

PROJECT CONCEPT PAPER(Draft)

1. EXECUTIVE SUMMARY

Basic Information		
Project Title	Capacity Building for Regulatory Management System in Biopharmaceuticals Sector	
Project Overall Objective	The main objective of this project is to improve and develop regulatory capacity in biopharmaceutical sector by adopting knowledge and experiences from the Korean best practices	
Partner Country	Colombia	
Beneficiaries	Public officials and experts related to biopharmaceuticals regulatory affairs	
Project Duration	2019~ (2 Capacity Building Programs per year; 1 month for each program)	
Total Project Cost (Partner funding incl.)	MFDS	KRW324,500,000(USD 302,705) (Exchange rate : USD 1 = KRW1,072)
	Partner	-
Contact Point	MFDS	Ministry of Food and Drug Safety of Korea (MFDS) Tel: 82-43-719-3311 e-mail: leeykyoung@korea.kr
	Partner	National Institute of Surveillance of Food and Medicines (INVIMA)-INVIMA (Colombia) Tel: 57-1-297-8700(ext. 3897) e-mail: msanchez@invima.gov.co
Project Design		
Objective 1 : Understand and learn South Korea's regulatory system and policies in biopharmaceuticals sector	<p>Activity 1: INVIMA sends to the MFDS the topics of interest, guidelines proposals and other documents, that INVIMA has been working on in the matter.</p> <p>Activity 2 : Dispatch of Korean regulatory expert to the agency</p> <ul style="list-style-type: none"> - Propose necessary regulation and guideline for biopharmaceutical industry - Technical cooperation to improve biopharmaceutical regulatory practices <p>Activity 3 : Inviting public officials and experts to capacity building programs in Korea</p> <ul style="list-style-type: none"> - Develop training module and curriculum for understanding the regulatory system of Korea's pharmaceutical industry - Hold a capacity building workshops focused on Korea's best practices in 	

	development of biopharmaceutical industry
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Monitoring and Evaluation Plan

Plan for monitoring and Evaluation	Monitoring and Evaluation of the above planned activities will be carried out jointly by MFDS and INVIMA at semi-annual basis.					
	Main Indicators(Outcome, Output level)					
	Indicator*	Unit of Measure	Base- line	End line	Data source Methodology	Responsibility for Data Collection
	No. training & workshops held	M based on survey			Endline survey in target area	MFDS
No. working-level meetings held	M based on survey					

2. PROJECT BACKGROUND

2.1 Background and Objective

- Capacity Building is an important tool for narrowing the knowledge gap between the donor and recipient countries. It aims to share technical skills and knowledge to build the capacities for sustainable development of the recipient country.
- Ministry of Food & Drug Safety of Korea, with its extensive knowledge and experiences in the biopharmaceutical sector, has developed capabilities to support the regulatory management capacity of Colombia.

- The increasing trade volume between Korea and Colombia in biopharmaceuticals sector has raised the issues in the safety and public health, wherein regulatory collaboration is needed to ensure the trade of safe products between the countries.
- This project is designed to improve and develop regulatory capacity of public officials in the colombian government, by consulting knowledge and experiences extracted from MFDS's best practices through capacity building programs. It also aims at facilitating subsequent networking among the officials and experts through mutual visits to partner countries, thereby strengthening the ties between two countries.

3.MAIN TASK PHASES

3.1Program Description

A. Basic Direction and Overall Goals

Expected Accomplishment 1 : Improved regulatory management capabilities of INVIMA public officials

Expected Accomplishment 2 : Strengthened bilateral cooperation and expanded network of experts in the field of biopharmaceuticals

B. Activities

- Summary

Activities	Input	Output	Outcome
<u>Activity 1</u> Dispatch of Korean regulatory expert to INVIMA	<u>MFDS:</u> - Capacity building programs on regulatory affairs - Working level meetings with MINSA staffs	- Number of training programs provided - Number of workshops held	- Improved regulatory management capabilities of INVIMA public officials and experts

<u>Activity 2</u> Inviting officials and experts to Korea for capacity building programs	MFDS: - Program modules and curricula - Programs on regulatory affairs - Hosting workshops and networking opportunities		
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○ Details on activities

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(1) Activity 1 : Dispatch of Korean regulatory expert to the agency

- Dispatch biopharmaceutical experts in areas such as Biosimilars, Vaccine, Pharmacovigilance, GMP, etc
- Technical cooperation to improve biopharmaceutical regulatory practices
- Host seminars on the partner country's biopharmaceuticals industry upon Korean delegation's visit

Components	Details	Cost KRW(USD)
Regulatory Experts Airfare	5,000,000 KRW * 10persons * 1 term	50,000,000 (USD 46,641)
Accommodation (per diem)	10persons*10days*300,000 KRW	30,000,000 (USD 27,985)
Honorarium	18,000,000 KRW	18,000,000 (USD 16,791)
Translation fee	22,000,000 KRW	22,000,000 (USD 20,522)
Others (Venue, transports, etc)	80,000,000 KRW	80,000,000 (USD 74,626)
Total Cost per year		200,000,000 (USD 186,567)

(2) Activity 2 : Inviting officials and experts to Korea for attending capacity building programs

- Develop program modules and curricula for understanding the regulatory system of Korea's pharmaceutical industry
- Hold a capacity building workshops with a focus on Korea's best practices in the development process of biopharmaceutical industry

Components	Details	Cost KRW(USD)
Partner Country Officials Airfare	5,000,000KRW*6persons	30,000,000 (USD 27,985)
Accommodation (per diem)	6persons*15days*300,000 KRW	27,000,000 (USD 25,186)
Honorarium	12,000,000 KRW	12,000,000 (USD 11,194)
Translation Fee	18,000,000 KRW	18,000,000 (USD 16,791)
Assistant Staff	40MM * 3person s* 1 year	120,000,000 (USD111,940)
Others(Venue, transports, etc)	30,000,000 KRW	30,000,000 (USD 27,985)
Total Cost per year		124,500,000 (USD116,138)

3.2 Budget Estimate

- This capacity building project is estimated to cost USD 483,574 of which all will be financed on a grant basis by MFDS. The INVIMA will provide in-kind contributions if necessary.

Unit:KRW(USD)

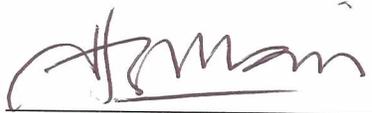
		Total	1st Year	2nd Year	3rd Year and After
Foreign Contribution	Dispatch of Korean regulatory expert to the agency	200,000,000 (USD 186,567)	200,000,000 (USD 186,567)	200,000,000 (USD 186,567)	200,000,000 (USD 186,567)
	Inviting regulators to South Korea for capacity building training	124,500,000 (USD 116,138)	124,500,000 (USD 116,138)	124,500,000 (USD 116,138)	124,500,000 (USD 116,138)
Local Contribution		-	-	-	-
Total		324,500,000 (USD 302,705)	324,500,000 (USD 302,705)	324,500,000 (USD 302,705)	324,500,000 (USD 302,705)

3.3 Proposed Schedule

- This capacity building project will be implemented from the first quarter of 2018. The

proposed schedule are as follows:

Activity	1st Year (2018)				2nd Year (2019)				3rd Year(2020)			
	1/4	2/4	3/4	4/4	1/4	2/4	3/4	4/4	1/4	2/4	3/4	4/4
Dispatch of Korean regulatory expert to the agency			→				→				→	
Inviting regulators to South Korea for capacity building training		→				→				→		



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