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**QUALITY MANUAL**

**Version 1.0 2018**

**Review interval: Annual**

**Your department**

Your laboratory’s address

Director:

Contact details:

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# Preface

This document together with specified procedure manuals represents the Quality Management System of your department’s laboratory. It has been compiled to meet the requirements of The International Standard ISO 15189:2012 ‘Medical Laboratories – Requirements for Quality and Competence’ (hence known as ‘The International Standard’) and appropriate national and international standards. All procedures specified herein are mandatory.

**DOCUMENT HISTORY & CHANGES**

* Changes necessitate reissue of the Quality Manual incrementing the version number
* Changes since the last version was issued are added to the changes log below. Previous changes are incorporated into the re-issued version. The changes log below details all changes made to the SOP.
* Changes to page 1 or headers and footers are not included in the changes log
* Additions to the changes log are not shown as changes.

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| --- | --- | --- | --- |
| Version | Section | Date | Brief description of change |
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# i. Abbreviations and acronyms – please amend to your laboratory’s requirements

|  |  |
| --- | --- |
| BDQ | Bedaquiline |
| BSL3 | Biosafety level 3 |
| CCM | Centre for Clinical Microbiology |
| EMB | Ethambutol |
| EQA | External Quality Assessment |
| GCP | Good Clinical Practice |
| GCLP | Good Clinical Laboratory Practice |
| INH | Isoniazid |
| ISO | International Organization for Standardization |
| KAN | Kanamycin |
| LIS | Laboratory Information System |
| LQMS | Laboratory Quality Management System |
| LZD | Lineozolid |
| MFX | Moxifloxicin |
| PZA | Pyrazinamide |
| QC | Quality Control |
| QM | Quality Manual |
| QMS | Quality Management System |
| QSE | Quality System Essential |
| RMP | Rifampicin |
| SM | Streptomycin |
| SOP(s) | Standard Operating Procedure(s) |
| UCL | University College London |
| UKAS CPA | United Kingdom Accreditation Service Clinical Pathology Accreditation |
| WHO | World Health Organization |

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# 1. Introduction to the Quality Manual

## 1.1 Overview of the organization – amend for your laboratory (CCM example below)

The Centre for Clinical Microbiology (CCM) is a constituent research group in the Research Department of Infection within the Division of Infection and Immunity and its UCL staff are located at the Royal Free Campus. The postal address is: The Centrefor Clinical Microbiology, Department of Infection, Royal Free Campus, University College London, Rowland Hill Street, London NW3 2PF, UK.

The laboratory has adopted a quality management system for the purpose of the effective and efficient use of its resources. All employees are committed to the culture of quality. All staff share responsibility for identifying nonconformities or opportunities for improvement, recording these instances so that corrective or preventive actions can be taken to ensure the laboratory meets the needs of its customers.

## 1.2 Mission statement – amend for your laboratory (CCM example below)

The aim of the Centre for Clinical Microbiology is to apply new technologies to improve the diagnosis and treatment of the patients served by our partner hospitals. We have global collaborations and projects, these are anchored in and informed by the experience developed at UCL.

A priority for our work is antimicrobial resistance and we have programmes focused on enhanced detection and management of resistant organisms, particularly in the hospital environment. The work of the UCL CCM has an emphasis on respiratory infection with studies on the microbiome and resistome in patients with chronic lung disease such as COPD. A significant element of the CCMs work is to contribute to all stages of the TB drug development pathway with projects on evaluation of new compounds as well as supporting the laboratory aspects of phase II and III clinical trials. The CCM, in partnership with the TB Alliance acts as a central laboratory for multi-centre clinical trials working towards registration of new treatment regimens for tuberculosis. An underlying theme is the development of biomarkers of treatment outcome, whether transcriptomic analysis of in vitro treatments or the more complex picture of monitoring outcome in patients.

An important element of the work of CCM is capacity development, we provide training for laboratory scientists both on site and in London participating in several networks designed to enhance skills in microbiology laboratories. A recent collaboration is with colleagues in the Bartlett to develop the [Biosafety Design Initiative](https://www.ucl.ac.uk/biosafety-design-initiative), which undertakes training and research focused on reducing transmission of infections in the built environment.

## 1.3 Vision statement – amend to your laboratory

The [Centre for Clinical Microbiology](https://www.ucl.ac.uk/infection-immunity/centre-clinical-microbiology) (CCM) aims to reduce the burden of infectious disease through research to improve diagnosis and treatment of microbial infections.

## 1.4 Scope (please edit this to suit the needs of your laboratory)

The Quality Manual (QM) fulfils two functions. It describes the Quality Management System for the benefit of the laboratory’s own management and staff, and it provides information for users and for inspection and accreditation bodies. It is the responsibility of the Quality Manager to review the QM according to the review interval detailed on page 1 of this manual.

The Quality Manual can be regarded as the index volume to separate volumes of management, laboratory, clinical and quality procedures. The sections of the Quality Manual are arranged so that they equate with ISO 15189:2012 (see contents table). Under the title of each Quality System Essential (QSE) there is a brief description of the way in which the UCL CCM seeks to comply with the particular standard and references are given to appropriate procedures.

The quality manual includes, but is not limited to:

* The quality policy (section 2).
* A description of the scope of the quality management system.
* The organization and management structure of the laboratory and its place in the parent organization (section 3)
* A description of the roles and responsibilities of laboratory staff and management (including the laboratory director and quality manager) for ensuring compliance with ISO 15189:2012 (section 5.1).
* A description of the structure and relationships of the documentation used in the quality management system.
* The documented policies established for the quality management system and reference to the managerial and technical activities that support them.

There is one printed copy of the quality manual, the location of which is shown on page 1. All laboratory and relevant staff have access to the Quality Manual and referenced documents. All relevant laboratory, and other staff sign and date the signature page to acknowledge that they have read and understood the use and application of the Quality Manual and the referenced document.

# 2. Quality Policy

Two copies of this 2 page policy are available. The one here in the QM folder, located describe location (CCM\_POLICY\_002) and the one displayed on your department’s noticeboard.

The quality policy of your institute and department is given below:

* your institute and department management is dedicated to providing the resources necessary to maintain the laboratory quality management system and to ensure the laboratory’s participation in the institutional quality plan.
* The laboratory is committed to continual improvement, meeting internal requirements, partner and collaborator requirements, and providing a basis for the establishment and review of the quality objectives.
* Quality practices are communicated within the organization, understood and adhered to by all employees.
* The laboratory ensures a competent workforce to deliver quality results in a timely and to the highest possible level of quality and in compliance with ISO 15189:2012.
* your institute and department laboratory has no involvement in any activities that would diminish confidence in the laboratory’s competence, impartiality, judgement or operational integrity.
* your institute and department management and personnel are free from any undue commercial, financial, or other pressures and influences that may adversely affect the quality of their work.
* Where potential conflicts in competing interests may exist, they are openly and appropriately declared.

your institute and department **incorporates values of:**

* Commitment to quality and full compliance with accreditation
* Commitment to Health & Safety and Welfare for all
* Maintain confidentiality and Data Protection
* Demonstrates responsibility, professionalism and accountability
* Treat each other with respect, dignity and honesty
* Value and support our staff by training and development
* Support R&D to improve future clinical trials

**In order to ensure that the needs and requirements of users are met,** your institute and department **will:**

* Operate a Quality Management System to integrate the organisation, procedures, processes and resources.
* Provide a framework for establishing and reviewing quality objectives and plans
* Ensure that all personnel are familiar with the contents of this quality manual and all procedures relevant to their work.
* Commit to the health, safety and welfare of its entire staff and comply with relevant environmental legislation. Visitors to the department will be treated with respect and due consideration will be given to their safety while on site.
* Uphold professional values and commit to good professional practice and conduct.
* Provide a friendly and caring atmosphere in the workplace so that we all, of whatever gender, age or grade, feel socially comfortable and unthreatened at all times.

your institute and department **will comply with the standards set by ISO 15189:2012**

your institute and department **is committed to:**

* Staff recruitment, training, development and retention at all levels to provide a full effective service to its users
* The proper procurement and maintenance of such facilities, equipment and other resources as are needed for completion of tasks required by Clinical Trials Partners.
* The collection, transport and handling of all specimens in such a way as to ensure the correct performance of tests.
* Reporting results of tests in ways which are timely and accurate.
* The assessment of user satisfaction, by way of internal and external audit, in order to produce continual improvement of the quality of the laboratory.
* Annual review of the quality policy and quality management system to ensure suitability.

