Module I	**Introduction**
	What is Regulatory Affairs
	Origin and purpose of regulatory Affairs
	Need of Regulations
	History and Development in Regulations
	Role and Responsibilities of regulatory affairs
	Industrial Scope
Module II	**Quality Assurance and Regulatory Regiment**
	Introduction to Quality System of Pharma Industry
	Documentation control and flow
	Good Manufacturing Practices (ICH Q7)
	Documents required for the regulatory Submission
	Regulatory Inspection and Compliance
	Role of QA in Regulatory Submission
Module III	**Role of QC Department in Regulatory**
	Certificate of Analysis
	Specification
	Raw Data
	Stability (ICH Q1A-Q1E)
Module IV	**Role of R & D & Production in Regulatory Department**
	Product Development
	Technology Transfer
	Process validation
	Tablet/Capsule Manufacturing Flow

Module V	**Regulatory IMP Guidance**
	Introduction to ICH
	Various product of ICH mainly Guidelines (Q,S, E,M)
	Detailed introduction of Some IMP Guidelines
	Common Technical Document (ICH M4)
	Electronic Submission (eCTD)
	Introduction to WHO
Module VI	**Regulations and Regulatory Submissions in Regulated Market**
	Types of Regulatory Application IND, NDA, ANDA, BLA, US DMF, EDMF
	Process of Marketing Authorization and Variation Filling in EU
	Process of Marketing Authorization in US FDA
	DMF/EDMF Filing in US and Europe
Module VII	**Regulations and Regulatory Submissions in Semi regulated Market**
	History and Current Process of Import of medicine in India
	Regulation and Process of Marketing Authorization in Asian Countries
	Introduction of ACTD
	Brief Introduction of Various Regulatory Bodies and Their Regulations (CIS Countries, African Countries, Latin and Central American Countries)
	Basic Regulatory Requirement and Tracking System of Documents
Module VIII	**Clinical Trials**
	Non clinical and Clinical Phases trial Phases
Module IX	**Project**