STP Clinical Science (Pharmaceutical Science) Handbook 2025/26

Description

MSc Clinical Science (Pharmaceutical Science)

PROGRAMME HANDBOOK

2025/26

Division of Pharmacy and Optometry

School of Health Sciences

Faculty of Biology, Medicine and Health

Welcome to the Programme

MSc Clinical Science (Pharmaceutical Science)

Welcome to the MSc Clinical Science (Pharmaceutical Science) postgraduate programme.

This student handbook provides details of the University of Manchester Programme leading to the MSc in Clinical Science (Pharmaceutical Science). It includes information about the aims and learning outcomes, structure, content, admissions, assessment and programme management. Please read it thoroughly. It should also be read in conjunction with related University documentation.

In Section A, there is a summary of how the course is structured while, in Section B, each of the course units are described. Please refer to the SHS handbook for information on the various University regulations.

Each of you will bring your personal experience and knowledge to the programme. Sharing that knowledge and experience with your tutors and other students in person and through the online discussion boards will significantly enhance the learning experience.

We have made every effort to provide you with the most up-to-date and accurate information. However, some minor details may change during the course of your studies. All changes and additions will be brought to your attention. If there is something not answered within the handbook please do not

hesitate to contact us.

We hope that your time here studying with Manchester will be enjoyable and successful.

General information about the Division of Pharmacy and Optometry and School of Healthcare Sciences is contained in this handbook, the SHS handbook, and more information can be obtained from the following web sites:

- The Pharmacy home page: https://www.bmh.manchester.ac.uk/pharmacy/
- The Faculty of Biology, Medicine and Health home page: https://www.bmh.manchester.ac.uk/
- The University of Manchester home page: http://www.manchester.ac.uk/

Listed below are contact details for your Programme Team,

Ruth Barnes
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Division of Pharmacy and Optometry
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Email: philip.jones-3@manchester.ac.uk

Divisional Administration Contacts

Head of Division: Prof. Kaye Williams

Divisional Operations Manager: Grant Boyle

The School address is:

Division of Pharmacy and Optometry
The University of Manchester
Stopford Building
Oxford Road
Manchester
M13 9PT

To access Stopford Building you will need a University of Manchester ID card. To obtain your student card, please contact the Student Services Centre (+44 (0)161 275 5000 / ssc@manchester.ac.uk).

Academic staff:

- Ruth Barnes, Programme Director (ruth.barnes@manchester.ac.uk)
- Sue Renn, Deputy Programme Director (sue.renn@manchester.ac.uk)
- Sarah Ward, Lecturer in Pharmaceutical Science (sarah.ward-2@manchester.ac.uk)

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Section A: Programme Structure

Rationale and General Description

This three-year taught part-time Masterâ??s programme is suitable for students who wish to improve their knowledge, understanding and research expertise prior to embarking on a research PhD or when considering training for a career in clinical pharmaceutical sciences. The Masterâ??s level qualification meets the needs of those requiring a higher degree and the programme is designed to provide training, skills and knowledge that would help support subsequent applications to clinical training.

The programme is part-time and delivered over a 3-year period. The taught elements are delivered in discrete blocks and are integrated around work-based practice.

During the first year of the course, students are enrolled on two compulsory units covering a wide range of topics on:

- PHAR61630 Introduction to Pharmaceutical Science 1
    - Foundations of healthcare and clinical science
    - Regulation and quality assurance
- PHAR61730 Introduction to Pharmaceutical Science 2
    - Introduction to Radiopharmacy
    - Introduction to Aseptics
    - Introduction to Production and Quality Control

During the second year of the course, students are enrolled on two compulsory units:

- PHAR61650 Specialist Pharmaceutical Science 1
    - Research methods
    - Aseptics
    - Radiopharmacy
- PHAR61750 Research Project 1
    - Students will also put forward and commence a research proposal.

During the third year of the course, students enrolled on two compulsory units covering specialist training on:

- PHAR71880 Specialist Pharmaceutical Science 2
    - Production
    - Quality Control
    - Preparation for Practice
- PHAR61770 Research Project 2
    - Students will complete their research dissertation.

This taught element of the course comprises seminars, workshops and several forms of independent learning. Throughout the second and third years, students will also be working on a dissertation, which involves a substantial piece of empirical work. Dissertation topics are chosen and developed by students in consultation with their supervisor and the programme team.

Programme Aims

Students will become members of a School that leads research and development in areas of pharmaceutical science. The ethos fosters excellence in pure and applied research and in developing treatment approaches. The educational aims of the programme are to provide students with an understanding of core principles and features of pharmaceutical science or professional training. The course will produce students who:

1. have an in-depth knowledge and understanding of key theoretical, clinical and methodological issues in the application of clinical and health psychology.
2. understand the role of psychological processes and states in disease and illness and understand the inter-relationships between emotion, behaviour, cognition, personality and well-being.
3. have experience and training in a range of qualitative and quantitative research methods.
4. have knowledge of core principles and features of interventions within pharmaceutical science

5. have an understanding of the ways in which clinical scientists work within healthcare and related services at the level of individuals, groups and populations.
6. meet regional and national demand for highly qualified clinical scientists with an understanding of theoretical and methodological applications of pharmaceutical science

Programme Learning Outcomes

Students, on successful completion of the programme, will:

- Develop professional practice. Students should be able to demonstrate personal qualities that encompass communication skills, self-management, self-awareness, acting with integrity, taking responsibility for self-directed learning, critical reflection and action planning to maintain and improve performance. Students will have the ability to work, where appropriate, in partnership with other professionals, often as part of a multidisciplinary team, with the public, service users, patients and their carers as partners in their care, embracing and valuing diversity.
- Impart basic, core scientific knowledge, skills and experience in their specialism, enabling them to critically evaluate and critique current research and innovation methodologies. In the healthcare setting, the patient and the public are at the centre of care and students prioritise patient safety. Students will be equipped to deal with complex scientific and clinical issues both systematically and creatively, make sound judgements in the absence of complete data, and to communicate their conclusions clearly to specialist and non-specialist audiences including patients and the public.
- Develop a conceptual understanding and advanced scholarship in and, where appropriate, propose new research questions and hypotheses.
- Develop scientific and clinical leadership skill based on the continual advancement of their knowledge, skills and understanding through the independent learning required for continuing professional development. They will develop the ability to critique, analyse and solve problems, define and choose investigative and scientific and/or clinical options, and make key judgements about complex facts in a range of situations.

A copy of the programme specification can be found on Clinical Science (Pharmaceutical Science) Announcements on Canvas.

Details of the aims and learning outcomes associated with specific course units are found under the appropriate headings in Section B.

Credit Requirements

To be awarded a degree, you have to accumulate the requisite credits by passing the assessments for course units and thus gaining the credits associated with them. Students must accrue 180 postgraduate credits to qualify for the degree of MSc. Further details on Credit Requirements can be found in the Postgraduate Taught Regulations Document.

Supervisory Arrangements

Each student will be allocated an academic advisor at the start of the programme. The University defines the role of academic advisor as follows:

- To assist students with the process of induction and orientation into academic life and the University community and respond promptly to any communication from him/her;
- To work with students to build personal academic relationships;
- To retain an interest in their studentsâ?? personal and general academic and professional development throughout their academic careers while at the University, providing information and guidance on academic choice;
- To monitor both academic performance and student engagement in a proactive manner and advise on constructive strategies to enable improvement, for example through the use of a personal portfolio or personal development plan;
- To offer general academic advice to their allocated students on their general progress and development towards the fulfilment of the Purposes of a Manchester Education, and to signpost relevant careers and skills development provision to enhance employability;
- To listen and offer students help and advice about pastoral/non-academic matters and to signpost students to other student services for further assistance if necessary;
- To ensure that a note is kept of discussions at each meeting (with the student) and any follow-up actions agreed with the student;
- To provide references.

Dissertations

At the beginning of Year 2, all students are required to submit a research proposal for the research project, which must provide details of a work-based supervisor. The research proposal will be reviewed by a team of academic staff who will allocate an appropriate academic supervisor.

The University defines the role of supervisor as follows:

- Giving guidance about the nature of research and the standard expected, the planning of the research programme, literature and sources, attendance at taught classes where appropriate and about requisite techniques (including arranging for instruction where necessary);
- Maintaining contact through regular meetings (the frequency of meetings being appropriate to the research being undertaken and agreed in advance);
- Being accessible to the student at other appropriate times for advice and responding to difficulties raised by the student;
- Giving detailed advice on the necessary completion dates of successive stages of the work so that the thesis may be submitted within the agreed timescale;
- Requesting written work or reports as appropriate and returning written material with constructive criticism and in reasonable time;
- Ensuring that for degrees where an oral examination is required the student is adequately prepared by arranging for the student to present his or her work to staff and graduate seminars.
- Ensuring that the student is made aware when progress is not satisfactory and facilitating improvement with advice and guidance;
- Establishing at an early stage the Supervisorâ??s responsibilities in relation to the studentâ??s written work, including the nature of the guidance and comments to be offered as the work

proceeds and on the draft of the thesis before it is submitted. It must be made clear to the student that research for a higher degree is undertaken within the general principle that a thesis must be the studentâ??s own work;
- Making students aware of other researchers and research work in the department;
- Providing pastoral support and advising students, where appropriate, of University support services;
- Bringing to the attention of the students the health and safety regulations and academic rules, regulations and codes of practice of the University.

