

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Educational Workshops on Current Good Manufacturing Practices; Public Workshops

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshops.

SUMMARY: The Food and Drug Administration (FDA) is announcing a series of educational workshops on quality pharmaceutical production under current good manufacturing practice (CGMP). The workshops, which will be held in collaboration with the Parenteral Drug Association (PDA), are intended to educate participants on current methods for compliance with good manufacturing practices (GMP). The workshops are being offered to help ensure effective CGMP programs and to further the common goals of FDA and providers of quality pharmaceutical products.

DATES: See table 1 in the **SUPPLEMENTARY INFORMATION** section of this document.

ADDRESSES: See table 1 in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT:

Erik N. Henrikson, Center for Drug Evaluation and Research (HF-18), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-9190, erik.henrikson@fda.hhs.gov, or

Wanda Neal, Parenteral Drug Association, 4350 East West Hwy., suite 200, Bethesda, MD 20814, 301-656-5900, FAX: 301-986-0296, neal@pda.org.

SUPPLEMENTARY INFORMATION:**I. General Information***A. Who Should Attend?*

This announcement is directed towards professionals involved in the manufacture, control, and regulation of pharmaceutical products who will benefit from these workshops, including process/production engineers, manufacturing personnel, quality assurance/quality control and regulatory affairs professionals, consultants, regulatory investigators, and CGMP compliance officials. Other entities or individuals may also be interested in attending.

B. Where and When Will These Workshops Be Held?

We have scheduled four workshops. The locations and times are listed in table 1 of this document.

TABLE 1.—WORKSHOP LOCATIONS AND SCHEDULES

Workshop Address	Dates and Local Times
Hyatt Regency Bethesda, 1 Bethesda Metro Center, Bethesda, MD 20814	November 1 and 2, 2007, from 9 a.m. to 5 p.m. each day
The Gresham Hotels, 23 Upper O'Connell St., Dublin 1, Ireland	December 10 and 11, 2007, from 9 a.m. to 5 p.m. each day
Peking University, Beijing, China 100871	April 21 and 22, 2008, from 9 a.m. to 5 p.m. each day
Grand Hyatt Shanghai, Jin Mao Tower, 88 Century Blvd., Pudong, Shanghai, China 200121	April 24 and 25, 2008, from 9 a.m. to 5 p.m. each day

C. How Can I Participate?

You can participate in person. Anyone interested in the GMP workshops can register through the contact person (see **FOR FURTHER INFORMATION CONTACT**).

D. Is There a Registration Fee for This Workshop?

Yes, a registration fee is required for this workshop. The registration fee includes workshop reference materials and meals. Registration fees for the Bethesda, MD and Dublin, Ireland workshops are listed in table 2 of this

document. The registration fee for both China locations (Beijing and Shanghai) is \$550 with no discounts. All fees are given in U.S. dollars.

TABLE 2.—REGISTRATION FEES FOR THE BETHESDA, MD AND DUBLIN, IRELAND WORKSHOPS

Date of Registration	PDA Member	Nonmember	Government Employee or Health Authority	Academic	Student
Through October 1, 2007	\$1,295	\$1,695	\$350	\$350 ¹	\$150
After October 1, 2007	\$1,495	\$1,895	\$405	\$405 ¹	\$180

¹ Must be PDA member to receive this rate.

E. How Can I Get Additional Information?

The notice of participation form, information about the workshops, and other related documents are available from the contact person (see **FOR FURTHER INFORMATION CONTACT**) and on the Internet at <http://www.fda.gov/cder/workshop.htm>.

II. Background Information

A. Why Is FDA Cosponsoring These Workshops?

FDA is cosponsoring these 2-day workshops to provide information and training opportunities for industry as well as CGMP compliance officials.

B. What Will Be Covered?

The workshops will provide information on specific topics designed to educate and guide participants on methodologies and implementation of CGMP as applied to quality drug manufacturing. Presentations by both FDA and industry will provide a regulatory and practical perspective on the current relevant critical topics.

Dated: 9.14.07

September 14, 2007.



Jeffrey Shuren,
Assistant Commissioner for Policy

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