

Title: Open Awards Level 7 End-point assessment for ST0586 Regulatory Affairs Specialist

Specialist

Industry: Health and science

Code: ST0586



Qualified

Typical Duration

30 months

Maximum Funding

£21000

National Level

Level 7

Entry Requirements

Individual employers will set their own selection criteria but entrants will typically already have a degree in science, engineering or law.



Any mandatory qualifications?

Apprentices without English or maths GCSE at grade A* to C or equivalent must achieve Level 2 approved English or maths qualifications (either Functional Skills Level 2 or GCSE).

For those with formally recognised special educational needs, learning difficulties or disabilities, who struggle to achieve the regular English and / or maths minimum requirement due to the nature of their difficulty or disability, the minimum English and / or maths requirement is Entry Level 3 (subject to conditions within the funding rules) and British Sign Language qualifications are an alternative to English qualifications for whom this is their primary language.

In addition, apprentices on this standard are required to develop a Vocational Competence, Training and Development Log for use on the Viva Voce, which must be submitted to Open Awards alongside other gateway evidence.

Role Profile

A Regulatory Affairs Specialist is responsible for developing and implementing strategies that allow a company to legally develop, manufacture, market and supply healthcare and / or veterinary products.

The role critically evaluates the evidence generated during the development and use of the product for its suitability to support obtaining and managing marketing authorisations, CE marks and approvals for clinical studies in line with legal requirements.

This role may be performed within an organisation that may range in size from innovative SME businesses to major multinational companies.

A Regulatory Affairs Specialist may also work within service companies offering consultancy support to manufacturers or in the relevant competent authorities or Notified Bodies where they will be assisting in the review and assessment of regulatory and technical dossiers prior to issuing a licence.

On-programme stage

During this stage the apprentice is employed within the regulatory affairs sector and completes both on-the-job and off-the-job training and learning, which should enable them to develop the knowledge, skills and behaviours set out within the apprenticeship standard.



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Completion and certification

Open Awards will issue a summary of results following successful completion of all End-point Assessment (EPA) requirements.

Open Awards will also request the apprenticeship completion certificate on behalf of an apprentice once they have completed their apprenticeship.

How will the learner be assessed?

The EPA consists of two distinct assessment methods which are equally weighted:

- Project showcase based on a case study – report (4000 words, presentation (20 minutes) and questioning (25 minutes)
- Viva voce – 45 minutes

Performance in the EPA will determine the apprenticeship grade of fail, pass, or distinction.

The EPA must be completed within a six month period, after the apprentice has met the EPA gateway requirements.

Progression opportunities

Apprentices who successfully achieve this apprenticeship could progress into the following job roles:

Regulatory Associate, Strategist or Executive, Regulatory Affairs Manager, Regulatory Compliance Professional, Medical Device Competent Person.

Successful completion will enable the apprentice to become a Member or Registered Member (M/TOPRA) of the professional body, The Organisation for Professionals in Regulatory Affairs (TOPRA) as appropriate, and to apply for professional registration as a Registered Scientist (RSci) through TOPRA or the Science Council, providing parity with other scientific professions.

Why choose Open Awards Qualified?

Open Awards have been in business for 40 years. During that time, we have helped thousands of learners get started on the education ladder, return to learning, achieve qualifications to help their careers and progress into further and higher education.

Building on this expertise, we have become an end-point assessment organisation (EPAO) for a growing number of apprenticeship standards in England approved by the Institute for Apprenticeships and Technical Education (IfATE).

Our EPAO number is: EPA0565

More information www.openawards.org.uk

