SAUDI FOOD & DRUG AUTHORITY (SFDA) CERTIFICATE IN PHARMACEUTICAL REGULATORY AFFAIRS

2 January 2020

Saudi Food & Drug Authority (SFDA) Certificate Program in Pharmaceutical Regulatory Affairs

Program Overview:

SFDA Certificate Program in Pharmaceutical Regulatory Affairs provides a comprehensive background and training required of regulatory affairs professionals to address issues related to pharmaceutical approval submissions and post-approval activities. In addition, it involves hands on training on how to prepare different types of pharmaceutical file submissions to the SFDA.

The program will help professionals interested in working in the pharmaceutical regulatory field to understand the SFDA regulatory requirements for pharmaceutical products.

Program Objective:

To help regulatory affairs professionals understand the SFDA regulatory requirements and provide them with tools which enable them to perform their role properly.

Program Duration:

The program will be 30 hours in total.

Program Plan:

Trainees will learn the following courses as described below. There will be an assessment test following each course and trainees have to score at least 60 out of 100 in each course to receive the certificate.

Course	Description
Introduction to Regulatory Affairs	This course provides trainees with an oversight on the pharmaceutical regulation and pharmaceutical products lifecycle before being available in the market. In addition, the course explains the rule of the authorities and the regulatory professionals in the product lifecycle. In addition, it covers the classification of pharmaceutical products. Furthermore, it explains the regulatory framework for drug approvals
Preclinical and Clinical Guidelines and Clinical Trials Regulation	This course explains the requirements for Non clinical studies and clinical studies in support of producing regulatory filings for products approval. In addition, trainees will understand the SFDA regulatory requirements to conduct clinical trials in Saudi Arabia.
Good Manufacturing Practices (GMP)	This course provides a basic understanding of current Good Manufacturing Practice (CGMP) regulations and their impact on product quality and patient safety. It covers a wide range of issues, including why regulations were created and are enforced worldwide, how pharmaceutical companies ensure compliance with the regulations, reasons for making quality products, US and EU regulations, the consequences for failing to comply with any regulations and associated regulatory actions.
Chemistry Manufacturing & Control (CMC)	The objective of this course is to provide a strong understanding of the importance and underlying principles for CMC requirements from the regulatory perspective. Participants will learn to develop a

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	cost effective, risk managed CMC regulatory compliance strategy to move these products into commercialization and maintain CMC regulatory compliance once market approval has been obtained.
Biologics and Biotechnology Products	This course provides details of biological drug product development and the local regulatory requirements for successful submissions. In addition, several topics regarding biotechnology will be covered in this course that includes gene therapy in cells coming from plants, insects, or mammalians using viral and bacterial vectors, and industrial technology for producing vaccines.
Generic Products	The objective of this course is to provide trainees with overview and background of the Generic drugs. The product development process, regulatory requirements and various differences of the generic drugs vs. novel drugs are discussed in details. The course also covers in depth discussion of laws, regulations and guidelines for the registration of Generic drugs.
Post-Approval Activities and Compliance	This course will provide an overview and analysis of the various regulatory activities that take place post-approval: In particular, the current regulatory climate will be discussed in depth and numerous examples will be provided to illustrate effective filing of notification techniques. Common issues which have caused difficulties for pharmaceutical firms will also be discussed. In addition, pharmacovigilance guidelines will be explained in details.
Hands on Training in eCTD submission	In this course, trainees will practice preparing the eCTD file for submission.