PTQA Handbook 2025-26

Description

MSc Pharmaceutical Technology
and Quality Assurance

PROGRAMME HANDBOOK

2025/26

Division of Pharmacy and Optometry

School of Health Sciences

Faculty of Biology, Medicine and Health

Welcome to the Programme

MSc Pharmaceutical Technology and Quality Assurance

Welcome to the Pharmaceutical Technology and Quality Assurance postgraduate programme.

This student handbook provides details of the University of Manchester Programme leading to the MSc in Pharmaceutical Technology and Quality Assurance and the Diploma/Certificate (exit awards). 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 Health 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 the contact details for your Programme Team,

Ruth Barnes
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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

The aim of the Pharmaceutical Technology and Quality Assurance (PTQA) programme is to develop NHS, and industry staff, in the technical pharmacy specialties related to manufacture of medicines including manufacturing, aseptic compounding, radiopharmacy, clinical trials, quality assurance and quality control. The programme will equip students with the necessary transferable, intellectual and professional skills to permit them to develop their academic and professional potential throughout their career by fostering lifelong learning in the pursuit of excellence in scholarship and practice.

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

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

Compulsory unit:

- **PHAR61780** Foundations of PTQA
- **PHAR61730** Introduction to Pharmaceutical Science 2
    - Introduction to Radiopharmacy
    - Introduction to Aseptics
    - Introduction to Production/QC

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

Compulsory units:

- **PHAR62780** Advanced Pharmaceutical Science 1
- **PHAR62790** Advanced Pharmaceutical Science 2

Students choose SIX options from the TEN subjects below to be studied in the two compulsory units above:

- Advanced QA
- Aseptics
- Clinical trials
- Medical gas testing
- Preparation for Practice
- Production
- Quality Control
- Radiopharmacy
- Research methods
- Role of the QP

During the third year of the course, students will undertake a research project and will be enrolled on course unit **PHAR61810.**

The taught element of the course comprises seminars, workshops and several forms of independent learning. Throughout the third year, 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 technology and quality assurance. 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 technology and quality assurance or professional training. The course will produce students who:

1. Critically apply knowledge of pharmaceutical technology and quality assurance to a range of specialist medicines management areas in the field of pharmaceutical technology and quality assurance.
2. Critically analyse evidence to make judgements regarding complex quality assurance issues in pharmaceutical practice.
3. Lead on enhancing the achievement of standards and upholding necessary standards and legal requirements in specific areas of practice.
4. Apply in-depth knowledge and experience of techniques for evaluating and managing the risks to patients from pharmaceutical technology and quality assurance.
5. Take a proactive and self-reflective role in working.
6. Critically and creatively evaluate current issues in practice and conduct research which advances pharmaceutical technology and quality assurance.

Programme Learning Outcomes

Students, on successful completion of the MSc programme, will be able to:

- Apply knowledge of pharmaceutical technology and quality assurance to specific areas of practice related to their career pathway.
- Display a critical understanding of the regulatory processes and practices involved in conducting research in a health service or academic setting.
- Understand the role of the technical services professional in ensuring the safety of the patient, particularly related to manufacture and quality control with reference to key patient care pathways.
- Discuss the principles of Quality Assurance, EU Good Manufacturing Practice (GMP) and Pharmaceutical Quality Systems and be able to critically evaluate the application of regulatory controls.
- Describe and critically evaluate the classification of controlled areas, the monitoring of such areas and the gowning requirements. Students should be familiar with the routine operation and cleaning of facilities and clean air devices.
- Explain the principles of aseptic manipulation and discuss the key standards, practices and Quality Assurance arrangements relating to aseptic preparation and dispensing of medicines and their application to patient safety and patient centred care.

- Describe the principles of pharmaceutical formulation (properties of excipients and ingredients, criticality of final packaging, principles of sterilisation) and manufacturing. Students should be able to explain the factors affecting formulation, stability and preservation.
- Discuss the role of pharmacy technical services staff in radiopharmacy in the diagnosis and treatment of disease using radiopharmaceuticals and be able to recognise the different types of radiopharmaceuticals in routine clinical practice together with any particular problems arising from their use.
- Discuss the importance of radiation hygiene and safe working in radiopharmaceutical preparation.
- Systematically and critically employ the knowledge and understanding obtained during the taught component of the programme to address an original research question through the design and undertaking of a comprehensive research project and production of a dissertation.
- Critically reflect on and challenge their own practice, the practice of others and the organisation and delivery of pharmacy technical services in order to ensure use of appropriate values and best practice in delivering patient care and management.
- Appraise and interpret information from different sources in order to develop a coherent critical analysis of issues relating to the practice and delivery of pharmacy technical services.
- Perform detailed investigations in order to establish the root cause of exceptions using a variety of tools available. To perform detailed risk assessments and to allocate appropriate corrective and preventive actions (CAPA).
- Critically evaluate the performance of new analytical technologies in the context of the specific requirements of the health service.
- Critically analyse and objectively evaluate data from the key performance indicators of the Pharmaceutical Quality System.
- Critically appraise the impact of the pharmaceutical production process on the quality of the clinical outcomes.
- Synthesise, 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.
- Interpret and interrogate scientific data statistically leading to the generation of valid and defensible scientific conclusions.
- Apply the principles of EU Good Manufacturing Practice (GMP) to develop a safe new product.
- Use and critically review a Pharmaceutical Quality System; use a change control system, evaluate internal and external auditing.
- Perform all manufacturing activities in accordance with requirements for Good Manufacturing Practice (GMP) and Pharmaceutical Quality Systems.
- Lead on enhancing the achievement of standards and upholding necessary standards and legal requirements in pharmacy technical services.
- Work within the principles and practice of instruments, equipment and methodology used in pharmacy technical services.
- Make judgement on the effectiveness of processes and procedures. Contribute to the strategies for practice development and change at both a team and organisational level to enhance access to and effectiveness of pharmacy technical services.
- Design a scientifically valid experimental strategy to address a specific research question relevant to modern pharmacy technical services.
- Produce a cogent dissertation that contains a critical analysis and evaluation of data generated during a research project, and a concise and scientifically valid interpretation of the experimental