Centre Director – (provide name)

Signed: Date:

# 3. QSE: Organization

## **3.1 Organization policy**

The Centre Director (insert name) has the authority, competence and responsibility for the services provided.

Your institute and department management ensures the following:

* there are no activities that could compromise laboratory performance;
* there are appropriate procedures to ensure ethical respect of patient samples and confidentiality of patient information;
* duties and responsibilities of laboratory personnel are defined;
* appropriate communication is established within the laboratory;
* a Quality Manager, Laboratory Manager and a Health & Safety Officer are designated.

##

## **3.2 Conflict of interest**

Your institute and department is not engaged in any activity that might influence its technical judgment. The laboratory is not committed to any commercial, financial or other pressure provided by any particular organisation that could influence its technical judgment or affect its competencies and trust.

**3.3 Ethical Conduct**

The requirements of Ethical standards of those working in medical laboratories are derived from medical ethics and other codes and incorporate the same principles. Ethical practice can be regarded as good technical practice accompanied by proper attitudes and behaviour.

The WHO guidelines cover the ethical considerations with regard to collection of samples, performing tests, storage and access of records, retention and disposal of samples and use of samples for research purposes. [WHO, Ethical Practice in Laboratory Medicine and Forensic Pathology part 1 (A copy is present in the Quality Folder, section 3).

All laboratory staff in your department are required to undertake training in GCP and GCLP. Certificates are held in the Staff Training Records folder (Location of this).

##

## **3.4 Organization chart**

Your department is part of your institute. The liability and indemnity insurance certificates are held by your institute



The Organisation of your institute and department (2018) consists of 21 professionals. Staff names along with their roles are displayed on the CCM Noticeboard.



##

## **3.5 Internal communication**

Your institute and department management ensures appropriate communication takes place to keep staff members informed.

Weekly laboratory meetings are held for all personnel in the laboratory describe when. During the meetings:

* Issues with laboratory safety are reviewed
* Risk assessments and SOPs are reviewed and action items pertaining to the laboratory are defined and assigned to relevant members of staff
* All information on general organisation, actions and projects is communicated.
* A rota is assigned to allow regular updates of studies being undertaken in the centre
* Items important to Quality are raised and discussed

Minutes are taken to capture meeting discussions, followed by a written report which is circulated by e-mail. This includes defined action points together with updates and these are reviewed at the following meeting. To provide a record, meetings are saved on the shared drive for your institute and department. All your institute and department personnel have access to this drive.

There is also a weekly meeting for personnel involved in the clinical trials. During the meetings:

General update of each trial

Discussion of issues at the sites.

Discussion of department-specific trial issues

Minutes of this meeting are taken by your institute and department Administrator and distributed to the team via e-mail.

Health & Safety forum – held quarterly and attended by the Health & Safety Officer.

* The relevant points are fed back at the weekly laboratory meeting and discussed

## **3.6 Personnel responsibilities**

Roles important for maintenance of quality are listed here and other roles are given in detailed Job Descriptions held by your institute HR and the Training folder (describe location).

**Centre Director**

* develops the quality management system with the Quality Manager
* approves the quality management system
* ensures that the necessary human and material resources, as well as the necessary information, are available to enable effective operation and control of the processes of the quality management system;
* delegates tasks to qualified personnel;
* manages contracts;
* ensures adequate training;
* ensures internal and external communication.

**Quality manager**

* assesses the facilities, procedures, practices, and training of personnel involved in the laboratory’s activities, in regard to the quality management system;
* reviews the quality plan annually and recommends any revisions needed to the laboratory’s director/manager;
* seeks advice from different departments and specialists and may require assistance from independent experts;
* establishes an internal audit programme and informs the laboratory director/manager of audit outcomes;
* ensures that the quality management system is managed and maintained;
* implements and maintains the quality management system;
* establishes and monitors all processes and procedures for the quality management system;
* resolves nonconformities;
* ensures that action is taken in order to obtain continuous improvement of processes/activities;
* ensures all staff has up-to-date with QMS training.

**Health and safety officer/Deputy Health and Safety Officer**

* ensures health and safety standards are adhered to within the working environment
* represents your institute and department at campus/institute H&S forums and ensures recommendations arising from the meetings are implemented, where appropriate
* investigates incidents and ensures they are appropriately documented

**Laboratory Manager**

* oversees the day-to-day running of the BSL2 laboratory
* assigned delegated responsibility of the BSL3 laboratory
* plans and co-ordinates the work schedule of the Research Assistants that directly report to him/her;
* provides technical advice on laboratory quality procedures to personnel;
* performs laboratory tests
* stores and archives laboratory isolates
* controls and maintains equipment;
* part of the rota for routine quality measurements e.g. temperature monitoring
* ensures stock management
* ensures activities/processes included in the scope of the quality management system are identified and performed in compliance with this manual;
* applies the necessary techniques and criteria in order to verify that established processes/activities and their implemented controls are effective;
* evaluates and identifies new products.
* checks performance of internal quality controls to validate the tests.
* organises and runs EQA for drug testing to provide evidence of laboratory quality

For other personnel in the department such as Research Assistants, their activities are related directly to the project that they are assigned to and vary accordingly. Personnel qualifications for each position are documented within the position’s job description. The qualifications reflect the appropriate education, training, experience and demonstrated skills needed, and are appropriate to the tasks performed.

### 3.7 Job descriptions

The laboratory provides job descriptions (JD) that describe responsibilities, authorities and tasks for all personnel and are held by your institute HR department.

### 3.8 Personnel introduction to the organisational environment

The programme to introduce new staff to the organization is provided by the document - Induction Manual (insert document number here) and induction checklist (insert document number here) or Induction Manual non-laboratory staff (insert document number here) and induction checklist (insert document number here) depending on JD. All induction training evidence to be filed in the Staff Training Folder or Student/Visitor training folder (describe location). The induction includes a welcome from the Centre Director and then other sections can be completed by any competent staff as a way of encouraging team introduction and the welcome process.

