

Pharmaceutical Design, Production, and Monitoring (Colombia)

April 1 (Sun.) – April 14 (Sat.), 2018
Seongnam & Seoul, Republic of Korea



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1. TITLE: Pharmaceutical Design, Production, and Monitoring (Colombia)

2. PERIOD: April 01 (Sun.)– April 14 (Sat.), 2018

3. GOAL

To increase capacities for the planning and implementation of the strategic policies in the area of drug medicine through education

4. OBJECTIVES

- a) Establishing drug medicine development strategies through the understanding of the drug medicine quality control strategies and policies in Korea
- b) Implementing policies that can facilitate drug manufacturing technologies in Colombia
- c) Setting up a drug medicine quality management system to strengthen Colombia's national competitiveness
- d) Design drug medicine quality management policies to improve Colombia's quality management system and policies in the field of drug medicine

5. NUMBER OF PARTICIPANTS: 15 participants

6. LANGUAGE OF INSTRUCTION: Spanish (via interpretation)

7. VENUE: Seongnam & Seoul, Republic of Korea

8. TRAINING INSTITUTE: Hyundai Research Institute (<http://www.hri.go.kr>)

9. ACCOMMODATIONS: KOICA ICC & Hyundai associated training facility

10. QUALIFICATIONS OF APPLICANTS:

- This is a third-year course designed to support the capacity building of Colombian officials or people working for drug medicine-related departments. Participants can gain hands-on experience through various practices in drug medicine development strategies together with in-depth theoretical knowledge. It targets manager level staff having relevant work experience and knowledge of the drug medicine part.

Mandatory	<ul style="list-style-type: none">a) Be nominated by his/her government;b) Be in good health both physically and mentally, enough to take the course;c) Have not participated in the same or similar KOICA fellowship program for the past 3 years - unless otherwise specified;d) Have at least 5 years of work experience in pharmaceutical fielde) Be a member of the Ministry of INVIMA (relevant departments), or national medical universities(excluding those in degree programs)f) Be a government employee in a <u>managerial position who have specialized knowledge regarding the pharmaceutical field</u>g) Have a willingness to show a high level of participation and commitment throughout the course and contribute to the capacity building of his/her organization after the completion of the program;;
Preferable	<ul style="list-style-type: none">a) Working knowledge of computers and PowerPoint software;b) Moderate proficiency in English

11. CLOSING DATE FOR APPLICATION: March 9, 2018

12. 3-YEAR PROGRAM OVERVIEW (TENTATIVE)

	1 st year	2 nd year	3 rd year	To-be Planned
Goal	Establishing drug medicine development strategies of Colombia and action plan through the understanding of Korea's drug medicine quality control strategies			
Objective	<p>Have at least 5 years of work experience in the drug medicine and/or other relevant fields</p> <p>- Non-participant of the KOICA's training programs for the past 3 years</p>	<p>- Overall participants' qualification is the same with that in the 1st year.</p> <p>- Include at least one senior-level official in the drug medicine and/or other relevant fields</p>	<p>- Overall participants' qualification is the same with that in the 1st year.</p> <p>- Work for the drug medicine and/or other relevant departments</p> <p>- Include at least two senior-level officials in the drug medicine and/or other relevant fields</p>	<p>- Developing Colombia's drug medicine management systems and policies</p> <p>- Capacity building of Colombian officials who work in the drug medicine and/or other relevant fields</p>
Main Activities	<p>Training in Korea (2 weeks)</p> <p>Country Report</p> <p>Action plan</p> <p>Field trip</p>	<p>Training in Korea (2 weeks);</p> <p>Workshop in target countries</p> <p>Country Report</p> <p>Action plan</p> <p>Field trip</p>	<p>Training in Korea (2 weeks);</p> <p>Workshop in target countries</p> <p>Country Report</p> <p>Action plan</p> <p>Field trip</p>	<p>- Developing graduate program curriculum for nursing school</p> <p>- Monitoring nursing quality control systems in each country</p>
Output	Establish an Action Plan to promote medicine manufacturing technology in Colombia	Establish an Action Plan to promote medicine manufacturing technology in Colombia	Establish an Action Plan to promote medicine manufacturing technology in Colombia	Development of Colombia's drug medicine policies and strengthening of officials' capabilities

