Taking that leap in the dark

***Sarah Roberts**, former TOPRA President, talks about career options and the variety of roles she has held as a regulatory affairs professional. Interview conducted by* **Julie Warner**, *Consultant Editor,* Regulatory Rapporteur

Q Could you tell our readers a bit about your background, and how you arrived at a career in regulatory affairs?

A Prior to moving into regulatory affairs I was a perpetual student. I have a degree in pathobiology with subsidiary chemistry, a Masters in Toxicology and a PhD in biochemistry. After completing those I undertook postdoctoral work at the Dana Faber Cancer Institute in Boston, US, and then for Cancer Research UK at the Grey Laboratories at Mount Vernon Hospital. It was during this time that I started to question whether bench science was going to be a long-term career option for me. I had friends from university who had gone on to become Clinical Research Associates within pharma companies and they started to inform me of the different roles available within pharma. For me it was important at the time to keep my scientific brain occupied but I knew bench research was not going to provide me with the career prospects and diversity I wanted for the future. The more I discovered about regulatory affairs it seemed the perfect mix of science, variety and excellent career prospects.

Actually getting that first role within regulatory still is and always has been a challenge. I was lucky enough to spot an advertisement in *New Scientist* looking for an entry level role at a global contract research organisation (CRO) and they saw the transferable skills that I could offer and gave me the chance to change career paths. I will always be grateful for that opportunity and owe huge thanks to the team that helped develop my skills over those first few years, as it has informed choices and decisions as my career has developed.

Working at a CRO was an excellent way to start my regulatory career; it allowed me access to a diverse portfolio of medicinal products and medical devices in development and I wasn't restricted to a specialist sub-area – the regulatory world was truly my oyster. I was also able to work more closely within a global team environment which has enabled me to work effectively with experienced professionals from many different countries throughout my career so far.

Q What does your current role involve, and what are your favourite aspects of this role?

A In my current role, I lead the Global Regulatory Affairs function at PRA Health Sciences where we support the development of products throughout their clinical development. The majority of this work entails support of global clinical trials where my team perform all the country-level submissions required to initiate a clinical study. In addition, we support companies with their orphan drug designations, paediatric plans, scientific advice and other regulatory support globally.

My current role is much more focused on growing and managing a large team, ensuring that we have the right people, processes and systems to be able to deliver our work commitments and meet our corporate goals. At the current time, we have in excess of 450 regulatory professionals working in my team at PRA Health Sciences. The team of regulatory professionals I work with gives me the most satisfaction in my current role. I am probably biased, but I have an amazing team, who come together in a supportive community to overcome the everyday regulatory challenges we all face. I am very proud of each and every one of them.

Q How well did your previous experience prepare you for your current position?

A For the majority of my regulatory career I have worked for global CROs in different areas of regulatory affairs. My key area of interest is products in development prior to marketing, although during my career some of the time I have been in roles focused on very early proof-of-concept/Phase I studies, other times on global Phase II–IV studies and other times on regulatory consulting including marketing authorisation applications. The most rewarding phases of my career are when I have been able to combine all three.

In June 2012, I completed my MBA from Henley Management College, University of Reading (the perpetual student thing is a lifetime affliction!). I have really enjoyed being able to combine my regulatory knowledge with the more general business/management knowledge I have accrued since that time.

My previous experience has enabled me to understand my team's diversity, the day-to-day challenges they face and what is needed to support the team and PRA to meet goals and deliverables. My role allows me to bring together my regulatory (science-bias) and business (career-bias) skills and experience which, for me, is the best of both worlds.

Q How do you feel your role as TOPRA President informed your day job (and vice versa)?

A TOPRA represents professionals in regulatory affairs engaged in a broad spectrum of regulatory affairs activities who need to be supported through their professional organisation. In the past I felt that TOPRA's target was biased to providing greater support for professionals working within pharma/device companies and less for those working in consultancy and CROs. It was important for me to represent the large number of regulatory professionals working in these other diverse organisations.

On the same theme, some of the challenges that faced TOPRA at the time were also mirrored within our own organisation, namely how to appropriately provide that support to individuals. For example, how do we effectively communicate with our team/members? How do we incorporate advancing technologies into our business in order to stay relevant to the team/industry/membership? This mirroring within our own organisation meant that all the board members had actively engaged conversations with slightly different approaches, which I think helped facilitate some good and innovative decision-making during that time.

Q How has your thinking and approach had to evolve as your career has progressed?

A My approach has absolutely had to change in order to facilitate growth in my career. When I first started in regulatory affairs I was focused on projects and completing those projects, without much thought for when my next project would be starting. My field of vision was relatively limited to the project team I was working with.

As I started to manage bigger teams, this approach would not be feasible. I now have to often take a 30,000-foot holistic view of projects but be able to quickly drill down to the details as required by the business. I very much lean on others (have I mentioned I have a great team?) to be able to effectively deliver on all the project and business deliverables expected of a team and organisation of our size.

One approach that has not changed over time has been recognising that positioning a complex regulatory argument needs to be tailored to the audience appropriately. Regulatory professional to regulatory professional interactions often look at the detail in a piece of guidance or legislation and how that can be effectively applied to the situation at hand. For those outside of our profession, their eyes glaze over with awe at the sheer eyewatering level of detail. In those scenarios it's important to position the explanation and discussion appropriately. This is a skill that many regulatory professionals possess as we are regularly required to take very complex information and make this suitable for assessment by someone who is seeing the data for the first time.

