Introduction to Quality Management Systems

LABORATORY QUALITY WORKSHOP

21-22 October 2020

THE GLOBAL HEALTH NETWORK

Enabling research by sharing knowledge

PANDORA

Pan-African Network For Rapid Research, Response and Preparedness for Infectious Diseases Epidemics

CANTAM

Central Africa Clinical Research Network

www.theglobalhealthnetwork.org

CASE SCENARIO

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- 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 2-8C. 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?

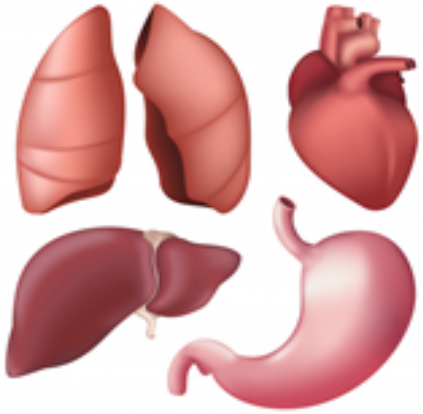
ROLE OF CLINICAL LABORATORIES

Research / Clinical Trials / Clinical Laboratories

- 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

INTRODUCTION TO QMS

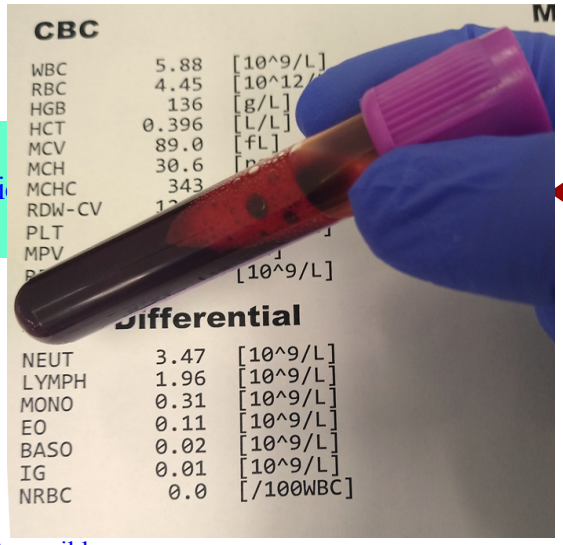
Body Organs



dy Organic materials transform into informati

complex

Performed properly



Quality Control (QC)

Performed in the best possible ways

- Minimize errors in the Lab

❑People
❑Procedures
❑Processes

❑Accurate
❑Reliable
❑Reproducible
❑Repeatable

Quality Assurance (QA)

QUALITY MANAGEMENT SYSTEMS (QMS)

RELATIONSHIP BETWEEN QC / QA / QMS

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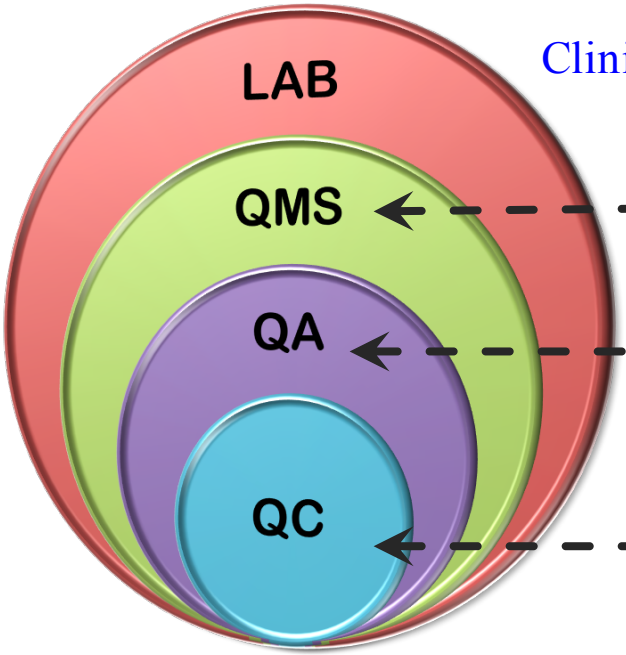


