

Case Study: Ksenia Sitara

Regulatory Affairs
Apprenticeship – Level 7

Senior QC Officer, Analytical
Services Group at Oxford
Biomedica



Industry Sector:
Life Sciences



About Science Industry Partnership

The members of Science Industry Partnership (SIP) have formed a powerful, collective approach to skills on behalf of the science-based sector. We recognise the urgent and common need to build a skills pipeline to meet our future ambitions for growth, competitiveness and innovation. In order to meet UK skills challenges the SIP conducts regular research to provide the evidence base on skills and in turn set out key recommendations. We provide one central voice to Government to ensure the science sector is heard and understood, particularly in light of a rapidly developing skills policy landscape.

About TOPRA

TOPRA is the professional membership organisation for individuals working in healthcare regulatory affairs. TOPRA works with members internationally to enable and promote excellence across the healthcare regulatory profession. Its mission is to represent and promote the profession of healthcare regulatory affairs globally. To do this it provides exceptional support, world-class education and definitive accreditation for all regulatory professionals, and celebrates excellence in regulatory practice.

What is your background and what attracted you to the regulatory apprentice scheme?

I graduated from Aristotle University, Greece, with a BSc (Hons) in Chemistry and moved to UK in 2014. In my current role, I lead a small team who are responsible for compliance and continuous improvement. I started my career in the pharmaceutical industry as a clean room technician in the manufacture of aseptic pharmaceuticals at ITH Pharma. In 2015, I joined Alliance Medical as a clean room operator in manufacturing of radioactive pharmaceuticals and later moved into quality control (QC) as an analyst. I have worked at Oxford Biomedica since June 2017, when I joined as a QC Officer.

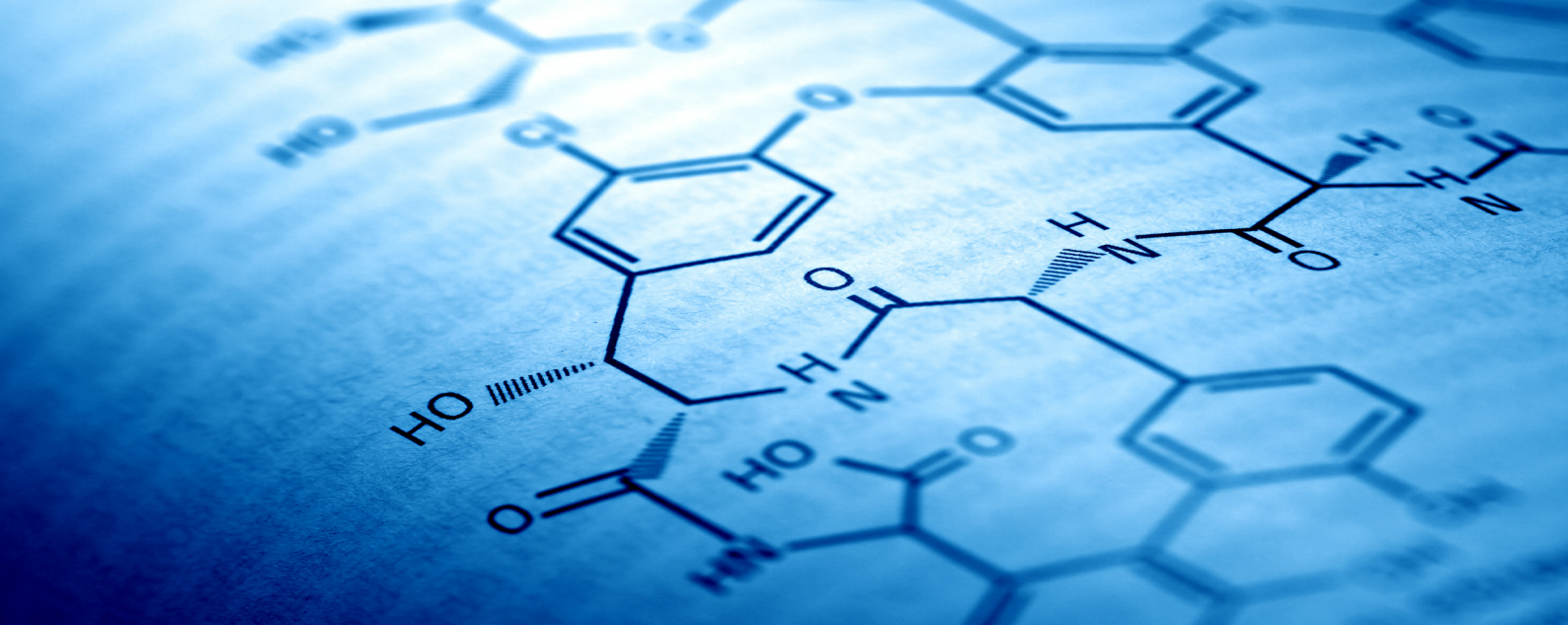
I was once asked where I saw myself in five years and I answered “in regulatory”. Realistically, I had never expected this to happen within five years, or even at all without the relevant experience. At this stage of my life, it would not be suitable for me to quit my job in order to start a full-time MSc. That is why, in early 2019, when Oxford Biomedica offered me a Level 7 Apprenticeship in Regulatory Affairs, I agreed without hesitation. The course fits perfectly with what I want and need. It allows me to become qualified in two-and-a-half years while earning a living. I will have an MSc degree and will be able to work as a regulatory affairs specialist.

