Technical University of Mombasa

Faculty of Applied and Health Sciences

DEPARTMENT OF PURE AND APPLIED SCIENCES

UNIVERSITY EXAMINATION FOR THE DEGREE OF BACHELOR OF TECHNOLOGY IN APPLIED CHEMISTRY

BTAC 11M / BTAC 12J/12M

ACH 4311: VALIDATION AND REGULATORY AFFAIRS

SEMESTER EXAMINATION

DECEMBER 2013 SERIES 2 HOURS

Instructions to candidates:

This paper consist of FIVE questions
Answer question ONE (compulsory) and any other TWO questions

QUESTION ONE

a) Define the following terms:

(i) Acceptance number (Ac) **(1 mark)**
(ii) Regulatory body **(1 mark)**
(iii) Process validation **(1 mark)**

b) Explain the following:

i) The role of a quality control unit **(2 marks)**
ii) The importance of acceptance testing **(4 marks)**
iii) The principle of employees' empowerment **(4 marks)**
iv) The term 'analyzing the problem' which is the second step of the six steps of the problem-solving process **(2 marks)**
v) The importance of documentation evidence in validation **(3 marks)**

c) (i) Name the TWO types of acceptance sampling **(2 marks)**

(ii) Explain the sampling process by each of the TWO types acceptance sampling mentioned in C(i) above **(3 marks)**

d) Define equipment qualification according to the EC guide to Good Manufacturing Practice. **(2 marks)**

e) Discuss the following :

(i) Twyla Dell's sentiments about employees' motivation **(2 marks)**
(ii) The term 'employee involvement' **(2 marks)**
(iii) Give the full name of the acronym "ICH' **(1 mark)**

QUESTION TWO

a) Define the term method 'Validation' according the U.S FDA's 1987 guideline , general Principles of Validation **(2 marks)**

b) Explain the following:

(i) Validation policy **(10 marks)**
(ii) The role of validating analytical methods **(6 marks)**
(iii) The role of equipment operational qualification **(2 marks)**

QUESTION THREE

a) Explain the importance of any TWO of the criteria upon which testing laboratories should be selected **(10 marks)**

b) Discuss what ISO/IEC 17025 (5.2) quality standard says about human aspect of quality **(10 marks)**

QUESTION FOUR

Construct the sampling flow process and indicate the requirements at each step of the process **(20 marks)**

QUESTION FIVE

Outline the FOUR statements within the U.S.FDA 21CFR 211.192 regulatory requirements that deal with out-of-specification test results. **(20 marks)**