What is the best strategy to achieve compliance with QMS- and QC-requirements in the clinical laboratory?

Moderators

Egon AMANN – Chair, Committee of Analytical Quality (C-AQ)

Sedef YENICE – Chair, Committee of Clinical Laboratory Management (C-CLM)
What is the Goal of this Workshop?

• To enhance the participants’ understanding of strategies for dealing with several important aspects of QC before running patient tests and the key steps to establish an effective QMS,

• To have the laboratory specialists and technical coworkers more effectively address the problems in implementing continuous quality improvement efforts in the clinical laboratory.
## Strategy and Schedule

<table>
<thead>
<tr>
<th>PHASE</th>
<th>TIME (min)</th>
<th>ACTIVITY</th>
<th>By</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5</td>
<td>Opening</td>
<td>Moderators</td>
</tr>
<tr>
<td>2</td>
<td>5</td>
<td>Spontaneous group forming – max. 5 or 6 person per group and hand out of a questionnaire to groups</td>
<td>Moderators</td>
</tr>
<tr>
<td>3</td>
<td>10</td>
<td>Group Discussion. Experimenting with the ideas and finding most burning <strong>top three issues</strong> and listing those issues on flip charts by group leaders</td>
<td>Group Members</td>
</tr>
<tr>
<td>4</td>
<td>15</td>
<td>Following group discussions, group leaders will present their outcomes for the entire participants – 3 minutes max. for each group</td>
<td>Group Leaders</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>Completion and collection of the questionnaires Conclusion: Evaluating, deciding, and listing actions</td>
<td>Moderators</td>
</tr>
</tbody>
</table>
What We’ll Cover Today

<table>
<thead>
<tr>
<th>International Standards</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO 15190:2003</td>
<td>Medical laboratories -- Requirements for safety</td>
</tr>
<tr>
<td>ISO/IEC 17025:2005</td>
<td>General requirements for the competence of testing and calibration laboratories</td>
</tr>
<tr>
<td>ISO 22870:2006</td>
<td>Point-of-care testing (POCT) -- Requirements for quality and competence</td>
</tr>
<tr>
<td>ISO/TS 22367:2008</td>
<td>Medical laboratories -- Reduction of error through risk management and continual improvement</td>
</tr>
<tr>
<td>ISO 15189:2012</td>
<td>Medical laboratories -- Requirements for quality and competence</td>
</tr>
<tr>
<td>CLSI</td>
<td>CLSI in US developed the quality management framework and organized the topics as the &quot;12 Quality System Essentials&quot; based on both ISO 15189 and CLSI GP26-A3 documents</td>
</tr>
<tr>
<td>SLIPTA</td>
<td>Stepwise Laboratory Quality Improvement Process Towards Accreditation implemented by ASLM in Africa</td>
</tr>
</tbody>
</table>

**Quality Management System (QMS)**

- Stepwise plan for implementing a QMS
- To implement the QMS in a logical way, the activities are divided over 4 phases (or stages) of implementation, with each phase having a specific focus.

The requirements in each phase are defined by international standards.
Quality Management System (QMS)

Indispensable Elements

Organization and Management

RESOURCES
- PERSONNEL
- EQUIPMENT
- PURCHASING AND INVENTORY
- FACILITY AND SAFETY

PROCESS
- DOCUMENTS AND RECORDS
- PROCESS MANAGEMENT
- INFORMATION MANAGEMENT

CONTINOUS IMPROVEMENT
- ASSESSMENT
- NONCONFORMITY MANAGEMENT
- CONTINUAL IMPROVEMENT

Customer Focus

The Core - Primary Laboratory Process consists of 3 stages

Pre-Analytical
- Sample Request
- Sample Collection
- Sample Transport
- Sample Reception
- Sample Registration

Analytical
- Sample Preparation
- Sample Processing
- Sample Examination
- Recording of Results

Post-Analytical
- Reporting of Results
- Storage of Sample
- Disposal of Sample

http://www.selectscience.net/
Logical structure to the process of implementing the QMS

By WHO, CDC, CLSI

QMS affects each single process of lab and consists of several layers

- **Phase 1**: Ensuring that the primary process of the laboratory operates correctly and safely
- **Phase 2**: Controlling and assuring quality and creating traceability
- **Phase 3**: Ensuring proper management, leadership and organization
- **Phase 4**: Create continuous improvement and prepare for accreditation

The basis of the pyramid consists of inspection

https://www.who.int/lqsi/
To implement the QMS in a logical way, the activities are divided over four phases of implementation, with each phase having a specific focus. The Stepwise plan is constructed such that, even when a laboratory does not reach full implementation of the QMS, it has already improved its quality service provision from Phase 1, and as such has benefited already.

