Modernising Scientific Careers Programme

MSc in CLINICAL SCIENCE

CLINICAL PHARMACEUTICAL SCIENCE

Learning Outcomes and Indicative Content

2013/14
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Section 1: Overview of Scientist Training Programme

1.0 Background

This document sets out the proposed structure, high level learning outcomes and indicative content for the 3-year, part-time Masters in Clinical Sciences that forms part of the Scientist Training Programme (STP). The programme combines and integrates the generic professional practice learning together with an introduction and specialist learning in Clinical Pharmaceutical Science.

The diagram below depicts the overall STP.

Modernising Scientific Careers: Scientist Training Programme (STP): Diagrammatic representation of employment-based, pre-registration 3 year NHS commissioned education and training programme

1.1 Scientist Training Programme in Clinical Pharmaceutical Science

The diagram overleaf provides an overview of the programme each trainee in Clinical Pharmaceutical Science will follow.
1.2 Professional Practice

Good Scientific Practice (GSP) sets out the principles and values on which good practice undertaken by the Healthcare Science workforce is founded and GSP is contextualised within each STP programme. Good scientific practice underpins both the MSc in Clinical Science and the work based training. Details of the professional practice components to be covered within each MSc programme are found in this document whilst the professional practice curriculum for the work based learning guides for each of the current STP programmes can be found at: [http://www.networks.nhs.uk/nhs-networks/msc-framework-curricula/stp/msc-clinical-science-learning-outcomes-indicative-content-and-work-based-trainee-learning-guides-for-2012-13-trainees](http://www.networks.nhs.uk/nhs-networks/msc-framework-curricula/stp/msc-clinical-science-learning-outcomes-indicative-content-and-work-based-trainee-learning-guides-for-2012-13-trainees). Each work based learning programme contains a generic professional practice module which is developed and contextualised within each theme and specialism.
1.3 Scientist Training Programme Outcomes

Introduction

The Scientist Training Programme (STP) is an integrated education and training programme combining academic study leading to the award of an NHS commissioned MSc in Clinical Science and a work based training programme. Successful completion of both elements of the STP will lead to the award of a Certificate of Completion of the STP (CCSTP) by the National School of Healthcare Science (NSHCS). Holders of the CCSTP will then be eligible to apply to the Academy for Healthcare Science for a Certificate of Attainment and will which in turn confers eligibility to apply to the Health and Care Professions Council (HCPC) HCPC for registration as a Clinical Scientist.

Whilst the STP programme is an integrated programme, the MSc in Clinical Science focuses on the knowledge and understanding that underpins practice and places it within the broader clinical and scientific context. The work based training programme focuses on the acquisition and development of skills alongside the application of knowledge within the healthcare science sector/specialism. The demonstration of appropriate attitudes and behaviours spans both aspects of the programme.

PROGRAMME OUTCOMES

Graduates of the STP will possess the essential knowledge, skills, experience and attributes required of a newly qualified Clinical Scientist. STP graduates will have clinical and specialist expertise in a specific healthcare science specialism, underpinned by broader knowledge and experience within a healthcare science division or theme. They will be competent to undertake complex scientific and clinical roles, defining and choosing investigative and clinical options, and making key judgements about complex facts and clinical situations. Many will work directly with patients and all will have an impact on patient care and outcomes. They will be involved, often in lead roles, in innovation and improvement, research and development and/or education and training.

On completion of the STP all graduates should be able to demonstrate:

Professional Practice

1. Professional practice that meets the professional standards of conduct, performance and ethics defined by *Good Scientific Practice* and the regulator (HCPC) and is safe, lawful and effective and within the scope of practice for the role undertaken whilst maintaining fitness to practise.
2. Personal qualities that encompass communication skills, self management, self-awareness, acting with integrity and the ability to take responsibility for self-directed learning, maintaining their own health and well being, critical reflection and action planning to maintain and improve performance.
3. The ability to be an independent self-directed learner acting autonomously in a non-discriminatory manner when planning and implementing tasks at a
professional level, contributing to the education and training of colleagues and providing mentoring, supervision and support as appropriate.

4. The ability to work, where appropriate, in partnership with other professionals, often as part of a multidisciplinary team, supporting staff, service users and their relatives and carers whilst maintaining confidentially.

5. The ability to work with public, service users, patients and their carers as partners in their care, embracing and valuing diversity.

**Scientific and Clinical Practice**

6. A systematic understanding of relevant knowledge, and a critical awareness of current problems, future developments and innovation in health and healthcare science practice, much of which is at, or informed by, the forefront of their professional practice in a healthcare environment.

7. Clinical and scientific practice that applies basic, core scientific knowledge, skills and experience in a healthcare setting, places the patient and the public at the centre of care prioritising patient safety and dignity and reflecting NHS/health service values and the NHS Constitution.

8. The ability to perform appropriate diagnostic or monitoring procedures, treatment, therapy or other actions safely and skillfully adhering to applicable legislation and in compliance with local, national and international guidelines.

9. The ability to deal with complex scientific and clinical issues both systematically and creatively, make sound judgements in the absence of complete data, and to communicate their conclusions clearly to specialist and non-specialist audiences including patients and the public.

10. The ability to define and choose investigative and scientific and/or clinical options, and make key judgements about complex facts in a range of situations.

11. Originality in the application of knowledge, together with a practical understanding of how established techniques of research and enquiry are used to create and interpret knowledge in healthcare and healthcare science and their specialism.

**Research, Development and Innovation**

12. A comprehensive understanding of the strengths, weaknesses and opportunities for further development of healthcare and healthcare science as applicable to their own clinical practice, research, audit, innovation and service development which either directly or indirectly leads to improvements in patient experience, clinical outcomes and scientific practice;

13. Conceptual understanding and advanced scholarship in their specialism, enabling them to critically evaluate and critique current research and innovation methodologies and, where appropriate, propose new research questions and hypotheses;

**Clinical Leadership**

14. Scientific and clinical leadership based on the continual advancement of their knowledge, skills and understanding through the independent learning required for continuing professional development.
15. The ability to critique, analyse and solve problems, define and choose investigative and scientific and/or clinical options, and make key judgements about complex facts in a range of situations.

Section 2: MSc Clinical Science (Clinical Pharmaceutical Science)

The diagram below depicts the broad framework around which all degree programmes must be structured. However, each division within the Modernising Scientific Careers Programme (MSC) has interpreted and adapted this framework.

HIGH LEVEL FRAMEWORK
MSc IN CLINICAL SCIENCE

2.1 Clinical Pharmaceutical Science Route Map

Clinical Pharmaceutical Science will offer an MSc in Clinical Sciences (Clinical Pharmaceutical Science) within Physical Sciences and Biomedical Engineering. The route map overleaf shows how the high-level framework has been interpreted for the MSc in Clinical Pharmaceutical Science.
### MSc Clinical Science: Clinical Pharmaceutical Science

<table>
<thead>
<tr>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
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<tbody>
<tr>
<td>Introduction to Clinical Pharmaceutical Science including: Quality Control, Aseptics, Radiopharmacy and Manufacturing underpinning knowledge for rotational work based training [40]</td>
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<tr>
<td>[Route map of STP in Clinical Pharmaceutical Science. In Year 1, trainees begin by following the generic curriculum common across all STP Training Programme (blue) together with some division/theme specific modules (yellow). In Year 2, trainees specialise (orange) in Clinical Pharmaceutical Science]</td>
<td>[Clinical Pharmaceutical Science]</td>
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#### Credits

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Section 3: Generic Modules

The generic MSc modules studied by all trainees on each of the STP programmes are Healthcare Science and Research Methods. Professional Practice is also generic and is integrated across the 3-year STP in both the MSc and work based learning programme. For details of the complete Professional Practice Curriculum and Good Scientific Practice to which the professional practice module aligns please see Appendix.

Please note that at the time of preparing this draft an interim review of this Healthcare Science module is underway and an updated version will be published at the end of March 2013.

Year 1: Generic Module
Healthcare Science
[20 credits]

The overall aim of this introductory module is to provide trainees with knowledge and understanding of the basic science and scientific knowledge that will underpin study in any of the three divisions of healthcare science namely Life Sciences, Physical Sciences and Biomedical Engineering and Physiological Sciences within the Scientist Training Programme. This module will also introduce the frameworks underpinning professional practice across the divisions providing the building blocks for future development of professional practice in the workplace.

