	Module I	**Introduction**
	1.1	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**
	2.1	Introduction to Quality System of Pharma Industry
	2.2	Documentation control and flow
	2.3	Good Manufacturing Practices (ICH Q7)
	2.4	Documents required for the regulatory Submission
	2.5	Regulatory Inspection and Compliance
	2.6	Role of QA in Regulatory Submission
	Module III	**Role of QC Department in Regulatory**
	3.1	Certificate of Analysis
		Specification
		Raw Data
		Stability Management
	Module IV	**Role of R & D & Production in Regulatory Department**
	4.1	Tablet/Capsule Manufacturing Flow
	4.2	Technology Transfer
	4.3	Process validation
	4.4	Product Development

	Module V	**Regulatory IMP Guidance**
	5.1	Drug Regulations as per D&C Act in India For Dossier & DMF.
	5.2	Guidelines of Different Countries.
	5.3	Introduction to PIC/S.
	5.4	Common Technical Document (CTD).
	5.5	Electronic Submission (eCTD)
	Module VI	**Regulations and Regulatory Submissions in Regulated Market**
	6.1	Introduction to Dossier Structure and Master Dossier Compilation.
	6.2	Introduction to DMF structure and DMF Compilation.
	6.3	Types of Regulatory Application IND, NDA, ANDA, BLA, US DMF, EDMF Process of Marketing Authorization and Variation Filling in EU
	6.4	Process of Marketing Authorization in US FDA DMF/EDMF Filing in US and Europe
	6.5	Guidelines For Excipient Registration and Ayurvedic Registration.
	Module VII	**Regulations and Regulatory Submissions in Semi regulated Market**
	7.1	History and Current Process of Import of medicine in India Regulation and Process of Marketing Authorization in Asian Countries
	7.2	Introduction of ACTD
	7.3	Brief Introduction of Various Regulatory Bodies and Their Regulations (CIS Countries, African Countries, Latin and Central American Countries)
	7.4	Basic Regulatory Requirement and Tracking System of Documents
	Module VIII	**Clinical Trials**
	8.1	Introduction to Clinical Trials BE Studies.