<table>
<thead>
<tr>
<th>#</th>
<th>QUALITY SYSTEM ESSENTIALS</th>
<th>PHASE 1</th>
<th>PHASE 2</th>
<th>PHASE 3</th>
<th>PHASE 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Facilities and Safety</td>
<td>Upgrading laboratory biosafety</td>
<td>Hazardous Materials</td>
<td>Retention schedule for storing materials</td>
<td>NONE</td>
</tr>
<tr>
<td>2</td>
<td>Organization</td>
<td>Quality Management and Quality Project Team</td>
<td>Leadership</td>
<td>Development of a quality manual, Quality Year Plan, Budget planning</td>
<td>Compliance of required elements defined in the SOP</td>
</tr>
<tr>
<td>3</td>
<td>Personnel</td>
<td>Job description, Training of staff members</td>
<td>Competency Assessment</td>
<td>Replacement matrix, Potential conflicts of interest among laboratory staff</td>
<td>Continuous Education Program</td>
</tr>
<tr>
<td>4</td>
<td>Equipment</td>
<td>Equipment register, SOP</td>
<td>Equipment maintenance system</td>
<td>NONE</td>
<td>Validation of equipment</td>
</tr>
<tr>
<td>5</td>
<td>Purchasing and Inventory</td>
<td>Stock inventory register</td>
<td>Adequate stock and ordering system</td>
<td>Selection and evaluation of suppliers, referral laboratories, contracts</td>
<td>NONE</td>
</tr>
<tr>
<td>6</td>
<td>Process Control</td>
<td>SOPs for all the tests routinely performed</td>
<td>Sample Management</td>
<td>Validation of methods and equipment, IQC activities, TAT, CAPA</td>
<td>Quality indicators</td>
</tr>
<tr>
<td>7</td>
<td>Documents and Records</td>
<td>Master SOP</td>
<td>Document control system</td>
<td>NONE</td>
<td>NONE</td>
</tr>
<tr>
<td>8</td>
<td>Information Management</td>
<td>NONE</td>
<td>Information management system</td>
<td>Archive for Laboratory Records</td>
<td>NONE</td>
</tr>
<tr>
<td>9</td>
<td>Customer Service/Focus</td>
<td>NONE</td>
<td>Biological Reference Intervals, Decision values</td>
<td>Client satisfaction survey</td>
<td>Communication with clients</td>
</tr>
<tr>
<td>10</td>
<td>Assessment</td>
<td>NONE</td>
<td>IQC, QC for Quantitative, Qualitative &amp; SemiQuant. procedures</td>
<td>Setting up an internal audit system</td>
<td>External Audit, Action plans</td>
</tr>
<tr>
<td>11</td>
<td>Occurrence (Nonconformity) Management</td>
<td>NONE</td>
<td>NONE</td>
<td>NONE</td>
<td>SOP for handling complaints</td>
</tr>
<tr>
<td>12</td>
<td>Continuous Improvement</td>
<td>NONE</td>
<td>NONE</td>
<td>NONE</td>
<td>FMEA for proactive risk management</td>
</tr>
</tbody>
</table>
Quality Management Systems für Laboratories

- e.g. ISO 15189

Quality Policy

Quality Assurance

- All actions designed to ensure the quality of diagnostic results

- Other aspects of good laboratory practice

- Quality Control

- Internal quality control

- External quality control
### Table 1 Comparison of internal quality controls/external quality assessment

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Internal quality controls</th>
<th>External quality assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Results</td>
<td>Known</td>
<td>Unknown</td>
</tr>
<tr>
<td>Results available</td>
<td>Immediately</td>
<td>Only when report issued</td>
</tr>
<tr>
<td>Frequency</td>
<td>Daily, per batch, per shift</td>
<td>Periodically, e.g. once in four weeks or every two to four weeks or twice yearly, or once annually</td>
</tr>
<tr>
<td>Analyte concentration</td>
<td>Normal, pathological</td>
<td>Multiple concentrations, e.g. 6–8</td>
</tr>
<tr>
<td>Assessed</td>
<td>Precision</td>
<td>Accuracy and precision</td>
</tr>
<tr>
<td>Comparisons</td>
<td>Only within a single laboratory</td>
<td>Across all laboratories participating in the round robin test</td>
</tr>
</tbody>
</table>
Steps to adopt any voluntary QM standard

