NIMS UNIVERSITY, JAIPUR

SYLLABUS

PG Diploma in Pharmaceutical Production Management

POST GRADUATE DIPLOMA IN PHARMACEUTICAL PRODUCTION MANAGEMENT (Duration: 1 Year)

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S.NO	YEAR-1	Theory
1.	Pharmaceutical Industry & Production Planning	100
2.	Product Development	100
3	Regulatory Guidelines	100
4	Human Resources Management	100

(1). Pharmaceutical Industry and Production Planning:

(A). **Pharmaceutical Industry Developments:** Licenses for Formulation Industry, Plant Location- Factors Influencing

(B). **Plant Layout:** Factors Influencing, Special Provisions, Storage space requirements, Sterile and Aseptic area layout

(C) **Pharmaceutical Process Flow and Work Study:** General Flow Patterns, Work Station Design, Process Flow Diagrams, Work Study and Work Measurements

(D) **Production Planning:** General Principles, Production Systems, Calculation of Standard cost, Process Planning, Routing, Loading, Scheduling, Despatching of Records, Production Control.

(E) **Material Management:** Value analysis and Vendor Development

(F) **Maintenance Management:** Corrective maintenance, Scheduled maintenance, Preventive maintenance, Predictive maintenance and Replacement analysis.

(G) **Waste Management:** Solid Waste Management, Effluent Analysis and Treatment

(H) **Industrial Hazards and Plant Safety:** Fire hazards, mechanical hazards and electrical equipments, chemicals and pharmaceuticals, monitoring and preventing systems, Safety Management.

(I) **Time Management:** Time Management Concept, Time Management Generations, Prioritization of Work- Time Allotment, Implementation of Time Management Programme.

(J) **Warehousing:** Design, Construction, Maintenance and sanitation for materials and products, Good warehousing practices.

(2). Product Development:

(A). **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.

(B). **Optimization techniques in pharmaceutical formulation and processing**: Concept of optimization, optimization parameters, Classical optimization, Statistical Designs, Optimization Methods (EVOP, The Simplex and The Lagrangian).

(C). **Bioprocess Technology:** Design and Operation of Fermenters, Fermentation Technology, Fermentation Process Kinetics, General Fermentation Process Economics

(D). **Herbal Technology:** Processing, Equipment and Analytical Profiles of Extract Drugs, Isolation, estimation and Standardization of phytoconstituents (with special emphasis on HPLC and HPTLC).

(E) **Pilot Plant Scale-up Techniques:** Significance of Pilot scale-up Phase to affect and orderly set-up from the laboratory procedures and formulations to routine production procedures, raw materials and process, physical lay-outs, personnel requirements, and reporting responsibilities. Input specifications and in-process and finished product specifications.

(F). **Packaging of pharmaceutical dosage forms:** Introduction, 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.

(G). **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.

(H). **Enzyme Technology:** Production, isolation and purification of enzymes, Applications in pharmacy and Immobilized enzymes and its future applications.

(3) Regulatory Considerations:

(A) US-FDA Guidelines

(B) ICH Guidelines

(C) ISO 9000

(D) 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, Q.A Vs Q.C.

(E) **Pharmaceutical documentation:** Introduction, objectives of documentation, general requirements, and various types of documentation related to industrial work.

(F) GMP-cGMP

(G) WHO Guidelines

(H) Factories Act 1948: Objectives, Approval licensing and Registration of factories, inspecting staff, health and safety, welfare, working hours, penalties and procedures.

(I) Intellectual property rights and patents laws, GATT, WTO, TRIPs and TRIMs.

(4) Human Resources Management

(A) Human Resource Planning

(B) Job Analysis and Design

(C) Recruitment

(D) Personnel selection

(E) Orientation and Placement

(F) Training and Development

(G) Performance Appraisal

(H) Remuneration and Salaries

(I) Compensation and Incentives

(J) Motivation

(K) Job design

(L) Computer application in pharmaceutical production and management