

Post Implementation Review on Interactive Workshop:

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

Managed and Prepared by:

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April 14, 2016

Activity: Interactive Workshop (IW) suggested by IFCC Functional Units, National Societies, and Regions

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

Moderators: Egon Amann (C-AQ) and Sedef Yenice (C-CLM)

Date: March 20th, 2016

Time: 45 minutes ea. session presented 3 times

Interactive Workshop Performance

Session	Time Schedule	Size of Participants
1	15.45 - 16.25	15
2	16.25 - 17.05	6
3	17.05 - 17.45	2
Total		23

Goals

- 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,
- To capture the findings for future IFCC events.

Strategy

To conduct the IW three times with each lasting for 45 minutes and consist of 4 phases:

Phase	Time (min)	Contents
1	5	Initial “impulse“ lecture by the IW moderators to present the agenda, aims, and instructions for activity.
2	5	Spontaneous group forming with 5 participants per group by having each person choose a chair at a roundtable. (Number of the groups depends on the availability of participants). Then, a questionnaire is handed out of groups.
3	10	Group discussion -“exploring” - experimenting with the ideas and finding most burning top three issues and listing those issues on flip charts.
4	15	Following group discussions, group leaders present their outcomes for the entire participants– 3 minutes max. for each group.
	10	Concluding activity - “closing” – evaluating, deciding, and listing actions.

The outcomes have been collated by the moderators and presented as an “IW Summary”.

As for logistics, flip charts for recording participants’ ideas, marker pens, and group name placeholders have been provided.

Finally, moderators asked participants for comments on what aspects of the workshop were most useful and how future workshops to be improved.

The IW represented a “bottom up” approach and achieved the objectives such that actual and “real” laboratory issues concerning IQC and EQA questions including any regulatory requirements to be addressed by IW participants.

Questionnaire

C-CLM and C-AQ jointly established the questionnaire to develop a comparative database on QMS and QC activities from the participants of developing countries. The database report is planned as a tool for the following purposes:

- Comparison – To compare the results with those of participants.
- Assessment and Learning – To provide data to C-CLM and C-AQ to facilitate internal assessment and learning the improvement process of their activities.
- Additional Information - To obtain supplemental information to help the participants from developing countries identify their complicated issues and areas with potential for improvement in QMS and QC.

Questionnaire Content

The questionnaire was designed to assess participants’ opinions about the major challenges they faced in implementation of quality management and quality control. The questionnaire includes 41 items that measure 7 areas or composites of QMS and QC:

1. Accreditation status
2. Mandatory and non-mandatory regulations or requirements in their laboratory
3. Strategic objectives in QM
4. Top challenges in achieving the objectives
5. Stage of the implementations related to QMS
6. Main challenges in implementing QC
7. Areas to be improved as a result of effective QMS and QC

The questionnaire also includes two questions that ask respondents to provide an overall grade on QMS and QC for their laboratory.

Interactive Workshop Conformance

High involvement of participants was encouraged to set the stage for an interactive session. Participants were directed to choose a chair at a table and form a discussion group. Then, an individual was asked to serve as the group leader.

IW has conformed to expectations for the above-stated goals by:

- Successful interactive group discussions
- Outcome measures through the instrument of questionnaire

Questionnaire Administration Statistics

- Number of Respondents: 14 out of 23 (60,87%)
A total of 14 respondents out of total 23 IW participants submitted data for the questionnaire. The response rate was 60.87 percent.

Respondent Characteristics

- Country of participant who responded the questionnaire in alphabetical order: Argentina (AR), Belgium (BE), Germany (DE), Guatemala (GT), India (IN), Indonesia (ID), Iran (IR), Malaysia (MY), Nigeria NG), Russia (RU), South Africa (ZA), United Kingdom (UK), USA (US), Uruguay (UY)
- The top three respondent work areas were:
 - Biochemistry/Clinical Chemistry (45 percent)
 - General Laboratory (27 percent)
 - Immunology or Pathology or Quality Management (9 percent)

See SECTION E: Background Information

- The top three respondent staff positions were:
 - Department Head (30 percent)
 - Pathologist or Non-Physician Lab Director (20 percent)
 - Physician Lab Director or Professor/Instructor or Lab Technician (10 percent)

See SECTION E: Background Information

Identification of Achievements

Significant findings to effect the future projects of C-CLM and C-AQ were obtained. Statistical analysis of the answers to the questionnaire is as follows.

Areas of Strength for Respondents

The five areas of strength or composites with the highest average percent positive responses were:

(Percent positive is the percentage of positive responses (e.g., Agree, Strongly agree) to positively worded items or negative responses (e.g., Disagree, Strongly disagree) to negatively worded items).

1. Accreditation achieved – 93 percent positive and the scope of the accreditation most applied is ISO 15189.

See SECTION A: Work Area/Unit.

