BHARATHIAR UNIVERSITY: COIMBATORE-641 046
CENTRE FOR COLLABORATION OF INDUSTRY AND INSTITUTION(CCII)
POST GRATUATE DIPLOMA IN PHARMACEUTICAL REGULATORY AFFAIRS
(For the CCII students admitted from the academic year 2014-15 and onwards)

SCHEME OF EXAMINATIONS

Paper	Course Title	Dur. Hrs	Total Marks
	SEMESTER-I		
I	Quality assurance, validation and GMP guidelines	3	100
II	Practical –I (Quality assurance, validation and GMP guidelines)	3	100
III	Pharmaceutical Acts and Practices Involved in Manufacturing	3	100
IV	Practical –II (Pharmaceutical Acts and Practices Involved in manufacturing)	3	100
	SEMESTER-II		
V	Pharmaceutical Regulatory Requirements	3	100
VI	Practical –III(Pharmaceutical Regulatory requirements)	3	100
VII	Drug Regulatory Affairs Including International Regulations	3	100
VIII	Project		100
	TOTAL		800

SEMESTER-I

PAPER I: Quality assurance, validation and GMP guidelines

Unit-1

Concept of Quality, Quality by design, Basic concepts of Pharmaceutical Validation.

Unit-2

ICH Guidelines and ISO 9000 Series. Good Manufacturing Practices (GMP) and cGMP Guidelines. Evolution and Principles of cGMP,

Unit-3

WHO-GMP requirements and United States Food and Drug Administration (USFDA) guidelines on Pharmaceutical manufacturing. Schedule-M,

Unit-4

Stability testing: ICH and WHO guidelines, Photo stability studies.

Unit-5

Good Laboratory Practices (GLP): scope of GLP, Standard Operating Procedures (SOP).

References books

1. Good Manufacturing Practices for Pharmaceuticals: A Plan for Total Quality Control from Manufacturer to Consumer, Sidney J. Willig, Marcel Dekker, 5th Ed.
2. Pharmaceutical quality assurance and management, Bhusari kp, vol, 2011.
3. Quality planning and Analysis by JM Juran and FM Gryna, Tata McGrawHill- India.
4. Total Quality Management, Dale H. Besterfield, Pearson Education, 3rd Ed., 2003.
5. Total Quality Management, Principles, Implementation & Cases, Sharma D.D., Sultan Chand & Sons, New Delhi, 2000.
6. Quality Assurance of Pharmaceuticals Vol 2 Ed 2: WHO Library Cataloguing in Publication.

PAPER II: Practical –I (Quality assurance, validation and GMP guidelines)

Name of the experiments

1. Documentation for in process and finished products Quality control tests for Solid dosage forms.
2. Documentation for in process and finished products Quality control tests for Semisolid dosage forms.
3. Documentation for in process and finished products Quality control tests for parenteral.
4. Documentation for in process and finished products Quality control tests for ophthalmic preparations.
5. Documentation for in process and finished products Quality control tests for modified release preparations.

References

1 .Lachman L Liberman Theory and practice of industrial pharmacy by 3 rd edition

2. Pharmaceutical Quality Assurance by Manohar A. Potddar, 2nd edition 2007, Nirali Prakashan, Mumbai
3. Guidelines by FDA, MHRA, Pharmaceutical and Medical Devices Agency, TGA, DCG.

PAPER III: Pharmaceutical Acts and Practices Involved in Manufacturing

Unit-1

Brief study of following laws-Drugs and Cosmetics Act 1940 and its rules 1945, The Environmental Protection Act31986 & Occupational l Safety and Health Administration (OSHA)

Unit-2

The Narcotics Drugs and Psychotropic Substances Act. Medicinal and Toilet Preparations (Excise Duties) Act, 1955. The Pharmacy Act, 1948.

Unit-3

Quality evaluation and batch release: change control, Deviation-(planned and unplanned), corrective action and preventive action (CAPA)

Unit-4

Documentation in pharmaceutical industry: Batch Formula Record, Master Formula Record, Distribution records, Drug Master Files.

Unit-5

Regulatory aspects regarding Pharmaceutical packaging systems. Patents, Copyrights, Trademarks,

References books

1. The drugs and cosmetics act 1940 – Deshpande, Nilesh Gandhi, 4th edition, Susmit Publishers, 2006.
2. United States Pharmacopeia (USP)
3. Indian Pharmacopeia.
4. GMP by Mehra.

