Institute for Apprenticeships & Technical Education

CLINICAL PHARMACOLOGY SCIENTIST (INTEGRATED DEGREE)

Details of standard

Occupation summary

This occupation is found in a wide range of public or private Clinical Research Organisations (CRO's including the NHS, Academia, Health Authorities and Clinical Research Facilities), and Pharmaceutical or Biotechnology Industries.

The broad purpose of the occupation is to design, analyse, interpret and report clinical research and clinical trials aimed at understanding what a drug is doing to the body (pharmacodynamics), what happens to a drug in the body (pharmacokinetics), and how it works in terms of treating a particular disease. They will also offer clinical pharmacology expertise to resolve issues that arise during conduct of studies. It is a varied role, supporting the discovery and development of new medicines, and improving understanding of existing ones. The Clinical Pharmacology Scientist is well-placed to aid in all aspects of medicine management. For example, they can provide specialist advice to healthcare professionals and researchers on the interactions of different medicines and how these might affect patients and research participants. In addition, the Clinical Pharmacology Scientist will form a key component of National Institute for Health Research (NIHR) Biomedical Research Centres (BRCs), Clinical Research Facilities (CRFs) and other academic groups, with a focus on driving the development and translation of novel therapeutics in an academic setting. They will also provide expertise in preparation and writing of grant applications.

In their daily work, an employee in this occupation interacts with a wide range of individuals and teams. Depending on the organisation they work in, these interactions may be internal or external.

For example, these interactions can be management-based (e.g., Direct Reports and Teams, Project Teams, Line Managers and Senior Managers), or scientifically driven. The central role of the Clinical Pharmacology Scientist is demonstrated by the array of these scientifically-driven interactions. The scientifically-driven interactions are likely to include non-clinical Scientists (e.g., Pharmacologists, Safety Pharmacologists, Toxicologists); Regulatory Specialists; Regulatory Agencies; Ethics Committees; Clinical Trial Investigators; Pharmacokineticists and Pharmacokinetic/Pharmacodynamic Modellers; Medical Clinical Pharmacologists; Chemistry, Manufacturing and Controls Scientists and Pharmacists, Bioanalysis Experts, commercial colleagues (Legal Teams, Sales and Marketing teams, Financial teams), Drug Metabolism and Pharmacokinetics Scientists, Data Managers, Statisticians and Quality Control/Quality Assurance Teams. In CRFs and BRCs, the Clinical Pharmacology Scientist will also interact with individual Chief and Principal Investigators and will be key a member of individual study teams. They will interact across the academic environment, including with clinical academics, non-clinical academics, pre- and post-

doctoral scientists. In addition, they will liaise closely with industry and CRO partners as well as academic funding bodies or charities.

Clinical Pharmacology Scientists also play a key role in advising, supporting and listening to the broad health and life sciences sector. They might also interact with stakeholders such as Professional Bodies, Universities and Educational Bodies, Customers, External Partners, Non-Governmental Organisations (NGOs), Contract Research Organisations, Sector Forums, Patient Groups, Media, Technical Specialists, Suppliers and Sector Skills Councils.. An employee in this occupation will be responsible for the design of research, individual trials or a series of trials designed to test a medicine of interest, as part of a multi-disciplinary team. Throughout the conduct of these trials and research, Clinical Pharmacology Scientists provide scientific and technical leadership, driving strategy. As well as design, they take responsibility for the subsequent analysis and interpretation of data generated in these trials. Therefore, their input and recommendations are critical to ensuring that the outputs of clinical research and clinical trials are meaningful. A Clinical Pharmacology Scientist could find themselves working at the preclinical-clinical interface, determining whether a potential new medicine is safe, establishing whether it works in humans, right through to ensuring the right data are available to support regulatory interactions so that patients get the medicines they need as soon as possible. They will work through phases 1 to 4 of drug development (i.e., from testing whether a drug is safe to use to determining what the long-term risks and benefits are) as well as life cycle management (e.g., developing more palatable or easier to swallow tablets for patients). Ultimately, before a new medicine is approved for use, a Clinical Pharmacology Scientist will summarise the known clinical pharmacology of that medicine to support registration in regions around the world, and will contribute towards developing the information that doctors and patients need to use the medicine appropriately.