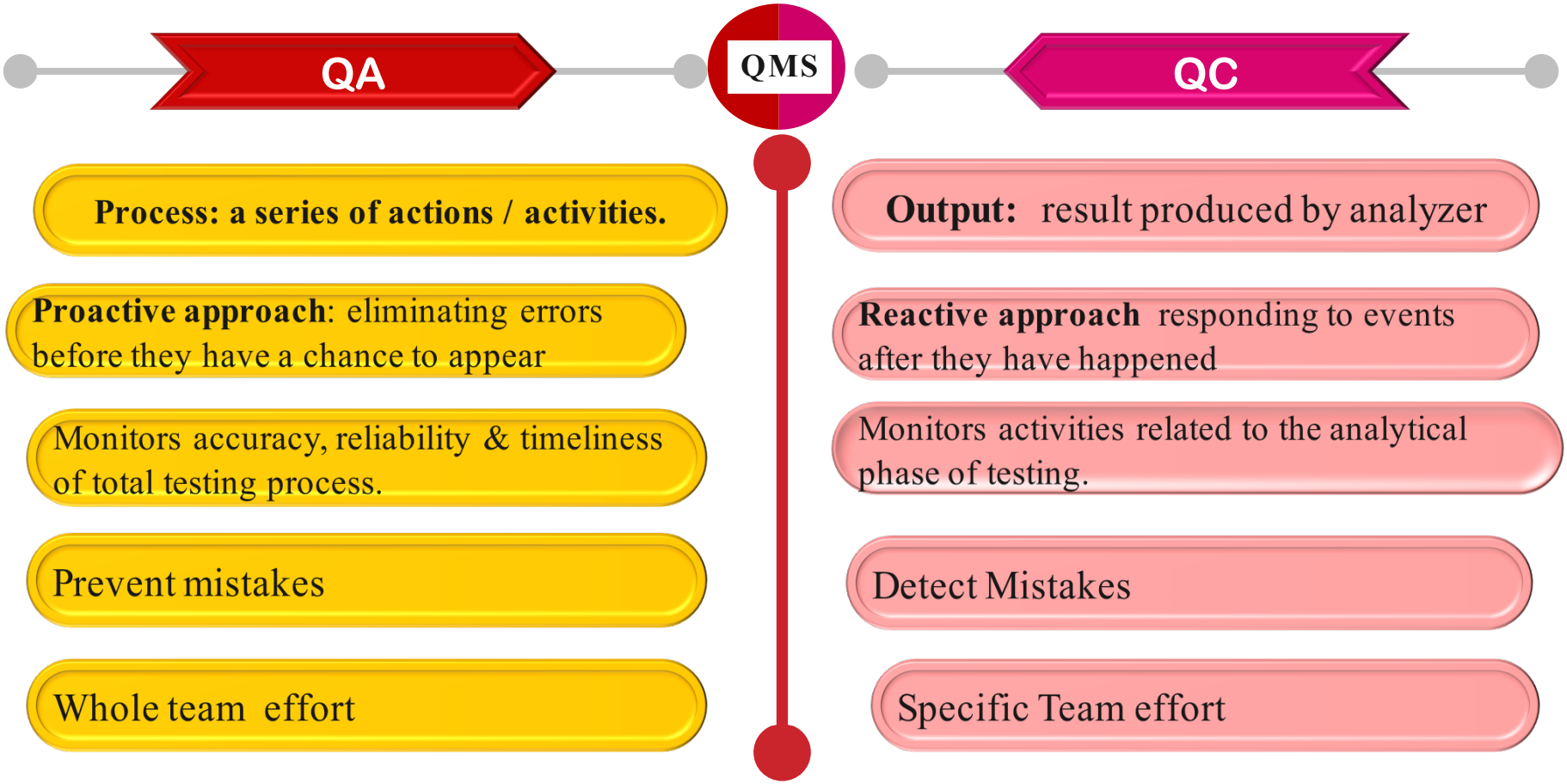
Clinical, Clinical Trials, Research Laboratories

