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| <b>Module Title:</b>    | Quality Practices  |
| <b>Academic year:</b>   | 2009 2010  |
| <b>Credit Value:</b>    | 3  |
| <b>Pre- requisites:</b> |  |
| <b>Assessment:</b>      | Continuous Assessment 40%<br>Final written exam 60%  |
| <b>Aims</b>             | This module aims to provide the student with the following:<br>An understanding and knowledge of the quality requirements, regulatory bodies and practices relevant to industry  |
| <b>Module Content</b>   | <p>Introduction to the Pharmaceutical Industry: Historical case studies, types of pharmaceutical companies, GMP, QA and QC roles, company quality organisation, main regulatory authorities, Pharmacopoeias; QC testing, stability Testing</p> <p>Drug Development Cycle: phases in drug development</p> <p>Documentation: typical SOP format, batch records, production records</p> <p>Auditing: types, organisation</p> <p>Calibration: purpose and method</p> <p>Introduction to Validation: validation purpose, phases, documents.</p> |

**Intended Learning Outcomes:**  
(September 2007)

At the end of this module the student will be able to:

1. Describe the organisational structure of Pharmaceutical companies and the drug development cycle.
2. Identify the main regulatory bodies and documentation requirements.
3. Explain the purpose of validation and its role in GMP.
4. Identify the main steps involved in a GMP audit.
5. Source and interpret Pharmacopoeial monographs.
6. Calibrate an instrument and draft a calibration report.