The document includes, but is not limited to: introduction to your department and areas in which the person will work, staff facilities, health and safety requirements (including fire and emergency), and occupational health services. New starters are required to complete the following within 6 weeks of commencing employment:

|  |  |  |  |
| --- | --- | --- | --- |
|   | **How often is it renewed** | **How to complete this training** | **Personnel required to complete it** |
| GDPR  | one off | <https://www.ucl.ac.uk/gdpr-training> | everyone mandatory |
| Good clinical practice | **biennially**  | <https://globalhealthtrainingcentre.tghn.org/elearning/short-courses/> | everyone mandatory |
| Good clinical laboratory practice | **biennially**  | <https://globalhealthtrainingcentre.tghn.org/elearning/short-courses/> | everyone mandatory |
| Basic fire safety  | one off | http://www.ucl.ac.uk/estates/safetynet/training/ | everyone mandatory |
| Induction checklist | one off | Local to CCM  | everyone mandatory |
| Local induction & Fire Safety form | One off | Fire Warden | everyone mandatory |
| Green awareness  | one off | https://www.ucl.ac.uk/human-resources/working-ucl/induction | everyone mandatory |
| Information security | one off | https://www.ucl.ac.uk/human-resources/working-ucl/induction | everyone mandatory |
| safety induction | one off | https://www.ucl.ac.uk/human-resources/working-ucl/induction | everyone mandatory |
|   | **How often is it renewed** | **How to complete this training** |  **Personnel required to complete it** |
| Fire safety talk | **annually** | Sheila Sherlock education centre - Thursday mornings | everyone mandatory |
| Freedom of information | one off | https://www.ucl.ac.uk/human-resources/working-ucl/induction | everyone mandatory |
| Staff online diversity training | one off | https://www.ucl.ac.uk/human-resources/working-ucl/induction | everyone mandatory |
| Unconscious bias training  | one off | https://www.ucl.ac.uk/human-resources/working-ucl/induction | everyone mandatory |
| Display screen equipment assessment | one off unless DSE changes | http://www.ucl.ac.uk/estates/safetynet/training/ | everyone mandatory |
| your department principles of laboratory safety | one off | moodle | Lab staff recommended & mandatory for PhD students |

The terms and conditions of employment are outlined in the contract generated from Human Resources (HR).

All staff must read and sign to acknowledge understanding of:

Quality Manual (insert document number here)

Quality Policy (insert document number here)

All Laboratory Staff must also read and sign to acknowledge understanding of:

Health and Safety Policy (insert document number here)

Procedure in the event of a biological spillage or chemical event (insert document number here)

Procedure in the event of an incident including inoculation (insert document number here)

Procedure for risk assessment (insert document number here)

Procedure for disinfection (insert document number here)

Storage and removal of waste (insert document number here)

Operation of microbiological safety cabinets (insert document number here)

Safe handling of HG2 organisms and material containing them (insert document number here)

Other SOPs and risk assessments must be read as requested by the supervisor and will be dependent on the project.

##

## **3.9 Supporting documents**

|  |  |
| --- | --- |
| Procedures/Processes |  |
| Quality manual | insert document number here |
| Quality policy | insert document number here |
| Health & Safety Policy | insert document number here |
| Staff competence and training | Staff Training Folder |
| Induction Manual laboratory staff | insert document number here |
| Induction Manual non-laboratory staff | insert document number here |
| Annual Fire safety training (courses held in the Sheila Sherlock centre, RFH) | Spreadsheet of attendance held by local DSO |
| Mandatory new starter training  | See table above |
| Mandatory new starter Policy, RA and SOP reading | See table above |
| Forms/Logs |  |
| Meeting minutes | Describe where these are kept |
| Induction checklist Laboratory staff | insert document number here |
| Induction checklist Non- Laboratory staff | insert document number here |
| Staff training  | Staff Training records folder: describe location |

#

# 4. QSE: Facilities and Safety

## **4.1 Policy**

The laboratory is provided with sufficient space and reliable infrastructure to perform its work, to ensure the quality, safety and efficacy of the services provided, and to meet national safety regulations.

The building infrastructure, including the Biosafety level 3 (BSL3) laboratories, are maintained by the Royal Free Hospital as our landlord. They may also use external contractors.

The laboratory design provides an efficient and safe environment for the laboratory staff, other health care personnel, patients, and the community.

Laboratory personnel are trained in the basics of safety and biohazard management issues (see training section 9.5).

## **4.2 Facilities – please amend to describe your laboratories**

The laboratory has several rooms, each designated for specific uses; for example, offices, consumables storage facilities, toilets and laboratory working areas.

Floorplan of laboratory space.



## **4.3 Security – please amend to describe your laboratories:**

Access to all facilities is restricted to authorised personnel at the point of entry to the UCL CCM. Access is regulated by an access card (magnetic card). A doorbell alerts UCL CCM personnel of visitors requiring entry. A log is maintained in the Research Office/meeting room for all visitors (insert document number here).

Access to the BSL3 is assigned to the magnetic entry card only for specific personnel that have fulfilled the following:

* a general training on biosafety concerning BSL3 level work
* an induction by the appropriately trained personnel working in the BSL3
* hands-on training in the laboratory prior to lone working
* completion of a BSL3 training record once it is deemed they are competent

Access to the BSL3 is terminated at the end of staff contracts

Access to the BSL2 laboratory outside the normal working hours (Monday to Friday 8am to 6pm) is restricted for students and inexperienced staff, who must get permission from their supervisor and a member of staff must be present at all times. Out of hours working must be recorded by e-mail, ahead of time to the Supervisor, detailing expected start and finish times. A message must be sent to the CCM WhatsApp Group, in real time, to record start and finish times. The Lone Working policy should be referred to (Health and Safety Policy insert document number here). The lone working log must be completed on entry and exit (insert document number here).

At **ALL** times a BSL3 trained individual, with BSL3 access and capable of responding to a BSL3 incident must be present while anyone is working in either of the BSL3 laboratories. Out-of-hours BSL3 working is discouraged and permission **MUST** be sort from the supervisor in advance.

A 24-hour security service is in effect. This service is provided via the Royal Free Hospital Trust. The facilities and zones at risk are linked to an alarm system at the central post of security.

## **4.4 Working environment**

All manipulations presenting a risk of contamination (for the operator, environment and/or sample) is isolated from other activities.

Working areas are kept clean and are well maintained.

A complete and thorough description of safety rules is available and all personnel are trained in safety and biohazard management issues when working with chemicals and samples. Further details can be found in the Health and Safety Policy (insert document number here) and individual Risk Assessments (describe location). All procedures require risk assessment prior to commencement of activities – see Procedure for risk assessment (insert document number here).

## **4.5 Waste disposal – amend to describe the waste disposal in your laboratory**

Waste (chemical, biological and other) is segregated and disposed according to national regulations on waste disposal. People in charge of the waste disposal are trained to handle biohazardous waste: Storage and removal of waste SOP (insert document number here). See also Operation of the autoclaves (insert document number here). Describe who is responsible for removal of autoclaved/waste for incineration after transfer into the yellow carts.

Toxic chemical waste is collected by the outsourced facilities management company Mitie. Further details are given in the Storage and removal of waste SOP (insert document number here).

**4.6 Supporting documents**

|  |  |
| --- | --- |
| Procedures/Processes |  |
| Health and Safety Policy  | insert document number here |
| Storage and removal of waste SOP | insert document number here |
| Operation of the autoclave SOP | insert document number here |
| Forms/Logs |  |
| Incident report form | Describe location |
| Visitors/Engineer admission form (permit to work) | Describe location, insert document number here |
| Weekly Laboratory Housekeeping log  | insert document number here |
| Lone working form | insert document number here |

# 5. QSE: Equipment

## **5.1 Policy**

Your department management ensures that equipment is properly selected, installed, validated, maintained and disposed of according to established procedures and manufacturer's instructions to meet the needs of the laboratory to perform quality sample testing and research activities.

## **5.2 Selection of equipment**

This section is developed in chapter 6 Purchasing and Inventory.

## **5.3 Installation and acceptance Criteria**

New instruments and equipment are installed, calibrated and documented by the vendor (e.g. for pipettes, MSCs etc.) who assures satisfactory performance. Items requiring in-house validation (e.g. hot blocks) are tested and the data recorded on the equipment validation form (insert document number here).

Describe who (e.g. estates) ensures space, ventilation, humidity and electricity meet specifications for satisfactory performance.

Your institute and department provides documentation that each instrument meets all the required criteria for its use in the laboratory.