Monitors the entire system

Measure process performance

Measure method/procedure performance

Compare & Contrast: QA & Q C

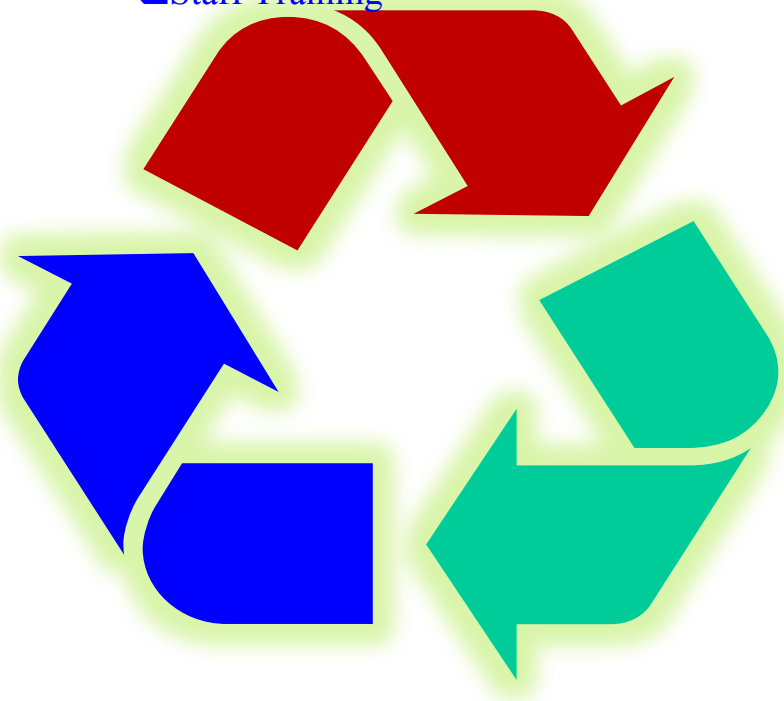


QMS PHASES

