BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

TRAINING TITLE:

Annual Product Reviews (WORK-010)

OVERVIEW:

The Annual Product Review (APR) or Product Quality Review (PQR) is an organized and comprehensive review of all production, analytical, stability, complaints, changes, deviations, and customer data associated with pharmaceutical product so as to monitor the drug product's quality and improve where necessary. The APR/PQR must be conducted with the objective of verifying consistency of process to highlight any trends and to ensure that Master Batch Records are in accordance with the registered file. It is developed to assess drug performance annually and to determine the need for any manufacturing process and control procedures change.

TARGET GROUP FOR THE TRAINING:

This training is aimed at all the personnel involved in the development of APR/PQR reports in an organization regulated by FDA and/or other international regulatory bodies. Attendees at this training should include personnel from the following areas: Regulatory Affairs, Manufacturing, Quality Assurance, Product/Process Development, Research & Development, Maintenance, and so on.

LEARNING OBJECTIVES:

- Define the importance of the APR/PQR in an organization regulated by FDA and other regulatory bodies
- Recall the basic contents of an APR/PQR report
- Develop a methodology to develop a comprehensive APR/PQR report

MATERIALS:

Each participant will receive:

- MS PowerPoint presentations
- Certificate of Attendance
- Final Exam (70% minimum score required to approve the course

TRAINING DURATION:

7 contact hours

ACCREDITED IACET PROVIDER

BEC is authorized by IACET to offer
0.7 CEUs for this program.
FULL attendance to the learning event
is mandatory to receive CEUs.

COURSE INSTRUCTOR:

Provimar Goytía Cruz is a process improvement consultant within the FDA-regulated industry, where she has over 10 years of experience. Through her career, she has held positions such as: Q.C. Laboratory Analyst, Manufacturing Supervisor, and Q.C. Laboratory Supervisor, among others. Since March 2012, she is fully devoted to consulting under Business Excellence Consulting Inc., focusing on the development of Annual Product Reviews. Provimar received her Masters Degree in Manufacturing Competitiveness in Pharmaceutical Product from the Polytechnic University of Puerto Rico and her Bachelor of Sciences in Chemistry degree from the University of Puerto Rico, Cayey Campus.

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Title: Annual Product Reviews

Lunch from 12:00 – 13:00.

Coffee break: 15 min. each during morning and afternoon session. Time schedule are rough estimates and may vary consequently.

Agenda	
8:30 – 9:00	**Introduction to APR / PQR** • Objectives • Benefits • APR / PQR Schedule
9:00 – 10:15	**Regulatory Basis** • 21 CFR 180(e) • Eudralex Vol. 4 • ICH Q10 • ICH Q7A 2.5 • ICH Q7A 12.6 • Comparisons
10:15 – 10:30	**Break**
10:30 – 12:00	**Contents of APR / PQR** • Introduction • Executive summary • Batches manufactured • Starting materials • Analytical and trend analysis • Stability data • Statistical information for APR / PQR
12:00 – 13:00	**Lunch**
13:00 – 15:00	**Contents of APR / PQR (cont.)** • Retain / reserve samples examination • Product complaints • Medical complaints • Returned / salvaged drug product • Validations • Qualification status and adequacy of equipment, facilities, and utilities • Field alerts

15:00 – 15:15	**Break**
15:15 – 17:00	**Contents of APR / PQR (cont.)** • Recalled batches • Product rework and reprocessing • Manufacturing / packaging in-process controls • Deviations, OOS, and investigations • Change controls • Compliance with regulatory attributes • Marketing authorization variations and commitments • Technical and/or quality agreements • Conclusions and recommendations