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

Moderators

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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

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

What We'll Cover Today

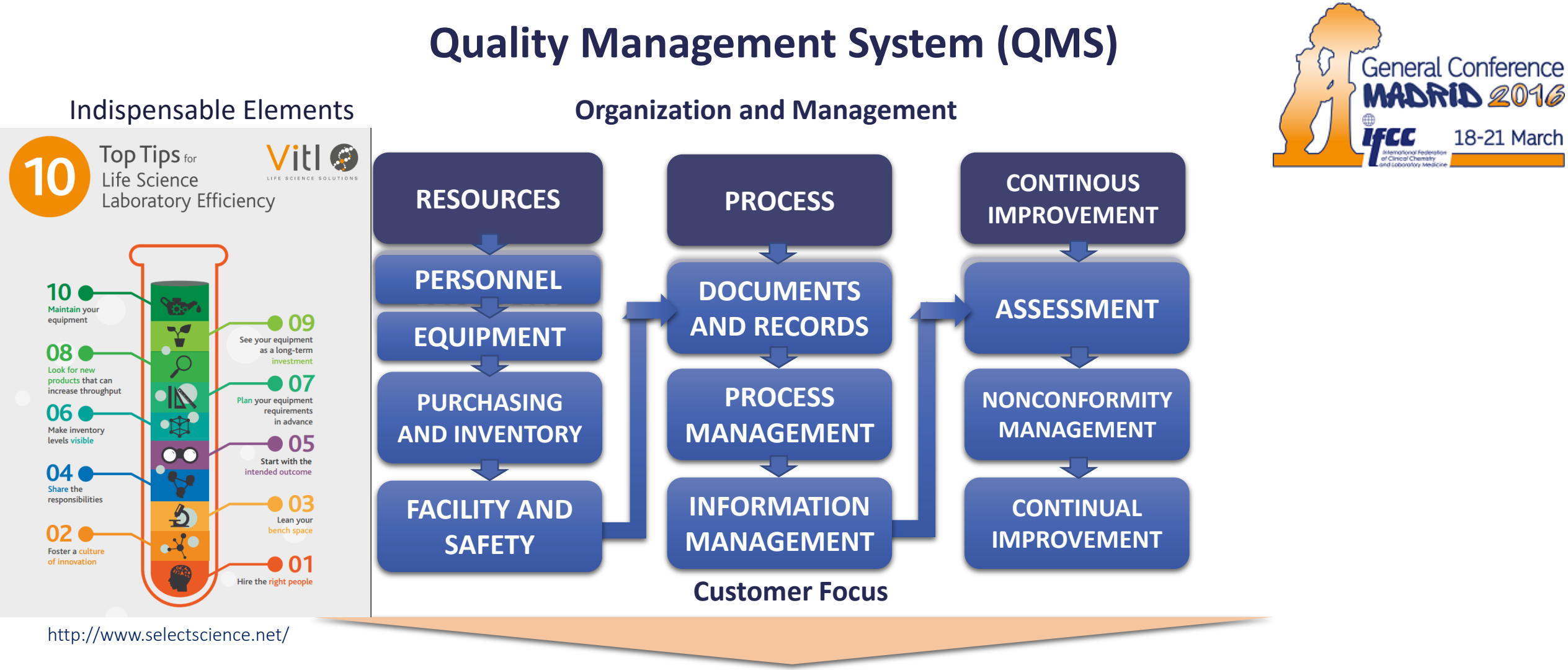
International Standards	Definition
ISO 15190:2003	Medical laboratories -- Requirements for safety
ISO/IEC 17025:2005	General requirements for the competence of testing and calibration laboratories
ISO 22870:2006	Point-of-care testing (POCT) -- Requirements for quality and competence
ISO/TS 22367:2008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

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.

