

QUALITY MANAGEMENT SYSTEM, AUDITOR AND AUDITEE – LIFE CYCLE

27TH NOVEMBER'2020

10AM TO 5PM

UMDC - Behind IoBM,
korangi Creek. Karachi.

Overview

The Quality Management system (QMS) may vary from organisation to organisation based on Industrial needs, business priorities and Regulations. The most commonly used model for quality improvement is recommended as QMS

Quality management system are key elements of Good manufacturing Practices. To demonstrate that organization in compliance of Good Manufacturing Practices, QMS plays an integral role. Policies, procedure and practices represent the true picture of QMS in any manufacturing organization. Stronger the QMS, complaint will be the facility.

This course is designed to give insight about how to demonstrate QMS during audit by responding auditor questions. This course will help to enhance the capability to effectively handle the questions and queries during national and international audits. The course will refer to the understanding on QMS under various regulation and standards, that entails a QMS based on ISO concepts and principles on Good Manufacturing Practices. This course will support the organisations to integrate QMS in overall functions and become compliant with any QMS audit including GMP FDA, MHRA, EMA , ISO.



Course Objectives

- Understand Quality Management Systems and its key components
- To gain insight of Why QMS is important part of GMP and the correlation
- Attendees will gain understanding on audit cycle, and How to make preparation for an audit?
- To understand the requirements and expectations from QMS audit
- To underpin the role of auditee and auditor in the process
- Provide a structural approach for QMS operational implementation including role of people in the organisation, organisational processes and controls and resource allocation.
- To enable participants to identify a framework and skill on How to demonstrate QMS during audit.
- To provide understanding on Comparison of different standards



Our Partners



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Course Outline

Role of QMS in GMP Compliance
 QMS elements and 5 Quality processes (Document control, CAPA, Training control, Audit Management, Risk Management)
 Development of QMS infrastructure
 Integration of QMS within GMP framework
 Audit and review cycle
 Audit preparation for internal and external audits
 The role of documents, practices and records that impact product quality, safety and audit compliance
 Document requirements and internal checklist
 Real time examples

Who should attend

Quality professional, including QA, QC, Microbiology staff
 Production staff
 Regulatory staff
 Internal Auditors

Fee Structure

REGULAR COURSE FEE: PKR 18000/- PER DELEGATE EXCLUSIVE OF ANY TAX

10% DISCOUNT ON 3 OR MORE NOMINATIONS FROM SAME ORGANISATION

INCLUDE COURSEWORK, LUNCH, REFRESHMENTS, CERTIFICATE, AND BUSINESS NETWORKING

FOR INDIVIDUAL AND GROUP REGISTRATION(S)-
 PLEASE CONTACT
 BINISH ARSHAD
 MOBILE: 0336 2092 011
 EMAIL: OFFICE@P-IMPACT.PK

OR REGISTER VIA WEBSITE
[HTTPS://P-IMPACT.PK/REGISTER/](https://p-impact.pk/register/)
 INFO@P-IMPACT.PK
 MOBILE:0345 202 7552

Course fee
18,000/-

Previous Events by Positive Impact



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Subject Expert



Kashifa Khanum
GM Quality Operations and R&D

A dedicated Pharmacy professional and industry expert for Quality Operations, Regulatory Affairs, Validations, product development, bioequivalence studies. She has indepth insight and experience working in Pharmaceutical sector for above 20 years.

She has made significant contributions and have publications in renowned journals and forums. She has served several Multinational & National Pharmaceutical companies in Quality operation and materials management departments. She has worked through various projects leading to efficient quality management system.

With her expertise she lead on various QMS standard development and implementation including ISO9001:2015, 14001:2015, 18001, 22000. She has successful track record in development of various QMS sections like compliance, stability studies and validation. Her contribution in development of QMS is recognized in form of successful facility audit by National international regulatory bodies, a few are Ukraine Ministry of Health against PIC/s and EU standards, Moldova Ministry of Drug and Poison, DRAP in Pakistan, offsite audit by NHPDHealth Canada.

She has been conducted training on different forums and shared real time experience under GMP and QMS umbrella. Her sessions are interactive and create a two way dialogue in the training session. She is acknowledged in her profession for her contribution in providing training, learning and awareness sessions to quality, production and engineering, marketing, business development and product development staff including.

She has lead on delivering modules related to her expert area including; GMP, QMS, Good documentation Practices, Risk management, validations, PQR, procedure and practices, process flow, investigation tools, Sampling techniques and system implementation for compliance audits.

Our Clients

