## PROGRAMME APPROVAL FORM
### SECTION 1 – THE PROGRAMME SPECIFICATION

1. **Programme title and designation**
   - Pharmaceutical Analysis and Quality Control

2. **Final award**
   - | Award | Title                                | Credit value | ECTS equivalent | Any special criteria |
     |-------|--------------------------------------|--------------|-----------------|---------------------|
     | MSc   | Pharmaceutical Analysis and Quality Control | 180          | 90              | N/A                 |

3. **Nested awards**
   - | Award | Title | Credit value | ECTS equivalent | Any special criteria |
      |-------|-------|--------------|-----------------|---------------------|
      | N/A   | N/A   | N/A          | N/A             | N/A                 |

4. **Exit awards**
   - | Award | Title                                | Credit value | ECTS equivalent | Any special criteria |
      |-------|--------------------------------------|--------------|-----------------|---------------------|
      | PGCert| Pharmaceutical Analysis and Quality Control | 60           | 30              | Modules - any combination to a minimum value of 60 credits |
      | PGDip | Pharmaceutical Analysis and Quality Control | 120          | 60              | Modules - any combination to a minimum value of 120 credits |

5. **Level in the qualifications framework**
   - M

6. **Attendance**
   - | Mode of attendance | Full-time | Part-time | Distance learning |
     |---------------------|-----------|-----------|------------------|
     |                     | ✓         | ✓         | N/A              |

   - | Minimum length of programme | 12 months | 24 months | N/A              |
   - | Maximum length of programme | 3 years   | 6 years   | N/A              |

7. **Awarding institution/body**
   - King’s College London

8. **Teaching institution**
   - King’s College London

9. **Proposing department**
   - Department of Pharmacy

10. **Programme organiser and contact**
    - Dr. A. F. Drake
    - Department of Pharmacy
    - Franklin-Wilkins Building
    - Waterloo Campus
    - Extension. 4839
    - a.drake@kcl.ac.uk

11. **UCAS code (if appropriate)**
    - NA

12. **Relevant QAA subject benchmark/professional and statutory body guidelines**
    - There are no specific benchmark statements for this Masters programme. However, some relevant statements can be found in the QAA Subject Benchmark Statements for Pharmacy:
      - http://www.qaa.ac.uk/crntwork/benchmark/phase2/pharmacy.htm

13. **Date of production of specification**
    - 02 June 2005 (March 2007 Implementation CF)

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PAF modified by ASQ re: exit awards: 8 April 2010
PAF finalised for 2011/12: 23 August 2011
PAF modified by QAS for 2012/13: 2nd March 2012
PAF finalised for 2012/13: 19 September 2012
16. **Educational aims of the programme**

- Provide an appropriate learning environment for a post-graduate programme that enables the delivery of high quality teaching and research methods
- Provide an intellectual challenge to students at the postgraduate level
- Encourage the student to be capable of working confidently and adopting a mature, professional and safe attitude to their work
- Encourage the student to develop independent and self critical learning to maximise their own potential
- Increase the depth of the student’s knowledge, technical and transferable skills in an integrated manner to enhance their current and future roles
- Facilitate students to develop their transferable skills that include advanced study practices, precision and clarity in verbal and written communication, numeracy, team work and decision making
- Enhance critical, analytical problem-solving skills, evidence-based decision making skills and the use of information technology
- Establish a firm foundation for the pursuit of professional qualifications, and continuing professional development in the pharmaceutical industry, or healthcare sector
- Enhance competence in numerical methods used in the pharmaceutical sciences
- Develop an appreciation of the underlying science of biopharmaceutics and drug delivery
- Provide an advanced understanding of drug absorption, distribution, metabolism, excretion and pharmacokinetics
- Develop an advanced understanding of the principles of drug analysis by chromatographic and spectroscopic and other pharmacopeial methods
- Have a comprehensive understanding of the drug development process and the role of regulatory agencies
- Provide the ability to critically review the scientific literature, critically analyse information, synthesise and summarise conclusions
- Provide an appreciation of the role of Pharmaceutical Analysis and Quality Control
- Establish a comprehensive understanding of the scope and limitations of various analytical techniques for identification, determination of molecular structure and analysis of complex mixtures
- Encourage independent thought and scientific leadership

17. **Educational objectives of the programme/programme outcomes**

The programme provides opportunities for students to develop and demonstrate knowledge and understanding and skills in the following areas:

- Subject knowledge
- Pharmaceutical-related cognitive abilities and skills
- Pharmaceutical-related practical skills
- Transferable key skills

All areas are defined in detail below

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**Knowledge and understanding**

The programme provides a **knowledge and understanding** of the following:

**Subject Knowledge**

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These are achieved through the following teaching/learning methods and strategies:
• A knowledge and understanding of:
  o Drug Delivery
  o Drug Disposition
  o Statistics and Numerical Methods
  o Quality Assurance and Regulatory Affairs
  o Modern Instrumental Techniques
  o Drug Metabolism
  o Pharmacokinetics
  o Clinical Pharmacokinetics
  o Biochemical Toxicology

