Job Description, Consultant Pharmacist –Clinical Trials and Advanced Therapies

Organisation: iMATCH, University of Manchester NHS Foundation Trust

Document version number: 1

Date written: June 2019

Funded by UK Research and Innovation

Coordinated by CATAPULT Cell and Gene Therapy

claims, losses or damages that are related to the use or reliance whatsoever in the content of the document or any part thereof, except to the extent that such liability cannot be excluded by law. We do not seek to exclude or limit in any way our liability to the user for personal injury or death caused as a result of our negligence or seek to exclude or limit our liability for fraud or fraudulent misrepresentation by us.

We reserve the right to make changes and improvements to any information contained within this document, at any time and without notice. Where this document contains hyperlinks to other websites operated by parties not connected to us, such hyperlinks are provided for your reference only. We do not control such websites and are not responsible for their contents. The inclusion of hyperlinks from this document or the website to such websites does not imply any endorsement of the material on such websites or any association with their operators. We accept no responsibility of any nature whatsoever for linked web sites or any information contained in them.

Funded by
UK Research and Innovation

Coordinated by
CATAPULT Cell and Gene Therapy

MANCHESTER UNIVERSITY NHS FOUNDATION TRUST

JOB DESCRIPTION

Job Title: Consultant Pharmacist –Clinical Trials and Advanced Therapies

Grade: Band 8c

Division: Clinical Scientific Services

Directorate: Pharmacy

Base: Pharmacy Department MFT

ORGANISATIONAL RELATIONSHIPS

Managerially Accountable to: Chief Pharmacist

Reports to: Chief Pharmacist

Organisation Chart: See Appendix 1

Our Trust Values:

Pride	Respect	Empathy	Consideration	Compassion	Dignity
I will show pride by being the best in everything I do	I will show regard for the feeling, rights and views of others	I will show empathy by understanding the emotions, feelings and views of others	I will show thoughtfulness and regard for others, showing consideration for their feelings and circumstances	I will show understanding, concern and contribute to providing a safe, secure and caring environment for everyone	I will show respect and value all individuals and their diverse needs

JOB PURPOSE

Aim of the role:
The Consultant Pharmacist, as the expert within their Specialist Area of practice, provides a dynamic link between clinical practice and service development by creating new models for delivering patient care ensuring the

best experience and outcomes for patients from their medicines whenever and wherever their care is delivered

- The post holder is employed by Manchester University NHS Foundation Trust. Clinical trials and ATMPs are delivered across different sites in the organisation. The post holder will have leadership and management responsibility for the development and delivery of effective pharmacy services for Clinical Trials and Advanced Therapy Medicinal Products (ATMPs). The post holder will work in conjunction with the clinical pharmacy leads, pharmacy aseptic staff and Quality Assurance specialists to develop the provision of an efficient, high quality, professional and well-coordinated service capable of meeting all statutory, regulatory and NHS requirements relating to Clinical trials and ATMPs. The key responsibilities are as below:

- To provide a service to the Clinical Trials pharmacy service and ATMPs optimising patient outcomes and improving the patient experience, working within patient care pathways across sectors and healthcare boundaries

- To manage, strategically lead and co-ordinate the pharmacy team in the provision of a safe, effective and efficient clinical pharmacy service to the Clinical Trials pharmacy service and ATMP, in accordance with local and national standards and strategy

- To contribute to improving health outcomes for patients using a holistic approach to care, ensuring the safe and effective use of medicine through provision of medicines-related aspects of patient care

- To ensure pharmacy clinical trials services are provided in a safe, efficient manner and are compliant with relevant EU legislation and professional regulations.

- To ensure pharmacy clinical trials services are fully aligned to support the Trust's research strategy and the Pharmacy and Medicines Management Services Strategy.

- To lead Pharmacy support at MHRA GCP inspections ensuring access to documentation

- To provide with expert advice to the national CT pharmacy advisory group, Trust's R&I Division and Clinical Trials Principal Investigators in respect of all aspects of IMP manufacture, procurement and use and of adherence to associated legislation.

- Provide professional leadership to Clinical trials pharmacy staff and manage the Lead Pharmacists ensuring compliance with regulations and standards.

- To lead, manage, develop and be responsible for Medicines Clinical Trials and Advanced Therapy Medicinal Products pharmacy services across MFT.