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

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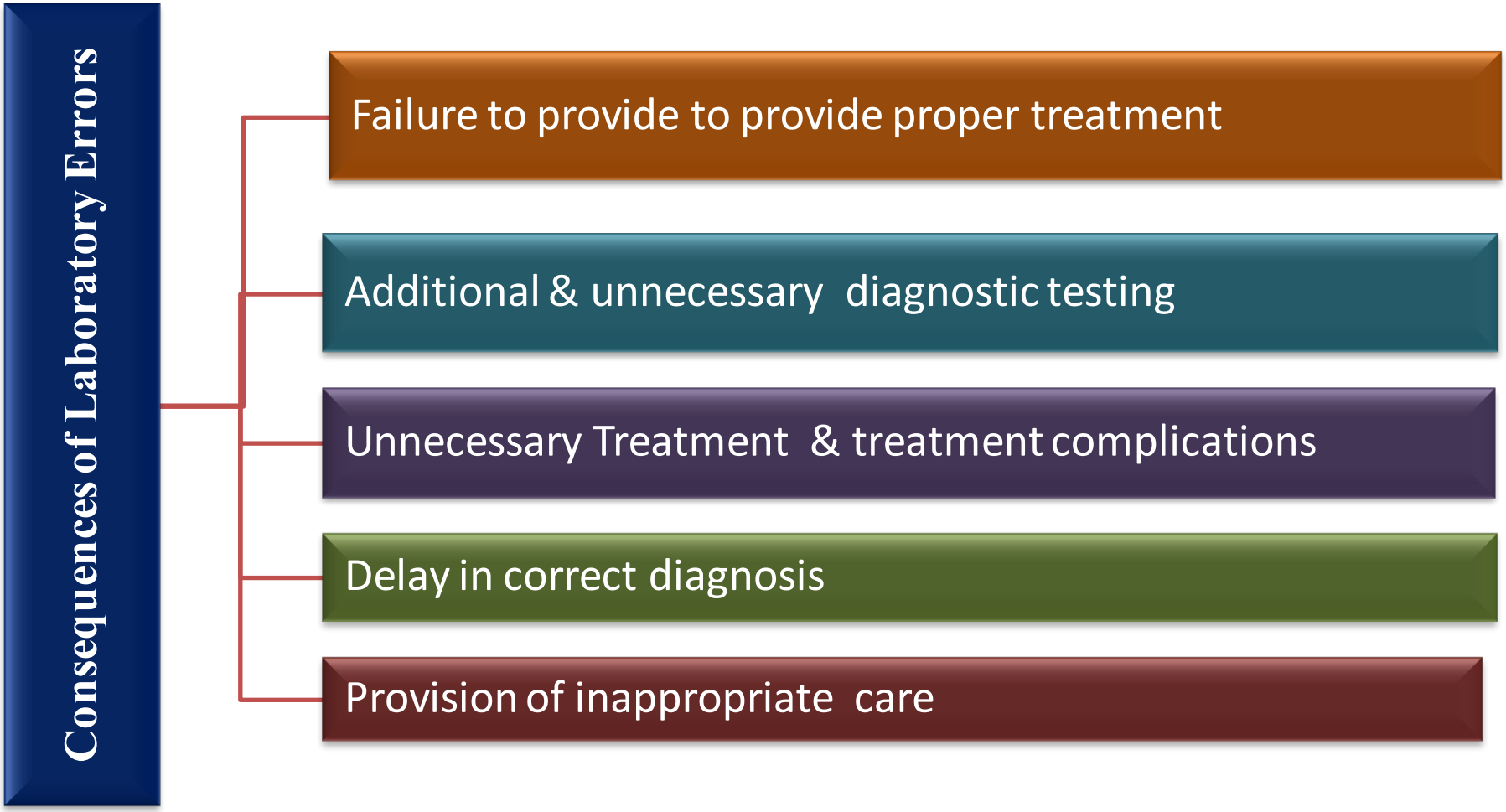
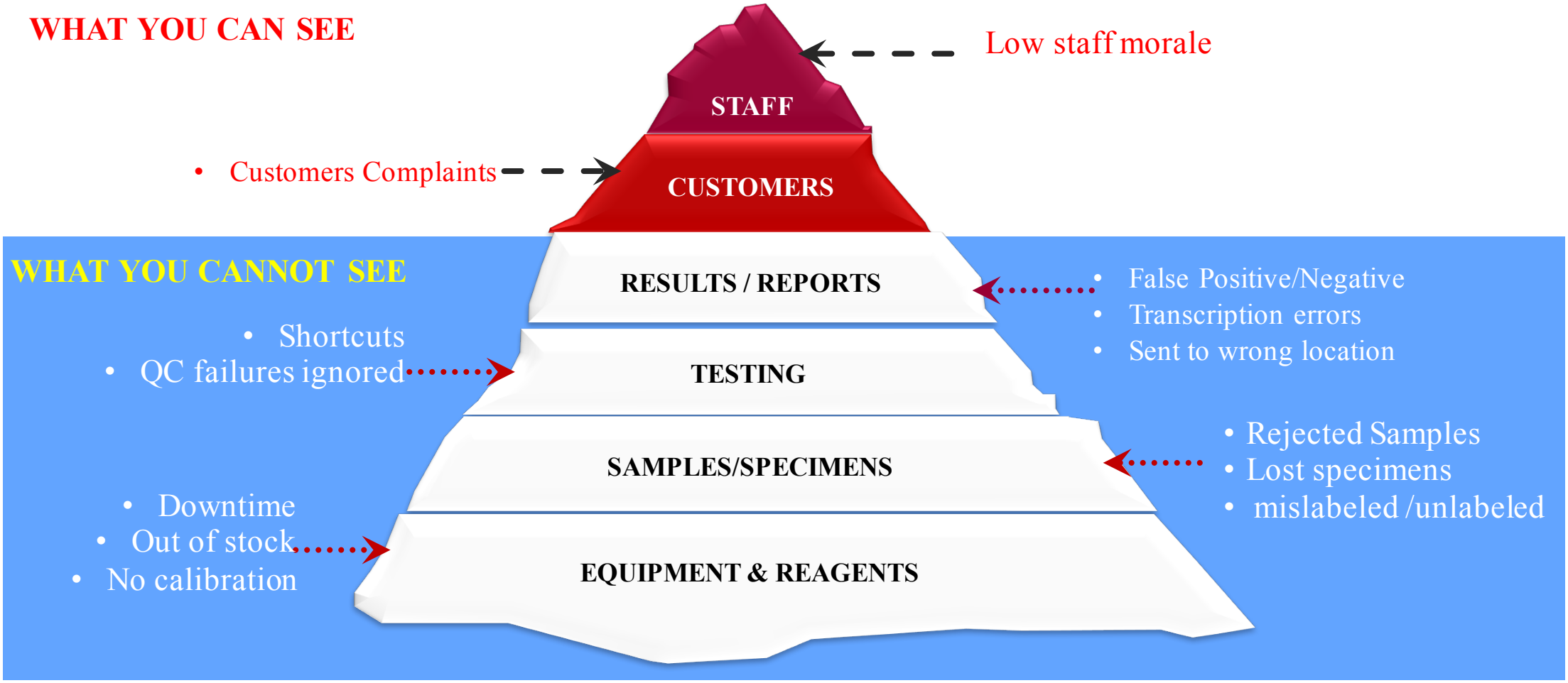


