# PROPOSAL FOR THE DEVELOPMENT OF REGIONAL CENTRE OF REGULATORY EXCELLENCE (RCORE) MANUAL FOR VACCINES AND BIOLOGICAL PRODUCTS

**FOOD AND DRUGS AUTHORITY**

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## 1.0 Introduction

The competencies of the various national medicines regulatory agencies (NMRAs) in Africa vary which leads to generally porous regulatory systems for medicines and vaccines registration.

To improve the safety and quality of health technologies in Africa, the New Partnership for African Development (NEPAD) agency launched a program to designate Regional Centers of Regulatory Excellence (RCOREs) with the specific objective of bridging existing gaps between African NMRAs through strengthening regulatory capacity of African Union member states.

As part of its mandate to strengthen regulatory capacity development in Africa, the NEPAD Agency through its AMRH program has currently designated 11 Regional Centers of Regulatory Excellence (RCOREs) in eight different functions, as shown in Figure 1.

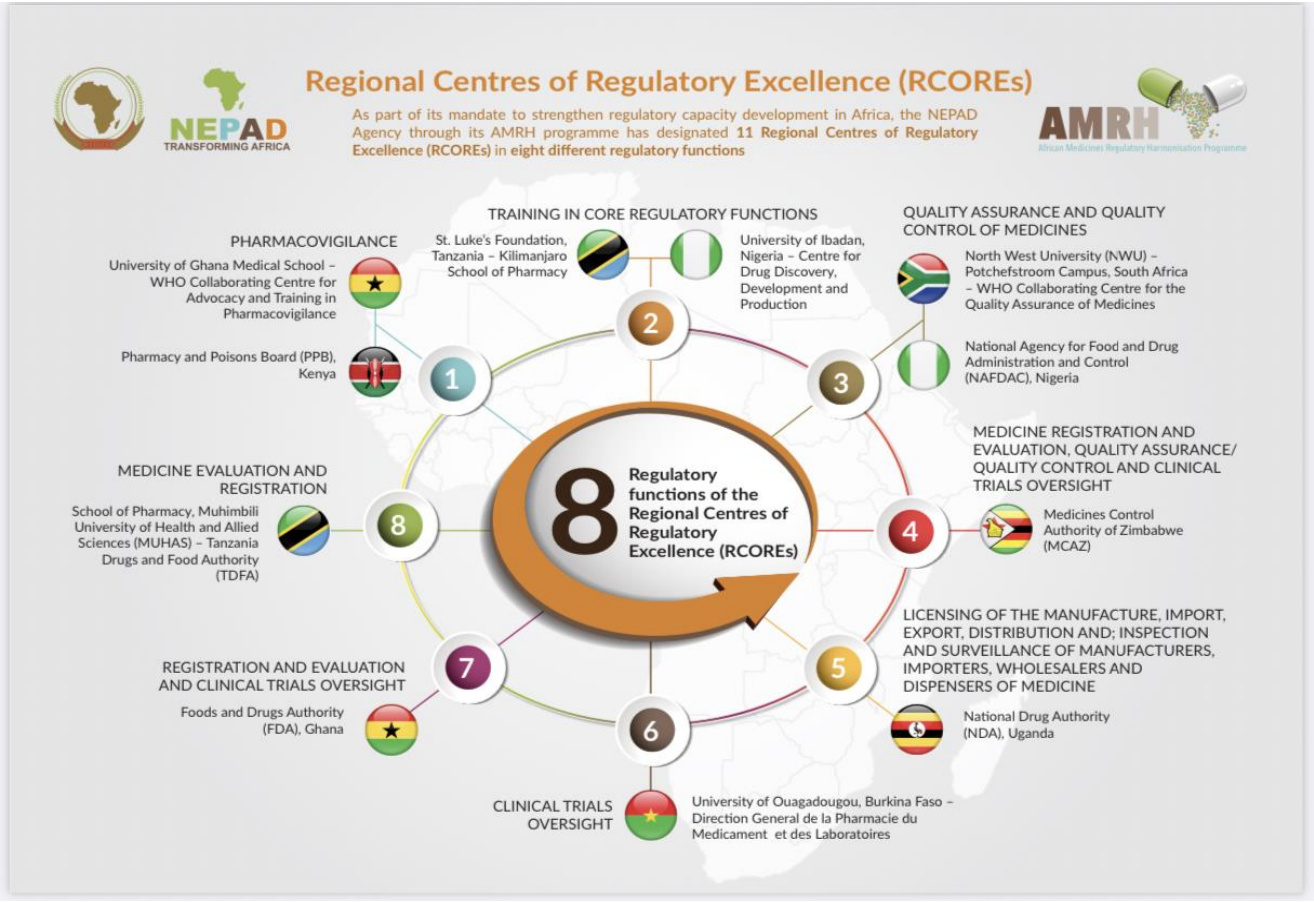


*Figure 1. 11 Designated RCOREs and their Regulatory functions in Africa*

The Food and Drugs Authority (FDA) has been designated as an RCORE in Medicine Registration and Clinical Trials since May 2014 and in Pharmacovigilance.

