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

[LL 934] NOVEMBER 2017 **Sub. Code: 2934**

M.PHARM. DEGREE EXAMINATION
(PCI New regulations 2016)
SEMESTER-I
PHARMACEUTICS – MPH
PAPER IV – REGULATORY AFFAIRS

Q.P. Code : 262934

Time : Three hours **Maximum : 75 Marks**

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

1. a) Discuss the documentation process in pharma industry.
   b) Post marketing surveillance and pharmaceuticals.

2. Write in detail the developing of clinical trials protocols and other working procedures for conducting the clinical trials.

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

1. Significance of HATCH – WAXMAN ACT.
2. Managing changes during post approval stages.
3. Activities of CRO.
4. Investigator brochure.
5. Regulation for the approval of medical devices.
6. Regulatory requirements of TGA.
7. HIPAA and its usefulness in clinical trials.

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

[LM 934] MAY 2018 **Sub. Code: 2934**

M.PHARM. DEGREE EXAMINATION
(PCI New regulations 2016)
SEMESTER-I
PHARMACEUTICS – MPH
PAPER IV – REGULATORY AFFAIRS

Q.P. Code : 262934

Time : Three hours **Maximum : 75 Marks**

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

1. Explain the *Invitro* drug product performance and its limitations.

2. Write a note on:
   a) ICH guidelines related to safety and maintenance.
   b) Regulatory requirement of ANDA generic drug approval in US.

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

1. Master formula record and distribution records.
2. Regulatory requirements of EU.
3. Institutional review board for clinical trials.
4. Post marketing surveillance.
5. Global submission process for non clinical drug development as IND.
6. Scale up process and its significance.
7. CTD and ETCD format and its usefulness in regulatory affairs.

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

[LN 934] NOVEMBER 2018 **Sub. Code: 2934**

M.PHARM. DEGREE EXAMINATION
(PCI New regulations 2016)
SEMESTER-I
PHARMACEUTICS – MPH
PAPER IV – REGULATORY AFFAIRS

Q.P. Code : 262934

Time : Three hours **Maximum : 75 Marks**

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

1. Discuss the drug regulatory submission requirements for European union, medicines and Health Care products regulatory agency and Therapeutic Goods Administration.

2. Explain the steps involved in carrying out a clinical trial. Write the responsibilities and functional modalities for institutional review board.

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

1. Amendments of Hatch Waxman Act.
2. Bioequivalence studies with pharmacokinetic end points.
3. Regulatory approval procedure for biologics.
4. International conference on Harmonization quality guidelines.
5. Investigational brochure.
6. Health Insurance portability and accountability act.
7. Importance of pre formulation studies in scale up process.

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

[LO 934] MAY 2019 **Sub. Code: 2934**

M.PHARM. DEGREE EXAMINATION
(PCI New regulations 2016)
SEMESTER-I
BRANCH I – PHARMACEUTICS – MPH
PAPER IV – REGULATORY AFFAIRS

Q.P. Code : 262934

Time : Three hours **Maximum : 75 Marks**

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

1. Give an account of outsourcing bioavailability and bioequivalence studies to contract research organization.

2. Discuss the following:
   a) NDA regulatory approval process.
   b) Active pharmaceutical ingredients and its specifications.

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

1. Post market surveillance.
2. Regulatory requirements of MHRA.
3. Investigator brochure.
4. HIPAA and its significance in clinical trials.
5. Regulatory requirement for product approval of biological products.
6. Independent ethics committee formulation and its working procedures.
7. Safety monitoring in clinical trials.

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

[LP 934] NOVEMBER 2019 **Sub. Code: 2934**

M.PHARM. DEGREE EXAMINATION
(PCI New regulations 2016)
SEMESTER-I
BRANCH I – PHARMACEUTICS – MPH
PAPER IV – REGULATORY AFFAIRS

Q.P. Code : 262934

Time : Three hours **Maximum : 75 Marks**

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

1. Explain in detail the various stages involved in FDA's new drug approval process.

2. What are Clinical trials? Explain the regulatory guidelines of the documentation, clinical study design with respect to various phases involved in clinical trials.

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

1. What is considered protected health information under HIPAA?
2. Electronic common technical document (eCTD).
3. Importance of *Invitro* drug characterization.
4. Generic drug user fee amendments (GDUFA).
5. Master formula record.
6. Objectives of CDER.
7. Guidelines of ICH – Q, S.

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

[LQ 0121] JANUARY 2021 Sub. Code: 2934

(APRIL 2020 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION

SEMESTER-I (PCI New regulations 2016)

PHARMACEUTICS – MPH

PAPER IV – REGULATORY AFFAIRS

Q.P. Code : 262934

Time : Three hours Answer ALL Questions Maximum : 75 Marks

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

1. Describe the outsourcing protocol for the bioavailability and bioequivalence studies to contract research organization.

2. Discuss the drug approval submission process for investigational New Drug Application and New Drug Application.

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

1. Labeling review process in ANDA.
2. Regulatory process approval for Active Pharmaceutical Ingredient.
3. Investigational Medicinal Product dossier.
4. International Conference on Harmonization Efficacy Guideline.
5. Informed consent process.
6. Pharmacovigilance in safety monitoring.
7. Waivers of *In vivo* bioequivalence requirements.

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

[MPHARM 0921] SEPTEMBER 2021 Sub. Code: 2934
(OCTOBER 2020 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER-I (PCI New regulations 2016)
PHARMACEUTICS - MPH
PAPER IV – REGULATORY AFFAIR
Q.P. Code : 262934

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

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

1. a) Discuss about the Abbreviated NDA approval process.
   b) The Drug Price Competition and Patent Term Restoration Act.