- Deputise for the Chief Pharmacist at the Trust R&D Governance, providing regular updates on pharmacy services, performance metrics and on developments with Advanced Therapy Medicinal Products.

- To be the Lead specialist for clinical trials and ATMPs pharmacy services in the Trust, clinical trial stakeholders and associated organisations including; R&D, The University of Manchester, Chief and Principal Investigators & the pharmacy clinical trials teams to ensure that Investigational Medicinal Products (IMPs) are handled in accordance with statutory requirements for Good Clinical Practice.

- Be responsible for pharmacy clinical trials services working practices to assure the Trust of compliance with the Human Medicines Regulations 2012 SI No.1916 and the applicable SI including: Medicines for Human Use (clinical trials) Regulations 2004 and subsequent amendments; The Medicines for Human Use (Clinical Trials) and blood safety and quality (Amendment) Regulations 2008, SI No.941; EU Directive 2001/20EC, International Convention of Harmonisation (ICH) guidelines for Good Clinical Practice (GCP)

- To assure trust compliance with ATMPs Regulations including SI 1394/2007, incorporated into an amendment Directive 2001/83/EC, together with Directive 2009/120/EC ; and 2009 “Detailed guidelines on Good Clinical Practice specific to advanced therapy medicinal products and SI 2010/1882.

- Updates and advises the Chief Pharmacist and wider Pharmacy Senior Management Team on pharmacy clinical trial services and Advanced Therapy Medicinal Products providing assurance on compliance with legislation, capacity and capability.

- Act as the pharmacy expert on Advanced Therapy Medicinal Products contributing to their safe and efficient handling within the Trust and compliance with regulation and guidance.

- Lead pharmacy input into the Trust Advanced Therapy Medicinal Products Assurance Group providing expert Quality Assurance advice on the safe handling of products and compliance with legislation and guidance.

- To use innovation to support effective patient outcomes, safety and experience aligned with relevant national agenda.

- To lead, undertake, supervise and publish research in Specialist Area.

- In line with the National Profiles for Pharmacy, produced by NHS Employers, the consultant pharmacist post requires the postholder to:
  a. Be responsible for leading and delivering highly specialist pharmacy service; undertake relevant risk management and ensure compliance with medicines legislation
  b. Provide expert advice on pharmaceutical matters in specialist field
  c. Lead and develops clinical audit; co-ordinate and undertake research; provide specialist training

---

MAIN DUTIES AND RESPONSIBILITIES

Statutory Professional Responsibilities

- Practice within the professional boundaries described by the General Pharmaceutical Council.
- Undertake annual professional revalidation comprising; Continuing professional development (CPD) entries, reflective account and peer discussion.
- Follow legal, ethical, professional and employers codes of conduct.
- Undertake formal GCP and GMP training and maintain competency.
- To contribute to local, regional and national training initiatives for clinical trials and Advanced Therapy Medicinal Products services.

Expert professional practice

- To be recognised as an expert within the speciality of clinical pharmacy, locally and nationally and/or internationally
- Provide senior level expert advice to the Trust R&I division, Chief Investigators & the Trust on Investigational Medicinal Products (IMPs) and take responsibility for their procurement, storage and handling on site.
- Act as the main pharmacy link to research stakeholder groups including; the Manchester British Clinical Research Centre, Manchester Clinical Trials Unit and The University of Manchester Research and Governance team.
- Provide expert advice on the trust use of advanced therapy medicinal products (including gene therapy, somatic cell therapy and tissue engineered products) ensuring compliance with prevailing regulations and guidance.
- Oversee pharmacy governance arrangements for ATMPs ensuring they are of appropriate quality for their intended use and introduced safely.
- Lead expert pharmacy support to the Trust Advanced Therapy Medicinal products Assurance Group including;
  - Development of trust policy and SOPs
  - Compliance with legislation and guidance
  - Technical and regulatory assessment and advice
  - Ensure that staff handling ATMPs have the appropriate skills and expertise
  - Ensure robust links with specialist pharmacy teams including; clinical trials, QA/QC, formulary and procurement.

