Bioinformatics Institute of India

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INDUSTRY PROGRAM IN PHARMA REGULATORY AFFAIRS

Examination Assignments

April, 2017

Instructions for Examination Assignments – April, 2017

- Electronic (email), printed and hand written submission of the assignments are acceptable.
- Do not copy from the answers of other participants. If it is noticed the assignment of such participants will not be accepted.
- The assignment for each paper should be written separately. Do not write the assignment for all the papers in continuity. However, all the assignments are to be submitted together.
- No two or more participants should submit their assignments in same envelope.
- The participants should mention their Name and Enrollment Number on each page of submitted assignment copy.
- The last date of submission of Assignments is **30th April, 2017.**
- The assignments have to be submitted to:

  The Program Director

  Bioinformatics Institute of India

  H-109, Ground Floor, Sector-63, (Behind Haldiram) Noida-201307

  U.P. INDIA

- Participants are advised to keep a photocopy of submitted assignments.
- The participants should mention their Name and Enrollment Number on the envelope.
- The participant should also mention “Examination Assignment” at the top of the envelope.
- The result will be announced by 2nd week of June, 2017.
- For any query mail us on info@bii.in

Module 1: Pharma Regulation, Practices and Procedure

Examination Assignment April, 2017

Max. Marks: 75

Instructions:

- SECTION-A: Attempt any five questions.
- SECTION-B: Attempt any five questions.

SECTION-A

Short Answer Type Questions: (60-80 Words) **5 × 5 = 25 Marks**

1. What is PAHO? Explain its role in healthcare.
2. Give a brief review on ANVISA.
3. What is the role of state drug regulatory authority?
4. What are FDD and FDQCC?
5. What is section 1 for biomarker qualification submission?
6. Who can be the State Vigilance Officer (Drug)?
7. Give any two important role of head regulatory affair EMEA.

SECTION - B

Long answer type questions: (250-300 Words) **5 × 10 = 50 Marks**

1. Explain SOPs.
2. What is CDL? Explain the function of CDL.
3. Give the detail hierarchal presentation of U.S food and drug Administration.
4. What are the principles of GMP? What is Schedule M? How it is related with GMP? Explain in detail.
5. Give your review on performance of Drug regulatory authority of India?
6. Explain E-Governance. What is the procedure of e-CTD?
7. Explain the function of Indian Pharmacopoeial Commission (IPC) in detail.

Module 2: Pharma Patents, IPR and Regulation

Examination Assignment April, 2017

Max. Marks: 75

Instructions:

- SECTION-A: Attempt any five questions.
- SECTION-B: Attempt any five questions.

SECTION - A

Short Answer Type Questions: (60-80 Words) **5 × 5 = 25 Marks**

1. Define functional genomics.
2. Write about the TRIPS agreement.
3. What do you mean by Generic medicine?
4. How WTO provisions different from Indian patent system.
5. What are the four broad theories about the principal purposes of patents?
6. What are the costs of filling a patent application in India?
7. What is the relationship between the Paris convention and the TRIPs agreement?

SECTION - B

Long answer type question: (250-300 Words) **5 × 10 = 50 Marks**

1. Explain:
   a) Generic drugs
   b) Domestic patenting
2. Explain the adverse consequence of broad patent.
3. Give a detailed note on PARIS convention.
4. What strategy of intellectual property rights is followed in Bioinformatics?
5. Give the theory of prospect development.
6. Give the amendment of legislations covering IPR in India; also provide its effect on Indian pharmaceutical and Biotech industry.
7. Explain theory of invention-Inducement.

Module 3: Pharma Regulatory Regime IN USA, EU and India

Examination Assignment April, 2017

Max. Marks: 75

Instructions:

- SECTION-A: Attempt any five questions.
- SECTION-B: Attempt any five questions.

SECTION - A

Short Answer Type questions: (60-80 words) **5 × 5 = 25 Marks**

1. Give the name of observers of ICH.
2. Discuss the structure and administration of ICH.
3. What is the rule for packaging and labeling of Homeopathic medicine?
4. What is Pharmacovigilance? What is the need of Pharmacovigilance?
5. What is Waxman-hatch act (1984)?
6. Give the classification of Narcotic drugs in UN system.
7. Define the following terms:

   (i) Nuremberg Code (ii) FDAMA Act (iii) Orphan Drug Act

   (iv) Waxman-Hatch Act (v) DPCO

SECTION - B

Long Answer type Questions: (250-300 words) **5 × 10 = 50 Marks**

1. What are the stages involved in the progress of an application through the UK licensing system?
2. Explain clinical trial exemption scheme (CTX).
3. Explain FDA's IRR in detail. What all information does IRR provide?
4. Explain full ICH process for Major Harmonisation in detail.
5. What are the major differences and similarities in pharmacovigilance of India USA and EU give a brief review.
6. Is pharmacovigilance of India lacks behind USA and EU, give a brief review.
7. In which year Harrison Act was established? Describe the purpose of the Harrison Act in detail.