## **5.4 Equipment Inventory and master file**

All equipment is uniquely identified (serial number).

An inventory and master file is maintained for each piece of equipment (insert document number here).

The inventory represents the list of all equipment, and persons in charge of the different pieces of equipment. The equipment inventory is stored on your department shared drive and supporting documents, such as calibration records, are stored in the Equipment Folder (describe location). Updating of this inventory is ensured by the persons in charge of the equipment. The same for the attribution of the inventory number of each piece of equipment.

The following information is in the master file:

* name of the equipment
* brand (manufacturer)
* serial number
* model and year (if known)
* location
* cost (only for newly acquired pieces of equipment)
* date of purchase (only for newly acquired pieces of equipment)
* type of maintenance, if required (contract with an external company, in house, etc.)
* any regular preventive maintenance to be performed, and frequency to perform these activities
* calibration activities
* record of preventive maintenance activities
* record of repairs
* Certificates of calibration
* Who is responsible for maintaining the equipment

##

## **5.5 Validation**

The laboratory validates each new piece of equipment if required.

The validation process depends on the type of equipment and its use in the laboratory. Reproducibility and accuracy tests are performed, documented, reviewed and approved before the instrument is used in the testing environment (insert document number here).

The member of staff responsible conducts or delegates the required calibrations of the equipment and maintains records of all interventions on the equipment.

Use and maintenance of each piece of equipment is based on the manufacturer's instructions.

A standard operating procedure (SOP) on the use, maintenance and safety risks of the equipment is accessible in the location of the equipment if required. Details of equipment are given in the equipment inventory (insert document number here).

The operating manual of each piece of the equipment is available.

## **5.6 Preventive maintenance and repair**

Preventive maintenance is recorded where applicable (e.g. MGIT maintenance insert document number here).

Maintenance contracts and warranty service are documented and maintained by the Laboratory Manager (Equipment Inventory Log insert document number here) is maintained describe electronic location.

Defective or malfunctioning equipment is identified with a label alerting that it is not in use.

Equipment requiring service due to a malfunction is decontaminated following manufacturers requirements and a decontamination form attached (insert document number here).

Serviced or repaired equipment is calibrated to ensure it meets the manufacturer’s performance criteria.

Daily temperatures are recorded for relevant equipment such as fridges, freezers and incubators (insert document number here or using an electronic system if you have one).

##

## **5.7 Decommissioning – amend to describe your laboratory**

Obsolete equipment is decontaminated and removed from the laboratory. Removal is performed by the Outsourced Contactor ‘Dump The Junk’. Details are given on the NHS Trust website.

## **5.8 Supporting documents**

|  |  |
| --- | --- |
| Processes/Procedures | ID Code |
| Selection and acquisition of equipment (see chapter 6 Purchasing and Inventory) |  |
| Equipment management and control SOP  | insert document number here |
| Fumigation of Microbiology safety cabinets | insert document number here |
| Forms/Logs |  |
| Decontamination of laboratory equipment form | insert document number here |
| Service certification records | Equipment folder |
| Equipment Inventory log | insert document number here  |
| BSL3 monthly maintenance check form | insert document number here |
| Maintenance BSL3 | insert document number here |
| Temperature logs | insert document number here |
| Fumigation form | insert document number here |
| Equipment validation form | insert document number here |
|  |  |

#

# 6. QSE: Purchasing and Inventory

## **6.1 Policy – amend to describe your institute**

Your institute and department ensures an uninterrupted supply of consumables and/or services are available to perform all quality laboratory functions.

Your institute and department maintains a list of preferred/approved suppliers that meet the requirements for the product or service to be purchased via the MyFinance online ordering system. The laboratory strives to purchase high quality reagents at a reasonable cost and without bias.

A your institute Contracted Supplier is a supplier who has been awarded a framework agreement or contract by Procurement Services or one of the various consortia that your institute has access to. Suppliers are normally appointed to a framework following an advertised tender and competition. Sometimes these suppliers are labeled preferred suppliers in the My Finance system.

The laboratory has a procedure for ordering and receipting supplies (describe it).

When supplies are delivered the following is recorded in the Stock Receipt Book:

* identity of the reagent or consumable;
* manufacturers name;
* batch number
* condition when received (e.g. acceptable or damaged, temp);
* who received them
* date of arrival

The laboratory has an inventory management system for equipment (insert document number here).

The laboratory selects its referral laboratories and is responsible for all tests performed by these laboratories. Vendors are approached with our requirements and the service is negotiated on basis of cost, turnaround time, quality and accreditation.

## **6.2** **Reagents and consumables management**

The laboratory ensures that the procedures for the purchase, receipt and storage of all reagents guarantee that the quality of testing is not compromised. For trial related activities all lots of reagents are recorded for the set of samples tested to ensure traceability. These records form part of the controlled worksheets standardized for each study. Where required e.g. reagents for ZN testing, each new batch of reagents has QC performed prior to use. This is documented in the relevant trial Quality Form filed in the trial file held in the locked cupboard in describe location.

Environmental conditions for the storage of all reagents and consumables are monitored and documented. Fridge and freezer temperatures are recorded daily using either a thermometer (insert document number here) or electronic system.

Reagents prepared in the laboratory must have a name and date.

Tristel is the disinfectant of choice used by the your institute and department. Preparation must be performed daily Procedure for Disinfection (insert document number here). Preparation of your validated disinfectant e,g. Tristel is recorded on (insert document number here) Daily preparation of Tristel.

## **6.3 Selection and evaluation of providers**

The laboratory evaluates the providers for the reagents, consumables and equipment. The evaluation should be conducted against defined criteria which may include:

* value for money
* post-delivery support
* availability
* in-country distribution
* registration of the provider.

Evaluation of these criteria is provided by your institute who secure discounted deals for UCL laboratories. These companies are called ‘Preferred Suppliers’ in the online MyFinance system.

For purchases of large pieces of equipment (value >£50,000) UCL requires quotations be obtained from three independent suppliers (https://www.ucl.ac.uk/finance/purchasing/po-over-50k).

## **6.4 Procurement**

### 6.4.1 Equipment procurement

The laboratory ensures that when purchasing, leasing or acquiring new equipment, it conforms to the established requirements (for example testing capacities). See chapter 5 Equipment.

### 6.4.2 Reagents, consumables and materials

Purchasing orders

The orders for purchase of supplies (reagents, consumables and materials) are requested using the UCL MyFinance system and submitted electronically to the appropriate approvers.

Receipt of orders

The laboratory confirms receipt of the supplies with the assistance of the UCL Finance Department by electronically receipting the item and storing the delivery note. Delivery notes are kept for 7 years. The date of receipt is recorded is recorded in the Stock Receipt Book.

The person in the laboratory taking receipt of the supplies crosschecks the information indicated on the package and accompanying documents with the data of the order. All items are immediately transferred to their relevant storage area e.g fridge. A logbook is kept recording whether the temperature requirement of the item was appropriate on arrival.

## **6.5 Stock management and inventory**

The laboratory has a stock management system to ensure consumables are stored under correct environmental conditions and are used prior to their expiration dates.

A regular inventory is performed.

## **6.6 Referral laboratories / subcontracting**

The laboratory is responsible for all tests performed by another laboratory on samples that are referred. The laboratory selects its referral laboratories and is responsible for all tests performed by these laboratories. Vendors are approached with our requirements and the service is negotiated on basis of cost, turnaround time, quality and accreditation.

Subcontracting of samples may occur under any of the following circumstances:

* test not performed routinely by the laboratory
* instrument breakdown or reagents not available
* workload restrictions
* client requested turnaround time cannot be met.

Where a laboratory subcontracts any part of the calibration of equipment, this work is contracted with a company complying with the requirements of this quality manual.

