POSITIVE IMPACT

3rd OCTOBER '2020

10 am to 5 pm

UMDC - Behind IoBM, korangi Creek. Karachi.

The Common Technical Document (CTD) and its effective implementation

OVERVIEW

The Common Technical Document (CTD) is a set of specifications for an application dossier for the registration of Medicines and designed to be used across Europe, Japan and the United States. CTD is one of the standards hosted by The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

CTD is an agreed way for assembling quality, safety and efficacy information in a common format. CTD became the mandatory format for new drug applications in the EU and Japan and strongly recommended format of choice for NDAs submitted to FDA, United States. It is currently acknowledged as a global format for regulatory submissions.

This course will provide an edge to pharmaceutical experts on first-hand knowledge and up to date guidelines for developing dossiers. The course will equip attendees with robust knowledge on international guidelines. This can be an edge for many aspiring and leading pharmaceutical companies in Pakistan to explore their potential in Global markets

Course Objectives

- To introduce and describe ICH guidelines
- Proactive techniques to develop dossiers
- To enable implementation of CTD triangle
- Understand regulations and requirements
- Effectively using the E-CTD

Who should attend

CEOs, Regulatory affairs Directors and manager, Finance director and managers, QA/QC directors and managers, Pharma entrepreneur, Academics and Public authorities like DRAP.

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Learning Outcomes

- Empower the personnel to deliver and implement ICH guidelines and standard application
- Understanding of CTD theory and practice for establishing dossiers
- Effectively apply methodological approach for standardization of sampling and data records
- Use Tools for implementing regulatory framework
- Effectively access the ECTD for dossier submissions

Course Outline

- ICH guidelines
- Preparing for summaries, reports and data
- The CTD triangle and modular approach
- Complete the Quality and Pharmaceutical section of drug dossier.
- Regulatory framework
- Technical and regulatory requirements for CTDs submissions
- Creating dossiers by effectively using modules
- E-CTD
- Current trends as per various agencies
- Methodological approach of sampling and data submission
- EU laws on falsified medicine

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

COURSE FACILITATOR

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.

REGULAR COURSE FEE: PKR 25,000/- 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)-
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25,000/-

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