**SECTION 1: MODULE SPECIFICATIONS**

1. Title of the module

**PHAM 1123 -GxP (Business Option)**

1. School which will be responsible for management of the module

**Medway School of Pharmacy**

1. Start date of the module

 **2013**

1. The cohort of students (onwards) to which the module will be applicable

**2012**

1. The number of students expected to take the module

**10-30 per cohort**

1. Modules to be withdrawn on the introduction of this proposed module and consultation with other relevant Schools and Faculties regarding the withdrawal

**N/A**

1. Level of the module *(e.g. Certificate [C], Intermediate [I], Honours [H] or Postgraduate [M])*

**I**

1. The number of credits which the module represents

**15 credits**

1. Which term(s) the module is to be taught in (or other teaching pattern)

**The module is part of the Foundation Degree in Applied Bioscience Technology which is being delivered primarily through e-learning on a part-time basis over three years.**

1. Prerequisite and co-requisite modules

**None**

1. The programme(s) of study to which the module contributes

**Foundation Degree in Applied Bioscience Technology**

1. The intended subject specific learning outcomes and, as appropriate, their relationship to programme learning outcomes
* Demonstrate an understanding of pharmaceutical/industry GxP requirements (**POs: A2, A3, B13, B19**)
* Have the ability to apply the relevant GxP legislation that is applicable to their own work environment (**POs: A2, A3, A8, A10, A11, B13, B14, B19, C21, C22, C24, D32, D33**)
* Be able to apply the relevant tools and techniques used in GxP risk based compliance to a work related activity, producing a summary report and recommendations (**POs: A2, A3, A5, A7, A8, A10, A11, B13, B14, B16, B19, C21, C22, C24, D27, D32, D33**)
* Understand the role of audits in quality management and carry out an internal compliance audit in accordance with the legislative requirements (**POs: A2, A3, A5, A7, A8, A10, A11, B13, B14, B16, B19, C21, C22, C24, D27, D32, D33**)
* Know how to complete a non-conformance investigation and deviation report using the appropriate investigation techniques (**POs: A2, A3, A10, A11, B13, B14, B19, C24**)
1. The intended generic learning outcomes and, as appropriate, their relationship to programme learning outcomes
* An ability to analyse, evaluate and correctly interpret data (**POs: A2, B14, B19, C21, C22, D28, D29**)
* An ability to present and communicate data (**POs: D26, D27**)
* An ability to obtain and use information from a variety of sources as part of self-directed learning (**POs: D25, D32, D33**)
* Time-management and organisational skills within the context of self-directed learning (**POs: D31-D33)**
1. A synopsis of the curriculum
* Basic Introduction to GxP
* Good Laboratory Practices (GLP)
* Good Manufacturing Practices (GMP)
* Reasons for validation
* Non-Conformance investigations and Reporting
* Good Aseptic Practices (GAP)
* Good Clinical Practices (GCP)
* Risk Based Compliance
* Quality Audits
1. Indicative Reading List

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| --- | --- | --- | --- | --- |
| **ISBN number** | **Author** | **Date** | **Title** | **Publisher** |
| 9780853697190 | MHRA | 2007 | Rules and Guidance for Pharmaceutical Manufacturers and Distributors | Pharmaceutical Press |
| 978-91-977151-1-9 | Anna Lunden | 2008 | The GMP Handbook | Lunden-Ellow |

1. Learning and Teaching Methods, including the nature and number of contact hours and the total study hours which will be expected of students, and how these relate to achievement of the intended learning outcomes.

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| **Activity** | **e-learning** | **e-activities/****Practicals / Work activities** | **MSCL / CAL** | **Total hours** | **Learning Outcomes** |
| Teaching | 25 | 15 | 15 | **55** | A2, A3, A5, A7, A8, A10, A11, B13, B14, B16, B19, C21, C22, C24, D27, D32, D33 |
| Private study | 15 | 5 | 10 | **30** | A2, A3, A5, A7, A8, A10, A11, B13, B14, B16, B19, C21, C22, C24, D27, D32, D33 |
| Work-based experience |  | 60 |  | **60** | A4, A5, A7, A8, A10- A12, B18, B19, C20-C22, C24, D27, D30- D33 |
| Formal assessment |  |  |  | **5** |  |
| **Total hours** |  |  |  | **150** |  |

**Online e-learning** is intended to present the key information directly relating to the learning objectives.

**E-activities, practicals and work activities** serve to reinforce material presented online and also relate directly to the learning objectives. These are specifically based on enabling students to relate their theoretical knowledge to the practice of GxP in their own and other companies.

**MSCL** serves to reinforce and support materials presented in the above forms in the students’ minds. They also form part of the self-directed learning for the student.

**Private study** encompasses the revising of all material presented in the above various forms of teaching and learning, together with the opportunity to explore and read more widely around specific topics (this may already have been suggested in the MSCL materials).

1. Assessment details: Assessment methods and how these relate to testing achievement of the intended learning outcomes.

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| **Method of assessment** | **Learning outcomes assessed (POs & SSLOs)** | **Weighting** | **Outline details** |
| Continuous assessment (1) | A2, A3, A5, A7, A10-A12, B13, B16, B18, B19, C21, C22, C24, D27, D32, D33 | 20% | Risk based compliance report |
| Continuous assessment (2) | A2, A3, A5, A7, A10-A12, B13, B16, B18, B19, C21, C22, C24, D27, D32, D33 | 20% | GxP audit report |
| Continuous assessment (3) | A2, A3, A5, A7, A10-A12, B13-B16, B18, B19, C21, C22, C24, D27, D32, D33 | 20% | Based on assessment of myFolio entries. |
| Continuous assessment (4) | All subject specific learning outcomes (SSLOs) | 40% | 40 minute MCQ assessment |

**The pass mark for this module is 40%. The aim of the assessment is that there should be an equal balance between ‘application’ (ie. reflection related to practical/work experience) and ‘theory’ (ie. examination), but that neither should enable the student to obtain a pass grade independently and in its entirety.**

1. Implications for learning resources, including staff, library, IT and space

**The programme will be delivered using Moodle as a Virtual Learning Environment (VLE) and myFolio will be used to hold all Reflective Portfolio entries and Personal Development Plans.**

1. **The School recognises and has embedded the expectations of current disability equality legislation, and supports students with a declared disability or special educational need in its teaching. Within this module we will make reasonable adjustments wherever necessary, including additional or substitute materials, teaching modes or assessment methods for students who have declared and discussed their learning support needs. Arrangements for students with declared disabilities will be made on an individual basis, in consultation with the University’s disability/dyslexia support service, and specialist support will be provided where needed.**

***If the module is part of a programme in a Partner College or Validated Institution, please complete the following:***

1. Partner College/Validated Institution: **N/A**
2. University School (for cognate programmes) or Faculty (for non-cognate programmes) responsible for the programme:

**SECTION 2: MODULE IS PART OF A PROGRAMME OF STUDY IN A UNIVERSITY SCHOOL**

**Statement by the School Director of Learning and Teaching/School Director of Graduate Studies (as appropriate):** "I confirm I have been consulted on the above module proposal and have given advice on the correct procedures and required content of module proposals"

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| BOApampaDirector of Learning and Teaching Dr Buge ApampaPrint Name | Date |

**Statement by the Head of School:** "I confirm that the School has approved the introduction of the module and, where the module is proposed by School staff, will be responsible for its resourcing"

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| Head of SchoolProfessor Iain CummingPrint Name | Date October 2011 |