Bioinformatics Institute of India

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INDUSTRY PROGRAM IN PHARMA QUALITY ASSURANCE AND QUALITY CONTROL

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: Quality Assurance in Pharma Industry I

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 are real time stability studies?
2. What is a reserve sample?
3. What is the role of QA in a project development?
4. Discuss all the sampling plans with appropriate examples.
5. What are the documents required by importing agency for custom clearance?
6. What do you understand by shelf-life of a drug?
7. Discuss all the sampling plans with appropriate examples.

SECTION-B

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

1. What is the safety required in drug control laboratories?
2. Write a short note on batch certificate.
3. How collaboration between drug regulatory authorities is beneficial for consumers and what are difficulties faced in it?
4. Give a brief review on
   a) Justification of a clinical trial
   b) Ethical principle for clinical trial
   c) Regulatory requirements for clinical trial
   d) Investigator and site of investigation for clinical trial
5. Explain the uses of Herbal products in medicines.
6. What are the technical data required for regulatory assessment?
7. How collaboration between drug regulatory authorities is beneficial for consumers and what are difficulties faced in it?

Module 2: Quality Assurance in Pharma Industry- II (WHO Perspective)

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 are master formulae?
2. What are the uses of detergent in pharmaceuticals?
3. Discuss sterilization by gases & fumigants with examples.
4. What are the advantages of an autonomous DRA?
5. Define 'Markers' with respect to herbal medicinal product.
6. What are rejected and recovered materials?
7. What are the methods for effective drug regulation?

SECTION-B

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

1. What is the need of documentation for Quality assurance?
2. Give the principles of Hazard Analysis & Critical Control Point (HACCP).
3. Explain briefly any two essential elements for quality management in the drug industry.
4. Explain how special inspection is carried out?
5. Briefly discuss the measures required during the packaging operations of pharmaceutical products.
6. Explain the application of Hazard analysis and critical control point methodology to pharmaceuticals.
7. Provide guidelines for inspection when pharmaceutical products are suspected to be counterfeit, spurious or substandard.

Module 3: Good Manufacturing Practices, Quality Assurance & 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 the production and process control (subpart E) of food GMP's?
2. Write a short note on device master record?
3. What are the responsibilities of Head of the production department?
4. What are GMP guidelines for the storage area of herbal medicines?
5. Give the principles of Quality Management?
6. How sanitation and hygiene can be achieved in a pharma plant, give its importance?
7. Write a note on self-inspection?

SECTION-B

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

1. How the prevention of Cross-contamination in production must be done?
2. Discuss the responsibilities of Head of the production department.
3. Give the product quality review.
4. How the production departments regulate the quality of a drug?
5. What are the purpose and contents of analytical worksheet?
6. What are the steps should be taken before any processing operation to start?
7. What are the criteria for laboratory management and infrastructure?

Module 4: Quality Assurance & Control
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 six sigma approaches?
2. Briefly explain ISO.
3. Write few principles and duties of production process.
4. Discuss different types of standards of calibration.
5. What do you mean by robustness?
6. What do you mean by audit? What is the audit of calibration system?
7. Write down the analytical method validation characteristics.

SECTION-B

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

1. Explain *in-situ* testing.
2. Discuss the basic principles of total quality management.
3. What are the benefits of people involvement in a pharmaceutical organization?
4. Discuss the procedure for the quality check of a drug.
5. Describe the 4 main stages required to implement TQM.
6. Discuss the role of an inspector during an inspection.
7. What according to you would classify as Objectionable Organisms in pharmaceuticals production and why?

Module 5: 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. Write a short note on the Pharmacy Act, 1948.
2. What is Mutual recognition?
3. Write a short note on phase I clinical trials.
4. What are the methods for effective drug regulation?
5. What GMPs are prescribed for ayurveda, siddha and unani medicines?
6. What are the recommended precautions against contamination during manufacturing operations of alternative medicines?
7. What are the advantages of an autonomous DRA?

SECTION-B

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

1. Origin of Federal Food and Drug Regulation 1906. Discuss.
2. Discuss the functions of central drug laboratory.
3. Write short note on Jurisdictional Issues and Fast Track Approval.
4. Give a comparative analysis on performance of drug regulatory authorities.
5. Write a brief note on the schedule M of drugs & cosmetics Act, 1947.
6. What is PAN AMERICAN HEALTH ORGANIZATION (PAHO)?
7. How to formulate Drug legislation?

Module 6: Statistical Quality Control & Biostatistics

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. Write a short note on sampling.
2. Define variance and standard deviation.
3. Explain the standard deviation of the distribution of sample statistics.
4. Write down the types of numerical descriptive measure
5. Define mean and median with suitable example.
6. Explain the standard deviation of the distribution of sample statistics.
7. What is probability?

SECTION-B

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

1. What are random variables? Give examples.
2. Explain binomial Probability distribution.
3. Give an introduction to estimation.
4. Discus about Poisson distribution?
5. Explain regression & correlation and its use in pharmaceutical research work with a perfect explanation.
6. Find the median of the dataset consisting of the observations 7,4,3,5,6,8 and 10.
7. What is range? Explain with formula.