The relationship between the Student and his/her Supervisor is of central importance. Both the Student and the Supervisor have a responsibility to ensure that the dissertation is completed within the prescribed period of the programme. Supervisors and students should establish at their initial meeting clear and explicit expectations of each other in order to minimise the risks and problems of misunderstanding, personality clashes, inadequate supervision and unsatisfactory work. **Timetables for Progress Monitoring meetings must be closely observed.**

If you have any queries or concerns at any time during your period of study, there is a range of people you can approach:

- Your Student Representatives
- The Programmes Team
- Your Supervisor
- Your Academic Adviser
- The Programme Director
- The Divisional Director of Education (Dr Ruth Ledder)
- The Head of Division (Prof. Kaye Williams)

Course Assessments

Full details of modes of assessment for each Course Unit are provided in Section B.

The programmes contain a range of both formative and summative assessment tasks which have been designed to establish studentâ??s knowledge and understanding of the stated learning outcomes for the course unit.

Formative assessments

- These are developmental assessments which assess your learning as you work through the unit and whenever possible form part of the preparatory work for, and link to the summative assessments.
- Formative assessments do not contribute towards the final mark but are an important part of your assessment in that feedback from these assessments will enable you to develop and improve before moving on to the summative assessment.
- Formative assessments are marked as a pass or fail, feedback will be offered to guide your learning.

- You must attempt all formative assessments within a course unit and if you do not pass you should discuss your learning needs with the course unit lead.

Summative assessments

- Each unit includes at least one summative assessment. These have been designed to assess your learning and the practice-based application of it.
- Each assessment task is allocated a percentage weighting towards the final mark.
- The minimum weighting of any individual summative assessment will be 10%.

Criteria of Levels of Achievement

You must achieve a mark of at least 50% in all summative assessment components within a course unit to achieve a pass.

You will be eligible for the award of a distinction at Masters level if you achieve an average mark of 70% or more, based on the weighted programme as a whole. If credit has been awarded as a result of referral, you will not be eligible for the award of distinction.

You will be eligible for the award of a merit at Masters level if you achieve an average mark of 60% or more, based on the weighted programme as a whole. If credit has been awarded as a result of referral, you may still be eligible for the award of merit.

Postgraduate Taught Degree Regulations for Students

Postgraduate Taught degrees at the University of Manchester are based on the National Framework for Higher Education Qualifications (FHEQ). This framework requires students to achieve credit at Masters level in order to get an award. For a standard postgraduate taught Masters programme this will normally mean passing 180 credits. A standard Postgraduate Diploma will normally have 120 credits and a Postgraduate Certificate 60 credits. The way in which you study these credits will be defined later in the programme handbook and the programme specification.

The University sets standards relating to your performance on every unit but also on your progression through the programme. Your programme and course unit specifications will set out the requirements for passing the credit on individual units.

The full PGT Degree Regulations can be accessed at:
http://www.regulations.manchester.ac.uk/postgraduate-degree-regulations/.

The following guidance should be read in conjunction with the Introduction to the Postgraduate Degree Regulations for Students:
http://www.tlso.manchester.ac.uk/degree-regulations/

Exemptions to the PGT Degree Regulations:

Please be aware that the MSc Clinical Science (Pharmaceutical Science) programme has some higher requirements to the University degree regulations and details of these are outlined below.

- The course unit pass mark is 50%.
- The programme will operate a 50% pass rate across all assessments. Where there is more than one assessment in a subject area, the average mark in that subject must be greater than 50%
- The programme will not apply any compensation rules
- An average mark of 50% must be achieved for each course unit with no individual component mark below 50%
- In accordance with the Universityâ??s PGT Degree Regulations, the resit pass mark is 50% but this mark will be capped at 40% (unless the previous mark was within the compensation zone (40-49%) in which case the original mark will stand) and it is this mark that will be used to calculate the programme GPA.
- As a requirement of the professional body, a resit pass mark will be recorded as 50R on the University transcript but the programme GPA will be calculated as described under the above point (ie as 40% or between 40% and 49% if the original mark was in the compensation zone).

Criteria for Awards

Award of Masters Degree

The award of Master degree is based upon credit accumulation using a pass mark of 50%.

Distinction

Exceptional achievements over the course of the Programme according to the taught masters marking scheme will be rewarded with the degree of Masters with Distinction.

To obtain a Distinction, students must have:

- accrued 180 credits;
- have passed all units with no referrals;
- have achieved an overall weighted average of 70% or more across the programme;

Students who have compensated or have been referred in any course units are not eligible for the award of Distinction. In addition, the dissertation must be submitted by the end of the period of programme, unless there are significant mitigating circumstances, approved in advance for missing the end of programme deadline.

Merit

To obtain a Merit, students must have accrued 180 credits AND have achieved an overall weighted average of 60% or more across the programme, including any provision made for referred units.

Pass

To obtain a pass, students must have accrued 180 credits including any provision made for referred units.

Progression

You must achieve a mark of at least 50% in all summative assessment components within a course unit to achieve a pass.

Reassessment

Reassessment as a result of a fail is known as a â??Referralâ?•. Reassessment as a result of approved and verified mitigating circumstances is known as â??Deferralâ?• and may be permitted where students are reassessed as a first attempt, for which no penalty applies.

Students may be referred in up to half of the total taught credits. The combined total number of credits referred on MSc Clinical Science (Pharmaceutical Science) cannot exceed half the taught credits. Decisions with regard to which components should be reassessed are made by the Examination Board. When a student is referred they will normally be permitted to retake the assessment/exam on one further occasion.

At the recommendation of the Board of Examiners, students will normally be allowed one resubmission of a failed dissertation or project and this will normally be within four months of the date of the publication of the result.

The pass mark for a reassessment is the same as the first attempt (i.e. 50% for masters). When a reassessment is passed, the mark is capped at the lowest compensable fail mark (i.e. 40R), unless the previous mark was within the compensation zone, in which case the original mark will stand with a suffix â??Râ??. This mark is used in the weighted average/total mark for the final award. The capped mark is applied to the whole unit and not the failed component. However, in units comprising three distinct 10-credit components, failure of one 10-credit component will not be considered as failure of the whole 30-credit unit.

Please refer to the â??Programme Exemptions to PGT Degree Regulationsâ?? section of the handbook where specific exemptions applicable to the programme will be listed.

Available Degree Classifications

Overall programme mean average of between 50.0%-59.9% MSc Pass
with 180 credits successfully completed

Overall programme mean average of between 60.0%-69.9% MSc with Merit
with 180 credits successfully completed

NB If either the Taught Average or Dissertation mark fails within the buffer zone of 58.0-59.9 the student may be considered for the award of Merit. Further information please see the Postgraduate Taught Regulations.

Overall programme mean average of â?¥ 70% MSc with Distinction
with 180 credits successfully completed
and no mark < 50% on any Course Unit at first attempt

NB If either the Taught Average or Dissertation mark falls within the buffer zone of 68.0-69.9 the student may be considered for the award of Distinction. For further information please see the Postgraduate Taught Regulations.

Submission of Assessments

Please refer to the SHS handbook for more information.

Late Submission Penalty (including the Dissertation)

Please refer to the SHS handbook for more information.

Assignment Word Count (including the Dissertation)

In accordance with the University Policy on Marking:

Each written assignment has a word limit, which you must state at the top of your first page. It is acceptable, without penalty, for you to submit an assignment within a range that is plus 10% of this limit. If you present an assignment with a word count exceeding the specified limit + 10%, the assignment will be marked but 1% will be deducted from this mark for up to every 100 words over the limit given including the leeway.

For an original word limit that is 3,000 words and an assignment that is marked out of 100: If a submission is made that is 3,301 words then it exceeds the 10% leeway, and is less than 100 words over the original limit and should receive a 1 mark deduction. For 3,401, the deduction is 2 marks, etc.

In accordance with accepted academic practice, when submitting any written assignment for summative assessment, the notion of a word count includes the following without exception:

All titles or headings that form part of the actual text. This does not include the cover page or reference list.

All words that form the actual essay.

All words forming the titles for figures and tables, are included but this does not include figures themselves, or data in tables. Text in tables or boxes should be included in the word count.