- Be responsible for Pharmacy working practices to assure the Trust of compliance with the Medicines for Human Use (Clinical Trials) Regulations 2004 (EU Directive 2001/20EC), International Convention of Harmonisation (ICH) guidelines for Good Clinical Practice (GCP).
- Provide advice to all trust research stakeholders in respect of all aspects of IMP/ATMP manufacture, procurement and use and of adherence to associated legislation.
- To maintain a comprehensive knowledge of national regulations and directives, legislation and recommendations from the Department of Health, the European Medicines Agency (EMA), the MHRA, NHS England and the General Pharmaceutical Council and Royal Pharmaceutical Society relating to IMPs, ATMPs and GCP. To be responsible for the impact of changes to these standards and implementing change where required.
- Provide expert and management support for MHRA GCP inspections, other national regulatory bodies and sponsor inspections, collaborating and communicating complex regulatory information to ensure that action is undertaken to resolve any findings.
- Ensure that clinical trials and advanced therapy medicinal products services are integrated into the pharmacy clinical governance agenda and play a lead role in the agenda and work of the Pharmacy Governance Group.
- To appropriately manage difficult and ambiguous problems, managing uncertainty, and to make decisions with limited information.

Service Development & Performance Management

- Strategically plans, develops and monitors pharmacy services for clinical trials and ATMPs, taking overall responsibility for ensuring the safe, clinically effective and economic management of medicines and compliance with current legislation, professional standards and organisational objectives.
- To work with the relevant stakeholders in developing a model of care delivery for the management of ATMPs for both trial and non-trial use, including prescribing, preparation, storage, dispensing, administration and patient monitoring.
- To support the managed introduction of new ATMPs and IMPs, by supporting clinicians in making submissions to the Medicines Management Committee or equivalent and/or Early Phase Safety committee and to support the organisation finance manager in securing funding before usage.
- To liaise and develop processes, procedures and future roles with aseptics, QA departments, Stem Cell Laboratory and Manufacturing Units.
- Develop & maintain a database of pharmacy-relevant knowledge to support pharmacy staff, researchers and clinical staff who access and handle ATMPs.
- Develops expertise across the Trust in clinical trials and ATMPs.
- Manages the Specialist Clinical Trials and ATIMP pharmacists based in the Trust, setting and reviewing objectives according to Trust strategy and objectives.

- Takes overall responsibility for the identification and management of risk issues (particularly those related to medication) across the Clinical Trials and ATMP pharmacy service including ensuring that systems are in place and incidents are investigated, with appropriate corrective action undertaken
- Contributes to the development of the Trust Clinical Pharmacy Strategy and Operational Plan in conjunction with the Deputy Chief Pharmacist, Clinical Services and other key stakeholders.
- Responsible for proposing and implementing changes in practice, policy or procedure relating to medicines management in Clinical Trials and ATMPs within the Trust.
- Building effective working relationships with clinical and managerial staff locally and nationally, within the Clinical Trials national advisory group, as well as centres approved to administer ATMPs.
- To take a lead in introducing strategies to help manage the reporting and analysis of Clinical Trials and ATMP medicines expenditure across the Trust.
- To identify issues and problem solve whilst also developing and implementing solutions in conjunction with colleagues and other teams in the Trust and with external partners.
- To attend meetings and present information and reports nationally/regionally/locally as required.
- To understand, communicate and implement national policy relevant to their role through network activities.
- To work with local and national commissioners and stakeholders in investigating innovative treatment pathways.
- To be a member of and actively participate in MFT Trust-wide committees relevant to the role, including the ATMP Assurance Group Committee.
- To lead on business planning to maintain appropriate investment in staffing and resources required to deliver clinical trials and Advanced Therapy Medicinal Products pharmacy services in line with national standards and in conjunction with the Chief Pharmacist.
- Support the Chief Pharmacist in the development and delivery of Hospital pharmacy transformation plans, ensuring optimal service provision within available resources in line with corporate and national initiatives.
- Prepare long-term plans for a phased replacement of, and addition to major capital assets within the Clinical Trials and Advanced Therapy Medicinal Products pharmacy service

Teaching, training, Research, Audit and Evaluation

- Lead on external and internal audits relevant to clinical trials and advanced therapy medicinal products services.
- Agree standards with relevant section heads and be responsible for monthly KPI reporting for the pharmacy and medicines optimisation services dashboard.
- Leads and delivers training of pharmacy staff in all aspects of clinical trials and advanced therapy medicinal products as required. Supports relevant training for nursing and medical staff.

