

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

Food and Drug Administration/Industry Exchange Workshop on Medical Device Quality Systems Inspection Technique (QSIT); Public Workshops; Addendum

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA), is announcing additional workshops in the series of FDA/Industry Exchange Workshops. The original list of workshops was published in the **Federal Register** of September 10, 1999. Topics for discussion at these workshops include: Development of QSIT, Compliance Program and Warning Letter (Pilot), Management Controls, Corrective and Preventive Action, Design Controls, and Industry Perspective of QSIT. These additional workshops will enhance the medical device community's understanding of QSIT, and the device industry's establishment of effective quality systems, thereby preventing regulatory problems during inspections.

*Date, Time, and Location:* See Table 1 in the **Supplementary Information** section of this document.

*Registration:* Send registration information (including name, title, firm name, address, telephone, and fax number) along with the correct payment amount to the Registrar. Fees cover refreshments, organization and site costs, and materials. Because space is limited, interested parties are encouraged to register early. Please arrive early to ensure prompt registration. If you need special accommodations due to a disability, please inform the Registrar at least 7 days in advance of the workshop. A sample registration form is provided at the end of this document.

*Contact Person:* Herman B. Janiger, Food and Drug Administration, Northeast Region, (HFRNE-17), 850 Third Ave., Brooklyn, New York 11232, 718-340-7000 ext. 5528.

**SUPPLEMENTARY INFORMATION:**

In the fall of 1999, FDA field offices will begin using the QSIT nationwide as the primary tool for medical device inspections. QSIT was developed using a collaborative effort with stakeholders and was tested in the three districts. The additional workshops are scheduled as follows:

TABLE 1.

Workshop Address	Date and Local Time	Deadline to Register and Fee	Registrar and Cosponsor	FDA Contact Person
Costa Mesa: Wyndham Garden Hotel at Orange County Airport, 3350 Avenue of the Arts, Costa Mesa, CA 92626, 714-751-5100.	Tuesday, November 16, 1999, 8:30 a.m. to 4:30 p.m.	Friday, November 12, 1999, \$90.00	PeriAnn DiRocco, Orange County Regulatory Affairs Discussion Group (OCRA), PMB 624, 5405 Alton Pkwy. 5A, Irvine CA 92604-3718, Phone/FAX 949-348-9141, e-mail Sdirocco@aol.com.	Marcia Madrigal, Small Business Representative, Pacific Regional Office, 510-637-3980.
Irvine: Hilton Orange County Airport, 18800 MacArthur Blvd., Irvine, CA 92612, 949-833-9999	Wednesday, November 17, 1999 8:30 a.m. to 4:30 p.m.	Friday, November 12, 1999 \$90.00	PeriAnn DiRocco, Orange County Regulatory Affairs Discussion Group (OCRA), PMB 624, 5405 Alton Pkwy. 5A, Irvine CA 92604-3718, Phone/FAX 949-348-9141, e-mail Sdirocco@aol.com.	Marcia Madrigal, Small Business Representative, Pacific Regional Office, 510-637-3980.

The above workshops further implement the FDA Plan for Statutory Compliance (developed under section 406 of the FDA Modernization Act (21 U.S.C. 393)) by working more closely with stakeholders and ensuring access to needed scientific and technical expertise. They also comply with the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121), which requires outreach activities by Government agencies directed to small businesses. This notice announcing the workshops and a registration form may be accessed at the CDRH website at <http://www.fda.gov/cdrh/fedregin.html>. The following information is requested for registration:

REGISTRATION FORM

Quality System Inspection Technique (QSIT)

Regional Medical Device Workshop

Instructions: To register, complete this form and mail with registration fee to the Registrar for the workshop you wish to attend.

Date, \_\_\_\_\_

Location, \_\_\_\_\_

Fee enclosed, \_\_\_\_\_

Name, \_\_\_\_\_

Title, \_\_\_\_\_

Company, \_\_\_\_\_

Address, \_\_\_\_\_

Telephone, \_\_\_\_\_

Fax, \_\_\_\_\_

E-mail \_\_\_\_\_

Dated: 11-5-99  
November 5, 1999



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Margaret M. Dotzel  
Acting Associate Commissioner for Policy

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