All in-text (that is, bracketed) references other than direct quotes from the pharmaceutical standards documents, which can be excluded.

All directly quoted material.

Certain assessments may require different penalties for word limits to be applied. For example, if part of the requirement for the assessment is conciseness of presentation of facts and arguments. In such cases it may be that no 10% leeway is allowed and penalties applied may be stricter than described above. In such cases the rules for word count limits and the penalties to be applied will be clearly stated in the assessment brief and in the

submission details for that assessment.

Where these mark reductions result in a fail, the unit will be treated as a failed unit in accordance with the Universityâ??s Degree Regulations.

Please refer to the SHS handbook for more information. Where the above guidance differs from that in the SHS handbook the above guidance takes precedence.

Submitting work

Please refer to the SHS handbook for more information.

Feedback for assessments

Please refer to the SHS handbook for more information.

Dissertations

The dissertation involves a student working closely with their supervisor to develop and implement an empirical research project. Details of what is involved, and of how and when to submit the dissertation are provided on the Canvas spaces for PHAR61750 Research Project 1 and PHAR61770 Research Project 2.

The University of Manchester guidance on presentation of taught Masters Dissertations is available at: **Guidance for the presentation of Taught Masters dissertations**

The guidance explains the required presentation of the dissertation, and failure to follow the instructions in the guidance may result in the dissertation being rejected by the examiners.

Monitoring Progress â?? Dissertations

In order to monitor their progress, students will have regular, scheduled meetings with their dissertation supervisor. Progress forms should be completed at these meetings. These meetings are in addition to the normal dissertation supervisory meetings between the student and supervisor, of which there should be a minimum of 6 per academic year for part-time students.

In addition, students may request meetings with the Programme Director at any point throughout their studies if there are additional matters they wish to discuss.

Attendance

Students are expected to attend all scheduled teaching and learning sessions in every year of study, unless alternative arrangements or flexibility in attendance has been agreed for individual students, if unavoidable circumstances such as illness prevents you from attending or if absence has been authorised. This includes both on-campus teaching as well as online/blended, distance or remote

learning modes of delivery.

If you are unable to attend a teaching session you should inform the programme director in the first instance to catch up on missed learning and for support with teaching materials. For absences of 1-2 days, you do not need to tell the Student Support and Wellbeing Team.

If you expect to miss one or more full weeks of teaching, you must notify the Student Support and Wellbeing team on shs.attendance@manchester.ac.uk, as well as your Academic Advisor. Please provide a reason for this to help the team provide appropriate guidance and signposting as required. You may want to consider applying for mitigating circumstances if your absence impacts on any assessments, which the Student Support and Wellbeing team can support you with.

Attendance is monitored through the SEAtS system. You should have this downloaded to your phone or laptop to check in during teaching sessions, or make your session instructor know if you cannot check in. For further information about the system, please see the SHS Student Information site for Attendance on SharePoint.

If your attendance is deemed to be too low, someone from the Student Support and Wellbeing team will be in touch to check in with you and make sure that you are ok. If the poor attendance continues without a valid reason, your Academic Advisor will be informed. If there is still no improvement in your attendance, you will be asked to a meeting with your Programme Director. This is in line with the university policy on monitoring attendance.

Programme Management

The Programme Committee will be primarily responsible for monitoring the programme and will report directly to the Pharmacy and Vision Sciences Postgraduate Teaching and Learning Committee. This committee in turn reports to the School of Health Sciences PGT Committee. Special responsibility for the programme will be taken by the Programme Directors, the Divisional Director of Education and the Head of Division. The Programme Committee will, in liaison with the Pharmacy and Vision Sciences Teaching and Learning Committee, take responsibility for programme structure, development and delivery. The Programme Director will be responsible for admissions to the programme.

The Programme Director, in liaison with the Divisional Director of Education and the Postgraduate Programmes Manager, will be responsible for Quality Assurance for the programme.

Election of a Student Representative

Your representation plays a vital and important part in helping us to maintain and improve the quality of the programme we deliver. Early in Semester 1, students will be asked to select one individual to represent their interests to the MSc Programme Board. The student representative will be required to attend some compulsory training and attend one Programme committee per year. The reps will also organise group feedback sessions at the end of each semester for all students to voice opinions on the programme.

Student Evaluation

We will ask you to complete a brief, online evaluation form at the end of each teaching session given on the course. These questionnaires are reviewed by the unit leads and the Programme Team. The responses to these evaluations will be considered when reviewing the structure and content of the programme. Your feedback is extremely important, not only for programme quality assurance but also to the University in meeting the requirements of external quality assessment.

Role of the External Examiner

External Examiners are individuals from another institution or organisation who monitor the assessment processes of the University to ensure fairness and academic standards. They ensure that assessment and examination procedures have been fairly and properly implemented and that decisions have been made after appropriate deliberation. They also ensure that standards of awards and levels of student performance are at least comparable with those in equivalent higher education institutions.

External Examinerâ??s reports

External Examinersâ?? reports relating to this programme will be shared with student representatives and details of any actions carried out by the programme team/School in response to the External Examinersâ?? comments will be discussed. Students should contact their student representatives if they require any further information about External Examinersâ?? reports or the process for considering them.

The External Examiner for this programme is: *To be confirmed*
Name of Institution:
Position at current Institution:

Please note that it is inappropriate for students to make direct contact with External Examiners under any circumstances, in particular with regards to a studentâ??s individual performance in assessments. Other appropriate mechanisms are available for students, including the Universityâ??s appeals or complaints procedures and the UMSU Advice Centre. In cases where a student does contact an External Examiner directly, External Examiners have been requested not to respond to direct queries. Instead, External Examiners should report the matter to their School contact who will then contact the student to remind them of the other methods available for students. If students have any queries concerning this, they should contact their Programme Office (or equivalent).

Role and Responsibilities of Unit Leads

- To develop and update the unit specification in consultation with lecturers and programme directors, ensuring a coherent selection of teaching material and assessments to fit with the overall aim of the programme and its specifications
- To liaise with programme administrators and the lecturers on their unit to ensure that the information on their unit in the programme handbook is accurate
- To liaise with programme administrators and lecturers to organise examining, marking and student feedback

- To develop and monitor the Canvas E-Learning site for their unit, in liaison with lecturers for the sessions in their unit
- To liaise with students concerning queries relating to teaching and assessments for the unit that are not specific to an individual teaching session
- To attend programme meetings and the programme exam board in order to liaise with programme directors and student representatives
- To consider and act upon student feedback, staff feedback, and external examiner feedback, in order to modify the structure, content and processes within their unit, in discussion with the programme team

Responsibilities of the Student

- Pursuing the programme with a positive commitment, taking full advantage of the resources and facilities offered by the academic environment and, in particular, contact with the Supervisor, other staff and research students;
- Discussing with the Supervisor the type of guidance and comment believed to be most helpful, and agreeing a schedule of meetings;
- Ensuring that he/she is aware of the health and safety regulations and academic rules and regulations and codes of practice of the University;
- Successfully completing any training programme arranged within the prescribed time period;
- Taking the initiative in raising problems or difficulties, however elementary they may seem, bearing in mind that prompt discussion and resolution of problems can prevent difficulties and disagreements at a later stage;
- Maintaining the progress of the work in accordance with the stages agreed with the Supervisor, including in particular the presentation of written material as required, in sufficient time to allow for comments and discussion before proceeding to the next stage. Where possible, students will be given details of the work programme for the academic year at the beginning of the year;
- Agreeing with the Supervisor the amount of time to be devoted to the research and the timing and duration of holiday periods;
- Checking the completeness and accuracy of the text of the thesis submitted; failure to check the thesis carefully may result in the thesis being failed or cause a delay in the award of a degree.

Section B: Syllabus, Course Units and Route through the Programme

Syllabus

Year One

Compulsory Components

PHAR61630 Introduction to Pharmaceutical Science 1 (30 credits)

PHAR61730 Introduction to Pharmaceutical Science 2 (30 credits)

Year Two

Compulsory Components

PHAR61650 Specialist Pharmaceutical Science 1 (30 credits)

PHAR61750 Research Project 1 (30 credits)

Year Three

Compulsory Components

PHAR71880 Specialist Pharmaceutical Science 2 (30 credits)

PHAR61770 Research Project 2 (30 credits)

Course Unit Specifications

PHAR61630 Introduction to Clinical Pharmaceutical Science 1

PFHCS Co-ordinator: Dr Phil Macdonald

Course Unit Co-ordinators: Ruth Barnes (UoM), Sue Renn (UoM), Sarah Ward (UoM)

Credit Rating: 30 credits

- 20 credits â?? Professional Foundations of Healthcare and Clinical Science
- 10 credits â?? Introduction to Regulation and Quality Assurance

Course Unit Aims

This unit will provide trainees with context and foundations to their practice in healthcare as a Clinical Scientist. Central to this, the module provides students with an essential grounding in pharmaceutical quality assurance which underpins all GMP activities, and the means to ensure the provision of safe, effective, high quality patient centred care.