findings.

A copy of the programme specification can be found on the PTQA 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. The Awards of Postgraduate Diploma (requiring 120 credits), and Postgraduate Certificate (requiring 60 credits) are also available. Students may be permitted to receive an award of credits on the basis of demonstrated learning that has occurred at some point in the past (Accreditation of Prior Experiential Learning â?? APEL), either through awards from an educational institution or training provider, or through uncertified learning gained from experience. Further details on Credit Requirements and APEL 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

The dissertation (PHAR61810) involves a student working closely with their supervisor to develop and implement an empirical research project. All students taking the MSc 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 Programme 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 studentsâ?? 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.

To obtain a pass for the Postgraduate Certificate you are required to successfully pass 60 credits, for the Postgraduate Diploma you are required to successfully pass 120 credits, and for the Masters you are required to successfully pass 180 credits.

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 PTQA programme has some higher requirements to the University degree regulations and details of these are outlined below.

- The course unit pass mark for all levels (i.e. Postgraduate Certificate, Diploma and Masters) 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 (i.e. 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 been 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

To progress to the dissertation / research element of the Masters programme, students must have passed all taught units (120 credits). Postgraduate programmes can be referred in up to half of the taught credit; this includes credits on a PG Certificate or PG Diploma award. Students may also resubmit the dissertation equivalent on one occasion, subject to the mark restrictions. The number of credits referred and those compensated cannot exceed half the taught credits in total. Please refer to the SHS handbook for more information.

Award of Postgraduate Diploma

To obtain a Postgraduate Diploma award, students must have accrued 120 credits (as specified by the programme), including any provision made for referred units.

Award of Postgraduate Certificate

To obtain a Postgraduate Certificate award students must have accrued 60 credits (as specified by the programme), including any provision made for referred units.

Unless otherwise specified in the exemptions, the awards of Postgraduate Diploma and Postgraduate Certificate degree are based upon credit accumulation using a pass mark of 50% for which there is no classification other than pass/fail.

Exit Awards

Exit awards are available for students who do not satisfy the criteria for the programme they are registered on or who need to exit the programme early due to unforeseen circumstances.

To be considered for a PG Diploma (120 credits; exit point) students must have accrued 120 credits across the programme.

To be considered for a PG Certificate (60 credits; exit point) students must have accrued 60 credits across the programme.

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 PTQA 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 and 50% for Postgraduate Diploma/Certificate). 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 a 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 50.0% or more Certificate Pass
with 60 credits successfully completed

Overall programme mean average of 50.0% or more Diploma Pass
with 120 credits successfully completed

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 falls within the buffer zone of 58.0-59.9 the student may be considered for the award of Merit. For 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.

Students who register originally for a Diploma, but subsequently wish to transfer to the MSc course, will be allowed to do so if they attain, in assessments of the taught Course Units, the level of achievement specified above for the award of the MSc.

Students must be awarded 120 credits before being permitted to progress to the Dissertation stage of the programme.

Submission of Assessments

Please refer to the SHS handbook for more information.

Late Submission Penalty (including the Dissertation)

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 table. Text in tables or boxes should be included in word count.

All in-text (that is, bracketed) references.

All directly quoted material other than direct quotes from the pharmaceutical standards documents which can be excluded.

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 space for PHAR61810 Research Project.

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 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 Consortium Lead for Postgraduate Taught Programmes 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 Evaluations

We will ask you to complete a brief online evaluation form for each teaching session given on the course. These questionnaires are reviewed by the unit leads and the Programme Director. 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: *To be confirmed*
Position at current Institution: *To be confirmed*

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 Leaders

- 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

PHAR61780 Foundations of PTQA (30 credits)

PHAR61730 Introduction to Pharmaceutical Science 2 (30 credits)

Year Two

Compulsory Components

PHAR62780 Advanced Pharmaceutical Science 1 (30 credits)

PHAR62790 Advanced Pharmaceutical Science 2 (30 credits)

Year Three

Compulsory Component

PHAR61810 Research Project (60 credits)

Course Units

Year One

PHAR61780 Foundations of Pharmaceutical Technology and Quality Assurance (PTQA)

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

Credit Rating: 30 credits

Course Unit Aims

The unit provides the background knowledge required by the students undertaking the Pharmaceutical Technology and Quality Assurance (PTQA) programme. Students following different career paths will all require the core knowledge provided by this unit in order to progress through their own choices and to gain an appreciation of alternative routes through the programme.