1. Systematic understanding of knowledge in the specialised area of Pharmaceutical Analysis and Quality Control
2. Assemble and enhance the knowledge required to understand techniques, methodologies or regulatory matters in the area of Pharmaceutical Analysis and Quality Control
3. Integration of subject knowledge into a Sustained Research Project
4. Techniques for research and academic enquiry
5. The ethical and safety issues surrounding Pharmacy research

The modules are taught by subject specialists, including visiting professionals. The teaching and learning strategies; lectures; practical laboratory experiments and exercises; tutor-led tutorials; students and tutor presented seminars; appropriate computer-assisted learning (CAL); directed private study; industry-based workshops and problem-based learning workshops are given.

Assessment:

The assessment methods associated with each module are given.

Points 1 - 5 will be assessed using various combinations of coursework assignments; essays, practical laboratory sessions, oral and poster presentations, case studies, research project and formal written examinations.

The nature of the assessment is appropriate to the subject area and learning outcomes.

Skills and other attributes

<table>
<thead>
<tr>
<th>Intellectual skills:</th>
<th>These are achieved through the following teaching/learning methods and strategies:</th>
</tr>
</thead>
<tbody>
<tr>
<td>6. Recognise and use appropriate theories, concepts and principles from a range of scientific disciplines in a critical manner</td>
<td>Intellectual skills set out in points 6 – 13 are developed through workshops, practical sessions, seminar and tutorial work and coursework assignments. The authorship of an extended independent research project encourages the integration of knowledge and skills and application to new problems (Skills 8 - 13).</td>
</tr>
<tr>
<td>7. Integrate theory with practice</td>
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<tr>
<td>8. Assemble and integrate evidence and apply it in a balanced way</td>
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<tr>
<td>9. Analyse, synthesise and summarise information critically</td>
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<tr>
<td>10. Acquire, collate, appraise, analyse and interpret data</td>
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<td>11. Formulate hypotheses, design experiments and interpret statistical information</td>
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<tr>
<td>12. Apply knowledge and understanding to address familiar and novel problems</td>
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<tr>
<td>13. Assemble and integrate evidence to produce a balance argument</td>
<td></td>
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</tbody>
</table>

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Skills 8 -13 are integrated into the research project dissertation.

Student-centred learning, involving library-based research, information and data retrieval and presentations will be encouraged to reinforce and enhance these skills.

These are achieved through the following teaching/learning methods and strategies:

Subject practical skills 14 – 28 are developed in a coordinated and progressive manner throughout the programme. These skills are developed in the laboratory classes, workshop tutorials, computer-based sessions and during the research project. Practicals associated with The Principles of Analytical Techniques module will train student in GLP criteria, essential for employment in industry. Critical analysis skills are developed throughout the programme in both laboratory-based and class-based scenarios in preparation for the critical evaluation of the literature and generated data within the written research thesis/dissertation.

Assessment:

A variety of assessment methods are used to assess subject practical skills.

Skills 14 - 16 are assessed during the project and via the various practical sessions within the different modules. These include the requirement to produce written laboratory reports, critically evaluate data generated by applying appropriate statistical methods to evaluate the pharmaceutical data.

Skills 17 – 20 and 23 - 25 are assessed during the practical workshops, written laboratory reports, coursework essays and individual coursework assignments.

Skills 21 and 22 are assessed during workshops and associated coursework assignments.

Practical skills:

14. Plan, conduct, evaluate and report the results of laboratory practical investigations
15. Critically evaluate results to ensure they are correct accurate precise, reliable and trustworthy.
16. Appraise and apply COSHH safety assessments to practical work
17. Apply appropriate practical techniques to evaluate drug release from different dosage forms
18. Apply appropriate practical techniques to evaluate drug distribution and physicochemical properties of medicines
19. Apply appropriate practical techniques for the analysis and quantification of pharmaceutical mixtures and products
20. Apply GLP criteria in laboratory sessions
21. Evaluate and disseminate recent changes in Pharmaceutical Regulation
22. Critically assess and evaluate potential drug toxicity
23. Plan, select and evaluate the use of modern spectroscopic, instrumental, chemical and bio-analytical techniques in a pharmaceutical context
24. Apply appropriate regulatory requirements for quality assurance and product licensing of medicines, to ensure that the regulatory criteria of safety, quality, efficacy and potency are consistently met
25. Fully appreciate the need to use equipment and instruments that comply with specifications
26. Retrieve, synthesise and present data from a variety of sources
27. Analyse statistically generated scientific data
28. Direct, plan and execute self directed...
Generic/transferable skills:
29. Communicate ideas effectively both orally and in writing
30. Analyse and appraise the literature in a critical manner
31. Critically assess issues of sample selection, accuracy, precision and uncertainty, in the collection and analysis of data
32. Utilise appropriate numerical and statistical problem-solving skills
33. Utilise information technology resources (information retrieval)
34. Critically appraise and evaluate in a reasoned fashion
35. Work independently and as part of a team
36. Manage time and resources to complete all aspects of the programme
37. Undertake reflective practice

These are achieved through the following teaching/learning methods and strategies:

Generic/transferable skills detailed in points 29 – 37 are developed in a contextual manner throughout the programme. These skills are highlighted using problem solving, practical laboratory sessions, IT, information retrieval, CAL, poster and presentation skills. These skills are enhanced during tutorials, seminars, laboratory classes, workshop tutorials and coursework assignments.

