CePAT Sub-Saharan Africa | Center for Pharmaceutical Advancement and Training
A USP Global Health Impact Program

Medical Devices

About CePAT

The U.S. Pharmacopeial Convention's Center for Pharmaceutical Advancement and Training (USP–Ghana [CePAT]) in Accra, Ghana, was established to help build human resource capacity in pharmaceutical quality assurance and quality control by training local professionals to serve as technical experts. CePAT delivers an integrated platform of training, testing and consulting services to support a sustainable approach to medicines quality assurance. USP–Ghana (CePAT) is included under USP's ISO 9001:2008 certification and its QC testing laboratory has earned accreditation to ISO/IEC 17025:2005.

Course Overview

National regulatory frameworks supporting the regulation of medical devices vary greatly among countries, as does the degree of technical capacity of personnel to carry out dossier evaluations that adequately assess the safety, quality and efficacy of medical devices. CePAT offers an interactive and practical training to help build the necessary knowledge and skills in the registration of medical devices so that participants can apply that knowledge to their countries' regulatory frameworks.

Next CePAT Course

Duration: Five days

Location: USP–Ghana (CePAT) Accra, Ghana

Format: Lecture and case studies

Date: May 14 - 18, 2018

To apply and be considered a candidate, contact cepat@usp.org or visit usp.org/cepat.

Fees may apply. A welcome dinner will be provided. Group photos will be taken during the course.

Who Should Attend

National regulators, medical device manufacturers and procurement agents involved in medical device quality assessments; professionals involved in dossier assessments with a focus on medical devices; consultants and individuals interested in the regulatory procedures to assess the safety, efficacy and quality of medical devices

Learning Objectives

- Understand the principles of medical device regulation to ensure the safety, efficacy and quality of medical devices
- Know the requirements of technical documentation for approval of medical devices
- Know how to audit medical device manufacturers based on various QMS guidelines
- Know how to develop a system for medical device regulation

Course Topics

- Introduction to Medical Devices
- Content of Medical Devices Technical Documentation
  - CSTD
  - STED
  - Conformity Assessments
- Quality Management Systems of Medical Devices
  - QA of Medical Devices
  - Auditing of Medical Devices manufacturers
  - FDA QSR
  - GHTF
  - ISO 13485

For more information, please visit usp.org/ghana.