

## Developing a career in Regulatory Affairs – a graduate’s perspective

With his degree in Biology at Oxford Brookes University followed by a Masters in Environmental Science at the University of Aberdeen, Graham Donaldson thought he would eventually forge a career for himself in the environmental sector. But when an opportunity to work in Regulatory Affairs came along, Graham took it, and for the past four years he has been building his expertise at TRAC Services, a consultancy based in Cornwall. Here, he shares his experiences and explains how new graduates can follow in his footsteps.

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During my time as an undergraduate, through my courses in biology and anthropology, I developed an interest in environmental biology and environmental issues. I also studied more natural history and ecology on an undergraduate exchange project at California State University, where I did my research project, and then went on to do a masters in environmental science in Aberdeen. At that time I planned to pursue a career within the environmental sector, whether in a consultancy or government agency.

### **Entering Regulatory Affairs**

It was important to me that I used the knowledge and skills I had gained at university within my professional career and on returning home to Cornwall, I signed up with Unlocking Cornish Potential (UCP) – the Combined Universities in Cornwall (CUC) graduate development scheme.

Shortly after signing up, I was contacted by UCP regarding a position for a life sciences graduate within a Regulatory Affairs consultancy in Cornwall. To be honest, RA was completely unknown to me in terms of the profession and what was involved.

However, when the job description arrived it looked interesting, and I was keen to follow it up, having previously considered a career within the pharmaceutical sector, but not specifically RA. After I was offered the job by TRAC, I looked forward to seeing what the world of RA had in store for me.

On my first day I spent my time making notes, writing down all of the acronyms I would be using. At the time these notes made no sense to me whatsoever and I realised that I had a whole new language to learn! But, what also struck me from day one, was that I was now working and liaising with clients, which was fantastic.

### **What’s involved?**

It’s been four years since I first started working in RA. Through the UCP Project, I had a year-long project to work on, the objectives of which were:

- To develop expertise in RA
- To provide support to the business in order to increase capacity
- To develop relationships with new and existing clients and introduce them to the additional services we could offer them at TRAC.

During that first year I attended monthly peer group sessions where a number of topics were discussed within the group. I also had an external mentor, Dr Steve Brewer, a biotechnology consultant who tutored me on the drug discovery and drug development process. This enabled me to discuss aspects of the entire pharmaceutical industry, giving me a broader insight into the role of RA, which was extremely beneficial.

I also participated in other training programmes, such as Project Management and e-marketing events, and benefited from TRAC's internal training programme, which was led by the Director of Regulatory Affairs, Jonathan Trethowan.

I found TOPRA's one-week residential Introductory course extremely useful, as it gave an overview of the whole sector as well as providing some good contacts with other people who were at the same stage in their careers, working in a range of different companies.

Ongoing training within the RA sector is invaluable and indeed essential, and I have continued to learn from specific training courses over the past four years. These include Good Manufacturing Practice, CMC-specific (Chemistry, Manufacturing and Controls), as well as general courses such as a diploma in NLP and a certificate in management.

Because the RA profession is one that never stands still, there is something new to learn every day and, as a result, I try to record all of the training I do in addition to building a wider knowledge base through reading, presentations, my own research or trapping key information when doing tasks for the first time.

One of the major attractions of a career in RA is that no two days are the same. From a job satisfaction perspective and a continued interest and development perspective, this is very important.

While training opens you up to the wider issues concerning the profession, RA is a client-focused role and, like learning to drive, you may know the theory and pass the test, but the real learning and knowledge comes from 'hands on' project work.

RA is such a diverse profession, it offers a wealth of opportunities for people working within it, whether in one of the large multinational pharmaceutical companies or in the growing number of smaller regulatory consultancies that provide outsourced RA input to pharmaceutical companies that have no or few in-house regulatory resources.

What really hits home when you start working in RA is that your work directly contributes to safeguarding the health and wellbeing of many millions of people around the world. The pharmaceutical industry relies on RA professionals, as do the people using the products.

I mainly work in the CMC area of RA. This has involved working on compliance and manufacturing source transfer projects. For example, if a company is transferring a product between sites I will ensure that this is registered in every market affected. This will involve looking at a wide range of components, including the manufacturing processes and validation, the analytical techniques used and the stability of the product. I work with numerous pharmaceutical professionals from Quality Assurance and analytical scientists to logistics and global supply managers.

### **Getting a foot on the ladder**

While I was at Aberdeen University I attended careers fairs and talked to companies who were looking for science graduates. Now I now attend graduate careers fairs on behalf of TRAC looking for life sciences graduates.

My main advice to graduates looking to get into the profession is to do the basics well. Have a good CV. Put emphasis on the key points you have learned in your studies that are relevant to RA.

There is a lot of useful advice on the TOPRA careers webpage for people looking to get into RA. Do your research, especially on topics about the pharmaceutical industry that are currently in the news. Nobody will expect you to know everything about a hugely diverse field, but it will show your interest and willingness to learn.

As in any career path, there is no substitute for a positive attitude and enthusiasm. These are the qualities that will make you stand out. You can learn about RA and the pharmaceutical industry, but you will need to show commitment to take the opportunities that will come your way.

Work experience is invaluable but can be hard to get. Although it may seem like taking another year before you graduate, taking a sandwich-year placement may be a good idea, and in the long term this approach can be very beneficial.

Keep up-to-date with what's happening in the industry. Look at the TOPRA website more widely. See who specialises in RA – you may be surprised at the range and size of organisations involved, not necessarily big pharma companies. Additionally, look at the many pharmaceutical trade magazines and websites, which provide daily updates about the pharma industry. There are also many specialist RA recruitment consultants, so it is helpful to sign up with these.

### **Attracting the best talent**

The challenge for the industry is two-fold. First, to attract the best graduates into the profession, and second, to create the opportunities for these graduates in the first place.

Many graduates have asked me just how can they can get around the 'two years experience required' in most job adverts.

As the industry moves to outsource further RA work from internal teams within big pharma to consultancies, there are growing opportunities within these smaller consultancies to create graduate opportunities, so this issue may be addressed in time.

In addition, I am involved in a TOPRA working group whose role it is to bring RA to an undergraduate audience, through closer working links with universities, to explain the opportunities that exist within RA.

For those graduates who get that opportunity, RA provides an extremely varied and interesting career. One day you may be looking at scientific data, chairing meetings or giving presentations. The next you may be on a flight to meet a new client or start a new project.

The type of organisation that employs you will define the kind of work you will do. It may be difficult to differentiate between companies, so it is worth looking at the

types of work they do, as there are many varied roles undertaken in RA. Working for a small consultancy will be very different to being in a department of a multinational company or a government regulatory agency, and each will provide different opportunities.

RA will draw on the scientific and legal knowledge you gained at university, but you will constantly be building on those skills. You may become an expert in an area you had never heard of before.

You will be working with highly qualified colleagues whose experience, expertise and understanding of the industry will be an invaluable resource for you, so tap into that knowledge base and use it for your own development.

### **Conclusion**

RA provides graduates with a varied, interesting, ever-evolving and extremely rewarding career. However, few graduates will have heard of it, let alone considered it as a career option before university. For those graduates who do get that initial foot on the ladder, the opportunities provided and the ability to grow are extremely rewarding.

Would I recommend a career in Regulatory Affairs? Absolutely.