Outline of the session

- Why is a laboratory quality system important?
  - Group exercise
  - Discussion
- Laboratory Quality Management System (LQMS) Training Toolkit
  - Content
  - Structure
- Discussion
Why a laboratory quality system is important? - Exercise

- 2 groups of participants
- Each group receives a scenario & questions
- Each group designate a moderator and a rapporteur
- 30 minutes to answer the questions
- Write elements of answer on paper cards (write BIG)
- The moderator will debrief in plenary

Why a laboratory quality system is important? – Wrap up

- Wrap up the previous activity + discussion
- Introduction of the toolkit
What is “quality”?

- Quality is defined as conformance to requirements, not as 'goodness' or 'elegance'.
- “Laboratory quality” often refers to accuracy, reliability, and timeliness of the reported test results.

Achieving a 99% level of quality means accepting a 1% error rate
In France a **1% error rate** would mean **everyday**

- 14 minutes without water or electricity
- 50,000 parcels lost by postal services
- 22 newborns falling from midwives’ hands
- 600,000 lunches contaminated by bacteria
- 3 bad landings at Orly Paris airport

Result: **1% failure**
Essential to all aspects of health care are laboratory results that are

- accurate,
- reliable, and
- timely

Laboratory errors cost in

- time
- personnel effort
- patient outcomes
How do we achieve excellent performance in the laboratory?

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.
CLSI Quality Stage Model

<table>
<thead>
<tr>
<th>Stage</th>
<th>Activities Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Quality Management</td>
<td>Management approach centered on sustained high quality, by focusing on long-term success through customer satisfaction.</td>
</tr>
<tr>
<td>Quality Cost Management</td>
<td>Includes the stages below and also the economic aspects of the “cost of quality.”</td>
</tr>
<tr>
<td>Quality Assurance</td>
<td>Planned and systematic activities to provide confidence that an organization fulfills requirements for quality.</td>
</tr>
<tr>
<td>Quality Control</td>
<td>Operational process control techniques to fulfill requirements for quality and governmental compliance.</td>
</tr>
</tbody>
</table>

Sensitization/Realization

Complexity of a Laboratory System

- Data & Laboratory Management
- Safety
- Customer Service

- Preexamination
  - Personnel Competency Test Evaluations
  - Sample Receipt and Accessioning
  - Sample Transport

- Examination
  - Patient/Client Prep
  - Sample Collection
- Postexamination
  - Record Keeping
  - Quality Control Testing

- Reporting
Path of Workflow

THE PATIENT -> Test selection -> Sample Collection

Preexamination Phase

Sample Transport

Laboratory Analysis Examination Phase

Result Interpretation Postexamination Phase

The Quality Management System Model

The 12 QSEs function as the building blocks

The 12 QSEs function as the building blocks
WHY is the Path of Workflow essential to consider in health laboratories?

The **entire process** of managing a sample must be considered:
- the beginning: sample collection
- the end: reporting and saving of results
- all processes in between.

Laboratory tests are influenced by
- laboratory environment
- knowledgeable staff
- competent staff
- reagents and equipment
- quality control
- communications
- process management
- occurrence management
- record keeping
Twelve Quality System Essentials

set of coordinated activities that function as building blocks for quality management

Path of Workflow
Implementing Quality Management **does not** guarantee an **ERROR-FREE** Laboratory

But it detects errors that may occur and prevents them from recurring

Laboratories **not** implementing a quality management system guarantees UNDETECTED ERRORS
Laboratory Quality Management System

Coordinated activities to direct and control an organization with regard to quality.

ISO 9000:2000

Innovators of Quality

Walter Shewhart 1891-1967

W. Edwards Deming 1900-1993

Joseph Juran 1904-2008 (103 years)

Philip Crosby 1926-2001

Robert Galvin b. 1922
A Brief History of Quality Management

Quality Management is not new.

<table>
<thead>
<tr>
<th>Innovator</th>
<th>Date</th>
<th>Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Walter A. Shewhart</td>
<td>1920s</td>
<td>Statistical Process Control</td>
</tr>
<tr>
<td>W. Edwards Deming</td>
<td>1940s</td>
<td>Continual Improvement</td>
</tr>
<tr>
<td>Joseph M. Juran</td>
<td>1950s</td>
<td>Quality Toolbox</td>
</tr>
<tr>
<td>Philip B. Crosby</td>
<td>1970s</td>
<td>Quality by Requirement</td>
</tr>
<tr>
<td>Robert W. Galvin</td>
<td>1980s</td>
<td>Micro Scale Error Reduction</td>
</tr>
</tbody>
</table>

Standards Organizations

<table>
<thead>
<tr>
<th>ISO</th>
<th>CLSI</th>
</tr>
</thead>
<tbody>
<tr>
<td>International Organization for Standardization</td>
<td>Clinical and Laboratory Standards Institute (formerly known as NCCLS)</td>
</tr>
<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>
</tr>
</tbody>
</table>
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

- The foundation of international medical laboratory quality management
- Medical laboratories–Particular requirements for quality and competence
CLSI Quality Documents

**HS1-A2 A Quality Management System Model for Health Care**
- describes quality system model, 12 essentials
- aligns to ISO 15189 and parallels ISO 9000
- applies to all health care systems

**GP26-A3 Application of Quality Management System Model for Laboratory Services**
- describes laboratory application of quality system model
- relates the path of workflow to the quality system essentials
- assists laboratory in improving processes
- relates to HS1-A2 and ISO 15189

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**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.
Training Toolkit

Goals

Provide **comprehensive materials**

- to **design and organize** training workshops
- for **all stakeholders** in health laboratory processes
Partnership

- **WHO** Lyon Office; U.S. Centers for Disease Control and Prevention (CDC); Clinical and Laboratory Standards Institute (CLSI)

- Based on training sessions and modules provided by CDC and WHO in more than 25 countries, and on guidelines developed by CLSI for implementing a quality management system in health laboratories

Who should use this Toolkit?

Trainers in **national or international** settings

- select and **customize** materials

- to meet the needs for **local target audiences**
  - laboratory directors
  - quality managers
  - laboratory technologists
How is the Toolkit organized?

- Based on internationally recognized standards
  **ISO 15189**
  **CLSI GP26-A3**
- 18 modules organized following the CLSI
  **“12 Quality System Essentials”**

### Modules

- Introduction
- Facilities and Safety
- Equipment
- Purchasing and Inventory
- Sample Management
- Introduction to Quality Control
- QC for Quantitative Tests
- QC for Qualitative Tests

**Assessment**

- Audits
- External Quality Assessment
- Norms and Accreditation
- Personnel
- Customer Service
- Occurrence Management
- Process Improvement
- Documents and Records
- Information Management
- Organization
Structure & Materials

- Group discussions
- Case studies
- Exercises
- Simulations
- Interactive presentations

Training techniques
And also...

- Training tips and techniques
- Evaluation models and examples

CD-Rom including

- a small introduction printed booklet
- all materials in electronic format
Browse interface

ASSESSMENT:
9- Audits

Learning Objectives
At the end of this module, participants will be able to:
- develop a process to prepare your laboratory staff for an external audit;
- e.g., and identify and internal audit;
- audits from a laboratory audit;
- prepare for taking corrective actions.

QA:
- Contact sheets (doc)
- Activity sheet (doc)
- Presentation (doc)

Material for the Trainers:
- Activity sheet (doc)
- Presentation (doc)

Optional Material for the Trainers:
- Lab QM Assessment Tool - User Manual (doc)

Browse folders

File and Folder Tasks
- Make new folder
- Publish this folder to the web
- Share this file

Other Places
- Details