

INSTITUTE	FACULTY OF PHARMACY
PROGRAM	MASTER OF PHARMACY (REGULATORY AFFAIRS)
SEMESTER	1
COURSE TITLE	GOOD REGULATORY PRACTICES
COURSE CODE	13MR0101
COURSE CREDITS	4

Objective:

- 1 This course is designed to impart fundamental knowledge on various good regulatory practices viz., cGMP, GLP, GALP, and GDP for Pharmaceuticals, Cosmetics, Food & Nutraceuticals, Medical devices, In-vitro Diagnostic Medical Devices (IVDs), and biological products and understand the rationale behind these requirements and will propose ways and means of complying with them.

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

- 1 The key regulatory and compliance elements with respect to Good Manufacturing Practices, Good Laboratory Practices, Good Automated Laboratory Practices, and Good Documentation Practices.
- 2 Prepare and implement the checklists and SoPs for various Good Regulatory Practices
- 3 Implement Good Regulatory Practices in the Healthcare and related Industries
- 4 Prepare for the readiness and conduct of audits and inspections.

Pre-requisite of course: Nil

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	Current Good Manufacturing Practices Introduction, US cGMP Part 210 and Part 211. EC Principles of GMP (Directive 91/356/EEC) Article 6 to Article 14 and WHO cGMP guidelines GAMP-5; Medical device and IVDs Global Harmonization Task Force (GHTF) Guidance docs.	12
2	Good Laboratory Practices Introduction, USFDA GLP Regulations (Subpart A to Subpart K), Controlling the GLP inspection process, Documentation, Audit, goals of Laboratory Quality Audit, Audit tools, Future of GLP regulations, relevant ISO and Quality Council of India (QCI) Standards	12

Contents : Unit	Topics	Contact Hours
3	Good Automated Laboratory Practices Introduction to GALP, Principles of GALP, GALP Requirements, SOPs of GALP, Training Documentation, 21 CFR Part 11, General checklist of 21 CFR Part 11, Software Evaluation checklist, relevant ISO and QCI Standards.	12
4	Good Distribution Practices Introduction to GDP, Legal GDP requirements put worldwide, Principles, Personnel, Documentation, Premises, and Equipment, Deliveries to Customers, Returns, Self-Inspection, Provision of information, Stability testing principles, WHO GDP, USP GDP (Supply chain integrity), relevant CDSCO guidance, and ISO standards.	12
5	Quality management systems Concept of Quality, Total Quality Management, Quality by Design, Six Sigma concept, Out of Specifications (OOS), Change control. Validation: Types of Validation, Types of Qualification, Validation master plan (VMP), Analytical Method Validation. Validation of utilities, [Compressed air, steam, water systems, Heat Ventilation and Air conditioning (HVAC)] and Cleaning Validation. The International Conference on Harmonization (ICH) process, ICH guidelines to establish quality, safety, and efficacy of drug substances and products, ISO 13485, Sch MIII, and other relevant CDSCO regulatory guidance documents.	12
Total Hours		60

Textbook :

- 1 Good Laboratory Practice Regulations, Sandy Weinberg, Fourth Edition. Drugs and the Pharmaceutical Sciences., 2016

References:

- 1 Good Laboratory Practice Regulations, Good Laboratory Practice Regulations, Sandy Weinberg, Fourth Edition. Drugs and the Pharmaceutical Sciences., 168.
- 2 Good Pharmaceutical Manufacturing Practice, Rational and Compliance, Good Pharmaceutical Manufacturing Practice, Rational and Compliance, by John Sharp, CRC Press, John Sharp., 2004
- 3 Establishing a cGMP Laboratory Audit System, A Practical Guide, Establishing a cGMP Laboratory Audit System, A Practical Guide, by David M. Bleisner, Wiley Publication, 2006
- 4 How to practice GLP by PP Sharma, How to practice GLP by PP Sharma, Vandana Publications, Delhi Vandana Publication, 2006
- 5 Laboratory Auditing for Quality and Regulatory Compliance, Laboratory Auditing for Quality and Regulatory Compliance, Donald C. Singer, Drugs and the Pharmaceutical Sciences Vol.150. Donald C. Singer, Raluca-Ioana Stefan, 2019
- 6 Drugs & Cosmetics Act., Drugs & Cosmetics Act., Rules & Amendments., 1940

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