

# REGULATORY AFFAIRS SPECIALIST FOR ADVANCED THERAPIES

Working as part of a multidisciplinary team to ensure advanced therapies are appropriately licensed before being sold or supplied



Level 7 (at end of programme), equivalent to Master level competence



26-30 months duration, depending on prior learning



maximum funding available from Apprenticeship Levy not yet approved



Targeted for new graduates or existing staff development within your business following BSc/BEng qualification

## Occupation Summary:

A Regulatory Affairs Specialist is responsible for developing & implementing strategies that allow a company to legally develop, manufacture, market and supply healthcare products & critically evaluate the evidence generated during the development and use of products for its suitability to support obtaining and managing marketing authorizations & approvals for clinical studies in line with legal requirements. 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.

**Typical job roles may include:** Regulatory Associate, Strategist, or Executive, Regulatory Affairs Manager, Regulatory Compliance Professional, Medical Device Competent Person

### Knowledge

- Knowledge of the regulatory environment in which they work, the organisation involved & how legislation is developed
- Regulatory function throughout the product lifecycle
- Evidence for regulatory decision making: science, content & structure
- Theory & practical reality of different regulatory procedures
- Impact of regulatory decision making on the business, patients & future developments

### Skills

- Manage and deliver multiple projects
- Seek evidence-based strategies to act decisively without bias
- Recognise negotiation strategies and use direct and diplomatic approaches
- Think analytically and offer creative solutions
- Develop and deliver high level communication materials to a variety of audiences
- Manage & share knowledge
- Select and use appropriate IT systems in support of regulatory function

### Behaviours

- Value honesty, act & take decisions in line with the law & corporate objectives
- Openness to the scrutiny of others and personal responsibility
- Work autonomously, recognising when it is appropriate to seek input from others
- Commitment to personal development
- A positive attitude to compliance
- Commitment to needs of all stakeholders within and outside the organisation



## Training Provider Analysis:

This is an exciting **new apprenticeship** standard completed by the Trailblazer Employers but yet to be ready for delivery due to funding approval.

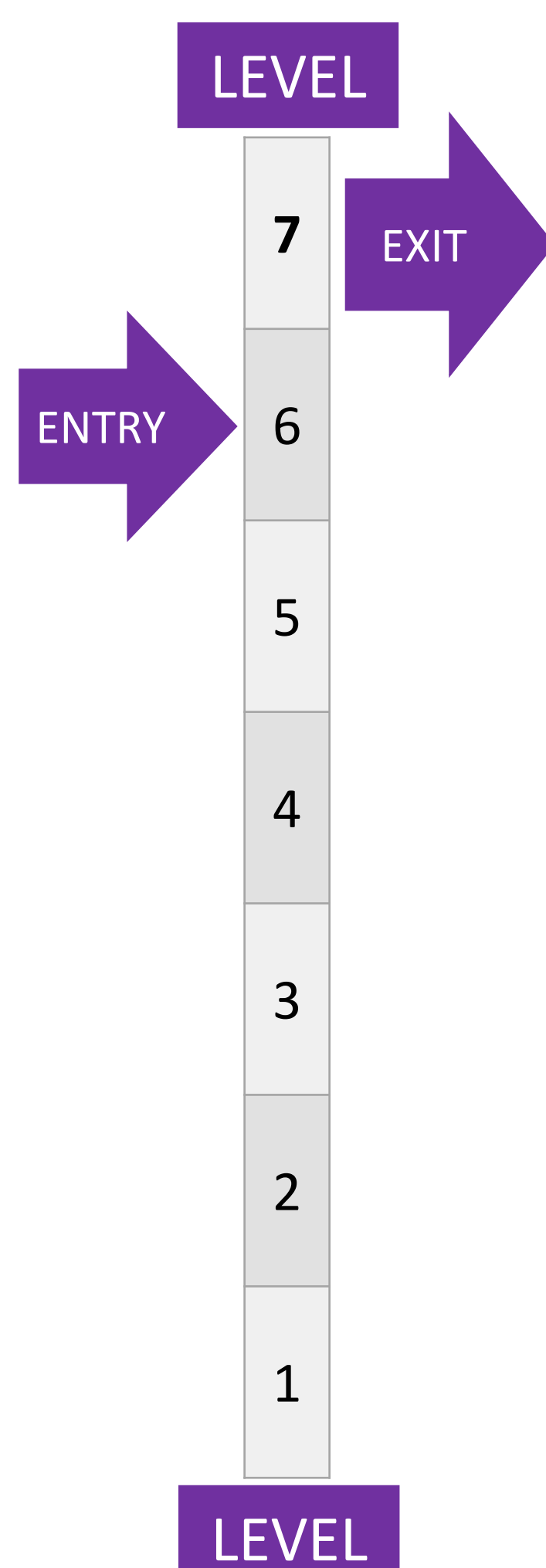
Training provider analysis across higher education revealed few Universities looking to develop provision.

**University of Hertfordshire** are leading development in this area in association with TOPRA (The Organisation for Professionals in Regulatory Affairs) which could be ready for delivery in Autumn 2019.



## Entry requirements:

- Individual employers will set their own selection criteria but entrants will typically already have a bachelors degree in science, engineering or law.
- Apprentices without Level 2 English and maths will need to achieve this level prior to endpoint assessment.
- For those with an education, health and care plan, the English and maths minimum requirement is entry Level 3.



## Progression Routes:

- At the end of the apprenticeship apprentices will have achieved specific Level 7 occupational competence.
- Following successful completion of endpoint assessment the apprentice will operate as a Regulatory Affairs Specialist.
- The apprenticeship is aligned with professional registration with TOPRA at MTOPRA level and also RSci with Science Council providing parity with other science related disciplines.



Is this an apprenticeship standard for new graduates or existing staff to address a regulatory skills shortage in your business?