- Ensure all clinical trials and advanced therapy medicinal products management is reported to and discussed with the Chief Pharmacist on a regular basis
- Undertake regular audit using national and locally developed audit tools within clinical trials and advanced therapy medicinal products to ensure that all legal, professional and service requirements are met. Ensure the audit cycle is completed, especially where action points were identified.
- Create and assist with the audit and research in the use of medicines as appropriate in line with local policies and procedures.
- To seek funding to support research through sponsorship, research grant applications.
- To identify gaps in the evidence base, undertake research, and support others undertaking research. To submit and publish findings in appropriate peer reviewed journals.
- Participate in and contribute to the preparation and publication of benchmarking reports where required.
- Ensure that all pharmacy staff involved with clinical trials services/handling ATMPs have the appropriate qualifications and training and that these are maintained.
- To monitor medicines use within Specialist Area, includes recording of significant clinical interventions and risk management including:
    - Investigating and resolving of all complaints in Specialist Area
    - Recording significant clinical incidents/near misses
    - Ensuring compliance with medicines legislation and local policies
    - Investigating and resolving of all medication incidents and complaints in the directorate
- To participate in:
    - mandatory training in line with Trust and Departmental requirements
    - Continuing Professional Development, reflection and change practice to meet the professional requirements of the General Pharmaceutical Council and to ensure specialist knowledge and skills are current.
    - the induction and training of allocated pharmacy and non-pharmacy staff.
    - Trust appraisal schemes, identify training needs and maintain personal development plan.
    - Pharmacy Lunchtime Meetings and Education Programme. This will include occasionally presenting large teams of staff (30+).
- To manage the training of staff in Pharmacy and other departments in relation to IMPs and ATMPs. To ensure competency is assessed, updated and re-assessed where required.
- To continuously update highly specialist knowledge of issues relating to Clinical Trials and ATMPs including
    - National Legislation and Guidance
    - North West Guidance
    - Trust Initiatives
    - Relevant published literature

- To contribute to local and national educational meetings and training courses related to Clinical Trials and/or ATMPs, as per Trust education and training strategy.
- Designs, plans, organises, participates in and supervises multidisciplinary and pharmacy led audit/research for ATMPs (within the University of Manchester, as well as nationally, in collaboration with other research groups).
- Presents and/or publishes results of work locally, nationally and internationally in peer reviewed journals and at national & international meetings.
- To guide and support others undertaking research when required.
- To provide teaching for the pharmacy and Specialist Area staff as agreed within organisation, for example to other health professionals within local health economy and to HEI's supporting Education leads in the organisation and where appropriate, support postgraduate qualifications.
- To act as knowledge resource for medicines-related issues within the pharmacy and teams and more widely as appropriate

Communication and Working relationships

To develop positive working relationships with all NHS staff in all areas of work to ensure the safe and effective use of medicines and resolution of identified pharmaceutical care issues.

To collaborate and share learning with clinical trials and advanced therapy medicinal products pharmacy services colleagues in the wider healthcare system, regionally and nationally as part of established specialist pharmacy networks.

To produce and ensure quality of specialist written information or advice for the education of designated patients or other healthcare professionals when necessary with Senior Medicines Management Pharmacists.

To ensure adequate verbal or written communication is adopted with other healthcare professionals, patients and carers when providing specialist advice to ensure the safe and effective use of medicines and the resolution of identified pharmaceutical care issues in specialist areas. This may include communication with patients or carers having language difficulties, physical and mental disabilities.

To provide highly specialised evidence based medicines advice where appropriate to ensure safe, effective, economical and timely use of medicines.

To present relevant information to a wide audience at identified forums and meetings in line with the needs of the department, specialist area and Trust.

To promote, and participate in, team working within the Pharmacy Department.