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

Knowledge and understanding:

- Discuss and critically evaluate the application of regulatory controls to pharmaceutical technology and Quality Assurance.
- Discuss and critically evaluate the principles of Quality Assurance (QA) and EU Good Manufacturing Practice (GMP) and Pharmaceutical Quality Systems (PQS).
- Evaluate incident reports relating to pharmaceutical preparation and the impact that these have had on pharmacy regulations and guidance.
- Implement the fundamentals of good document design throughout the whole PQS.
- Design and construct manufacturing, Quality Assurance and Quality Control documentation.
- Discuss in detail the health and safety aspects of Pharmaceutical Technology and Quality Assurance.
- Describe and critically evaluate the process to be following when recalling a product from the market.
- Critique the requirements for outsourcing and purchasing of pharmaceutical products.

Intellectual skills:

- Follow regulatory standards and guidance.
- Evaluate scientific and clinical literature and present appropriately.
- 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:

- Prepare technical documents; product specifications, investigation reports.
- Prepare risk assessments using a variety of tools and techniques.

- Interpret complex data and report on the findings.
- Prepare for an internal or external audit.
- Identify shortcoming in existing procedure and recommend change.
- Assess the impact of change.

Transferrable skills and personal qualities:

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

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, video/ audio lectures and discussion boards.

Assessment

- 1 week formative discussion board.
- 5 formative online e-assessments.
- 1.5 hours online examination. This comprises 60% of the unit mark.
- A 3,000 words group written assignment. This comprises 30% of the unit mark.
- 1,000 words individual reflection. This comprises 10% of the unit mark.

Recommended Reading

1. Beaney, A. 2016. Quality Assurance of Aseptic Preparation Services (54th Edition), Royal Pharmaceutical Society and NHS PQAC, ISBN 978 0 85711 307 8 (The â??Yellowâ?? Guide)
2. EU Legislation â?? Eudralex
    a. Volume 1 â?? EU pharmaceutical legislation for medicinal products for human use
    b. Volume 2 â?? Notice to applicants and regulatory guidelines for medicinal products for human use
    c. Volume 3 â?? Scientific guidelines for medicinal products for human use

Online at https://health.ec.europa.eu/medicinal-products/eudralex_en

1. Guidelines for good manufacturing practices for medicinal products for human and veterinary use (Volume 4)
    a. Chapter 1 â?? Pharmaceutical Quality System
    b. Chapter 4 â?? Documentation
    c. Chapter 8 â?? Complaints and Product Recall
    d. Chapter 9 â?? Self Inspection
    e. Part III â?? GMP related documents
        1. Site Master File

2. Q9 Quality Risk Management
3. Q10 Note for Guidance on Pharmaceutical Quality System

Online at https://health.ec.europa.eu/medicinal-products/eudralex_en

1. 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

1. The Human Medicines Regulations 2012 (SI 2012 No. 1916)

Online at http://www.legislation.gov.uk/uksi/2012/1916/pdfs/uksi_20121916_en.pdf

1. The Medicines Act 1968

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

1. 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

1. Thalidomide and its sequelae

Online at http://www.sciencedirect.com/science/article/pii/S0140673612604681

1. WHO Quality Assurance of Pharmaceuticals (Volume 2)

Online at
http://www.who.int/medicines/areas/quality_safety/quality_assurance/QualityAssurancePharmVol2.pdf

PHAR61790 Introduction to Pharmaceutical Sciences 2

Unit leads:

RADIOPHARMACY: Bev Ellis (Consultant Radiopharmacist, MFT), Victoria Gibson (Kings College, London)

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 Methods

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

Assessments

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)
9. 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
10. Allwood, M (Ed. et al) 2001 *The Cytotoxics Handbook 4th Ed*. Oxford: Radcliffe Medical Press ISBN 1-8577-5504-9
11. Midcalf, B, Phillips, WM, Neiger JS and Coles T (Eds) 2004 *Pharmaceutical Isolators* London: Pharmaceutical Press ISBN: 978-0-85369
12. Executive Letter â?? EL (96) 95 â?? issued 20 December 1996
13. 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
    2. British Pharmacopoeia 2015
16. Skoog, West and Holler, 2000 *Analytical Chemistry: An introduction 7th Edition*. London: Thomson Learning ISBN 0-03-020293-0
17. Miller JN, Miller JC, 2010 *Statistics and Chemometrics for Analytical Chemistry,* Prentice Hall, ISBN-10 0273730428, ISBN-13 978-0273730422
18. Denyer, Hodges, Gorman and Gilmore (Ed), 2011 *Hugo and Russellâ??s Pharmaceutical Microbiology (8th Edition)* Wiley-Blackwell, ISBN-10 1444330632, ISBN-13 978-1444330632
19. 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

Year Two

PHAR62780 Advanced Pharmaceutical Science 1/ PHAR62790 Advanced Pharmaceutical Science 2

The advanced pharmaceutical science unit aims to develop studentsâ?? knowledge and understanding which was gained in Year 1. Year 2 of the programme, which comprises two advanced pharmaceutical science 30 credit units, allows students to specialise in specific areas of pharmacy technical services and leadership.

