

Securing your first regulatory role

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The healthcare industry is a highly regulated market and encompasses a wide range of disciplines including agrochemicals, animal health and medical devices. In this chapter we will be reviewing the career opportunities open to candidates entering the probably the largest sector of the biopharmaceutical industry for human health.

That critical first role!

Historically, Regulatory Affairs is an extremely difficult sector to break into straight from university as most RA professionals have gained experience in different roles within the industry before seeking a career within RA. It is true to say that most pharmaceutical companies are not looking to take on inexperienced candidates and are looking for RA professionals with a minimum of 18-24 months experience who can 'hit the ground running'. The exception to this are companies that run internships or development programmes, eg, where over a 2-year period you would undertake three placements within differing areas of RA giving you a broad understanding of the regulatory environment and regulatory process from development to commercialisation. These programmes are few and far between and competition for places is intense.

The options open to graduates are therefore limited to a few organisations that will invest in the training and development required for a new entrant to make a valuable contribution to the regulatory department and they can be broken down into three different groups, generics companies, CROs and regulatory consultancies. Your choice of entry into the pharmaceutical industry is likely to have a significant influence on your future career path as the experiences gained will vary from one group to another.

Here is a summary of what each group is looking for from a graduate or postgraduate and the likely career paths available:

Generic pharmaceutical companies

This is an extremely fast-paced, commercial environment and applicants will have to have had some work experience, ideally within the pharmaceutical industry, so sandwich courses with internships would be really useful. If this is not available then your choice of vacation work should enable you

to demonstrate some of the core competencies required in an entry level role, such as time management and attention to detail. In this case your CV should be seen as a marketing tool to enable you to get an interview. You should tailor your CV and covering letter to match the job description and core competencies for the role; you should also be able to demonstrate an understanding of the product development and regulatory process for generic products. It goes without saying that your CV and covering letter should be free of any grammatical and spelling mistakes.

If you are fortunate enough to be interviewed, your interviewer will be looking to assess you against the core competencies and you will need to demonstrate how you have the experience on either a personal or work-related front that match these competencies.

If successful you will over time be exposed to many regulatory processes such as Chemistry, Manufacturing and Controls (CMC), MAs and variations and renewals for the older more established products. You are not going to be exposed to products within clinical development and this may restrict your career path to the generic industry or to local affiliate roles within the wider pharmaceutical industry.

Contract research organisations

These were the traditional routes for graduates to gain their first role in RA. However, the market has changed and many CROs are suffering from cost pressures and a lack of resources, so are unable to invest the time and manpower required to train and develop a fresh graduate. This is compounded by the fact that the CRO will be unable to charge the client for your work while you are being trained. This means that they will be highly selective in their graduate recruitment and demand either a first class honours degree or MSc in one of the key scientific disciplines as a minimum entry level.

The core competencies required are similar to that of a generic company, however, candidates will be required to demonstrate an understanding of the phases of clinical development and how that impacts upon the regulatory process. This is also a fast-paced environment where time management and attention to detail are critical competencies. In this role, however, due to the lack of resources, candidates will have to be self-starters and be able to demonstrate how they will seek out the relevant information and get on with it!

CROs by their very nature concentrate their activity within the clinical development programme from Phase I through to Phase III and successful candidates may have a bias towards submission of clinical trial applications (CTAs). While *prima facie* this appears quite restrictive it is a skill set that many

pharmaceutical companies require and there are likely to be opportunities to move across onto the client side and gain a wider range of regulatory knowledge. The optimal time to seek employment within pharmaceutical companies from a CRO background would be with 18-24 months' experience otherwise you tend to run the risk of becoming too specialised!

Regulatory Affairs consultancies

The issues within regulatory consultancies are very similar to a CRO, however, the good news is that there are some specialist consultancies that will invest in new talent straight from university. In fact there is one leading consultancy whose business model has been based on recruiting postgraduate talent and investing long-term in their personal development. As a result staff retention has been excellent – their beautiful if somewhat isolated location helps too!

The key differences with working for a consultancy, rather than a CRO or generics company, are that there is potential to be exposed to roles and procedures throughout the regulatory lifecycle from clinical development through to commercialisation. However, not all consultancies are the same and it is down to the individual to understand what the consultancy offers its clients and gain an insight into the training and development programme offered by the company. Otherwise you may become too specialised in one particular aspect of RA which may potentially affect your marketability to the pharmaceutical industry in the future. In addition the candidates will be working closely with clients and therefore will require excellent communication skills.

The long-term view

As previously discussed most regulatory professionals started their career in other roles within the pharmaceutical Industry before transferring into RA. The entry points have been extremely varied and range from laboratory-based work within the research function through to clinical development, pharmacovigilance and data management. In a lot of cases the entry criteria is lower and a good quality 2:1 or even 2:2 will enable you to secure a role.

Once you have established a good reputation within this role, this will be a minimum of 18-24 months, and have demonstrated the core competencies required within a regulatory role then you should start looking for an internal transfer. As with all the other roles your choice of entry into RA is critical for your career development. Choose well!