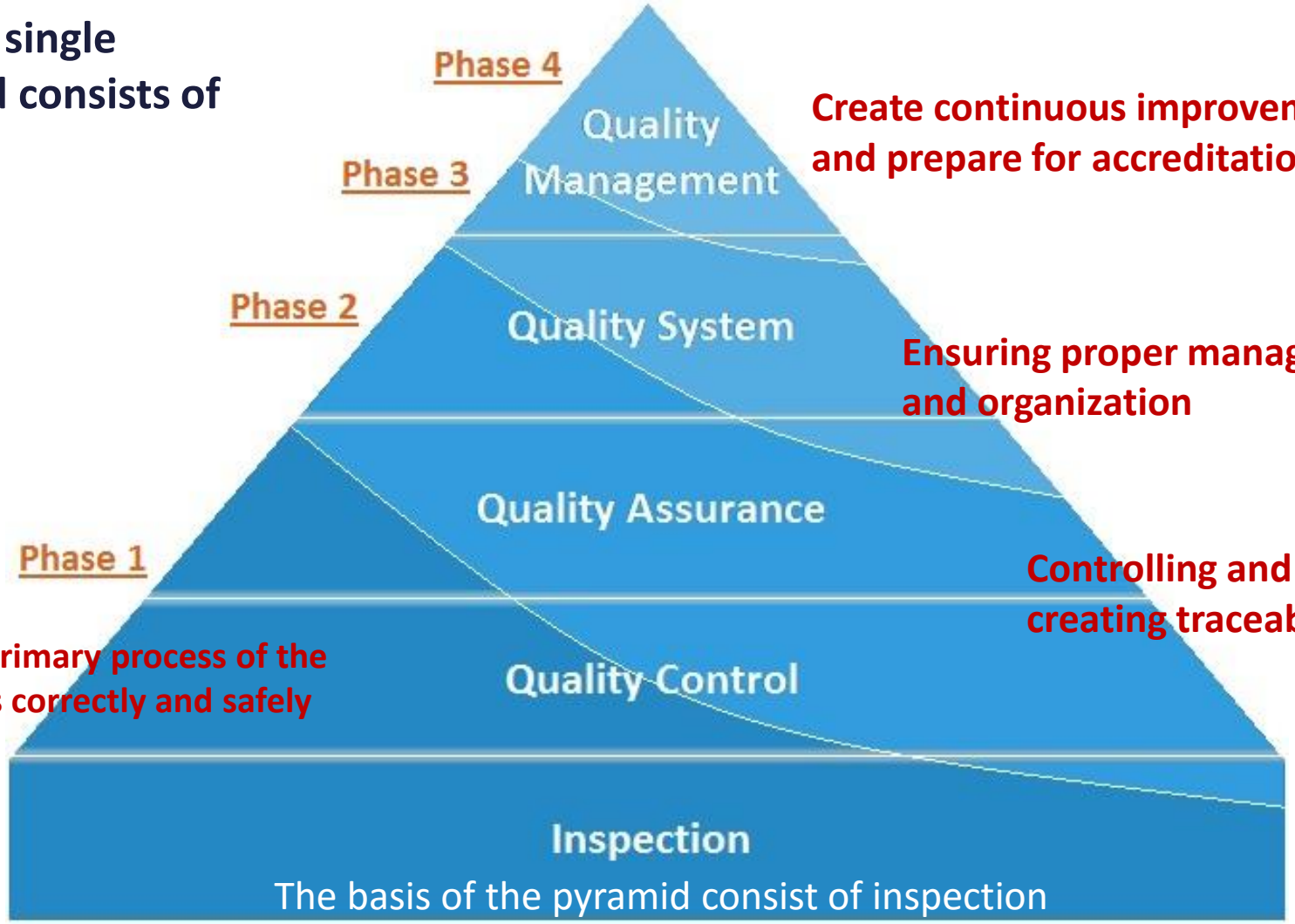
Quality Management System (QMS)



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



Create continuous improvement and prepare for accreditation

Ensuring proper management, leadership and organization

Controlling and assuring quality and creating traceability

Ensuring that the primary process of the laboratory operates correctly and safely

The basis of the pyramid consist 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.

