INSTITUTE	**FACULTY OF PHARMACY**
PROGRAM	**MASTER OF PHARMACY (REGULATORY AFFAIRS)**
SEMESTER	**1**
COURSE TITLE	**DOCUMENTATION AND REGULATORY WRITING**
COURSE CODE	**13MR0102**
COURSE CREDITS	**4**

Objective:

1 This course is designed to impart fundamental knowledge on documentation and general principles involved in regulatory writing and submission to agencies.

Course Outcomes: After completion of this course, student will be able to:

1 Know the various documents pertaining to drugs in the pharmaceutical industry.
2 Understand the basics of regulatory compilation.
3 Create and assemble the regulation submission as per the requirements of agencies.
4 Follow up on the submissions and post-approval document requirements.

Pre-requisite of course:B. Pharm. Qualified

Teaching and Examination Scheme

Theory Hours	Tutorial Hours	Practical Hours	ESE	IA	CSE	Viva	Term Work
4	0	0	75	15	10	0	0

Contents : Unit	Topics	Contact Hours
1	**Documentation in the pharmaceutical industry** ExploratoryProduct Development Brief (EPDB) for Drug Substance and DrugProduct, Product Development Plan (PDP), Product DevelopmentReport (PDR), Master Formula Record, Batch ManufacturingRecord and its calculations, Batch Reconciliation, BatchPackaging Records, Print pack specifications, Distributionrecords, Certificate of Analysis (CoA), Site Master File and DrugMaster Files (DMF).	12

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Contents : Unit	Topics	Contact Hours
2	**Dossier preparation and submission:** Introduction andoverview of dossiers, contents, and organization of dossier,binders, and sections, compilation and review of the dossier. Papersubmissions, overview and modules of CTD, electronic CTDsubmissions; Electronic submission: Planning electronicsubmission, requirements for submission, regulatory bindings andrequirements, Tools and Technologies, electronic dossiersubmission process and validating the submission, ElectronicSubmission Gateway (ESG). Non-eCTD electronic submissions(NeeS), Asian CTD formats (ACTD) submission. Organizing, processing, and validation of submission. Submission in Sugamsystem of CDSCO.	12
3	**Audits** Introduction, Definition, Summary, Types of audits, GMPcompliance audit, Audit policy, Internal and External Audits,Second Party Audits, External third-party audits, Auditingstrategies, Preparation and conducting an audit, Auditing strategies,audit analysis, audit report, audit follow up. Auditing/inspection ofmanufacturing facilities by regulatory agencies. Timelines foraudits/inspection. GHTF study group 4 guidance document.ISO 13485.	12
4	**Inspections** Pre-approval inspections, Inspection ofpharmaceutical manufacturers, Inspection of drug distributionchannels, Quality systems requirements for national goodmanufacturing practice inspectorates, inspection report, modelcertificate of good manufacturing practices, Root cause analysis,Corrective and Preventive Action (CAPA).	12
5	**Product life cycle management** Prior Approval Supplement(PAS), Post Approval Changes [SUPAC], Changes BeingAffected in 30 Days (CBE-30), Annual Report, Post-marketing Reporting Requirements, Post approval Labeling Changes,Lifecycle Management, FDA Inspection, and Enforcement,Establishment Inspection Report (EIR), Warning Letters, Recalls,Seizure, and Injunctions. ISO Risk Management Standard.	12
Total Hours		**60**

Textbook :

1 Compliance auditing for Pharmaceutical Manufacturers., KarenGinsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London NewYork,, Washington D.C.Karen Ginsbury, Gil Bismuth, 1994

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References:

1 Compliance auditing for Pharmaceutical Manufacturers. , Compliance auditing for Pharmaceutical Manufacturers. , KarenGinsbury and Gil Bismuth, Interpharm/CRC, Boca Raton, London NewYork, , Washington D.C.Karen Ginsbury, Gil Bismuth, 1994

2 Pharmaceutical Manufacturing Handbook, Regulations and Quality, Pharmaceutical Manufacturing Handbook, Regulations and Quality, byShayne Cox Gad. , Wiley-Interscience, A John Wiley, and Sons, Inc.,Publications,John Wiley & Sons, 2008

3 Handbook of microbiological Quality control, Handbook of microbiological Quality control, Rosamund M. Baird,Norman A. Hodges, Stephen P. Denyar. CRC Press., Taylor & Francis Group, 2019

4 Laboratory auditing for quality and regulatory compliance, Laboratory auditing for quality and regulatory compliance, Donald C.Singer, Raluca-loana Stefan, Jacobus F. Van Staden. , Taylor andFrancis , 2005

5 Implementing Juran's Road Map for Quality Leadership: Benchmarksand Results, Implementing Juran's Road Map for Quality Leadership: Benchmarksand Results, By Al Endres, Wiley, 2000

6 Understanding, Managing and Implementing Quality: Frameworks,Techniques, and Cases, Understanding, Managing and Implementing Quality: Frameworks,Techniques, and Cases, By Jiju Antony, Preece, Routledge, , 2002

7 Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report , Organizing for High Performance: Employee Involvement, TQM, Reengineering, and Knowledge Management in the Fortune 1000: The CEO Report , by Edward E. Lawler; Susan Albers Mohrman; GeorgeBenson, , Jossey-Bass, 2001

8 Corporate Culture and the Quality Organization, Corporate Culture and the Quality Organization, by James W. Fairfield-Sonn, , Quorum Books, 2001

9 The Quality Management Sourcebook: An International Guide toMaterials and Resources, The Quality Management Sourcebook: An International Guide toMaterials and Resources, by Christine Avery; Diane Zabel,, Routledge,, 1997

10 The Quality Toolbox, Second Edition, The Quality Toolbox, Second Edition, Nancy R. Tague, ASQ Publications., 1995

11 Juran's Quality Handbook, Sixth Edition,, Juran's Quality Handbook, Sixth Edition,, Joseph M. Juran and Joseph A. De Feo, , ASQ Publications., 1951

12 Root Cause Analysis, The Core of Problem Solving and CorrectiveAction,, Root Cause Analysis, The Core of Problem Solving and CorrectiveAction,, Duke Okes, ASQ Publications., 2009

13 International Medical Device Regulators Forum , International Medical Device Regulators Forum , (IMDRF) MedicalDevice Single Audit Program , (MDSAP)., 2011

Suggested Theory Distribution:

The suggested theory distribution as per Bloom’s taxonomy is as follows. This distribution serves as guidelines for teachers and students to achieve effective teaching-learning process

Distribution of Theory for course delivery

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Remember / Knowledge	Understand	Apply	Analyze	Evaluate	Higher order Thinking / Creative
10.00	20.00	25.00	25.00	10.00	10.00

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