Management

Accountable for the direct management of the Lead Clinical Trials Pharmacists at ORC, Wythenshawe Hospital and The University of Manchester and the Chief Clinical Trials Technician.
Continually review skill mix to meet service needs and professional standards in force at the time, and implementing change management to new requirements.
Develop and motivate staff; ensure annual appraisal and personal development planning
To ensure regular individual and team meetings for the clinical trials services staff.
Manage the Lead Pharmacist services and Chief Clinical Trials Technician to:

- Ensure clinical trials services meet the needs of the Trust within allocated resources according to an agreed capacity plan
- Ensure the handling of Investigational Medicinal Products and Advanced Therapy Medicinal Products in line with all necessary legislation and standards
- Ensure the quality management system, to meet necessary governance standards are in place.
- Be responsible for the staffing budgets and the procurement, maintenance of equipment and resources within the clinical trials and Advanced Therapy Medicinal Products services.
- Advise on the suitability and purchasing of equipment for clinical trials services,
- Support budgetary control for relevant pharmacy cost centres including clinical trials.
- To encourage pharmacists in the Clinical Trials pharmacy service and pharmacist providing ATMP therapies, to be aware of developments and develop expertise in their area of specialist practice and share good practice and act as a resource.

Work with the Chief Pharmacist in the delivery of Pharmacy Performance Standards

Leadership

Provide clinical and professional leadership to pharmacy clinical trials and Advanced Therapy Medicinal products services in accordance with the pharmacy strategy, priorities and objectives.

- Identify and promote best practice
- Motivate and inspire others to excel in practice
- Ensure that issues relating to clinical trials and advanced therapy medicinal products services including changes in practice are communicated to all pharmacy staff as appropriate

- Work collaboratively with all pharmacy staff and management, to ensure implementation of local and nationally agreed pharmacy service objectives
- Ensure operational policies are kept up to date with legal and professional developments
- Set standards, operational guidelines and safe systems of work. To monitor the compliance with these and ensure action is taken in the event of failure or incidents.
- Lead innovation and work actively to continuously improve services

Develop, implement and review the departmental strategy for pharmacy clinical trials and advanced therapy medicinal products services.

Ensure strategic input and implementation of plans for pharmacy clinical trials services regionally and nationally where appropriate.

Risk and Governance

Responsible for developing of strategies for risk assessing and mitigation strategies of ATMPs, sponsored and host clinical trials, working with colleagues in pharmacy and other departments

Undertake clinical audit and practice research within the pharmacy department.

To identify, assist in the development of and supervise audits to be carried out by pre-registration pharmacists and diploma students when related to ATMPs

To participate in Quality Assurance Audit and other audits / inspections e.g. CQC Inspection as directed by the Principal Pharmacist. To assist in provision of responses to audit findings within agreed timescales.

To ensure all appropriate statutory, advisory and clinical requirements are followed when participating in the provision of all medication including those used within clinical trials.

To assist in the implementation of Trust and National policies for safe medicines practice related to ATMPs

To promote risk management by participating in local and Trust error reporting systems.

To ensure all staff, including self, handle drugs and highly toxic substances (e.g. cytotoxic agents, ATMPs) in the correct and safe manner following Trust and National legislation.

To ensure complaints and HIRs related to ATMPs are investigated and are used as lessons for learning and trends are monitored and analysed as appropriate

Policy

To be responsible for the adherence and upholding of all Trust and departmental policies and procedures.

Hours of duty

The workload of the full-time post holder is assessed as 37.5 hours per week.

Appraisal

The post holder will be appraised by the Chief pharmacist

Health and safety

The Trust has a statutory responsibility to provide and maintain a healthy and safe environment for its staff to work in. You equally have a responsibility to ensure that you do nothing to jeopardise the health and safety of either yourself of anyone else. The trust's Health and Safety Policies outline your responsibilities regarding Health and Safety at Work.

Safe working practices and safety precautions must be adhered to. Protective clothing and equipment must be used where appropriate.

All accidents must be reported to the Duty Manager and you are asked to participate in accident prevention by reporting potential hazards

Infection prevention

Work with the antimicrobial pharmacist and infection prevention team to reduce hospital acquired infection and ensure effective use of antimicrobial agents in accordance with national and local guidelines within the directorate

As a member of a clinical team your personal contribution to reducing healthcare associated infections (HCAIs) require you to be familiar with the Trust's Hand Decontamination Policy, Personal Protective Equipment Policy, safe procedures for using aseptic techniques and safe disposal of sharps. You are required to attend induction training and mandatory training in Infection Prevention.

