**Course Topics**

* *ICH Guidelines*
* *SUPAC Guidelines*
* *Regulatory Guidelines*
* *Regulatory Submission*

*USFDA*

*EMEA*

*Indian (Domestic)*

* *Preparing response to Deficiencies*
* *DMF’s*

**Part I**

1. ***ICH GUIDELINES***
2. ***SUPAC GUIDELINES***
3. ***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**

1. ***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**

1. *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