NON-QMS / NON-GCLP LAB (tip of Iceberg)



LAB ACCREDITATION / GCLP COMPLIANT

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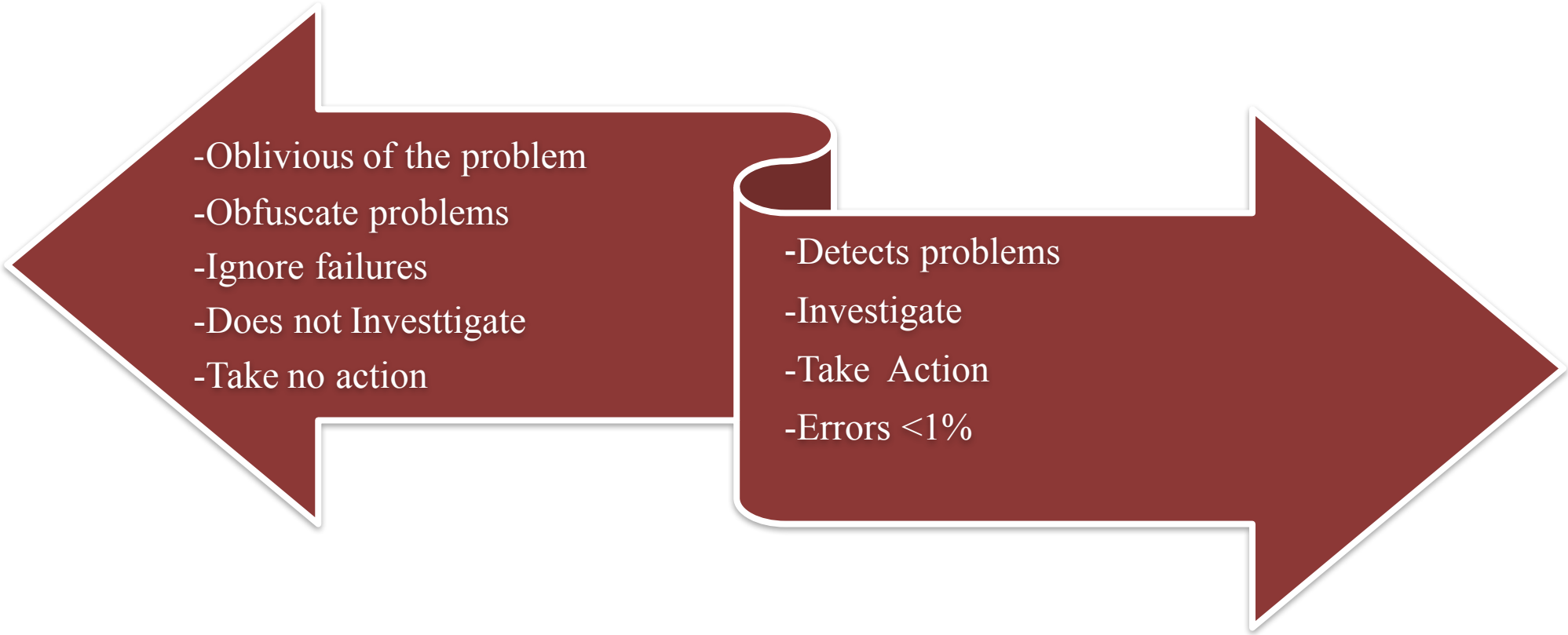
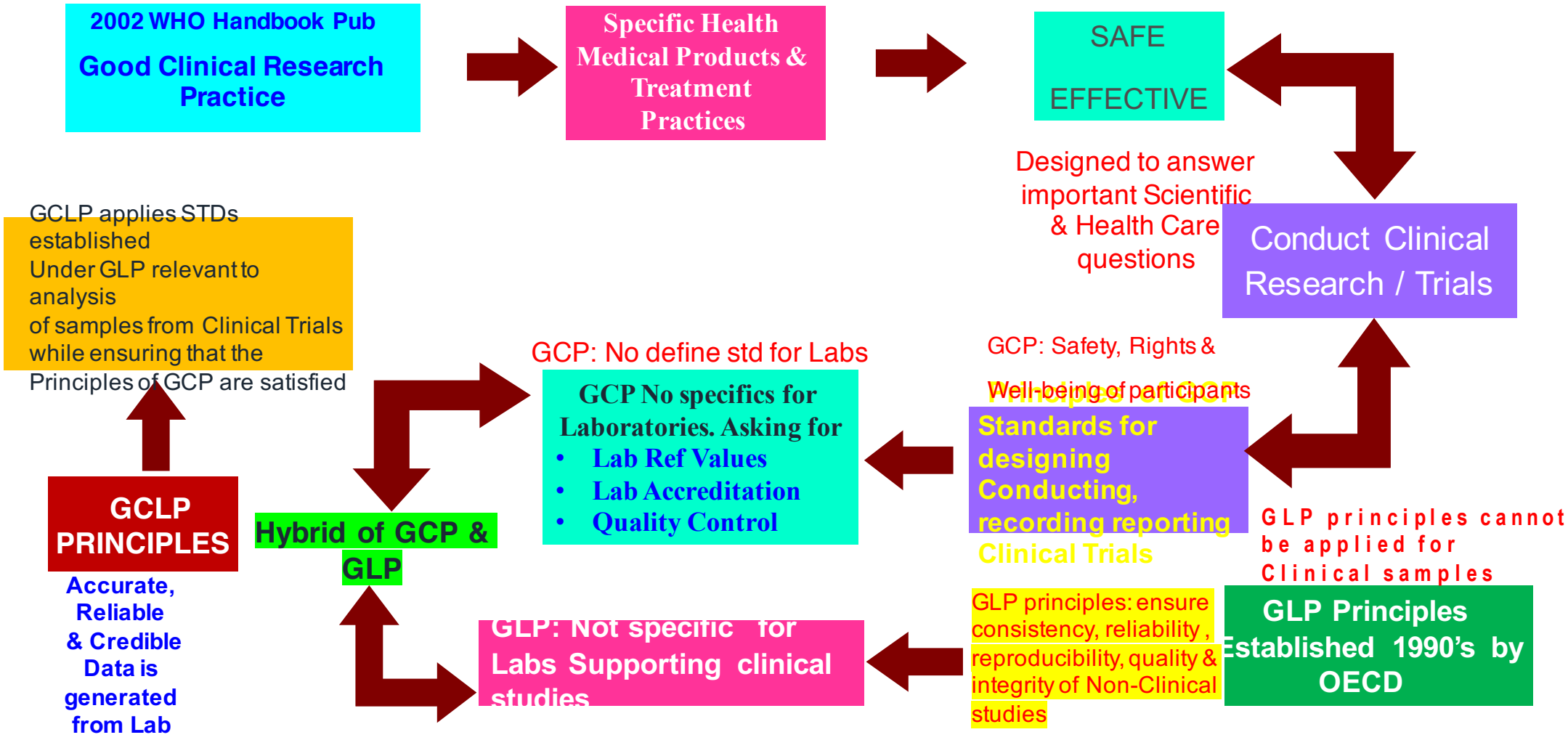


