

Clinical Pharmaceutical Science

Scientist Training Programme (STP)



Health Education North East

What is the STP?

The structure of the Scientist Training Programme



University

- MSc in Clinical Science:
- Academic teaching and assessment



Employer

- Work-based training:
- Practical training and assessment
 - Contract of employment

Themed Healthcare Science Divisions

Life Sciences

- Analytical Toxicology
- Anatomical pathology
- Blood transfusion science/transplantation
- Clinical biochemistry including paediatric metabolic biochemistry
- Clinical genetics/Genetic Science
- Clinical embryology & Reproductive Science
- Clinical immunology
- Cytopathology including cervical cytology
- Electron microscopy
- External quality assurance
- Haematology
- Haemostasis and thrombosis
- Clinical Immunology
- Histocompatibility & immunogenetics
- Histopathology
- Microbiology
- Molecular pathology of acquired disease
- Phlebotomy
- Tissue banking

Physiological Sciences

- Audiology
- Autonomic neurovascular function
- Cardiac physiology
- Clinical perfusion science
- Critical care science
- Gastrointestinal physiology
- Neurophysiology
- Ophthalmic and vision science
- Respiratory physiology
- Urodynamic science
- Vascular science

Bioinformatics including

- Clinical Bioinformatics and Genomics
- Computer science and modelling
- Health Informatics

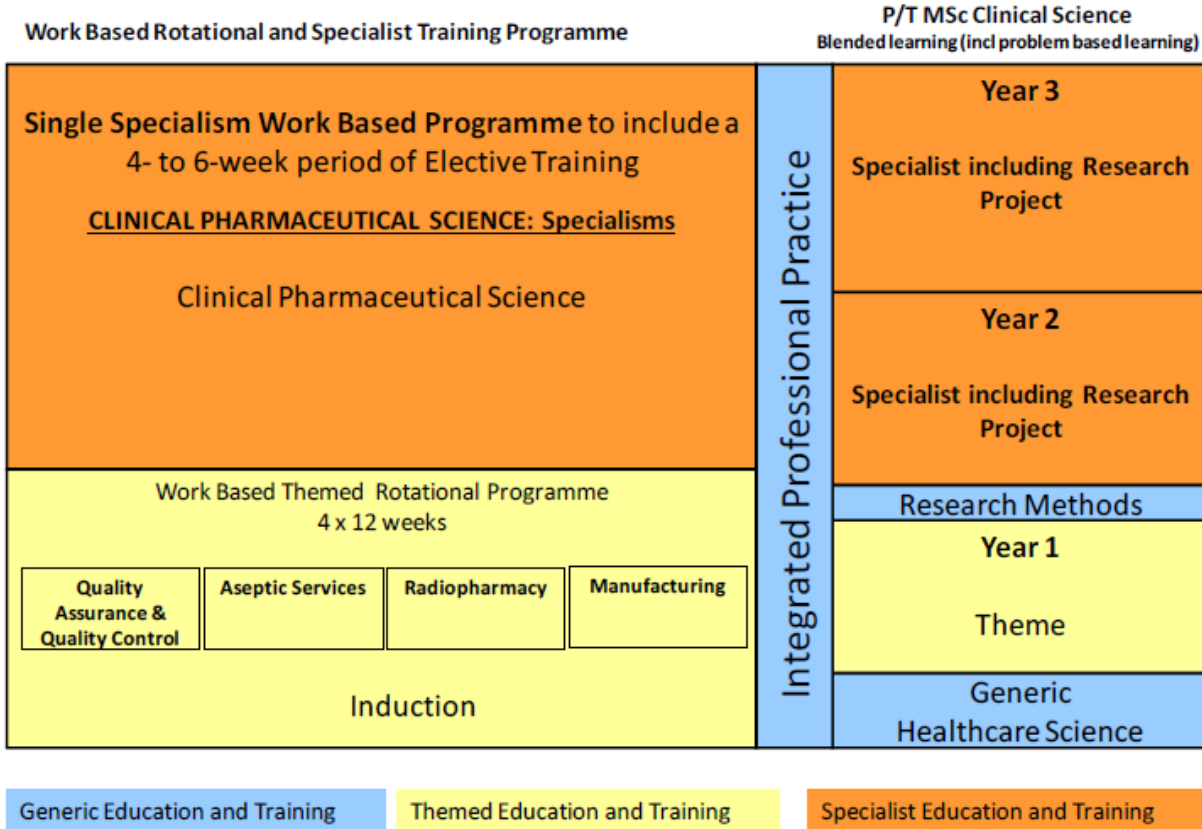
Physical Sciences and Biomedical Engineering

