NIMS UNIVERSITY

SYLLABUS

OF

POST GRADUATE DIPLOMA IN PHARMACEUTICAL PRODUCTION MANAGEMENT– PGDPPM

VERSION 1.2

DIRECTORATE OF DISTANCE EDUCATION

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

POST GRADUATE DIPLOMA IN PHARMACEUTICAL PRODUCTION MANAGEMENT– PGDPPM

Eligibility	:	Graduate in Science Stream
Programme Duration	:	1 Year
Programme Objectives	:	Pharmaceutical Management is a division of management that deals with chemical and health sciences and ensures the effective and safe use of pharmaceutical drugs. Pharmaceutical Management integrates business strategy with science and technology and the unique perspective of the industry. A management program in this area trains students on Enterprise Management, Leadership, Advanced Business Concepts and Technology Management and Advanced Pharmaceutical Management.
Job Prospects	:	Pharmaceutical sector is one of well known professional career options in India. The majority of the job opportunities for a graduate in this field are available in a research institute, government department, universities, pharmaceutical industry and teaching hospitals. Pharmaceuticals is a huge industry which constantly requires management specialists for smooth, productive and effective running of their respective firms. Pharmaceutical management always needs professional workers; hence there is no lack of employment opportunities in this field. Pharmaceutical management also offers sensible job opportunities for their professionals in terms of business or by opening their own business. Common job profiles of students after completing PGDPPM include: Sales Managers, Drug Cost Accountant, Drug Distribution Manager, Sales & Marketing Manager, Pharmaceuticals Distributors, Self Marketing & Distributorship and Market Researcher & Drug Developer.

YEAR I

Course Code	Course Title	Theory/ Practical	Continuous Assessment (Internals)	Credits
PHM15101	Pharmaceutical Industry & Production Planning	70	30	6
PHM15102	Product Development	70	30	6
PHM15103	Regulatory Guidelines	70	30	6
HRM15101	Human Resources Management	70	30	6
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 INDUSTRY & PRODUCTION PLANNING – PHM15101

UNIT	CONTENTS
1	**Pharmaceutical Industry Developments:** Licenses for formulation Industry, Plant Location- Factors Influencing.
2	**Plant Layout:** Factors Influencing, Special Provisions, Storage space requirements, Sterile and aseptic area layout.
3	**Pharmaceutical Process Flow and Work Study:** General flow patterns, Work station design, Process flow diagrams, Work study and Work measurements.
4	**Production Planning:** General principles, Production systems, Calculation of standard cost, Process planning, Routing, Loading, Scheduling, Dispatching of records, Production control.
5	**Material Management:** Value analysis and Vendor development, Maintenance Management- Corrective maintenance, Scheduled maintenance, Preventive maintenance, Predictive maintenance and Replacement analysis.
6	**Waste Management:** Solid Waste Management, Effluent Analysis and Treatment, Industrial hazards and Plant safety - Fire hazards, Mechanical hazards and Electrical hazards.
7	**Time Management:** Time Management Concept, Time Management Generations, Prioritization of Work, Time Allotment, Implementation of Time Management Programme.
8	**Warehousing:** Design, Construction, Maintenance and sanitation for materials and products, Good Warehousing practices.

LEARNING SOURCE: Self Learning Materials

ADDITIONAL READINGS:

A. Marketing Planning for the Pharmaceutical Industry: John Lidstone, Janice MacLennan; Gower Publishing Ltd.

B. Location, Capacity expansion and production planning in Pharmaceutical Industry under Stochastic Demand: Chinmay R Abhyankar.

C. Pharmaceutical Production: Bill Bennett and Graham Cole; Institution of Chemical Engineers.

PRODUCT DEVELOPMENT – PHM15102

UNIT	CONTENTS
1	**Process Variables:** A consideration of Physico-chemical Characteristics of new drug molecules with respect to different dosage form, Solubility Phenomenon in Pharmaceuticals, Enhancement of Solubility, Stability Studies.
2	**Optimization Techniques in Pharmaceutical Formulation and Processing:** Concept of Optimization, Optimization parameters, Classical optimization, Statistical Designs, Optimization Methods (EVOP, The Simplex and The Lagrangian).
3	**Bioprocess Technology:** Design and Operation of Fermenters, Fermentation Technology, Fermentation Process Kinetics, General Fermentation Process Economics.
4	**Herbal Technology:** Processing, Equipment and Analytical Profiles of Extract Drugs, Isolation, Estimation and Standardization of Phytoconstituents (with special emphasis on HPLC and HPTLC).
5	**Pilot Plant Scale-up Techniques:** Significance of Pilot Scale-up Phase to affect and orderly set-up from the laboratory procedures, Formulations to Routine Production procedures, Raw materials and Process, Physical lay-outs, Personnel requirements and reporting Responsibilities, Input specifications in-process and finished product specifications.
6	**Packaging of Pharmaceutical Dosage Forms:** Introduction to packaging of Pharmaceutical Dosage Forms. Glass - the absolute barrier, Elastomeric closures, Plastic, Metal, Paper and Board, Special packaging, Analysis and Control of Packaging Materials, Blister and Strip packaging and their evaluations.
7	**Stability Testing of Pharmaceutical Products:** Physicochemical factors affecting stability of drugs, Methods to find out degradation pathways, Determination of shelf life by accelerated stability testing, Brief review of ICH, Guidelines related to stability study.
8	**Enzyme Technology:** Production, Isolation and Purification of Enzymes, Applications in Pharmacy and Immobilized Enzymes and its future applications.

LEARNING SOURCE: Self Learning Materials

ADDITIONAL READINGS:

A. Product Development : A structured Approach to Consumer Product Development, Design and Manufacture: Anil Mital, Anoop Desai, Anand Subramanian, Aashi Mital; Butterworth-Heinemann.

B. New Product Development: Michale Z. Brooke, William Ronald Mills; Routledge.

REGULATORY GUIDELINES– PHM15103

UNIT	CONTENTS
1	US-FDA Guidelines, ICH Guidelines, ISO 9000
2	**Quality Control:** Quality Assurance and Validation - Introduction, Need of validation, Importance, Advantages, Phases of validation, Types of validation, Concept of Quality Assurance, Definition/scope, Requirements for effective Q.A, quality system validation, Quality Assurance Vs Quality Control.
3	**Pharmaceutical Documentation:** Introduction, Objectives of Documentation, General requirements and various types of Documentation related to Industrial Work.
4	**Important Guidelines:** GMP-cGMP, WHO Guidelines.
5	**Factories Act 1948:** Objectives, Approval Licensing and Registration of Factories, Inspecting staff, Health and safety, Welfare, Working hours, Penalties and procedures.
6	**Rights and Law:** Intellectual Property Rights and Patents Laws, GATT, WTO, TRIPs and TRIMs.

LEARNING SOURCE: Self Learning Materials

ADDITIONAL READINGS:

A. Regulation and Quality – Pharmaceutical Manufacturing Handbook; Shayne Cox Gad, Wiley.

B. The Pharmaceutical Regulatory Process: Ira R Berry, Marcel Dekker, 2005.

HUMAN RESOURCES MANAGEMENT – HRM15101

UNIT	CONTENTS
1	Human Resource Planning, Job Analysis and Design
2	Recruitment, Personnel selection. Orientation and Placement, Training and Development
3	Performance Appraisal, Remuneration and Salaries, Compensation and Incentives.
4	Motivation, Job design, Computer application in pharmaceutical production and management.

LEARNING SOURCE: Self Learning Materials

ADDITIONAL READINGS:

A. Human Resource Management: Mirza S Saiyadain; Tata McGraw-Hill Education.