G. PULLA REDDY COLLEGE OF PHARMACY
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Affiliated to **Osmania University** Approved by **PCI** & Accredited by **NAAC**
Mehdipatnam, Hyderabad - 500028. Telangana State.

M. PHARM FIRST SEMESTER (PCI) REGULAR EXAMINATIONS, APRIL – 2026

Branch: REGULATORY AFFAIRS

Subject: GOOD REGULATORY PRACTICES

Subject Code : MRA101T **QP Code: MRAI01TE26**
Time: 03 Hours **Max Marks: 75**

Note: Answer Any **FIVE** Questions. **5 X 15 = 75M**

S. No	Questions
1	Describe Global Harmonization Task Force (GHTF) guidance documents for medical Device and IVD
2	Explain how Quality by Design (QbD) tools are applied in quality management to ensure product quality and process efficiency.
3	Design a comprehensive GLP compliance framework based on USFDA regulations (Subpart A to Subpart K) to ensure quality and reliability in laboratory studies & add a note documentation of quality audit? (10+5)
4	List the key requirements of 21 CFR Part 11 and the components of the general checklist and software evaluation checklist for GALP?
5	Evaluate and justify the differences between stability testing principles, WHO Good Distribution Practices (GDP), and USP GDP (supply chain integrity) in ensuring pharmaceutical product quality and supply chain integrity.
6	Analyze the key provisions of US cGMP (Parts 210 and 211) and explain their role in ensuring the quality of pharmaceutical products.
7	Design a quality system using Six Sigma, OOS handling, change control, and validation to ensure product quality in pharmaceutical industries.
8	List the roles of ISO standards and Quality Council of India (QCI) standards in maintaining quality and regulatory compliance in organizations.

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M. PHARM FIRST SEMESTER (PCI) REGULAR EXAMINATIONS, APRIL – 2026
Branch: REGULATORY AFFAIRS
Subject: DOCUMENTATION AND REGULATORY WRITING

Subject Code : MRA102T **QP Code: MRAI02TE26**
Time: 03 Hours **Max Marks: 75**

Note: Answer Any **FIVE** Questions. **5 X 15 = 75M**

S. No	Questions
1	Define a Drug Master File (DMF) and list its types and key components.
2	Explain the concept and key features of Batch Manufacturing Record (BMR) and Master Formula Record (MFR) in pharmaceutical manufacturing.
3	Explain the concepts of Common Technical Document (CTD) and ASEAN Common Technical Dossier (ACTD), and describe the differences between them.
4	Define audits and list the steps involved in the preparation and conduct of audits.
5	Describe the process of root cause analysis in investigating a deviation with examples
6	Summarize the steps involved in the implementation of a CAPA (Corrective and Preventive Action) process.
7	Define warning letters and recalls, and list their key features with examples.
8	Define post-approval labelling changes and list the steps involved in the process.

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M. PHARM FIRST SEMESTER (PCI) REGULAR EXAMINATIONS, APRIL – 2026

Branch: REGULATORY AFFAIRS

Subject: CLINICAL RESEARCH REGULATIONS

Subject Code : MRA103T **QP Code: MRAI03TE26**

Time: 03 Hours **Max Marks: 75**

Note: Answer Any **FIVE** Questions. **5 X 15 = 75M**

S. No	Questions
1	A) Compare and contrast four phases of clinical drug development process. (10 Marks) B) Justify the significance of phase 0 studies. (5 Marks)
2	Recall historical perspectives pertaining to ethics in clinical research.
3	Analyse the differences in regulations to conduct drug studies for approval of NDA and ANDA as per US FDA.
4	Explain Good Clinical practice guidelines as per ICH GCP E6.
5	Interpret the general biostatics principles applicable to clinical research.
6	Demonstrate the usage of efficacy guidance in geriatrics and choice of control groups in clinical trials.
7	Explain in detail about protection of human rights and financial disclosure by clinical investigators with relevant forms.
8	Describe FDA safety reporting requirements for INDs and BA/BE studies.

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M. PHARM FIRST SEMESTER (PCI) REGULAR EXAMINATIONS, APRIL – 2026
Branch: PHARMACEUTICS
Subject: REGULATORY AFFAIR

Subject Code : MPH104T **QP Code: MPHI04TE26**
Time: 03 Hours **Max Marks: 75**

Note: Answer Any **FIVE** Questions. **5 × 15 = 75 M**

S. No	Questions
1	Explain in detail the Drug Master File (DMF) with types and contents. 15 Marks
2	a) Describe *in vitro* and *in vivo* drug product performance evaluation. 8 Marks b) Explain role of Contract Research Organization (CRO) in outsourcing BA/BE studies. 7 Marks
3	Discuss the regulatory pathways for approval of biologics including Biological Licence Application (BLA) requirements. 15 Marks
4	a) Define and explain Chemistry, Manufacturing and Controls (CMC) in regulatory affairs. 8 Marks b) Write a note on post-approval changes and variations. 7 Marks
5	Discuss regulatory requirements of EU, MHRA, and TGA. 15 Marks
6	Discuss the global submission process of New Drug Applications (NDA) and Abbreviated New Drug Applications (ANDA) with regulatory requirements. 15 Marks
7	a) Write short note on non-clinical drug development. 8 Marks b) Explain Adverse Drug Reaction (ADR) reporting procedures. 7 Marks
8	a) Explain Health Insurance Portability and Accountability Act (HIPAA) regulations and their impact on clinical study processes. 10 Marks b) Explain informed consent. 5 Marks