This module will build on the knowledge, skills and experience gained during undergraduate studies with learning developed and applied further in division and specialism specific modules.¹

Learning Outcomes: Knowledge and Understanding

On successful completion of this module the trainee will:

1. Outline the chemical, cellular and tissue level of organisation of the body.
2. Describe the function of blood as a tissue, blood cells (types and life times).
3. Know the structure and function of the skin.
4. Know the structure and function of the skeletal system.
5. Describe the organisation, basic structure and function of the central, peripheral and autonomic nervous system.
6. Know the normal structure and function of the respiratory system including ventilation, gaseous exchange and blood gas transport.
7. Know the normal structure and function of the heart, blood vessels and lymphatic system.
8. Know the anatomy and physiology of vision, hearing and equilibrium.
9. Know the normal structure and function of the GI tract including digestion and absorption of food, the liver and liver function tests.
10. Know the normal structure and function of the kidney including anatomy and function of the endocrine system, electrolyte and acid-base balance and hormonal

¹This module should build on the knowledge gained during undergraduate studies with learning developed further in division and specialism specific modules
11. Know the anatomy and physiology of the male and female reproductive tract.
12. Know the principles of inheritance, DNA and genetics including carrier status, genetic crosses/pedigree/punnet squares/cross diagrams.
13. Know the cellular, tissue and systems responses to disease including cell death, inflammation, neoplasia, hypertrophy, hyperplasia, tissue responses to injury and repair.
14. Explain how factors affecting health may contribute to inequalities in health between populations.
15. Explain the basic concepts underpinning health economics and their applicability to healthcare science.
16. Know the basis of health protection including principles of surveillance.
17. Examine patients’ responses to illness and treatment and consider the impact of psychological and social factors, including culture, on health and health-related behaviour.
18. Know the basic principles of physics that underpin healthcare science e.g. ultrasound, radiation...
19. Explain the structures and processes that underpin quality assurance including quality control, assurance, quality improvement and clinical governance.
20. Know and apply basic principles of communication with respect to key features of effective patient interviews and information giving; working with groups of the population who have particular communication needs such as children, those with learning disabilities and management of emotional responses within the scientist-patient interaction
21. Know the basic principles and structures underpinning history taking and clinical examination.
22. Know and understand the importance of the concept of shared leadership and the associated personal qualities and behaviours that promote shared leadership.
23. Understand the structure and management of health and social care services and the management of local healthcare systems in the United Kingdom.

Indicative Content

- Review of the organisation, structure and function of the body
- Review of basic genetic concepts
- Review of the pathological processes underpinning common diseases:
  - Cell death
  - Inflammation
  - Neoplasia
  - Hypertrophy
  - Hyperplasia
  - Tissue response to injury and repair
- Factors affecting health and their contribution to inequalities in health between populations
- Basis of health protection including principles of surveillance.
- Patients’ responses to illness and treatment including the impact of psychological, social factors and culture
- Basic principles of physics underpinning common techniques used in healthcare science e.g. ultrasound, radiation
- Basic principles of quality assurance including quality control, assurance, quality improvement and clinical governance.
• Health Economics
• Communications skills
• Introduction to history taking and clinical examination.
• Introduction to leadership within the NHS.
• Introduction to the structure of the NHS

Year 2: Generic Module
Research Methods
[10 credits]

The overall aim of this module is to ensure that the trainee has the knowledge, skills and experience of the role of research, development and innovation in the NHS in improving patient care including prevention, diagnostics, treatment and service delivery. On completion of this module and the research project trainees should be able to generate ideas, assess, plan, conduct, evaluate, interpret and report research and innovation projects, which includes original research and disseminate the findings and where appropriate the adoption of the findings. Trainees should also be able to use research to improve practice.

Learning Outcomes: Knowledge and Understanding

On successful completion of this module the trainee will:

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

Learning Outcomes: Practical Skills
On successful completion of this module the trainee will:

1. 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.
2. Identify, discuss and critically evaluate a research, innovation or audit project that has resulted in an improvement in patient care, diagnostics or service delivery.

Indicative Content

Research Methods/Approaches
- Differentiation between audit and research
- Cohort studies
- Qualitative
- Quantitative
- Systematic review
- Meta-Analysis
- Sampling techniques
- Clinical Trials (pre-clinical to translational)
- Epidemiological Studies
- Study Design
- Hypothesis generation and testing

Ethical and Governance Research Frameworks
- Good Clinical Practice
- Human
- Animal Research
- Innovation
- Audit

Research, audit and innovation process
- Literature searching and referencing
- Innovation pathway (Invention, Evaluation, Adoption and Diffusion)
- Idea generation
- Patient/user involvement
- Peer/expert review
- Practical and financial criteria and constraints affecting research
- Dissemination/implementation
- Intellectual property
- Quality Assurance
- Monitoring and Reporting
- Archiving
- Roles and responsibilities of the research/innovation team

Data analysis techniques
- Data validity, reliability and appropriateness
- Application and interpretation of statistical techniques
- Power calculation
Clinical Guidelines
- Evidence based practice
- Statutory and advisory regulatory bodies.

Research and Innovation Funding
- Sources of funding including Research Councils and Charities
- Grant Applications
Section 4: Division/Theme Specific Modules

This section covers the theme specific modules that will be studied by all trainees undertaking the Clinical Pharmaceutical Science STP.

**Division:** Physical Sciences and Biomedical Engineering  
**Theme:** Clinical Pharmaceutical Science  
**Year 1:** Introduction to Clinical Pharmaceutical Science (40 Credits)  
Rotation A: Regulation and Quality Assurance  
Rotation B: Aseptics  
Rotation C: Manufacturing  
Rotation D: Radiopharmacy

This module provides the trainee with the knowledge that underpins the four work based rotations in the rotational work based learning programme.

**Learning Outcomes: Knowledge and Understanding**

On successful completion of this module the trainee will:

1. Discuss the role of the Clinical Scientist in Clinical Pharmaceutical Sciences in ensuring the safety of the patient, particularly related to the manufacture and quality control with reference to key patient care pathways.

**Regulation and Quality Assurance**

2. Discuss and critically evaluate the application of regulatory controls to pharmaceutical technology and quality assurance.
3. Discuss and critically evaluate the principles of Quality Assurance (QA) and Good Manufacturing Practice (GMP) and Quality Management Systems.
4. Design and construct manufacturing QA and QC documentation.
5. Discuss in detail the health and safety aspects of Pharmaceutical Technology and QA.
6. Describe and critically evaluate the classification of controlled areas, the monitoring of controlled areas for viable and non-viable particles, the limits to be applied to viable and non-viable particles and the cleaning of controlled areas.
7. Describe and critically evaluate the gowning required for working in controlled areas and be able to demonstrate putting the gowning on in a controlled and appropriate manner.
8. Describe and critically evaluate the operation, monitoring, cleaning and sterilisation of an isolator.
9. Describe and critically evaluate the process to be following when recalling a product from the market.
10. Describe and critically evaluate the three routes to obtaining a product licence including the associated timelines.
11. Describe the contents of an electronic Common Technical Document (eCTD) for a licensed product, with the CMC section be described in detail.

**Aseptics**

12. Describe the principles of basic pharmaceutical microbiology.
13. Explain key chemical and physical reactions affecting the stability of medicinal products.

14. Resolve drug formulation and administration problems, particularly where they relate to the modification, optimisation.

**Manufacturing**
15. Describe the principles of pharmaceutical formulation and processing
16. Describe the properties of excipients and ingredients in pharmaceutical products.
17. Explain the factors affecting formulation, stability and preservation of pharmaceutical product
18. Perform mathematical calculations relevant to pharmaceutical formulation.