The laboratory ensures and can demonstrate that its subcontractor is competent to perform the activities in question. Documentation relating to the referral laboratory’s accreditation is stored in the Quality File in describe location.

## **6.7 Supporting documents**

|  |  |
| --- | --- |
| Procedures/Processes | ID Code |
| Selection and acquisition of equipment, reagents, consumables and service providers (see chapter 5 Equipment) |  |
| Equipment and Management control  | insert document number here |
| Preparation of tristel (SOP) | insert document number here |
| UCL procurement policy  | https://www.ucl.ac.uk/procurement/suppliers/purchasing-at-ucl |
| Forms/Logs |  |
| Stock Receipt book | Stock Receipt book |
| Equipment Inventory log | insert document number here |
| MyFinance over £50K checklist | https://www.ucl.ac.uk/finance/purchasing/po-over-50k |
| Temperature logs | insert document number here |
| Preparation of tristel (daily log) | insert document number here |

# 7. QSE: Process Management

## **7.1 Policy**

The laboratory provides personnel with written instructions that shall be used to ensure the correctness and reliability of test results. All trial related activities have authorised Standard operating procedures (SOPs). For research activities some repetitive routine tasks are covered by an SOP (SOP Inventory log (insert document number here)), however since research requires continuous method development, as part of the process, some activities are risk assessed only (Risk Assessment inventory exists in UCL safetyNet (https://www.ucl.ac.uk/estates/safetynet/). Policies, SOPs and RAs are version controlled. These are written and reviewed by the appropriate personnel. SOPs and Policies are reviewed once every two years. RAs are reviewed annually. The QM will assign the review to the author or another appropriate member of staff. Staff writing and authorising risk assessments are required to undertake UCL’s online training for risk assessment (http://www.ucl.ac.uk/estates/safetynet/training/).

For trial related activities it is the responsibility of the Laboratory Monitoring Lead and Clinical Trial Assurance and Data Manager to ensure that all SOPs are in place prior to commencement of laboratory work.

For your institute and department generated documentation it is the responsibility of the Quality Manager and Quality Team that all documentation is controlled using the your institute and department laboratories control procedure (CCM Document Control policy (insert document number here)).

## **7.2 Sample management**

## 7.2.1 Specimen collection and transport

The your department laboratory receives samples from international sites involved in the clinical trials. The laboratory provides written instructions for specimen collection and transport (GATB UCL Chain of Custody). Specimen transport follows national and international transport guidelines or regulations.

Specific details for specimen handling and processing are given in the Trial Manuals.

7.2.2 Specimen/sample receiving

The laboratory establishes written specimen/sample acceptance and rejection criteria for each test offered and provides this information to its customers, as applicable. All specimens/samples are inspected according to these acceptance/rejection criteria (GATB your institute Chain of custody).

The laboratory rejects specimens/samples that are not suitable for processing. The requestor is notified of the reason for rejection. If the specimen/sample is critical and cannot be rejected, a safety assessment is made before we proceed with the examination. If it is safe then the tests are performed and a notation is made on the report.

For Clinical Trials a unique registration number is assigned to each specimen/sample to be analysed as part of the study trials. This is generated at the site laboratory and the same identifier is used for subsequent processing at your department. All patient’s data is removed and samples are shipped with only the study identifier recorded.

Other samples coming into your department

No patient identifiers are on samples. If patient identifiers are linked to a study number this is via a password protected database/spreadsheet held on a your department computer. Patient information is not held on unencrypted devices. Questionnaires and other hardcopy data is maintained in a locked cupboard in describe location.

**7.2.3. Specimen/sample handling, preparation and storage**

If the specimen needs to be shared for different tests throughout the laboratory and/or storage purposes, each aliquot (sample) is labelled individually with the unique registration number.

Samples are stored under proper temperature and safety conditions.

## **7.3 Method validation**

##

The methods developed in the laboratory have been through a documented validation process. Validation is performed with each batch of tests e.g DST for *M. tuberculosis* clinical isolates is accompanied by simultaneously testing for reference strain H37Rv. The validation of a run is recorded on the LRF associated with the trial it relates to. If the validation fails then this is highlighted and the LRF is scored through to indicate a failed run.

The methods used in the laboratory, that have been published in scientific reviews or transmitted by national or international reference centres, have been verified and documented under the laboratory's conditions and adapted where necessary.

The methods and techniques used in the laboratory are described in the standard operating procedures (SOPs) and associated documents (SOP Inventory and RA inventory).

## **7.4 Summary of the main laboratory tests performed:**

List examinations performed in the CCM laboratory and references to the corresponding SOPs.

|  |  |
| --- | --- |
| Procedures | ID Code |
| Ziehl-Neelsen (Z-N) or Kinyoun Smear Microscopy  | Clinical Trial Manuals |
| HAIN GenoType Assays |
| Liquid Culture by Mycobacteria Growth Indicator Tube (MGIT) |
| Drug susceptibility Testing (DST) by MGIT |
| Minimum inhibitory Concentration by agar proportion |
| Isolate subculture on Lowenstein Jensen (LJ) |
| Staining of slides |
| Culture of isolates on liquid and solid media |
| Specimen receipt and rejection |
| DNA extraction and quantification |
| Rezazurin Microtitre Assay (REMA) |
| Whole Genome Sequencing  |
|  |
| SOP inventory log | insert document number here |
| Risk assessment inventory log | insert document number here |
| Document control and archiving polict | insert document number here |
| GATB UCL Chain of custody |  |

## **7.5 Quality Control**

The laboratory has a Quality Control (QC) programme with written policies and procedures.

Laboratory technical staff are trained to review and take appropriate action regarding quality control data.

Internal quality controls are required to ensure the results are valid.

The laboratory quality control program is a monitoring system that:

* first, provides immediate information for making the decision about the acceptability of sample processing results;
* second, provides a method for evaluating data over time to help in making decisions about the overall performance of the test procedure. These controls are run on both qualitative (result is positive or negative) and quantitative (result is a number or value) tests. The resulting data is recorded in such a way that trends are detectable and, where practicable, statistical techniques are applied to the reviewing of the results.
* Equipment calibration and servicing are monitored.
* We are part of an External Quality Assessment (EQA) with INSTAND. Bi-annually we receive *M. tuberculosis* isolates to test for Mycobacteriology to check drug sensitivity for the following drugs: INH, RMP, EMB, PZA, MFX, KAN and SM and MIC for LZD and BDQ. The EQA certificates are stored in the QM folder under Process Management.

The examinations’ results are documented by the Research Assistants/Laboratory Manager on the corresponding paper trial records and recorded in a computer to create a permanent traceable record.

If QC results are not validated, sample examination results cannot be reported.

