CHN 67: CHAIN Quality Assurance SOP (MASTER)

Purpose

The purpose of this Quality assurance SOP is to describe procedures used in CHAIN study in reference to GCLP, in order to:

- Set up a quality laboratory management system for CHAIN study.
- Maintain sample integrity.
- Generate test results that are technically sound and have the required accuracy and precision that meet study requirements.

Responsibility

This SOP applies to nursing staff, study clinicians and lab staff of study sites who will be involved in CHIAN study. It is the responsibility of the users to follow the guidelines stipulated herein.

The Principal Investigator (through the study coordinator when applicable) retains the overall responsibility of implementation of these standard procedures.

The Study Laboratory Coordinator is responsible for answering questions you may have about the content of this SOP and any other relevant study documentation. Please contact that the Study Laboratory Coordinator through your site coordinator.

All CHAIN study laboratory personnel must be conversant with GCLP guidelines for DAIDS through the link: https://www.niaid.nih.gov/sites/default/files/gclp.pdf

Abbreviations/Definitions

GCLP – Good clinical Laboratory Practices
SOP – Standard Operating Procedure
DAIDS – Division for AIDS
PMI – Preventive Maintenance and Inspection
QA – Quality Assurance
QAS – Quality assurance system
QC - Quality Control
LJ – Levy Jennings
IQA – Internal QA
EQA – External QA
AMR – Anti-Microbial Resistant
CBC – Complete Blood Count
CAPA – Corrective Action-Preventive Action
PPE – Personal Protective Equipment

Required material

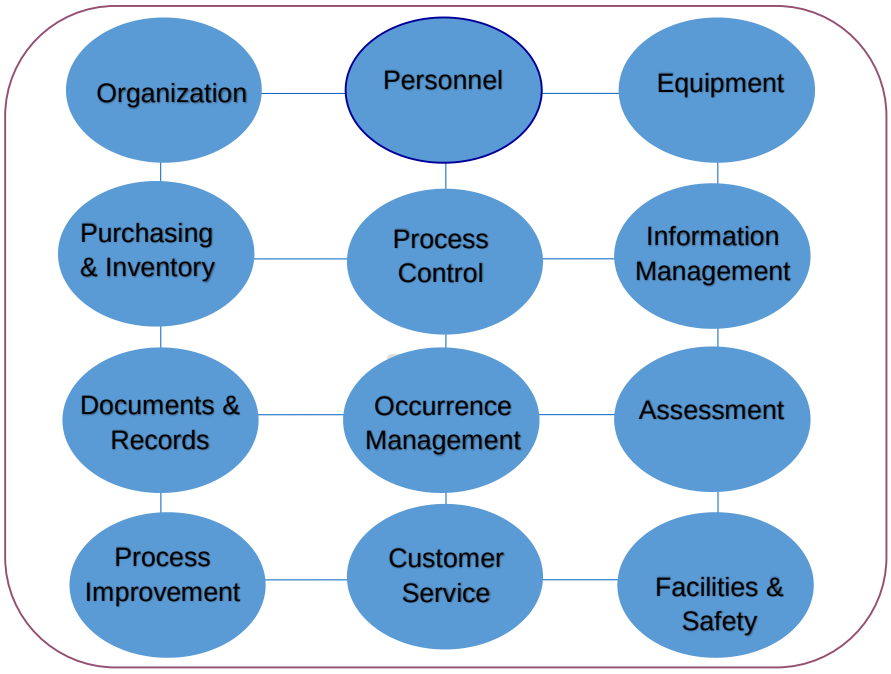
- Quality assurance SOP

Methods

1.0 General considerations

Quality assurance involves the entire testing process: pre-analytical, analytical (testing), and post-analytical processes (results and analysis). The site lab must establish or file and follow written procedures for a comprehensive quality assurance program to maintain overall quality of the total testing process.

The QA program must address the following area shown in the table below.



