check the information must be recorded on the calibration record together with details of repairs. Ensure the action to be followed if a pipette fails a calibration check is also adhered to.
4. Each time a pipette is repaired it should be calibrated again to ensure it is within it acceptable range.
5. If the pipette is acceptable, re-label it with the next ‘calibration check due’ date.

**Table 1**

|  |  |  |
| --- | --- | --- |
| **Pipette ranges** | **Set volume** | **Specified range weight of water \*** |
| 10 - 20 μl | 20 μl | 19.7 - 20.3 mg |
| 10 - 50 μl | 20 μl | 19.7 - 20.3 mg |
| 10 - 100 μl | 50 μl | 49.6 - 50.6 mg |
| 50 - 200 μl | 100 μl | 99.2 - 101.2 mg |
| 20 - 500 μl | 250 μl | 248.6 - 252.6 mg |
| 200 - 1000 μl | 500 μl | 496 - 506 mg |
| 1000 - 5000 μl | 2000 μl | 1985 - 2026 mg |

\*This value has been corrected for deionised water at 18.5°C and 907 mbar air pressure (Z = 1.0025). It is to be used for calibration checks undertaken within the temperature range 12.0 - 25.0°C.

# Related documents

* UoB-ARC-SOP-001 Archiving
* UoB-CRL-QCD-011 Calibration of Balances
* 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) and/or from the RGT (researchgovernance@contacts.bham.ac.uk).

# Pipette ID:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Date (dd-mm-yyyy): |  | Individual deliveries (mg) |  |  |  |  |  |
|  |  |  |  |  |
| **Balance ID number:** |  | Mean total (mg) |  |
| **Pipette function OK?** |  | Mean per channel (mg)(multi-channel only) |  |
| Seal check OK? |  | Pass/Fail |  |
| Set volume (μl) |  | Checker name |  |
| Signature |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Date (dd-mm-yyyy): |  | Individual deliveries (mg) |  |  |  |  |  |
|  |  |  |  |  |
| Balance ID number: |  | Mean total (mg) |  |
| **Pipette function OK?** |  | Mean per channel (mg)(multi-channel only) |  |
| Seal check OK? |  | Pass/Fail |  |
| Set volume (μl) |  | Checker name |  |
| Signature |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Date (dd-mm-yyyy): |  | Individual deliveries (mg) |  |  |  |  |  |
|  |  |  |  |  |
| Balance ID number: |  | Mean total (mg) |  |
| Pipette function OK? |  | **Mean per channel (mg)**(multi-channel only) |  |
| **Seal check OK?** |  | Pass/Fail |  |
| Set volume (μl) |  | **Checker name** |  |
| Signature |  |

### Action to be followed if pipette fails calibration check: