Global Health Partnerships

“The Key to Quality: CLSI Approach to developing QMS

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Learning Objectives

• Explain and define the Quality System
• List the quality system essential elements
• Discuss relationship of this quality model to ISO and CLSI standards
• Describe the purpose and advantages of a Quality Manual
• Be able to format your Quality Manual
Global Health Partnerships
LSDB: Tbilisi, Georgia
Republic of Georgia
დაარსებულიყო რეგიონული და საზოოფიზიონო-ჰიგიენაში სამუშაოების შესაძლო ფუნქციის თარგმანის მიღების სახელშეფერად საბჭოური მიერ გამოცემულ ბიუროგრაფიულ ფაქტორებისთან დაკავშირებით.

2010 წლის 5 აგვისტო
2010 წლის დაარსებულიყო რეგიონული და საზოოფიზიონო-ჰიგიენაში სამუშაოების შესაძლო ფუნქციის თარგმანის საბჭოური მიერ გამოცემულ ბიუროგრაფიულ ფაქტორებისთან დაკავშირებით.

კ. ლ. ა. ს. ი.
NCDC
Before
After
NCDC

- founded in 1996 served as Georgian Station for the plaque
- Economic collapse health care system became non-existent
- Support of CDC, WHO, NIH and others developed case definitions
- Programs for prevention and surveillance
- research
DTRA: DEFENSE THREAT REDUCTION AGENCY

- Vision: “to make the world safer by reducing the threat of weapons of mass destruction

- BTRP: Bio-Threat Reduction projects

- Russia, Kazakhstan, Uzbekistan, republic of Georgia, Azerbaijan and Ukraine

- CDC Partnership
  - build laboratory management capacity and strengthen disease surveillance of dangerous pathogens
  - surveillance and prevention
Objectives:

• Consolidate and secure dangerous pathogen collections into central reference labs or repositories

• Improve the safety and security of biological facilities

• Enhance partner states’ capabilities to detect, diagnose, and report bio-terror attacks and potential pandemics

• Engage scientists with biological weapon-related expertise in research that supports force protection, medical countermeasures, diagnostics, and modeling.
Since 2009, CLSI (GHP) partnered with CDC (DLS) to provide guidance on standards to implement QMS at the NCDC and LMA.

Goal was to establish standardized lab practices to deliver timely and accurate results (emphasis on EDPs).

2010 initial assessments performed by CLSI.

May 2010 CLSI follow-up visit.

September audited laboratories with additional checklist.

Follow-up visits to assist with the development of the Quality manuals.
Challenges

• Highly complex testing (RT PCR, PFGE, Sequencing)
• EQA, Training, Orientation
• Reagent expiration/Costs/validation
• Where to begin?
• Translations (variation)
• Strategizing
• BTRP SOPs and National Quality Assurance Program
Accomplishments

• Developed draft process to implement BTRP SOPs

• Organized and focused Quality teams

• Drafts of Introduction, Organization, Personnel and Documents and Records complete

• Working on Equipment, logs etc

• Initiated implementation of BTRP SOPs
Is there a choice?

QUALITY LOW PRICES

SALSA COUNTER

"Which one do you want?"
Quality and the Delivery of Health Care

Essential to all aspects of health care are **laboratory results** that are

- accurate,
- reliable, and
- timely
“Quality means doing it right when no one is looking.”

Henry Ford
"They don't make them the way they used to."
QUALITY is ACHIEVED BY:

• Determining the customer’s precise requirements

• Ensuring that all resources, facilities and skills required to meet the customer’s requirements are available

• Planning, documenting and implementing management procedures to ensure that the customer’s requirements are met consistently

• Ensuring that staff are trained and provided with the resources to do the job right the first time
QUALITY is ACHIEVED BY: [cont]

• Ensuring that all activities are undertaken correctly

• Ensuring that when things go wrong, effective corrective action is taken to avoid repetition of errors

• Undertaking regular reviews and audits of all processes

• Total and organized commitment from management
Complexity of Laboratory System

- Data and Lab Management
- Safety
- Customer Service

- Patient/Client Prep
- Sample Collection

- Record Keeping
- Quality Control Testing

- Reporting

- Pre-Analytic

- Personnel Competency Test Evaluations

- Sample Receipt and Accessioning

- Sample Transport

- Post-Analytic
Twelve Quality System Essentials

set of coordinated activities that function as building blocks for quality management
A Systems Approach to Quality

- Considers all components within a system
- Identifies the connection and relationship (e.g., cause and effect) among the components

Example: the human body system
A headache may be caused by disorder of other components in the system
Quality Management System Definition

Coordinated activities to direct and control an organization with regard to quality (ISO, CLSI).