2.0 QAS essentials

2.1 Equipment installation, validation and maintenance

2.1.1 New Equipment in the lab should undergo installation qualification, Operation qualification and performance qualification.

2.1.2 SOP should be created for routine PMI by the lab staff and service contracted PMI by qualified vendors for all lab equipment's.

2.1.3 PMI charts should be developed, filled, reviewed and signed by site lab contact or designee.

2.2 General QC measures

2.2.1 The laboratory must have a site-specific, written QC plan which clearly defines procedures for monitoring analytic performance for all lab reagents and tests. This program ensures the consistent identification, documentation and resolution of QC issues.

2.2.2 QC for biochemistry and hematology should be done on daily basis. QC reports for should thereafter be generated in LJ charts broken down into months or by standard QC batch number.

2.3 IQA/EQA for AMR, CBC and Clinical chemistry

2.3.1 Laboratory should participate in EQA or a blinded IQA scheme for AMR in microbiology, CBC and clinical chemistry.

2.3.2 Reports should be filed in the lab.

2.3.3 Critical values indicated below should be tracked to confirm if they are normal;

a) Clinical Chemistry

Test	Normal	Deranged	Critical
Sodium	135-145	126-134 and 145 to 159	<125 and >160
Potassium	3.5-4.5	2.1-2.4 and 4.6-5.9	<2.0 and >6
Creatinine	0-80	81-174	>175
Phosphate	1.3-2.6	0.7-1.2 and >2.6	<0.6
Calcium (corrected)	2.1-2.8	1.8-2.0 and >2.8	<1.7 and >3.5
Magnesium	1.6-2.5	0.7-1.5 and >2.6	<0.6 and >3.2
Albumin	32-40	20-31	<20
ALT	7-60	>60	>250
Total bilirubin	<40	>40	>200
Blood glucose	3.5-8	1.8-3.5 and 8-15	<1.8 and >15

b) CBC

Test	Normal	Deranged	Critical
Haemoglobin	9-15	4-<9 and >15	<4
WCC	6-15	1-<6 and 15-29	<1 and >30
Neutrophil count	1-8.5	0.6-1 and 8.6-24	<0.5 and >25
Lymphocyte count	2-7	0.5-2 and 7.1 -25	>25
Platelets	150—400	50-150 and 400-999	<50 and >1000

2.4 **Occurrence Management**

2.4.1 In GCLP, occurrence management addresses non-conformities that happen in the lab. Non-conformances are actions that do not comply with the Laboratory standard requirements. The nonconformance should be investigated to identify the root-cause and analysis done to detect the patterns or trends. The actions shall be documented to allow tracking and verify their effectiveness.

2.4.2 The following steps should be taken and recorded:

2.4.2.1 Description of the problem/non-conformance

2.4.2.2 Implementing an immediate action/correction

2.4.2.3 Performing an investigation and determining root cause

2.4.2.4 Implementing an effective corrective action

2.4.2.5 Performing follow up to assess the effectiveness of the corrective action implemented.

2.4.2.6 Closure.

2.4.3 The above exercise 2.4.2 is termed as CAPA.

2.5 **GCLP training and accreditation.**

2.5.1 Lab personnel should undergo initial GCLP training and refresher training after every year. Online courses by global health network for basic GCLP training.

2.6 **Specimen & data trail records**

2.6.1 Specimen should have sample chain of custody that can be audit trailed. All sample transport to the lab from the clinical area or field, must be transported with a CHAIN CRF and a transport log.

2.6.2 Lab personnel should countercheck samples against CRF and transport log, sign and file them.

2.7 **Compliance with SOP**

2.7.1 Training and competency on all CHAIN SOPs should be performed.

2.7.2 The primary objective of the Training and Competency assessment system is to provide a systematic framework for training and competency assessment and documentation of these events in a timely and effective manner.