These units allows students to select SIX optional 10 credit units.

Students can choose from:

- Aseptics
- Radiopharmacy
- Production
- Quality Control
- Advanced Quality Assurance
- Role of the Qualified Person (QP)
- Pharmaceutical Medical Gases
- Clinical Trials
- Preparation for Practice
- Research Methods

Aseptics

Unit Leads: Ruth Barnes, Sue Renn and Emma Ward (UoM)**:**

Credit Rating: 10 credits

Course Unit Aims

The Aseptics unit builds on the background knowledge provided in the Introduction to Aseptics (PHAR61730 â?? Introduction to Pharmaceutical Science 2). Students will be able to explain the function and operation of equipment and clean rooms. They will know and understand commissioning procedures and be able to critically evaluate monitoring data and diagnose problems.

Course Unit Learning Outcomes

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

- 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.
- Critically analyse the procedures required for outsourcing and sub-contracting services relating to aseptics.
- Critically analyse pharmaceutical microbiological aspects of aseptic preparation and their application in the workplace.
- Critically evaluate the design, commissioning, and use of clean rooms/clean air devices.
- Critically evaluate process and operator validations.
- Discuss human factors and how it relates to errors, deviations and CAPA.
- Apply integrative knowledge of the formulation, stability and preparation of specialist, aseptic dose forms.
- Investigate emerging therapies and technologies related to aseptic services.
- Interpret stability data to determine the shelf life of the product.
- Critically evaluate a range of microbiological and physical monitoring methods.
- Construct risk assessments on preparation activities.
- Interpret and analyse monitoring data and diagnose problems.
- Assist with clean room commissioning and routine monitoring.
- 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

A 2,000 words written assignment. This comprises 100% of the unit mark.

Recommended reading

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. 2016. Quality Assurance of Aseptic Preparation Services (5th Edition), Royal Pharmaceutical Society and NHS PQAC , ISBN 978 0 85711 307 8 (The â??Yellowâ?? Guide)
4. Sandle T, Saghee MR 2013 Cleanroom Management in Pharmaceuticals and Healthcare. Euromed Communications Ltd. ISBN 978-1-899015-83-2

Radiopharmacy

Unit Leads: Bev Ellis (Consultant Radiopharmacist, MFT), Victoria Gibson (Kings College, London) and Ruth Barnes, Sue Renn, Sarah Ward (UoM)

Credit Rating: 10 credits

Course Unit Aims

The aim of the Radiopharmacy Advanced unit is to build on the background knowledge provided in the Radiopharmacy module (Introduction to Clinical Pharmaceutical Science 2). 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.

Course Unit Learning Outcomes

- Explain the role of the Clinical Scientist in Radiopharmacy in the diagnosis and treatment of disease using radiopharmaceuticals, including the contribution to patient management and patient centred care
- Critically evaluate commonly used diagnostic and therapeutic radiopharmaceuticals.
- Discuss the principles of Positron Emission Tomography (PET) radiopharmaceuticals and the organisation of a PET radiopharmacy.
- Critically appraise the preparation and clinical use of radiopharmaceutical and issues which may arise.
- Demonstrate a critical awareness of radiation protection in radiopharmaceutical preparation.
- Discuss the need for automation in radiopharmaceutical preparation and the possible ways in which this might be achieved.
- Describe the functions of the different cell types routinely labelled in nuclear medicine, outline the most significant points in the labelling procedures used and list the most common clinical

indications for these radiopharmaceuticals.
- Discuss innovations and clinical trials within radiopharmacy.
- Interpret stability data to determine the shelf life of the product.
- Critically evaluate a range of microbiological and physical monitoring methods.
- Critically appraise the impact of the radiopharmaceutical production process on the quality of clinical outcomes.
- Work safely in the radiation environment.
- Perform a range of radiopharmaceuticals.
- Perform radiochemical purity testing on a range of radiopharmaceuticals and interpret results
- Interpret and analyse monitoring data and diagnose problems.
- Assist with clean room commissioning and routine monitoring.
- 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
- Show appreciation of the way in which legislation, standards and quality management interface with normal working life.

Teaching and Learning Methods

A teaching block including face-to-face and online lectures, workshops and practicals.

E-Learning: evidence-based learning supported by course notes, audio lectures and discussion boards.

Assessment

A 2,000 words written assignment. This comprises 100% of the unit mark.

