



Careers in Regulatory Affairs

ESRA Rapporteur Article 2

This is the second of two articles on careers in regulatory affairs, originally published in the September / October 2002 issue of ESRA Rapporteur. It is written specifically for the more experienced regulatory affairs professional. It aims to give some ideas on what could be the next step with the “10 year” mark looming. Hopefully it will give everyone some food for thought about career decisions.

With many years of experience in industry under your belt, how often do you take time out to consider “you” and where you are going? It is easy to get so wrapped up in the day-to-day activities of our organisation (our team, our responsibilities and ever-looming deadlines – not to mention the needs of our families) that we simply dismiss the fact that we too have a career to progress.

By this stage of our professional life, most of us will have reached some form of management level, whether it be project, people or both. Experience may have been channelled down one specific route – CMC, local markets, generics, OTC etc – or may be broader, having developed across R&D and marketing with a mix of products and responsibilities. Whatever your background, you will probably have reached a stage when you know exactly what you enjoy (and what you don’t!). This is often a time when people feel completely settled in a role that fits their lifestyle, safe in their comfort zone, familiar with the products, projects, team and direction of the company or it can be a time when they start to get restless with the familiarity, routine and maybe surrounding uncertainty, particularly if they feel vulnerable and out of control in a potential M&A situation. In other words, we could well have lost our passion for work. Do we need to reawaken it and explore what the options are and which direction we could be taking?

There are many directions open to RA professionals, but at the same time it can seem as though they reduce as you move up the career ladder and traditional hierarchy. There are fewer senior management positions than junior roles. Your expertise may only be suitable to a specific sector. Your options might also be limited due to family or personal commitments. The key is to think more laterally and creatively, not only about what you would like to do, but why. This will enable you to prioritise the essential elements of your next move. Having completed this “wish list” you will have a clearer picture, the ability to direct your search, ask for help and be choosy in order to ensure that you are progressing and not just trading one thing in for more of the same.

Let’s consider four next-step scenarios:

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Project management

It may be that having worked through a “typical” RA career path, you have gained well-rounded experience including people as well as project management. Maybe you have come to the conclusion that even though it is often socially accepted that people management is the only career progression, in fact you do not get a “buzz” from it. You would much prefer to be managing projects, leading scientific discussion, influencing regulatory authorities – directing, motivating and developing others in that capacity. This takes a certain level of maturity to admit, although once done, can open up many opportunities.

For example, one move may be to work for a small start-up company ready to recruit its first RA professional. This will give you the opportunity to be “hands-on” as well as contribute strategically, often not only from an RA perspective, but also at a business level. Many professionals who have taken this option have found themselves involved in a wealth of tasks and decisions that they would never have been exposed to in a more established company. They are not only visible in the truest sense; they are also truly accountable, as the company’s regulatory expert, having been given make-or-break responsibilities of the kind they never faced in a big company context.

The challenges may not be any greater, but they will be different in a young and progressive company. You will be faced with “growing pains” and constant change that will be experienced in ways that you don’t see in big pharma. There is also often a lack of infrastructure, procedures, processes, formal channels of communication, all of which can lead to frustrations and at the same time bring great satisfaction as you help put it in place.

As with all options, it is important to weigh up the positives as well as the negatives and to speak with people who have experienced it. Most people who make this kind of move after spending many years in larger organisations never look back.

Another option is the consultancy or advisory route and this may be with a contract research organisation (CRO), an established RA consultancy or as a freelancer. The last of course raises many questions (not least, “will I be lonely?”) and has many elements to it. It is not always as glamorous as it may seem in terms of the type of projects you are awarded – though some top-class people can clearly define their business focus and are in a position to select their workload. There are other elements to consider too: managing your business and finances as well as your client’s projects, the potential travel involved, home/office set up, IT support and the hours you may be working.