PART II**COURSE MODULE****1. COURSE MODULE**

MODULE	MAIN LECTURES & DISCUSSIONS	STUDY VISIT
Module 1. Overview of Korea's medical policy management	<ul style="list-style-type: none">▷ Understanding of Korea's drug management policies<ul style="list-style-type: none">• Managing the New Product Development Process• Giving the best medical policy export example (Nepal drug medical management system)▷ Safety management system and policy of the drug medicine industry<ul style="list-style-type: none">• Current status of Biopharmaceutics• Introduction to the CMO	- Seoul National University Hospital
Module 2. Drug medicine quality control and political support	<ul style="list-style-type: none">▷ Manufacturing and incineration of drug medicine<ul style="list-style-type: none">• Understanding of process control in drug medicine• Significance of drug medicine's progress of production• Understanding of process control in drug medicine▷ Market access of drug medicine<ul style="list-style-type: none">• Introduction to market access strategy and effectiveness	- Korea international Trade Association - Hyangnam pharmaceutical area
Module 3. International pharmaceutical R&D	<ul style="list-style-type: none">▷ International drugs patent acquisition<ul style="list-style-type: none">• The pharmaceutical affairs law and road safety rules for drug medicine• Development strategies of the Recognition of State system▷ Biosimilar, generic research and development<ul style="list-style-type: none">• In-depth investigation on biosimilar and generics	- Handok pharmaceutical research laboratory
Module 4. Country Report & Action Plan	<ul style="list-style-type: none">▷ Country Report▷ Action Plan: Problem Clarification, Execution Plan Development, and Presentation	-
EXTRACURRICULAR ACTIVITIES	<ul style="list-style-type: none">▷ Seoul city tour and Korean Folk Village (http://www.koreanfolk.co.kr/)▷ Company Tour: Samsung Innovation/ Hyundai Motor Company http://www.samsunginnovationmuseum.com http://tour.hyundai.com/#/main	

1. GUIDELINES FOR THE PREPARATION FOR THE COUNTRY REPORT

A Country Report is an in-depth report that contains an analysis of the current development issues facing participants' countries in their fields of expertise. The KOICA's Fellowship Program includes a Country Report Presentation session where participants have an opportunity to share these issues with other participants and Korean experts. Throughout the course, participants will engage in debates and discussions to resolve them.

The Country Report is directly aligned with an Action Plan. Based on what participants have presented and discussed throughout the course, participants are requested to present an Action Plan towards the end of the program with an aim of developing feasible measures to apply the knowledge, technology and experience learned to their workplace.

Program participants are requested to prepare and submit their Country Report individually or as a group to the Hyundai Research Institute Program Manager via e-mail at **Kang@hri.co.kr** or **zeroslove1@gmail.com** no later than **March 16, 2018**. The Country Report should be typed in English and double-spaced in MS PowerPoint or Word format. The length of the report should not exceed twenty A4-sized pages.

All participants are supposed to give a 15-minute presentation on their Country Report individually or as a group on the second day of the program. For more effective presentations, a projector, slide projector, overhead projector, and multimedia TV will be available for use (PowerPoint presentations are preferred).

2. TOPICS TO BE COVERED IN THE COUNTRY REPORT

A. Programs to improve Colombia's Drug Medicine Development Strategy

Possible subject 1: What differences have been made for the last two years in the biomedical field in Colombia?

Possible subject 2: Describe Colombian biosimilar and generic products' international competencies

Possible subject 3: Introduce biomedical technologies that Colombian medical companies have? What kind of supporting activities have been made in Colombia to boost the R&D sector?

B. Details of Country Report Preparation

- What differences have been made for the last two years in the biomedical field in Colombia?

- Throughout the last 2 years, KOICA and HRI had operated invitation programs and this is the 3rd and last year program. Country report and action plan has been made throughout trainings.

- On this country report, trainees should describe what kind of differences have been made.

- The training topic is divided into two: Biosimilar/generic products research and development, medical products (especially drugs) Intellectual property, and Source technology management. Please let us know if there is any other topic that you would like to deal with

- Through this 3rd year training program, KOICA and HRI would like to see tangible results. If there are any developments made for the last 2 years of training, please let us know. (It can be policy/strategy changes in Colombia which have been affected by the training, or newly established cooperation in the biopharmaceutical area and others between Korean government agencies or Korean companies and those in Colombia.)

- **History and future of Colombian biosimilar, generic R&D**

- What strategy does the Colombian government take to develop R&D and to boost private R&D development?