Recommended reading

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: 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 Radiopharmaeuticals: 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

Production

Unit Leads: Helen Callaby (QP) and Ruth Barnes (UoM)

Credit Rating: 10 credits

Course Unit Aims

The production unit builds on the background knowledge provided in Introduction to Production/QC (PHAR61730 â?? Introduction to Pharmaceutical Science 2)

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.

Course Unit Learning Outcomes

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

- 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.

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, video/audio lectures and discussion boards.

Assessment

2,000 words written assignment. This comprises 100% of the unit mark.

Recommended Reading

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

Quality Control

Unit Leads: Ruth Barnes (UoM)

Credit Rating: 10 credits

Course Unit Aims

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.

Course Unit Learning Outcomes

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

- 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.

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

- A 2,000 words assignment. This comprises 100% of the unit mark.

Recommended reading

1. Guidelines for good manufacturing practices for medicinal products for human and veterinary use (Volume 4)
2. 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
3. British Pharmacopoeia 2014
4. Skoog, West and Holler, 2000 *Analytical Chemistry: An introduction 7th Edition*. London: Thomson Learning ISBN 0-03-020293-0
5. Miller JN, Miller JC, 2010 *Statistics and Chemometrics for Analytical Chemistry,* Prentice Hall, ISBN-10 0273730428, ISBN-13 978-0273730422
6. Denyer, Hodges, Gorman and Gilmore (Ed), 2011 *Hugo and Russellâ??s Pharmaceutical Microbiology (8th Edition)* Wiley-Blackwell, ISBN-10 1444330632, ISBN-13 978-1444330632
7. 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

Advanced Quality Assurance

Unit Leads: Ruth Barnes, Sue Renn, Sarah Ward (UoM)

Credit Rating: 10 credits

Course Unit Aims

The unit builds on the knowledge gained in the Foundations of PTQA unit in year 1. This will assist students in further developing the knowledge to identify, assess and manage risks within the pharmacy technical environment and to carry out quality assurance audits of services and service providers within this field.

The unit provides the students with a higher understanding of pharmaceutical quality assurance, appropriate for more senior roles or for students considering taking up a position in QA. 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), including audit and risk assessment methods and the operational benefits and challenges of a robust system.

The unit will provide students with the core knowledge to identify, assess and mange risks within the pharmacy technical environment and to carry out quality assurance audits of services and service providers within this field. The module will incorporate the relevant national standards and legislation that apply within this area of practice and introduce them to the use of common risk management tools and strategies used in pharmaceutical environments.

Course Unit Learning Outcomes

- By the end of this course, students will be able to:
- Discuss and critically evaluate the application of regulatory controls to pharmaceutical technology and Quality Assurance.
- Discuss and critically evaluate the principles of Quality Assurance (QA) and EU Good Manufacturing Practice (GMP) and Pharmaceutical Quality Systems (PQS).
- Critically evaluate manufacturing, Quality Assurance and Quality Control documentation.
- Discuss in detail the health and safety aspects of Pharmaceutical Technology and Quality Assurance, including COSHH and the handling of hazardous medicinal products.
- Describe and critically evaluate the routes to obtaining a Manufacturing Authorisation including the associated timelines.
- Critically evaluate the process to be followed when recalling a product from the market.
- Describe the contents of an electronic Common Technical Document (eCTD) for a licensed product, with the Chemistry Manufacturing and Controls (CMC) section being described in detail.
- Undertake a proactive approach in applying the theory of risk management to patient care

- Demonstrate a working knowledge of the relevant standards and legislation required for risk management
- Critically evaluate compliance with national standards using the audit and risk assessment processes
- Demonstrate the skills and in-depth knowledge required to design and conduct audit and implement action plans
- Describe and critically evaluate the processes to be followed when performing audit and inspections and preparing and assessing action plans relating to these.
- Follow regulatory standards and guidance.
- Evaluate scientific and clinical literature and present appropriately.
- 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.Prepare technical documents; product specifications, investigation reports.
- Prepare and assess risk assessments using a variety of tools and techniques.
- Interpret complex data and report on the findings.Prepare to perform an internal or external audit.
- Identify shortcoming in existing procedure and recommend change.
- Assess the impact of change.
- Carry out thorough risk assessments using a variety of tools and techniques.
- Identifying different types of risk.
- Suggesting and implementing risk reduction measures.
- Read, interpret and apply standards and guidance to working practices.
- Demonstrate professionalism and ethical awareness.
- Communicate effectively with professional colleagues and service users.
- Select and apply appropriate analysis or assessment techniques and tools.

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, video/audio lectures and discussion boards.

Assessment

A 2,000 words written assignment. This comprises 100% of the unit mark.