**Radiopharmacy 1**
19. Discuss the UK regulatory requirements which apply to the design and operation of radiopharmacies and the different possible solutions to these requirements.
20. Recognise the different types of radiopharmaceuticals in routine clinical practice together with any particular problems arising from their use.
21. Describe the types of activities normally undertaken in a hospital radiopharmacy.
22. Describe the ways in which radiopharmaceuticals are prepared.
23. Discuss the general principles of QA in everyday life and in hospital pharmacy in particular including the most important means of control of aseptic preparation.
24. Describe how the principles of QA are routinely applied in a radiopharmaceutical production system.
25. Explain the nomenclature, principles, and mechanisms of atomic reactions
26. Describe the design and principles of particle accelerators and nuclear reactors and their relevance for production of radionuclides used in Nuclear Medicine.
27. Describe in both qualitative and quantitative terms the interactions of radiation with biological systems and discuss the relative risks of nuclear medicine procedures compared to other potentially hazardous life events.
28. Describe the principles of the most important types of radiation detectors used in Nuclear Medicine together with the way in which they are normally employed.
29. Describe the structure of the atom, the most important means of radioactive decay of unstable nuclei and the types of radiation emitted.
30. Recognise the radionuclides used in nuclear medicine and discuss the relationships between their physical properties, their clinical applications, and their strengths and weaknesses.
31. Describe the radiopharmaceutical chemistry of these radionuclides and discuss the influence of these chemical properties on the biodistribution of their radiopharmaceuticals.
32. List the different formulations used in nuclear medicine; describe their properties and the way in which these formulations are prepared; discuss the significance of the development of radiopharmaceutical kits and describe the function of the various reagents used therein.
Learning Outcomes: Associated Work Based Learning

High level description of the work based learning that accompanies this academic module. Further details of the work based programme can be found in the work based learning guide including the Clinical Experiential Learning, Competences and Applied Knowledge and Understanding.

On successful completion of this module the trainee will:

**Regulation and Quality Assurance**
1. Perform pharmaceutical development and formulation exercises
2. Use and critically review a Quality Management System
3. Take part in the audit process by witnessing an audit or being audited
4. Perform pharmacovigilance risk assessments
5. Assist in and evaluate internal and external auditing of suppliers and/or contract manufacturers.
6. Use a change control system to document a change to a product, facility or controlled documentation.

**Aseptics**
1. Identify and speciate micro-organisms using a microscope, gram straining and API strips.
2. Assist in performing a preservative efficacy test and the interpretation of the results.
3. Interpret stability data when determining the shelf life of a product.

**Manufacturing**
4. Manipulate a range of active pharmaceutical ingredients in a range of dosage forms, including the use of common excipients.
5. Assist in the operation of a range of various pieces of pharmaceutical manufacturing equipment, e.g. autoclaves, dry heat sterilising ovens, filling machines, filter integrity tester safely.

**Radiopharmacy**
1. Use the correct local procedures for entering and leaving the different types of controlled areas within the department.
2. Monitor an area for possible radioactive contamination and decontaminate the area if necessary.
3. Operate a $^{99m}$Mo-$^{99m}$Tc generator as follows:
   a. Calculate the expected theoretical technetium-99m yield of the generator.
   b. Elute the generator
   c. Measure the radioactivity of the eluate and calculate the elution efficiency.
   d. Perform a molybdenum breakthrough assay.
   e. Complete the documentation to record these activities
4. Prepare a technetium-99m labelled radiopharmaceutical from a ‘kit’ using appropriate radiation safety precautions
5. Calculate the volume of the preparation required to administer a (nominal) dose:
   a. immediately
   b. 4 hours later
6. Draw the required dose into a syringe and label.
7. Complete the documentation which would normally be used to record these activities in the radiopharmacy.

8. Measure the radiochemical purity of a prepared radiopharmaceutical such as \(^{99m} \text{Tc-MDP}\) using a miniaturised 2-system TLC assay.
   a. Calculate percentage purity and see if it meets the required specification
   b. Repeat the assay towards the end of the shelf-life of the material
   c. Complete the documentation to record these activities

9. Perform a constancy, linearity and geometry calibration check on an isotope assay calibrator.

10. Assist in normal daily preparation of radiopharmaceuticals.

11. Observe Radiopharmaceutical administration(s) and subsequent imaging of the patient(s).

12. Observe a nuclear medicine reporting session.

13. Assist in the radiolabeling of white blood cells.

14. Assist in the preparation and administration of an \(^{131} \text{I}\) therapy dose.

Indicative Content

**Clinical Pharmaceutical Science in key patient and care pathways**
- Diagnosis using radioactive materials
- Treatment relevant to the patient and care pathway including Chemotherapy
- Treatment using radioactive materials
- The role of regulation, Good Manufacturing Practice, aseptic techniques and quality assurance is ensuring patient safety

**Regulation and Quality Assurance**

- **Regulatory Aspects**
  - The Medicines Act and its implication to “specials” manufacturing and preparation activities, with particular attention on hospital-based work.
  - Consolidated Human Medicines Regulations
  - The rules governing medicinal products in the European Community
  - Environmental Protection Act
  - Consumer Protection Act
  - EEC Directives
  - Statutory Instruments
  - Medicines Act leaflets
  - Clinical Trials directive and UK implementation
  - Specifications and standards (British Pharmacopoeia, Ph, Eur, etc.)
  - Official reports (Farwell, Clothier, Rosenheim etc.) of relevance/importance

- **Quality Assurance**
  - Quality Assurance, including management and organisational aspects
  - Quality Risk Management
  - Quality Management Systems
Quality Audits: participation in internal and external audits and inspections, follow-up and reporting, including relevant aspects of Clinical Governance, Controls Assurance standards, Risk Management/Assessment and Critical Point Analysis

The role of the Qualified Person

Quality System Review.

BS.5750 – ISO 9000 etc.

LGC Schemes and Pharmassure Laboratory of Government Chemist (LG)

Governance and Controls Assurance, Risk Management and Critical Point Control Analysis.

UKAS

Good Manufacturing Practice (GMP)

International Good Manufacturing Practice (GMP) guidelines and standards.

Quality Assurance and technical information database.

Defective products, complaints and recall procedure

Inter-relationships between disciplines involved in quality assurance

Royal Pharmaceutical Society Hospital standards

• Documentation and Records
  
  Quality Assurance / Control Documentation
  
  Sampling programmes
  
  Standard Operating Procedures (SOPs).
  
  Specifications / worksheets
  
  Testing methods
  
  General laboratory records
  
  Status labelling systems etc.
  
  Information Management systems
  
  Change Control
  
  Manufacturing Documentation
  
  Master formula and manufacturing method
  
  Batch manufacturing records
  
  Batch packaging records
  
  Standard Operating Procedures, log books etc.
  
  Special records e.g. sterilisation, clinical trials, exception/deviation reports etc.
  
  Cross-contamination monitoring
  
  Cleaning schedules
  
  Materials management documents etc.
  
  Exception/Variation reporting

• Document Design
  
  Authorisation, control and indexing the documentation
  
  Updating and version control
  
  Archiving and alternatives to paper documents.
  
  (Microfilm, Electronic Data Processing) etc.

• Product Licence Application
Relationship of documentation to Product License data and any subsequent modifications.
Construction of application form and data required.

Manufacturing

- **Pharmaceutical Formulation and Processing**
  - Sources, preparation and purification of major drug substances and excipients
  - Formulation
  - Stability studies
  - Drug administration systems
  - Analytical method development
  - Specification development
  - Equipment calibration
  - Rational approach to process validation

- **Principles of formulation:**
  - Solutions, topical liquids
  - Semisolids, creams and ointments,
  - Injections including parenteral infusions e.g. nutrition mixtures
  - Tablets, capsules, cachets
  - Specialised dose forms for medicinal purposes (powders, depot products, inhalation products, transdermal products)
  - Extemporaneous preparation

- **Properties of excipients and ingredients in pharmaceutical products**
  - Thickeners, sweeteners, buffers, tonicity adjusters, preservatives, flavours and stabilisers

- **Principles of Rheology (viscosity and fluid flow)**

- **Key chemical and physical reactions involved in the preparation, stabilisation, and degradation of medicinal products:**
  - Solubility, dissolution,
  - Ionisation, de-ionisation of water, conductivity
  - pH and acid-base reactions
  - Precipitation, salting out, flocculation
  - Complexation etc.
  - Redox reactions, (oxidation, reduction, redox potentials)
  - Partitioning, phase separation,
  - Thermal issues, boiling point, melting point, volatilisation/vapours
  - Thermolabile degradation / effects of temperature etc.