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“This is a lifestyle choice” and one where the decision to take the flexibility and freedom is rationally balanced with the lack of a guaranteed monthly wage slip. Another crucial element to consider with freelancing is actually marketing and developing your business. Some of the pressure can be taken away by registering with an interim management consultancy. They too can give you advice and guidance on the reality of the option. Personal research and networking with RA freelancers is essential. Seek their advice as well as that of your bank/financial adviser who will help with planning your business and the financial aspect. It is becoming an increasingly popular route in RA, because it is a refreshing and stimulating way of working that brings variety and increases awareness of business, the industry and people within it on an international scale.

A good stepping stone to setting up as an independent is to be employed and gain experience in the more-secure environment of a CRO or RA consultancy. As mentioned in the last article, this is highly recommended. It will provide a good insight into the service sector, which is a very different way of working compared to a pharmaceutical company. It will help you develop some essential new personal and technical skills. These include: managing not only numerous projects at one time but also numerous clients, advising on and pulling together bids and proposals, supporting business development activities as well as developing business yourself.

You will experience a faster-paced environment where the emphasis is on delivery, revenue generation and the “bottom line”. It is therefore important to choose your CRO or consultancy carefully. Establish what kinds of projects you will work on and make sure they match your “wish list” as closely as possible. At the same time, the very nature of consultancy requires you to be flexible. No-one can predict precisely which projects will be won and in many ways, you as the expert will play an important part in that. Research the options, get a list of the CRO’s current clients and an idea of its reputation in the industry. Speak with as many people as you can to get a sense of the type and size of CRO or consultancy you would prefer. As with any company, focus on its culture to help you decide whether it fits with your ethics and values. Like freelancing, time spent in this arena will broaden your knowledge base and enhance your career options enormously.

The final option to be covered is the “people management” route. You will probably have gained some experience in this already and found that you enjoy the day-to-day operations, nurturing, developing and motivating people, helping to sort out conflicts and ensuring resource and delivery. As with any other business or function, RA needs strong, supportive, forward-thinking, fair

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and robust managers and leaders. People will see you as a role model and it can be an extremely rewarding task.

If people management is what drives you, and you are looking for your first major step having gained some experience, it is sensible not to be too choosy about the type of regulatory support the team is providing, eg, strategic centre versus local affiliate. (This may be the role of RA Manager or Head of RA – although titles can be misleading and should not be taken at face value). Each brings its own line management challenges and once you have established expertise at this level you can develop your responsibilities further with, for example, an international or multi-functional team as an (Associate) Director or even Vice President of RA. Of course, the level and depth of experience gained and your credibility as a manager will vary depending upon the type of the company, and the size and expertise of the team. This should be remembered when deciding if a new job will build greater personal credibility for you.

Continued professional development

With all these options, continuing professional development is essential if you are to progress in your career. This should be a mix of self-development initiated by taking advantage of opportunities around you and the support of an organisational climate that promotes life-long learning for its entire staff. If working independently, there is obviously a greater emphasis on you and a greater financial impact. Whether the impact be personal time or money, it should be seen as an investment, just as a company would use a percentage of its revenue in R&D to ensure it remains a viable enterprise.

You are not alone

Whatever change you are considering in your career, it is sensible to seek some objective help from a former manager or a trusted career consultant, with whom ideally you have built a solid relationship through your career. Choose someone who knows you, who you trust and maybe has guided you in past decisions. If you do not have such a relationship, think about the “head-hunter” who has called. Who have you been most prepared to spend time chatting to? Who has been the most professional, informative and considerate of your time and efforts (this might be where you kick yourself for not taking the time to hear about a potential opportunity!). If no one comes to mind, find a trusted colleague, fellow RA professional and network to find out whom they would recommend. Ideally, you will have a mentor – someone who is interested in you and has been there to guide your career. Seek their help.

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When speaking with them, be positive. After all it is important that you are looking to leave your current position to progress your career, not just to get out of an unbearable situation. Be clear in your mind about what is important to you in your next move, what you really enjoy and as mentioned above, be ready to explain why.

It is not easy to make the move out of our comfort zone. With new challenges and a new role there can often be frustration and the disheartening “deskilled” feeling – something that gets more difficult with age! If the move is right for you, you will know it. So if it’s on your mind to consider a move – do some exploration, network, be brave and go for it!

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