Course Topics

ICH Guidelines

SUPAC Guidelines

Regulatory Guidelines

Regulatory Submission

USFDA

EMEA

Indian (Domestic)

Preparing response to Deficiencies

DMF's

Part I

ICH GUIDELINES

SUPAC GUIDELINES

INTRODUCTION AND GENERAL OVERVIEW OF PHARMACEUTICAL INDUSTRY

Functions and types of DOSAGE Forms

Definitions and various departments in an industry

RA as a Profession and its Importance

Code of ethics of regulatory profession

Functions of RA

Importance of QA and its Link with RA.

Origin of drug development process and filings

Part II

REGULATORY SUBMISSION

USFDA

Drug Firm Establishment Registration with US-FDA (FEI No.)

NDC No. and DUNS

Generic Drug Submission

Preparation, Review and Submission of Application to USFDA.

Technical Support in CMC-Writing

Technical writing of Specifications, Test Procedures, Method/ Process Validation Protocols/Reports, BMR/BPR

Manufacturing Formula and Process

Preparation of Labels and Pack Insert

Consulting and preparation of all modules (M-1, M-2, M-3, M-5) for registration purpose in any country as per latest country specific guidelines.

Review, evaluation and Gap Analysis for compiled dossiers

Respond to deficiencies raised by regulatory authorities

EMEA

EU Commission

Procedures

Guidelines and Eudralex

Gap Analysis

Dossier writing for MAA

Preparation of SmPC, PIL

Responses to deficiencies.

Life Cycle management

Part III

Indian Regulatory Filing and Emerging markets

Dossier preparation

ICH CTD, ASEAN CTD and Country specific formats.

Prepare documents for company registrations in various countries.

Review, evaluation and gap analysis for compiled dossiers.

Renewal of registrations.

Prepare documents to file variations in case of Approved/Registered products.

Arrange GMP inspections

Preparation of SMF

Quality overall summary

Technical Support in CMC-Writing

Technical writing of Specifications, Test Procedures, Method/ Process Validation Protocols/Reports, BMR/BPR

Manufacturing Formula and Process

Preparation of Labels and Pack Insert

Review, evaluation and gap analysis for compile dossiers.

Respond to deficiencies raised by regulatory authorities.

Part IV

DMF

Introduction of DMF's

DMF process

DMF Formats

DMF contents

Difference between US and Europe DMF's

Highlights

Critical Review of Dossier and Preparation of GAP Analysis Report

Re-formatting old Dossier/DMF, NTA to CTD/eCTD format

Technical Support in CMC-Writing, SOP Writing, Protocol Writing, Expert report (QOS) preparation

Technical writing of Specifications, Test Procedures, Method/ Process Validation Protocols/Reports, BMR/BPR, Manufacturing Formula and Process

Handling deficiencies

Life Cycle Management