- **Cooperation between the parties in the field of intellectual property and biomedicine.**

- What kind of cooperation has been made between those two fields to develop international competency of the Colombian biomedical field.

1. GUIDELINES FOR BUILDING AN ACTION PLAN

An Action Plan is a specific plan created by participants on how they can apply their learning to their work performance. Action Planning is a process which will help them identify their objectives and explore what steps they need to take to achieve their goals. Establishing and implementing the Action Plan will contribute not only to their development professionally and individually but also to desirable organizational change.

A good Action Plan contains detailed information like what can be done, who will do it, and how and when. Please keep in mind that meeting the financing requirement including budget and timeline is crucial to make their action plan feasible and applicable to their workplaces.

All participants are requested to make a presentation on their Action Plan individually or as a group at the end of the course. They are encouraged to make the most of their weekends and free time to further their knowledge acquired from the course and better build their Action Plan.

Participants can receive feedback from Korean experts who will share their insight and help upgrade the Action Plan. Even after participants return to their home countries, KOICA will continue to follow up with participants on the progress being made through the implementation of their Action Plan. KOICA looks forward to all participants achieving their desired outcomes.

2. TOPICS TO BE COVERED IN THE ACTION PLAN

- a) Identify various problems related to Colombia current situation in medical development
- b) Analyze causes and devise the best way to solve pharmaceutical problems in Colombia.
- c) Consider how it will affect the current problems and what advantages can be made in the future. (Examples)
 - Possible Subject 1: Master plan for Colombia biosimilar/ generic products R&D
 - Possible Subject 2: Colombian pharmaceutical patent management

- Possible Subject 3: International pharmaceutical competency development strategy
- d) Discuss how it can be applied to your current work including a budget and a financing plan.
- e) Expected Results and Impact

3. STEPS FOR THE ACTION PLAN

- **[Step 1] Present Country Report**

- On the 1st day of the course, participants are to share their current situation and issues of their interests through Country Report presentation
- HRI will provide an orientation for Action Plan

- **[Step 2] Lecture on Action Plan and Team-Building**

- Lecture on Action Plan building process
- Team-Building according to the selection of Action Plan topic

- **[Step 3] Group Discussions/ workshops**

- Brainstorming and group discussions for developing an Action Plan
- Consult with experts and receive feedbacks

- **[Step 4] Complete the Action Plan**

- Finalize an Action Plan for the development of new policies/programs or upgrade their existing policies, systems and practices
- Presentation on the final Action Plan and getting feedback

1. TRAINING INSTITUTE**Hyundai Research Institute (<http://www.hri.co.kr>)**

Hyundai Research Institute (HRI), the think tank of Hyundai Group, has played a great role for research in Korea. HRI has also significantly contributed to making Hyundai Business Group one of the leading corporations in Korea. Hyundai Learning Center (HLC), HRI's training center, has provided a variety of HRD training including leadership and management for the last 33 years. We have trained not only corporate employees but also government officials in Korea. We have developed a training program on Korea's infrastructure development for the Ministry of Land, Infrastructure and Transport in order for the Korean government to share Korea's experience in infrastructure development with other developing countries. We have also designed and implemented a training program for Taiwanese government officials so that they could learn about Korea's economic development.

Objectives of HRI/HLC training program are:

- to help our trainees develop their leadership in the areas of their own specialties
- to help them apply what they have learned to their own situations
- to help them establish a global network through which they can cooperate to achieve a mutually satisfactory goal

2. CONTACT INFORMATION

- **Korea International Cooperation Agency (KOICA)**

- KOICA CS Center: +82-1588-0434
- Websites: <http://www.koica.go.kr>
<http://training.koica.go.kr>
<http://www.facebook.com/koica.icc>

- **Program Manager: Ms. Juyoung PARK**

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- E-mail: jyp1@koica.go.kr

- **Program Coordinator: Ms. Jiwon YOO**

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- **Hyundai Research Institute (HRI)**

- **Program Manager: Mr. Jaesung KANG**

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- Home page: <http://www.hri.co.kr>

INTRODUCTION to KOICA



is a development cooperation agency of the Republic of Korea established in 1991. KOICA's mission is to reduce poverty, promote living standards and help realize sustainable, equitable and inclusive development in developing countries. To accomplish its mission, KOICA has been actively involved in enhancing developing countries' socio-economic infrastructure and institutions, providing people in the developing world with opportunities for better lives and improving their well-being.

