POSITIVE IMPACT

12TH FEBRUARY'2019

9 am to 5 pm

UMDC - Behind IoBM,
korangi Creek. Karachi.

Good Manufacturing Practices (GMP) for Pharmaceuticals – FDA standards

OVERVIEW

Good manufacturing practices (GMP) are required by Pharmaceutical industry to conform with internationally recommended standards and guidelines. The GMP provides a system for assuring the product is produced according to the quality standards.Adhering to GMP standards will minimise the risks and maximise production efficiency.
GMP compliant sites will benefit from;

o More credibility to International buyers.
o Offer a competitive advantage for contract manufacturers
o Eligible to participate in Millions of USD tenders Internationally.
o Improved capacity to manufacture products
o Help to reduce operating costs and duplication
o Cost savings like batch returns, Incident claims etc.

The course is designed to stimulate the dialogue and systematically builds the knowledge on guidelines relevant to GMP. Many international organisations developed standards for GMP, however FDA has explicitly focused on general principles of GMP in 21 CFR 210 and 211. The course will empower pharmaceutical manufacturer to work more efficiently on GMP standards and enjoy the leading edge of compliance status.

COURSE OBEJECTIVES

This course is lead and developed by an academic and industry expert and designed to enable participants to

o Understand GMP – Good Manufacturing Practices
o Know why we need GMP in businesses
o Be aware of GMP regulations/guidelines worldwide
o Understand 21 CFR 210 and 211
o Confidently step forward for GMP and compliance.

WHO SHOULD ATTEND:

o Industrial pharmacy professionals
o Industry leaders and strategists
o Pharmacist working in Dispensing, Production and Quality functions
o Engineers, Chemists and Microbiologists in pharmaceutical industries
o Regulatory and technical affairs professionals
o Quality control and Quality Assurance professionals

OUR PARTNERS

INTERNATIONAL ASSOCIATES®
TECHNICAL PARTNER

UMDC UNITED MEDICAL & DENTAL COLLEGE
KNOWLEDGE PARTNER

PPMA Pakistan Pharmaceutical Manufacturers' Association
SPONSER

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

LEARNING OUTCOMES:

o Understanding of Good Manufacturing Practices as required by FDA
o Enable attendees to find out the gaps and build a framework for GMP.
o Apply knowledge to improve the workplace environment
o Attain knowledge of international standards and guidelines.
o Relate tools learned from the course to structure and implement GMP
o Have a monitoring system in place to maintain the standards at work place.

COURSE OUTLINE

The course will broadly cover the topics below using real work scenarios and case studies;

o GMP Journey – from history to the guidelines
o GMP guidelines and looking at impact of non-compliance in modern world
o International guidelines and regulations for GMP
o Impact of GMP implementation and adaptations
o How to meet challenges related to GMP practices.
o International guidelines and regulations for GMP
o Best Practice Scenarios

INVESTMENT IN KNOWLEDGE DEVELOPMENT: RS.15,000 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
DR. FAHAD JAWED
MOBILE: 0345 202 7552
EMAIL: OFFICE@P-IMPACT.PK

OR REGISTER VIA WEBSITE
HTTPS://P-IMPACT.PK/REGISTER/
INFO@P-IMPACT.PK

Course Facilitator

DR. TARIQ ALI, PhD
Associate Professor, Dow University of Health Sciences

Over 19 years' experience of working in academia, Research, and Manufacturing operations, Dr Ali has authored 20 research publications in international reputed journals. He is also a Program reviewer for graduate & post-graduate level of studies in pharmaceutical and medical sciences for different universities. With his significant contributions in Glaxo SmithKline, Reckitt Benckiser, and Sanofi, he is known for his expertise in Pharmaceutical Manufacturing operations, quality and compliance.

He has been conducting trainings for pharmaceuticals over many years. He is a subject expert on GMP Practices, Halal Pharmaceutical Certifications, Pharmaceutical Quality Management, Industrial Pharmacy, Pharmaceutical Technology, Forensic Pharmacy, Physical Pharmacy and Instrumentation & Organic Chemistry. He has also conducted various trainings in supply chain covering Risk Assessment, Tablet Manufacturing Process and Bioavailability. Some of his training sessions to production staff covers Health and Safety, Uniform Protocols, Accidents and its awareness, Status Labelling and LOTO procedures.

His work in quality management and compliance include ISO compliance Audits, GMP Audits,Regulatory Audits, Model Factory Audits, Micro risk Audits and Health & Safety Audits. He is career advisor and youth counsellor. His work and significant achievements have contributed greatly to the Pharmaceutical industry.

PREVIOUS SUCCESSFUL EVENTS BY POSITIVE IMPACT UK