- **Mathematical principles and calculations for pharmaceutical sciences**
  - Buffering and related calculations
  - Dilutions and dose adjustments
  - Tonicity adjustments

- **Miscellaneous**
Principles of drug absorption and uptake
Transport across membranes
Principles of compounding parenteral nutrition mixtures

Aseptics

- **Pharmaceutical Microbiology**
  - Micro-organisms, Microbial growth (form and actions of microbes)
  - Sources of microbiological contamination,
  - Potential risks from microbial contamination. (Pathogens and infection risks)
  - Spoilage and control / preservation

Radiopharmacy

- UK regulatory requirements which apply to the design and operation of radiopharmacies and the different possible solutions to these requirements
- Radiopharmaceuticals in routine clinical practice together with any particular problems arising from their use
- Activities normally undertaken in a hospital radiopharmacy
- Radiopharmaceuticals preparation
- Quality Assurance in Radiopharmacy in particular and describe the most important means of control of aseptic preparation and how the principles of QA are routinely applied in a radiopharmaceutical production system
- Nomenclature, principles, and mechanisms of atomic reactions
- The design and principles of particle accelerators and nuclear reactors and their relevance for production of radionuclides used in Nuclear Medicine
- Qualitative and quantitative terms the interactions of radiation with biological systems, discuss the relative risks of nuclear medicine procedures compared to other potentially hazardous life events
- The principles of the most important types of radiation detectors used in Nuclear Medicine together with the way in which they are normally employed
- The structure of the atom, the most important means of radioactive decay of unstable nuclei and the types of radiation emitted therefrom
- Radionuclides used in nuclear medicine
  - the relationships between their physical properties, their clinical applications, and their strengths and weaknesses
  - the radiopharmaceutical chemistry of these radionuclides
  - the influence of these chemical properties on the biodistribution of their radiopharmaceuticals
  - the different formulations used in nuclear medicine; properties and preparation
  - radiopharmaceutical kits and reagents used therein
### Section 5: MSc Specialist Modules for Clinical Pharmaceutical Science

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<th>Year 3 Specialist Modules</th>
<th>Module Titles</th>
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<tr>
<td></td>
<td>Research Methods</td>
<td>10</td>
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<td>Production</td>
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<td></td>
<td>Quality Control</td>
<td>10</td>
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<tr>
<td></td>
<td>Research Project in Clinical Pharmaceutical Science</td>
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<table>
<thead>
<tr>
<th>Year 1 Core Modules</th>
<th>Module Titles</th>
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<tbody>
<tr>
<td></td>
<td>Healthcare Science integrating science and professional practice</td>
<td>20</td>
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<tr>
<td></td>
<td>Introduction to Clinical Pharmaceutical Science Underpinning knowledge for rotational elements and integrated professional practice</td>
<td>40</td>
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</tbody>
</table>

**Legend:**
- Blue: Generic Modules: Common to all divisions of Healthcare Science
- Yellow: Division/Theme Specific Modules: Common to a division or theme
- Orange: Specialist Modules: Specific to a specialism
This module provides the trainee with the knowledge that underpins the specialist module in the practice of Clinical Pharmaceutical Science and provides the trainee with the knowledge and understanding that underpins and is applied to work based learning.

**Learning Outcomes: Knowledge and Understanding**

On successful completion of this module the trainee will:

1. 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 products and Investigational Medicinal Products including cytotoxic drugs for the treatment of cancer.
2. Apply management principles to the detailed structure of the production process.
3. Describe the principles of quality assurance in relation to pharmaceutical production.
4. Show the relevance of pharmaceutical law and regulations.
5. Explain the process of product design.
6. Explain and critically evaluate the theory and practice of pharmaceutical manufacturing, assembly, preparation and dispensing.
7. Apply the principles of processing in regard to pharmaceutical production.
8. Explain the principles of sterilisation by irradiation, filtration, gas, moist and dry heat.

**Learning Outcomes: Associated Work Based Learning**

High level description of the work based learning that accompanies this academic module. Further details of the work based programme can be found in the work based learning guide including the Clinical Experiential Learning, Competences and Applied Knowledge and Understanding.

On successful completion of this module the trainee will:

1. Design labels which comply with the legal requirements and BP requirements, and use appropriate colours to improve identification.
2. Manufacture a range of various pharmaceutical dosage forms.
3. Operate a range of various pieces of pharmaceutical manufacturing equipment, e.g. autoclaves, dry heat sterilising ovens, filling machines, filter integrity tester safely.
4. Interpret the data output of autoclaves and dry heat sterilising ovens.
5. Validate autoclaves and dry heat sterilising ovens.
6. Perform validation and routine monitoring of a WFI and Purified Water system.
Indicative Content

• Quality Assurance
  o Quality Assurance
  o Quality Audits

• Product Design
  o Packaging requirements
  o Labelling requirements and regulations
  o Stability considerations

• Manufacture, Assembly, Preparation and Dispensing
  o Solid dose forms
  o Liquid oral medicines
  o External liquids
  o Semi-solids (ointments, creams, gels and pastes)
  o Sterile topical liquids
  o Irrigations
  o Injections and infusions
  o Miscellaneous others

• Processes
  o Weighing
  o Measuring
  o Milling
  o Mixing
  o Filling
  o Sealing
  o Filtration - clarification/sterilisation

• Sterilisation Methods
  o Application of Microbiology to Sterilisation Techniques
    o HTM 2010 - Sterilisers
    o Sterilisation by moist heat
    o Sterilisation by dry heat
    o Gaseous sterilisation
    o Sterilisation by irradiation

• Pharmaceutical Water
  o Water purification and storage
  o Pharmaceutical handling and quality
  o HTM 2031 – Clean Steam
  o HTM 2030 – Washers
This module provides the trainee with the knowledge that underpins the specialist module in the practice of Clinical Pharmaceutical Science and provides the trainee with the knowledge and understanding that underpins and is applied to work based learning.

**Learning Outcomes: Knowledge and Understanding**

On successful completion of this module the trainee will:

1. Discuss the role of the Clinical Scientist in Pharmaceutical Sciences in ensuring the safety of the patient, particularly related to the manufacture of licensed and unlicensed products and Investigational Medicinal Products, with reference to key patient pathways such as cancer.
2. Explain the theory and use of all pharmaceutical microbiological and analytical techniques and instruments in a pharmaceutical quality control laboratory.
3. Discuss the quality of medical products, including raw materials, licensed and unlicensed products, "specials", Investigational Medicinal Products (IMPs), medical and surgical devices and medical gases.
4. Discuss the responsibilities required for managing a quality assurance system.
5. Discuss the role of quality audits and quality system reviews.
6. Justify the choice of, and apply statistical methods to sampling and testing.

**Learning Outcomes: Associated Work Based Learning**

High level description of the work based learning that accompanies this academic module. Further details of the work based programme can be found in the work based learning guide including the Clinical Experiential Learning, Competences and Applied Knowledge and Understanding.

On successful completion of this module the trainee will:

1. Lead an internal or external audit
2. Review the Quality System
3. Produce and interpret trended reports from the quality system.
4. Qualification of equipment or premises including design qualification (DQ), installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ).
5. Perform a range of analytical and microbiological techniques.
Indicative Content

Techniques and Instrumentation
- Volumetric analysis - aqueous and non-aqueous
- Identification tests, test tube reactions, limit tests
- Gravimetric analysis
- Refractometry
- Melting point
- Polarimetry
- Spectroscopy - UV/Visible
- Spectroscopy – Infra-red (IR)
- Spectroscopy – Atomic absorption
- Electrochemistry / pH
- Particulate measurement, liquids
- Solid Dose Forms, Physical testing methods (e.g. hardness, friability, disintegration; theoretical only)
- Dissolution (theoretical only)
- Thin layer Chromatography (TLC)
- High-performance liquid chromatography (HPLC)
- Gas Chromatography
- Ion separation Chromatography
- Endotoxin and pyrogen testing (theory)
- Pharmaceutical microbiology - \textit{sterility} testing, non-sterile product microbiology, water systems testing, preservative efficacy testing

The QC department
- Control of quality and the role of the quality controller
- Unlicensed products and “Specials”
- Involvement in Clinical Trials
  - Governance
  - Ethics
  - Quality Assurance
  - Monitoring

Product testing
- Purchased medicines
- Raw Materials
- Final products

Medical Gases
- Range and users of medical gases
- HTM 02 and permit-to-work system
- Role of ‘Quality Controller’ in Medical Gas Testing
- On-site testing

Statistics
- Application of statistical methods to sampling and testing methods
The overall aim of this module, building on the Research Methods module is for the trainee to undertake a research project that shows originality in the application of knowledge, together with a practical understanding of how established techniques of research and enquiry are used to create and interpret knowledge in a specialism of healthcare science. The research project may span scientific or clinical research, translational research, operational and policy research, clinical education research, innovation, service development or supporting professional service users to meet the expected learning outcomes. Research projects should be designed to take into account the research training required by individual trainees and the needs of the department in which the research is to be conducted.