Assessment:
All generic/transferable skills are assessed through the various assessment strategies adopted throughout the programme. A variety of assessment methods are used to assess transferable key skills.

Skill 29 is assessed via oral presentations and workshop seminars.

Skills 30 – 33 are assessed via various coursework assignments within the different modules, the research project and workshop seminars; including CAL.

Skills 34 - 35 are assessed during the project, problem-solving assignments, practical reports and the final written dissertation.

Skill 36 is developed throughout the programme by adhering to deadlines and completing the written dissertation.

Skill 37 is developed throughout the programme to understand limitations in student’s knowledge and the need to rectify deficiencies.

18. Statement of how the programme has been informed by the relevant subject benchmark statement(s)/professional, regulatory and statutory body guidelines

There are no specific benchmark statements for this programme; however, attention has been placed upon the QAA benchmarking statements for pharmacy so that the programme and curriculum are informed by the specific subject knowledge, abilities and skills outlined in these statements.

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The Royal Society of Chemistry is currently developing requirements for postgraduate competency criteria. The programme team will monitor this development and react accordingly when necessary. The NPL, LGC and other similar bodies hold meetings to encourage the adoption of accredited analytical procedures. Members of Academic Staff attend such meetings.

19. Programme structure and award requirements
(a) numbers of introductory, core, compulsory and optional modules to be taken in each year of the programme with related credit values
MSc: 5 core modules (180 Credits in total).
PGDip modules any combination to a minimum value of 120 credits
PGCert modules any combination to a minimum value of 60 credits

(b) range of credit levels permitted within the programme
7

(c) maximum number of credits permitted at the lowest level
180 MSc, 120 Dip, 60 Cert

(d) minimum number of credits required at the highest level
180 MSc, 120 Dip, 60 Cert

(e) progression and award requirements (if different from the standard)
None

(f) maximum number of credits permitted with a condoned fail (core modules excluded)
As all modules are core a condoned fail is not permitted

(g) are students permitted to take a substitute module, as per regulation A3, 20.7?
No

(h) other relevant information to explain the programme structure
MSc in Pharmaceutical Analysis and Quality Control
Students taking the MSc part-time over two years will be required to take and pass the core modules (120 credits) in the order specified below:

Part Time, Two Years
Year 1, Principles of Analytical Techniques, Numerical Methods and Regulatory Affairs, Advanced Spectroscopic, Instrumental, Chemical and Bio-analytical Techniques
Year 2, Principles of Drug Delivery and Disposition, Advanced Separation Science, Quality Control and Regulatory Matters, Research Project

Students are required to submit the research project in the second year of study.
Programme Structure

<table>
<thead>
<tr>
<th>Title</th>
<th>Credit level</th>
<th>Credit value</th>
<th>Status (I, Cr, Cp, O) for each type of programme</th>
<th>Progression</th>
<th>Assessment</th>
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<tbody>
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<td>Single</td>
<td>Joint</td>
<td>Major/ minor</td>
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<tr>
<td>7BBPM010 Principles of Drug Delivery and Disposition</td>
<td>7</td>
<td>30</td>
<td>Cr</td>
<td></td>
<td>Yes</td>
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<tr>
<td>7BBPM011 Principles of Analytical Techniques, Numerical Methods and</td>
<td>7</td>
<td>30</td>
<td>Cr</td>
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<td>Yes</td>
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<td>Regulatory Affairs</td>
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<tr>
<td>7BBPM015 Advanced Spectroscopic, Instrumental, Chemical and</td>
<td>7</td>
<td>30</td>
<td>Cr</td>
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<td>Yes</td>
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<tr>
<td>Bio-analytical Techniques</td>
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<tr>
<td>7BBPM016 Advanced Separation Science, Bioanalytical Techniques,</td>
<td>7</td>
<td>30</td>
<td>Cr</td>
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<td>Yes</td>
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<tr>
<td>Quality Control and Regulatory Matters</td>
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<tr>
<td>7BBPM014 Research Project</td>
<td>7</td>
<td>60</td>
<td>CrCp</td>
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<td>Yes</td>
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<td>(7BBPM019)</td>
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<tr>
<td>7BBPM019 Literature Review Project</td>
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<td>60</td>
<td>CrCp</td>
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20. Marking criteria
All modules will be marked in accordance with the Schools marking criteria where such exist or else in accordance with the Colleges general marking criteria.