POSITIVE IMPACT

30th MARCH '2019

10 am to 5 pm

UMDC - Behind IoBM,
korangi Creek. Karachi.

AUDIT AND ASSURANCE FOR PHARMACEUTICAL PROCESSES.

OVERVIEW

Audit and assurance are processes that go hand in hand. Assurance is defined as a mechanism to confirm the conformance while audit is a tool that facilitates assurance process. Both lead into a detail evaluation of company's performance under nominated standard, reflected through data , activity and records. Both Audit and Assurance are evidence based and are part of same process of verifying the information on company's records for accuracy and compliance.

Learning about Auditing is a critical function within a pharmaceutical company. Pharmaceutical industry is one of the most regulated industry for quality, standards and compliance. Companies spends huge amount of money to get the compliance certifications, that are key for licensing, trading and existing in the market. It provides management with information about how effectively the company controls the quality of their processes and products and prepare them to comply for audits.

This course is aimed at providing tools for the professionals in the Pharmaceutical sector to embed standards and have skills to audit those standards. The course will provide an auditees journey during an audit, including having robust process to facilitate and retrieve physical, documentary and interview led evidence to support audit findings. The course will provide skills on key arms of audit

1. Writing audit summary
2. Establishing assessment grounds and quality reviews
3. Preparing evidence and practices
4. Play positive role in opening and closing meetings as an auditee and
5. Control points and operational controls for assessment process.

OUR PARTNERS

UMDC – United Medical & Dental College

EMC Pakistan Private Limited – EMC

PPMA®

GSUK – Sustainability defined

LEARNING OUTCOMES

1. To understand and embed Assurance process and audit activities that provide an independent, objective assessment of Legal, Quality and Statutory compliance
2. To provide skills to the attendees to pinpoint the data required for records to reflect fair and accurate claims related to the standard.
3. To empower attendees for Recurring analysis of a company's operations and maintaining a rigorous system of internal controls
4. To enable organisation to understand and manage non-conformities
5. Enable participants to understand different aspects in manufacturing of product, quality measures and systems.
6. Provide tools for quality control and assurance, avoiding risk to the product quality and efficiency
7. Enable attendees to learn and identify three types of non-conformities and having a process in place to remove them from the system.
8. The course will enable personnel working in pharma industry to see their operations from the eyes on an auditor.

0345 202 7552 http://p-impact.pk info@p-impact.pk M-1 Mezzanine Floor, Bridge view
D5, KCHS, Shaheed-e-Millat Road, Karachi

WHO SHOULD ATTEND

- Manufacturing and production
- Regulatory and compliance
- Quality affairs and control
- Plant Operational managers and directors
- Warehousing and distribution
- Auditors

COURSE OUTLINE

- Types of audit
- Structuring the audit process
- elements of audit cycle (PDCA)
- Internal reviews, check list for audit preparation
- Technical file preparation and data gathering for evidence
- Tracking and managing Non-conformities
- Root cause analysis and Reifications/ corrections
- Auditors basic skills (ASK)
- Ensuring impartiality of internal audit
- Understanding risks and compliance standards.

INVESTMENT IN KNOWLEDGE DEVELOPMENT: RS.15000 PER DELEGATE EXCLUSIVE OF ANY TAXES
GROUP DISCOUNT: 10% DISCOUNT ON MORE THAN 3 NOMINATIONS FROM SAME ORGANISATION
INCLUDE COURSEWORK, LUNCH, REFRESHMENTS, CERTIFICATE, AND BUSINESS NETWORKING

FOR INDIVIDUAL AND GROUP REGISTRATION(S)-
PLEASE CONTACT
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OR REGISTER VIA WEBSITE
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SUBJECT EXPERT

Mazhar Shams R. Ph., CRCP
(B. Sc, B. Pharmacy, M. Phil, JAVADA (Japan))

Regulatory and Quality Affairs professional having around 19 years hand on experience in these areas. He had opportunity to work in stringent environment of Japan, considering its regulatory body, PMDA,one of the reference authority in Pakistan. Working in both local and MNC environment he is aware of the challenges, opportunities and strength of both streams of Pharmaceutical industry of Pakistan.

Besides holding an M. Phil degree in Pharmaceutics Mazhar has completed his Pharmaceutical manufacturing and QA diploma from Japan that makes him more aware about working in a stringent regulatory environment and its challenges. Currently he is heading Regulatory Affairs department and had worked with prestigious and leading MNCs and Local business in the capacity of Regulatory lead and QA professional.

OUR CLIENTS

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