



TECHNICAL UNIVERSITY OF MOMBASA

FACULTY OF APPLIED AND HEALTH SCIENCES

DEPARTMENT OF PURE AND APPLIED SCIENCES

UNIVERSITY EXAMINATION FOR:

BTAC/BTIC

ACH 4311: VALIDATION AND REGULATORY AFFAIRS PAPER 2

SERIES: MAY 2016

TIME: TWO HOURS

DATE: MAY 2016

Instructions to Candidates

You should have the following for this examination

-Answer Booklet, examination pass and student ID

This paper consists of **FIVE** questions. Attempt **question ONE** and **any other TWO**.

Do not write on the question paper.

Question ONE

- a) Write the following acronyms in full:
- | | |
|-----------|----------|
| (i) CGMPs | (1 mark) |
| (ii) ICH | (1 mark) |
| (iii) FDA | (1 mark) |
| (iv) GLPs | (1 mark) |
- b) Define the following terms:
- | | |
|--|-----------|
| (i) Sampling plan according to IUPAC | (2 marks) |
| (ii) Taylorism | (2 marks) |
| (iii) Validation according to FDA 1987 | (2 marks) |
| (iv) Specificity | (2 marks) |
- c) State the following:
- | | |
|--|-----------|
| (i) The TWO types of quality control | (2 marks) |
| (ii) The THREE method validation documents | (3 marks) |

- (iii) The most important regulations applying to validation (3 marks)
- (iv) State first TWO layers of Abraham Maslow's hierarchy of needs (2 marks)
- d) Explain the following:
 - (i) The main aim of acceptance sampling (5 marks)
 - (ii) ONE aim of proactive inspections (3 marks)

Question TWO

- a) Outline the following:
 - (i) FOUR basic criteria upon which testing laboratories should be selected (4 marks)
 - (ii) The objective of inspection and testing (6 marks)
- b) Discuss the importance of teamwork and communication skills recommendations during recruitment of new employees quality control (6 marks)
- c) Explain the role of KEBS as a regulatory agency (4 marks)

Question THREE

- a) Explain the term, "defining the problem", which is the first of the six steps of problem solving process in working teams (8 marks)
- b) Discuss documentation in process validation lifecycle (12 marks)

Question FOUR

- a) (i) Explain the importance of a correction plan and corrective actions after an Out-of-Specification result has occurred (3 marks)
- (ii) State any THREE parameters of method validation (3 marks)
- (iii). Outline the THREE tasks of quality assurance during an Out-of-Specification result (6 marks)
- b) Discuss the goal of international conference on harmonization (ICH) (8 marks)

Question FIVE

- a) Outline the contents of validation protocol (7 marks)
- b) Discuss the importance of acceptance testing (10 marks)
- c) Explain the role of quality control (3 marks)