**Learning Outcomes: Knowledge and Understanding**

On successful completion of this module the trainee will:

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

**Learning Outcomes: Practical Skills**

On successful completion of this module the trainee will:

1. Design, plan and undertake a research project to test a hypothesis from conception to completion/archiving in accordance with ethical and research governance regulations drawing on expert advice where necessary and involving patients and service users.
2. Analyse the data using appropriate methods and statistical techniques and interpret, critically discuss and draw conclusions from the data.
3. Prepare a written project that describes and critically evaluates the research project clearly identifying the strengths and weaknesses.
4. 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.
5. Prepare a summary of the research project suitable for non-specialist and lay audience.

**Indicative Content**
- Critical evaluate of the literature/evidence base
- Reference management
- Identification of a research question
- Research ethics and regulatory requirements including issues related to access and use of information
- Data protection and confidentiality guidelines
- Patient Safety
- Patient Consent
- Sources of funding/grants
- Peer review/expert advice
- Possible risks and balancing risk vs benefit
- Project management techniques and tools
- Roles and responsibilities of those involved in the research
- Monitoring and reporting
- Data Analysis
- Data Interpretation
- Criteria/metric for assessing and grading research data and publications in the Scientific, NHS and HE Sectors
- Range of formats and modes of presentation of data
- Requirements for publications submitted to scientific, education and similar journals
- Current conventions in respect of bibliography and referencing of information

**Division:** Physical Sciences and Biomedical Engineering  
**Theme:** Clinical Pharmaceutical Science  
**Specialism:** Clinical Pharmaceutical Science  
**Year 3:** Radiopharmacy 2  
**[15 Credits]**

This module provides the trainee with the knowledge that underpins the specialist module in the practice of Clinical Pharmaceutical Science and provides trainees with the knowledge and understanding that underpins and is applied to work based learning.

**Learning Outcomes: Knowledge and Understanding**

On successful completion of this module the trainee will:

1. Discuss 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
2. Discuss the regulations controlling transport of radioactive materials in the UK and describe the means taken to comply with these regulations.
3. Explain the mechanisms by which commonly used radiopharmaceuticals localise in their target tissues.
4. Describe those problems which might arise during the preparation and clinical use of radiopharmaceuticals and know how to identify and solve them where appropriate.
5. Describe the possibilities for interactions both desired and undesirable between radiopharmaceuticals and other medications.
6. Access and evaluate sources of reference information on all aspects of radiopharmaceuticals.
7. Describe the general principles of PET imaging and the organisation of a PET radiopharmacy and list the products most commonly used therein together with their clinical indications.
8. Describe the types of procedures routinely employed in hospital radiopharmacy management.
9. Explain the QC parameters which determine the quality of radiopharmaceuticals.
10. Describe the analytical methods by which these parameters are measured.
11. Discuss the significance of the development of radionuclide generators for Nuclear Medicine, and the principles of their design and operation, describe the 99Mo/99mTc generator system and give examples of other generators in routine use.
12. Discuss the importance of radiation hygiene and safe working in radiopharmaceutical preparation.
13. Discuss the need for automation in radiopharmaceutical preparation and the possible ways in which this might be achieved.
14. Discuss the physical and chemical properties required of a therapeutic radiopharmaceutical and list the products approved for general use in Nuclear Medicine together with their clinical applications.
15. 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.

Learning Outcomes: Associated Work Based Learning

High level description of the work based learning that accompanies this academic module. Further details of the work based programme can be found in the work based learning guide including the Clinical Experiential Learning, Competences and Applied Knowledge and Understanding.

On successful completion of this module the trainee will:

1. Order, receive, unpack and store radioactive materials follow the local procedures.
2. Prepare a package for transport of a radiopharmaceutical by road.
3. Calculate the transport index and prepare the necessary documentation to accompany the package.
4. Review documentation including local radiation safety rules, ARSAC certificates, Environment Agency authorisations, Site master file, Operating procedures etc.
5. Perform the normal daily preparation of radiopharmaceuticals.
6. Participate in Radiopharmaceutical administration(s) and subsequent imaging of the patient(s).
7. Participate in a nuclear medicine reporting session.
8. Perform the radiolabeling of white blood cells.
9. Prepare and administer an $^{131}$I therapy dose.
10. Assess the risks (pharmaceutical and radiation) associated with planned new facilities or services for radiopharmacy.
11. Specify design features for new radiopharmacy facilities or services.
12. Perform in radiopharmacy quality audits.
13. Critically appraise the framework for quality audit of radiopharmacy a radiopharmacy service against legislative requirements.
14. Perform quality assurance tests of equipment used in the preparation and quality control of radiopharmaceuticals.
15. Manage equipment associated with the preparation and quality control of radiopharmaceuticals.
16. Advise Nuclear Medicine services on Good Manufacturing Practice (GMP) and radiation safety requirements for radiopharmacy service.
17. Write and disseminate standard operating procedures (SOP) for the quality management system for the preparation and quality control of radiopharmaceuticals.
18. Perform a range of non-imaging in-vivo and in-vitro tests using radiopharmaceuticals.
19. Advise Nuclear Medicine services on the properties, use, formulation and suitability of radiopharmaceuticals used in diagnosis and therapy.
20. Advise Nuclear Medicine services on special dosage formulations of radiopharmaceuticals.
21. Investigate unusual clinical findings in patient scans to determine any possible relationship to administered radiopharmaceuticals and report findings, maintaining patient confidentiality.
22. Assess whether unusual clinical findings affect the validity of the patient scan due to radiopharmaceutical defects or medicines interactions.
23. Investigate adverse medicines reactions and explain the likely interrelationship between patient symptoms or reaction or reaction and administered radiopharmaceutical.
24. Advise Nuclear Medicine services on the potential medicine interactions and interventions that may affect radiopharmaceutical performance or the outcome of a patient investigation or treatment.
25. Advise Nuclear Medicine services when an undesired patient radiation exposure may arise from either misadministration or maladministration of a radiopharmaceutical.
26. Advise Nuclear Medicine services on the suitability and formulation of non-radioactive medicines used to enhance nuclear medicine studies.
27. Prepare appropriate reports on radiopharmaceutical defects and adverse reactions.
28. Advise Nuclear Medicine services on the administration of medicines for the protection of organs from unwanted radiation exposure.
29. Advise Nuclear Medicine services on the requirements for cessation of breastfeeding prior to administration of radiopharmaceuticals.
30. Assess and interpret radiopharmaceutical in-process and end products quality test results e.g HPLC, thin-layer chromatography, pyrogen tests etc.

Indicative Content

- Regulations controlling transport of radioactive materials in the UK and the means taken to comply with these regulations
- The mechanisms by which commonly used radiopharmaceuticals localise in their target tissues
- Problems which might arise during the preparation and clinical use of radiopharmaceuticals and know how to identify and solve them where appropriate
- Interactions both desired and undesirable between radiopharmaceuticals and other medications
- Sources of reference information on all aspects of radiopharmaceuticals.
- Cyclotrons and the production of PET radiopharmaceuticals
- The general principles of PET imaging
- The organisation of a PET radiopharmacy
- PET radiopharmaceuticals and their production
- Clinical indications for the use of PET
- Routine procedures used in hospital radiopharmacy management
- The organisational and financial aspects of a commercial radiopharmacy
- The relative advantages of commercial and non-commercial systems
- QC parameters which determine the quality of radiopharmaceuticals
- The analytical methods by which QC parameters are measured
- The principles of radionuclide generators, their design and operation including the 99Mo/99mTc generator system other generators in routine use
- Radiation hygiene and safe working in radiopharmaceutical preparation
- Automation in radiopharmaceutical preparation
- Physical and chemical properties of therapeutic radiopharmaceuticals
- Therapeutic radiopharmaceutical products approved for general use in Nuclear Medicine together with their clinical applications
- The functions of the different cell types routinely labelled in nuclear medicine
- Cell labelling procedures
- Clinical indications for cell labelling
This module provides the trainee with the knowledge that underpins the specialist module in the practice of Clinical Pharmaceutical Science and provides trainees with the knowledge and understanding that underpins and is applied to work based learning.

