Quality Control Document:

Equipment Maintenance Schedule

# Purpose

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

This document provides an equipment maintenance record that can be used to document equipment servicing and maintenance and instructions on how to complete this record.

# Instructions

1. Remove this first instruction page.
2. Update the trial/study ID in the header.
3. Update the footer, retaining the document reference information relating to this quality control document (QCD).
4. Set up a separate equipment maintenance record for each piece of equipment.
5. Record the name, unique ID number and location of the equipment.
6. Record the additional equipment information i.e. manufacturer, model and serial number
7. Routine servicing is often carried out by equipment manufacturers under service contracts or agreements. Record whether a service agreement is in place and the frequency at which services are to be performed.
8. Decide on and record the frequency at which maintenance will be carried out.
9. Record in the table each time any maintenance or servicing is carried out, stating whether it was a service or maintenance in the procedure column.
10. If routine maintenance missed for any reason, indicate this on the records with a statement such as ‘not taken’ or ‘not carried out’ so that the record is not left blank.
11. If an item of equipment fails a service, record this information together with details of repairs. Consider whether a reportable issue has occurred and if so, document accordingly **as per the quality control document (QCD)** Reportable Issues (UoB-CRL-QCD-02) and the Reportable Issues SOP (UoB-CRL-SOP-005).
12. Ensure that all records are stored safely and securely in the Laboratory Master File throughout the trial and archived with the other trial documents when the trial closes. Refer to the Archiving SOP (UoB-ARC-SOP-001).

1. Following servicing or maintenance, some equipment such as balances, thermometers and pipettes may require regular calibration. Where this is the case, ensure this is being performed and documented. Refer to the QCDs Calibration of Balances (UoB-CRL-QCD-011)*,* Calibration of Thermometers *(*UoB-CRL-QCD-012), andCalibration of Single-Channel and Multi-Channel Pipettes (UoB-CRL-QCD-013).

# Related documents

* UoB-ARC-SOP-001 Archiving
* UoB-CRL-QCD-011 Calibration of Balances
* UoB-CRL-QCD-012 Calibration of Thermometers
* UoB-CRL-QCD-013 Calibration of Single-Channel and Multi-Channel Pipettes
* UoB-CRL-QCD-024 Reportable Issues
* UoB-CRL-QCD-024 Reportable Issues
* 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)).

# Equipment Name:

# Equipment Unique ID Number:

# Equipment Location:

|  |  |  |  |
| --- | --- | --- | --- |
| **Manufacturer:** |  | **Model:** |  |
| **Service agreement:** |  | **Serial number:** |  |
| **Service frequency:** |  | **Maintenance frequency:** |  |

### **Record in the table below each time a service or maintenance is performed**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Date (dd-mmm-yyyy) | Procedure | Date next due | Notes(Include pass, fail, repairs, replacements) | Initials |
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