NIMS UNIVERSITY

SYLLABUS

OF

POST GRADUATE DIPLOMA IN DRUG REGULATORY AFFAIRS – PGDDRA

VERSION 1.2

DIRECTORATE OF DISTANCE EDUCATION

Shobha Nagar, Jaipur-Delhi Highway (NH-11C), Jaipur- 303121
Rajasthan, India

POST GRADUATE DIPLOMA IN DRUG REGULATORY AFFAIRS – PGDDRA

Eligibility	:	Graduate in Science Stream
Programme Duration	:	1 Year
Programme Objectives	:	The pharmaceutical, biotechnology and medical device research and development industries are among the most highly regulated industries globally. As pharmaceutical sector is growing rapidly, there is a need of regulatory affairs professionals to cater the current needs of industries for the global competition. Regulatory affairs professionals are the link between pharmaceutical industries and worldwide regulatory agencies. Pharmaceutical Industry, being one of the highly regulated industries, is in immense need of people than ever before who are capable of handling issues related to regulatory affairs in a comprehensive manner.
Job Prospects	:	After the completion of PGDDRA, you will find a challenging career in a hospital and healthcare industry Common job profiles of students after completing PGDDRA include: Medical and Health Services Managers, Hospital Administrator, Manager, Senior Manager, Hospitals and other Senior Leadership Positions.

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

DETAILED SYLLABUS

INSTRUCTIONAL METHOD: Personal contact programmes, Lectures (virtual and in-person), Assignments, Labs and Discussions, Learning projects, Industrial Training Programmes and Dissertation.

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.

LEARNING SOURCE: Self Learning Materials

ADDITIONAL READINGS:

A. A Textbook of Clinical Pharmacy Practice : G Parthasarathi, Karin Nyfort-Hansen, Milap C Nahata, Orient Longman Pvt. Ltd, 2005.

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.

LEARNING SOURCE: Self Learning Materials

ADDITIONAL READINGS:

A. Quality Assurance of Pharmaceuticals Vol 2 Ed 2 : WHO Library Cataloguing in Publication.

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.

LEARNING SOURCE: Self Learning Materials

ADDITIONAL READINGS:

A. Medical Product Regulatory Affairs: John J. Tobin and Gary Walsh; Wiley Blackwell.

B. New Drug Development: Mark P. Mathieu; Barnett Educational Services, 2008.

ASSIGNMENTS/PROJECT – PRJ15101

Every student/candidate shall be provided with one assignment task for a period of one month which must be submitted to the head of institution for completion of the course.