## 1.1 Objective of an RCORE

After being designated, RCOREs are anticipated to create a regulatory workforce in Africa by carrying out the following tasks.

- Increasing the regulatory workforce and regulatory function performance in African Union member states through academic and technical regulatory science training relevant to various regulatory functions and managerial elements.

- Support the development of skills through practical training, twinning, and exchange programs among NMRAs, placement in pharmaceutical industry.

- Establish a forum where regulators and researchers can regularly exchange thoughts, information, and experiences with the goal of advancing Good Regulatory Practices (GRP) in the direction of regulatory harmonization, work-sharing, collaboration, and reliance.

- Execute operational research to test innovations and interventions in pilot settings to identify best practices for replication by other National Medicines Regulatory Agencies.

## 2.0 FDA's experience as an RCORE

The FDA, Ghana was designated by the New Partnership for African Development (NEPAD) and the African Regulatory Harmonization (AMRH) as a Regional Centre of Regulatory Excellence (RCORE) in Medicine Registration and Clinical Trials in May 2014.

As an RCORE, the FDA in collaboration with the School of Public Health, University of Ghana, continue to build capacity in Clinical Trials regulation within the sub-region and improve access to medicine though harmonization of regulatory requirements. This has resulted in the training of over 54 regulators from all over Africa.

Since the inception of the RCORE project, emphasis has been on training regulators involved in the processing of Clinical Trial applications due to the availability of

sponsorship and training manual on clinical trials. The registration of vaccine and medicines has not experienced similar support in terms of funding, coupled with the fact that the training manual for registration and/or marketing authorization for medicines and vaccines have not been fully developed in the case of medicines and not developed in the case of vaccines.

## 3.0 Problem Statement

The RCORE initiative in Ghana has centered its efforts on clinical trials as explained above with a void created in the registration of medications ever since it began. The Vaccine and Biological Product Department is working to create an RCORE training manual that will help to fill knowledge gaps in vaccine and biological product regulation by National Regulatory Authorities in the African region as Ghana prepares to upgrade its WHO GBT Maturity level 3 to level 4 and begin local vaccine production. The covid-19 pandemic has thought us a lesson on preparedness and need for capacity building.

The developed training manual will serve as a guide for trainers to train regulators in the regulation and procedures for processing marketing authorization applications for vaccines and biological products. This fellowship training will ensure that trainees develop sufficient capacity to evaluate product development dossiers for submitted MA applications. The efficient implementation of the RCORE fellowship will contribute to the promotion and the implementation of the principles of Good Regulatory Practices (GRP) towards regulatory harmonization, work-sharing, collaboration, and reliance.

## 4.0 Vaccines and Biological Products RCORE Programme

The Vaccines and Biological Products RCORE fellowship programs will be a total of twenty-week intensive program targeted at the underlisted categories of

- Research Scientists involved in vaccines and Biological Products
- Pharmaceutical industry persons especially those involved in vaccines and biological products
- Staff of national medicines regulatory agencies (NMRAs)
- Post-graduate students in the area of vaccinology and Regulatory science
- Persons interested in Vaccines and Biological Products Regulation

The fellowship program will include theory as well as practical sessions to be facilitated by Vaccines and biological products assessment experts from FDA and School of Public Health, University of Ghana.

The proposed RCORE manual will be used for instruction and as a resource tool. For wider circulation, the Manual will be made available in both printed and electronic versions.

Three fellowship programs are proposed to be included in the RCORE training manual as listed below:

- Fellowship- Vaccines and Biological Products Registration (Quality, Safety and Efficacy)
- Fellowship-Specialization in Vaccines and Biological Products Registration (Quality Assessment, API and FPP)
- Fellowship-Specialization in Vaccines and Biological Products Registration (Clinical Assessment and nonclinical assessment– PK/PD, Safety and Efficacy)

Table 1, 2 & 3 provides the proposed modules to be taught during the RCORE training program. The detailed content will be developed and reviewed by a team of Vaccine and Biological products assessment experts and academicians from FDA and University of Ghana.

**Table 1. Fellowship- Vaccines and Biological Products (VBP) Registration (Quality, Safety and Efficacy)**

| PERIOD | Module | ACTIVITY |
|---|---|---|
| Week1 | Module 1 | Introduction: VBP Registration and VBP – 5 Days |
| Week 2 | Module 2 | Biological Drug Substance – Assessment – 5 Days |
| Week 3 | Module 3 | Product Development (3.2.P.1, 3.2.P.2, 3.2.P.4 and 3.2.P.7) - 5 days |
| Week 4 | Module 4 | Finished product manufacturing, validation scale-up (3.2.P.3) – 5-days |
| Week 5 | Module 5 | Control of Finished Product (3.2.P.5) – 5-days |
| Week 6 | Module 6 & Module 7 | Impurities in Biological Drug Substance and FPP – 3 days |

| | | |
|---|---|---|
| | | Module 7 – Stability studies protocol and report (3.2.S.7 and 3.2.P.8) – 3 days |
| Week 7 | Module 8 | Bioanalytical Methods – 5 days |
| Week 8 | Module 9 | Clinical Assessment (Clinical Pharmacology, Safety and Efficacy) |
| Week 9 | Module 10 | Product Information (SmPC, PIL and Labels) |
| Week 10 | | Variation<br>Full Dossier Assessment by participant – 4 days |