- Students will engage with lecturers and reading material to gain a full understanding of the regulatory framework governing pharmaceutical preparation and manufacture within the NHS, with a fundamental understanding of Pharmaceutical Quality Systems (PQS) .
- Trainees will develop a framework of skills and knowledge to evaluate and evolve practice in the context of the wider healthcare landscape. Throughout this module trainees will have opportunities to develop their professional skills.

The unit provides the students with an essential grounding in pharmaceutical quality assurance which underpins all GMP activities. Students will engage with lecturers and reading material to gain a full understanding of the regulatory framework governing pharmaceutical preparation and manufacture within the NHS.

It will also provide a fundamental understanding of Pharmaceutical Quality Systems (PQS) and the operational benefits and challenges of a robust system. The key documents of a PQS will be defined.

Course Unit Learning Outcomes

By the end of the course, students will be able to:

PFHCS (20 credits)

Knowledge and understanding:

1. Critically evaluate your personal responsibilities, challenges and limitations of your practice as a healthcare scientist in respect to the standards and ethical boundaries including confidentiality, informed consent and safeguarding.
2. Critically appraise the contribution of healthcare science and multi-professional working in the provision of patient care within the structure and function of health and social care including effective communication and leadership.
3. Critically evaluate the principles of methodologies which ensure the quality of practice in healthcare science.
4. Critically evaluate the principles of patient centred care applied to healthcare in the NHS including approaches to managing health which aim to promote wellbeing and reduce health inequalities.
5. Critically appraise the requirements for continuous development, evolution and improvement of services and standards in healthcare and innovations which impact healthcare science and healthcare.

Intellectual skills:

1. Critically reflect on professional and personal behaviour
2. Present scientific and clinical information appropriately
3. Formulate a critical argument
4. Evaluate scientific and clinical information
5. Compare and contrast a range of leadership models
6. Appraise the ethical foundations of professionalism, including critical reflection, and how these relate to the clinical scientist, the patient, the practice of healthcare science and the wider healthcare environment.

Practical skills:

1. Present information clearly in the form of verbal and written reports.
2. Communicate complex ideas and arguments in a clear and concise and effective manner to both clinical professional and lay individuals
3. Work effectively as an individual or part of a team.
4. Demonstrate Leadership

5. Take a patient history

Transferable skills and personal qualities:

1. Be able to communicate effectively with professional colleagues and service users.
2. Consistently operate within sphere of personal competence and level of authority.
3. Manage personal workload and objectives to achieve quality of care.
4. Work in partnership with colleagues, other professionals, patients and their carers to maximise patient care.

Introduction to Regulation and QA (10 credits)

Knowledge and understanding:

1. Discuss the role of the Clinical Scientist in Pharmaceutical Sciences in ensuring the safety of the patient, related to pharmaceutical preparation, manufacture and quality assurance.
2. Evaluate error reports relating to pharmaceutical preparation and the impact that these have had on pharmacy regulations and guidance.
3. Critically evaluate the application of regulatory controls to pharmaceutical technology and quality assurance.
4. Critically appraise the principles of quality assurance and EU good manufacturing practice (GMP) and quality management systems.
5. Critique documentation relating to pharmaceutical preparation, manufacturing, quality assurance and quality control.
6. Discuss the health and safety aspects of pharmaceutical technology and quality assurance.
7. Critique the requirements for outsourcing and purchasing of pharmaceutical products.

Intellectual skills:

1. Follow regulatory standards and guidance.
2. Evaluate scientific and clinical literature and present appropriately.
3. Critically appraise concepts and measures of quality and quality assurance and their links with the effective and efficient management of resources and improvement of service delivery.

Practical skills:

1. Prepare technical documents; product specifications, investigation reports.
2. Prepare risk assessments using a variety of tools and techniques.
3. Interpret complex data and report on the findings.
4. Prepare for an internal or external audit.
5. Identify shortcoming in existing procedure and recommend change.
6. Assess the impact of change

Transferable skills and personal qualities:

1. Read, interpret and apply standards and guidance to working practices.
2. Demonstrate professionalism and ethical awareness.
3. Communicate effectively with professional colleagues and service users.

4. Select and apply appropriate analysis or assessment techniques and tools.

Teaching and Learning Processes

1. A teaching block including face-to-face and online lectures and workshops.
2. E-learning: evidence-based learning supported by course notes, video/audio lectures, and discussion boards.

Assessment

- Reflective written assignment, 3,000 words (50%)
- 1 week formative discussion board
- Online e-assessment x5, 15 minutes (Formative)
- Written assignment (group of 4-6), 3,000 words (35%)
- Written assignment (individual reflection), 1,000 words (15%)

Recommended reading

Professional Foundations of Healthcare and Clinical Science:

Donaldson, Liam J. and Paul Rutter, 2017. Donaldsonsâ?? essential public health. (4TH Edition)

Tony Hope; Medical Ethics A Very Short Introduction: Oxford University Press 2004

Chloe Baxter, Mark G Brennan, Yvette Coldicott, Maaike Moller; the practical guide to Medical Ethics & Law 2nd Edition: PasTest (2005)

Barr J and Dowding L (2019) Leadership in Health Care Sage Publications (London) (4th Edition)

http://www.healthtalkonline.org/

http://www.england.nhs.uk/2013/03/26/nhs-constitution/

Introduction to Regulations and QA:

Beaney, A. 2016. Quality Assurance of Aseptic Preparation Services (5th Edition), http://www.rpharms.com/support-pdfs/rpsâ??qaaps-standards-document.pdf

EU Legislation â?? Eudralex

- Volume 1 â?? EU pharmaceutical legislation for medicinal products for human use
- Volume 2 â?? Notice to applicants and regulatory guidelines for medicinal products for human use
- Volume 3 â?? Scientific guidelines for medicinal products for human use
- Online at https://health.ec.europa.eu/medicinal-products/eudralex_en

Guidelines for good manufacturing practices for medicinal products for human and veterinary use (Volume 4)

- Chapter 1 â?? Pharmaceutical Quality System
- Chapter 4 â?? Documentation
- Chapter 8 â?? Complaints and Product Recall
- Chapter 9 â?? Self Inspection
- Part III â?? GMP related documents
    - Site Master File
    - Q9 Quality Risk Management
    - Q10 Note for Guidance on Pharmaceutical Quality System
- Online at https://health.ec.europa.eu/medicinal-products/eudralex_en

Explanatory Memorandum to the Human Medicines Regulations 2012 (2012 No. 1916)
Online at http://www.legislation.gov.uk/uksi/2012/1916/pdfs/uksiem_20121916_en.pdf

The Human Medicines Regulations 2012 (SI 2012 No. 1916)
Online at http://www.legislation.gov.uk/uksi/2012/1916/pdfs/uksi_20121916_en.pdf

The Medicines Act 1968
Online at http://www.legislation.gov.uk/ukpga/1968/67/pdfs/ukpga_19680067_en.pdf

MHRA Guidance Note 14: The supply of unlicensed medicinal products (â??specialsâ?•)
Online at https://www.gov.uk/government/publications/supply-unlicensed-medicinal-products-specials

Thalidomide and its sequelae
Online at http://www.sciencedirect.com/science/article/pii/S0140673612604681

WHO Quality Assurance of Pharmaceuticals (Volume 2)
Online at
http://www.who.int/medicines/areas/quality_safety/quality_assurance/QualityAssurancePharmVol2.pdf

PHAR61730 Introduction to Pharmaceutical Sciences 2

Unit leads:

RADIOPHARMACY: Bev Ellis (Consultant Radiopharmacist, CMFT), Victoria Gibson (Radiopharmacy Consultant)

ASEPTICS: Ruth Barnes, Sue Renn, and Sarah Ward (UoM)

PRODUCTION AND QUALITY CONTROL: Ruth Barnes, Sue Renn, and Sarah Ward (UoM)

Credit Rating: 30 credits

Course Unit Aims

The unit aims to provide students with background knowledge of radiopharmacy, aseptic preparation, pharmaceutical production and quality control. The unit provides a good proportion of practical study enabling students to appreciate how the theory applies in practice.

The radiopharmacy element allows students to appreciate the unique needs of the department in ensuring radiation protection.

The aseptic element provides students with an in-depth working knowledge of pharmaceutical microbiological aspects of aseptic manufacture and preparation. Students will also develop an ability to evaluate the use of cleanrooms and clean air devices to maintain patient safety.

