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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

Medical Device Quality Systems Inspection Technique; Notice of Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a workshop on the FDA Quality System Inspection Technique (QSIT). The topics to be discussed include: The development of QSIT, compliance program and warning letter pilot, management controls, corrective and preventative actions, design controls, production and process controls, and industry perspective of QSIT. The purpose of this QSIT workshop is to increase understanding of QSIT in the medical device community. By explaining this new inspection technique, FDA intends to ensure that the medical device industry takes appropriate action to establish effective quality systems and to prevent regulatory problems when inspections occur.

Date and Time: The workshop will be held on March 8, 2000, from 8:30 a.m. to 4:30 p.m.

Location: The workshop will be held at the Condado Plaza Hotel, 999 Ashford Ave., San Juan, PR 00907.

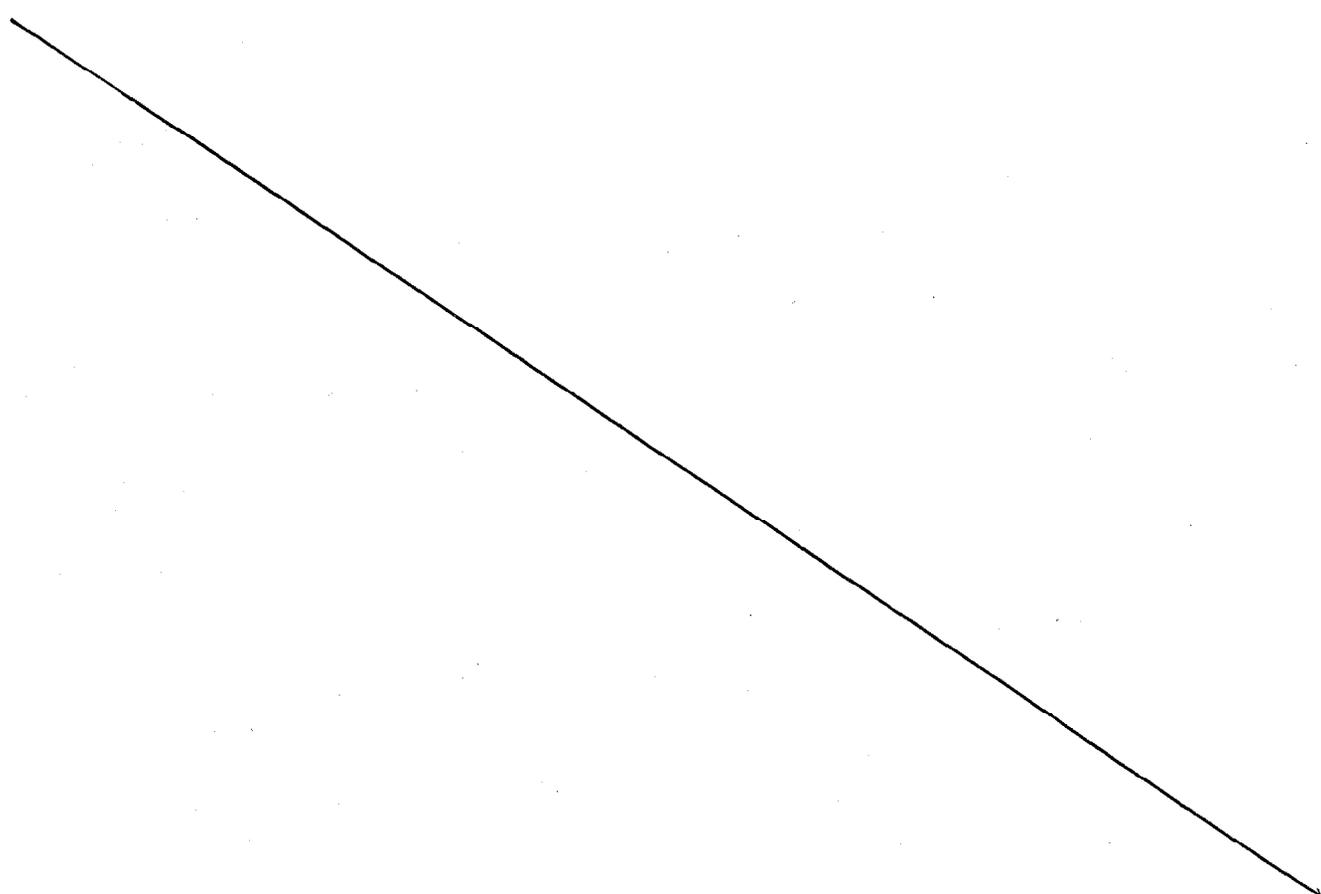
Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) along with a registration fee of \$125.00 to Jose P. Rodriguez, Director of Special Programs and Seminars, the Puerto Rico Manufacturers Association, P.O. Box 195477, San Juan, PR 00919-5477, 787-759-9445, ext. 204, FAX 787-756-7670. The fee covers refreshments, organization and site costs, and materials. Space is limited; therefore 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 Jose P. Rodriguez (address above) at least 7 days in advance of the workshop.

Contact: H. Gordon Cox, Supervisory Investigator, FDA San Juan District Office, 466 Fernandez Juncos Ave., San Juan, PR 787-729-6801.

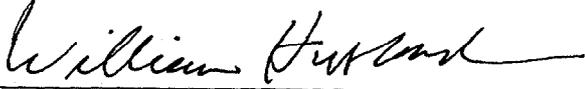
SUPPLEMENTARY INFORMATION: In the fall of 1999, the FDA field offices began using QSIT nationwide as the primary tool for medical device good manufacturing practice/quality system (GMP/QS) inspections. QSIT was developed using a collaborative effort with stakeholders, and it was tested in three districts.

The workshop helps to implement the objectives of section 406 of the FDA Modernization Act (21 U.S.C. 393) and the FDA Plan for Statutory Compliance, which includes working more closely with stakeholders and ensuring access to needed scientific and technical expertise.



The workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121) by providing outreach activities directed to small businesses.

Dated: February 23, 2000



William K. Hubbard
Senior Associate Commissioner for Policy, Planning, and Legislation

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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