World Health Organization

TRAINING ON LABORATORY QUALITY MANAGEMENT AND BIOSAFETY FOR NATIONAL INFLUENZA CENTRES

UNIVERSITY OF SIENA, SIENA, ITALY

23-27 JULY 2018

PROVISIONAL PROGRAMME

Purpose:
To increase participants' understanding of and capacity to implement Laboratory Quality Management Systems (LQMS) including best practice in laboratory biosafety in their respective laboratories.

By the end of the training participants should be able to:

- Understand and explain the model of Laboratory Quality Management System and 12 Quality System Essentials (QSE) as a systematic approach to quality management, its importance and benefits
- Describe major elements of some QSE, link them together and with other QSEs related to influenza laboratory surveillance
- Discuss selected approaches and tools for assessment and monitoring of quality management activities
- Understand and apply the concept of stepwise implementation of LQMS, demonstrate knowledge and skills to use the Laboratory Quality Stepwise Implementation (LQSI) tool in their daily practice

Day 1: 23 July 2018		
8:30 – 9:00	Opening remarks	WHO, Anne Moen
9:00 – 9:30	Introduction of trainers and participants	Trainers, participants
9:30 – 10:00	Objectives of the training	Magdi Samaan
10:00 – 10:30	Pre-test	All participants
10:30 – 11:00	Coffee break	
11:00 – 12:00	**Introduction to Laboratory Quality Management System** *Explain the importance of a quality management system; List the essential elements of a quality management system*	Michael Pentella, UIOWA
12:00 – 12:30	**Sample management and transport** *Name some sample collection errors that could lead to incorrect laboratory examination results; List contents that should be included in a handbook designed for people who collect samples off-site; Provide a rationale for rejecting unsatisfactory samples*	Simona Puzelli, NIC Italy
12:30 – 13:30	Lunch	
13:30 - 14:30	**Sample management and transport cont'd** *Describe a system for sample handling, including collection, transport, storage, and disposal; Explain the importance of maintaining sample integrity and assuring that all regulations and requirements are met when transporting samples*	Simona Puzelli, NIC Italy
14:30 – 15:00	**Quality control for influenza labs** *Define quality control and describe its relationship to the overall quality management system; Describe differences in quantitative, semi-quantitative, and qualitative examinations; Differentiate accuracy and precision; Select control material for a specified examination method; Establish acceptable control limits for a method when only one level of control material is available* *LOD and semiquantitative QC for PCR test*	Simona Puzelli, NIC Italy
15:00 – 15:15	Coffee break	
15:15-16:15	**External quality assessment (EQAP)** *Discuss the importance of an EQA program in improving the quality of laboratory test results; Describe at least three EQA methods and the advantages and disadvantages of each; Outline a method to investigate an unacceptable test result from an EQA sample; WHO EQAP*	Magdi Samaan
16:15 – 16:30	**Group Photo**	

Day 2: 24 July 2018		
8:30 – 9:30	**Document control and information management** *Explain the difference between documents and records; Explain the important steps, or elements, of a laboratory document management system; Describe important elements of an information management system; Describe the advantages and disadvantages of a computerized information management system*	Jayme Parker, APHL
9:30 – 10:30	**Reporting influenza virological surveillance data to FluNet** *Virological data and reporting to WHO platforms; FluNet reports*	Anne Moen, WHO
10:30 – 11:00	Coffee break	
11:00 – 12:00	**NIC TORs and Performance review process**	Magdi Samaan, WHO
12:00 – 12:30	**Virus sharing** *WHO Guidance on IVPP and seasonal influenza virus sharing; SFP and sharing for VCM; CVVs*	Amal Barakat, WHO
12:30 – 13:30	Lunch	
13:30 - 14:30	**Packaging and Shipping** *This brief refresher lecture will describe proper packaging and shipping for Category A and B agents. Participants will then participate in an interactive demonstration of preparing package inserts and labeling for different agents.*	Luca Nelli, Siena and Magdi Samaan, WHO
14:30 – 15:00	**Packaging and Shipping Exercise**	Magdi Samaan, WHO
15:00 – 15:30	Coffee break	
15:30 – 16:30	**Internal audits** *Plan and manage an internal audit* *Discuss how to use results from a laboratory audit* *Advocate for the importance of taking corrective actions*	Jayme Parker, APHL Exchange with spill clean up

