4th PMDA Training Seminar

- Reviewing of Generic Drugs -

February 3 to 7, 2014, Tokyo, JAPAN



Introduction

The Pharmaceuticals and Medical Devices Agency (PMDA) is pleased to announce its fourth PMDA Training Seminar for International Regulatory Authorities scheduled for February 3-7, 2014.

The PMDA training seminar is established for the exchange of drug and medical device regulatory information between the PMDA and its counterpart agencies all over the world.

The training is not open to the pharmaceutical industry or non-regulatory authorities. The training is not intended for Japan government employees.

Eligible Participants

Participation in the PMDA Training Seminar is limited to officials who are engaged in review of generic drugs. Confirmation of registration and additional meeting information will be sent to the approved participants.

Registration

Application form is in Word / PDF format.

Please download here. MS-WORD PDF

Please fill and send to:4th_training_seminar@pmda.go.jp

Registration will close **November 30, 2013**. Please be sure to allow enough time to obtain your visa.

Fee

There is no registration fee for this program.
However, attendees are responsible for their own travel, lodging and food expenses.

Day 1 (Monday, February 3, 2014)	
10:00 - 10:10	Welcome and Introduction
10:10 - 12:00	Training overview / Schedule Overview of PMDA (Organization, Activities)
12:00 - 13:00	Luncheon Seminar(Scheduled)
13:00 - 15:00	Japanese Drug Regulation - Pharmaceutical Affairs Act - Approval, license and review OTC, Quasi-drugs - Review Process - Regulations
15:00 - 15:30	Break
15:30 - 16:30	GCP - Regulations (Ministerial Ordinances, Notifications) - Inspection process
16:30 - 17:30	GMP - Regulations (Ministerial Ordinance, Notifications) - Inspection process

Day 2(Tuesday, February 4, 2014)	
9:00 - 10:30	Review of Pharmaceuticals - Review Process - Project management
10:30 - 11:00	Break
11:00 - 12:00	Biosimilars - Regulations (Ministerial Ordinance, Notifications, guidelines)
12:00 - 13:00	Luncheon Seminar(Scheduled)
13:00 - 14:30	Bioequivalence - Review Process - Regulations
14:30 - 15:00	Break
15:00 - 17:00	Group Work 1(Bioequivalence) - Case Study

Day 3 (Wednesday, February 5, 2014)

All Day	Tour of the Factory for Generic Drugs

Day 4 (Thursday, February 6, 2014)

9:00 - 10:00	Japanese Pharmacopoeia - History and Legal status - System of establishing JP Master File System
10:00 - 10:30	Break
10:30 - 12:00	Quality(CMC) - Review Process - Regulations
12:00 - 13:00	Luncheon Seminar(Scheduled)
13:00 - 15:00	Group Work 2 (Quality) - Case Study
15:00 - 15:30	Break
15:30 - 17:00	Reports from Attendee

Day 5 (Friday, February 7, 2014)

9:00 - 10:00	Post-marketing Safety Measures for Pharmaceuticals - Collection and Analysis of ADR Information - Information Provision - Consultation Services
10:00 - 10:30	Break
10:30 - 11:30	Relief Services - Relief System for Adverse Health Effects - Relief System for Infections Acquired through Biological Products
11:30 - 13:00	Luncheon Seminar(Scheduled)
13:00 – 14:00	Regulatory Science Science Board
14:00 - 14:30	Break
14:30 - 15:30	Wrap up of the Training Seminar

Location

Pharmaceuticals and Medical Devices Agency (PMDA)

Shin-kasumigaseki Building, 3-3-2 Kasumigaseki,
Chiyoda-ku,Tokyo 100-0013, Japan

Access

5 minutes walk from Exit 11 of Toranomon Station on the Ginza Line
8 minutes walk from Exit 3 of Kokkai-gijido-mae Station, on the Marunouchi Line, Chiyoda Line
8 minutes walk from Exit A13 of Kasumigaseki Station, on the Marunouchi Line, Chiyoda Line, Hibiya Line
10 minutes walk from Exit 8 of Tameike-sannno Station, on the Ginza Line, Nanboku Line

Contact Us

For more information, please contact:

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The participants will be welcome to join
PMDA 10-year Anniversary Forum
Let's celebrate together!

Further information will be provided:
www.pmda.go.jp/english