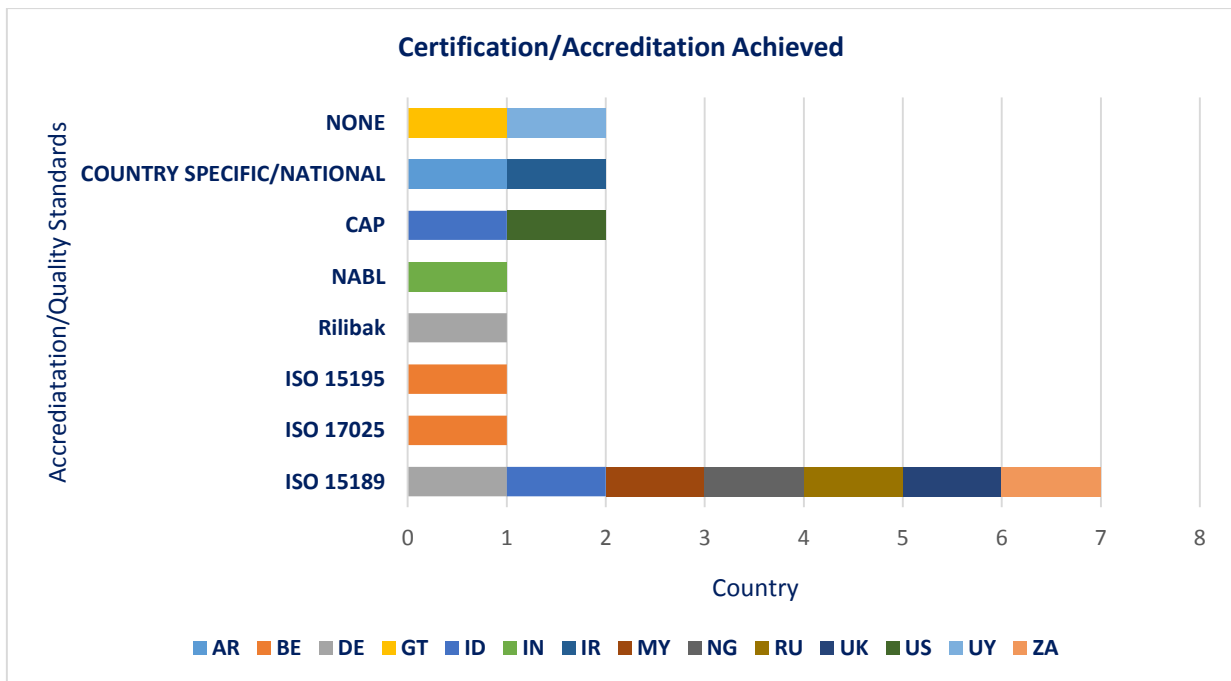
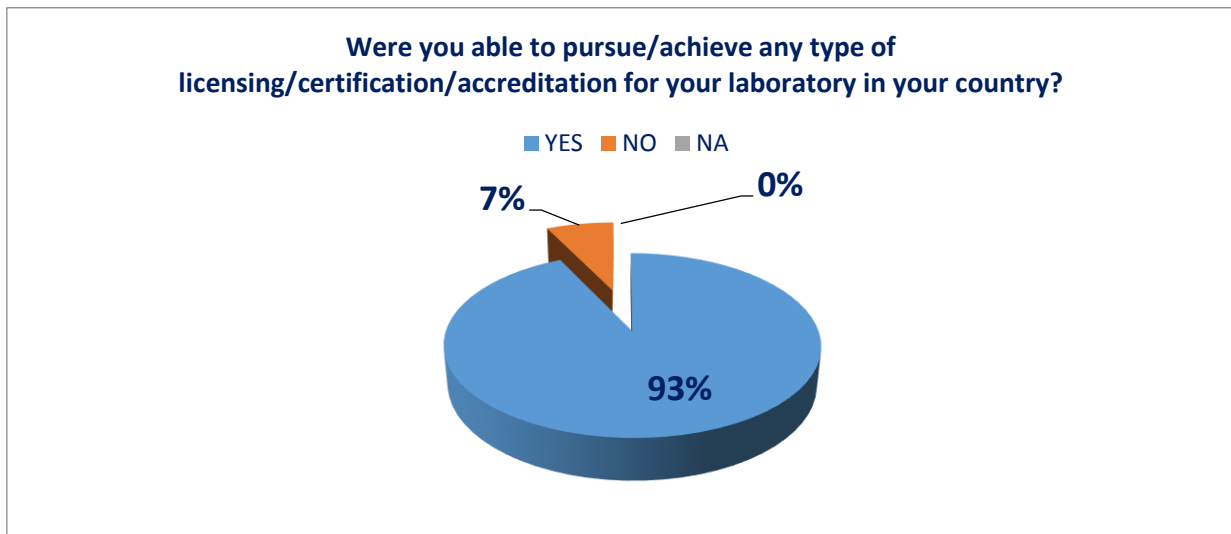
2. Overall grade on QMS – 43 percent positive – very good.
3. The stage of implementations related to QMS is Phase 4 – 55 percent positive.
4. The top strategic objective for the laboratory in quality management – 69 percent positive – to improve patient safety is extremely important.
See SECTION B: Quality Management System (QMS).
5. Overall grade on QC - 42 percent positive - excellent.
See SECTION C: Quality Control (QC).

