Clinical PROFESSIONALS | THE ACADEMY

Accredited cpd Course

Training Academy

Modular Training Course Overview

Science Council Employer Champion
Investing in talent

110 CPD HOURS

The Clinical Professionals Training Academy has been designed to develop each entry level candidate and provide them with full working knowledge of the Clinical Research Industry. Each Candidate will complete a modular training course that will provide them with the essential knowledge to fully perform an entry level role in the work place.

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Clinical Professionals modular training course is tailored to entry level Life Sciences graduates wishing to pursue a career within the core functional areas of a clinical trial; e.g. CTA (Clinical Trial Administrator), Regulatory Administrator, PV Associate, Data Manager, Medical Information Associate, and Quality Assurance Associate. This course will equip them with the appropriate knowledge of the Clinical Research industry and in-depth insight into the critical role competencies and tasks. This course will enable the participants to hit the ground running in any organisation they go on to join at entry level.

Each candidate will be provided with both classroom and on the job structured training from Clinical Professionals. The classroom aspect of the training will be delivered on site by our in-house industry experts and will encompass lecture style training along with workshops, tests, assessments and discussion forums. Once the modular course has been completed each candidate will undergo an interview process with a hiring company and on selection will be coached and mentored by a qualified member of the Clinical Professionals team whilst on placement with the organisation, to ensure that the transition into their new career is fully supported leading to high quality on- boarding, support and ease of transition into industry.

A report published by the Technician Council in 2014 indicated an alarming skills gap between current technician numbers in the UK and the 450,000 needed by 2020. These technicians, which include clinical research professionals, will be essential to underpin a growing innovation economy. The report called on government, public sector employers, industry leaders and professional bodies to support development of these critical individuals. The Science Council have recognised this course and awarded Clinical Professionals as an 'Employer Champion'. There is a module within the course on the Science Council and careers within science and clinical research, and all Graduates/candidates attending the course, after 12 months of continued professional development by our training team alongside core competency assessment, can register for the **Science Technician** professional level.

Clinical Professionals are proud to have received CPD Accreditation for their First to Industry Academy course. This course is designed with the needs of industry and the not for profit sector, but also with the view to providing a valuable addition to the skillsets of the graduates who attend. CPD accreditation from the CPD Standards Office (https://www.cpdstandards.com/) provides The Academies with independent verification of our commitment to lifelong learning and providing the best available content and training to our clients.

The CPD Standards Office

CPD PROVIDER: 21658
2017 - 2019

www.cpdstandards.com

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RSciTech Registered Science Technician

Modules	Content
ONLINE MODULE 1 **Clinical Trials - A History** **(Pre-Academy Preparation)**	Online Module 1 covers the principal elements of the history of clinical trials covering historical events such as the first clinical trial conducted by James Lind in 1747, the Nuremberg Code, the Thalidomide disaster, the Declaration of Helsinki, through to the Northwick Park incident in 2006 and Biotrial incident in France in 2016. The module creates the appropriate landscape to understand why the International Council (formerly Conference) for Harmonisation Good Clinical Practice guidelines were developed, as well as the importance of regulation of the industry.
ONLINE MODULE 2 **Trial Terminology** **(Pre-Academy Preparation)**	Online Module 2 will support the candidate to navigate the mine field of abbreviations and acronyms that are associated with clinical trials. This module will primarily introduce the candidates to common terms relating The People, The Places, and The Processes involved in clinical trials. Candidates will also be provided with an extensive list of clinical research abbreviations and acronyms and will be expected to be familiar with the majority of these by the end of the course, so that they can work and converse confidently when placed in an entry-level job.
ONLINE MODULE 3 **Who's Who in Research** **(Pre-Academy Preparation)**	Online Module 3 elaborates on the information provided in the Trial Terminology online module by describing further the various roles and departments that the candidates might encounter during their career. This ranges from Project Management, Data Management, Quality, Regulatory Affairs, Legal teams and much more.
ONLINE MODULE 4 **Good Documentation Practice**	Online Module 4 will aid the candidate in developing an understanding of the importance of good documentation practice in a clinical trial and its purpose in enabling the reconstruction of trial activity and confirmation of collected data.
ONLINE MODULE 5 **Science Council** **Presentation**	The Science Council provides an overview of why graduates should be registered with a professional body. The presentation will also cover how to become registered with the Science Council and how to maintain registration via continuing professional development.

