

**OPS**



Organización  
Panamericana  
de la Salud



ORGANISMO ANDINO DE SALUD  
CONVENIO HIPÓLITO UNANUE



SECRETARÍA EJECUTIVA  
**COMISCA**  
CONSEJO EL MINISTRO DE SALUD DE COLOMBIA Y ESTADOS UNIDOS



**SICA**  
Sistema de la Integración  
Centroamericana

## **Global Fund Multi-Country Grant**

**“Strengthening laboratory diagnosis of TB in the Americas region”**

## **Workshop for accreditation under ISO 15189 criteria for Tuberculosis laboratories**

### **Participating lecturers:**

**Maribel Espinosa Pulido, BS, Colombia**

**Roberto Carboni Huerta, BS MBA, Chile**

**October 2021**

## **GENERAL OBJECTIVE**

Provide a Workshop for the accreditation of Tuberculosis laboratories under ISO 15189:2012 criteria and identification of those that have significant progress in the implementation of their Quality Management System (QMS).

## **SCOPE OF WORK**

The workshop aims to train professionals and technicians from 17 countries using virtual tools. They will be responsible for the accreditation process in the TB Supranational Laboratories and National Reference Laboratories in the Americas region.

## **WORKSHOP DATE**

The training activity will be in the form of a virtual interactive workshop that will last 5 days between November 15 and 19, 2021, from 09:00 to 13:00. (World Time Peru, UTC-5).

The activity includes Pre-Test, Virtual Workshop, and Post-Test activities.

## **WORKSHOP AGENDA**

- Development of a Pre-Test evaluation to the workshop participants, they would have 24 hours to enter a digital platform (it will be sent to the participants' emails) and they will have 2 hours to answer a questionnaire of 10 selection questions multiple. The Pre-Test must be sent before the start of the workshop (Monday, November 15, 8:00 am).
- The responses of the participants and their corresponding evaluations will be presented during the workshop and will serve to make the final adjustments and improvements of the topics to be discussed.
- On November 14, a survey will be made available to participants, the purpose of which is to establish the level of implementation of the QMS in their laboratories.
- Workshop participants must develop a Post-Test activity that will be found on a digital platform. Participants would have 24 hours to enter the platform and 2 hours to answer a questionnaire of 10 multiple-choice questions.

- To obtain certification of the Workshop it is necessary to answer the Pre and Post-Test and have 100% attendance on the days of the workshop.

## **METHODOLOGICAL DESIGN**

As requested, the activity has been designed in the form of a virtual interactive Workshop, with the participation of professionals from 17 TB laboratories in the region.

The requested program includes topics considered of priority interest by the laboratory staff. The required topics were complemented with the requirements of ISO 15189.2012 to present to the attendees a comprehensive vision of the Accreditation Standard and to identify the areas of opportunity in the implementations or advances that have advanced in their laboratories.

### **Support methodology**

#### **Virtual lectures**

Each day (total 5 days), the activities will be carried out through four synchronous sessions, 45 minutes long and with a 15-minute break between each one. The activities will be directed by the two speakers in equal parts.

During the presentation, aspects related to the interpretation of the requirements of the standard and the tools necessary for its proper implementation will be discussed. The lecturers will pay special attention to the aspects required by the laboratory staff.

The lecturer will carry out an expository induction using didactic material such as PowerPoint presentations and cases of their experience regarding the subject. The methodological strategy seeks to acquire knowledge associated with the practical implementation of the normative requirements of ISO 15189.

At the end of each session, students will be able to ask questions, comments and interact with the speakers.

Additionally, the program considers time for the representatives of 6 laboratories (Chile, Peru and Mexico, Argentina, Colombia, and Guatemala) to present their progress status in the implementation of the Quality Management System in PowerPoint format. This 15 - 20 minutes presentation will respond to a questionnaire prepared by the lecturers whose answers will guide the preparation of the Final Report that will contain a proposal regarding the steps to follow in the laboratory accreditation process.

As part of the good practices for attendees, it is suggested to enter the platform 15 minutes in advance to allow the registration of attendance, resolve doubts, or possible technical failures and not compromise the time dedicated to training and presentations.

## **Support material**

At the end of the workshop, participants will receive the class material in PDF format with notes and complementary reading articles.

## **Pre and Post-test activity**

The pre and post-test will have the following characteristics:

- 10 questions
- Multiple selection format
- 2 hours to reply
- Overall rating 10.0
- Approval score 7.0. The approval condition will only apply to the Post-Test activity.

## **Expected requirements of the participants**

- Basic knowledge of ISO 15189:2012 requirements. It is recommended to read the document beforehand (it is sent together with the workshop agenda).
- Have a zoom account (the link for each day will be sent by email and it is at the end of the agenda).
- Register with your full name to track your attendance.