Security

The post holder has a responsibility to ensure the preservation of NHS property and resources.

Confidentiality

The post will maintain confidentiality at all times in respect to their work.

Team Briefing

The Trust operates a system of team briefing which is based on the principle that people will be more committed to their work if they fully understand the reasons behind what is happening in their organisation and how it is performing.
It is expected that all employees will attend the team briefing sessions.

Equal Opportunities

Manchester University NHS Foundation Trust encourages Equal opportunities and operates an Equal Opportunities Policy. All individuals regardless of race, ethnicity, nationality, gender or disability are encouraged to apply for all advertised posts.

Smoking

The Trust operates a no smoking policy. The policy applies to staff, patients and visitors and extends to the hospital grounds as well as internal areas. Staff appointed will undertake not to smoke on hospital premises.

Review

This job description will be reviewed periodically in consultation with the post holder to reflect the changing nature of the duties and requirements of the service.

Date: June 2019

Manchester University NHS Foundation Trust
Pharmacy Division

PERSON SPECIFICATION: Consultant Pharmacist Clinical Trials and ATMP (Advanced Therapy Medicinal Products) Band 8c

NB. This Person Specification has been mapped against the RPS Advanced Pharmacy Framework (APF) as per Competency Column

ATTRIBUTES	Competency as per APF	ESSENTIAL	DESIRABLE
Registration		Current membership of the General Pharmaceutical Council Current membership of the Royal Pharmaceutical Society	
Qualifications and 1. Expert professional practice	1.1 Expert Skills and Knowledge	• BPharm or MPharm degree • MSc in Pharmacy Practice or equivalent • Formal Management Qualifications • Job related Postgraduate qualification e.g. clinical diploma, or equivalent vocational experience • Substantial experience as clinical trials pharmacist and expert knowledge and understanding of clinical trials and GCP, aseptic series and GMP, MHRA license requirements. • Expert knowledge and understanding of governance of ATMPs	• PhD qualification in a healthcare science. • Further qualification in relevant technical or management area • Independent Prescribing Qualification • Publications in the area of expertise, including contributions to national guidance • Faculty Member or Fellow Royal Pharmaceutical Society
	1.2 Delivery of Professional Expertise	• Active member in national advisory groups • Accountable for the delivery of professional services	
	1.3 Reasoning and Judgement Including: -Analitycal skills -Judgemental skills -Interpertational skills -Option Appraisal	• Ability to make decisions in complex situations • Ability to take action based on own interpretation of broad professional policies/procedures when necessary • Ability to make decisions in the absence of evidence or data • Demonstrate ability to identify problems, analyse root cause and propose solutions for complex problems • Able to identify and manage risks • Ability to recognise own limitations and boundaries and need to consult with senior colleagues	
	1.4 Professional Autonomy 4.5 Managing Performance 4.6 Project Management	• Ability to interpret national policy and strategy in order to establish goals and standards for others within the defined area • Responsible for the Clinical Trials service and safe implementation of ATMPs	

Communication and 2. Collaborative Working Relationship	2.1 Communication, Including ability to: -Persuade -Motivate -Negotiate -Empathise -Provide reassurance -Listen -Influence and -Networking skills -Presentation skills 4.9 Working across boundaries	• Ability to communicate highly complex information at all levels and overcome barriers to understanding • Demonstrable experience of affect and manage change and to motivate others • Excellent negotiating skills • Must behave in a professional manner at all times • Team building skills • Demonstrated ability to influence senior medical staff, multidisciplinary teams and management • Able to promote and evaluate best practice within clinical trials services • Able to improve service quality at operational management level • Recognition as an expert nationally through publications / presentations or officer in a national group and collaborations; extending service delivery across regional boundaries	• Working across boundaries to build relationships and share information, plans and resources
	2.2 Teamwork and Consultation	• Ability to communicate and present complex information where the content of the discussion is based on professional opinion	
3. Leadership and 4. Management (some of the management competencies are demonstrated across other competencies in the table)	3.1 Strategic Context	• Knowledge of ATMPs governance and regulations • Proven track record of exerting influence at a strategic level and contribution to national guidelines.	• Demonstrates active participation in creating national policies • Management of a clinical trials service • Knowledge of Quality management systems (ISO9001) • Ability to deliver lectures, workshops and formal presentations
	3.2 Governance	• Experience as a team leader • Extensive management experience clinical trials pharmacy service • Current knowledge and understanding of guidance and legislation governing clinical trials and ATMPs, including GCP and GMP	
	3.3 Vision 3.4 Innovation 3.5 Service Development 4.7 Managing change 4.8 Strategic Panning 4.1 Implementing National Priorities	• Experience in training and supervision of other staff • Previous experience of contributing to the operational and strategic direction of the pharmacy department and align and contribute to the Trust Vision. To produce demonstrable improvement through innovation • Ability to interpret national policy and strategy in order to establish goals and standards for others within the defined area • Shapes the response of the service to national priorities • Understanding of quality assurance and the pharmaceutical quality system • Demonstrable commitment to CPD • Professional and personal integrity • Participates in development of services in line with local, Trust and national	

