Semester II Examinations 2013/2014

Exam Code(s) 3BS9, 3BPC1, 1OA1
Exam(s) Third Science, Third Biopharmaceutical Chemistry, Overseas Students

Module Code(s) CH339
Module(s) Validation Enterprise/Industrial Validation

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INSTRUCTIONS: Answer 3 questions
All questions carry equal marks.
Answer one question from each section and not more than two questions from any one section.
Use separate answer book for each question

Duration 2 hours
No. of Pages 3
School(s) Chemistry

Requirements: None
MCQ
Handout
Statistical Tables
Graph Paper
Log Graph Paper
Other Material
Section A

1. Answer all parts

(a) With respect to manufacturing regulations, describe what is meant by the term Validation and discuss its origin and aims. [15 marks]

(b) Manufacturers in the food and drug industries are not legally required to possess a Validation Master Plan (VMP) however the majority will have produced such a document. Discuss the advantages of creating a VMP dossier. With respect to the manufacturing of pharmaceuticals and biopharmaceuticals discuss the concept of industrial validation and the role of the Validation Master Plan (VMP). [10 Marks]

2. Answer all parts:

(a) Define the term Process Analytical Technology (PAT). [5 marks]

(b) Discuss the origins of Process Analytical Technology (PAT) and what led to the framework document by the FDA ‘Pharmaceutical cGMP’s for the 21st Century-A Risk Based Approach’. [5 marks]

(c) A drug manufacturing company uses real time Near Infra-Red technology to monitor the drying of an active pharmaceutical ingredient (API). Describe how the company can use this information to reduce the overall cycle time of drug manufacturing and therefore reduce manufacturing costs. [5 marks]

(d) With respect to Process Analytical Technology explain the following terms:
   i) Six Sigma [5 Marks]
   ii) Chemometrics [5 Marks]

3. Discuss cleaning validation under the following headings:

(a) Equipment to be cleaned [5marks]
(b) Personnel responsibilities [5marks]
(c) Sampling methods [5marks]
(d) Record keeping [5marks]
(e) Establishment of Limits [5marks]
Section B

3. Answer all parts:

a) Describe the following terms DES, TAVI, ICD          [10 Marks]

b) Categorize the following medical devices in terms of type and explain what each type means 1) hospital bed, 2) urinary catheter, 3) electrocardiograph [5 Marks]

c) What drug component information and finished drug eluting stent data is required to be gathered during the development of a drug eluting stent product? [5 Marks]

d) What is meant by the term IVIVC and what is the role of IVIVC in drug eluting stent development . [5 Marks]

4. Answer all parts:

a) List the typical phases that a company must go through when developing a medical device new product? [5 Marks]

b) Explain the difference between Bradyarrhythmias and Tachyarrhythmias and outline symptoms of both? [5 Marks]

c) Describe three devices currently competing in the TAVI market, and outline 5 potential complications of TAVI? [10 Marks]

d) Describe the path to regulatory approval for a TAVI device in the EU? [5 marks]

6. Answer (a), (b) and (c)

(a) What are the main aims of REACH? [5 marks]

(b) Why is substance identity such a critical part of the REACH registration process? [10 marks]

(c) Describe the mandatory analytical chemistry data that must be supplied to demonstrate substance identity? [10 marks]