## TOPICS

<b>Date</b>	<b>Schedule</b>	<b>Proposed topic</b>	<b>Speaker</b>
Monday, Nov 15	08:45 – 09:00	<b>Opening</b>	ORAS-CONHU
	09.00 – 09.45	<b>Quality concepts and standards</b> <b>Differences between ISO 15189 and 17025</b>	Roberto Carboni MS MBA
	Break 15 min	4.1 Organization and responsibility of management	
	10.00 – 10.45	4.2 Quality Management System Quality system planning <b>Process management</b> <b>Standardization of processes</b>	
	10.45 – 11.00	Break	
	11.00 – 11.45	4.3 Control of documents and records 4.4 Contracts for the provision of services <b>Vendor management</b> 4.5 Examinations carried out by outsourced laboratories 4.6 External services and supplies	Maribel Espinosa BS
	12.00 – 12.30		
	12.30 – 13.00	Chile Laboratory Presentation <i>20 minutes for presentation, 10 minutes for questions and discussion</i>	
Tuesday, Nov 16	09.00 – 09.45	4.7 Advisory services <b>Customer (user) satisfaction</b>	Maribel Espinosa BS
	Break 15 min	4.8 Resolution of complaints 4.9 Identification and control of non-conformities	
	10.00 – 10.45	<b>Non-conformities and improvement minutes</b>	
	10.45 – 11.00	Break	
	11.00 – 11.45	4.10 Corrective actions 4.11 Preventive actions 4.12 Continual improvement <b>Compliance and continuous improvement</b> <b>Root cause analysis</b>	Roberto Carboni MS MBA
		12.00 – 12.30	
	12.30 – 13.00	Mexico Laboratory Presentation <i>20 minutes for presentation, 10 minutes for questions and discussion</i>	
Wednesday, Nov 17	09.00 – 09.45	4.13 Control of records 4.14 Evaluation and audits <b>Risk analysis and management</b> <b>Management indicators</b> <b>Training of internal auditors</b>	Roberto Carboni MS MBA
	Break 15 min	4.15 Management review	
	10.00 – 10.45		
	10.45 – 11.00	Break	
	11.00 – 11.45	5.1 Personnel <b>Organization of human resources</b> <b>Management of staff competence</b>	Maribel Espinosa BS
	Break		

	12.00 – 12.30		
	12.30 – 13.00	Peru Laboratory Presentation <i>20 minutes for presentation, 10 minutes for questions and discussion</i>	
Thursday, Nov 18	09.00 – 09.45	5.2 Facilities and environmental conditions <b>Spill response and reporting</b>	Maribel Espinosa BS
	Break	5.3 Laboratory equipment <b>Maintenance of equipment and metrological operations</b>	
	10.00 – 10.45	5.4 Pre-analytical processes	
	10.45 – 11.00	Break	
	11.00 – 11.45	5.5 Analytical processes <b>Method validation or verification of qualitative methods</b>	Roberto Carboni MS MBA
	Break		
12.00 – 12.30			
	12.30 – 13.00	Argentine Laboratory Presentation <i>20 minutes for presentation, 10 minutes for questions and discussion</i>	
Friday, Nov 19	09.00 – 09.45	5.6 Quality assurance of measurement procedures <b>Quality assurance</b>	Roberto Carboni MS MBA
	Break	5.7 Post analytical processes	
	10.00 – 10.45		
	10.45 – 11.00	Break	
	11.00 – 11.45	5.8 Notification of results 5.9 Communication of results 5.10 Laboratory information management <b>Conditions that must be met after accreditation and for how long this process is maintained</b>	Maribel Espinosa BS
	Break		
12.00 – 12.30			
	12.30 – 13.00	Colombia, Guatemala Laboratory Presentation <i>20 minutes for presentation, 10 minutes for questions and discussion</i> Conclusions	

**Note:** The aspects required by the laboratories are indicated in bold.

## **LINKS TO ACCESS THE ZOOM PLATFORM**

**From November 15 to 19, 2021**

Monday, November 15, 2021

[https://us02web.zoom.us/meeting/register/tZAqf-uqrzsvGdaU7kuavANZ0C\\_j5rJ0tST9](https://us02web.zoom.us/meeting/register/tZAqf-uqrzsvGdaU7kuavANZ0C_j5rJ0tST9)

Tuesday, November 16, 2021

[https://us02web.zoom.us/meeting/register/tZAlcuqqpjwiEtNOI1eVkg5lc6HX\\_gfzRTkM](https://us02web.zoom.us/meeting/register/tZAlcuqqpjwiEtNOI1eVkg5lc6HX_gfzRTkM)

Wednesday, November 17, 2021

<https://us02web.zoom.us/meeting/register/tZEuce-vrDgiHtdA27556XTaCNYVrw8VLWfR>

Thursday, November 18, 2021

<https://us02web.zoom.us/meeting/register/tZEscOutpsjHtZ8FWYEQ6XUZ7Zbe1EEhDts>

Friday, November 19, 2021

<https://us02web.zoom.us/meeting/register/tZcrduirqz8qHtEd6dJ4-CdzUvDewr0M6b4c>

### **emails of participating lecturers:**

BL Maribel Espinosa Pulido, Colombia: [maribelespinosapulido@yahoo.com.mx](mailto:maribelespinosapulido@yahoo.com.mx)

BQ Roberto Carboni Huerta, Chile: [rcarboni@laboratorioconsultores.cl](mailto:rcarboni@laboratorioconsultores.cl)