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

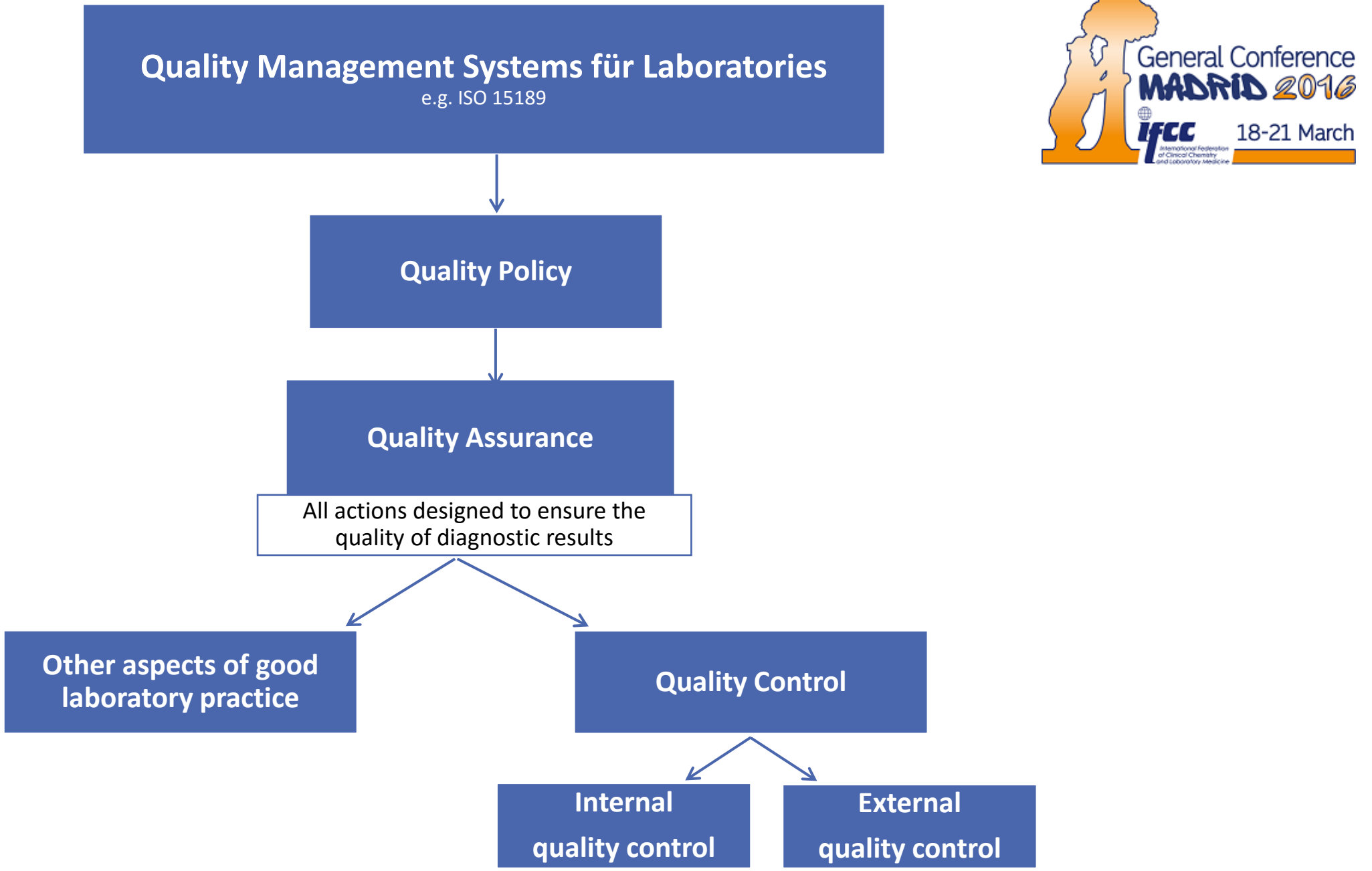


Table 1 Comparison of internal quality controls/external quality assessment

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

Amann E. Quality assurance in medical laboratories. Paths to global competence standards. www.q-more.com/en/ | q&more 01.15

Steps to adopt any voluntary QM standard

1) Read the document – e.g. ISO 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

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Interactive Workshop - March

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Moderators: Egon Amann (C-AQ) and S

Questionnair

Instructions

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

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

- *"Quality Control" is defined as the set of activit ensure that all quality requirements are being me 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 act control, quality assurance and quality improvement.*
- *"Quality Management System" is defined as sy meeting quality objectives.*

SECTION A: Your Work Area/Unit

In this questionnaire, think of your "Work area/Unit" as the dep organization where you spend most of your work time or provide mos

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

   If you answered "Yes" to the previous question, plea licensing/certification/accreditation that was achieved.

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

SECTION B: Quality Management Systen

3. Please give your laboratory an overall g

☐ A	☐ B
Excellent	Very Good

4. Which non-mandatory QMS- related reg

5. What is the top strategic objective for yo

   Please rate the importance of the follow

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

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.

	Strongly Disagree ▼	Disagree	Neither	Agree	Strongly Agree
a) Lack of executive support and commitment.....	☐1				
b) Quality is considered a "department" not a "responsibility"	☐1				
c) Disparate quality systems and data sources	☐1				
d) Quality metrics are not effectively measured.	☐1				
e) No formal process for capturing non-conformances.....	☐1				
f) No formal process for continuous improvement.....	☐1				
g) Audit and compliance management is ad-hoc.....	☐1				
h) Lack of Leadership.....	☐1				
i) Lack of efficient implementation of LIS	☐1				
j) No formal process for managing risk.....	☐1				
k) Lack of training support and guidance for QM.....	☐1				
l) Lack of implementation plan.....	☐1				
m) The implementation of the QMS is difficult.....	☐1				

7. Which of the following phase best describes the stage of your impleme
   - ☐ a. Phase 1
   - ☐ b. Phase 2
   - ☐ c. Phase 3
   - ☐ d. Phase 4
   - ☐ e. If other, please specify:

SECTION C: Quality Control (QC)

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

☐ A	☐ B	☐ C	☐ D
Excellent	Very Good	Acceptable	Poo

9. Which non-mandatory QC-related regulations or requirement standar

10. What are your laboratory's main challenges in implementing QC?

    Please indicate your agreement or disagreement with the following statements about your laboratory.

	Strongly Disagree ▼	Disagree ▼	Neither ▼	Agree ▼	Strongly Agree ▼
a) Lack of training support and guidance for IQC.....	☐1	☐2	☐3	☐4	☐5
b) Lack of training support and guidance for EQC.....	☐1	☐2	☐3	☐4	☐5
c) Lack of budget to finance EQC materials	☐1	☐2	☐3	☐4	☐5
d) QC failures are not meaningfully managed.	☐1	☐2	☐3	☐4	☐5
e) No formal process for running QC.....	☐1	☐2	☐3	☐4	☐5
f) No technical support for instruments.....	☐1	☐2	☐3	☐4	☐5
g) No middleware applications to assess QC.....	☐1	☐2	☐3	☐4	☐5

SECTION D: Your Opinions

11. 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.

12. IFCC EMD C-CLM and C-AQ are eager to continue to improve the scientific content and value we 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


Obrigado
Gracias
Merci
Thank you
Danke
Grazie
Ευχαριστώ
General Conference
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