When problems occur the laboratory investigates, corrects and repeats sample testing (see chapter 11 Nonconforming Event Management). Non-conformities and items requiring improvement are captured on continuous quality improvement (CQIF) form (insert document number here). Any trial-specific QC failures are recorded on the relevant CQIF form for the trial.

|  |  |
| --- | --- |
| Quality Control - Procedures | ID Code |
| Ziehl-Neelsen (Z-N) or Kinyoun Smear Microscopy  | GATB\_Myco Lab Control Manual\_V1.0\_12 July 2018 |
| HAIN GenoType Assays | GATB\_Myco Lab Control Manual\_V1.0\_12 July 2018 |
| Liquid Culture by Mycobacteria Growth Indicator Tube (MGIT) | GATB\_Myco Lab Control Manual\_V1.0\_12 July 2018 |
| Drug susceptibility Testing (DST) by MGIT | GATB\_Myco Lab Control Manual\_V1.0\_12 July 2018 |
| Minimum inhibitory Concentration | GATB\_Myco Lab Control Manual\_V1.0\_12 July 2018 |
| Isolate subculture on Lowenstein Jensen (LJ) | GATB\_Myco Lab Control Manual\_V1.0\_12 July 2018 |
| Maintenance of QC Strains  | insert document number here |
| Quality Control Forms  | All attachments are part of main document: GATB\_Myco Lab Control Manual\_V1.0\_12 July 2018 |
| Location of work  | Attachment Ai |
| Laboratory Staff responsibility log | Attachment Aii |
| Equipment Temperature Log Form | Attachment B |
| Biosafety level 3 Laboratory Daily Checklist | Attachment C |
| Room Temperature Log Form | Attachment D |
| Ziehl-Neelsen or Kinyoun Stain Reagents | Attachment Eii |
| MGIT TUBES and PANTA/Growth Supplement | Attachment Eiii |
| Blood Agar Plates | Attachment Eiv |
| Lowenstein Jensen Media | Attachment Ev |
| MPT64 Antigen Assay | Attachment Evii |
| MGIT SIRE Drug Susceptibility Testing Kit | Attachment Eviii |
| MGIT PZA Drug Susceptibility Testing Kit | Attachment Eix |
| Moxifloxacin and Kanamycin Drug Susceptibility Testing | Attachment Ex |
| MIC Testing: Drug | Attachment Exi |
| Microscopic Examination of Acid-Fast Smears | Attachment I |
| MGIT 960 Daily Maintenance Log | Attachment J |
| MGIT Calibration Tube Log | Attachment K |
| GenoType® MTBDRplus Version 2 | Attachment Li |
| GenoType® MTBC | Attachment Lii |
| GenoType® MTBDRsl (Version 2) | Attachment Liii |
| GenoType® Mycobacterium CM/AS | Attachment Liv |
| MPT64 Antigen Assay Routine QC | Attachment Lv |
| EQA certificates | Quality Manual |
| Continuous quality improvement forms (CQIF) | insert document number here |

## **7.6 Reporting**

Clinical trial relevant results are reviewed by the Clinical Trials Assurance & Data Manager or delegated and agreed upon before transmission. If discrepancies occur the Clinical Trials Assurance & Data Manager or delegated individual initiates corrective actions.

Final reports are signed by the Clinical Trials Assurance & Data Manager or Laboratory Monitoring Lead and released to the requestor.

## **7.7 Sample retention and disposal**

Retention of clinical trial samples is done according to the study’s specified criteria and respects national regulations.

Research samples are disposed of at the end of a project or sooner if they are no-longer required. It is a your institute and department policy that unlabelled or poorly labelled samples are discarded.

For disposal of samples, refer to chapter 4 Facilities and Safety.

## **7.8 Supporting documents**

|  |  |
| --- | --- |
| Processes/procedures | ID Code |
| Document control and archiving policy | insert document number here |
| Chain of custody SOP | Clinical Trial Manuals |
| Identification and control of non-conformities | insert document number here |
| Procedure for investigation of incidents | https://www.ucl.ac.uk/estates/safetynet/ |
| Forms/Logs |  |
| SOP inventory log | insert document number here |
| Risk assessment inventory log | insert document number here |
| Report Forms template NC007/008 | NC007/8 trial files |
| Report form template STAND | STAND trial files |
| Report form template NiX | NiX trial files |
| Report form template ZeNiX | ZeNiX trial files |
| Continuous quality improvement form (CQIF) | insert document number here |

# 8. QSE: Assessments

## **8.1 Policy**

The laboratory performs ongoing quality assessments such as:

* periodic review of examination requests, suitable methods and sampling requirements;
* monitoring and evaluation of customer feedback, staff suggestions and impact of potential failures on examination results and customer expectations;
* monitoring of determined quality indicators, corrective actions undertaken, and follow-up;
* participation in proficiency testing programme and review of the corresponding reports;
* Participation in internal and external audits.

The laboratory strives to continuously improve the quality of laboratory performance, the effectiveness of the quality management system and the reliability of test data.

The laboratory does its best to identify and resolve any nonconformity that may affect laboratory performance.

## **8.2 Internal assessments**

## 8.2.1 Internal Audits

During internal audits, information is gathered about:

* processes and operating procedures
* staff competence and training
* equipment
* environment
* handling of samples
* quality control and validation of results
* recording and reporting practices.

Audits are carried out according to SOP Procedure for internal and external audit (insert document number here). The findings are compared with the laboratory’s internal policies and to ISO 15189:2012. Any breakdown in the system or departure from procedures should be identified according to Continuous quality improvement form (insert document number here).

Any gap or nonconformity in performance shows if the policies and procedures that the laboratory has set require revision or are not being followed. This is also captured on the Continuous quality improvement form (insert document number here).

Bi-annual walk rounds of the department are conducted by the two senior staff (grade 8 and above) to act as routine monitoring. This is reported on an internal horizontal audit form (insert document number here or insert document number here) and CQIFs are completed accordingly.

8.2.2 Review and follow up of corrective actions

All corrective actions undertaken in the laboratory will be reviewed and their follow up evaluated.

This is described in the chapter 11 Nonconforming Event Management.

**8.2.3 Quality indicators**

Quality indicators have been determined to monitor the quality objectives of the laboratory.

This monitoring is detailed in chapter 12 Continual Improvement.

**8.2.4 Staff suggestions**

All staff are encouraged to offer suggestions for improvement of any aspect of the laboratory. These are captured at the weekly all staff meeting and documented in the minutes. These suggestions are recorded, evaluated and implemented if useful. Feedback on the suggestions implemented is provided to the staff.

## **8.3 External assessments**

## 8.3.1 External audits

Proficiency testing via External Audit serves as a tool for quality improvement in the laboratory. One of the major benefits is to assess the laboratory QMS and implement corrective and preventative measures to address any issues identified.

List of the External audit programmes in which the laboratory participates:

* The GATB Alliance
* The HSE
* MSF
* UKAS CPA
* Others

### For External audits the procedure for internal and external audits SOP is referred to (insert document number here).

### 8.3.2 Customer feedback

Customer feedback is collected and reviewed on a regular basis. This is described in the chapter 10 Customer Focus.

Assessment reports are shared with all staff. Corrective actions are undertaken accordingly.

## **8.4 Supporting documents**

|  |  |
| --- | --- |
| Processes/Procedures | ID Code |
| Procedure for Internal and external audits SOP | insert document number here |
| Identification and control of non-conformities | insert document number here |
| See chapters 10 Customer Focus, 11 Nonconforming Event Management, and 12 Continual Improvement |  |
| Forms/Logs |  |
| Wednesday Laboratory meeting minutes | Add location |
| Internal horizontal audit for BSL2  | insert document number here |
| Internal horizontal audit for BSL3 | insert document number here |
| Staff suggestion forum | Wednesday meeting |
| Clinical Trials meeting | Wednesday meeting – trials meeting |
| Quarterly Health and Safety meeting – Health & Safety Manager feed back | Wednesday meeting |

# 9. QSE: Personnel

## 9.1 Policy

The laboratory recognizes that its most important resource is its personnel.

The laboratory management defines staff educational requirements and competency qualifications necessary for conducting laboratory procedures.

The laboratory management strives to ensure recruitment is unbiased and in accordance with the your institution and department HR Policy (see section 9.2).

The laboratory works with the Human Resources department to ensure education qualifications and references of job applicants are checked and to ensure legal contracts/agreements are signed by all parties prior to employment or within a set period.