MODULE 1 **Clinical Trials - A History** **(Face to Face Review)**	This first face to face module reviews the candidates understanding of the Pre-Academy Online Module material and offer them an opportunity to discuss the events which have shaped the way clinical trials are organized and regulated today.
MODULE 2 **Trial Terminology** **(Face to Face Review)**	This module is designed to revisit the Pre-Academy Online Module to underline the wide variety of Trial Terminology in use and to provide an opportunity for discussion of unfamiliar terms.
MODULE 3 **Drug Discovery & Development** **Part 1 – Pre-Clinical Development** **Part 2 – Drug Development (Ph.1-4)**	Module 3 works through the lifecycle of a compound. Beginning with the drug discovery process, we navigate through pre-clinical testing, IND submission, Phase I-IV clinical trials (including examples of different types of trials within each phase), and NDA/MAA submission. Explanations will be provided regarding for each stage, why they are critical for development as well as output needed for each stage that will lead the drug to market. Post-marketing trials will also be looked at in detail and why these are important, providing some case studies of post-marketing surveillance studies. The candidates will take part in an investment bank activity where they will discover the difficult decisions which are made when developing drugs for market.
MODULE 4 **Trial Design**	Module 4 gives an overview of a clinical trial design. Beginning with a study hypothesis, we then go through topics such as trial design (i.e. adaptive, randomised, controlled, blinding, umbrella trials, etc.), sample size, and the protocol. Trial designs will be covered in details, including fixed trials, adaptive studies, randomised, blinded, controlled, umbrella trials, orphan drugs, pre- and post-approval commitment studies, observation studies, etc. The module concludes with a workshop where candidates will design their own clinical trial. This will then be built upon over the course and is a great learning exercise for the candidates to utilise the knowledge they have gained.
MODULE 5 **Ethics, Morals, Fraud and Misconduct** **Part 1 – Ethics & Morals** **Part 2 – Fraud & Misconduct**	Module 5 looks at the ethics and morals associated with clinical trials, and challenges the candidates to make distinctions between the two. The role of the research ethics committee is introduced; the subject/patient and their rights is discussed, including a discussion and workshop on vulnerable populations and how they are included and protected in clinical trials. The module also gives an overview of Fraud and Misconduct, including a case study of a misconduct case, which challenges the candidates to think critically in order to determine the root cause of the problem.

MODULE 6 **Regulatory and Ethics** **Part 1 - Regulatory Overview** **Part 2 – CTIMPs: EU & UK Legislation** **Part 3 - Ethics, HRA & Site Set-Up**	Module 6 provides the candidate with a comprehensive overview of the Regulatory and Ethics processes and guidelines, which are vitally important to the patient/subject and also the validity of the trial. Parts 1 and 2 of Module 6 includes the Regulatory Authority's roles and responsibilities – with particular focus on the MHRA – and covers the CTA application and approval process. In addition, the candidates are introduced to the upcoming EU Clinical Trials Regulation EU No 536/2014 and the implications on approvals across Europe. Part 3 of Module 6 concentrates on the Regulatory and Ethics arena in the UK. We cover Ethics committees - their set up, responsibilities and the vital part that both the Regulatory and Ethics Committees play in the integrity of a clinical trial. We also highlight the roles of the Health Research Authority and Research & Development in site set-up and approvals. Module 6 also includes a section covering an introduction to the Integrated Research Application System (IRAS).
MODULE 7 ICH GCP	This will be a broad module covering ICH GCP, comprehensively detailing what it is, its importance and why we follow it. Module 7 links to all of the modules taught so far by reiterating how ICH GCP shapes legislation worldwide. The Module includes information regarding the changes included in the new revision, the first revision since the introduction of ICH GCP in 1996. The module also highlights the implications of ICH GCP for CTAs in their day-to-day work.
MODULE 8 **Informed Consent**	What is consent? Why is it necessary? Module 8 studies the different types of patient information sheets and will work through open discussions in detail around giving consent. This module will cover who can give and take consent and how it differs in vulnerable populations. The rules and regulations surrounding consent including the process and translation will be covered in detail. The module also covers the 20 essential elements of an informed consent form.
MODULE 9 **Protocol and Investigator's Brochure**	The Protocol - what is it? Why do we have it? Module 9 will provide candidates with an understanding of the importance of the Protocol. Substantial amendments and Non-Substantial Amendments and the approval process will also be discussed. They will also be given the opportunity to review a comprehensive Protocol template and how the content reflects the areas covered so far. The Investigator Brochure will be covered in detail.