Areas with Potential for Improvement for Respondents

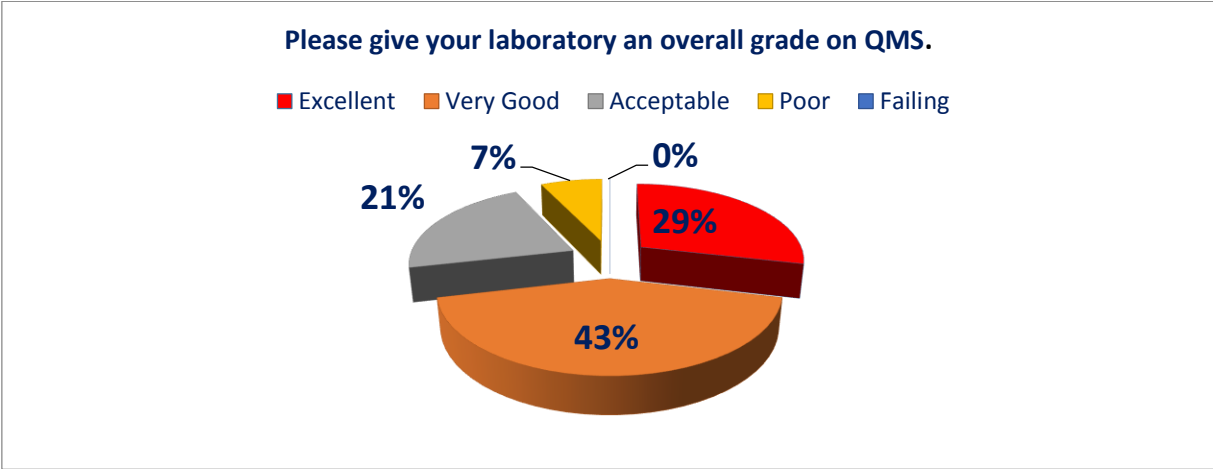
The five areas that showed potential for improvement or with the lowest average percent positive responses were:

1. Accreditation not achieved – 7 percent positive and respondents who gave the answer “none” are the countries of GT and UY.
See SECTION A: Work Area/Unit.
2. Top challenge in achieving the strategic objective for QM – 25 percent positive – strongly agree on the lack of implementation plan.
3. Top challenge in achieving the strategic objective for QM – 55 percent positive – disagree on the lack of leadership.
See SECTION B: Quality Management System (QMS).
4. The main challenge in implementing QC – 70 percent positive – strongly disagree on no formal process for running QC.
5. The main challenge in implementing QC – 10 percent positive – strongly agree on QC failures are not meaningfully managed and/or lack of training support and guidance for EQC.
See SECTION C: Quality Control (QC).

