Northeastern University London

The Regulatory Environment Course Descriptor

Course Title	The Regulatory Environment	Faculty	EDGE Innovation Unit (London)
Course code	NCHNAP492	Course Leader	Professor Scott Wildman (interim)
Credit points	15	Teaching Period	This course will typically be delivered over a 6-week period.
FHEQ level	4	Date approved	
Compulsory/ Optional	Compulsory	Date modified	
Pre-requisites	None		
Co-requisites	None		

Course Summary

This course promotes all aspects of quality control, awareness and adherence to quality guidelines and regulations, with a focus on accuracy and safety in all aspects of bioscience work. It examines the need for health and safety regulations and the use of risk assessments to ensure the best possible understanding of the contexts within which scientists operate and how to mitigate accidents. Learners will examine the internal and external regulatory environment pertinent to the bioscience and health sectors, for example Medicines & Healthcare Products Regulatory Authority (MHRA), Control of Major Accident Hazards (COMAH), Control of Substances Hazardous to Health (COSHH), Good Laboratory Practice (GLP) and Good Manufacturing Practice.

Course Aims

- For learners to understand and be able to implement safe laboratory working practices and regulations.
- For learners to understand the regulatory environment with which the bioscience and health sectors operate, including historical perspectives and ethics.
- For learners to understand modern regulatory and safety advances such as pharmacovigilance and fast track approval.

Learning Outcomes

On successful completion of the course, learners will be able to:

Knowledge and Understanding

K1a Understand the underlying national and international regulatory principles, policies and frameworks that governs the life science and health sector.

K2a Understand the importance and how to implement good laboratory practice, risk assessments, safety policies and regulatory procedures in an organisational context.

K4a Understand the underlying principles, ethics, policies and procedures used in laboratory safety.

Subject Specific Skills

S1a Develop and evaluate a risk assessment for laboratory work.

S2a Evaluate the regulatory environment including government legislation and the Health the Safety Executive that govern the operation of the bioscience and/or health sectors.

S4a Conceptually plan a safe workplace project, adhering to regulatory procedures.

Transferable and Professional Skills

T1a Take personal responsibility in professional development and learning.

T3a Display a developing technical proficiency in written English and an ability to communicate clearly and accurately in structured and coherent pieces of writing.

T4a Promote professionalism in safety and regulatory adherence.

Teaching and Learning

This is an e-learning course, taught throughout the year.

This course can be offered as a standalone short course.

Teaching and learning strategies for this course will include:

- Online learning
- Online discussion groups
- Online assessment

Course information and supplementary materials will be available on the University's Virtual Learning Environment (VLE).

Learners are required to attend and participate in all the formal and timetabled sessions for this course. Learners are also expected to manage their self-directed learning and independent study in support of the course.

The course learning and teaching hours will be structured as follows:

- Off-the-job learning and teaching (6 days x 7 hours) = 42 hours
- One-the-job learning (12 days x 7 hours) = 84 hours (e.g. 2 days per week for 6 weeks)
- Private study (4 hours per week) = 24 hours

Total = 150 hours

Workplace assignments (see below) will be completed as part of on-the-job learning.

Assessment

Formative

Learners will be formatively assessed during the course by means of set assignments. These will not count towards the final degree but will provide learners with developmental feedback.

Summative

Assessment will be in two forms:

AE	Assessment Type	Weighting	Online submission	Duration	Length
1	Set Exercises	50%	Yes	Requiring on average 20 – 25 hours to complete	-
2	Written Assignment (case study based)	50%	Yes	Requiring on average 20 – 25 hours to complete	-

Feedback

Learners will receive formal feedback in a variety of ways: written (via email or VLE correspondence) and indirectly through online discussion groups. Learners will also attend a formal meeting with their Academic Mentor (and for apprentices, including their Line Manager). These bi or tri-partite reviews will monitor and evaluate the learner's progress.

Feedback is provided on summatively assessed assignments and through generic internal examiners' reports, both of which are posted on the VLE.

Indicative Reading

Note: Comprehensive and current reading lists for courses are produced annually in the Course Syllabus or other documentation provided to learners; the indicative reading list provided below is used as part of the approval/modification process only.

Books

- Lezotre, P-L. (2014). *International cooperation, convergence and harmonization of pharmaceutical regulations : a global perspective.* Amsterdam : Elsevier ; Oxford ; Sand Diego, CA : Academic Press 2014
- Fleming, D. O., & Hunt, D. L. (2006). *Biological safety : principles and practices* (4th ed.). Washington, D.C. : ASM Press 2006
- Brock, W. J., Hastings, K. L, McGown, K. M. (2013). *Nonclinical safety assessment a guide to international pharmaceutical regulations.* Chichester, West Sussex : John Wiley & Sons.

Journals

Learners are encouraged to read material from relevant journals on the regulatory environment as directed by their course leader.

Electronic Resources

Learners are encouraged to consult relevant websites on the regulatory environment.

Indicative Topics

- Quality management
- Health and safety
- Regulations and safety protocols

Version History

Title: NCHNAP492 The Regulatory Environment Course Descriptor **Approved by: Academic Board** **Location: Academic Handbook/Programme specifications and Handbooks/ Undergraduate Apprenticeship Programmes/BSc (Hons) Bioscience with Digital Technologies Programme Specification/Course Descriptors**					
Version number	**Date approved**	**Date published**	**Owner**	**Proposed next review date**	**Modification (As per AQF4) & category number**
3.0	October 2022	January 2023	Scott Wildman	September 2026	Category 1: Corrections/clarifications to documents which do not change approved content or learning outcomes Category 3: Changes to Learning Outcomes
2.0	January 2022	April 2022	Scott Wildman	September 2026	Category 3: Changes to Learning Outcomes
1.0	September 2021	September 2021	Scott Wildman	September 2026	