COURSE NAME: **POST GRADUATE DIPLOMA IN DRUG REGULATORY AFFAIRS - PGDDRA**

YEAR I

Course Code	Course Title	Theory/ Practical	Continuous Assessment (Internals)	Credits
DRA15101	Pharmaceutical Practices and Regulation.	70	30	8
DRA15102	Quality Assurance, GMP and Regulation.	70	30	8
DRA15103	Drug Regulatory Affairs including International Aspects.	70	30	8
PRJ15101	Project	200		4
			Total	28

YEAR I

PHARMACEUTICAL PRACTICES AND REGULATION – DRA15101

UNIT	CONTENTS
1	History, Development, Scope and nature of International and Indian Pharmaceutical Legislations.
2	CDCSCO - Schedule Y.
3	Understanding the Pharmaceuticals, Pharmaceutical products and Pharmaceutical market.
4	Requirement of regulatory aspects for product design, Manufacture and distribution in India with emphasis on following acts.
5	Pharmaceutical Documentation.
6	Standard operating procedure.

QUALITY ASSURANCE, GMP AND REGULATION – DRA15102

UNIT	CONTENTS
1	Quality assurance and validation.
2	ICH Guidelines and ISO 9000 Series.
3	Optimization techniques in Pharmaceuticals formulation and processing.
4	Regulatory aspects regarding Pharmaceutical packaging systems.
5	GMP and cGMP Guidelines.
6	Patents, Copyrights, Trademarks, Geographical indication, Biodiversity, Unfair competition and industrial design, TRIPs and TRIMs.

DRUG REGULATORY AFFAIRS INCLUDING INTERNATIONAL ASPECTS– DRA15103

UNIT	CONTENTS
1	A detailed regulatory aspects in Developed Country (U.S) and Developing Country (Brazil).
2	Regulatory aspects of pharmaceuticals and bulk drug manufacturer.
3	Documentation related to manufacturing and quality control.
4	Clinical trial and regulation including IND submission.
5	NDA submission.
6	Abbreviated New Drug Application **(**ANDA) submission.
7	International regulatory agencies (USFDA, MHRA, TGA, ANVISA).
8	Drug master file.
9	Common technical documentation (CTD); Traditional and E- submission.
10	Hatch-Waxman Act.
11	ICH guidelines.

ASSIGNMENTS/PROJECT – PRJ15101