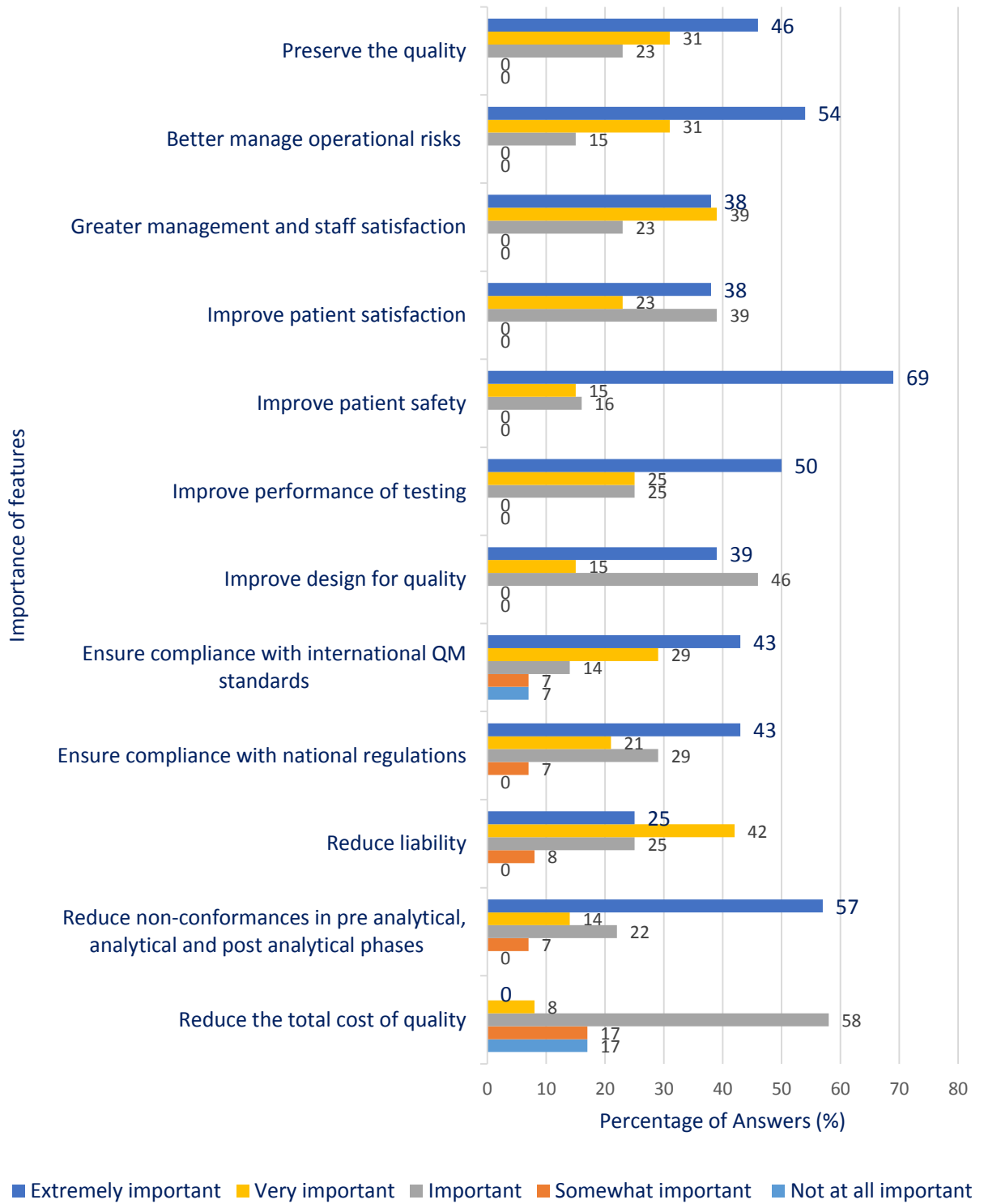
SECTION A: Work Area/Unit



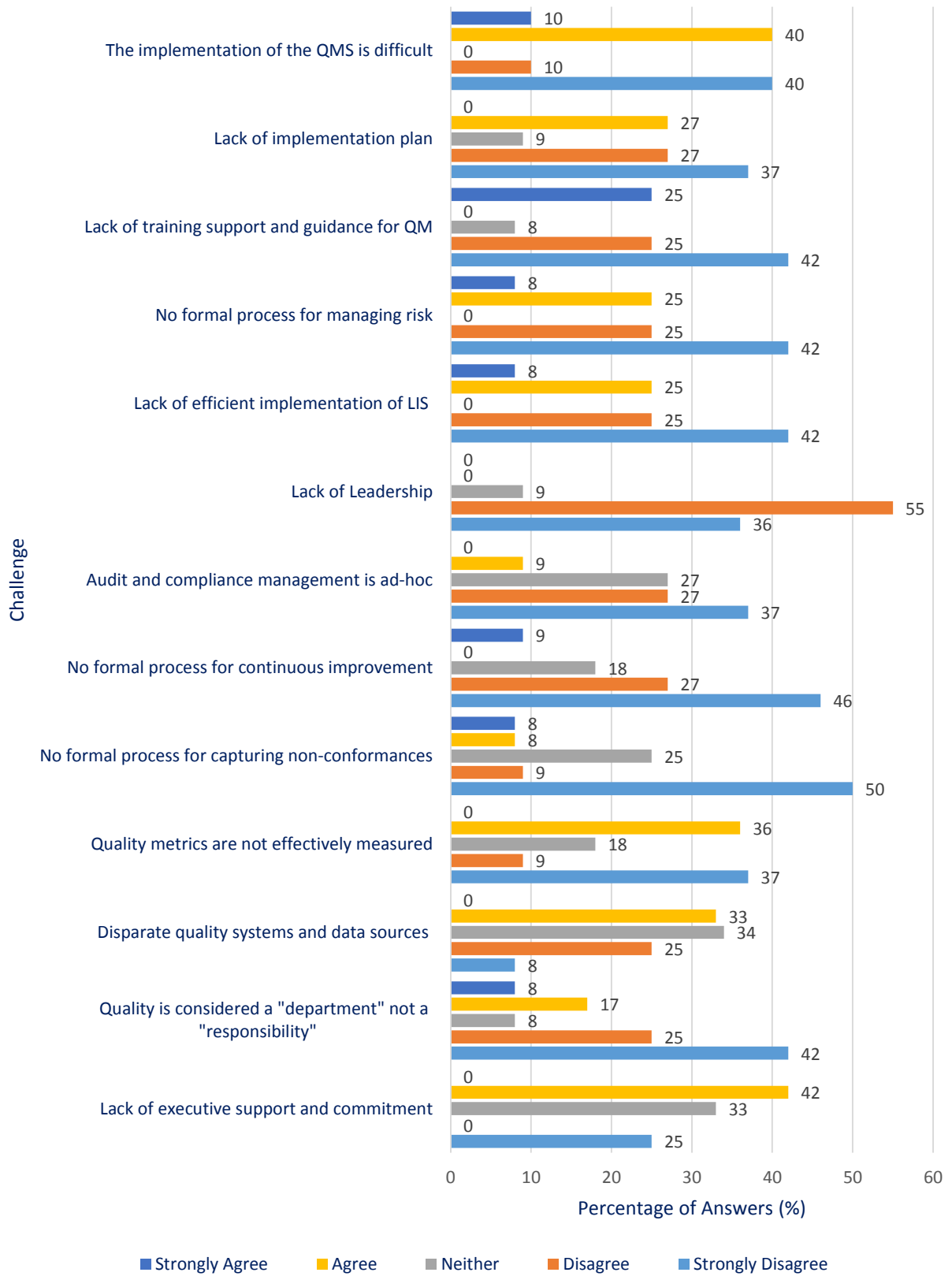
SECTION B: Quality Management System (QMS)



What is the top strategic objective for your laboratory in quality management (QM)?