Recommended Reading

1. Beaney, A. 2016. Quality Assurance of Aseptic Preparation Services (5th Edition) http://www.rpharms.com/support-pdfs/rpsâ??qaaps-standards-document.pdf
2. EU Legislation â?? Eudralex
    a. Volume 1 â?? EU pharmaceutical legislation for medicinal products for human use
    b. Volume 2 â?? Notice to applicants and regulatory guidelines for medicinal products for human use
    c. Volume 3 â?? Scientific guidelines for medicinal products for human use

Online at http://ec.europa.eu/health/documents/eudralex/

1. Guidelines for good manufacturing practices for medicinal products for human and veterinary use (Volume 4)
    a. Chapter 1 â?? Pharmaceutical Quality System
    b. Chapter 8 â?? Complaints and Product Recall
    c. Chapter 9 â?? Self Inspection
    d. Part III â?? GMP related documents
        i. Q9 Quality Risk Management
        ii. Q10 Note for Guidance on Pharmaceutical Quality System

Online at http://ec.europa.eu/health/documents/eudralex/

4. 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

5. The Human Medicines Regulations 2012 (SI 2012 No. 1916)

Online at http://www.legislation.gov.uk/uksi/2012/1916/pdfs/uksi_20121916_en.pdf

6. The Medicines Act 1968

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

7. 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

8. WHO Quality Assurance of Pharmaceuticals (Volume 2)

Online at
http://www.who.int/medicines/areas/quality_safety/quality_assurance/QualityAssurancePharmVol2.pdf

9. First Class Service: Quality in the New NHS Department of Health 1998

(read the summary pages)

10. The NHS Plan â?? Pharmacy Plan Department of Health 2000

(read the summary pages)

11. An Organisation with a Memory Department of Health 2000

(read the summary pages)

12. Doing Less Harm Department of Health 2000

(read the summary pages)

13. Woods K. Prevention of Intrathecal Medication Errors â?? a Report to the Chief Medical Officer Department of Health April 2001

(read the summary page â?? page 1.)

13. Toft B. External Inquiry into the Adverse incident that occurred at Queens Medical Centre, Nottingham, 4th January 2001 Department of Health, April 2001

(read Chapter 5 â?? Conclusions & Recommendations p 40-47).

15. Shaw R.S.; Beaney A., Beaumont I.M.; Knowles M. Quality Audits and their Application to Hospital Pharmacy Technical Services 1999 pub. NHS QC Committee

The role of the QP

Unit Leads: David Caulfield (The Newcastle Upon Tyne Hospitals NHS Foundation Trust), Ruth Barnes, Sue Renn and Sarah Ward (UoM)

Credit Rating: 10 credits

Course Unit Aims

This unit develops the studentâ??s understanding of the role and professional duties of the QP within the NHS and industry environments. The module delivers core knowledge required on the pharmaceutical law and regulations applicable to the manufacture of pharmaceuticals and provides students with an appreciation of the process required to become a registered QP in the UK.

Students learn the skill to apply all the elements of the QP study guide in their workplace. With sufficient practical experience after the unit students should have the skills to be assessed for formal QP status.

The module will provide students with the core knowledge to identify, assess and mange risks within the pharmacy technical environment and to carry out quality assurance audits of services and service providers within this field. The module will incorporate the relevant national standards and legislation that apply within this area of practice and introduce them to the use of common risk management tools and strategies used in pharmaceutical environments.

Course Unit Learning Outcomes

- Demonstrate and in-depth knowledge of the role and professional duties of the Qualified Person as defined by EU law.
- Interpret the current pharmaceutical law and regulations and apply them to the manufacture of pharmaceuticals.
- Apply the extensive body of knowledge required by the QP to the workplace.
- Critically analyse processes and systems to assure the quality of pharmaceuticals and maintain patient safety.
- Undertake a proactive approach in applying the theory of risk management to patient care.
- Applying statistical methods to determine robustness or validity of data.
- Use effective negotiation skills.
- Communicate difficult decisions.
- Maintain a pragmatic approach during challenging debates.

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

A 2,000 words written assignment. This comprises 100% of the unit mark.

Recommended reading

1. Volume 4 Good Manufacturing Practice (GMP) Guidelines
    1. Chapter 2 â?? EU Guidance on Good Manufacturing Practice
    2. Annex 13 â?? Manufacture of Investigational Medicinal Products
       Online at https://health.ec.europa.eu/document/download/a0b206a0-5788-406b-9e20-e0525b16e712_en?filename=guideline_adopted_1_en_act_part1_v3.pdf
    3. Qualified Person documents:
    1. Guidance notes for applicants for QP status
    2. QP study guide
    3. Code of practice
       Online at http://www.rpharms.com/development/qualified-person.asp
2. TSET competencies of Qualified Persons. A framework for individuals seeking nomination as a pharmaceutical Qualified Person.
3. Manufacture of sterile medicinal products, Annexe 1
   Online at http://www.picscheme.org/publication.php?id=8
4. Consultation Letter MLX275 â?? Recommendations for the Labelling and Packaging of Medicines. (Issued 21 Aug 2001 by SA Norton, MCA); together with the â??Report to the Committee on Safety of Medicines from the Working Group on Labelling and Packaging of Medicinesâ?•
    1. Controls Assurance Standards for

Pharmaceutical Medical Gas Testing

Unit Lead: Theresa Hughes (Principal QA Pharmacist, Royal Berkshire Hospital) and Ruth Barnes, Sue Renn, Sarah Ward (UoM)

Credit Rating: 10 credits

Course Unit Aims

This unit develops the studentâ??s knowledge of medical gas systems including structure and components of the relevant COSHH and Health and Safety regulations required to practice in this field. The unit will provide in-depth working knowledge of the chemical and physical properties of testing for contaminants in medical gas systems, with particular reference to the role of the Medical Gas expert in patient safety and care.

