

Module Title:	GMP and Statistics
Academic year:	2008 – 2009
Credit Value:	5 – Mandatory
Pre- requisites:	None
Assessment:	50% Continuous Assessment (C.A.), 50% Final Exam
Aims	This module aims to provide the students with the necessary skills to enable them to know, and appreciate the need for Good Manufacturing Procedures in a Quality Control environment, explain the principles of Out of Specification Investigation, Analytical Methods Validation and Sampling, and to know and explain the statistics applicable in the Quality Control Environment.
Module Content	<ul style="list-style-type: none"> • The basic principles of GMP as they apply to QC • The role of each of the following areas in a QC department: Incoming Quality, In-Process Testing, Release Testing, Stability and Shelf Life Sampling and Testing • Devise and use control charts • The principles of analytical method validation and its stages • The need for and procedure of investigation into out of trend and out of specification analytical results • Identify statistical methods to evaluate data • Identify the impact of the QC function on the manufacturing process • The requirements for calibration of analytical equipment • The documentation requirements for QC • The role sampling plays and the differing methods available • How to use the USP and EP • The statistical methods most frequently used in QC • Record raw data, carry out calculations on the data, compare it to the current specification and determine if it complies • Validate an analytical method and present the data including any statistical analysis.

<p>Intended Learning Outcomes:</p>	<p>On successful completion of this module the student should be able to:</p> <ol style="list-style-type: none"> 1. Outline the necessity and function of GMP specifically within the QC environment. 2. Identify the SOPs required within a QC laboratory 3. Discuss the principles of Out of Specification Investigation, Analytical Methods Validation and Sampling. 4. Describe all documents required in Quality Control, Testing Methods, Specifications, Testing Records, Sampling Plans, etc 5. Explain the requirement for Laboratory Controls, e.g. sample control and tracking, reference standards and reagent control, calibration, maintenance and operation of laboratory equipment, the use of log books, 6. Define the samples required in the QC dept. e.g. composite samples, single samples, retain samples and stability samples. 7. Evaluate and investigate test results 8. Know and understand the statistics applicable in the Quality Control Environment. 9. Use statistics to interpret data, mean, standard deviation, percentage of cumulative variation, outlier tests. 10. Set up and use a sampling plan and know what samples should be taken and how often. 11. Discuss the requirements for stability samples and testing, including the statistics for the interpretation of data. 12. Define laboratory raw data 13. Explain the requirements for raw data in the laboratory 14. Know of the systems in QC depts, that can be used to collect and control data and their compliance requirements, 21 CFR Part 11 for computerised systems. 15. Explain the requirements for Analytical Method Validation and the statistics required to interpret the data. 16. Apply relevant data analysis techniques including correlation, regression, students t-tests, etc
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