The production and QC elements will prepare students to evaluate and develop services in production and QC of pharmaceuticals. Content includes principles and management of pharmaceutical production, requirements of QA in application to theory and practice of manufacturing and sterilisation of products and techniques used for analysis of starting materials, packaging components and finished pharmaceutical products

All elements will develop the studentsâ?? understanding of the principles of pharmaceutical science and formulation. Students will understand the process of designing a new product and building the analytical specifications and stability studies to bring a new product to market.

Course Unit Learning Outcomes

By the end of the course unit, students will be able to:

Knowledge and understanding:

Introduction to Radiopharmacy (10 credits):

1. Discuss the role of the Clinical Scientist in Pharmaceutical Science in ensuring the safety of the patient, with regard to the preparation, manufacture, quality assurance and quality control of radiopharmaceuticals.
2. Critically appraise the UK regulatory requirements and guidance relating to the design and operation of radiopharmacies and discuss the possible conflicts between these requirements.
3. Critically evaluate the radionuclides used in nuclear medicine and the different types of radiopharmaceuticals in routine clinical practice.
4. Apply integrative knowledge of the operation of a hospital radiopharmacy department and the activities undertaken in a hospital Nuclear Medicine department.
5. Critique the application of the principles of quality assurance in radiopharmacy.
6. Critically evaluate the application of the principles of radiation protection in radiopharmacy.
7. Demonstrate extended understanding of the interactions of radiation with biological systems.
8. Discuss the theory and practice of radiolabelling of blood cells.

Introduction to Aseptics (10 credits):

1. Discuss the role of the Clinical Scientist in Pharmaceutical Sciences in ensuring the safety of the patient, related to aseptic preparation, manufacture and quality assurance.
2. Discuss standards and guidance relevant to aseptic preparation and aseptic manufacture including the requirements for documentation in aseptic services.
3. Demonstrate extended understanding of how a cleanroom functions to maintain a clean environment.

4. Explain the principles of aseptic manipulation, transfer processes, and cleanroom comportment within pharmacy aseptic services.
5. Describe the principles of basic pharmaceutical microbiology and environmental monitoring in pharmaceutical aseptic services.
6. Critically appraise the application of cleaning and disinfection agents and methods pharmaceutical aseptic services.
7. Explain key chemical and physical reactions affecting the stability of medicinal products.
8. Critically appraise common errors in aseptic processes and their potential consequences.

Introduction to Production and Quality Control (10 credits):

1. Describe the stages of the manufacturing process of various product types.
2. Apply integrative knowledge of the principles of sterilisation by irradiation, filtration, gas, moist and dry heat.
3. Describe the principles of quality assurance in relation to pharmaceutical production.
4. Critically evaluate the routine analytical techniques used in quality control of pharmaceuticals.
5. Demonstrate a critical awareness of the process for defining a test specification.
6. Describe the role of the QC (MGPS) in testing piped medical gas systems

Intellectual skills:

1. Follow regulatory standards and guidance.
2. Evaluate scientific and clinical literature and present appropriately.
3. Critically appraise concepts and measures of quality and quality assurance and their links with the effective and efficient management of resources and improvement of service delivery.

Practical skills:

1. Prepare technical documents; product specifications, investigation reports.
2. Prepare risk assessments using a variety of tools and techniques.
3. Interpret complex data and report on the findings.
4. Prepare for an internal or external audit.
5. Identify shortcoming in existing procedure and recommend change.
6. Assess the impact of change.

Transferable skills and personal qualities:

1. Read, interpret and apply standards and guidance to working practices.
2. Demonstrate professionalism and ethical awareness.
3. Communicate effectively with professional colleagues and service users.
4. Select and apply appropriate analysis or assessment techniques and tools.

Teaching and Learning Processes

1. A teaching block including face-to-face and online lectures and workshops.
2. E-Learning: evidence-based learning supported by course notes, video/audio lectures and discussion boards.

Assessment

Radiopharmacy:

- 6-week discussion board (33%)

Aseptics:

- 15-minute video (33%)

Production/Quality Control:

- 1,000-word assignment (34%)

Recommended Reading

Radiopharmacy

1. Zolle, I (Ed) 2007 *Technetium-99m Pharmaceuticals: Preparation and Quality Control in Nuclear Medicine*. Berlin: Springer ISBN-10: 3-540-33989-2 ISBN-13: 978-3-540-33989-2
2. Theobald, T. 2010 *Sampsonâ??s Textbook of Radiopharmacy 4th Edition*. London: Pharmaceutical Press ISBN-10: 0853697892 ISBN-13: 978-0853697893
3. ARSAC: Notes for guidance
   Online at http://www.arsac.org.uk/notes_for_guidance/
4. Saha, G.B. 1998 *Fundamentals of Nuclear Pharmacy 5th Edition*. New York: Springer Science and Business Media ISBN-10: 0387983414 ISBN-13: 978-0387983417
5. Welch, M.J and Redvanly, C. S. (Ed) 2002 *Handbook of Radiopharmaceuticals: Radiochemistry and applications*. Chippenham: John Wiley & Sons Ltd ISBN-10: 0471495603 ISBN-13: 978-0471495604
6. Kowalsky, R and Falen, S.W. 2011 *Radiopharmaceuticals in Nuclear Pharmacy and Nuclear Medicine 3rd Edition*. Washington: American Pharmacists Association ISBN-10: 1582121184 ISBN-13: 978-1582121185
7. Quality Assurance of Radiopharmaceuticals
   https://www.bnms.org.uk/page/UKRGGuidelines
8. Guidelines for the safe preparation of radiolabelled blood cells
   https://www.bnms.org.uk/page/UKRGGuidelines
9. Responsibilities of Chief Pharmacists for the purchase and supply of radiopharmaceuticals
   Online at: https://www.bnms.org.uk/page/UKRGGuidelines

Aseptics

1. Farwell, J. 1994 *Aspetic dispensing for NHS patients: a guidance document for pharmacists in the United Kingdom*. London: Department of Health
2. Lund W. (Ed) 1994 *The Pharmaceutical Codex 12th Edition*. London: Pharmaceutical Press ISBN-10: 0853692904 ISBN-13: 978-0853692904
3. Validation, p.389-397
4. Pharmaceutical Microbiology, p.483-508
5. Aseptic Processing, p.561-568

6. Cleanrooms for pharmaceutical production, p.569-576
7. Beaney, A. (Ed) 2006 *Quality Assurance of Aseptic Preparation Services: 4th Edition*. London: Pharmaceutical Press ISBN 0-85369-615-2
8. Guidelines for good manufacturing practices for medicinal products for human and veterinary use (Volume 4)
    1. Annex 1 â?? Manufacture of sterile manufactured products. Online at https://health.ec.europa.eu/document/download/e05af55b-38e9-42bf-8495-194bbf0b9262_en?filename=20220825_gmp-an1_en_0.pdf
9. Allwood, M (Ed. et al) 2001 *The Cytotoxics Handbook 4th Ed*. Oxford: Radcliffe Medical Press ISBN 1-8577-5504-9
10. Midcalf, B, Phillips, WM, Neiger JS and Coles T (Eds) 2004 *Pharmaceutical Isolators* London: Pharmaceutical Press ISBN: 978-0-85369
11. Executive Letter â?? EL (96) 95 â?? issued 20 December 1996
12. Executive Letter â?? EL (97) 52 â?? issued 22 August 1997

Introduction to Production & QC:

1. EU Legislation â?? Eudralex. Guidelines for good manufacturing practices for medicinal products for human and veterinary use (Volume 4)
    1. Chapter 3 â?? Premises and Equipment
    2. Chapter 4 â?? Documentation
    3. Chapter 5 â?? Production
2. Lund W. (Ed) 1994 The Pharmaceutical Codex 12th Edition. London: Pharmaceutical Press ISBN 0-8536-9290
3. HTM 2010
4. HTM 2030
5. HTM 2031
6. Lund W. (Ed) 1994 *The Pharmaceutical Codex 12th Edition*. London: Pharmaceutical Press ISBN-10: 0853692904 ISBN-13: 978-0853692904
    1. Section 1 â?? Dosage Forms
    2. Section 2 â?? Product Design, Development and Presentation
7. Aulton, M. E. (Ed) *Aultonâ??s Pharmaceutics: The Design and Manufacture of Medicines 3rd Edition*. Edinburgh: Churchill Livingston ISBN 10:0443101086, 13:978-0443101083 (earlier editions of this book were called Pharmaceutics: The Science of Dosage Form Design)
8. Rees, J.A. and Smith, I 2011 *Introduction to Pharmaceutical Calculations 3rd Edition*. London: Pharmaceutical Press ISBN 10:8536 96039, 13:978 0853696032
9. Lapham, R and Agar H 2009 *Drug Calculations for Nurses 3rd Edition*. London: Hodder Arnold ISBN-10: 0340987332, ISBN-13: 9780340987339
10. Florence, A.T. and Attwood, D 2011 *Physicochemical Principles of Pharmacy 5th Edition*. London: Pharmaceutical Press ISBN-13: 9780853696087
11. Patrick, J. Sinko 2010 *Martinâ??s Physical Pharmacy 6th Edition*. Philadelphia: Lippincott Williams and Wilkins ISBN 0-8121-1438-8
12. Miller J.C. and Miller J. 2010 *Statistics and Chemometrics for Analytical Chemistry 6th Edition*. Prentice Hall ISBN-10: 0273730428 ISBN-13: 978-0273730422
13. Jackson, M. and Lowey, A. 2010 *Handbook of Extemporaneous Preparation 1st Edition*. London: Pharmaceutical Press ISBN-13: 9780853699019

