Introduction to apprenticeship – medicines

Core Knowledge		Training
Regulatory Affairs Specialists know and understand:		
The regulatory environment	The regulatory environment in which they work, the organisations involved and how legislation is developed. The differences and similarities between the major regulatory environments, be they sectoral (e.g. medicines or devices) or geographic (e.g. UK, EU or other regions). Potential and actual future developments in the regulatory environment and their implications.	**Essentials of European Pharmaceutical Regulatory Affairs** **Essentials of European Medical Device Regulatory Affairs** ***www.topra.org/basics*** **4x global development webinars** ***www.topra.org/webinars***
The regulatory function throughout the product lifecycle	The role and importance of the Regulatory Affairs function and how it fits into the product lifecycle. The optimum development pathway which may include expedited pathways. Regulatory strategy (in a global environment). How to enable successful interactions between the relevant regulatory authorities and industry. The importance of other key functions such as quality management systems, risk assessment, health economics, marketing, commercial, their product lifecycle expectations and the impact on patient access to products. The post-marketing requirements. The requirements and procedures for product lifecycle management. The importance of vigilance/ pharmacovigilance and risk management. Quality and compliance standards.	**Introduction To EU Pharmaceutical Regulatory Affairs** ***www.topra.org/introcourse*** **Webinar: Introduction To Health Technology Assessment (HTA)** ***www.topra.org/webhta16*** **CRED Managing Lifecycle and Variations Effectively,Webinar: Introduction to Pharmacovigilance for Regulatory Professionals** ***www.topra.org/var19***
The evidence for regulatory decision making: science, content and structure	The fundamentals of drug and device development and the regulatory requirements. The importance of Good Manufacturing, Laboratory and Clinical Practice and Quality Systems. The need for scientific data (for example clinical evaluation or toxicology), its evaluation, interpretation and drawing conclusions. The identification of gaps in data, their implications and proposing solutions. The rationale for the choice of scientific technique, procedures and methods used. The requirements for clinical development and the conduct of clinical trials. The content and structure of the regulatory documentation and technical files. The importance of product information (for example labelling and patient information) and identification. The differences in the regulatory documentation between major regulatory markets. How the benefit/risk of a product is determined.	**Masterclasses: Regulatory Strategy for a New Chemical Active Substance; Regulatory Requirements for a New Active Substance: Quality; Regulatory Control of Clinical Operations. Options: Regulatory Strategy for a New Active Substance Global Clinical Development; Data for Abridged Applications and Specialised Products; Registration of Biological, Biotech and Adv Therapy Products; The US Regulatory Environment; Drug-Device Combinations and Other Technologies; Medical Device based Masterclass - choose two depending on work requirements. CRED Writing Effective Product Information.** ***www.topra.org/masterclasses***
Regulatory procedures	The theory and practical reality of different regulatory procedures. The strategy for choosing and using the different regulatory procedures and product classifications.	**CRED European Regulatory Procedures (ERP)**
Regulatory impact	The impact of regulatory decision-making on the business, patients and future developments. Scientific progress in areas of interest. The roles and responsibilities of themselves and other stakeholders and how they interact in the delivery of healthcare.	**Masterclass: Regulatory Strategy from Development to the Market Place** ***www.topra.org/masterclasses***
Core Skills		**Training**
Regulatory Affairs Specialists can:		
Manage and deliver multiple projects	Simultaneously coordinate and plan multiple activities/projects in a highly regulated environment, ensuring completion to time, within budget and to an acceptable quality. Deal with complex issues both systematically and creatively.	**CRED Project Management for Regulatory Affairs Professionals**
Act decisively	Seek and use evidence-based strategies to take decisions in the absence of complete data and in complex and unpredictable situations impartially, fairly and on merit, without bias in an open and transparent manner. Recognise when it is appropriate to refer the decision. Think critically, take accountability and lead decision making processes, outlining and omissions and justifications of the decisions taken.	**Embedded in courses included**
Influence and negotiate	Recognise negotiation strategies and use them with direct and diplomatic approaches, obtaining and maintaining the trust and respect of other stakeholders whilst managing complex interdependencies.	**CRED Present, communicate, influence and negotiate (Title TBC)**
Think analytically and offer creative solutions	Engage in research and the evaluation of data to assess its suitability to support risk and safety arguments in a structured and logical manner; alert stakeholders to gaps in evidence. Create and offer alternative approaches to mitigate and manage risk where required. Manage the development and application of evidence-based strategies for operational plans. Demonstrate self-direction and originality in problem solving, practise with a high level of autonomy.	**Embedded in courses included**
Present and communicate	Develop and deliver high level materials that present and communicate complex research information and data analyses to a wide variety of audiences in different settings and through multiple media. Written and oral communication that is effective when influencing, negotiating, facilitating and resolving conflicts in risk and safety management with stakeholders. Develop and deliver management level presentations which resonate with senior stakeholders, both business and technical.	**Embedded in courses included**

Manage and share knowledge	Research and organise data from various sources, storing the results in a way that optimises retrieval. Develop and manage a network of contacts to share appropriate information and advice. Know when to share information and who to share it with. Use knowledge to improve the efficiency of work where possible.	**Masterclass Data Management and Digitalisation in Regulatory Affairs and embedded within other courses included** ***www.topra.org/masterclasses***
Using own initiative to contribute to a team	Work autonomously on specific areas of responsibility, in particular leading the development and implementation of the regulatory strategy, whilst interacting with colleagues to contribute to the delivery of project outcomes, recognising the contribution of other functional team members.	**Regulatory behaviours webinar workshop - Team work**
Work with IT platforms	Select and use appropriate and required IT systems in support of the regulatory function.	**Embedded in courses included**
Core Behaviours		**Training**
Regulatory Affairs Specialists demonstrate:		
Integrity	Value honesty, act and take decisions in accordance with the law and corporate objectives. Recognise and respect confidentiality. Understanding and respect for the rights and protection of participants (human and animal) in the development process.	**Regulatory behaviours webinar workshop - Integrity**
Accountability	Openness to the scrutiny of others to ensure accountability for the decisions or actions taken and the identification of lessons learnt. Take personal responsibility for working professionally. Meeting business needs through leading and managing regulatory deliverables for assigned projects.	**Regulatory behaviours webinar workshop - Accountability**
Independence	Work autonomously, recognising when it is appropriate to seek input from management or others, contribute and communicate effectively within a wide, multi-disciplinary team.	**Regulatory behaviours webinar workshop - Independence**
Commitment to personal development	Take leadership to define and commit to personal development by developing their scientific and regulatory knowledge as the environment evolves. Ensuring an understanding of how developments in science, medicine, healthcare, and regulation will impact on future regulatory strategies and data requirements. Demonstrate the independent learning ability required for continuing professional development including critical reflection.	**Introduction to CPD tool and requirements and Registered Scientist professional registration workshop.**
Compliance	A positive attitude to compliance, influencing colleagues to be compliant and speaking up if errors or potential problems are identified.	**Regulatory behaviours webinar workshop - Compliance**
Customer focus	A commitment to meeting the needs of all stakeholders within and outside the organisation in the best interests of the end user and/ or patient.	**Regulatory behaviours webinar workshop - Customer focus**
Preparing for End-Point Assessment		
On-Programme assessment		

Total cost of training and assessment all included within the £21,000 apprenticeship funding allowance*

* There are additional costs if the apprentice also wishes to complete the MSc Regulatory Affairs