1) Read the document – e.g. ISO 15189:2012 or any standards
2) Does it meet your needs? – Time, Effort, Energy, Money
3) Perform a Gap Analysis
4) Prepare the Laboratory – Information, Education, Guidance, Culture
5) Develop an implementation plan – Gantt Chart your plan
6) Repeat the Gap Analysis
7) Determine your state of readiness
8) Make the accreditation decision – Do you want quality or accreditation or both?
9) Commit to the standard – 1st Achievement, 2nd Accomplishment
Interactive Workshop - March:
What is the best strategy to achieve GMS- and QC-requirements in the laboratory?
Moderators: Egon Amann (C-AQL) and

Questionnaire

Instructions
This questionnaire consists of 12 questions to assess QC and GMS about 5 minutes to complete.

If you do not wish to answer a question, or if a question does not apply:

- "Quality Control" is defined as the set of activities that ensure that all quality requirements are being met on materials of known substances along with patient precision of the complete examination process.
- "Quality Management" is defined as coordinated effort to implement their quality policy. These activities control, quality assurance and quality improvement.
- "Quality Management System" is defined as an activity of meeting quality objectives.

SECTION A: Your Work Area/Unit
In this questionnaire, think of your "Work Area/Unit" as the department or organization where you spend most of your work time. You can use:

1. Were you able to pursue/achieve any type of licensing/certification/certification for your country? Please tick one of the boxes.
   a. Yes
   b. No
   c. Not applicable

If you answered "Yes" to the previous question, please license/certification/certification that was achieved.

2. Which organization(s) issue such licensing/certification/certification certificates in your country? Please indicate your country.

6. What are your laboratory's top challenges in achieving this objective?
   Please indicate your agreement or disagreement with the following statements about your laboratory.

   a) Lack of executive support and commitment
   b) Quality is considered a "department" not a "responsibility"
   c) Disparate quality systems and data sources
   d) Quality metrics are not effectively measured
   e) No formal process for capturing non-conformances
   f) No formal process for continuous improvement
   g) Audit and compliance management is ad-hoc
   h) Lack of Leadership
   i) Lack of efficient implementation of LIS
   j) No formal process for managing risk
   k) Lack of training support and guidance for GM
   l) Lack of implementation plan
   m) The implementation of the GMS is difficult

7. Which of the following phases best describes the stage of your implementation?
   a. Phase 1
   b. Phase 2
   c. Phase 3
   d. Phase 4
   e. Other, please specify:

SECTION B: Quality Management System

3. Please give your laboratory an overall grade:

   A Excellent    B Very Good

4. Which non-mandatory GMS-related regulations:

5. What is the top strategic objective for your laboratory?
   Please rate the importance of the following:

   a) Reduce the total cost of quality
   b) Reduce non-conformances in pre and post analytical phase
   c) Reduce liability
   d) Ensure compliance with national regulations
   e) Ensure compliance with international standards
   f) Improve design for quality
   g) Improve performance of testing
   h) Improve patient safety
   i) Improve patient satisfaction
   j) Greater management and staff satisfaction
   k) Better manage operational risks
   l) Preserve the quality

SECTION C: Quality Control (QC)

8. Please give your laboratory an overall grade on QC:

   A Excellent    B Very Good    C Acceptable    D Poor

9. Which non-mandatory QC-related regulations or requirement standards:

10. What are your laboratory's main challenges in implementing QC?
   Please indicate your agreement or disagreement with the following statements about your laboratory:

   a) Lack of training support and guidance for QC
   b) Lack of training support and guidance for ECG
   c) Lack of budget to finance ECG materials
   d) QC failures are not meaningfully managed
   e) No formal process for running QC
   f) No technical support for instruments
   g) No middleware applications to assess QC

SECTION: Your Opinions
11. What aspects of your laboratory's work if any should be improved as a result of effective QC and GMS?
   Please list the three most burning challenges on GMS and QC-compliance-related tools in your laboratory.

12. What is the main aim of your workshop and why are you interested in the scientific and technical content and you provide in our activities and by learning from your experiences we hope to better meet your needs and those of clinical laboratory specialists worldwide.
   Is there any area of interest that you think we should explore with more frequency?
   Do you have any suggestion on how this workshop could be improved in the future?
Questions and Answers
Thank you