KOICA Fellowship Program

Human Resource Development (HRD) has been one of the most important factors in Korea's escape from the vicious cycle of poverty and underdevelopment which had lasted for many decades. With scarce natural resources, HRD has played a vital role in the process of the economic development of Korea, enabling the nation to emerge as an exemplary case of rapid economic growth powered by HRD. From its own experience, Korea fully recognizes the significance of HRD. With its extensive experience and know-how in HRD, Korea has greatly contributed to the international community by sharing its unique development experience with many other countries around the world.

The KOICA Fellowship Program is one of KOICA's main projects to help partner countries secure human resources for their development. Its primary objective is to share important technical skills and knowledge with partner countries as well as to help them build capacity for sustainable socio-economic development. The program deals with a wide range of topics, from public administration, economic development and science and technology to agriculture, health, and more. In order to meet the changing needs of partner countries, KOICA always strives to renovate and improve its Fellowship Programs.

Appendix 2.

KOICA FELLOWSHIP PROGRAM (CIAT)

KOICA has launched a brand-new name for the KOICA Fellowship Program in order to more effectively raise awareness about the program among the public and its partner countries.



In English, CIAT stands for Capacity Improvement and Advancement for Tomorrow and in Korean it means “seed (씨앗)” with hopes to contributing in the capacity development of individual fellows as well as the organizations and countries to which they belong.

The CIAT Program provides participants with opportunities to gain first-hand knowledge of Korea’s development experience. The programs are designed to enable participants to apply what they have learned to the development of their home countries. Since 1991, KOICA has offered about 4,255 courses to more than 69,981 participants from 172 countries.

Appendix 3.

KOICA FELLOWSHIP COMMUNITY

The Fellows' Facebook is a place for fellows to ask questions and write comments on KOICA fellowship programs. So, if you have questions regarding our program, please feel free to join our Facebook community.



facebook.com/koica.icc

Appendix 4.

MAP AND VENUE INFORMATION



Appendix 5.

INFORMATION ON DIRECTION TO KOICA ICC

- **Route:** Incheon International Airport → KOICA International Cooperation Center (ICC)
- **Arrival at Incheon International Airport Terminal (<http://new.airport.kr>)**

Flow:

- ▶ Fill out Arrival Card (or Immigration Card), Customs Declaration Form, Quarantine Questionnaire (on board)
- ▶ Present the Quarantine Questionnaire to the quarantine counter (on the second floor)
- ▶ Present your Arrival Card, Passport and other necessary documents to an officer at the immigration desk
- ▶ Claim your baggage on the first floor
- ▶ Hand in Customs Declaration Form at Customs
- ▶ Pass through the Arrival Gate
- ▶ Go to the KOICA Counter



Incheon International Airport opens *Second Passenger Terminal 2 (T2)*

on January 18, 2018

The new terminal is serviced by Korean Air (), KLM Royal Dutch Airlines (), Air France () and Delta Airlines ().

Accordingly, KOICA sets up an additional KOICA Counter in Terminal 2 as well.

Please check its location in advance by referring to the followings information.

KOICA Counter at Incheon International Airport Terminal 1 (IIAT1)		
IIAT 1 (T1)		<p>Location : Next to Gate 1 on the 1st floor (No.9-10)</p> <p>Contact Information Tel. : 82-32-743-5904 Contact : Ms. Jin-Young YOON</p>
KOICA Counter at Incheon International Airport Terminal 2 (IIAT2)		
IIAT 2 (T2)		<p>Location : Tourist Information Center (Close to Arrival Gate B)</p> <p>Contact Information Tel. : 82-32-743-5904 Contact : Ms. Jin-Young YOON</p> <p><small>*Contact information at T2 is subject to change</small></p>

- After passing through Customs, please go to the KOICA Counter. At the KOICA Counter, you can get detailed information about how to get to the KOICA International Cooperation Center (ICC).
- All the KOICA staff at the Incheon International Airport wear a name tag or has a sign for indication. Also, please note that there can be illegal taxis at the airport. Even if they approach you to offer rides, do not take the illegal taxis and check to see if they are KOICA staff.

"Please remember to read the Fellows' Guidebook. It is available from the Korean Embassy or KOICA Overseas Office in your country and provides valuable information regarding KOICA programs, allowances, expenses, regulations, preparations for departure and etc."