PAPER IV: Practical –II (Pharmaceutical Acts and Practices Involved in Manufacturing)
Name of the experiments

1. Protocol preparation for documentation of BMR (Batch manufacturing record)
2. Protocol preparation for documentation of packaging –Batch Packaging record.
3. Preparation of SOPs for various equipments and manufacturing processes as per ISO requirements.
4. Accelerated and Photo stability studies on dosage forms as per ICH Guidelines.
5. Patent challenge / non infringement (Para IV) case studies.

References

1. Guidance for industry on Submission of clinical trial Application for evaluating Safety and Efficacy by CDSCO (Central Drug Standard Control Organization).
2. Guidance for industry on Requirement of Chemical & Pharmaceutical Information including stability study data before approval of clinical trials/ BE studies by CDSCO.
3. Guidelines by FDA, MHRA, Pharmaceutical and Medical Devices Agency, TGA, DCG

SEMESTER-II

PAPER V: Pharmaceutical Regulatory Requirements

Unit-1

Introduction to Global Regulatory Authorities for pharma industries. Generic Drug Product development: Introduction to Hatch Waxman act and amendments, Code of Federal Regulations (CFR). Introduction to Common Technical dossier (CTD). Dossier preparation in CTD format, eCTD submissions.

Unit-2

National and global context –markets and trends. Market analysis and marketing strategy. Business environment: Political, economical, social and technological implications**.** Sales Plan: promotion, implementation feedback, Adverse drug reaction (ADR) reporting. Finance: Sales forecast, profit, distribution channel.

Unit-3

Drug Development Process, Clinical Trials and related norms and regulations.

Unit-4

Compliance guidelines, Govt. Audits (FDA (Food and Drug Administration), MHRA (Medicines and Healthcare Product regulatory Agency), PMDA (Pharmaceutical and Medical Devices Agency), TGA (Therapeutics Good Administration), DCG (Drug Controller General)

Unit-5

Drug regulation in India: Drug regulation in India CDSCO(Central Drug Standard Control Organization). National pharmaceutical pricing authority. Drug price regulation in India. Drug registration in India. Pharma and Healthcare products- Marketing, Import and Export regulations.

References books

1. Generic Drug product Development, Solid Oral dosage Forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143.
2. Guidebook for drug regulatory submissions-Sandy Weinberg By john Wiley & Sons.Inc.
3. The Pharmaceutical regulatory process, Second Edition edited by Ira R.Berry and Robert P. Martin, Drugs and the pharmaceutical Sciences.
4. Guidance for industry on Submission of clinical trial Application for evaluating Safety and Efficacy by CDSCO (Central Drug Standard Control Organization).
5. Principles of Pharmaceutical marketing,Smith M,3 rd,2004.

PAPER VI: Practical –III (Pharmaceutical Regulatory Requirements)

Name of the experiments

1. Preparation of Phase I, Phase II, Phase III clinical trial report for submission to regulatory authorities.
2. Preparation of global list of documents for registration of IND
3. Preparation of global list of documents for registration of NDA
4. Preparation of global list of documents for registration of ANDA.
5. Case studies on response with scientific rationale to USFDA Warning Letter

References

1. Guidance for industry on Submission of clinical trial Application for evaluating Safety and Efficacy by CDSCO (Central Drug Standard Control Organization).
2. Guidance for industry on Requirement of Chemical & Pharmaceutical Information including stability study data before approval of clinical trials/ BE studies by CDSCO.
3. Guidelines by FDA, MHRA, Pharmaceutical and Medical Devices Agency, TGA, DCG

PAPER VII: Drug Regulatory Affairs Including International Regulations

Unit-1

Chemistry, Manufacturing and controls (CMC), Post approval Regulatory affairs,

Unit-2

Clinical trials: Developing clinical trial protocols, Institutional Review Board/ Independent Ethics committee formation and working procedures, Informed consent-process and procedure

Unit-3

Documentation of drug trials and regulatory filings in US, Europe, UK, India, Japan, Canada, Australia, South Africa, etc.

Unit-4

Outsourcing Bioavailability and Bioequivalence studies to Contract Research organizations. Pharmaceutical labeling, advertising and promotion.

Unit-5

Breach report and handling of warning letters. Product Recalls and it types.

References books

1. Guidance for industry on Requirement of Chemical & Pharmaceutical Information including stability study data before approval of clinical trials/ BE studies by CDSCO.
2. New drug Approval Process: Accelerating Global Registrations by Richard A Guarino, MD, 5th edition, Drugs and the Pharmaceutical sciences.
3. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance by Fay A. Rozovsky and Rodney K. Adams
4. Guidebook for drug regulatory submissions / Sandy Weinberg. By John Wiley & Sons. Inc

PAPER VIII: PROJECT