

## SYLLABUS



# "ANALYTICAL QUALITY CONTROL COURSE FROM ABC TO SIGMA"

Responsible:

***Bact. Claudia Gil Puerta***

### General Objective:

- To present to the participants practical application tools to plan and monitor analytical quality and to support the achievement of clinically useful patient outcomes ensuring patient safety.

### Specific objectives:

- Review the systematic handling of internal quality control materials, their introduction into laboratory routine, daily evaluation and interpretation of statistical behavior;
- Approach methodologies that help laboratory professionals in clinical analysis and laboratory medicine carry out performance-based internal control planning;
- Train laboratory professionals in clinical analysis and laboratory medicine to define best practices for the external quality assessment program;
- Discuss ways to evaluate analytical performance using the results of internal controls and the external quality assessment program;
- Develop analyses that allow the management of analytical data available in the laboratory, allowing decision-making in a safe manner;
- Understand the evolution of quality control and current tools, allowing you to improve your critical sense by choosing the best options.

### Target audience:

- Laboratory medicine professionals (clinical analysis laboratories and diagnostic industry) managers, coordinators, supervisors and laboratory technicians working on technical processes and analytical quality (clinical pathologists, resident physicians, biomedical, pharmaceutical-biochemicals, biologists, laboratory technicians and undergraduate students in the laboratory area, as well as quality managers).

**Program content: 40 hours - The number of hours remaining in the Westgard part - see below for suggestions to the agenda.**

Modules	Classrooms	Topics	Professor
<b>Module I</b> <b>Introduction - Quality control as part of the quality management system</b>	Classroom 1	Main challenges and risks for the patient, in the pre-analytical, analytical and post-analytical phases.	Luisane
	Classroom 2	Planning of the quality management system.	Derliane
	Classroom 3	Concepts and definitions applicable to quality control.	Claudia
<b>Module II</b>	Classroom 1	Definition of Analytical Performance Specifications (EDA)	Luisane

<b>Specifies of Analytical Desempenho</b>	Classroom 2	Definition of Analytical Performance Specifications (EDA)	Luisane
	Classroom 1	Selection of EDA-compatible analytical systems defined	Claudia
<b>Module III Selection of Analytical Systems</b>	Classroom 1	Internal quality control materials	Derliane
	Classroom 2	Introducing CIQ in the routine	Luisane
	Classroom 3	Setting your own averages	Claudia
	Classroom 4	Rules de Westgard	Claudia
	Classroom 5	Daily evaluation of CIQ results	Derliane
	Classroom 6	Treating unacceptable ICQ results	Derliane
<b>Module IV Selection and implementation of an internal quality control</b>	Classroom 1	Internal control with interlaboratory comparison	Anne Lucia
	Classroom 2	Proficiency test	Claudia
	Classroom 3	Alternative external assessment	Derliane
	Classroom 4	Unacceptable results of the aptitude test	Derliane
<b>Module V Using internal control data compared to labs and fitness test</b>	Classroom 1	Six Sigma applied to clinical work	Luisane
	Classroom 1	Analytical performance specifications and selection of control materials for routine	Luisane
<b>Module VI Six Sigma Metric</b>	Classroom 2	Determination of mean and standard deviation representing stable performance	Derliane
	Classroom 3	Setting performance targets for internal quality control	Claudia
	Classroom 4	Selecting the CIQ strategy based on performance goals	Luisane
	Classroom 5	Tools to select the CIQ strategy	Derliane
	Classroom 6	Define the CIQ strategy for multiple devices	Claudia
	<b>Module VII Quality Control Statistical Planning</b>	Classroom 1	Setting performance targets for internal quality control
Classroom 2		Determination of mean and standard deviation representing stable performance	Derliane
Classroom 3		Setting performance targets for internal quality control	Claudia
Classroom 4		Selecting the CIQ strategy based on performance goals	Luisane
Classroom 5		Tools to select the CIQ strategy	Derliane
Classroom 6		Define the CIQ strategy for multiple devices	Claudia

<b>Module VIII</b> <b>Analytical quality guarantee</b>	Classroom 1	Periodic evaluation of internal control results	Luisane
	Classroom 2	Resolving unacceptable CIQ results over time	Derliane
	Classroom 3	Analytical quality performance indicators using internal quality control information, interlaboratory comparison program and aptitude test	Claudia
<b>Module IX</b> <b>Practical application</b>	Classroom 1	Study of a "case": case study of the application of lessons learned	Derliane

## Westgard Syllabus

1. Six Sigma concept: sigma scale, common scores and sigma equation for analytical processes
2. Six Sigma tool: method decision chart - graphical quality assessment
3. Six Sigma Tool: OPSPECS table for optimal planning of DC procedures
4. Six Sigma Tool: Standardized OPSPECS Charts for a Unified View of QaD Planning
5. Six Sigma performance specifications (total error allowed): sources, internationally recommended target survey (comparative assessment)
6. Six Sigma: Best Practices for Obtaining Bias and Inaccuracy Estimates
7. Six Sigma: How to analyze and evaluate the different sources of bias: Accuracy-based aptitude test (EP), consensus-based PE, interlaboratory program, tested controls, etc.
8. Exercise: calculation of the sigma metric of performance data from a laboratory published in Turkey.
9. Six Sigma - examples: study of individual Sigma calculation cases
10. Six Sigma - examples: case studies of results, benefits, efficiency, savings and other practical gains obtained from the implementation of Six Sigma
11. Advantages of adopting a Six Sigma quality system for laboratories, regions and countries
12. Examples of implementation of Sigma metric in real-world labs

Kind regards



**BACT. Claudia Gil Puerta**  
Academic Coordinator