Clinical Pharmacology Scientists are leaders and role models and are likely to have line management and other significant responsibilities within an organisation. This includes awareness of the budgetary implications of their projects and advising on wider company impacts of the trials around production costs and profitability of trial results.

Clinical Pharmacology Scientists are primarily office based, spending their time analysing data, writing reports and contributing to team discussions. The role will also involve some travel to client sites, conferences, workshops and seminars.

In addition to their scientific expertise, Clinical Pharmacology Scientists take a thoughtful approach, are excellent communicators and thrive in a team environment.

Typical job titles include:

Clinical pharmacokineticist **Clinical pharmacologist** **Clinical pharmacology scientist**

Quantitative clinical pharmacologist

Occupation duties

DUTY	KSBS
Duty 1 Lead on the application of quantitative approaches to determine appropriate doses of a drug to be used in trials at various stages of discovery and development	K1 K2 K5 K6 K9 S1 S4 S5 B1 B4 B5 B7
Duty 2 Lead on the design of series of clinical pharmacology trials or studies required to understand how a drug works in the body, including which trials/studies need to take place, in what order and when	K1 K3 K5 K6 K7 K8 K9 K11 S2 S3 S4 S6 S8 S9 B1 B3 B4 B5 B6
Duty 3 Lead on the design of individual clinical pharmacology trials or studies, or the clinical pharmacology components of trials or studies by advising on study objectives, design, endpoints, data collection, analysis and reporting	K1 K3 K4 K5 K6 K7 K8 K11 S2 S3 S4 S5 S6 S8 S9 B1 B4 B5 B6
Duty 4 Lead on the clinical pharmacology components of organisational interactions with Regulatory Agencies (e.g. the Medicines and Healthcare products Regulatory Agency) to ensure that planned trials or studies are being conducted in a safe and effective manner	K7 S6 S7 B1 B5 B6
Duty 5 Support the clinical pharmacology components of the licence application for a new drug	K7 S6 S7 B1 B4 B5 B6
Duty 6 Support or advise Principal Investigators during the conduct of clinical trials or studies by making recommendations about suitable doses, the use of co-medications, administration to specific populations (e.g., those with hepatic impairment, renal impairment, the young or elderly) and by taking an active role in relevant meetings	K1 K2 K8 K9 K11 S1 S4 S5 S8 B1 B3 B4 B5 B6
Duty 7 Contribute expertise to the preparation of technical documents such as clinical trial study synopses, clinical pharmacology plans, protocols, statistical and analytical plans, risk logs, clinical study reports and regulatory submissions	K4 K6 K8 K11 S3 S4 S5 S6 S8 B1 B4 B7

Duty 8 Lead and manage, as a member of a multidisciplinary team, complex communications (including reports, publications and presentations) with key stakeholders (team members, regulatory authorities and the public) to inform decision making, by ensuring that non-experts can understand the implications of the clinical pharmacology data	K7 K8 K11 S3 S5 S6 S8 B1 B3 B4 B6 B7
Duty 9 Use innovative approaches to improve efficiency of clinical pharmacology trials/studies, or their clinical pharmacology components (eg, the use of integrated adaptive designs)	K1 K2 K3 K9 S1 S2 S3 S4 S10 B1 B2 B7
Duty 10 Develop others through demonstration of best practice within the organisation by effective coaching, mentoring and training	K10 S10 B1 B3 B7
Duty 11 Achieve goals in accordance with budget and finance targets and take account of financial implications within a wider commercial and organisational context	K8 S9 B1 B2 B6
Duty 12 Provide leadership, specialist support and organisation of others in the work place to ensure projects meets the requirements of the organisational goals	K8 K10 K11 S8 S9 B1 B3 B7
Duty 13 Identify and implement change management initiatives to meet the demands of technical and organisational requirements	K8 S10 B1 B2 B3 B6 B7
Duty 14 Make decisions based on an understanding of the organisational and the wider business market (e.g. legal, technical, environmental, political and economic)	K8 K10 S9 S10 B1 B2 B3 B6 B7

