Introduction to Quality Management Systems

LABORATORY QUALITY WORKSHOP

21-22 October 2020
You are the Clinical Laboratory Manager in the Medical Research Centre. The Chemistry instrument needed replacement of laser/filter. The Engineer was informed upon which he flew and replaced the part and flew back. Since he did not wish to miss his flight, he said he will send the worksheet when he reach his office. The Lab staff on late shift reported to work after Engineer had left and he immediately processed 13 samples he found stored in the refrigerator 2-8°C. The Lab Tech, analyzed the samples, reported and released results to the Clinician on call. The Clinician on call noticed an elevated ALT, AST and gamma GT on 3 different results. The Clinician called the Lab to confirm the 3 results since they were not correlating with the patient conditions.

- What factors could have contributed to this scenario?
- How will you investigate this occurrence?
- Should the Doctor trust the other 10 results?
- Which phase of Quality System did this error occur?
- As the Laboratory Manager, what measures will you put in place to prevent this from recurring?
Laboratory provides service by transforming human organic materials into information.

Making participant management decision – information produced by the Lab can change the way Physician thinks and acts.

Determine eligibility of the study participants.

Monitoring the Safety of the intervention.

Determine the primary study endpoint.
QUALITY MANAGEMENT SYSTEMS (QMS)

INTRODUCTION TO QMS

Body Organic materials transform into information complex

People

Procedures

Processes

Minimize errors in the Lab

Quality Assurance (QA)

Perform properly

Quality Control (QC)

Performed in the best possible ways

Accurate

Reliable

Reproducible

Repeatable

QUALITY MANAGEMENT SYSTEMS (QMS)
RElATIONSHIP BETWEEN QC / QA / QMS

- **QC**: Measure method/procedure performance
- **QA**: Measure process performance
- **QMS**: Monitors the entire system

Clinical, Clinical Trials, Research Laboratories
Compare & Contrast: QA & QC

**QA**
- Proactive approach: eliminating errors before they have a chance to appear.
- Monitors accuracy, reliability & timeliness of total testing process.
- Prevent mistakes
- Whole team effort

**QC**
- Output: result produced by analyzer
- Reactive approach responding to events after they have happened
- Monitors activities related to the analytical phase of testing.
- Detect Mistakes
- Specific Team effort

QMS
QMS PHASES

PRE-ANALYTICAL PHASE
- Request Forms
- Sample collection / Transport / Storage
- Sample Labelling & identification
- Staff Training
- Errors 60%
  - Misidentification
  - Inappropriate Specimen Collection

POST-ANALYTICAL PHASE
- Review & Release of Results.
- Communication between Lab & Ward
  - Errors 23%
  - Transcription errors
  - Critical Value not reported

ANALYTICAL PHASE
- Sample Reception
- Equipment Validation
- Method validation
- IQC System
- Reagents & Kits validation
- Errors 15%
  - Undetected QC failure
  - Use of expired reagent

COMPLEMENTATRY PHASES
Poor QMS Leads to Lab Errors

Consequences of Laboratory Errors

- Failure to provide to provide proper treatment
- Additional & unnecessary diagnostic testing
- Unnecessary Treatment & treatment complications
- Delay in correct diagnosis
- Provision of inappropriate care
NON-QMS / NON-GCLP LAB (tip of Iceberg)

WHAT YOU CAN SEE
- Low staff morale
- Customers Complaints

WHAT YOU CANNOT SEE
- False Positive/Negative
- Transcription errors
- Sent to wrong location
- Rejected Samples
- Lost specimens
- mislabeled/unlabeled
- Shortcuts
- QC failures ignored
- Downtime
- Out of stock
- No calibration
- QC failures ignored
LAB ACCREDITATION / GCLP COMPLIANT

- Oblivious of the problem
- Obfuscate problems
- Ignore failures
- Does not Investigate
- Take no action

- Detects problems
- Investigate
- Take Action
- Errors <1%
KEY STEPS TO QMS IMPLEMENTATION

**STEP 1**

- COMMITMENT OF TOP MANAGEMENT
  - Motivation & support to staff.
  - Allocation of resources
  - Quality policy
  - Selection of standard

**STEP 2**

- INVOLVEMENT OF LAB STAFF
  - The staff should own the process
  - Buying in

**STEP 3**

- GAP ANALYSIS WITH SELECTED STANDARDS
  - Define the target
  - Develop a plan
  - Delegate Responsibilities

**STEP 4**

- IMPLEMENT THE QMS PLAN
  - Start with Technical areas – IQC & EQAS
  - Documentation – SOPs, Training etc

**STEP 5**

- LAB AUDIT
  - Train the Internal Auditor
  - Re-evaluate the Gap between std & current status
  - Implement CAPA

**The QMS Milestone**

- 1-2 years
- 3-6 Months
- 6-8 Months
ORIGIN OF GCLP

GCLP PRINCIPLES
- 2002 WHO Handbook Pub
- Good Clinical Research Practice
- Specific Health Medical Products & Treatment Practices
- SAFE
- EFFECTIVE
- Conduct Clinical Research / Trials

