Question Paper

Exam Date & Time: 02-May-2019 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.
MPharm - Pharmaceutical Regulatory Affairs
MPharm Semester 2 - End-Semester Examination May 2019
Date : 02/05/2019

Regulatory Aspects of Drugs and Cosmetics [PQA-MRA201T]

Marks: 75 **Duration: 180 mins.**

SECTION - A

Answer all the questions.

Answer the following (10 marks x 5 = 50 marks)

1) Explain the steps involved in the submission and approval process of MAA to the Saudi Food and drug authority. (10)

2) Eddison pharmaceutical company has replaced the manufacturing site of ATORVA, anti-hypertensive drug without any change in the manufacturing process. (10)
a. What type of variation is the above case as per ASEAN regulation. (2 marks)
b. Write the documents required for the approval of this variation. (8 marks)

3) Explain in detail about legislation and regulations for import, manufacture, distribution and sale of cosmetics in CIS countries. (10)

4) a. Write the documents required for variation filling for Type II variations in EU. (5 marks) (10)
b. Explain the processing timeline for Type II variation notification by EU health authority. (5 marks)

5) Discuss in detail about 21CFR-PART-316. (10)

SECTION - B

Answer all the questions.

Answer the following (5 marks x 5 = 25 marks)

6) Explain in detail about lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity. (5)

7) Explain the J-NDA drug regulatory approval process. (5)

8) a. Do a change in name / address of the marketing authorization holder is categorised as reason for MA transfer? (5)
b. If yes / no, justify the answer?
c. Write the application for transfer of marketing authorization.
(1+1+3 marks)

9) Write the organization chart for EDQM and responsibility of each (5)

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department of the EDQM.

10) a. Which category of drugs can be marketed through centralized procedure in EU? (5)
b. Write a comparison on decentralized and mutual recognition procedure in EU?
(1+4 marks)

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Question Paper

Exam Date & Time: 04-May-2019 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.
MPharm - Pharmaceutical regulatory affairs
MPharm Semester II - End Semester Examination, May 2019
Date : 04/05/2019

Regulatory Aspects of Herbal and Biologicals [PQA-MRA202T]

Marks: 75 **Duration: 180 mins.**

SECTION - A

Answer all the questions.

Answer the following (10 marks x 5 = 50 marks)

1) Discuss the data requirements for preclinical studies for approval of "similar biologics" in India. (10)

2) Explain the manufacturing process of biologic drug substance. Add a note on cell lines used in biologics production. (10)

3) Describe the requirements for IND for Phase III clinical trials for botanicals as per USFDA (10)

4) Discuss the EU guideline on stability of biologicals (ICH Q5C) (10)

5) What are the objectives and strategic goals of International Haemovigilance Network (IHN)? (10)

SECTION - B

Answer all the questions.

Answer the following (5 marks x 5 = 25 marks)

6) Discuss the guidelines on "selection of reference biologic" and "manufacturing process" for approval of similar biologics in India. (5)

7) What are "biosimilars"? Write any five differences between "biosimilar law" and "Hatch Waxman act. (5)

8) Discuss the guidelines on data requirements for "waiver of safety and efficacy study" and "immunogenicity" for clinical trial application of similar biologics in India. (5)

9) Discuss the contents and submission procedures for "FDA Form 2253" (5)

10) Discuss the key requirements to establish a blood bank in India. (5)

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Question Paper

Exam Date & Time: 06-May-2019 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.
MPharm - Pharmaceutical Regulatory Affairs
MPharm Semester II End-Semester Theory Examination- May 2019
Date : 06/05/2019

Regulatory Aspects of Medical Devices [PQA-MRA203T]

Marks: 75 **Duration: 180 mins.**

SECTION - A

Answer all the questions.

Answer the following (10 marks x 5 = 50 marks)

1) What is CE marking? Describe its certification processing routes for class I and class III medical devices (10)

2) Explain the rules and classify non- invasive Medical devices intended for the following with examples (10)
a. Contact with injured skin
b. All types of non-invasive devices with or without contact to the patient

3) Explain the different types of Adverse Event reporting systems with examples in China under CFDA (10)

4) Classify medical devices and explain in detail the medical device reporting system under USFDA. (10)

5) Classify Software as a Medical Device (SaMD) with examples and mention the risk management plan to be undertaken in case of modification in algorithm affecting the diagnosis or therapy delivered. (10)

SECTION - B

Answer all the questions.

Answer the following (5 marks x 5 = 25 marks)

6) Explain invasive devices per council directive 90/385/EEC (5)

7) Draw a flow chart on evaluation and validation process of medical device software. (5)

8) Explain the phases of life cycle of x - ray machine as a medical device. (5)

9) Mention the risk management steps to be undertaken in the following case. (5)
The medical device had an extracorporeal infusion device with multiple joints in which cyclohexanone and methylene chloride were used as welding agent. Recent changes to the welding

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process prompted concerns about safety during clinical use. While these solvents do an excellent job of bonding plastic materials, concerns about potential migration of the solvents during clinical use was very real. More than 35 welded joints had been identified in the product, which created a significant surface area from which the solvents might possibly leach into circulating blood. An additional concern was that the blood would circulate through the device multiple times during its typical two-hour use.

10) Draw the decision tree that implies to classify non- invasive medical devices as per GHTF. (5)

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Question Paper

Exam Date & Time: 08-May-2019 (02:00 PM - 05:00 PM)

MANIPAL ACADEMY OF HIGHER EDUCATION

Manipal Academy of Higher Education, Manipal MPharm Theory End-Semester Examinations.
MPharm - Pharmaceutical Regulatory Affairs
MPharm Semester 2 - End-Semester Examination May 2019
Date : 08/05/2019

Regulatory Aspects of Food and Nutraceuticals [PQA-MRA204T]

Marks: 75 **Duration: 180 mins.**

SECTION - A

Answer all the questions.

Answer the following (10 marks x 5 = 50 marks)

1) Atlantic cod is a functional food where as Seven Seas® is a nutraceutical. Comment. (10)

2) What are the requirements of production and process control requirements of US GMP for dietary supplements subpart F and G? (10)

3) VSO (Voluntary Service Organization) of MAHE decides to implement clean street food - Manipal. They decide to fund it through "Pradhan Mantri Kaushal Vikas Yojana". Is it possible? Explain. (10)

4) Why DSHEA was passed by US Congress? (10)

5) Explain the functions of European Food Safety Authority. (10)

SECTION - B

Answer all the questions.

Answer the following (5 marks x 5 = 25 marks)

6) Define the following: (5)

a. Nutraceuticals.
b. Medical Foods
c. Dietary Supplements
d. Functional Foods

7) What is WHO recommendation on infant feeding in areas of Zika Virus transmission and why? (5)

8) A. Fragments of Mango seed is found in a product labelled as "Natural Mango Pulp". Is it considered as contaminant within the purview of Food Safety Standard Act 2006? Justify your answer. (5)
B. A chocolate cake was found to contain barley starch. Is the manufacturer punishable under Food Safety Standard Act 2006? Justify your answer

9) What is a dietary supplement as per DSHEA? (5)

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10) Why allergen information is mandatory on food products as per European Food Safety Authority? Support your answer with relevant examples. (5)

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