QMS BUILDING BLOCKS

KEY STEPS TO QMS IMPLEMENTATION

ORIGIN OF GCLP

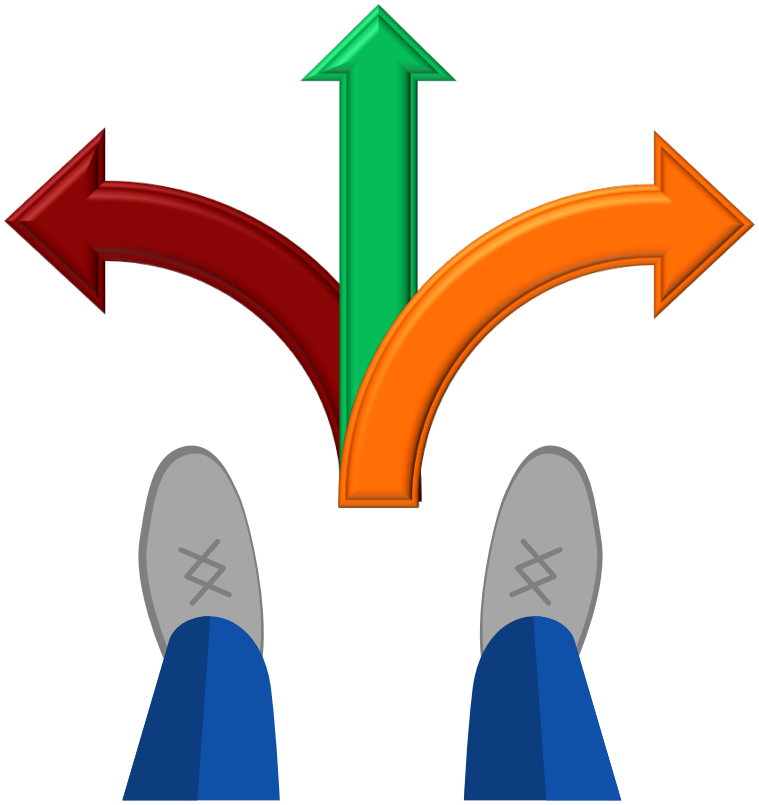


WHICH WAY TO GO?

