

中国防痨协会

中防痨发〔2019〕14号

中国防痨协会关于举办结核病实验室质量控制 培训班的通知

各疾病预防控制中心（结核病防治所）、各医疗卫生机构、科研院所、事业单位：

结核病实验室在结核病预防控制工作中发挥着日益重要的作用，建立和保持规范的实验室质量管理体系是保证实验结果的准确、可靠、及时的关键。为了规范和提高我国结核病实验室的管理水平，由中国防痨协会结核病基础专业分会、深圳市慢性病防治中心、复旦大学、NIH/NIAID 和美国约翰霍普金斯大学联合举办“结核病实验室质量管理体系培训班”，欢迎全国结核病预防和临床单位的结核病实验室负责质控的人员参加。培训班初步日程请见附件。

一、主办单位及承办方

主办单位：中国防痨协会结核病基础专业分会，中国防痨协会“一带一路”结核病控制合作中心，深圳市慢性病防治中心，NIH/NIAID，美国约翰霍普金斯大学。

承办方：深圳市慢性病防治中心，复旦大学基础医学院高谦教授课题组。

二、培训时间及地点

（一）培训时间

2019 年 5 月 28-6 月 1 号，5 月 27 号报到，6 月 2 号 撤离。

（二）培训地点

深圳市慢性病防治中心，深圳市罗湖区布心路 2021 号。

三、授课专家

Derek Armstrong 教授，NIH/NIAID, 美国约翰霍普金斯大学医学院。

四、培训详情

（一）培训规模：学员 25-30 人；

（二）培训语言：英文授课，简单中文翻译；

（三）培训形式：理论学习，小组讨论，实验室演示；

（四）培训费用：培训班免费，食宿、交通自理；

（五）学员要求本科及以上学历，有一定英文交流能力。

五、申请事宜

（一）申请流程

1. 申请人需要写一份培训班申请书，说明培训内容对自己工作的重要性以及对培训班的期望；

2. 需要单位同意参加培训班证明（在自己申请书上领导签字或盖章，扫描件）；

3. 培训组委会将根据学员的条件择优录取。

（二）申请方法

1. 报名请发送邮件至以下联系人邮箱，邮件题目注明“结核

病实验室质量管理体系培训班报名”；

2. 联系人：蒙粮广，17665329039，szjfk@163.com。

(三) 申请时间

申请截止日期 4 月 15 号。



Summary and Agenda

Quality Management Course Overview:

The role of the laboratory in combating tuberculosis disease is extremely important and assuring systems that are accurate, timely and reliable are critical to its success. Often there are challenges setting up and maintaining a Laboratory Quality Management System (LQMS) that are both practical and achieve success.

This course provides an overview to these systems and their relevant components, based on internationally recognized standards as set forth by the World Health Organization and their partner institutions. The importance of quality management in the TB laboratory will be discussed using a systems approach, highlighting the key components of a successful LQMS and the importance of quality assurance and quality control. Students will review critical elements in order to better understand key internal and external factors that can affect these quality systems from both a clinical and research perspective. Finally, course participants will be able to put into practice these “keys to success” through interactive case studies and a review of the current TB diagnostic landscape.

Structure: Lecture-based (PPT), group break-out sessions, hands-on activity (GeneXpert), lab tour (if possible-helpful for hands-on assessment of current practices and procedures)

Daily Schedule:

Day 1: Overview to Laboratory Quality Management Systems (QMS) in the TB Lab

- a. Introduction to Quality Management
- b. Five Pillars of every Quality System
- c. Laboratory Essentials for Quality
- d. Breakout session: Approaches in TB Laboratory QMS

Day 2: Quality Management System Essentials

- a. Setting up a QMS: Key Components
- b. Internal and external factors affecting quality
- c. Breakout Session: Documentation and SOPs

Day 3: Quality Assurance and Quality Control

- a. QA/QC Overview
- b. Importance of Quality Indicators
- c. Breakout Session: Xpert MTB/RIF Quality Assurance Program review

Day 4: Quality Systems and the TB Lab: Putting into Practice (Part 1)

- a. Review of Lab Core Processes (Pre-Analytical, Analytical, Post-Analytical)
- b. QMS and Data Management: Overview
- c. Breakout Session: Case Studies in TB Lab QA/QC

Day 5: Quality Systems and TB Laboratory Platforms: Putting into Practice (Part 2) and Wrap-Up

- a. Case Studies in TB Lab QA/QC (continued)
- b. Key Components of Quality-Assured TB Research
- c. Laboratory Tour and Assessment (optional)
- d. Wrap-up