



## **RCORE TRAINING AT FDA GHANA**

### **Background**

The training of three (3) LMHRA staff is one of the activities of the IGORCADIA Project Work Package # 3. This deliverable had experienced some delay respect the planned date due to the difficulty of getting an RCORE institution to conduct the training at an affordable cost in line with the appropriation made in the budget. Several contacts were made with different RCORE centers around African countries believed to have stringent regulatory bodies, including South Africa, Tanzania, Zimbabwe, Ghana and Nigeria. The Center for Pharmaceutical Advancement and Training (CePAT), a subgroup of the United States Pharmacopoeia Convention (USP) based in Accra, Ghana was also contacted.

Many of these countries either did not have the capacity to conduct the training or did not respond to our request. CePAT-Ghana responded twice, but with very exorbitant cost which far exceeded budgetary appropriation. Fortunately, the Food and Drug Authority (FDA) of Ghana responded favorably and with a responsible price of **U.S.\$2,200.00** per trainee. The date set by FDA Ghana (11<sup>th</sup> – 22<sup>nd</sup> February, 2019) was accepted by us the trainees. An approval was granted by EDCTP, and the LMHRA Team departed Liberia on 10<sup>th</sup> February 2019 via Kenya Airways for Accra, Ghana.

### **Reception and Hospitality of the Host**

Even though the LMHRA team was not received on arrival at the Kotoka International Airport as that was not part of the arrangement with FDA Ghana, we were able to proceed straight to the Essland Hotel which is a few kilometers away from FDA Ghana's main office complex via a local taxi cab.

We proceeded to the FDA Ghana's main office on the next day to commence the

training which started with an opening ceremony with executives of FDA Ghana. Subsequently, the training began.

Overall, the host was very hospital. They co-operated with us and guided us throughout our stay in Accra, Ghana.

### **Highlights from the Training – The Training Process and Achievements**

The training commenced on 11<sup>th</sup> February 2019. Three (3) technical arms of the FDA facilitated the training; namely: Registration Department, Enforcement Department and Medical Device Laboratory. The detailed schedule and topics covered are contained in the schedule attached.

The training was comprehensive and elaborated. It entailed presentations, illustrations, group discussions and hands-on activities where necessary. The key achievements of the LMHRA Team from the training are:

1. The team is now equipped with the skills to re-structure its guidelines to meet internationally accepted standards;
2. The team is now able to conduct medical device/in-vitro diagnostics dossier evaluation;
3. The team is now equipped with the skills to conduct medical device/in-vitro diagnostics inspection and enforcement of the laws or guidelines relative thereto;
4. The team is capable of conducting pre- and post-market inspection/surveillance of medical device/in-vitro diagnostics;
5. The team is now equipped with the skills to conduct quality control tests for most medical devices including in-vitro diagnostics such as those for infectious diseases (malaria, HIV & TB), pregnancy test kits, blood glucometer including, gloves, and condoms.

### **The Financial Aspect of the Trip**

The air tickets were purchased before our departure (US\$ 481 x 3 = US\$1,443.00), while the cost of training (US\$ 2,200 x 3 = US\$6,600.00) was paid in advancement via bank transfer to FDA Ghana's bank account. With the exception of the cost for lunch on Saturday and Sunday (February 16 & 17, 2019), the other expenses were paid in advance directly to the LMHRA team by the Accounts Department. Below is a breakdown of the expenses made by the LMHRA team:

1. Cost of transportation from Kotoka International Airport to Hotel = US\$ 15.00 \*
2. Hotel Accommodation = \$75/person/night x 13 nights x 3 persons = US\$2,925.00\*\*
3. Diets/Dinner -\$15/person/night x 13 nights x 3 persons = US\$ 585.00
4. Cost of Lunch (Sat. & Sun., 16<sup>th</sup> & 17<sup>th</sup> Feb. 2019) - \$15/person/day x 2 days x 3 persons = US\$90.00\*
5. Cost of transportation from Hotel to Kotoka International Airport = US\$ 15.00 \*

**NOTE 1:** \* These were expenses made jointly by the team since this amount was not given to us by the Chief Accountant, Mr. Del Nagbe. The total amount = US\$15 + 15 + 90 = **US\$120.00** (to be reimbursed to the LMHRA team by Mr. Nagbe upon approval by Cristina).

**NOTE 2:** This total does not have receipts because the taxi drivers in Accra, Ghana do not give receipts. Also, we didn't request receipts for diets because that's not required by EDCTP.

**NOTE 3:** \*\* This expense was made with a receipt which we have to present to the Finance Department.

### **The Next Steps**

The next steps are contained in the roadmap document which the Team has already drawn up and ready for presentation to the Managing Director, Mr. David Sumo upon my return from Morocco. This roadmap outlines all activities to be performed leading up to the regulation of in-vitro diagnostics and other medical devices within the scope of regulation by LMHRA. It includes roll-over training on IVD regulation to designated staff of LMHRA, upgrading the four (4) regulations we now have and development of more regulations, policies and procedures for IVD regulation.

### **Conclusion**

Overall, the training was rewarding and our achievements were beyond expectation. With the co-operation of all stakeholders, the objectives shall be achieved.