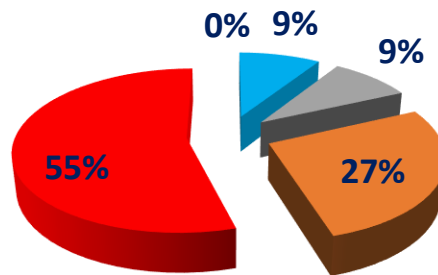


What are your laboratory's top challenges in achieving this objective?



Which of the following phase best describes the stage of your implementations related to QMS?

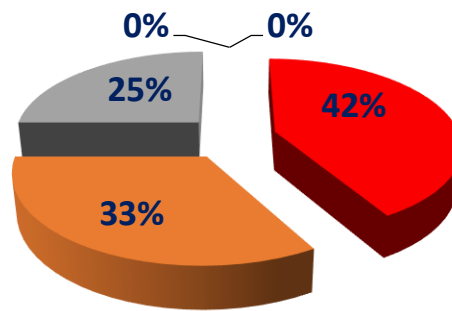
Phase 1 Phase 2 Phase 3 Phase 4 If, other



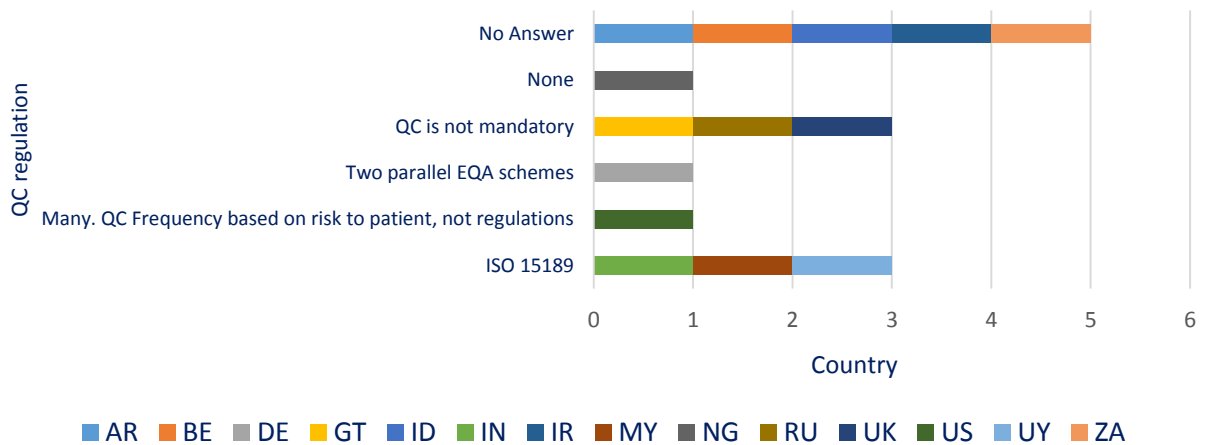
SECTION C: Quality Control (QC)