GCLP applies STDs established
Under GLP relevant to analysis
of samples from Clinical Trials while ensuring that the Principles of GCP are satisfied

GCP: No define std for Labs

GCP No specifics for Laboratories. Asking for
- Lab Ref Values
- Lab Accreditation
- Quality Control

GCP: Safety, Rights & Well-being of participants

GLP principles: ensure consistency, reliability, reproducibility, quality & integrity of Non-Clinical studies

GLP Principles Established 1990's by OECD

Hybrid of GCP & GLP

Specific Health Medical Products & Treatment Practices

GCP No specifics for Laboratories. Asking for
- Lab Ref Values
- Lab Accreditation
- Quality Control

GLP: Not specific for Labs Supporting clinical studies

2002 WHO Handbook Pub
Good Clinical Research Practice

Hybrid of GCP & GLP

Specific Health Medical Products & Treatment Practices

GCP: No define std for Labs

GCP No specifics for Laboratories. Asking for
- Lab Ref Values
- Lab Accreditation
- Quality Control

GCP: Safety, Rights & Well-being of participants

GLP principles: ensure consistency, reliability, reproducibility, quality & integrity of Non-Clinical studies

GLP Principles Established 1990's by OECD
WHICH WAY TO GO?
GCLP or ISO 15189/WHO AFRO SLIPTA

- GCLP Guidelines
  - Lab decides its own Standards.
  - Less cost implications

- ISO 15189/AFRO WHO SLIPTA
  - Lab follow the standards prescribed by a third party.
  - High Cost implications

Run concurrently
Good for Labs supporting multinational studies

BOTH GCLP & ISO 15189
COMPARE & CONTRAST (ISO15189 & GCLP Standards)

**GCLP**
- Specimen Transport Management.
- Infrastructures.
- Standard Operation Procedures.
- Validation & Verification
- Analytical Plan
- Archiving of Records
- Safety in Laboratories

**SHARE**
- Document Control
- Quality Management
- Corrective Actions
- Records Control
- Reporting of Results
- Laboratory Information System
- Audits

**ISO15189**
1. Customer Feedback
2. Resolution of complaints
3. Continuous Improvement
4. Preventive Action
5. Management Review
6. Quality Plan
7. Service Agreements
8. Identification & Control
9. Examination by Referral Lab
DIFFERENT STANDARDS SAME GOAL

POTENTIAL BENEFITS OF QMS / GCLP

LAB SYSTEMS
Efficient and Reliable

LAB PROCESSES – Standardized & Consistent

LAB PROCEDURES – Reproducible & Repeatable

LAB RESULTS
Accurate and Precise

LAB REPORTING
Timely and Prompt
You are the Clinical Laboratory Manager in the Medical Research Centre. The Chemistry instrument needed replacement of laser/filter. The Engineer was informed upon which he flew and replaced the part and flew back. Since he did not wish to miss his flight, he said he will send the worksheet when he reach his office. The Lab staff on late shift reported to work after Engineer had left and he immediately processed 13 samples he found stored in the refrigerator 2-8°C. The Lab Tech, analyzed the samples, reported and released results to the Clinician on call. The Clinician on call noticed an elevated ALT, AST and gamma GT on 3 different results. The Clinician called the Lab to confirm the 3 results since they were not correlating with the patient conditions.

1) What factors could have contributed to this scenario?
2) How will you investigate this occurrence?
3) Should the Doctor trust the other 10 results?
4) Which phase of Quality System did this error occur?
5) As the Laboratory Manager, what measures will you put in place to prevent this from recurring?
1) What factors could have contributed to this scenario?
   1) Analyzer part was replaced but Calibration was not done.
   2) Personnel issues
   3) Staffing / workload
   4) Staff handover
   5) Incomplete Equipment service

2) Should the Doctor trust the other 10 results? Why?
   – Doctor should not make any decision on the 13 results until root cause is investigated and resolved.
   – Results appears inaccurate
3) How will you investigate this occurrence?
   – Run the QC materials
   – Check Calibration
   – Repeat the 13 samples (old sample & fresh samples)

4) Which phase of Quality System did this error occur?
   - Pre-Analytical Variables
     ✓ Personnel
     ✓ Method
     ✓ Materials
     ✓ Instrument / machine
     ✓ Environment
5) As the Laboratory Manager, what measures will you put in place to prevent this from recurring?

- Use the incident as opportunity for Quality improvement
- Arrange for Laboratory staff Training
- Clarify the contract with the Vendor and spell out the scope of work.
- Standard Operating Procedure
- Equipment Log book
- Staff Handing over log
Acknowledgements

Prof Trudie Lang
Director, The Global Health Network

The Global Health Network Operational Team:
Liam Boggs  Helena Wilcox  Bonny Baker
Alex Segrt  Sada Aliyeva  Ken Awuondo
Zainab Al-Rawni  Lauren Whelan  Welile
Sinead

Funding:
The Bill and Melinda Gates Foundation