2.7.3 The should be performed:

2.7.3.1 When staff is newly hired.

2.7.3.2 When job responsibilities or duties change.

2.7.3.3 When recommended as part of a corrective action investigation.

2.7.3.4 When new procedures are introduced

2.7.3.5 After absence for a period during which certain changes have occurred.

2.7.4 Training method can be through; direct observation of routine assay/procedure performance or assessments of procedure performance through blinded testing of previously

2.7.5 Rating score should be documented to indicate; needs more training or competent to perform the task independently or competent to train and assess others.

2.8 **Specimen Reception, handling & transportation**

2.8.1 Site lab should designate a sample reception area. The reception process should involve counter checking lab CRF and transport log with specimen label.

2.8.2 Lab staff should be vaccinated against Hepatitis b.

2.8.3 Lab staff should consider all samples as potentially infectious and PPE must be worn in the lab.

2.8.4 Sample reception criteria should be based on the following:

Sample rejection criteria	Actions and Comments
Specimens not accompanied by a CRF.	Request sample courier to bring correct CRF. Continue with sample processing
Specimen in leaking containers	Reject and discard sample. Request for a second collection
Soiled requisition forms (specimen received with CRF soiled or wet with blood or any other fluid).	Reject and discard sample. Request for a second collection
Specimen with incomplete CRF entries e.g. DOB, gender, IDs.	Request clinical team to complete CRF. Continue with sample processing
Unlabeled Specimens	Reject and discard sample. Request for a second collection
Incorrectly Labeled (Mislabeled) Specimens	Reject and discard sample. Request for a second collection
Incorrect Container or preservative	Reject and discard sample. Request for a second collection
Presence of clots in anti-coagulated specimens	Reject and discard sample. Request for a second collection in the correct anti-coagulant.

2.8.5 When sample(s) are rejected, fill in a sample rejection form and feedback to the clinical team and study coordinator.

2.9 **Personnel training folders and evaluation**

2.9.1 GCLP requires that records of qualifications, trainings, experience, job descriptions, roles and responsibilities for each individual working within the GCLP research laboratory are maintained. Evidence of such qualifications is vital through up-to-date curriculum vitae, accreditation agency, the ethics committees and/or the regulatory authority.

2.9.2 Lab staff will be required to file their documents in the personal training file and to update them in their respective training folders;

- 2.9.2.1 Curriculum Vitae in a standard template (signed and dated)
- 2.9.2.2 A copy of individual's formal qualification.
- 2.9.2.3 A copy of individual's registration with the professional body or board.
- 2.9.2.4 Job Description for the position (signed by both the individual and the line manager or study coordinator or PI).
- 2.9.2.5 Roles and Responsibilities (signed by both the individual and the line manager or study coordinator or PI)
- 2.9.2.6 A record of Induction and Orientation Trainings.
- 2.9.2.7 Records of In-House / On-the-Job Trainings.
- 2.9.2.8 Records of assessment of competence.
- 2.9.2.9 Records Re-Trainings.
- 2.9.2.10 A certificate/record of Hepatitis vaccination.
- 2.9.2.11 Records of participation in Workshops, Seminars and conferences.

2.9.3 Lab staff are required to ensure that his/her file is current and updated

2.10 **Create opportunities towards quality improvement**

2.10.1 Site lab should meet on regular basis to identify site specific challenges relating to their lab. All discussions should be in minutes. All challenges identified should be recorded and a practical solution identified towards quality improvement.

3.0 References

3.1 DAIDS guidelines - https://www.niaid.nih.gov/sites/default/files/gclp.pdf

3.2 WHO GCLP guidelines - http://www.who.int/tdr/publications/documents/gclp-web.pdf?ua=1.

4.0 Document history

Version	Author	Approved by	Dated
1.0 CHN 67: CHAIN Quality Assurance (MASTER)	Robert Musyimi	Caroline Tigoi	25/07/2018

5.0 Site training record

All sites are required to maintain a master copy of this SOP that documents the site staff that have been trained on this SOP.

Document History				
Version No.	**Trained staff initials**	**Signature of trained staff**	**Date**	**Trainer's Initials**

6.0 Appendices