### Module Description

This module covers the science and practice of validation, as it applies within the pharmaceutical and medical device sectors. The use of risk management as part of the validation process is also covered.

### Learning Outcomes

**On completion of this module the learner will/should be able to:**

1. Explain the role of validation within Good Manufacturing Practice.
2. Identify and apply the various validation guidelines and standards in use.
3. Apply risk management tools as part of a validation exercise.
4. Prepare a validation document in accordance with regulatory guidelines.
5. Describe the major steps involved in the validation of critical pharmaceutical and medical device manufacturing operations.
6. Describe the approach taken to analytical method validation.
7. Complete various validation exercises.

### Indicative Syllabus

- Regulatory basis for validation
- Risk management and its role in validation including review of ISO 14971
- Equipment validation – DQ, IQ, OQ, PQ.
- Pharmaceutical process validation
- Analytical method validation and Good Automated Manufacturing Practice
- Validation of medical devices including key processes including sterilisation
- Change Control

### Teaching and Learning Strategy

Delivery of the module will include lectures, group work, in class discussion and analysis. Guest industry speakers will be invited to present on specialist topics.

### Assessment Strategy

50% continuous assessment 50% final examination; Examples of assessment include validation documentation preparation, application of risk assessment tools, short in class quiz/exam, report preparation on specialist topics,
Repeat Assessment Strategies

Repeat exam available

Indicative Coursework and Continuous Assessment: 50 %

<table>
<thead>
<tr>
<th>Form</th>
<th>Title</th>
<th>Percent</th>
<th>Week (Indicative)</th>
<th>Learning Outcomes</th>
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End of Semester / Year Formal Exam: 50 %

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<td>Final Exam</td>
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Full Time Delivery Mode Average Weekly Workload: 1.50 Hours

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<td>Weekly</td>
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Recommended Reading Book List


Literary Resources


Robert A. Nash and Alfred H. Wachter 2003, Pharmaceutical Process Validation. Marcel Dekker

A G Singh Rathore and Gail Sofer 2005, Process Validation in Manufacturing of Biopharmaceuticals. Taylor and Francis


Online Resources

Food and Drug Administration www.fda.gov

Irish Medicines Board www.imb.ie

European Medicines Agence www.emea.europa.eu

International Council for Harmonization www.ich.org

Programme Membership

GA_SQRAG_S07 201500 Certificate in Science in Quality & Regulatory Affairs

GA_SQUAG_B07 201400 Bachelor of Science in Quality for Industry