2. Explain about the Institutional Review Board, Independent Ethics Committee & Pharmacovigilance Monitoring in Clinical Trials.

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

1. CTD for Dossiers.
2. MFR – Master Formula Record.
3. Investigational Brochure (IB).
4. International Conference on Harmonization Efficacy Guideline.
5. Code of Federal Regulation.
6. What are the problems facing by CRO in outsourcing BA and BE.
7. Regulatory requirements of ROW.

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

[MPHARM 0122] JANUARY 2022 Sub. Code: 2934
(APRIL 2021 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER-I (PCI New regulations 2016)
PHARMACEUTICS - MPH
PAPER IV – REGULATORY AFFAIR
Q.P. Code : 262934

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

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

1. a) Write about the documents of generic drug product development in Pharmaceutical industry.
   b) Post marketing surveillance and pharmaceuticals.

2. What are the various steps involved in carrying out a clinical trial? Write the responsibilities and functional modalities for institutional review board.

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

1. Discuss the drug approval process in USFDA & EMA.

2. Why informed consent procedure is important in clinical trials?

3. IMP Dossiers.

4. HIPAA and its significance in clinical trials.

5. Scale up process and its significance.

6. Regulatory requirement of ANDA for Generic Drugs.

7. Protocol development in clinical trials.

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

[MPHARM 0422] **APRIL 2022** **Sub. Code: 2934**

(OCTOBER 2021 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER-I (PCI New regulations 2016)
PHARMACEUTICS - MPH
PAPER IV – REGULATORY AFFAIR
Q.P. Code : 262934

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

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

1. a) What are the regulatory requirements of EU and MHRA.
   b) Pharmacovigilance safety monitoring in clinical trials.

2. Discuss about the outsourcing bioavailability and bioequivalence studies to CRO.

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

1. What are the responsibilities of FDA organization in industry?
2. What is CTD & e CTD? Explain the Benefits.
3. What are the regulatory requirements of medical device distribution in US?
4. What is NDA & ANDA? Explain the NDA review process.
5. Distribution Records in Pharmaceutical Industry.
6. Hatch-Waxman Amendments.
7. CMC post approval regulatory affairs.

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

[M.PHARM 0922] **SEPTEMBER 2022** **Sub. Code: 2934**
(APRIL 2022 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New regulations 2016)
PHARMACEUTICS - MPH
PAPER IV – REGULATORY AFFAIR

Q.P. Code : 262934

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

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

1. What are the Regulation for Combination Products and Medical devices?

2. Enumerate the regulatory submission protocol for Investigational New Drug and New Drug Application.

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

1. Specify the different codes used in code of federal regulations.
2. State the regulatory requirements for Active Pharmaceutical Ingredient.
3. Write the components of common technical document.
4. Describe the procedure involved in informed consent process.
5. Discuss the role of pharmacovigilance in safety monitoring.
6. Write the factors affecting *in vitro* drug product dissolution.
7. Mention the parameters in chemistry manufacturing control.

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

[M.PHARM 0423] APRIL 2023 Sub. Code: 2934
(OCTOBER 2022 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New regulations 2016)
PHARMACEUTICS - MPH
PAPER IV – REGULATORY AFFAIR

Q.P. Code: 262934

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

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

1. Discuss the drug regulatory approval requirements for European Union, Medicines and Healthcare products Regulatory Agency and Therapeutic Goods administration.

2. Outline the steps involved in clinical trial protocol. Discuss the constitution and Functions of Independent Ethics Committee.

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

1. Write the Amendments in Hatch Waxman act.
2. Describe bioequivalent studies with pharmacokinetic endpoints.
3. What type of reviews are carried out by institutional review board?
4. What are the contents of Investigational brochure?
5. Mention the multidisciplinary guidelines related to international conference on harmonization.
6. Describe the scale up process approval challenges.
7. Discuss the severity grades of adverse event as per Food and Drug Administration guidelines.

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

[M.PHARM 0823] AUGUST 2023 Sub. Code: 2934
(APRIL 2023 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New Regulations 2016)
PHARMACEUTICS - MPH
PAPER IV – REGULATORY AFFAIR

Q.P. Code: 262934

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

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

1. Discuss the ways and means to obtain NDA, ANDA US registration for biologics and novel therapies. Add a note on Hatch-Waxman act amendments.

2. Discuss the developing protocols for Clinical trials and explain the role of Institutional review board and independent ethics committee.

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

1. ICH guidelines for post approval regulatory affairs.
2. Role of Investigation of medicinal products dossier.
3. Industry and FDA liaison.
4. ANDA regulatory approval process.
5. Role of Pharmacovigilance in clinical trials.
6. Significance of BE and drug product assessment in NDA approval process.
7. Regulatory requirements of TGA and ROW countries.

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

[M.PHARM 1223] DECEMBER 2023 Sub. Code: 2934
(OCTOBER 2023 EXAM SESSION)

M.PHARMACY DEGREE EXAMINATION
SEMESTER - I (PCI New Regulations 2016)
PHARMACEUTICS - MPH
PAPER IV – REGULATORY AFFAIR

Q.P. Code: 262934

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

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

1. Write in detail the global submission of IND, NDA & ANDA of nonclinical drug development. Discuss the importance of investigation of medical products dossier and investigator brochure.

2. Give an account of developing the clinical trial protocols. Discuss the role of Institutional review board and formulation and working process of independent ethics committee.

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

1. Regulatory requirements of EU and MHRA.
2. Significance of HIPAA in clinical trials studies.
3. Post marketing surveillance.
4. US registration procedure for biologics and novel therapies.
5. Documentation in Pharma Industry.
6. In-vitro drug product performance in ANDA regulatory approval process.
7. Significance of CTD and ECTD.

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