All personnel undertake mandatory training (see section 3.8 for new starter mandatory training). In addition the training below is required for particular work activities:

|  |  |  |  |
| --- | --- | --- | --- |
| **UCL's First Aid arrangements** | **one off**  | **https://www.ucl.ac.uk/hr/od/resources/mandatory\_training.php** | **Staff nominated as first aider at work** |
| **Assessment of display screen equipment foundation workshop** | one off | https://www.ucl.ac.uk/hr/od/resources/mandatory\_training.php | Staff appointed as DSE assessors |
| **Recruitment, selection and right to work HR policy briefing** | one off | https://www.ucl.ac.uk/hr/od/resources/mandatory\_training.php | All staff involve with any aspect of recruitment and selection of staff |
| **Appraisal workshop** | one off | https://www.ucl.ac.uk/hr/od/resources/mandatory\_training.php | All staff involved with appraisal of staff |
| **BSL3 Induction** | annually | see the delegated BSL3 manager to arrange | For BSL3 activities |
| **Laboratory risk assessment workshop** | one off | http://www.ucl.ac.uk/estates/safetynet/training/ | Anyone writing or authorising risk assessments |
| **Principles of risk assessment (online)** | one off | http://www.ucl.ac.uk/estates/safetynet/training/ | Everyone  |
| **Laboratory risk assessment**  | one off | http://www.ucl.ac.uk/estates/safetynet/training/ | Anyone authorising risk assessments |

All laboratory personnel respect the laboratory rules concerning health, safety and security.

The laboratory provides training to its staff according to the role specifications and the laboratory needs. In-house training is captured on specific CAFs, where required.

## **9.2 Recruitment**

The Centre Director follows your institution policy for recruitment (provide a link to policy)

## **9.3 Personnel Training file**

An individual administrative file is established for each staff member (temporary, permanent, trainee, etc.) that contains documents concerning the staff qualifications (diplomas, CV, training certificate, etc.). These documents are managed and stored by the Human Resources department.

The signed induction, competency assessments, training records, certificates and continuing education are stored in describe locaion in a controlled access area and updated regularly by the quality manager. Staff involved with clinical trial activities are required to have some additional documents in their records such as a copy of their job description.

Each new staff member or trainee requires an appointment with your institution Occupational Health. All details of which are stored with your institution Occupational Health.

## **9.4 Integration**

Staff orientation of all new employees is to be completed within 14 days of start date. Safety orientation occurs before an employee is assigned to duties.

All newly hired employees are trained comprehensively on all policies and procedures in the department that apply to their job description and assignments (see 9.6 Staff competency, below).

## **9.5 Training**

The laboratory provides training for all personnel, which includes the quality management system, assigned work processes and procedures, the laboratory information system, health and safety, ethics and confidentiality. The effectiveness of the training program is periodically reviewed. Training is captured using CAFs and certificates and stored in the staff training file (describe location).

## **9.6 Staff competency**

Staff competencies cover technical and practical skills and general knowledge.

Competency of each new employee is assessed and verified before permitting unsupervised work in the laboratory.

All employees authorised to use the BSL3 laboratory are assessed for BSL3 competency on an annual basis by completing BSL3 refresher training. Renewal of training for response in the event of a BSL3 incident is performed every six months (in-house training).

## **9.7 Personnel performance appraisal**

As per your institution policy each member of staff has an appraisal with their Supervisor every 12 months.

## **9.8 Continuous education**

A continuing education program is available for the professional development of staff. Expectations for staff participation are communicated for those education sessions that are deemed mandatory.

## **9.9 Non-permanent personnel**

Non-permanent personnel such as students follow the general laboratory orientation procedures for integration in the laboratory.

## **9.10 Supporting documents**

|  |  |
| --- | --- |
| Procedures/Processes | ID Code |
| UCL recruitment | https://www.ucl.ac.uk/human-resources/recruitment-and-selection-policy |
| GCLP and GCP training | <https://globalhealthtrainingcentre.tghn.org/elearning/short-courses/> |
| Performance appraisal  | https://www.ucl.ac.uk/human-resources/appraisal-review-and-development-scheme |
| Induction Manual laboratory staff | insert document number here |
| Induction Manual non-laboratory staff | insert document number here |
| Staff training and competence  | Staff training folder – Research Office 2 2/446 |
| Overview of Biosafety level 3 laboratories  | insert document number here |
| Forms/Logs |  |
| Induction form checklist for lab staff | insert document number here |
| Induction form checklist for non-lab staff | insert document number here |
| BSL3 induction /re-induction form | insert document number here |
| Performance appraisal form | https://www.ucl.ac.uk/human-resources/appraisal-review-and-development-scheme |
| Authorised BSL3 Lab personnel | insert document number here |

#

# 10. QSE: Customer Focus

## **10.1 Policy**

Your institution and department management is dedicated to providing quality and timely service to all partners and sponsors. The laboratory management commits to providing adequate resources to meet partner and sponsor requirements and to provide an on-going programme for continual improvement.

## **10.2 Partner/Sponsor satisfaction measurement**

The objective is to assess the satisfaction of our main partner: The TB-Alliance. This is performed via audit and quarterly meetings.

The analysis of audit results leads to implementation of corrective actions where needed.

## **10.3 Complaints management**

Complaints are managed in order to lead to corrective or preventive actions (also refer to chapter 11 Nonconforming Event Management, and chapter 12 Continual Improvement).

The objective is to ensure continuous improvement of the quality system by taking into account our Partner and Sponsor concerns. The Quality Manager will facilitate tracking and investigating potential non-satisfaction of Partners or Sponsors.

##

## **10.4 Supporting documents**

|  |  |
| --- | --- |
| Processes/Procedures | ID Code |
| See chapters 11 Nonconforming Event Management, and 12 Continual Improvement |  |
| Procedure for internal and external audit | insert document number here |
| Forms/Logs |  |
| Continuous quality improvement form (CQIF)  | insert document number here |
| Incident report form | https://www.ucl.ac.uk/estates/safetynet/ |

# 11. QSE: Nonconforming Event Management

## **11.1 Policy**

Your institution and department is committed to the identification, documentation, correction, and prevention of nonconforming events in all aspects of the quality management system including pre-examination, examination and post-examination processes. Procedures are in place that:

* designate the individuals responsible and actions necessary for handling nonconformities;
* ensures that each nonconforming event is documented, recorded, and reviewed at identified intervals, a root cause analysis performed, and that corrective action is taken and documented;
* define when testing procedures and data reporting will be withheld due to nonconformities and when, and under what conditions, examination can resume;
* defines the steps taken when examination data resulting from a nonconforming event has already been released.

##

## **11.2 Corrective Actions**

All nonconforming events (from occurrence reports, claims, audit reports, customer complaints, failed proficiency testing, etc.) are recorded, tracked, trends identified, and root cause analysis performed. The appropriate corrective actions are taken. Events that are specific to a clinical trial are recorded on the Clinical Trial note-to-file template and QC CQIF. Other general events are recorded on the Your institution and department CQIF (insert document number here). Copies of Clinical Trial CQIF (for QC failure) and clinical trial Note-to-Files are also maintained as part of the QMS. Your department events that are non-conformances according to the specified procedures and protocols are recorded on the Your department CQIF (insert document number here).

The results of an occurrence assessment are communicated to management and become part of periodic management review.

The objective is to ensure continuous improvement of the QMS.

## **11.3 Supporting documents**

|  |  |
| --- | --- |
| Procedures/Processes | ID Code |
| Documentation, review of nonconforming events and corrective actions | Audit reports – stored in the Quality Folder |
| Forms/Logs |  |
| Continuous Quality Improvement Form (CQIF) | insert document number here |

#

# 12. QSE: Continual Improvement

## **12.1 Policy**

The laboratory continuously improves the effectiveness of its quality management system and its processes, as stated in its quality policy and quality objectives.

