Regulatory Systems on Ensuring Access to Quality Medicines
適正な医薬品の供給･品質管理･使用に向けた薬事行政

Updated

Target Countries :

Course No. : J1804225 **No. :** 1884415

Sector : Health/Health System

Sub-Sector : Health/Other Health Issues

Language : English

Outline

In this program, participants will learn 1) regulatory related systems on pharmaceuticals, 2) supply chain systems for quality assured medicines through lectures and site-visits. Also, participants are expected to analyze the country's prioritized issues and discuss the applicable measurements for improving proper access to quality medicines in their own countries.

Objective/Outcome

【Objective】
This course targets administrators and pharmacists and provides lectures, observations and interactive discussions to improve access to quality-assured medicines, focused on regulatory system and supply chain for medicines, including countermeasure against substandard and falsified medicines.

【Outcome】
1. To be able to understand and compare pharmaceutical regulatory system in the heath service system of Japan and participating countries, as well as to understand trends of international collaboration among regulatory authorities.
2. To be able to understand regulatory management for access to quality medicines including inspection system.
3. To be able to understand actual operations in local government, medical institutions and manufactures for ensuring quality of medicines.
4. To be able to clarify own countrie's challenges through learning and sharing experiences as well as discussions.

Target Organization / Group

【Target Organization】
Medicines Regulatory Authorities and related organizations

【Target Group】
(1) Government officials who are engaged in making policies on pharmaceutical affairs and/or planning/implementation of pharmaceutical regulatory services, or
(2) Senior pharmacists of tertiary level hospital, who are engaged in management of supply and rational use of medicines and human development in close connection with the national pharmaceutical regulatory authorities and its relevant agencies. It is highly recommendable that he/she is a director of pharmaceutical department or equivalent.

Contents

1.
(1) Overview of pharmaceutical regulatory system in Japan (Legislation, Pharmaceutical approval system, Good Manufacturing Practices(GMP), Health insurance system and drug price listing, Safety measures, etc.),
(2) Trends in international cooperation among regulatory authorities
(3) Inception report presentation and discussion
2.
(1) Overviewing role of stakeholders to ensure quality-assured medicines (Activities by importers, manufacturing companies, wholesalers, hospitals and pharmacies),
(2) Pharmaceutical inspection system (Collaboration with local government, etc.),
3.
Field trip to Toyama prefecture (Local government, Pharmaceutical manufacturer and Pharmaceutical Research Institute)
4.
(1) Summing-up discussion,
(2) Feedback session of group programs,
(3) Final report making and presentation

Course Period	2018/7～2018/8
Department in Charge	Human Development Department
JICA Center	JICA Tokyo(Human Dev.)
Cooperation Period	2018～2020
Implementing Partner	Under Planning
Remarks and Website	