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) State the requirements and rationale over access to various manufacturing areas by personnel in a pharmaceutical manufacturing facility. (6 marks)

(b) Identify the various utilities and their operation to minimize adverse impact on quality in manufacturing. (10 marks)

(c) Describe the provisions that are required for sanitation and maintenance of buildings and facilities for a manufacturing establishment, such as in pharmaceutical manufacturing. (9 marks)

Question TWO

(a) List any SIX requirements for personnel as follows,

(i) General requirements (6 marks)

(ii) Key personnel. (6 marks)

(b) Good Manufacturing Practice ensures maintenance and continual improvement of product quality. Highlight the specific objectives of the following GMP activities, usually done as part of Quality Management Systems.

(i) Annual Product Quality Review (7 marks)

(ii) Self-inspection. (6 marks).

Question THREE

(a) Provide the essential areas of training for new recruits and visitors to a manufacturing facility. (6 marks)

(b) State FOUR requirements on hygiene that personnel in an analytical laboratory have to strictly observe. (8 marks)

(c) Describe the composition of following documentation useful in process validation and equipment qualification,

(i) Validation Master Plan (5 marks)

(ii) Qualification and validation protocols. (6 marks)

Question FOUR

(a) Describe the content and use of the following Quality documents,

(i) Quality manual (4 marks)

(ii) Standard operating procedures (SOPs). (6 marks)

(b) Highlight the importance and objectives of inventory control in materials management. (14 marks)

Question FIVE

(a) Provide any FOUR environmental best practices and expected benefits that the manufacturing industry may adopt. (8 marks)

(b) List any 5 specific objectives of the national Occupational Safety and Health (OSH) policy. (10 marks)

(c) Identify and discuss challenges in effectively implementing the OSH policy. (7 marks)

Question SIX

(a) Identify and describe the types of outsourcing for an analytical or pharmaceutical laboratory. (8 marks)

(b) Describe the criteria and steps that may be required to identify and choose a suitable laboratory for outsourcing. (10 marks)

(c) State the benefits and disadvantages of outsourcing of analytical or pharmaceutical laboratory work. (7 marks)