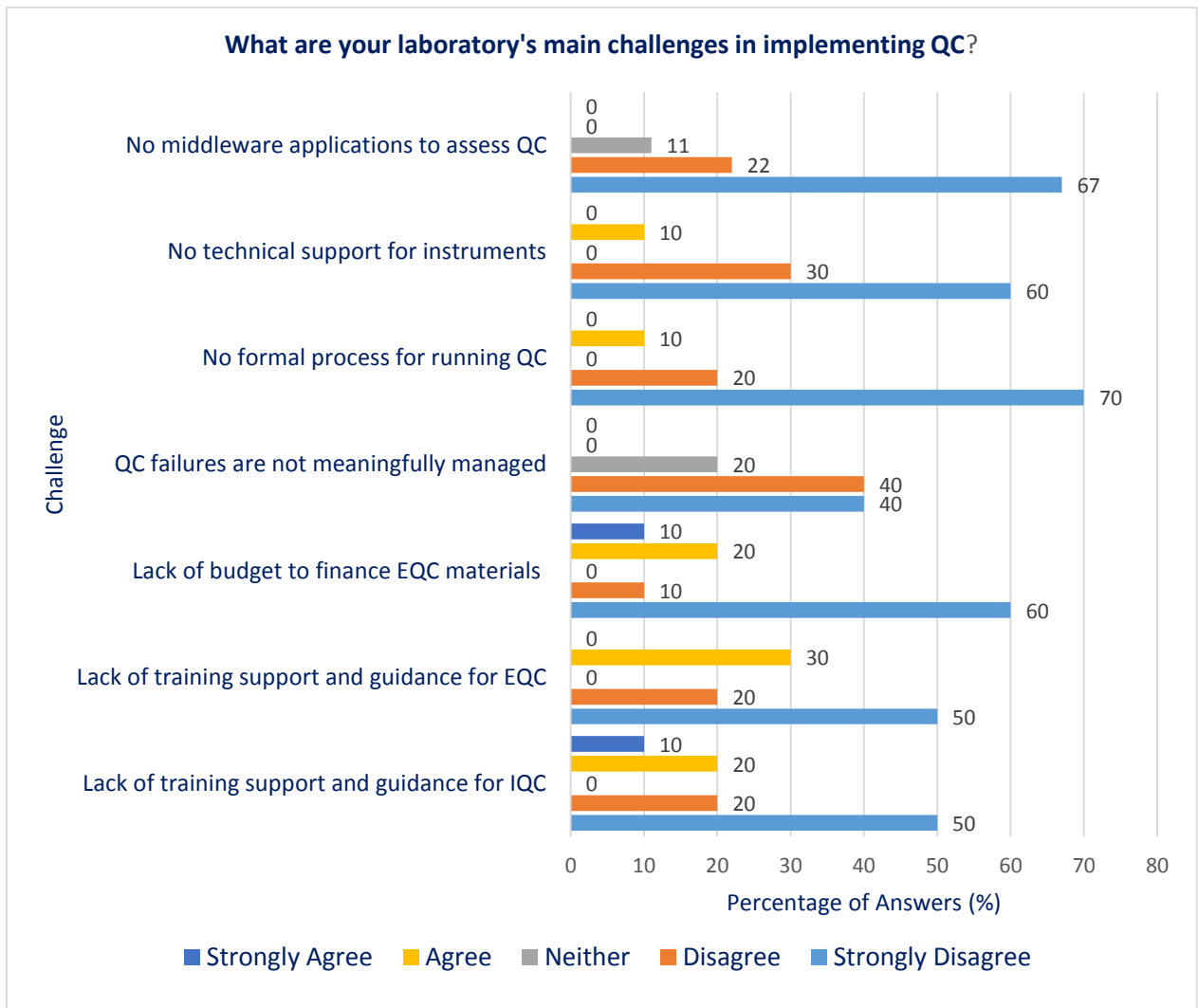
Please give your laboratory an overall grade on QC.

Excellent Very Good Acceptable Poor Failing



Non-mandatory QC-related regulations or requirement standards applied in laboratory





SECTION D: Opinions

What aspects of your laboratory's work (if any) should be improved as a result of effective QMS and QC?

Please list the **three most burning challenges** on QMS- and QC-compliance-related topics in your laboratory.

Most burning top three issues listed on flip charts by the group leaders are as follows:

Session 1 (15:45 - 16:25): 15 Participants

Group 1	Issues
	Competency of staff, Skills, and basic education
	Financial support missing
	Reference Material, EQA

Group 2	Issues
	EQA: cost, stability
	IQC / EQA behind clinical Chemistry
	Knowledge level of lab managers (e.g., Africa)

Group 3	Issues
	Training / competency assessment
	Verification of methods
	Pre-analytical phase

Session 2: (16:25 – 17:05): 6 Participants

Group 1	Issues
	Pre-analytical phase: Guide for the collection of samples of different tests missing
	Analytical Phase: Viability of controls, Reference materials for difficult tests missing

Group 2	Issues
	No punishment for non-compliant labs
	No accreditation system
	External audit process inadequate
	Too many labs

Session 3 (17:05 – 17:45): 2 Participants

Group 1	Issues
	Lack of qualified personnel
	Lack of leadership and motivation
	Financial limitations (for instruments, reagents, materials)

Answers to "What aspects of your laboratory's work (if any) should be improved as a result of effective QMS and QC?" in the questionnaire are grouped in line with quality system elements are as follows:

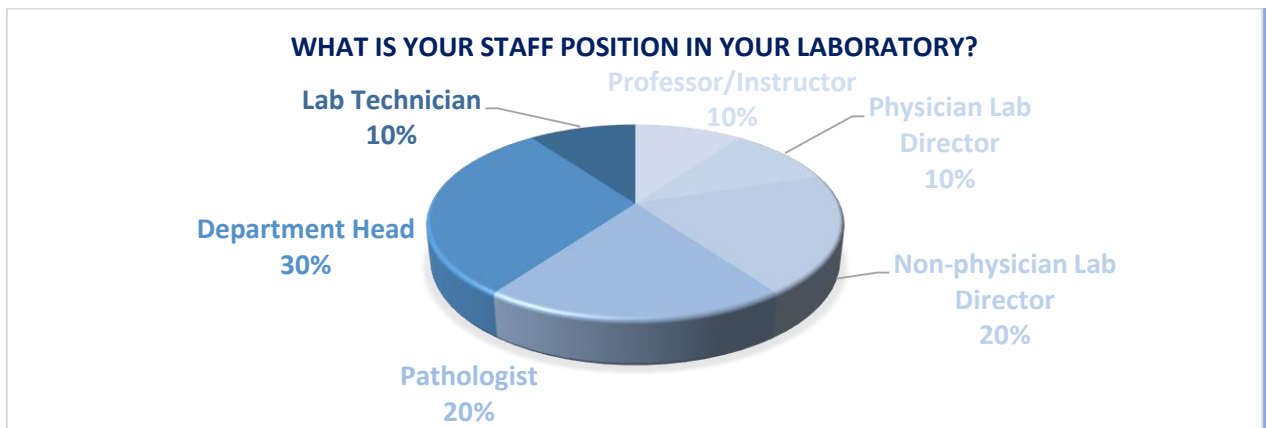
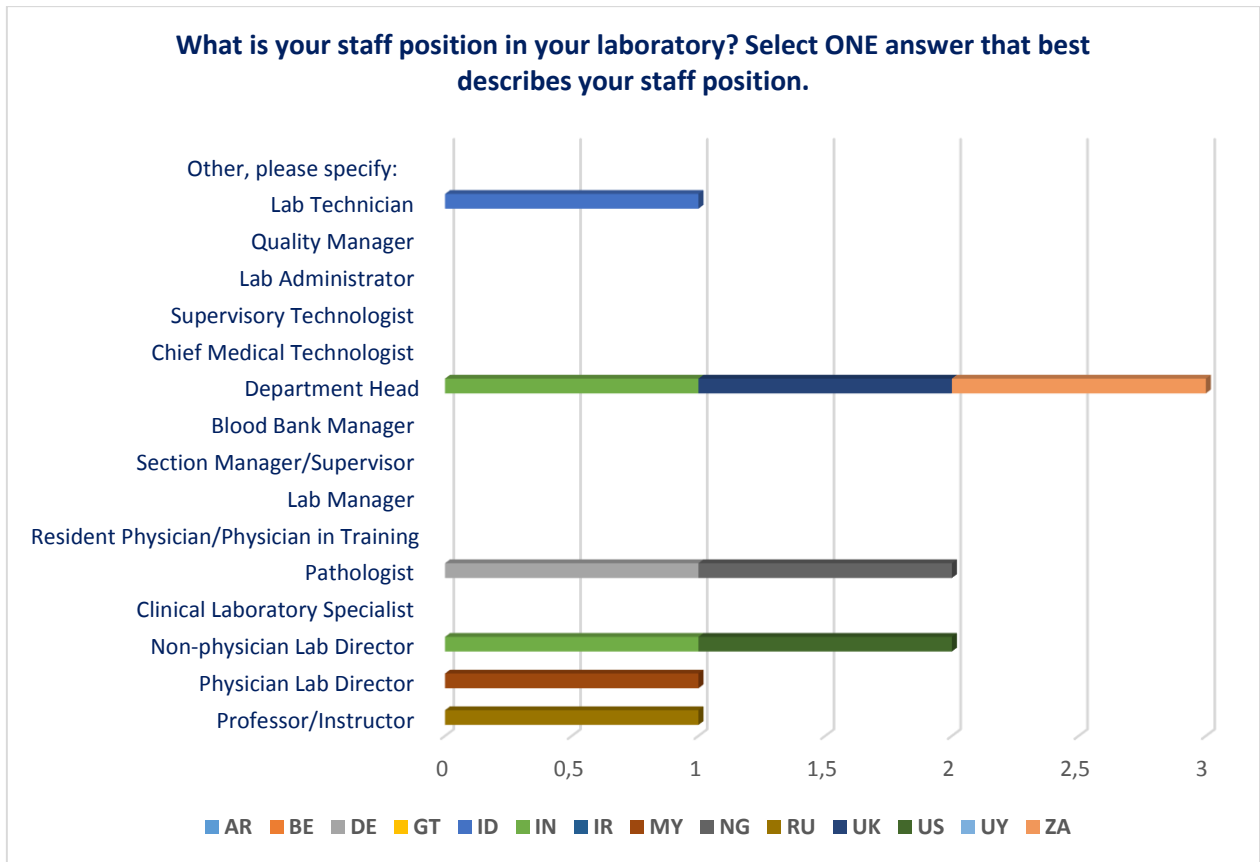
Facilities and Safety	Inadequate space
Organization	Lack of Leadership, lack of time
Personnel	Short of staff, staff limitation to adequately document details of lab operation, eg.reagent lots. etc., commitment of staff, lack of qualified personnel, education and training/competency assessment, lack of motivation, QUALITY CULTURE: not involved in quality
Equipment	Inadequate resources
Purchasing and Inventory	High costs, financial support for EQA, IQC
Process Management	Pre-analytical errors, making errors on handling specimens, training to prevent failure to follow SOP, analytical - verification of methods, verification of reference materials, operational procedures, establishment of processes in pre-analytical, analytical and post-analytical phases

Information Management	Inefficient LIS
Assessment	Regulatory problems, consistency in doing the system, communication, data presentation of QC performance (traffic lights) showing failed and not performed, ISO 15189 too much focusing on technical part and very little on medical part, no QC run in histo- and cytopathology