All aspects of the laboratory operation need to be addressed to assure quality; this constitutes a quality management system.
Laboratory Quality Systems Initiative

- Encourage all laboratories to use quality system concept
- Provide training and materials for use
- Provide technical assistance and support for quality system development and implementation
Framework

- Common definitions
- Importance of ISO/CLSI philosophy
- Aim for simplicity
- Convey importance of systems approach
References:
<table>
<thead>
<tr>
<th>ISO</th>
<th>CLSI</th>
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<tr>
<td>International Organization for Standardization</td>
<td>Clinical and Laboratory Standards Institute (formerly known as NCCLS)</td>
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<tr>
<td>Guidance for quality in manufacturing and service industries</td>
<td>Standards, guidelines, and best practices for quality in medical laboratory testing</td>
</tr>
<tr>
<td>Broad applicability; used by many kinds of organizations</td>
<td>Detailed; applies specifically to medical laboratories</td>
</tr>
<tr>
<td>Uses consensus process in developing standards</td>
<td>Uses consensus process in developing standards</td>
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ISO Documents - Laboratory

**ISO 9001:2000 Quality Management System Requirements**
Model for QA in design, development production, installation, and servicing

**ISO/IEC 17025:2005** General requirements for the competence of testing and calibration laboratories

**ISO 15189:2007** Quality management in the clinical laboratory
ISO 15189:2007

• Medical laboratories—Particular requirements for quality and competence

• The foundation of international medical laboratory quality management
QUALITY SYSTEM MANUAL

- Policies
  - “what to do”

- Processes
  - “how it happens”

- Procedures
  - “how to do it” - (SOPs)
• IF IT IS NOT WRITTEN DOWN IT DID NOT HAPPEN!!!
The Importance of Documentation

"About these experiments you've conducted for twelve years...no one remembers hiring you."

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At the starting blocks! Step-by-step!
Developing your quality manual (QM)

Step 1: Hire, appoint or delegate someone to take control of the QMS implementation process.

Step 2: Collect your start-up tools – a binder, paper, a notebook, pens, pencils, a flash drive or a computer. The manual can be paper-based or electronic.

Step 3: Select a team from lab management, staff and key stakeholders e.g. senior health administrators to develop your ‘Quality Policy Statement’ and to input, where feasible, into your general administrative policies especially if your lab is located within a larger organisation.

One step at a time.
Continued

- **Step 4**: Encourage all staff to get involved in developing policies and procedures and defining the processes that are required to translate written policies into action and train them.

- **Step 5**: Decide on the format of your manual

- **Step 6**: Initiate & complete the writing of your quality manual. Remember to get everyone involved

- **Step 7**: Conduct a document gap analysis (i.e the missing process & procedure documents)

- **Step 8**: Develop & initiate a plan to fill gaps
A Quality Manual should....

1. Address all Quality System elements

2. Contain or refer to quality procedures

"Documentation"

• The Key is to move towards:

  – Consistently repeating the best practices

  and

  – Improving those processes which are lacking
Quality Manual

- communicates information
- serves as a framework for meeting quality system requirements
- demonstrates management’s commitment to quality
Maintaining the Quality Manual

- communicates quality policy
- needs management approval
- requires updating
Customizing your manual ?!

- Formatting the manual
- Designing cover page
- Header and footer
- Table of contents
Path of Workflow

- Organization
- Personnel
- Equipment
- Purchasing & Inventory
- Process Control
- Information Management
- Documents & Records
- Occurrence Management
- Assessment
- Process Improvement
- Customer Service
- Facilities & Safety

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Implementing Quality Management does not guarantee an \textit{ERROR-FREE} Laboratory.

But it detects errors that may occur and prevents them from recurring.
ISO 15189:2007

• The foundation of international medical laboratory quality management

• Medical laboratories—Particular requirements for quality and compete
In summary

• Quality management is not new.

• Quality management grew from the good works of innovators who defined quality over a span of 80 years.

• Quality management is as applicable for the medical laboratory as it is for manufacturing and industry.
Key Messages

• A laboratory is a complex system and all aspects must function properly to achieve quality.

• Approaches to implementation will vary with local situation.

• Start with the easiest, implement in stepwise process.

• Ultimately, all quality management system elements must be addressed.