

# The Organisation for Professionals in Regulatory Affairs Limited

Monitoring visit report

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## Monitoring visit: main findings

### Context and focus of visit

From October 2018, Ofsted undertook to carry out monitoring visits to all newly directly funded providers of apprenticeship training provision which began to be funded from April 2017 or after by the Education and Skills Funding Agency and/or the apprenticeship levy. This monitoring visit was undertaken as part of those arrangements and as outlined in the 'Further education and skills inspection handbook', especially the sections entitled 'Monitoring visits' and 'Monitoring visits to providers that are newly directly publicly funded'. The focus of these visits is on the themes set out below.

The Organisation for Professionals in Regulatory Affairs Limited (TOPRA) has held a contract to offer apprenticeships since July 2019. They run the level 7 regulatory affairs specialist standards-based apprenticeship. Currently, TOPRA is the only provider to offer this programme. TOPRA's head office is in London. Apprentices work for employers that mainly operate within the life sciences sector across the country.

At the time of the monitoring visit TOPRA taught 48 apprentices, all of whom are aged over 19.

### Themes

#### **How much progress have leaders made in ensuring that the provider is meeting all the requirements of successful apprenticeship provision?**

#### **Reasonable progress**

Leaders have established effective partnerships with employers, who were closely involved in the development of the apprenticeship standard. Consequently, leaders have a thorough understanding of employers' needs. They have responded well to employers' requests for training employees who are new to their roles as regulatory affairs specialists.

Leaders have made thoughtful use of feedback from apprentices and employers to adapt the course. For example, they have included an optional module in advanced therapies for apprentices studying the medicines pathway. Leaders review frequently the content of the course. They ensure that teaching covers the most up-to-date regulatory legislation. Employers value the fresh ideas apprentices bring to their work.

Leaders ensure that they meet the requirements of the apprenticeship. Assessors discuss with apprentices in detail the opportunities they have for off-the-job training. These include shadowing their mentor at work and joining online masterclasses.

Where necessary, assessors meet with managers to agree changes to apprentices' work schedules so that they can complete their coursework. As a result, most apprentices stay on the course and are on track with their studies.

Leaders appoint volunteer teachers from the regulatory affairs sector who have a wide range of appropriate subject specialisms. They have in-depth experience of regulatory processes and current legislation. Apprentices greatly appreciate their teachers' highly relevant and up-to-date knowledge of their subjects.

Most apprentices are ambitious to progress in their careers. However, leaders do not provide apprentices with timely information and advice about their next steps when they finish their programme. They do not know about the wider options open to them beyond those offered by their employer.

Leaders do not assess rigorously enough the quality of training. They do not systematically provide teachers with feedback on how to improve their teaching skills. In a very small minority of instances, apprentices find teachers' presentations difficult to follow.

**What progress have leaders and managers made in ensuring that apprentices benefit from high-quality training that leads to positive outcomes for apprentices? Reasonable progress**

Leaders plan a logically sequenced curriculum for the regulatory affairs standard. They have carefully considered the foundation knowledge that apprentices need to learn before they can complete specialist modules. For example, apprentices first learn about the essential skills for the regulation of medical devices or pharmaceuticals. They then move on to study topics in greater depth such as the conduct of clinical trials. Apprentices benefit from the option of taking an additional masters-level degree course in regulatory affairs while on the apprenticeship.

Staff make effective use of the information they collect about apprentices' academic and technical starting points. They adapt appropriately the course for apprentices with prior knowledge of regulatory affairs. However, staff do not assess sufficiently the behaviours apprentices need to gain to complete the course. As a result, there is not a clear plan in place that shows how apprentices will develop the necessary workplace behaviours they need to succeed in their roles.

Most teachers give clear explanations of complex information. They teach succinctly the clinical concepts, technical language and methodology apprentices need to apply successfully at work. Apprentices recall confidently their understanding of topics such as European and American regulatory affairs legislation. They apply effectively their newly gained skills at work. For instance, apprentices competently take the lead on projects to revise their employers' regulatory documentation to ensure compliance with post-Brexit legislation.

During progress reviews, assessors do not give apprentices enough time to reflect on what they have learned. They do not help apprentices identify in detail how they apply their new knowledge and skills at work. Consequently, assessors do not set apprentices clear targets for the skills and knowledge they need to develop.

Teachers and assessors prepare apprentices well for their final examinations. Apprentices close to the end of their programme feel confident in giving their presentation to the external examiner.

**How much progress have leaders and managers made in ensuring that effective safeguarding arrangements are in place? Reasonable progress**

Leaders have suitable arrangements in place for safeguarding apprentices. They have developed appropriate policies and procedures for reporting, recording, and monitoring safeguarding concerns. These are currently untested.

The designated safeguarding leads have undertaken relevant training for their roles. Staff have received training in how to recognise and report safeguarding concerns. However, volunteer teachers have not received any safeguarding training. Leaders keep thorough records of safeguarding risks, including actions taken to lessen these risks.

Apprentices say they feel safe in training and at work. They know who to go to if they have any concerns.

Leaders have taken satisfactory steps to meet the requirements of the 'Prevent' duty. However, leaders have not identified the specific local and regional risks associated with extremism and radicalisation in the locations in which apprentices work. Apprentices have a limited understanding of how the dangers of extremism and radicalisation apply to their lives or work.

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