MODULE 10 **Investigational Product**	Drug supplies are often over looked when discussing clinical trials. In Module 10 we will address the plethora of topics to cover, including suitability of drug for population, packaging, shipments, depots, drug accountability, import and export, contamination of drug and what happens next. Interactive Voice Response systems are commonly used to distribute drug supplies; to conclude Module 10 we will cover what IVRS is and why we have it. The module includes a workshop where candidates will further develop their trial. They will design their trial drug, taking into account the cost of the end product and how it will be used once marketed, as well as considering distribution for global studies.
MODULE 11 **Patient Safety**	Module 11 will encompass the essential elements of patient safety on a trial, including relevant definitions and reporting timelines for adverse events, SAEs and SUSARS.
MODULE 12 **Insourced vs Out Sourced Studies and Oversight**	Many companies work in different ways. Module 12 will cover Pharma / Biotech *vs* CRO functions (outsourcing) and how they are intertwined. It will also cover the important aspect of Oversight, which is becoming more and more critical to the way trials are run.
MODULE 13 **Data Management and Statistics**	During the lifecycle of the trial data, integrity is essential. Data Management and Statistics (Biometrics) are a vital element in order to achieve your final results. Processes such as interim analyses, which enable companies to take a look at early data and often utilised to support marketing applications, will be discussed. Module 13 will cover the various steps in the data management process from study set-up, through study conduct and close-out, through to database lock and Clinical Study Report. Candidates will be introduced to the different types of data queries, and an overview of how they can support their CRA and the study from a data management perspective will be covered. They will also have the opportunity to review a Case Report Form template to gain an understanding of the information contained.
MODULE 14 **Patient Recruitment and Retention**	Once you have a study design it is then important to find appropriate sites, recruit suitable patients and retain them on the study for the duration. Different ways of recruiting and retaining patients will be discussed at length in Module 14. The appropriate patient recruitment and patient retention is vital for the success of the trial. To conclude this module, candidates will be asked to put together a recruitment strategy for the clinical trials they have designed and to create an advertisement for their clinical trial.

MODULE 15 **Essential Documents & Trial Master File** **Part 1 – Essential Documents** **Part 2 – The Trial Master File**	Module 15 is the backbone element for any CTA. The Trial Master File is the major artery for all clinical trials. This module will discuss the importance and function of the TMF in a trial and the essential documents as listed in ICH GCP. We will discuss an outline of the folder components and the candidates will have a practical opportunity to create their own Trial Master File. There will also be discussions around the recognised archiving regulations such as CFR part 11. We will cover paper *vs* eTMF systems and the importance of proper maintenance.
MODULE 16 **Audits and Inspections**	Module 16 explores in detail the rationale for Quality Assurance and the conduct of a study audit. It will also look at a typical site audit report and response. Inspections are critical for any company working in clinical research. This module will also encompass in detail 'What an Inspection is' and its purpose; how to prepare and conduct yourself during an inspection; the types of findings which can be raised and what they mean.
MODULE 17 **Monitoring & Study Close Out**	Module 17 covers the principal way of ensuring integrity of the trial data through monitoring. Why do we conduct monitoring and what is its purpose? We look at the different tasks associated with each type of site visit, and also discuss Risk-based Monitoring and Remote Monitoring. Module 17 will also cover study close out and the different reasons why a study is closed or terminated.
MODULE 18 **Part 1 - Interview preparation** **Part 2 – Next Steps**	This module will focus on preparing the candidates for interview. It will cover how to behave in different interview scenarios and how to handle competency based questions. It then takes them through the job search process and how we support them.
MODULE 19 **Business Etiquette**	This module will allow the candidates the opportunity to spend time with the Clinical Professionals Specialists who will be assisting them in their job search following completion of the Graduate Academy. They will learn some valuable lessons, which are often unspoken, but are important when starting your first job.

Homework and End of Academy Assessment	The graduates will be set homework each evening to reinforce the day's learning and to afford the training team the opportunity to gauge learning. Following the completion of the 24 modules, there will be a multiple choice question (MCQ) quiz to assess the graduates' understanding of the material covered to date. The graduates will also create and deliver a presentation to the group on a topic from the Academy, as well as take part in a practice interview with our recruitment team to fully prepare them for the next step.
Discussion with previous Training Academy graduates & Industry Professionals	Graduates will have the opportunity to discuss with previous Training Academy graduates how the Training Academy helped them secure a position within the clinical research industry, how it helped them in their new role and what tasks they undergo on a day-to-day basis. We also invite Industry Professionals to come and speak with the candidates about their careers and their experiences in their chosen field. This allows the Graduates great insight into the exciting possibilities which are in store for them. It is also a great way for them to make connections with individuals who will be able to offer advice in the future.