**Learning Outcomes: Knowledge and Understanding**

On successful completion of this module the trainee will:

1. Discuss and justify all Standards, Practices and Quality Assurance arrangements relating to aseptic preparation and dispensing of medicines and their application to patient safety and patient centred care.
2. Explain pharmaceutical microbiological aspects of aseptic manufacture and preparation and their application in the workplace.
3. Evaluate the use of clean rooms/clean air devices to the best of their design potential.
4. Discuss the correct commissioning procedures for a clean room environment.
5. Explain the function and operation of monitoring equipment and the maintenance of operational records.
6. Interpret monitoring data and diagnose problems.

**Learning Outcomes: Associated Work Based Learning**

High level description of the work based learning that accompanies this academic module. Further details of the work based programme can be found in the work based learning guide including the Clinical Experiential Learning, Competences and Applied Knowledge and Understanding.

On successful completion of this module the trainee will:

1. Critically evaluate the design of a clean room installations
2. Critically evaluate the clean room procedures manuals
3. Assist in quality assurance and the release of finished products
4. Observe in an MHRA inspection of a clean room installation
5. Assist in the commissioning of a clean room environment following modification or installation
6. Assist in and critically evaluate a range of environmental monitoring tests within a clean room environment including:
   a. In situ high efficiency leak testing (DOP)
   b. Operator protection testing (KI discus)
c. Toxic substance monitoring
d. Microbiological methods of monitoring (including control of contamination)
e. Clean room clothing monitoring

Indicative Content

Aseptic dispensing and production
- Aseptic Processing and GMP
- Aseptic Manufacturing
- Personnel Aspects and Training
- Facilities and Equipment (Design, constriction, commissioning and operation)
- Policies and Standards
- Process Design
- Process Validation
- Protective Clothing
- Documentation, as applicable to specialist activities
- Starting Materials and Components
- Storage and Handling
- Labelling of Aseptic Products
- Product Shelf Life
- QA and Release of Finished Products
- Transfer of Materials
- Pharmaceutical Microbiology as applied to Aseptic Dispensing and Preparation

CLEAN ROOMS

Environmental Considerations
- Premises design - dependent upon product
- Materials used in pharmaceutical plant
- Air conditioning and clean-room design
- (External) Environmental monitoring
- Secure and appropriate storage
- Maintenance of services

Clean Room Construction
- (Design, Construction, Commissioning and Operation)
- Clean/aseptic rooms
- Air filtration plant
- Clean air devices e.g. Laminar Flow Cabinets (LFCs), Isolators
- Control of particulate contamination
- Cleaning and disinfection

Environmental Monitoring
- Clean/aseptic rooms
- Clean air devices e.g. LFCs, Isolators
- In situ high efficiency leak testing (DOP)
- Operator protection testing (KI discus)
- Toxic substance monitoring
• Specification and Standards, e.g. BS 5295, BS 5726, ISO-EN 14644, US Federal 209E
• Microbiological methods of monitoring (including control of contamination)
• Clean room clothing monitoring
Appendix 1: Contributor List

Members of the STP MSc and Work Based Programme Physical Sciences and Biomedical Engineering: Clinical Pharmaceutical Science

Development of the STP curriculum for the MSc Clinical Sciences and Work Based programme for Clinical Pharmaceutical Sciences has been coordinated by the Modernising Scientific Careers team in liaison with the DH Modernising Pharmaceutical Careers programme and the National School of Healthcare Science working with NHS and Higher Education colleagues. The professionals who have contributed to the development of this Scientist Training Programme since 2010 include:

Mark Andrews  Head of Quality Control, Torbay Hospital, Devon
Alison Beaney  Pharmacy Production/QC Unit, Royal Victoria Infirmary, Newcastle upon Tyne
Beverley Ellis  Radiopharmaceutical Scientist, Nuclear Medicine Centre, Central Manchester University Hospitals
Adrian Hall  Head of Radiopharmacy, Department of Physics, Royal Marsden Hospital, London
Joanne Hayes  Deputy Director, Quality Control North West
Paul Maltby  Principal Radiopharmacist, Radiopharmacy Department, Royal Liverpool and Broadgreen University Hospital, Liverpool
Roisin O'Hare  Clinical Pharmacist, Queens University, Belfast
Nick Precious  Technical Director, Moorfields Pharmaceuticals
Peter Rhodes  Chair NHS Pharmaceutical Aseptic Services Group
Anne Richardson  Radiopharmacy Services Manager, Leeds Teaching Hospitals NHS Trust, Leeds
Mark Santillo  Regional Quality Assurance Officer, Department of Quality Assurance, South Devon Healthcare NHS Trust
Martin Stephens  Associate Medical Director for Southampton University Hospitals NHS Trust

Professional bodies and societies were invited to review this Learning Guide and their feedback has shaped the final publication:

UK Radiopharmacy Group
NHS Pharmaceutical Aseptic Services Group
Committee of Pharmacy Manufacturing Managers

Modernising Scientific Careers Professional Advisors
Dr Derek Pearson

National School of Healthcare Science Professional Lead
Dr Chris Gibson
Appendix 2: Amendments Following Publication

MSc Clinical Sciences (Clinical Pharmaceutical Science)

Amendments Following First Publication
Appendix 3: Good Scientific Practice

Good Scientific Practice

Section 1: The purpose of this document

There are three key components to the Healthcare Science workforce in the UK:

1. Healthcare Science Associates and Assistants who perform a diverse range of task based roles with appropriate levels of supervision.

2. Healthcare Science Practitioners have a defined role in delivering and reporting quality assured investigations and interventions for patients, on samples or on equipment in a healthcare science specialty, for example Cardiac Physiology, Blood Sciences or Nuclear Medicine. They also provide direct patient care and more senior Healthcare Science Practitioners develop roles in specialist practice and management.

3. Healthcare Scientists are staff that have clinical and specialist expertise in a specific clinical discipline, underpinned by broader knowledge and experience within a healthcare science theme. Healthcare scientists undertake complex scientific and clinical roles, defining and choosing investigative and clinical options, and making key judgements about complex facts and clinical situations. Many work directly with patients. They are involved, often in lead roles, in innovation and improvement, research and development and education and training. Some pursue explicit joint academic career pathways, which combined clinical practice and academic activity in research, innovation and education.

This document sets out the principles and values on which good practice undertaken by the Healthcare Science workforce is founded.

Good Scientific Practice sets out for the profession and the public the standards of behaviour and practice that must be achieved and maintained in the delivery of work activities, the provision of care and personal conduct.

Good Scientific Practice uses as a benchmark the Health Professions Council (HPC) Standards of Proficiency and Standards of Conduct, Performance and Ethics, but expresses these within the context of the specialities within Healthcare Science, recognising that three groups of the workforce, Biomedical Scientists, Clinical Scientists and Hearing Aid Dispensers are regulated by the HPC. The aim is that the standards are accessible to the profession and understandable by the public.

Good Scientific Practice represents standards and values that apply throughout an individual’s career in healthcare science at any level of practice. The standards will be contextualised by the role within Healthcare Science that an individual undertakes. This means that the standards must be interpreted based on the role that an individual performs. For example, in supervised roles where individuals
work within defined procedures, rather than autonomously, some standards will need to be interpreted appropriately for the context of the specific role. There will, however, always be a requirement for an individual to work within the limits of their scope of practice and competence.