What does your apprenticeship role involve?

My role involves on- and off-the-job training, including courses, masterclasses, study time and coursework. My employer gives at least 20% of my working hours off work for training, which is significant, and can be a day per week or a week per month. The apprenticeship is not all study and includes great networking opportunities. Since I enrolled in September 2019, I have met many people from other organisations on the same courses and events as me.

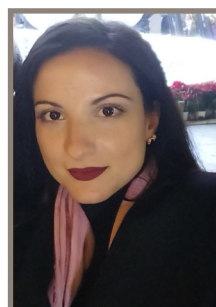
What have been the biggest challenges for the role and for the scheme in general so far?

My biggest challenge was to pass my Level 2 English exams in time to start the apprenticeship in September 2019. As a European Economic Area citizen, I am eligible for funding for the apprenticeship. However, I do not have GCSE in English because I graduated from a European High School and studied English as a second language. Thankfully, my employer and the [Advanced Therapies Apprenticeship Community \(ATAC\)](#) acted urgently to secure an exam date for me. I passed and was able to join the scheme on time. Balancing the workload from the apprenticeship and my manager role is another challenge.



What support network have you had during the apprenticeship?

My employer and ATAC sorted out the issue with my English exams swiftly. The company's apprenticeship levy covers the course costs, and my employer has paid an additional fee for the MSc certificate when I complete the course. My line manager makes sure I am not overloaded with work, and he is always there for me if I am struggling with anything or need advice. Additionally, TOPRA is always there for the apprentices any time we need help. From time to time, it has offered to change the schedule of the modules so that the coursework is more manageable.



Ksenia Sitara, Senior QC Officer, Analytical Services Group at Oxford Biomedica, and her supervisor Colin Stretch share their experiences of the Regulatory Affairs Specialist Apprenticeship so far. The Apprenticeship Standard was developed by the [Industrial Sciences and Life Sciences Trailblazer](#) (which has recently changed its name to Science Industry Apprenticeship and Technical Education Group - SIATE)

What is the one piece of advice you would give to people considering becoming an apprentice?

Apprenticeship is a great opportunity to accelerate your professional development and add an academic qualification to your CV. My advice is to be prepared to get out of your comfort zone and be prepared to juggle your apprenticeship and day job.



Views from supervisor, Colin Stretch, Oxford Biomedica

More and more, we are seeing people learn in different ways. An apprenticeship gives a way for people to achieve a recognised qualification without sacrificing their job and the experience gained in the workplace. It helps both the business and the individual to develop, and the reward for both parties is greater than either first imagined. The main benefits of a workplace apprenticeship include employee engagement, talent development, bringing in knowledge from TOPRA and other businesses, and inspiring others to achieve. In terms of challenges, they are mainly logistically or organisationally related. Although the scheme is well planned and communicated, it does require organisation from the apprentice and the line manager. It takes effort, but that makes the achievement that much more special.

I strongly recommend the apprenticeship scheme to anyone who wants to further develop their career. I think some people might fear the commitment and the length of the apprenticeship, but I think achieving an MSc in just a few years is great. Since the business has committed to your success, too, it will help you with discussions about your development.

For more information about the regulatory affairs apprenticeship scheme, visit: <https://www.topra.org/apprenticeship>

"Regulatory affairs is a profession developed from the desire of governments to protect public health by controlling the safety and efficacy of products in areas including pharmaceuticals, veterinary medicines, medical devices, pesticides, agrochemicals, cosmetics and complementary medicines, and by the companies responsible for the discovery, testing, manufacture and marketing of these products wanting to ensure that they supply products that are safe and make a worthwhile contribution to public health and welfare. A new class of professionals emerged to handle these regulatory matters for companies."
TOPRA

01925 515 220

sipmembers@cogentskills.com

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