	4.4 Managing Risk 4.2 Resource Utilisation 4.3 Standards of Practice 4.4 Managing Risk	initiatives. • Responsible for the staffing budgets and the procurement, maintenance of equipment and resources within the clinical trials and Advanced Therapy Medicinal Products services. • Support budgetary control for relevant pharmacy cost centres including clinical trials. • Responsible for the safe and secure handling of medications, in particular ATMPs throughout the Trust in line with Trust and departmental policies and procedures • Development of policies and procedures related to the safe handling of ATMPs and IMPs • Assist in the development and review of medication related policies and procedures • Responsibility to ensure appropriate costing clinical trials of ATMPs and ensuring pharmacy fees are recouped.	
Planning and Organisational Skills	3.6 Motivational	• Ability to manage time, people and resources to deliver outcomes • Good timekeeping and time management • Able to develop new systems of work • Able to negotiate effectively and write business cases • Ability to prioritise workload, work accurately under pressure, and meet deadlines • Self motivated with ability to motivate others	• Advance IT skills, including validation of electronic prescribing systems
Education, Training and Development	5.1 Role model	• Able to develop effective role model behaviour in others	• Contributing to the RPS mentorship schema • Accountable for the creation or development of higher education qualification • Shapes and contributes to national education and workforce planning and development policy
	5.2 Mentorship	• Ability to mentor at regional and national level	
	5.3 Conducting Education and Training	• Proven ability to plan and deliver education and training experiences at local, regional and national level	
	5.4 Professional development	• Proven ability to contribute to the professional development strategy	
	5.5 Links practice and Education	• Proven ability to contribute to the creation of higher education qualification	
	5.6 Educational Policy	• Ability to interpret national policy in order to design strategic approaches for local workforce education and development	
Research and Evaluation	6.1 Critical Evaluation	• Proven ability to peer review activities within working practice	• Research project supervisor for postgraduate students

	6.2 Identifies Gaps in the Evidence Base	• Ability to design a successful strategy to address research questions	
	6.3 Develops and Evaluates Research Protocols	• Proven active involvement in the critical review of research protocols	
	6.4 Creates Evidence	• Proven authorship of primary evidence and outcomes in peer review media	
	6.5 Research Evidence into Working Practice	• Ability to use research evidence to shape policy/procedure at an organisational and/or national level	
	6.6 Supervises Other Undertaking Research	• Ability to contribute to research supervision in collaboration with experts	
	6.7 Establishes Research Partnerships	• Proven ability to show leadership within research teams concerning the conduct of specialist research	
Physical Skills / Effort		• Able to walk long distances over the course of the day, climbing stairs on numerous occasions. • Standing for long periods of time in the aseptic services unit and clinical trials dispensary • Sitting at a desk for extended periods, to read and interpret trial protocols, design documentation and write reports, including periods using the computer • There may on occasion be a requirement to lift heavy loads • Handling ATMPs	
Responsibility for Patient/Client Care		• Ensures procedures in place to ensure preparation and dispensing of correct products for patients • Ensures safe preparation and dispensing of IMPs and ATMPs	
Mental Effort		• Requirement to concentrate for long periods of time, reading protocols, legislative documents or performing complex calculations • Frequent interruptions to work • Ability to think quickly and make decisions	
Emotional Effort		• On occasion may deal with distressed patients or relatives following a medication error • Dealing with treatments for patients with	

		terminal illnesses	