14. MHRA Guidance Note 14: The supply of unlicensed medicinal products (â??specialsâ?•) Online at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/373505/The_supply_o
15. Guidelines for good manufacturing practices for medicinal products for human and veterinary use (Volume 4)
    1. Chapter 6 â?? Quality Control
       Online at https://health.ec.europa.eu/document/download/c74c8720-27bf-4252-808f-d65a206a90bb_en?filename=2014-11_vol4_chapter_6.pdf
16. British Pharmacopoeia 2015
17. Skoog, West and Holler, 2000 *Analytical Chemistry: An introduction 7th Edition*. London: Thomson Learning ISBN 0-03-020293-0
18. Miller JN, Miller JC, 2010 *Statistics and Chemometrics for Analytical Chemistry,* Prentice Hall, ISBN-10 0273730428, ISBN-13 978-0273730422
19. Denyer, Hodges, Gorman and Gilmore (Ed), 2011 *Hugo and Russellâ??s Pharmaceutical Microbiology (8th Edition)* Wiley-Blackwell, ISBN-10 1444330632, ISBN-13 978-1444330632
20. HTM 0201 Medical gas pipeline systems

For non-chemists

1. Letts *GCSE Questions and Answers: Chemistry*. London: Letts Educational Ltd. ISBN 1-85805-647-0

PHAR61650 Specialist Pharmaceutical Science 1

Unit Leads:

ASEPTICS: Louisa Knowles (Advanced Pharmacist for Technical Services, UHB), Ruth Barnes, Sue Renn and Sarah Ward (UoM)

RADIOPHARMACY: Bev Ellis (Consultant Radiopharmacist, CMFT), Victoria Gibson (Radiopharmacy consultant)

RESEARCH METHODS: Dr Alain Pluen, Ruth Barnes, Sue Renn, and Sarah Ward (UoM)

Credit Rating: 30 credits

Course Unit Aims

The specialist pharmaceutical science unit comprises three 10 credit units.

The Aseptic portion of this unit builds on the background knowledge provided in Introduction to Aseptics. Students will be able to explain the function and operation of equipment and clean rooms. They will know and understand commissioning procedures and be in a position to critically evaluate monitoring data and diagnose problems.

The aim of Radiopharmacy is to build on the background knowledge provided in Introduction to Radiopharmacy. Students will gain an in-depth knowledge of how to operate at a much higher level

within a radiopharmacy dealing with complex issues that may arise. They will also learn of novel drug development and imaging modalities.

The research methods module will deliver the learning to enable students to undertake an evidence-based literature review, critically appraise the output, draw appropriate conclusions and report the findings, and where appropriate, use the findings to inform a research project.

Course Unit Learning Outcomes

By the end of the course unit, students will be able to:

Aseptics (10 credits):

Knowledge and understanding:

1. Critically evaluate standards, practices and quality assurance arrangements relating to aseptic preparation and manufacture of medicines, the differences between these, and their application to patient safety and patient-centred care.
2. Critically analyse the procedures required for outsourcing and sub-contracting services relating to aseptics.
3. Critically analyse pharmaceutical microbiological aspects of aseptic preparation and their application in the workplace.
4. Critically evaluate the design, commissioning, and use of clean rooms/clean air devices.
5. Critically evaluate process and operator validations.
6. Discuss human factors and how it relates to errors, deviations and CAPA.
7. Apply integrative knowledge of the formulation, stability and preparation of specialist, aseptic dose forms.
8. Investigate emerging therapies and technologies related to aseptic services.

Intellectual skills:

1. Interpret stability data to determine the shelf life of the product.
2. Critically evaluate a range of microbiological and physical monitoring methods.
3. Construct risk assessments on preparation activities.

Practical skills:

1. Interpret and analyse monitoring data and diagnose problems.
2. Assist with clean room commissioning and routine monitoring.

Transferable skills and personal qualities:

1. Effectively utilise a range of information sources.
2. Demonstrate capacity for self-learning and independent thinking and to utilise problem solving skills
3. Demonstrate effective communication skills (verbal and written).
4. Be able to set priorities and link these with effective time management.
5. Critically evaluate their personal performance both as an individual and within a team

6. Demonstrate skills in working collegiately and effectively with others as a member of a team.

Radiopharmacy (10 credits):

Knowledge and understanding:

1. Explain the role of the Clinical Scientist in Pharmaceutical Science in the diagnosis and treatment of disease using radiopharmaceuticals, including the contribution to patient management, patient safety and patient-centred care.
2. Critically evaluate commonly used diagnostic and therapeutic radiopharmaceuticals.
3. Discuss the principles of PET imaging, commonly used PET radiopharmaceuticals and the organisation of a PET radiopharmacy.
4. Critically appraise the preparation and clinical use of radiopharmaceutical and issues which may arise.
5. Demonstrate a critical awareness of radiation protection and safe working in radiopharmaceutical preparation.
6. Describe the functions of the different cell types routinely labelled in nuclear medicine, outline the different labelling methods and the most common clinical indications for these radiopharmaceuticals.
7. Discuss innovations and clinical trials within radiopharmacy.

Intellectual skills:

1. Interpret stability data to determine the shelf life of the product.
2. Critically evaluate a range of microbiological and physical monitoring methods.
3. Critically appraise the impact of the radiopharmaceutical production process on the quality of clinical outcomes.

Practical skills:

1. Work safely in the radiation environment.
2. Perform a range of radiopharmaceuticals.
3. Perform radiochemical purity testing on a range of radiopharmaceuticals and interpret results
4. Interpret and analyse monitoring data and diagnose problems.
5. Assist with clean room commissioning and routine monitoring.

Transferable skills and personal qualities:

1. Effectively utilise a range of information sources.
2. Demonstrate capacity for self-learning and independent thinking and to utilise problem solving skills
3. Demonstrate effective communication skills (verbal and written).
4. Be able to set priorities and link these with effective time management.
5. Critically evaluate their personal performance both as an individual and within a team
6. Demonstrate skills in working collegiately and effectively with others as a member of a team
7. Show appreciation of the way in which legislation, standards and quality management interface with normal working life.

Research Methods (10 credits):

Knowledge and understanding:

1. Discuss and critically evaluate the context within which research, development, innovation and audit are undertaken to improve patient care, promote innovation and improve service delivery.
2. Describe, compare and contrast a range of research methods/approaches, including cohort studies, qualitative, quantitative, systematic review, sampling techniques and clinical trials.
3. Explain and justify current UK ethical and governance frameworks and processes spanning the conduct of human and animal research, innovation and audit.
4. Critically evaluate the literature/evidence base to identify a research question and create a new approach or technique to improve patient care or service delivery.
5. Discuss and justify the research, audit and innovation process from idea generation to dissemination/implementation, including patient/user involvement and intellectual property.
6. Describe and evaluate a range of data analysis techniques to ensure the validity, reliability and appropriateness to the research aim, design and conclusion.
7. Describe how clinical guidelines are produced and the concept of evidence-based practice, including the role of current statutory and advisory regulatory bodies.
8. Identify potential sources of research and innovation funding for healthcare science/Clinical Scientists.

Intellectual skills:

1. To synthesis, analyse and systematically combine information obtained from different sources to develop a defined original research question and then to address it through the development of a coherent research project.

Practical skills:

1. Work within the principles and practice of instruments, equipment and methodology used in clinical pharmaceutical science.
2. Support safe storage and distribution of medicinal products.
3. Identify validation requirements for any changes to processes.

Transferable skills and personal qualities:

1. The ability to plan and devise a framework and timetable for action and carry these out systematically, either for individual purposes or in a group context.
2. Project management; taking responsibility for and planning a project from beginning to end.
3. Selection and use of appropriate methods to find solutions.

Teaching and Learning Processes

1. Teaching blocks including face-to-face and online lectures and workshops.
2. E-Learning: evidence-based learning supported by course notes, video/audio lectures and discussion boards.