- Biomechanical engineering
- Clinical measurement & Development
- Clinical Pharmaceutical Science
- Diagnostic radiology & MR physics
- Equipment management & clinical engineering
- Medical electronics & instrumentation
- Medical engineering design
- Clinical photography
- Nuclear medicine
- Radiation protection & monitoring
- Radiotherapy physics
- Reconstructive Science
- Rehabilitation engineering
- Renal dialysis technology
- Ultrasound & non-ionising radiation



Many of these disciplines require small workforce numbers and provide highly specialist services. These specialisms are within the health and social care system in the UK inclusive of the NHS, Public Health England and the NHS Blood & Transplant service and in the private & third sector delivering NHS services for patients

Programme Structure



Programme Structure

1st year

4 specialism rotations in:

- QA/QC
- Aseptics
- Radiopharmacy
- Production

Additionally:

- Professional Practice

2nd & 3rd year

4 longer rotations in:

- QA/QC
- Aseptics
- Radiopharmacy
- Production

Additionally:

- Professional Practice
- Elective placement
- Research project

Quality Control and Quality Assurance

- We can't always detect a problem with a medicine until it's too late
- Potentially very hazardous to patient
- Element of trust
- Cannot test the whole batch

Healthcare Science staff in Clinical Pharmaceutical Science work to ensure the medicines a patient receives are SAFE and FIT FOR PURPOSE

Good Manufacturing Practice (GMP)

1. Having detailed written instructions before any job is started
2. Following instructions exactly
3. Ensure the correct products and materials are being used
4. Ensure that the correct equipment is being used and that it is clean
5. Prevent contamination and mix up
6. Always guard against labelling errors
7. Always work accurately and precisely
8. Keep things clean and tidy
9. Be on the lookout for mistakes, errors, and bad practices and report them immediately
10. Make clear and accurate records of what has been done and the checks carried out



STP activities – Quality Control and Quality Assurance

- Quality management system review and updates
- Investigations and root cause analysis
- Change Control, unplanned deviations
- Qualification of equipment
- Analytical Method Development
- Analytical Chemistry and Microbiological testing
- Product Release
- Stability Studies and Shelf life assignment
- Audits
- Product Quality Review
- Risk Assessments



Production

- Production of a variety of sterile / non-sterile batch products including: oral solutions, oral suspension, creams, ointments, over-encapsulation, sterile injections and eye drops
- Newcastle Specials have a Specials Licence, Investigational Medicinal Products Licence
- 6 manufacturing zones: clean rooms which utilise for example: isolators, LAFC, VHP sanitation and terminal sterilisation autoclaves.
- All facilities, equipment, processes and operators must be validated and managed

STP Activities - Production

- General Manufacture
- Production Planning
- Batch Manufacturing Records
- Label Design
- Validations – facilities, equipment, process, operators
- Planned Preventative Maintenance
- Storage management and good distribution practice
- Investigation reporting
- New Product Introduction
- Formulation Studies



Aseptic Services

- Unlicensed injectable medicines
- Preparation is carried out under section 10 of the medicines act under the supervision of a pharmacist.
- Usually high-risk products including: parenteral nutrition, cytotoxics, mabs, CIVAs
- Individual products for named patients. Short shelf-life (<1week)