Students and trainees will be expected to be working towards meeting the expectations set out in this document. However, if an individual is undertaking further training and development following qualification from a professional training programme, he or she will be expected to be able to meet the standards in this document within their scope of practice.

The standards have been used to support curriculum development and will be used to underpin the process of judging individual equivalence, particularly for emerging specialisms.

The standards have been divided into five domains. The domains of Good Scientific Practice detailed in section 2 are:

1. Professional Practice
2. Scientific Practice
3. Clinical Practice
4. Research and development
5. Clinical Leadership

Section 2: The domains of Good Scientific Practice

Domain 1: Professional Practice

All patients and service users are entitled to good standards of professional practice and probity from the Healthcare Science workforce including the observance of professional codes of conduct and ethics. In maintaining your fitness to practice as a part of the Healthcare Science workforce, you must:

1.1  Professional Practice

1.1.1 Make the patient your first concern
1.1.2 Exercise your professional duty of care
1.1.3 Work within the agreed scope of practice for lawful, safe and effective healthcare science
1.1.4 Keep your professional, scientific, technical knowledge and skills up to date
1.1.5 Engage fully in evidence based practice
1.1.6 Draw on appropriate skills and knowledge in order to make professional judgements
1.1.7 Work within the limits of your personal competence
1.1.8 Act without delay on concerns raised by patients or carers or if you have good reason to believe that you or a colleague may be putting people at risk
1.1.9 Never discriminate unfairly against patients, carers or colleagues
1.1.10 Treat each patient as an individual, respect their dignity and confidentiality and uphold the rights, values and autonomy of every
service user, including their role in the diagnostic and therapeutic process and in maintaining health and well-being.

1.1.11 Respond constructively to the outcome of audit, appraisals and performance reviews, undertaking further training where necessary

1.2 Probity

1.2.1 Make sure that your conduct at all times justifies the trust of patients, carers and colleagues and maintains the public’s trust in the scientific profession

1.2.2 Inform the appropriate regulatory body without delay if, at any time, you have accepted a caution, been charged with or found guilty of a criminal offence, or if any finding has been made against you as a result of fitness to practice procedures, or if you are suspended from a scientific post, or if you have any restrictions placed on your scientific, clinical or technical practice

1.2.3 Be open, honest and act with integrity at all times, including but not limited to: writing reports, signing documents, providing information about your qualifications, experience, and position in the scientific community, and providing written and verbal information to any formal enquiry or litigation, including that relating to the limits of your scientific knowledge and experience

1.2.4 Take all reasonable steps to verify information in reports and documents, including research

1.2.5 Work within the Standards of Conduct, Performance and Ethics set by your profession

1.3 Working with colleagues

1.3.1 Work with other professionals, support staff, service users, carers and relatives in the ways that best serve patients’ interests

1.3.2 Work effectively as a member of a multi-disciplinary team

1.3.3 Consult and take advice from colleagues where appropriate

1.3.4 Be readily accessible when you are on duty

1.3.5 Respect the skills and contributions of your colleagues

1.3.6 Participate in regular reviews of team performance.

1.4 Training and developing others

1.4.1 Contribute to the education and training of colleagues

1.4.2 If you have responsibilities for teaching, develop the skills, attitudes and practices of a competent teacher

1.4.3 Ensure that junior colleagues and students are properly supervised

1.4.4 Support colleagues who have difficulties with performance, conduct or health

1.4.5 Share information with colleagues to protect patient safety

1.4.6 Provide work-based development for colleagues to enhance/improve skills and knowledge

Domain 2: Scientific Practice
As a part of the Healthcare Science workforce, you will keep your scientific and technical knowledge and skills up to date to effectively:

2.1 Scientific Practice

2.1.1 Develop investigative strategies/procedures/processes that take account of relevant clinical and other sources of information
2.1.2 Provide scientific advice to ensure the safe and effective delivery of services
2.1.3 Undertake scientific investigations using qualitative and quantitative methods to aid the screening, diagnosis, prognosis, monitoring and/or treatment of health and disorders appropriate to the discipline
2.1.4 Investigate and monitor disease processes and normal states
2.1.5 Provide clear reports using appropriate methods of analysing, summarising and displaying information
2.1.6 Critically evaluate data, draw conclusions from it, formulate actions and recommend further investigations where appropriate

2.2 Technical Practice

2.2.1 Provide technical advice to ensure the safe and effective delivery of services
2.2.2 Plan, take part in and act on the outcome of regular and systematic audit
2.2.3 Work within the principles and practice of instruments, equipment and methodology used in the relevant scope of practice
2.2.4 Demonstrate practical skills in the essentials of measurement, data generation and analysis
2.2.5 Assess and evaluate new technologies prior to their routine use
2.2.6 Identify and manage sources of risk in the workplace, including specimens, raw materials, clinical and special waste, equipment, radiation and electricity.
2.2.7 Apply principles of good practice in health and safety to all aspects of the workplace
2.2.8 Apply correct methods of disinfection, sterilisation and decontamination and deal with waste and spillages correctly.
2.2.9 Demonstrate appropriate level of skill in the use of information and communications technology

2.3 Quality

2.3.1 Set, maintain and apply quality standards, control and assurance techniques for interventions across all clinical, scientific and technological activities
2.3.2 Make judgements on the effectiveness of processes and procedures
2.3.3 Participate in quality assurance programmes
2.3.4 Maintain an effective audit trail and work towards continuous improvement

Domain 3: Clinical Practice
As a part of the Healthcare Science workforce, you will keep your clinical skills up to date and undertake the clinical duties appropriate to your role in order to effectively:

### 3.1 Clinical Practice

3.1.1 Ensure that you and the staff you supervise understand the need for and obtain relevant consent before undertaking any investigation, examination, provision of treatment, or involvement of patients and carers in teaching or research.

3.1.2 Ensure that you and the staff you supervise maintain confidentiality of patient information and records in line with published guidance.

3.1.3 Ensure that you and your staff understand the wider clinical consequences of decisions made on your actions or advice.

3.1.4 Demonstrate expertise in the wider clinical situation that applies to patients who present in your discipline.

3.1.5 Maintain up to date knowledge of the clinical evidence base that underpins the services that you provide and/or supervise and ensure that these services are in line with the best clinical evidence.

3.1.6 Plan and determine the range of clinical/scientific investigations or products required to meet diagnostic, therapeutic, rehabilitative or treatment needs of patients, taking account of the complete clinical picture.

3.1.7 Plan and agree investigative strategies and clinical protocols for the optimal diagnosis, monitoring and therapy of patients with a range of disorders.

3.1.8 Ensure that detailed clinical assessments are undertaken and recorded using appropriate techniques and equipment and that the outcomes of these investigations are reviewed regularly with users of the service.

3.1.9 Ensure the provision of expert interpretation of complex and or specialist data across your discipline in the context of clinical questions posed.

3.1.10 Undertake and record a detailed clinical assessment using appropriate techniques and equipment.

3.1.11 Provide specialised clinical investigation and/or analysis appropriate to your discipline.

3.1.12 Provide interpretation of complex and/or specialist data in the context of the clinical question posed.

3.1.13 Provide clinical advice based on results obtained, including a diagnostic or therapeutic opinion for further action to be taken by the individual directly responsible for the care of the patient.

3.1.14 Provide expert clinical advice to stakeholders in order to optimise the efficiency and effectiveness of clinical investigation of individuals and groups of patients.

3.1.15 Prioritise the delivery of investigations, services or treatment based on clinical need of patients.

3.1.16 Represent your discipline in multidisciplinary clinical meetings to discuss patient outcomes and the appropriateness of services provided.

3.1.17 Ensure that regular and systematic clinical audit is undertaken and be responsible for modifying services based on audit findings.