Course Unit Learning Outcomes

- Demonstrate an in-depth knowledge of relevant pharmacopoeial monographs, HTM 02 and permit to work relating to medical gases.
- Demonstrate a knowledge of health and safety relating to medical gases.
- Demonstrate a knowledge of medical gases production and properties, and the application of GMP to medical gas production.
- Demonstrate an in-depth knowledge of medical gas testing equipment including the calibration, maintenance and use in patient care.
- Interpret test results of medical gas systems and take appropriate actions
- Critically evaluate working practices and apply national standards.
- Evaluate and advise on the safe use and management of medical gases and medical gas cylinders.
- Critically appraise installations
- Analyse and interpret results.
- Evaluate findings and make recommendations.
- Apply advanced skill in analysis of:
    - Oxygen
    - Water
    - Nitrous oxide
    - Compressed air and oxygen concentrators
    - Contaminants
- Identify test requirements for new installations and for routine testing.
- Determine cause/fault in defective systems
- Effective communication with a multi-disciplinary team.
- Efficient working under pressure.

Teaching and Learning Methods

One week teaching block including workshops and practicals.

The teaching component is provided by Leeds CPD, Faculty of Engineering and Physical Sciences Leeds and is delivered by experts in their field.

E-Learning: evidence-based learning supported by course notes, audio lectures and discussion boards.

Assessment

- A 2,000 words written assignment This comprises 100% of the unit mark.

Recommended Reading

1. HTM 0201 Medical Gas Pipeline systems

Clinical Trials

Unit Lead: Sue Renn (UoM)

Credit Rating: 10 credits

Course Unit Aims

The unit aims to enable students to:

- Acquire and develop an advanced knowledge and in-depth understanding of the delivery of clinical trials in the specific settings of the NHS and the Clinical Research Organisation/Clinical Trials Unit.
- Acquire and develop the advanced skills to make an effective contribution to managing clinical trials.
- Demonstrate the ability to work in clinical trial practice to ensure the delivery of high quality services that meet national and international regulatory standards.
- Identify their own learning needs, develop themselves as critically reflective practitioners and advance their own learning to sustain continuing professional development, and work at the forefront of clinical trial practice.
- Critically evaluate literature, theories and methodologies and apply regulatory founded approaches to clinical trial delivery.

Course Unit Learning Objectives

- Demonstrate an advanced knowledge and detailed understanding of:
    - The history and structure of the NHS and the role the NHS plays in research
    - The key national and international regulatory frameworks and legislation with specific reference to clinical trial conduct within which the NHS operates
    - The range of clinical trials which may take place within various NHS settings
    - The roles of Sponsors, Contract Research Organisations and Clinical Trials Units in clinical trial management
    - Study design including protocol development, risk assessment and accurate data capture
    - NHS finance, research funding streams and associated processes
    - The multidisciplinary and multi-organisational requirements for study set-up and management
    - Contractual obligations and responsibilities of key stakeholders
    - The importance of clinical trial project management, budgeting and quality management processes
- Critically analyse, evaluate and where appropriate formulate an informed opinion about:
    - Clinical trial management in the public sector and the differences and challenges compared to private sector clinical trials
    - National and international clinical research legislation and how it impacts project delivery in the NHS
    - The effectiveness of current systems and processes to streamline clinical trial applications, set-up and management The future of clinical research in the NHS
- Analyse qualitative and quantitative data to determine their strength and validity.

- Complete practical exercises to demonstrate an understanding of the application of knowledge derived from the course material
- Engage in critically reflective practice as a process of continuous personal development.
- Critique information from a range of sources to formulate opinions
- Set up and conduct clinical trials in accordance with legislative requirements, demonstrating high level knowledge on a process-driven approach
- Networking with key stakeholders in own organisation to drive processes forward based on knowledge gained through course participation
- Assess current working practices based on knowledge and experience gained and adapt working processes as necessary
- Prioritise and effectively manage time to complete work by required deadlines

Teaching and Learning Methods

Students are provided with the learning material online. The learning material comprises 6 chapters covering the key areas to consider when conducting clinical trials for the NHS. Each chapter contains a number of exercises for students to check their learning as they progress through the unit. A reference list of further reading is provided for each chapter allowing the student to investigate the subject area more deeply, and the unit tutor is available to answer queries and provide guidance as required. The face-to-face workshop at the annual workshop event explores key areas of the unit through a range of hands-on exercises.

Assessment

6 weeks of assessed discussion board. This comprises 100% of the unit mark.