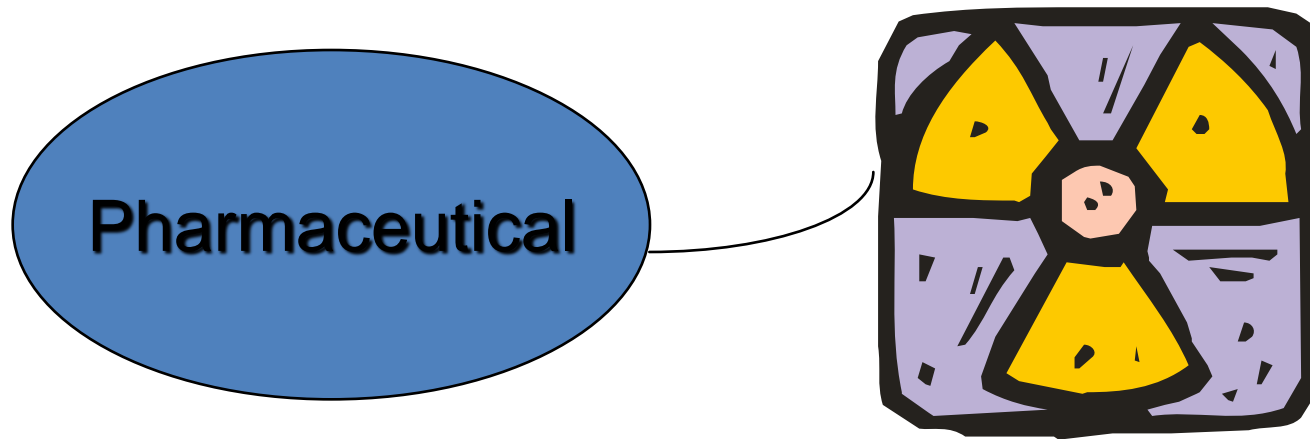
STP Activities - Aseptic Services

- Production
- Transfer Disinfection
- Process and Operator Validation
- Environmental Monitoring
- Staff Training
- Documentation review and updates
- Change Control
- Investigation and root cause analysis



A radiopharmaceutical has two essential components:

- A **pharmaceutical**, something that goes to the part of the body you want to look at
- tagged on to something that emits radiation – a **radionuclide**



- Use both Diagnostic and Therapeutic Radiopharmaceuticals

Radiopharmacy – Patient Pathway

Radionuclide Production



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Patient dose preparations



Interpretation



Patient Injection
and Scanning

STP Activities - Radiopharmacy

- Radiation safety and regulations (safety, transport and environmental agency)
- Investigations & Implementing improvements
- Production
- Staff training
- Documentation review and updates
- Validation of new equipment
- Routine Calibration of equipment
- Quality control
- Adverse effects & drug interactions
- Patient contact – observe therapies administration and patient scans



- Competencies
 - Skills/Knowledge/Understanding
- DOPs (Direct Observation of Practical Skills)
 - Manual Skills learnt and demonstrated
- OCEs (Observed Clinical Events)
 - Performance
- CBDs (Case Based Discussions)
 - Understanding and integration of knowledge from various sources

Potential roles upon completion

- Radiopharmaceutical Scientist
- Clinical Scientist: – QA / QC / Production Manager
- Pharmaceuticals: Microbiology, QC, Formulation Science, New Product Introduction, Regulatory Expert, Auditor
- Qualified Person
- Medical Gas Testing

STP Curriculum

- <https://curriculum.nshcs.org.uk/programmes/stp/SPE2-1-18>

EU GMP (Orange Guide)

- https://ec.europa.eu/health/documents/eudralex/vol-4_en

QAAPS (yellow guide)

- <https://www.rpharms.com/resources/professional-standards/quality-assurance-of-aseptic-preparation-services>

Other links:

- <http://www.ich.org/products/guidelines/quality/article/quality-guidelines.html>
- <https://pasg.nhs.uk/>
- <https://www.bnms.org.uk/ukrg/general/ukrg-homepage.html>
- <https://www.ema.europa.eu/>

Any Questions?