A management review is performed annually to evaluate the laboratory’s quality management system, evaluation activities, corrective actions and preventive actions.

The laboratory develops an action plan according to improvement needs annually and monitors the effectiveness of the actions undertaken.

## **12.2 Quality indicators**

The laboratory establishes quality indicators to monitor and evaluate performance of its processes annually.

Quality indicators:

* the traceability of the sample from receipt, through processing to archiving;
* the turnaround time from receipt of the sample to the submission of the report;
* the reliability of the competence of the technical staff (competency assessments for determined tests). This is recorded on a CAF and stored with training records.
* Up-to-date staff training records
* Internal QC results audits
* EQA reports
* Internal audits
* External audits

These indicators are regularly monitored as for their concordance with the defined objectives and the activities established in the laboratory. These indicators are presented during the annual management review.

## **12.3 Management review**

The annual management review ensures that the organization and the activities of the laboratory remain appropriate and efficient. Therefore, it allows the evaluation and continuous improvement of the efficiency of the quality system of the laboratory. The elements reviewed are related to the quality system management.

Elements of entry of the management review:

* quality objectives of the past year
* quality indicators
* occurrences and nonconforming events recorded
* customer complaints reports
* customer satisfaction survey reports
* internal audit reports
* proficiency testing reports
* corrective/preventive actions and follow up
* changes in work load or type of work
* all pertinent factors: resources, future activities, etc.

Elements of output of the management review:

* actions for improvement
* definition of the quality objectives for the next year
* establishment of new quality indicators in concordance with the new quality objectives
* improvement of the quality management system.

## **12.4 Preventive action**

The laboratory reviews the data and implements preventive actions allowing the laboratory to anticipate eventual nonconforming events in its activities. A follow up of the actions implemented for improvement is ensured in the same way as described in chapter 11 Nonconforming Event Management.

## **12.5 Supporting documents**

|  |  |
| --- | --- |
| Procedures/Processes | ID Code |
| Continual review | Audit reports in the QM folder |
| Quality indicators | Reports in the QM folder |
| See chapters 8 Assessments, and 11 Nonconforming Event Management |  |
| Evaluation activities (see chapter 8 Assessments) |  |
| Forms/Logs |  |
| Continuous Quality Improvement form (CQIF) | insert document number here |
| Non-conformity form | insert document number here |

# 13. QSE: Documents and Records

## **13.1 Policy**

The laboratory ensures that documents and records are managed from creation and receipt to archival and destruction, according to national laws, local regulations and international standards.

## **13.2 Documentation management**

The levels of documentation are represented in the pyramid below.

The quality manager reviews and approves all requests for amendments to existing documents and the development of new procedures, processes, and policies.

Staff are not permitted to make temporary amendments to documentation without the prior consent of the Quality Manager or Centre Director.

When new or modified policies, processes and procedures are instituted, an assessment of staff retraining requirement is made and if necessary retraining is provided.

The quality manual is reviewed annually. All laboratory procedures are reviewed after 2 years. The responsibility for the Quality Manual annual review lies with the Quality Manager.

The Quality Manager is responsible for the distribution of new documents, retrieval of old documents and maintenance of records of amendments.

## **13.3 Documents and records control**

The laboratory controls documents required by the quality management system and ensures that unintended use of any obsolete documents is prevented according to SOP: your department document control procedure (insert document number here). All documents are uniquely identified. Date of issue, unique identifier, version, total number of pages, number and location of copies, review date and authorizing signatories are included in the document.

Documents are signed as a paper copy or authorised electronically. Document control logs are maintained identifying the current valid versions or via electronic document control system and their distribution according to SOP inventory log (insert document number here) and Risk assessment inventory log (insert document number here).

A secure master file is maintained of all documents to prevent unauthorised access, loss or damage.

## **13.4 Archiving**

The Data Manager and Quality Manager are responsible for the proper archiving of documents and records.

The laboratory respects your institution regulations and GCP guidelines concerning the retention time of all records as given below:

* The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 makes the archiving of clinical trial documentation a legal requirement. The ICH GCP (Good Clinical Practice) Guidelines define and list all of the documents that are essential for the conduct of a clinical trial.
* EC Directive 2003/63/EC requires that essential documents be retained for at least fifteen years after completion or discontinuation of the trial or for at least two years after the last approval of a marketing application in the region.
* The Medicines for Human Use (Clinical Trials) Regulations require that the medical files of trial subjects are retained for at least 5 yearsafter completion of the trial.

## Archiving of documents is covered in Document Control and archiving policy (insert document number here)

## **13.5 Review of contracts**

Refer to section 6.6

##

## **13.6 Supporting documents**

|  |  |
| --- | --- |
| Procedures/Processes | ID Code |
| Document control and archiving policy  | insert document number here |
| Chain of custody for Nix | Clinical trial manuals |
| Chain of custody for ZeNix | Clinical trial manuals |
| Chain of custody for NC007/008 | Clinical trial manuals |
| Forms/Logs |  |
| SOP inventory log | insert document number here |
| Risk assessment inventory log | insert document number here |

# 14. QSE: Information Management

## **14.1 Policy**

Your institute and department has access to the data and information needed to provide a service that meets the needs and requirements of internal and external customers. There are documented procedures in place to ensure the confidentiality of patient information and the security of the data during each step of the process.

## **14.2 Information system – Security**

Your department follows Your institute guidance relating to Patient Identifiable Data (PID) and handling of PID is performed according to Control of patient identifiable data (insert document number here).

Identifiable data held by NHS Trusts may not be:

* Held outside Trust systems without the specific approval of your Trust’s Information Governance Manager and / or Caldicott Guardian
* Copied to portable devices, unless approved or supplied by the Trust’s IM&T / information governance function, using approved encryption software
* Stored on PC hard drives (the ‘C’ drive)
* Transmitted by email, except within nhsmail.
* Remote access to NHS systems must always be via equipment owned and controlled by the relevant Trust, enabled by a virtual private network.
* You must not attempt to circumvent NHS institutional firewalls by using remote desktop software such as GoToMyPC, and you must not connect or download data to your own mobile device, including smartphones.
* No identifiable data should be stored with ‘cloud’ providers.

All staff are required to undertake mandatory GDPR training and Information Security training (https://www.ucl.ac.uk/human-resources/working-ucl/induction)

Losses of personal and other sensitive data must be reported to your Departmental Data Protection Coordinator and the UCL Data Protection Officer (name of this person and email address). Security-related incidents should also be reported to the Computer Security Team. If NHS equipment and / or data are involved, you should use the local incident reporting and investigation procedure and report to the local risk team. Loss or unauthorised disclosure of information, or failure to report it, or to follow the above guidance, may be treated as a disciplinary matter, up to and including gross misconduct.

Where possible samples and data received at the your institute and department have already had Patient Identifiable Data (PID) removed and a study number assigned. There is a documented procedure to deal with samples still displaying PID (insert document number here).

## **14.3 Confidentiality**

The laboratory has a secure process for archiving and/or data disposal; refer to chapter 13 Documents and Records.

## **14.4 Supporting documents**

|  |  |
| --- | --- |
| Procedures/Processes | ID Code |
| UCL guidance on handling PID | http://www.ucl.ac.uk/library/about/records-office/infoprotect-res |
| Selection of an information management system (see chapter 6 Purchasing and Inventory) |  |
| Document control and archiving policy  | insert document number here |
| GDPR training | https://www.ucl.ac.uk/human-resources/working-ucl/induction |
| Information security training | https://www.ucl.ac.uk/human-resources/working-ucl/induction |
| Control of PID SOP | insert document number here |
| Back up | UCL IT |
| Forms/Logs |  |
|  |  |