Module 4: Regulatory Compliance for Pharma and Biotech Products
Examination Assignment April, 2017

Max. Marks: 75

Instructions:

- SECTION-A: Attempt any five questions.
- SECTION-B: Attempt any five questions.

SECTION - A

Short answer Questions: (60-80 Words) **5 × 5 = 25 Marks**

1. What is the meaning of warranty in license?
2. Define phRMA code.
3. Draw the flow chart for investigational new drug process.
4. What is main goal of National drug policy in India?
5. What is the difference between a License and a Strategic Alliance?
6. Explain the NDA in CTD format.
7. Explain CCAC guidelines on transgenic animals (1997).

SECTION - B

Long answer type questions: (250-300 Words) **5 × 10 = 50 Marks**

1. What are the steps taken by FDA for strengthening regulatory compliance? Explain.
2. Define investigational New Drug (IND) with proper flow chart.
3. What is e-CTD? What is the purpose of e-CTD? Explain the process of e-CTD in detail.
4. Explain Narcotic drugs & Psychotropic substances act 1985.
5. What are the policies involved in Pharma compliance program? Explain in detail.
6. In which year narcotic drugs and psychotropic substances act was established? How the illicit traffic was prevented in this act?
7. Define Drug master file. Discuss the FDA guideline for drug master files. Also explain the approval process for generics in detail.

Module 5: GMP, Quality Assurance and Regulation
Examination Assignment April, 2017

Max. Marks: 75

Instructions:
- SECTION-A: Attempt any five questions.
- SECTION-B: Attempt any five questions.

SECTION - A

Short answer type questions: (60-80 Words) **5 × 5 = 25 Marks**

1. What is Performance Qualification?
2. Define Quality Assurance and Quality Control.
3. Give the WHO Guidelines for Generic Drugs.
4. In case of food GMPs what is section 110.37 states?
5. Explain the principles of WHO GMP for Pharmaceutical products.
6. What is the process of sampling in case of herbal medicine?
7. What is the function of CDSCO and DCGI.

SECTION - B

Long answer type questions: (250-300 Words) **5 × 10 = 50 Marks**

1. What is SOPs? What is the purpose of SOPs? Explain in detail.
2. Discuss the specific tests/criteria for drug substances / products.
3. What are the recommended equipments for manufacturing of surgical dressings other than adsorbent cotton wool in schedule M?
4. What procedure was used for drug testing, approval or rejection in USA GMP regulation?
5. What are Universal tests / criteria for new drug substances?
6. What are the principles of quality assurance in pharmaceutical industry and how it’s beneficial for society, justify?
7. What are the WHO guidelines for GMP of finished herbal products?

Module 6: Clinical Trials & Regulation

Examination Assignment April, 2017

Max. Marks: 75

Instructions:

- SECTION-A: Attempt any five questions.
- SECTION-B: Attempt any five questions.

SECTION - A

Short answer type questions: (60-80 Words) **5 × 5 = 25 Marks**

1. Define Dose.
2. What CPMP/ICH/287/95 code E2BM indicate?
3. Define Adverse drug reaction, case record form, blinding.
4. Define Placebo effect and Psychological effect.
5. What are the various sampling methods?
6. Define various phases of vaccine trials (clinical trials of vaccine).
7. Define various Pharmacokinetic terms.

SECTION - B

Long answer type questions: (250-300 Words) **5 × 10 = 50 Marks**

1. Draw and explain Phase 0/phase I chart for clinical evaluation of new molecular entity.
2. What are the ethical challenges related to clinical trials?
3. List few limitations of Micro dosing.
4. What are the ethical challenges related to phase-0 trials?
5. What are the Major changes to clinical trial Legislations and procedures?
6. What is PRO? Explain its role and uses.
7. Explain phase 0 micro dosing. What are it’s advantages and limitations?