

# Inspection of The Organisation for Professionals in Regulatory Affairs Limited

Inspection dates:

13 to 15 December 2023

**Overall effectiveness****Good**

The quality of education

**Good**

Behaviour and attitudes

**Good**

Personal development

**Good**

Leadership and management

**Good**

Apprenticeships

**Good**

Overall effectiveness at previous inspection

Not previously inspected

**Information about this provider**

The Organisation for Professionals in Regulatory Affairs (TOPRA) is the professional membership organisation for individuals working in regulatory affairs for human and veterinary medicines and medical devices. It has held a contract to offer apprenticeships since July 2019. TOPRA's head office is in London. TOPRA works with levy and non-levy paying employers across England who are involved in the life sciences sector and pharmaceutical industries.

There are 48 apprentices studying the level 7 regulatory affairs specialist standards-based apprenticeship, all of whom are aged 19 and over. As part of their course, apprentices choose to study one of the two specialist pathways offered. These are in medical devices, and medicines and advanced therapies. TOPRA is the only provider to teach this standard in England.

TOPRA does not subcontract any of its provision.

## **What is it like to be a learner with this provider?**

Apprentices benefit greatly from teaching by skilled specialists in the regulatory affairs sector. Apprentices value the wealth of knowledge and experience teachers have in their field. As a result, apprentices learn about highly relevant innovative developments in topics such as gene therapy, which they apply successfully at work.

Apprentices gain valuable skills and knowledge that help them in their leadership roles. For example, in workshops, apprentices new to managing people practise holding difficult conversations. They gain the skills and behaviours they need to lead large teams of people and support their direct reports effectively.

Apprentices highly appreciate the opportunity to be part of the professional membership network they join as part of their course. They enjoy sharing ideas and information with apprentices in similar roles from a very wide range of organisations across the world. Consequently, apprentices learn new skills and knowledge that they use in international settings.

Apprentices voluntarily take part in useful activities outside of their training, such as special interest groups. For example, they learn how to conduct clinical trials. Apprentices develop their confidence to present their findings competently to their peers.

In a few instances, apprentices do not receive pre-course reading materials in enough time prior to the start of a workshop. Consequently, they are insufficiently prepared for the next topic they study.

## **What does the provider do well and what does it need to do better?**

Leaders have developed a highly relevant and ambitious curriculum that meets the needs of employers that license medical devices and medicines in the United Kingdom and the European Union. They offer apprentices the option to gain a masters-level qualification. Most apprentices achieve their apprenticeship successfully.

Leaders carefully plan the curriculum so that apprentices learn the essential knowledge and skills they need before specialising in their chosen field. For example, in the first training modules, apprentices learn how to project manage the licence application process. They learn how to identify the risks involved in not meeting the deadlines for getting products to the market. Apprentices develop useful skills in analysing and evaluating complex information, which they then apply when licensing medical devices.

Leaders now assess apprentices' prior skills and experience against the knowledge, skills and behaviours they will gain on the course. Leaders plan to include employers in these initial discussions so that they can tailor courses more successfully to meet

apprentices' individual needs. In a few cases, apprentices repeat knowledge they already know.

In most workshops, teachers plan useful tasks to help apprentices remember new knowledge. For example, teachers design well-structured case studies that apprentices work through in small groups. Apprentices recall capably the steps they need to take to identify when a new medical device requires a clinical study.

Leaders have a suitable understanding of the quality of teaching that apprentices receive. They visit workshops and give teachers constructive advice on how they can improve their teaching skills. Leaders suggest useful strategies for checking apprentices' understanding of what teachers have taught. Teachers change their practice effectively to include regular question and answer sessions and quizzes.

Leaders and employers work together closely so that apprentices have the necessary opportunities to apply at work what they have learned in workshops. Apprentices take on roles such as assistant project lead where they learn from experienced colleagues. They competently draft documents, plan meetings and develop effective working relationships with clients. As a result, apprentices make substantial progress at work. Employers trust new apprentices to manage entire projects with smaller clients.

Leaders have put in place effective support for the small number of apprentices with special educational needs and/or disabilities (SEND). Apprentices with dyslexia benefit from a range of specialist assistive technologies to help them with coursework. They have longer deadlines to submit assignments. Leaders meet frequently with apprentices to check how they are progressing. Consequently, apprentices with SEND achieve in line with their peers.

Apprentices take pride in their written work. They make sure they research topics widely and reference sources appropriately when they use scientists' quotes in their assignments. The feedback that teachers give apprentices on their written work is not routinely helpful enough. In a few instances, it is over positive. Teachers do not consistently provide clear guidance on how apprentices could improve their work. This means that not all apprentices know what to do to achieve a higher grade.

A minority of apprentices struggle to complete the coursework within expected timescales. Leaders provide apprentices with very helpful support to help them catch up when they fall behind. Leaders support apprentices well through their final examinations.

Leaders make sure that apprentices receive helpful advice on their next steps. In progress reviews, leaders help apprentices set short- and long-term career development goals. Apprentices discuss their goals with their line managers. Leaders organise careers fairs and send out newsletters that promote job vacancies. A few apprentices gain promotion or take on extra responsibilities when they finish their apprenticeships.

Leaders have recently revised how they teach apprentices about the dangers associated with extremism and radicalisation. At induction sessions, apprentices learn about the risks relevant to the field in which they work. For example, apprentices discuss the implications of the change in abortion laws in the United States. They have a well-considered understanding of the views of pressure groups who oppose the work they do. Apprentices know how to keep themselves safe from potential harmful threats online and in their personal lives.

Leaders and governors have an appropriate oversight of the quality of education. Governors ask leaders pertinent and challenging questions at board meetings when apprentices do not make the expected progress. Leaders carefully analysed the reasons for low achievement in previous years. They acted swiftly to make improvements in recording management information accurately.

## **Safeguarding**

The arrangements for safeguarding are effective.

### **What does the provider need to do to improve?**

- Improve how leaders identify apprentices' starting points. Make sure they use this information to adapt the curriculum so that apprentices do not repeat what they already know.
- Improve the quality of feedback apprentices receive on their work so that they know consistently what to do to improve it and achieve high grades.

## Provider details

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<b>CEO</b>	Kevin Pay
<b>Provider type</b>	Independent learning provider
<b>Date of previous inspection</b>	Not previously inspected

## Information about this inspection

The inspection team was assisted by the director of professional development, as nominee. Inspectors took account of the provider's most recent self-assessment report and development plans, and the previous inspection report. The inspection was carried out using the [further education and skills inspection handbook](#) and took into account all relevant provision at the provider. Inspectors collected a wide range of evidence to inform judgements, including visiting learning sessions, scrutinising learners' work, seeking the views of learners, staff and other stakeholders, and examining the provider's documentation and records.

## Inspection team

Sue Hasty, lead inspector	Ofsted Inspector
Saskia Niderost	Ofsted Inspector
Paul Manning	His Majesty's Inspector

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