Recommended Reading

1. Health and Social Care Act 2012: Factsheets. In: Health Do, editor. 2012.
2. Health Do. The NHS Constitution â?? the NHS belongs to us all. 2013.
3. Gaw A. Trial by Fire: Lessons from the History of Clinical Trials. First edition ed: SA Press; 2009. 100 p.
4. Hackshaw A. A Concise Guide to Clinical Trials. First edition ed: John Wiley & Sons; 2009. 226 p.
5. (NIHR) NIHR. Clinical Trials Toolkit website [Available from: http://www.ct-toolkit.ac.uk/routemap.
6. MHRA. Good Clinical Practice Guide: The Stationery Office; 2012.

Preparation for Practice

Unit Leads: John Landers (Deputy Director of Pharmacy, MFT), Maloni Talbot (Deputy Chief Pharmacist, Warrington and Halton Teaching Hospitals), Ruth Barnes, Sue Renn, Sarah Ward (UoM)

Credit Rating: 10 credits

Course Unit Aims

This module will enable the trainee to gain experience in the skills required for the leadership and 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:

- 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, video/audio lectures and discussion boards.

Assessment

2,000 words written assignment. This comprises 100% of the unit mark.

Recommended Reading

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
    1. 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/

Research Methods

Unit Leads: Ruth Barnes, Sue Renn, Sarah Ward (UoM)

Credit Rating: 10 credits

Course Unit Aims

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 this course, students will be able to:

- 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.
- Describe, compare and contrast a range of research methods/approaches, including cohort studies, qualitative, quantitative, systematic review, sampling techniques and clinical trials.
- Explain and justify current UK ethical and governance frameworks and processes spanning the conduct of human and animal research, innovation and audit.
- 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.
- Discuss and justify the research, audit and innovation process from idea generation to dissemination/implementation, including patient/user involvement and intellectual property.
- Describe and evaluate a range of data analysis techniques to ensure the validity, reliability and appropriateness to the research aim, design and conclusion.

- Describe how clinical guidelines are produced and the concept of evidence-based practice, including the role of current statutory and advisory regulatory bodies.
- Identify potential sources of research and innovation funding for healthcare science/Clinical Scientists.
- 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.
- Work within the principles and practice of instruments, equipment and methodology used in clinical pharmaceutical science.
- Support safe storage and distribution of medicinal products.
- Identify validation requirements for any changes to processes.
- 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.
- Project management; taking responsibility for and planning a project from beginning to end.
- Selection and use of appropriate methods to find solutions.

Teaching and Learning Methods

Online lectures and workshops.

E-Learning: evidence-based learning supported by course notes, video/audio lectures and discussion boards.

Assessment

1,000 words project proposal. This comprises 100% of the unit mark.

Formative presentation on project proposal.

Recommended Reading

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

Year Three

PHAR61810 Research Project

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

Practice-based Course Unit Co-ordinator: Work-based supervisor, nominated by student base on project topic

Credit Rating: 60 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.

The students will conduct a piece of empirical research that either addresses a specific research question in the field of 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 pharmaceutical sciences.

Course Unit Learning Outcomes

- Carry out a literature search in the topic area
- Synthesise and critically analyse the literature to inform the research project design
- Demonstrate an ability to design an appropriate research experiment.
- Employ appropriate techniques and methods to answer the research question
- Critically analyse data from and if appropriate, apply statistical analytical techniques to the data.
- Understand the limitations of the methods used.
- Critically review the data gathered and the literature to form a conclusion answering the research question.
- Present the results in both written and oral forms
- Discuss the stages of the research and innovation process from conceptualisation to dissemination and if appropriate translation into practice
- Critically demonstrate considerable in-depth skills in terms of research; critical thinking; reasoning; and analysis and synthesis of information.
- Generate timely and theoretically grounded research questions.
- Critically analyse, evaluate and interpret data from the specific enquiry.
- Apply appropriate and relevant statistical tools.
- 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.

- Plan and conduct a detailed, focused and current literature search
- Implement and manage data collection
- Conduct appropriate analytical techniques
- Analyse the data using appropriate methods and statistical techniques and interpret, critically discuss and draw conclusions from the data.
- Prepare a written project that describes and critically evaluates the research project clearly identifying the strengths and weaknesses.
- 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.
- Prepare a summary of the research project suitable for non-specialist and lay audience.
- Demonstrate independent thought
- Develop self-management project skills (e.g. time management, prioritisation of tasks)
- 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
- Engage in systematic and critical reflection of personal practice and the practice of others in relation to the enquiry.

Teaching and Learning Methods

Students carry out their research project in their place of work and each has an approved supervisor who they are expected to meet each month 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 10,000-15,000 words dissertation.

Students are supported by the Module Leader and the Module Director throughout the module via telephone, emails and visits where possible. The academic supervisor is the Module Leader for all students undertaking this module and the students have personal support from the Programme Manager during this module. In addition all students have a work-based tutor who offers them subject specific advice and personal support.

Assessment

- 10,000 â?? 15,000 words dissertation. This comprises 80% of the unit mark.
- 15 minutes presentation. This comprises 20% of the unit mark.

Recommended reading

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