TECHNICAL UNIVERSITY OF MOMBASA

FACULTY OF APPLIED AND HEALTH SCIENCES

DEPARTMENT OF PURE & APPLIED SCIENCES

UNIVERSITY EXAMINATION FOR:

MASTER OF SCIENCE IN CHEMISTRY

ACH 5114: ADVANCED QUALITY ASSURANCE TECHNIQUES (CGMP & DOCUMENTATION)

END OF SEMESTER EXAMINATION

SERIES: DECEMBER 2016

TIME: 3 HOURS

DATE: Pick Date Jan 2017

Instructions to Candidates

You should have the following for this examination
-Answer Booklet, examination pass and student ID
This paper consists of **SIX** Question(s). Answer any FOUR questions.
Do not write on the question paper.

Question ONE

(a) (i) In a manufacturing establishment two key personnel are the head of Production, and the head of Quality Control. List any FOUR key responsibilities for each of the personnel. (8 marks)

(ii) Identify SIX shared responsibilities between the head of Production and head of Quality Control related to quality. (6 marks)

(b) Highlight any FIVE general requirements for personnel in a manufacturing establishment. (5 marks)

(c) Describe THREE requirements for personnel hygiene. (6 marks)

Question TWO

(a) Identify key areas of training for personnel, providing an indication on appropriate time for the training. (14 marks)

(b) (i) Describe general factors that have to be taken into consideration in locating a pharmaceutical manufacturing facility. (6 marks)

(ii) Laboratory operations form part of key components or activities in pharmaceutical manufacturing. Highlight the provisions to be made and factors to be considered in the design and construction of a laboratory facility. (5 marks)

Question THREE

(a) A manufacturing facility often applies aseptic processing conditions, which require an operational cleanroom. Briefly describe the design, construction features and equipment required to maintain high environmental quality conditions. (13 marks)

(b) Define and explain the application of the following equipment validation terms;

(i) Installation Qualification (IQ) (4 marks)

(ii) Operation Qualification (OQ) (4 marks)

(iii) Performance Qualification (PQ). (4 marks)

Question FOUR

(a) Highlight the objectives of Material Management in a pharmaceutical or chemical manufacturing facility. (6 marks)

(b) Identify key requirements in the purchasing of materials. (6 marks)

(c) Provide a list of required documents and outline the processes in handling, sampling and storage of raw materials. (13 marks)

Question FIVE

(a) Define the following terms and provide appropriate applications in an analytical laboratory,

(i) Documents (3 marks)

(ii) Records (3 marks)

(iii) Document control. (4 marks)

(b) (i) Provide any 5 reasons for outsourcing of services. (10 marks)

(ii) List any 5 activities that are commonly outsourced in pharmaceutical manufacturing. (5 marks)

Question SIX

(a) Provide any THREE guiding principles of the Occupational Safety and Health policy. (6 marks)

(b) The Occupational Safety and Health Act No. 15 of 2007 (OSH) provides for Control of air pollution, noise and vibration (Sec. 89) and places the responsibility of enforcement of the law on the Directorate of Occupational Safety and Health Services. Discuss the apparent weaknesses of applying the OSH regulations to cases of pollution affecting communities neighbouring chemical manufacturing factories, such as, the case of lead pollution in Changamwe Mombasa. (12 marks)

(c) Define the following terms and show how they are interrelated;

(i) Quality Assurance (QA) (3 marks)

(ii) Good Manufacturing Practice (GMP) (2 marks)

(iii) Quality Control (QC). (2 marks)