KSBs

Knowledge

K1: Theoretical principles of drug action - How drugs interact with their targets, including drug-receptor theory and mechanisms of action - The principles pharmacokinetics (including Absorption Distribution Metabolism and Excretion), toxicokinetics and pharmacodynamics and their inter-relationship - The principles of toxicology, their application in safety assessment and in determination of the therapeutic index (the balance of safety versus efficacy in relation to dose) • How a drug's formulation and characteristics (e.g. bioavailability, permeability, solubility, formulation, gastrointestinal pH, prandial state) can affect how it performs in the body and impact upon dose selection

K2: Dose determination - The principles of pre-clinical safety testing, determination of safety margins and how they affect selection of appropriate clinical dose levels - The principles of using pre-clinical data to predict both human Pharmacokinectic/Pharmacodynamic (PKPD) and determine the appropriate dose - The principles of starting dose calculation and trial progression (including dose escalation)

K3: Study design and delivery - The types of pharmacology studies that are required/optional and whether to include and conduct them - How the following impact upon on dose selection, study design and outcomes: a) Drug-drug interaction b) Organ impairment c) Age d) Intrinsic factors (e.g. population) e) Extrinsic factors (e.g. food) - Pharmacology-related stopping criteria employed in the early phase studies - How to evaluate, monitor and address relevant risks to study delivery - The principles of risk-benefit analysis in relation to patient management - Standard, adaptive and other novel study designs, when to use them and the associated risks - The impact of immunogenicity on the PKPD of biotherapeutics - Optimisation of sampling timepoints - Trial progression strategies and how to use them appropriately (e.g. dose escalation) - Common types of protocol deviations that confound study results, impact the interpretation of results and may put subjects at undue risk - The principles of go-no-go decision matrices - The resource associated with clinical pharmacology studies (e.g. cost, timeframes)

K4: Study reporting and documentation - Content and generation of study documents (design synopsis, protocol, study report synopsis, clinical study report) - Reporting guidelines and best practice for documenting data, analysis processes and archiving to ensure reproducible results - Common types of protocol deviation that can impact on results and data interpretation

K5: The appropriate use of statistics - Essential statistical principles and tests used in the life sciences (e.g. sample size, power calculations) and in the design of clinical trials - Statistical concepts and tools for data analysis and data interpretation in different situations (e.g. big data, sparse data, missing data) - The principles of powering, estimation and modelling approaches including when to apply them to a particular study

K6: Analysis and interpretation - The role of data visualisation, summarisation and analysis - The role of an analysis plan and its component parts - The principles, limitations and appropriate application of various standard quantitative techniques (e.g. non-compartmental analysis, population modelling, physiologically based pharmacokinetic modelling) - The scope and capabilities of both typical and innovative bioanalytical techniques used for endpoint analysis - Methods of data research, review and synthesis

K7: Legal and regulatory principles - The principles of Good Clinical Practice (GCP), Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP) and Good Documentation Practice (GDocP) - Laws and relevant regulatory/guidance documents, including regional differences where appropriate - Regulatory processes and review cycle timelines - Licencing requirements - The clinical pharmacology content in drug labelling - The clinical pharmacology components of the marketing application - Data protection and confidentiality requirements when preparing materials (e.g. redaction, re-labelling and referencing public

domain case studies) - The principles of quality control, quality assurance and report processes - The principles of ethical business practice and relevant codes of conduct - The principles of research ethics and application to clinical trials and how these may differ for vulnerable populations (e.g. paediatrics, elderly)

