

## Careers in Regulatory Affairs

### ESRA Rapporteur Article 1

This is the first of two articles on careers in regulatory affairs, originally published in the July / August 2002 issue of ESRA Rapporteur. When asked to produce an article on careers in regulatory affairs (RA), it seemed only appropriate to provide a dual scope to the topic. For that reason this is the first of two articles for ESRA Rapporteur. This edition will focus on the importance of RA and the opportunities open to RA professionals as they begin and progress their careers. We hope that it will help those readers with more experience when encouraging young professionals/graduates to explore what can be a lifelong and secure career.

#### **The importance of regulatory affairs**

All functions within the pharmaceutical industry carry their own level of priority and importance, but for me it is regulatory affairs that rises to the top as the crème de la crème in the importance stakes. We have no doubt that those of you in the profession will agree! However, for those of you considering regulatory affairs as a career move, I would hope to have convinced you by the end of the article why it is worth pursuing.

Let us first of all define what regulatory affairs is. It is the function responsible for “obtaining and maintaining authorisations to market medicinal products in as many countries worldwide as necessary”. This of course is a very broad statement and the role itself encompasses many aspects that will be covered later. What this statement does tell us in its widest sense is that without the birth of the modern pharmaceutical regulations and the recruitment of people like you, following the tragedy of the Thalidomide case in the early 1960s, we would not have the assurance of safe and effective medication that we have today. And the implications of that really are worthy of consideration when we observe the level of regulation we have on a global scale and the apparent increased awareness of patients to treatment prescribed.

To look more closely at how RA is perceived we have taken three relevant groups: young scientists seriously considering RA, industry professionals and staff in governing bodies.

When we ask those wishing to move into RA why they are choosing regulatory affairs, the usual answer is “I can use my science and get involved in the entire drug development process” and, as we know, this is true. Being involved in the entire drug development process means that RA professionals interact with many different functions and it is important to know how they perceive it.

To simplify things we have categorised these functions into two – Research & Development (R&D) and Marketing Groups. To the R&D team, RA is an

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essential part of the drug development process. You are likely very early on in your career to find yourself involved in some form of Project Development team, initially supporting that team with regulatory documentation and information. As your knowledge and experience grows, you will become increasingly involved in strategic development plans. Your advice and regulatory expertise will be called upon and expected as an integral part of the overall drug development process. Your interactions and focus may differ depending upon whether you are based in a local affiliate company or a European or Global R&D Centre, but they will be broad.

For many, the first step into RA is via a local marketing company, which provides new starters with experience in the maintenance of licences – the ever-essential grounding necessary for a career in RA. Working closely with the marketing team, it is worth bearing in mind that their perception of RA might be more reserved and less responsive than an R&D team's (here is where your interpersonal and communication skills become essential!). To commercial people, RA's focus on legalities and regulations can be seen as obstructive to the business objectives and might prevent them from promoting or registering a product in a way that they know will generate the most profit. Whoever sits in this environment needs to take these attitudes into consideration and thrive on developing the necessary skills to obtain consensus and collaboration to reach a common goal. It can be an exciting, fast-paced environment, usually target driven (particularly in Generics or OTC companies) and will appeal to those who are keen to gain commercial awareness no matter at what stage of their careers.

Having looked internally at how RA is perceived, what about externally? One of the key elements of an RA role is the involvement with regulatory agencies and other governing bodies. This is an exciting element of RA and one which usually comes into place once a certain level of knowledge is gained, as would be expected. To legal bodies, RA is seen as an essential part of healthcare, regardless of country. Putting it very generally – without the information provided by you, how could an assessment of a product's safety / efficacy / QOL / costbenefit to the country's health insurers, National Health Service and the patient be made?

Another area where many people begin their RA career is in a contract research organisation (CRO) or consultancy. With the opportunity to work on a wide variety of projects with numerous companies, it is often commented that the experience you gain in these organisations in two months can be worth two years in a specialist department of a large pharmaceutical company. As with entering a local affiliate, the grounding you gain in this diverse environment will

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be invaluable to your career progression. For many it is also where they might end their careers – bringing the expertise and knowledge as a consultant. We believe that to experience a service company environment, at whatever stage of your career, will provide you with many essential skills and experience that cannot be gained in a sponsor company, I will cover this in greater detail in the second article.

**What's in it for you?**

Having been recruiting in regulatory affairs for many years for every size company from small and medium-sized enterprises (SMEs) to the largest in industry, internationally as well as the UK, for all levels of staff – from new recruits through to people heading towards the end of their career, we have one key message: you will never be out of a job for long! There is a defined career path and the level of status or breadth of knowledge and experience you achieve is really there for you to decide because of the vast array of potential opportunities awaiting you.

**A typical RA career path:**

	European small companies	Large companies	European medium companies	CROs / service companies
<b>Experience</b>	Local market	Multi-cultural interactions	Project management	Service environment
	Commercial focus	MRP/Centralised	Global team input	Client interface
	Licence maintenance	Coordination within a bigger arena	International markets	1st step management
	Part II emphasis		Life cycle management	Small team
	CTXs	Cross-functional & transatlantic project teams	Supervisory and training responsibility	Strategic advice for clients
	MCA/IMB interactions			Consulting
	1 Year	3 Years	5 Years	8 Years

None of us has a crystal ball and we might not be sure what we want to do in five years' time. That's OK – but we should take the time to consider what the options are. Not everyone will follow this path and the amount and type of experience you gain as you move through your career will depend on the size and focus of the company and department as well as many other factors. However, it does provide an insight into what kinds of things might lie ahead for you and the level of experience a potential employer might be looking for as your years in RA increase. Another key factor will be your ambition, your willingness to experience different companies (without flitting around) and consideration of the content of the job and how it will develop you – rather than

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merely counting the package!

So having demonstrated the technical requirements of RA, what about the personal skills and attributes that it is necessary to have and develop through your career? It is true that the majority of managers today consider these to be of even greater importance than the most fundamental qualifications and experience. The table below provides a list of some of the most common personal skills and attributes requested by clients when we are briefed to recruit in RA.

**Skills and attributes of a regulatory affairs professional:**

Skills	Attributes
Influence	Team player (cross-functionally)
Negotiate	Quality/accuracy focused
Persuade	Calm under pressure
Present	Interactive
Communicate articulately	Ambassador (promote regulatory affairs)
Listen actively	Positive
Interpret and consolidate data	Open to change
IT literate	Flexible
Work independently and cohesively	Adaptable
Accuracy	Self motivated / driven
Quality	Ethical
	Robust
	Willing to learn
	Enthusiastic
	Assertive and confident
	Respond effectively to challenges of opinion
	Sense of humour
	Multi-culturally aware

To have secured yourself a post means that you have already demonstrated some of these attributes and skills. As you move through your career, you will find that you will develop some naturally and require some support to acquire the others. What is important is being able to provide demonstrable examples if you are highlighting them to a potential employer. The time to plan for this is now, and with the help of a mentor or manager, it is good to at least have an idea of where your career is going and what your strengths and development needs are.

It is not only the regulatory environment and pharmaceutical industry that is ever-changing, the corporate world is a movable feast and we all need to be able to demonstrate our flexibility and a willingness to adapt to it – both

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technically and personally. As a qualified and committed individual, there is no limit to what you can achieve, and in regulatory affairs, you've picked an exciting and vibrant area in which to achieve it!

The second of the two articles on careers in regulatory affairs is written specifically for the more experienced regulatory affairs professional and is available by clicking [here](#). It aims to give some ideas on what could be the next step with the "10 year" mark looming.

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