THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[M.PHARM 0423] APRIL 2023 Sub. Code: 3003
(OCTOBER 2022 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New regulations 2016)
PHARMACEUTICAL REGULATORY AFFAIRS - MRA
PAPER III – CLINICAL RESEARCH REGULATIONS

Q.P. Code: 263003

Time : Three hours **Answer ALL Questions** **Maximum : 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. What are the various regulations to conduct drug studies in India? Summarize each of them.
2. Explain the Clinical Research regulations in European Union.

II. Write notes on: **(7 x 5 = 35)**

1. Discuss the FDA Guidance for Industry - Acceptance of foreign clinical studies.
2. Write a note on CFR 21 Part 50 and 54 of USFDA Guidance document.
3. Write a note on FDA Safety Reporting Requirements for INDs and BA/BE Studies.
4. Write a note on EudraLex (EMEA) Scientific guidelines for medicinal products for human use.
5. Write a note on EU Annual Safety Report (ASR).
6. Write a note on Pharmacovigilance for Medicinal Products for Human Use.
7. Write a note on EU MDD with respect to clinical research.

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[M.PHARM 0823] **AUGUST 2023** **Sub. Code: 3003**
(APRIL 2023 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New Regulations 2016)
PHARMACEUTICAL REGULATORY AFFAIRS - MRA
PAPER III – CLINICAL RESEARCH REGULATIONS

Q.P. Code: 263003

Time : Three hours **Answer ALL Questions** **Maximum : 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. Discuss the clinical research regulations in India.

2. Explain the Regulatory Guidance on Efficacy and Safety ICH Guidance.

II. Write notes on: **(7 x 5 = 35)**

1. Differentiate the ICH GCP and Indian GCP guidelines.
2. What are the General Biostatistics principles applied in clinical research?
3. Write a note on CFR 21 part 312 and 314 of USFDA Guidance document.
4. Write in brief about EU Directives 2001.
5. Write a note on ISO 14155.
6. Write in brief GHTF study groups.
7. Write notes on informed consent form.

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[M.PHARM 0524] MAY 2024 Sub. Code: 3003
(APRIL 2024 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New Regulations 2016)
PHARMACEUTICAL REGULATORY AFFAIRS - MRA
PAPER III – CLINICAL RESEARCH REGULATIONS

Q.P. Code: 263003

Time: Three hours **Answer ALL Questions** **Maximum: 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. Explain in detail about historical perspectives of clinical research.

2. Describe the applicable regulations to conduct clinical studies in USA.

II. Write notes on: **(7 x 5 = 35)**

1. Explain Good Clinical Practice Guidelines.
2. Write a note on 21 CFR Part 320: Bioavailability and Bioequivalence requirements.
3. Write a note on Indian GCP guidelines.
4. Explain the Ethical principles governing informed consent process.
5. Write a note on Clinical investigation and Clinical evaluation of medical devices.
6. Explain the responsibilities of sponsors, CRO and investigator in ethical conduct of clinical research.
7. Write a short note on FDA Med Watch.

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

[M.PHARM 0425] **APRIL 2025** **Sub. Code: 3003**

M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New Regulations 2016)
PHARMACEUTICAL REGULATORY AFFAIRS - MRA
PAPER III – CLINICAL RESEARCH REGULATIONS

Q.P. Code: 263003

Time: Three hours **Answer ALL Questions** **Maximum: 75 Marks**

I. Elaborate on: **(2 x 20 = 40)**

1. Discuss the ICMR Ethical Guidelines for Biomedical Research.

2. Explain the clinical research regulations with respect to USFDA.

II. Write notes on: **(7 x 5 = 35)**

1. Write a note on clinical evaluation of medical devices.
2. Write a note on the history of clinical trials along with the implementation of various laws and reports.
3. What is the role of placebo in clinical trial?
4. What are the general biostatistics principles applied in clinical research?
5. Write a note on ISO 14155.
6. Write in brief about EU Directives 2001.
7. Write a note on CFR 21 Part 50 and 54 of USFDA guidance document.

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