Q What has been your main career highlight to date?

A Without hesitation it would be being elected as President Elect for TOPRA. It was such an honour to be elected by the wider regulatory community.

Q If you could have done anything differently in your career, what would it be?

A I took some time deciding whether to study for an MBA. Working full time and doing a part-time Masters degree is quite demanding on both your professional and personal time. I wish I had taken the plunge earlier as it has really given me greater insight into the business challenges our profession faces. I promised my family once I completed it that it would be my last piece of formal study. But as they say… never say never!

Q What's the best piece of careers advice anyone has given you?

A Throughout the years I have received a lot of questionable careers advice, starting at school where the suggestions for careers were somewhat uninspiring. Sadly, those come to mind more readily than good examples. However, there is one piece of advice that I heard recently which resonated with me and that is to simply "be brave". Within regulatory affairs, we are operating in a constantly changing environment, often involving new areas, new countries, innovative science and technologies. To evolve as regulatory professionals, we must be brave in our approach and the choices and decisions we make.

Q Who is your role model, and why?

A This is probably the most challenging question to answer as I have long felt that in the UK (and somewhat globally) there is a real lack of female role models outside of the usual celebrities (and I would question their calibre as true/real role models).

In the business world, there are only seven CEOs of FTSE 100 companies who are female (there are nine companies with CEOs with the name David!). I would love to see this number changing more quickly than it has done with greater gender equality at the top of key organisations. Within the pharma industry it is not much better – but there are successful women CEOs within our industry such as Emma Walmsley, CEO of GlaxoSmithKline and Dame Louise Makin, CEO of BTG.

Closer to home, I am inspired by my team. I am very lucky to be working with a great team of people of whom I am immensely proud. Each of them has their own personal story and motivations but as a team we strive for innovation, equity, inclusion, support and balance in our roles. Their work ethic is outstanding and without exception they adopt a solution-orientated approach when faced with adversity. For me they are all role models (but again I am biased).

Q Looking to the future, what challenges await you personally?

A Organisations are in constant change, as is the regulatory environment, and my organisation is no exception. Ensuring we are able to meet the changing needs of regulators and sponsor organisations while meeting our own corporate goals is an ongoing challenge. We are just beginning to understand some of the implications of the impact of the EU GDPR [General Data Protection Regulation] and in a few years' time we will be working within the framework of the new EU Clinical Trial Regulation. We also have to consider the constantly evolving technology and use of data and the impact that has on regulatory science and operational excellence.

As a mum to two young children, they add in their own challenges to everyday life. All parents will understand the challenges of the logistics of childcare support balanced with ensuring that you meet the demands of your role. This can often be a fine balancing act!

Q How do you see the role of a regulatory affairs professional evolving in the next ten years?

A Over the past few years I have seen a lot of dynamic movement in regulatory and industry outsourcing. Typically, companies would outsource discrete projects such as a Phase III clinical study or orphan drug application. However, increasingly we are seeing a lot more outsourcing of embedded regulatory professionals, post-licensing activities, regulatory strategy support and other regulatory activities.

There are increasing numbers of strategic relationships at the regulatory level between pharma organisations and CROs and I think this trend will continue. Hubs are a buzzword within outsourcing in recent years and I expect hubs of regulatory professionals and services will become more common.

Q What advice would you give those looking to enter the profession?

A I have seen a lot of CVs in my current role and my biggest piece of advice would be to ensure that you tailor your CV/application for the role you are applying for. For example, highlight any relevant transferable skills. Also keep it quite short and snappy and make sure you draw the eye of the reader to those key points including the skills you have to offer. If you can pique interest in your CV with a Recruiting Manager then the details can be delivered during an interview or screening call. We like dashboards within PRA, so a skills dashboard on a CV is a great graphic tool to highlight those transferable skills quickly, without lots of text. The format and style of CVs has evolved over the years since I joined the workforce, so make sure your CV is kept up to date with current trends.

What about finding a mentor or advocate? LinkedIn and TOPRA could be sources to reach out to experienced regulatory professionals who might be able to offer support and guidance. If TOPRA had a mentoring programme that would be amazing for people wanting to get into the profession!

Q And finally, on a lighter note, what is your favourite holiday destination?

A I have been very lucky to travel extensively and have been to some beautiful countries and met some wonderful people during that time. We joke at home as we have a whole shelf of travel guides for some holidays we were planning prior to the arrival of my two girls. We are not the sort of family who can just relax on a beach holiday; we are rather more adventurous so, sadly, some of the planned holidays are not suitable for young children. However, for anyone looking for inspiration, I can highly recommend Japan where climbing Mt Fuji was a highlight, walking the Inca trail in Peru or sea kayaking off the Outer Hebrides in Scotland.

Until they are old enough to travel abroad and enjoy it, I have resigned myself to staycations and holidays in the UK. However, we are looking forward to trips to Cornwall and to visit family in Scotland later this year. All is not lost as it allows us to rediscover what a beautiful country we live in and all it has to offer, including Peppa Pig World (for those who are blissfully unaware, google it, it really is a place!)