

HIGH QUALITY SPECIALITY TRAINING IN QUALITY CONTROL FOR LABORATORY SCIENCES

(Dr. James Westgard y Dr. Sten Westgard)

MODULE I

QC BASIC LESSONS

QC Basic definitions in the clinical laboratory.

Students learned about:

- Controllable and not controllable aspects in pre, analytical, and post analytical phases
- How Internal QC evaluates precision, External QC evaluates accuracy and the importance to implement both QC's in the laboratory
- Differences between 1st and 3rd opinion controls
- QC planning: stability, cost effectiveness, matrix, variability and test's concentration, how to select the control level according to the medical decision levels
- Activity group: they had to choose the best QC between some brands comparing inserts and the Bernard Stantlad's tables of medical decision
- The correct handling of manufacturer's inserts. All the insert info was reviewed
- Informatics tools in the market: Internal QC management, analytical performance indicators, instruments & documents management
- Interlaboratory Comparison reports, how to analyze the results
- Qualitative and semi qualitative QC tests (microbiology and urinalysis)
- Serology QC, why and how to implement a basic quality program in this area
- Finally the students accredited the corresponding exam.

MODULE II

QC STATISTICAL TOOLS

Importance of statistical process control, QC planning and standards to consider.

Students learned about:

- Basic definitions: Precision, accuracy (differences and ways to distinguish each of them and their importance in the daily analysis). Measurement error: systematic and random error, causes and actions
- Statistical Filters: Dixon's
- Basic statistical tools, concepts and exercises: Mean: Types, calculations, how to validate and set the mean. Standard Deviation: meaning, calculation and interpretation. CV:

calculations and practical exercises. Z-score: how to calculate it, meaning and interpretation

- QC Graphics: Levey Jennings, Total Error, Box Chart
- Interlaboratory Reports: Regulations, differences between internal QC and external QC. Comparison types and analysis. Information issued in an interlaboratory report, calculations, formulas and statistical analysis (ISD -Index SD-, CVR Index -coefficient of variation-). Graph Interpretations in the interlaboratory comparison
- Concepts and exercises of advanced statistical tools: Bias: Analysis, sample graphics, types of bias, calculations and case studies for identification
- Total Error: Meaning, calculation and interpretation, integrated graphics explanation of the quality control and analysis with the Total Error Allowable
- Systematic Error and Random Critical Error: meaning, foundation, how to calculate and interpret them in an integrated QC chart
- QC Pillars: key concepts: current mean, true mean, coefficient of variation and quality requirements as a strategy to begin with a correct statistical process control

MODULE III: “Technical Competence Indicators”

In module III students analyzed and reviewed the following:

Students learned about:

Quality requirements.

- Stockholm consensus and update concepts in Milan meeting EFLM 1st Strategic Conference 2014. Laboratory performance criteria revised in 2014. Mauro Panteghini

Concepts:

- Medical Requirements, Experienced Professional judgment, Sources: Particular clinical situations, Based on the medical opinion, Based on national and international groups study, Based on institutions or experts
- Biological Variability, State of the art
- Quality Requirements tables (Dr. James Westgard)

Technical competence Indicators (quality management).

- Bias Index (IS). Objective: To measure the reliability of the results in terms of accuracy
Ideal ≤ 1

- Coefficient of Variation Index (ICV). Objective: To measure the reliability of the results in terms of precision
Ideal ≤ 1
- Index Total Error (IET). Objective: To measure the reliability of the results in terms of accuracy and inaccuracy
- Goal Quality Index (QGI). Objective: To identify specific sources when problems fail to meet the quality requirements are evident. <0.8 Inaccuracy. 0.8 to 1.2 Bias and Inaccuracy (Accuracy), 1.2 Bias (Accuracy)
- Six Sigma in the clinical laboratory
- Westgard Rules / Six Sigma

- External Quality Control
- Discussion of the points of ISO 15189: 2012 (5.6 assuring the quality of test results)

MODULE IV: “Breaking rules”

Students learned about:

- A Westgard Introduction of Principles and Practices
- Fundamentals of QC
- Performing QC Right (correctly)
- Performing the Right QC (designing rules appropriately)
- Examples - 2 controls and 3 controls
- Examples - "manual" and "automated" Westgard Rules
- (1) Examples - Break all the Rules!
- (2) Examples - Break all the Rules!
- (3) Examples - user- submitted and Celtec-supplied
- (4) Examples Real World QC Practices Review
- Review: Performing the Right Quality Control