### 3.2 Investigation and reporting
3.2.1 Plan and conduct scientific, technical, diagnostic, monitoring, treatment and therapeutic procedures with professional skill and ensuring the safety of patients, the public and staff

3.2.2 Perform investigations and procedures/design products to assist with the management, diagnosis, treatment, rehabilitation or planning in relation to the range of patient conditions/equipment within a specialist scope of practice

3.2.3 Monitor and report on progress of patient conditions/use of technology and the need for further interventions.

3.2.4 Interpret and report on a range of investigations or procedures associated with the management of patient conditions/equipment

Domain 4: Research, Development and Innovation

As part of the Healthcare Science workforce, research, development and innovation are key to your role. It is essential in helping the NHS address the challenges of the ageing population, chronic disease, health inequalities and rising public expectations of the NHS. In your role, you will undertake the research, development and innovation appropriate to your role in order to effectively:

4.1 Research, Development and Innovation

4.1.1 Search and critically appraise scientific literature and other sources of information

4.1.2 Engage in evidence-based practice, participate in audit procedures and critically search for, appraise and identify innovative approaches to practice and delivery of healthcare

4.1.3 Apply a range of research methodologies and initiate and participate in collaborative research

4.1.4 Manage research and development within a governance framework

4.1.5 Develop, evaluate, validate and verify new scientific, technical, diagnostic, monitoring, treatment and therapeutic procedures and, where indicated by the evidence, adapt and embed them in routine practice

4.1.6 Evaluate research and other available evidence to inform own practice in order to ensure that it remains at the leading edge of innovation.

4.1.7 Interpret data in the prevailing clinical context

4.1.8 Perform experimental work, produce and present results

4.1.9 Present data, research findings and innovative approaches to practice to peers in appropriate forms

4.1.10 Support the wider healthcare team in the spread and adoption of innovative technologies and practice

Domain 5: Clinical Leadership

All patients and service users have a right to expect that Healthcare Science services efficiently and effectively managed to meet service needs. As a leader in Healthcare Science, you will seek to effectively:

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5.1 Leadership

5.1.1 Maintain responsibility when delegating healthcare activities and provide support as needed
5.1.2 Respect the skills and contributions of your colleagues
5.1.3 Protect patients from risk or harm presented by another person’s conduct, performance or health
5.1.4 Treat your colleagues fairly and with respect
5.1.5 Make suitable arrangements to ensure that roles and responsibilities are covered when you are absent, including handover at sufficient level of detail to competent colleagues
5.1.6 Ensure that patients, carers and colleagues understand the role and responsibilities of each member of the team
5.1.7 Ensure that systems are in place through which colleagues can raise concerns and take steps to act on those concerns if justified
5.1.8 Ensure regular reviews of team performance and take steps to develop and strengthen the team
5.1.9 Take steps to remedy any deficiencies in team performance
5.1.10 Refer patients to appropriate health professionals
5.1.11 Identify and take appropriate action to meet the development needs of those for whom you have management, supervision or training responsibilities
5.1.12 Act as an ambassador for the Healthcare Science community

*Good Scientific Practice AHCS V.2 Final September 2012*
## Appendix 4: Glossary

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Experiential Learning</td>
<td>The cyclical process linking concrete experience with abstract conceptualisation through reflection and planning.</td>
</tr>
<tr>
<td>Clinical Experiential Learning Outcomes</td>
<td>The activities that the trainee will undertake to enable and facilitate their learning in the workplace.</td>
</tr>
<tr>
<td>Competence</td>
<td>The ability of an individual to perform a role consistently to required standards combining knowledge, understanding, skills and behaviour.</td>
</tr>
<tr>
<td>Competence statements</td>
<td>Active and outcome-based statements that provide a further breakdown of the Learning Outcomes – reflecting what the trainee will be able to do in the workplace at the end of the programme. Each competence should link back to the numbered Learning Outcomes.</td>
</tr>
<tr>
<td>Component</td>
<td>An indication of the type of module within a learning guide i.e; rotational, specialist or elective</td>
</tr>
<tr>
<td>Curricula</td>
<td>An outline of the expected educational outcomes across a subject area The learning that is expected to take place during the Scientist Training Programme described in terms of knowledge, skills and attitudes.</td>
</tr>
<tr>
<td>Division</td>
<td>A high level description of an area of practice within healthcare science. There are three divisions: Life Sciences, Physical Sciences and Biomedical Engineering and Physiological Sciences.</td>
</tr>
<tr>
<td>Domains of Learning</td>
<td>Cognitive (knowledge and intellectual skills), affective (feelings and attitudes), interpersonal (behaviour and relationships with others) and psychomotor (physical skills)</td>
</tr>
<tr>
<td>Feedback</td>
<td>Specific information about the comparison between a trainee’s observed performance and a standard, given with the intent to improve the trainee’s performance. (van de Ridder JMM, Stokking KM, McGaghie WC and ten Cate OT. What is feedback in clinical education? Medical Education 2008: 42: 189–19)</td>
</tr>
<tr>
<td>Good Scientific Practice</td>
<td>Non-statutory guidance on the minimum requirements for good practice for the healthcare science workforce.</td>
</tr>
<tr>
<td>Host Department</td>
<td>The department which is responsible for the 3-year training programme and which the training officer is based.</td>
</tr>
<tr>
<td>Job</td>
<td>A specific definition of the work activities, requirements, skills required to undertake work activities within a local context. This differs from a role – see below.</td>
</tr>
<tr>
<td>Key Learning Outcome</td>
<td>A defined learning outcome linked to relevant competence(s) within the workplace Learning Guide</td>
</tr>
<tr>
<td>Knowledge and Understanding</td>
<td>The knowledge and understanding that must be applied in the workplace to achieve the stated competence.</td>
</tr>
<tr>
<td>Learning Framework</td>
<td>The specification for work based learning contained within the Learning Guide</td>
</tr>
<tr>
<td>Learning Module</td>
<td>A distinct set of learning outcomes and competences that form part of a programme. Modules may be rotational, specialist, elective or professional practice and can be combined to meet the needs of specific programmes</td>
</tr>
<tr>
<td>Learning Outcome</td>
<td>A high level, outcome based statement that describes what a trainee will be able to do at the end of the module</td>
</tr>
<tr>
<td><strong>Mentoring</strong></td>
<td>Mentoring is a process in which a trainer (mentor) is responsible for overseeing the career and development of the trainee. The emphasis is therefore on the relationship (rather than the activity).</td>
</tr>
<tr>
<td><strong>Module Aim</strong></td>
<td>The overall objective of a work based learning module – defining the intended learning achievements of the trainee. The Aim works together with the ‘Scope’ statement to define the overall objectives and scope of the module</td>
</tr>
<tr>
<td><strong>Module Scope</strong></td>
<td>A statement within work based learning modules that defines the range/limits/ of the learning undertaken by the trainee in a module – patients/investigations/equipment/modalities etc</td>
</tr>
<tr>
<td><strong>National Occupational Standards</strong></td>
<td>Nationally recognised standards of expected workplace performance and level of competence for a role. The standards are outcome-based, defining what the role holder should to be able to do, as well as what they must know and understand to demonstrate competent work performance. National Occupational Standards are supported by nationally agreed frameworks of expected attitudes, behaviour and skills.</td>
</tr>
<tr>
<td><strong>Practical Skill</strong></td>
<td>A cognitive, psychomotor, physical or communicative ability that supports performance of required role.</td>
</tr>
<tr>
<td><strong>Programme</strong></td>
<td>The package of learning, teaching assessment and quality assurance leading to an award.</td>
</tr>
<tr>
<td><strong>Provider</strong></td>
<td>An organisation that delivers required training and learning activities, to specified quality assurance requirements</td>
</tr>
<tr>
<td><strong>Role</strong></td>
<td>A collection of functions undertaken in the workplace that represent the main broad areas of work for all similar workers at national level. A role differs from a job, the latter being defined specifically for a local context.</td>
</tr>
<tr>
<td><strong>Specialism</strong></td>
<td>A focused area of practice within a theme of healthcare science.</td>
</tr>
<tr>
<td><strong>Trainer</strong></td>
<td>A qualified individual who provides learning and development support for trainees</td>
</tr>
<tr>
<td><strong>Theme</strong></td>
<td>A cluster of related specialisms within a division of healthcare science.</td>
</tr>
<tr>
<td><strong>Work based learning</strong></td>
<td>Learning that takes place in a real work setting and involves the application of academic learning to real work activities</td>
</tr>
<tr>
<td><strong>Work Performance</strong></td>
<td>The requirements of satisfactory and consistent demonstration of competence in specified functions for a work role.</td>
</tr>
<tr>
<td><strong>Work place</strong></td>
<td>A real work setting in which the trainee can apply learning.</td>
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</table>