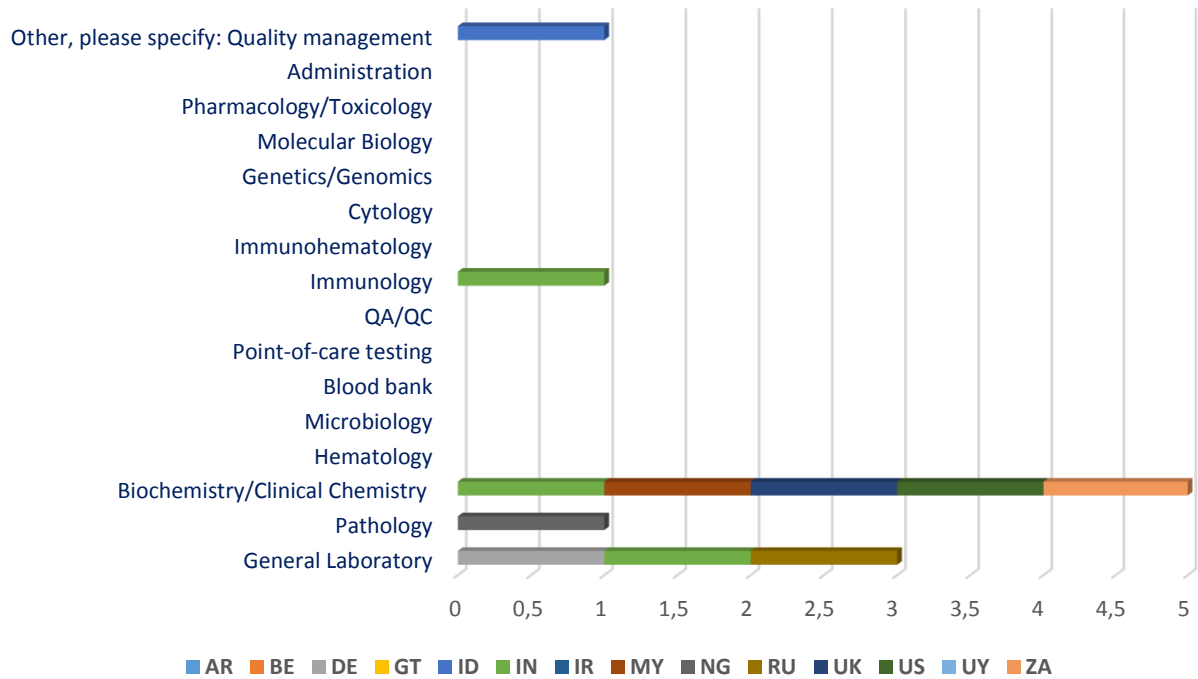
Answers to "Do you have any suggestion on how this workshop could be improved in the future?" are as follows:

- Motivation, involve people in quality
- Traceability of reagents
- Strategies in Quality Management
- Longer duration for discussion
- Structure to group doing discussion
- A good EQAS program with moderate expenses and maximum number of analytes (including immunoassays)

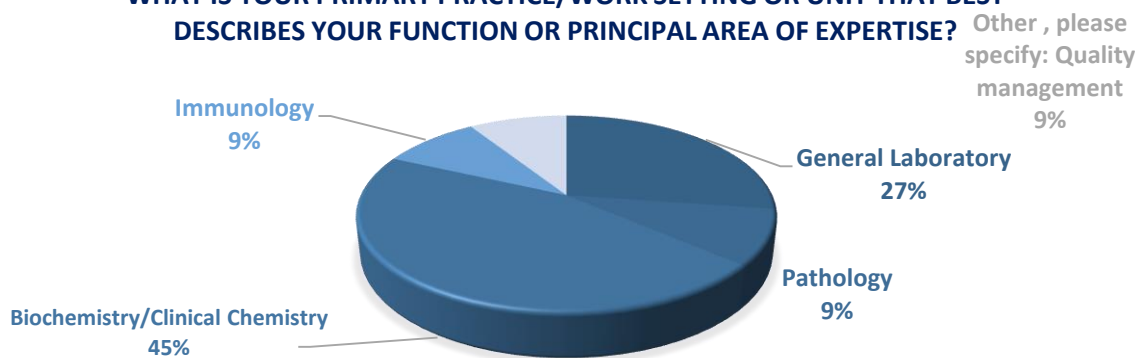
SECTION E: Background Information



What is your primary practice/work setting or unit that best describes your function or principal area of expertise?



WHAT IS YOUR PRIMARY PRACTICE/WORK SETTING OR UNIT THAT BEST DESCRIBES YOUR FUNCTION OR PRINCIPAL AREA OF EXPERTISE?



Identification of Weaknesses

- The size of participants in the IW is low.
- Participants from the developing countries are minor. Therefore, the results presented in this report may not represent the actual areas with potential for improvement or challenges in developing countries.
- The timing of each session to run an IW was limited for discussion part and no breaks were used between the two successive sessions.

Action Planning for Improvement

- To conduct an IW, announcements and recruitments are to be performed earlier.
- IW or course format and content to be designed on more specific topics.
- Paper questionnaire resulted in slightly lower response rate (60.87 percent) compared with the size of participants (14 out of 23). Web-only pre-IW/course and post –IW/course questionnaires or surveys are to be administered.
- The delivery of questionnaire results is not the end point and it is the beginning to plan actions on next steps to take.
- The Larger size of the population is required to collect more data using web-based survey. Further work is needed to administer and refine the questionnaire to get higher response rates.