GCLP or ISO15189/WHO AFRO SLIPTA

Run concurrently
Good for Labs supporting multinational studies

BOTH GCLP & ISO 15189



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

COMPARE & CONTRAST (ISO15189 & GCLP Standards)

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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 Feed back

2.Resolution of complaints

3.Continuous Improvement

4.Preventive Action

5.Management Review

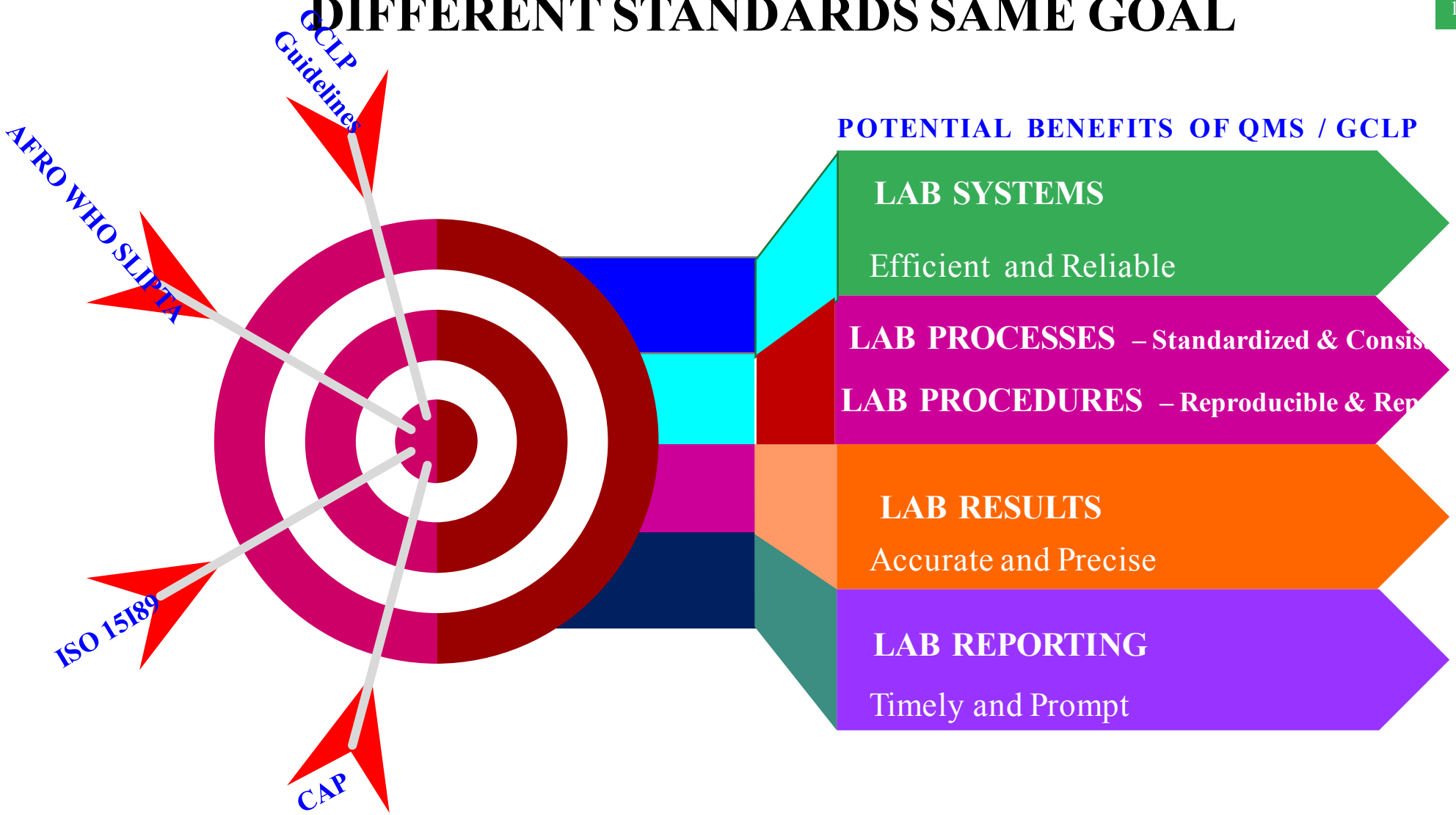
6.Quality Plan

7.Service Agreements

8.Identification & Control

9.Examination by Referral Lab

DIFFERENT STANDARDS SAME GOAL



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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

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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

CASE SCENARIO

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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

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