**Table 2. Fellowship-Specialization in Vaccines and Biological Products (VBP) Registration (Quality Assessment, API and FPP)**

| PERIOD | MODULE | ACTIVITY |
|---|---|---|
| Week 1 | Module 2 | Biological Drug Substance Assessment – 5 Days |
| Week 2 | Module 3 | Product Development (3.2.P.1, 3.2.P.2, 3.2.P.4 and 3.2.P.7) – 3 Days |
| Week 2-3 | Module 4 | Finished product manufacturing, validation and scale-up (3.2.P.3) – 3-days |
| Week 3 | Module 5 | Control of Finished Product (3.2.P.5) – 4-days |
| Week 4 | Module 6 & Module 7 | Impurities in Biological Drug Substance and FPP – 3 days.<br>Module 7 – Stability studies protocol and report (3.2.S.7 and 3.2.P.8) – 3 days |
| Week 5 | | Variation<br>Full Dossier Assessment by participant – 4 days |

**Table 3. Fellowship-Specialization in Vaccines and Biological Products (VBP) Registration (Clinical Assessment and nonclinical assessment– PK/PD, Safety and Efficacy)**

| PERIOD | MODULE | ACTIVITY |
|---|---|---|
| Week 1 | Module 1 | Introduction: VBP Registration and VBP – Days |
| Week 1 | Module 8 | Bioanalytical Methods – 4 days |
| Week 2 & 3 | Module 9 | Clinical & Nonclinical Assessment (Clinical Pharmacology, Safety and Efficacy) |
| Week 4 | Module 10 | Product Information (SmPC, PIL and Labels)-3 days |
| Week 4 & 5 | | Full Dossier Assessment by participant – 7 days |

## 5.0 Work plan

The RCORE manual will be developed in 20 working days which will be organized as one five-day residential meeting and one 15 days working and research session. The draft manual will be reviewed in 10 working days session.

### 5.1 Deliverables

The key deliverable from the project will be a designed RCORE manual for Vaccines and Biological products.

### 5.2 Project completion timeline

The expected timeline for completion of activity is 31st December 2022.

## 6.0 Proposed Budget

The estimated budget for the activity is One hundred and ninety-seven thousand, eight hundred Ghana Cedis only (Ghc197,800)

# 7.0 FDA Contact Person

The FDA contact person for all queries / follow up on the project is Dr. Edwin Nkansah, Director of Safety Monitoring and Clinical Trials Directorate.

- **Email: edwin.nkansah@fda.gov.gh**
- **Mobile Number: +233206059700**

## Appendix 1: Proposed Budget

| No. | Item | Unit Cost | No. of persons | Factor | Total (Ghc) | Total (USD)<br><br>1USD:8 Ghc | Comments |
|---|---|---|---|---|---|---|---|
| 1 | Conference facility in Volta Region | 380.00 | 8 | 5 | 15,200.00 | 1900.00 | Conference facility for 8 drafter for 5 days |
| 2 | Hotel Accommodation | 600.00 | 8 | 6 | 28,800.00 | 3,600.00 | Accommodation for 8 drafters for 6 nights |
| 3 | Expert fee for Manual Drafting | 600.00 | 8 | 20 | 96,000.00 | 12,000.00 | Expert fee for 8 persons to draft the manual. Consisting of 2 staff of School of Pharmacy, UG and 6 Staff from FDA |
| 4 | Expert fee for Manual Reviewer | 600.00 | 5 | 10 | 30,000.00 | 3,750.00 | 5 FDA officers to review the manual |
| 5 | Proof Reading of Manual | 2,000.00 | 1 | 1 | 2,000.00 | 250.00 | Fees to be paid to proofreader of final draft of manual |
| 6 | Transportation FDA staff from Accra to Volta Region | 1,500.00 | 2 | 1 | 3,000.00 | 375.00 | Two teams consisting of two drafters per vehicle |
| 7 | DSA for drivers | 400.00 | 2 | 6 | 4,800.00 | 600.00 | Two drivers for the two teams |
| 8 | Transportation for 15 meetings | 150 | 8 | 15 | 18,000 | 2,250 | Transportation for the 15 non-residential drafting sessions |
| 9 | **Total** | | | | **197,800.00** | **24,725.00** | |

**NB: The RCORE Manuals are high level documents targeted at professionals with a minimum qualification of 1st degree. A high level of expertise from both training and practical experience is therefore needed for the development of the manuals to be used for capacity building support for Ghana and other countries. The team of experts put together for developing the manual consist of regulators at the rank of Senior Regulatory officer and above, with a minimum of Masters degree and a minimum of 5 years practical experience. The team members from University of Ghana consist of Professors and Senior lecturers.**