Day 3: 25 July 2018		
8:30 – 9:30	**Risk Assessment** (Classroom) *This session will review definitions and terminology relating to risk management, mitigation and performance as well as provide methodologies and tools for conducting risk assessments. It will provide an overview of risk management systems.*	Michael Pentella, UIOWA
9:30 – 10:30	**Risk Assessment** (Classroom) ☣ Exercise 1 (kitchen) ☣ What is a hazard? ☣ What is risk? ☣ What is a threat? ☣ Risk equation	Magdi Samaan, WHO
10:30 – 11:00	Coffee break	
11:00 – 12:00	**Risk Assessment Exercise** (Classroom) ☣ Exercise 2 (Influenza), steps 1 and 2	Michael Pentella, UIOWA
12:00 – 12:30	☣ Exercise 2 (Influenza), steps 3, 4 and 5 ☣ Benefits of a robust risk assessment ☣ What is acceptable risk?	Michael Pentella, UIOWA
12:30 – 13:30	Break	
13:30 - 14:30	**BIORISK ASSESSMENT CONT'D** ☣ BioRAM Lite ☣ Exercise 3 (Pablo, seasonal Influenza, AI), step 1	Magdi Samaan, WHO
14:00 – 15:30	**BIORISK ASSESSMENT CONT'D** ☣ Exercise 3 (Pablo, seasonal Influenza, AI)), step 2 ☣ Recap and key messages	Magdi Samaan, WHO
15:30 – 15:45	Coffee break	
15:45 – 16:30	**Biorisk Mitigation** ☣ Mitigation measures ☣ Advantages and disadvantages Prioritization	Michael Pentella, UIOWA

Day 4: 26 July 2018		
8:30 – 9:30	**Facilities design** *Relate how facility design impacts the efficiency and safety of laboratory workers* *Describe practices to prevent or reduce risks* *Exercise: "Critical analysis of a simple laboratory floor plan" or Exercise: "Avian flu epidemic" (LQMS Toolkit, Activity 2-1)* *(if time permits)*	Michael Pentella, APHL
9:30 – 10:30	**Occurrence management** *Define the term "occurrence"* *Describe the essential quality monitoring tools* *Differentiate among remedial action, corrective action, and preventive action* *Describe the relationships between preventive action and risk management practices* *Define and describe root cause analysis*	Michael Pentella, UIOWA
10:30 – 11:00	Coffee break	
11:00 – 12:00	**Spill Clean-up Procedures** *This lecture will cover how to build appropriate spill kits based on risk assessments and proper procedures for spill clean-ups depending on the type of spill. With or without demonstration*	Jayme Parker, APHL
12:00 – 12:45	Lunch	
12:45 – 15:00	**Practical session in the lab (donning and doffing and lab audit) VisMederi lab**	Jayme and Michael
15:00 – 15:15	Coffee break (depends on lab facility design)	
15:15 –16:30	**Practical session in the lab (donning and doffing and lab audit) VisMederi lab cont'd**	Jayme and Michael

Day 5: 27 July 2018		
8:30 – 10:00	**Stepwise LQMS implementation: Use of LQSI tool** *Demonstration of LQSI tool* *Group exercise: "Use LQSI tool to assess your laboratory and identify major gaps"* *Group exercise: "Use LQSI tool to develop an action plan for LQMS improvement in your laboratory"* *Illustrative presentation*	Magdi Samaan, WHO
10:00 – 10:30	**Post-test**	All participants
10:30 – 11:00	Coffee break	
11:00 – 12:30	**Final evaluation of the training and Closing remarks and closure of training**	All participants
12:30 – 13:30	Lunch	