Assessment

Aseptics:

- Written assignment, 2,000 words (50%)

Radiopharmacy:

- Written assignment, 2,000 words (50%)

Research Methods:

- Project Proposal, 1,000 words (pass/fail)
- Formative â?? Presentation on project proposal, 10 minutes (pass/fail)

Recommended Reading

Aseptics:

1. Farwell, J. 1994 *Aspetic dispensing for NHS patients: a guidance document for pharmacists in the United Kingdon*. London: Department of Health
2. Lund W. (Ed) 1994 *The Pharmaceutical Codex 12th Edition*. London: Pharmaceutical Press ISBN 0-8536-9290
3. Beaney, A. (Ed) 2006 *Quality Assurance of Aseptic Preparation Services*: *5th Edition*. London: Pharmaceutical Press ISBN 0-85369-615-2
4. Sandle T, Saghee MR 2013 *Cleanroom Management in Pharmaceuticals and Healthcare*. Euromed Communications Ltd. ISBN 978-1-899015-83-2

Radiopharmacy:

1. Zolle, I (Ed) 2007 *Technetium-99m Pharmaceuticals: Preparation and Quality Control in Nuclear Medicine*. Berlin: Springer ISBN-10: 3-540-33989-2 ISBN-13: 978-3-540-33989-2
2. Theobald, T. 2010 *Sampsonâ??s Textbook of Radiopharmacy 4th Edition*. London: Pharmaceutical Press ISBN-10: 0853697892 ISBN-13: 978-0853697893
3. ARSAC: Notes for guidance
   Online at http://www.arsac.org.uk/notes_for_guidance/
4. Saha, G.B. 1998 *Fundamentals of Nuclear Pharmacy 5th Edition*. New York: Springer Science and Business Media ISBN-10: 0387983414 ISBN-13: 978-0387983417
5. Welch, M.J and Redvanly, C. S. (Ed) 2002 *Handbook of Radiopharmaceuticals: Radiochemistry and applications*. Chippenham: John Wiley & Sons Ltd ISBN-10: 0471495603 ISBN-13: 978-0471495604
6. Kowalsky, R and Falen, S.W. 2011 *Radiopharmaceuticals in Nuclear Pharmacy and Nuclear Medicine 3rd Edition*. Washington: American Pharmacists Association ISBN-10: 1582121184 ISBN-13: 978-1582121185

Research Methods:

1. Scientific review writing guidelines from:
   The Cochrane Collaboration (http://www.cochrane.org/resources/handbook/)
2. Mepham, B. Bioethics: an introduction for the biosciences. Oxford University Press.
3. Talbot-Smith A and Pollock A (2006) The new NHS: A guide: A Guide to Its Funding, Organisation and Accountability Routledge (London)
4. Bland, M. 2000. Introduction to Medical Statistics, 3rd Edition. OUP
5. Bowers, D, House, a, Owens. D. (2006) Understanding Clinical Papers. Wiley & Sons.
6. Rowntree, D. 2003. Statistics without tears: a primer for non-mathematicians. Allyn and Bacon, London.
7. Wardlaw, A.C. 2000. Practical Statistics for Experimental Biologists, 2nd edition. Wiley
8. Zar, H. 1998. Biostatistical Analysis, 4th Edition, Prentice

PHAR61750 Research Project 1

Academic Course Unit Coordinator: Dr Alain Pluen, Ruth Barnes, Sue Renn, and Sarah Ward (UoM)

Practice-based Course Unit Coordinator: Each student will be supervised by their own supervisors (NHS and UoM)

Credit Rating: 30 credits

Course Unit Aims

The unit aims to provide students with a unique experience of designing and proposing an original research project. It will develop the studentsâ?? ability to critically appraise published research, formulate and work with a relevant research question, understand and apply appropriate research and data-analytic methodologies. Students will refine scientific writing and presentation skills and will demonstrate independent learning skill.

Course Unit Learning Outcomes

Having attended the course, students will be able to:

Knowledge and understanding:

1. Discuss the stages of the research and innovation process from conceptualisation to dissemination and if appropriate translation into practice
2. Describe the purpose and importance of different kinds of research including scientific or clinical research; translational research; operational and policy research; clinical education research; innovation; service development; and supporting professional service users and relate these to the roles undertaken by Clinical Scientists in the traineeâ??s specialism.
3. Discuss and evaluate the use of reference manager systems.
4. Justify the rationale for research governance and ethical frameworks when undertaking research or innovation in the NHS.
5. Describe the process and requirements for publication in a peer reviewed journal and the current system of grading research publications.

Intellectual skills:

1. Critically demonstrate considerable in-depth skills in terms of research; critical thinking; reasoning; and analysis and synthesis of information.
2. Generate timely and theoretically grounded research questions.

Practical skills:

1. Design, plan and undertake a research project to test a hypothesis from conception to completion/archiving in accordance with ethical and research governance regulations drawing on expert advice where necessary and involving patients and service users.
2. Plan and conduct a detailed, focused and current literature search
3. Implement and manage data collection
4. Conduct appropriate analytical techniques
5. Manage and manipulate datasets

Transferable skills and personal qualities:

1. Demonstrate independent thought
2. Develop self-management project skills (e.g. time management, prioritisation of tasks)

Teaching and Learning Processes

Students carry out their research project in their place of work and each has an approved supervisor who they are expected to meet regularly over the period of the dissertation. The remainder of the time is spent carrying out the literature search, developing a method and doing the research finally presenting their results both orally and as a 10,000 â?? 15,000 word dissertation.

Students are supported by the academic supervisor, unit lead and programme director throughout the unit via telephone, emails and visits where possible. In addition, all students should have a work-based tutor who offers them subject specific advice and personal support.

Assessment

- Written assignment (part 1), 4,000-8,000 words. This assignment is not weighted, but must be a PASS
- Presentation, 15 minutes. This assignment is not weighted, but must be a PASS.

Recommended Reading

N/A â?? dependent on individual research project proposed

PHAR71880 Specialist Pharmaceutical Science 2

Unit Leads:

Quality Control: Ruth Barnes (UoM)

Production: Helen Callaby

Preparation for Practice: John Landers (Deputy Director of Pharmacy, Manchester Founder Trust), Maloni Talbot (Deputy Chief Pharmacist, Warrington and Halton Teaching Hospitals), Ruth Barnes, Sue Renn, Sarah Ward (UoM)

Credit Rating: 30 credits

Course Unit Aims:

The specialist pharmaceutical science unit comprises three 10 credit units.
The quality control unit aims to develop studentsâ?? knowledge and understanding of the techniques used for analysis of starting materials, packaging components and finished pharmaceutical products. Students will also be given the knowledge to decide on appropriate analytical methods for specific application and tools to critically evaluate data.
Production will prepare students to evaluate and develop services in production of pharmaceuticals. Content includes principles and management of pharmaceutical production, requirements of QA in application to theory and practice of manufacturing and sterilisation of products.
Preparation for practice will enable the trainee to gain experience in the skills required for the management of pharmaceutical services. This module aims to provide the trainee with a well-rounded skill set and to enable them to build the expertise necessary for leadership in practice in the NHS.

Course Unit Learning Outcomes:

By the end of this course, students will be able to:

Quality Control (10 credits)

- Discuss the role of the Clinical Scientist in Quality Control in ensuring the safety of the patient.
- Apply integrative knowledge of pharmaceutical microbiological analytical techniques and instruments.
- Demonstrate extended understanding of pharmaceutical chemical analytical techniques and instruments.
- Apply integrative knowledge of techniques and equipment used in the monitoring of pharmaceutical cleanroom environments.
- Critically evaluate the quality of medicinal products, including raw materials, licensed and unlicensed products, â??specialsâ??, IMPs, medical and surgical devices, and medical gases.
- Describe the process of writing a stability protocol, considering method suitability and validation.
- Demonstrate a critical awareness of the process for investigating questionable laboratory results, out of specification and out of trend data.
- Perform analytical method validation and equipment validation.
- Interpret QC data and investigate questionable data/results.
- Work within the principles and practice of instruments, equipment and methodology used in pharmacy technical services.
- Critically evaluate data and investigate anomalous results.
- Identify validation requirements for any changes to processes.
- Project management; taking responsibility for and planning a project from beginning to end.

- Selection and use of appropriate methods to find solutions.

