CePAT
Sub-Saharan Africa

Center for Pharmaceutical Advancement and Training
A USP Global Health Impact Program

Annual/Product Quality Review (APQR/PQR)

Don't miss this course offered by USP–Ghana's CePAT facility

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U.S. Pharmacopeial Convention

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Course Overview: APQR or PQR is a Good Manufacturing Process (GMP) requirement used to verify the consistency and appropriateness of an existing manufacturing process. It plays a critical role in identifying any trends in the process further leading to process or product improvements. This training will start with a review of the GMP requirements, GMP interpretations, expectations of medicines regulators and common GMP compliance problems associated with A/PQR programs.

This short course seeks to equip trainees/participants with practical and effective methods for performing an annual product quality review. These include the selection, collection, and organization of the critical information and data to perform the review; the development of specific instructions on "how to" perform the required trending for each section of the APQR (e.g., analytical data, complaints, investigations and deviations, etc.) as well as "how to" prepare, and what information to include, in the product quality review report.

Each trainee will receive a written procedure with the necessary details on "what and how to" trend, to ensure the performance of an effective and efficient annual product quality review. This written procedure will provide the critical information and details to guide the participant in the preparation of a company SOP on product annual review. Each participant will also receive an example of a product annual review report that outlines the necessary information to meet GMP requirements and FDA expectations.

Duration: Five (5) Days
Location: USP–Ghana/CePAT facility Accra, Ghana
Date: September 2017
Cost: Call for Quote
Early Bird: 10% Discount

For more information or to register, visit **usp.org/cepat** *or contact CePAT at* **cepat@usp.org.**

About USP–Ghana/CePAT

- Established in Ghana by United States Pharmacopeial Convention
- Built capacities of about 270 professionals from 40 countries in Africa in medicines registration, GMP, and Quality Control
- Center is ISO 9001 Certified
- Testing Lab is ISO/IEC 17025:2005 accredited

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