K8: The interconnected role of the clinical pharmacology scientist - The impact of clinical pharmacology on key decision points during drug development, and the information required to enable informed decisions - The environments in which clinical pharmacology scientists work - The other roles/stakeholders/bodies that interact with clinical pharmacologists and the exchanges that will need to be conducted - The impact of clinical pharmacology on the success of the project (e.g. scientific validity, commercial, key risk areas)

K9: Drug discovery and development - The stages of drug discovery and development - The principles of preclinical to clinical translation, translational research and experimental medicine. To include how biomarkers relate to disease processes and drug mechanism of action, and can be related to clinical safety and efficacy endpoints - The principles of reduction, refinement and replacement in the use of animals in research - How the principles of clinical pharmacology apply to new therapeutic approaches (e.g. cell-based therapies, antibody-drug conjugates, oncolytic viruses, Ribonucleic Acids (RNAs) - The principles of pharmacogenomics and impact on drug development - Innovative drug delivery and formulations

K10: Learning and development - The principles of learning and developing in the workplace, including ethical and safe practices with regards to coaching and mentoring (e.g. appropriate interactions, confidentiality) - The principles of, and good practice relating to, equality and diversity in the workplace - An awareness of relevant workplace leadership strategies and skills, including matrix leadership and change management in a scientific organisation

K11: Effective communication - How to assess the needs of stakeholders and tailor effective written and verbal communications to them - The scope and impact of different communication methods

Skills

S1: Dose determination - Calculate safe and efficacious human dose predictions (amount and schedule) from pharmacokinetic and toxicokinetics pre-clinical data using quantitative pharmacology methods (e.g. by allometry or physiologically based modelling) - Calculate recommended safe dose for first administration to humans based on pre-clinical data - Make predictions regarding viability/safety of additional dose levels and the likelihood of the effectiveness of a dose reduction strategy relative to maintaining and appropriate therapeutic window - Make recommendations about appropriate trial progression strategies (e.g. dose escalation) - Select and interpret data from a range of relevant sources (e.g. in silico models, biochemistry tests) in order to determine suitable doses for specific populations

S2: Study design and delivery - Perform robust data reviews, including appropriate extrapolation from available knowledge and data, and the use of appropriate techniques to determine the potential for clinically relevant drug-drug interactions - Design efficient, safe, scientifically robust and feasible study protocols and support the design of bespoke clinical pharmacology development plans. Design should consider preclinical data and the impact of external factors (e.g. characteristics of the drug, budgetary, competitive landscape) and use appropriate powering, estimation, modelling and adaptive approaches where applicable. - Optimise study assessments (e.g. the type and timing of pharmacokinetic sampling, biomarkers and other assessments) taking into account both study needs and subject well-being, and including appropriate assessment criteria (e.g. interim and final) for analysis - Consider and propose

methods (e.g. physiologically based pharmacokinetic modelling) alternative to clinical studies when appropriate - Contribute to the design and execution of go-no-go decisions

S3: Study reporting and documentation - Write flexible and robust protocols - Make relevant contributions to clinical study reports - Interpret data and contextualise results (Interim and Final)

S4: The appropriate use of statistics - Interpret statistical results appropriately (e.g. when summarising study outcomes) - Use appropriate software and graphical exploration to perform data analysis (e.g. exposure response, exposure safety) - Apply appropriate statistical techniques when analysing and summarising study outcomes, with support from statisticians where necessary

S5: Interpretation of clinical study results - Contribute to analysis plans that describe how data will be analysed, summarised and graphically displayed - Select and apply the most appropriate method of data visualisation and analysis - Interpret data during study delivery for any interim decision points and for final study reporting discussions and conclusions; - Interpret the collated output from across multiple clinical studies