Production (10 credits)

- Discuss the role of the Clinical Scientist in production in ensuring the safety of the patient, particularly related to the manufacture of licensed and unlicensed pharmaceutical products and investigational medicinal products.
- Critically evaluate manufacturing processes including the principles of pharmaceutical formulation and processing.
- Apply integrative knowledge of the properties of APIs and excipients in pharmaceutical products.
- Explain the factors affecting formulation, stability and preservation of pharmaceutical product.
- Perform mathematical calculations relevant to pharmaceutical formulation.
- Describe the criticality of final packaging.
- Define critical control points and critical quality attributes of production processes.
- Demonstrate a critical awareness of the process for investigating problems during manufacturing.
- Appraise and interpret information from different sources in order to develop a coherent critical analysis of issues relating to the practice and delivery of clinical pharmaceutical science services.
- Critically appraise the impact of the pharmaceutical production process on the quality of the clinical outcomes.
- Reviewing of technical agreements with suppliers and service providers.
- Demonstrate professionalism and ethical awareness.
- Apply the principles of EU Good Manufacturing Practice (GMP) to develop a safe new product.
- Perform all manufacturing activities in accordance with requirements for Good Manufacturing Practice (GMP) and Pharmaceutical Quality Systems.
- Work within the principles and practice of instruments, equipment and methodology used in pharmacy technical services.
- Support safe storage and distribution of medicinal products.
- Identify validation requirements for any changes to processes.
- Communicate effectively in a variety of settings with a range of individuals.
- Use logical and systematic approaches to problem-solving and decision-making.

Preparation for Practice (10 credits)

- Critically appraise departmental budgeting and reporting systems.
- Describe the requirements for tenders within the NHS.
- Explain the requirements for contracts and SLAs with external service providers.
- Summarise the guidance relating to training in NHS manufacturing and pharmacy technical services.
- Critically appraise different methods of training.
- Critically evaluate NHS management structures.
- Critically discuss and evaluate the principles of managing small teams within an NHS department.
- Evaluate budget and contracts data and present appropriately.
- Critically appraise concepts and measures of training and management and their links with the effective and efficient management of resources and improvement of service delivery.
- Interpret and analyse budget and contracts data and prepare reports.
- Critically appraise training methods.
- Critically discuss and evaluate the principles of managing small teams within an NHS department.

- Effectively utilise a range of information sources.
- Demonstrate capacity for self-learning and independent thinking and to utilise problem solving skills
- Demonstrate effective communication skills (verbal and written).
- Be able to set priorities and link these with effective time management.
- Critically evaluate their personal performance both as an individual and within a team
- Demonstrate skills in working collegiately and effectively with others as a member of a team.

Teaching and Learning Methods:

A teaching block including face-to-face and online lectures and workshops.
E-Learning: evidence-based learning supported by course notes, audio lectures and discussion boards

Assessment:

Quality Control

- 2,000 words assignment (33%)

Production

- 2, 000 words assignment (33%)

Preparation for Practice

- 2,000 words assignment (34%)

Recommended Readings:

Quality Control

1. Guidelines for good manufacturing practices for medicinal products for human and veterinary use (Volume 4)
    1. Chapter 6 â?? Quality Control
    Online at https://health.ec.europa.eu/document/download/c74c8720-27bf-4252-808f-d65a206a90bb_en?filename=2014-11_vol4_chapter_6.pdf
2. British Pharmacopoeia 2014
3. Skoog, West and Holler, 2000 *Analytical Chemistry: An introduction 7th Edition*. London: Thomson Learning ISBN 0-03-020293-0
4. Miller JN, Miller JC, 2010 *Statistics and Chemometrics for Analytical Chemistry,* Prentice Hall, ISBN-10 0273730428, ISBN-13 978-0273730422
5. Denyer, Hodges, Gorman and Gilmore (Ed), 2011 *Hugo and Russellâ??s Pharmaceutical Microbiology (8th Edition)* Wiley-Blackwell, ISBN-10 1444330632, ISBN-13 978-1444330632
6. HTM 0201 Medical gas pipeline systems

For non-chemists

1. Letts *GCSE Questions and Answers: Chemistry*. London: Letts Educational Ltd. ISBN 1-85805-647-0

Production

1. EU Legislation â?? Eudralex. Guidelines for good manufacturing practices for medicinal products for human and veterinary use (Volume 4)
    a. Chapter 3 â?? Premises and Equipment
    b. Chapter 4 â?? Documentation
    c. Chapter 5 â?? Production
2. Lund W. (Ed) 1994 The Pharmaceutical Codex 12th Edition. London: Pharmaceutical Press ISBN 0-8536-9290
3. HTM 2010
4. HTM 2030
5. HTM 2031

Preparation for Practice

1. NHS Budgets
    a. https://www.kingsfund.org.uk/projects/nhs-in-a-nutshell/nhs-budget
    b. https://www.england.nhs.uk/publications/business-plan/our-2022-23-business-plan/
    c. https://www.bma.org.uk/advice-and-support/nhs-delivery-and-workforce/funding/health-funding-data-analysis
    d. https://researchbriefings.files.parliament.uk/documents/SN00724/SN00724.pdf
    e. https://www.nuffieldtrust.org.uk/news-item/the-past-present-and-future-of-government-spending-on-the-nhs
2. NHS Commissioning
    a. https://www.england.nhs.uk/commissioning/#:~:text=What%20is%20commissioning%3F,get%
3. NHS Tendering Process
    a. https://www.healthcare-tenders.co.uk/nhs-tendering-process-explained
    b. https://www.england.nhs.uk/integrated-care-pioneers/resources/procurement/
    c. https://resolution.nhs.uk/wp-content/uploads/2021/04/CG21-Procurement-Policy-and-Procedure.pdf
    d. https://www.property.nhs.uk/media/3632/nhsps-suppliers-guide.pdf
4. NHS Structure https://www.england.nhs.uk/get-involved/nhs/
    a. https://www.england.nhs.uk/integratedcare/integrated-care-in-your-area/
    b. https://medicalschoolexpert.co.uk/the-structure-of-the-nhs/
5. Training Theory
    a. https://tips.uark.edu/using-blooms-taxonomy/
    b. https://en.wikiversity.org/wiki/Instructional_design/Psychomotor_behaviors/Introduction
    c. https://www.hee.nhs.uk/sites/default/files/documents/Improving%20safety%20through%20edu
    d. https://www.educationcorner.com/learning-theories-in-education/

PHAR61770 Research Project 2

Academic Course Unit Co-ordinator: Dr Alain Pluen, Ruth Barnes, Sue Renn, and Sarah Ward (UoM)

Practice-based Course Unit Coordinator: Each student will be supervised by their own supervisors (NHS and UoM).

Credit Rating: 30 credits

Course Unit Aims

The unit aims to provide students with a unique experience of designing, conducting and reporting an independent, original research project.

The students will conduct a piece of empirical research that either addresses a specific research question in the field of clinical pharmaceutical sciences or involves the development and evaluation of new or existing technologies.

The students will be required to undertake a thorough systematic review of the scientific literature relevant to the project, which will be written up and form the introduction to the dissertation. The dissertation will also contain a clear and informed description of the methodologies employed and presentation and analysis of the data generated and a logical, scientifically valid and robust discussion of the findings.

Students will be equipped with the skills to design and develop research proposals to constantly improve and develop clinical pharmaceutical sciences.

Course Unit Learning Outcomes

By the end of this course, students will be able to:

Knowledge and understanding:

1. Discuss the stages of the research and innovation process from conceptualisation to dissemination and if appropriate translation into practice
2. Describe the purpose and importance of different kinds of research including scientific or clinical research; translational research; operational and policy research; clinical education research; innovation; service development; and supporting professional service users and relate these to the roles undertaken by Clinical Scientists in the traineeâ??s specialism.
3. Discuss and evaluate the use of reference manager systems.
4. Justify the rationale for research governance and ethical frameworks when undertaking research or innovation in the NHS.
5. Describe the process and requirements for publication in a peer reviewed journal and the current system of grading research publications

Intellectual skills:

1. Critically analyse, evaluate and interpret data from the specific enquiry.
2. Apply appropriate and relevant statistical tools.

Practical skills:

1. Analyse the data using appropriate methods and statistical techniques and interpret, critically discuss and draw conclusions from the data.
2. Prepare a written project that describes and critically evaluates the research project clearly identifying the strengths and weaknesses.
3. Present a summary of the research project and outcome that conforms to the format of a typical scientific presentation at a national or international scientific meeting, responding to questions appropriately.
4. Prepare a summary of the research project suitable for non-specialist and lay audience.

Transferable skills and personal qualities:

1. In-depth and extensive capabilities in the analysis and synthesis of new and past evidence on the topic, as demonstrated and applied to their area of research
2. Engage in systematic and critical reflection of personal practice and the practice of others in relation to the enquiry.

Teaching and Learning Processes

Students carry out their research project in their place of work and each has an approved supervisor who they are expected to meet regularly over the period of the dissertation. The remainder of the time is spent carrying out the literature search, developing a method and doing the research finally presenting their results both orally and as a 10,000 â?? 15,000 word dissertation.

Students are supported by the academic supervisor, unit lead and programme director throughout the unit via telephone, emails and visits where possible. In addition, all students should have a work-based tutor who offers them subject specific advice and personal support.

Assessment

Dissertation of 10,000 â?? 15,000 words (100%)

Recommended Reading

N/A â?? dependent on individual research project proposed