S6: Critical evaluation and decision making - Contextualise results based on other internal and external information - Demonstrate aptitude in integrating information from a range of sources and critically evaluate it - Identify potential gaps in the clinical pharmacology understanding of a new molecular or biological entity - Identify the implications and making appropriate decisions (e.g. about study design and timing)

S7: Legal and regulatory principles - Complete the required clinical pharmacology components of clinical trial application and a licensing application - Contribute to writing the drug label - Develop and write relevant components of regulatory documents (e.g. investigator brochure, protocol, informed consent document) - Interpret questions and feedback from regulatory, ethics and other review bodies and formulate appropriately detailed and clear responses - Data protection and confidentiality requirements and avoid breaches

S8: Effective communication - Communicate effectively about their work and/or the work of their team to specialist and non-specialist audiences (e.g. oral presentation, protocols, consent forms and scientific reports) - Write scientific and technical documents that clearly convey interpretation and impact of findings - Discuss work constructively and objectively with internal and external stakeholders

S9: Study management - Assess risks to delivering a protocol for the clinical pharmacology package and formulate mitigation plans - Redact, relabel and reference public domain case studies to avoid confidentiality breaches

S10: Learning and development - Research, critique and assess new techniques and methodologies - Listen to learners to assess their understanding and adapt techniques to their needs, using ethical and safe practices when mentoring, coaching and training others

Behaviours

B1: Integrity and Reliability: The ability to work with integrity, showing respect for the confidentiality of information, taking responsibility for actions and with an intrinsic ethical stance to all aspects of day-to-day activities, ensuring actions are in the best interest of stakeholders. Work using the principles of the scientific method and with a concern for maximising the scientific value of a study or dataset

B2: Flexibility and Adaptability: A professional approach, no matter what challenges emerge. A willingness to consider the broader context of project and stakeholder needs. A willingness to engage with innovative practices and make suggestions for improvements. An ability to adjust to, function and flourish in a diverse environment.

B3: Team Working: The ability to lead group activities to arrive at a common goal. The ability to listen to a wide range of views and be inclusive when seeking input. An ability to work in a team, demonstrating respect for colleagues and the viewpoints of others. A willingness to share knowledge and expertise with others. The ability to maintain effective working relationships and collaborations.

B4: Advise and support: The ability to address comments or questions by drawing upon clinical pharmacology expertise and the application of broader principles and knowledge. The ability to identify uncertainties when making decisions and to highlight these, including any assumptions and limitations. An awareness of limits of knowledge and competence, operating within those limits.

B5: "Patients First" Attitude: Puts the patient first and respects their contribution by ensuring they are fully informed, and their views inform decision making processes

B6: Planning, Prioritisation and Organisation: Effective time management, organisation, and appropriate prioritisation, setting projects in the wider context and fiscal environment. Takes the initiative, working independently and coordinating effectively with others to deliver.

B7: Continuing Professional Development (CPD): Recognition of the importance of CPD and a commitment to lifelong learning in personal development and the support of others. Demonstrates curiosity, keeps up to date with relevant developments and proactively develops knowledge to ensure that scientific and business decisions are based on strong science.

Qualifications

English and Maths

Apprentices without level 2 English and maths will need to achieve this level prior to taking the End-Point Assessment. For those with an education, health and care plan or a legacy statement, the apprenticeship's English and maths minimum requirement is Entry Level 3. A British Sign Language (BSL) qualification is an alternative to the English qualification for those whose primary language is BSL.

Other mandatory qualifications

MSc in Clinical Pharmacology

Level: 7 (integrated degree)

Professional recognition

This standard aligns with the following professional recognition:

- British Pharmacological Society for Full Membership

Additional details

Occupational Level:

7

Duration (months):

30

Review

This apprenticeship standard will be reviewed after three years

Version log

VERSION	CHANGE DETAIL	EARLIEST START DATE	LATEST START DATE	LATEST END DATE
1.0	Approved for delivery	23/10/2020	Not set	Not set