

Interview: Henriette Vienings - Director, MRA Regulatory Consultants, South Africa



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The director of MRA Regulatory Consultants, Henriette Vienings reveals the important role they play in helping pharmaceutical companies navigate South Africa's regulatory environment, as well as the importance of the technological advancements in the sector. She also illustrates the various success factors that have allowed MRA Regulatory Consultants to remain a partner of choice in the industry.

To begin, Henriette, can you please introduce yourself, the company and your current focus as partner of MRA Regulatory Consultants?

MRA Regulatory Consultants was established in 2003 with initial focus on providing regulatory support to the pharmaceutical industry. We have four partners in the company, and my role, as one of the partners, is currently in the development of training platforms for the sector. There are many different endeavors to upskill regulatory personnel within the industry and bridge the gap between academic qualifications and actual work readiness. We are also very involved in compliance system development, which involves helping companies with negative Good Practice compliance standings improve their systems to a state of compliance and maintain/achieve product approval in the country. Likewise, we are assisting emerging companies that want to sell medicine in the country. The medical devices sector is another focus for us, as it is constantly

evolving and we will probably see by 2016 a new form of medical devices approval in South Africa. Since November 2013, we have also seen tremendous changes in the regulation of the complementary medicines' industry, which is slowly gaining traction in terms of registration and licensing. So, I am very much focused on compliance issues and being proactive and in anticipating the needs of our customers in the industry moving forward.

How would you evaluate the ability for new regulatory consultancies to enter the market?

The entry barriers to the consulting industry are very small because there are no requirements for consultants to license themselves in terms of their scope of service. Anyone exiting a company can decide to start consulting from their home, and a fair amount of people have already done that. However, with the evolution of technology, electronic platforms are now used more frequently for submissions. Everything is done in a more technologically advanced manner, and it becomes challenging for these new players to procure the system they need to be able to have the best service offering and maintain their independence.

What are the success factors of MRA Regulatory Consultants, as a regulatory consulting company serving the pharmaceutical industry for over ten years?

We have a highly experienced team of regulatory consultants who keep up to date with current requirements and emerging horizons in the regulatory landscape. We have a well trained team of operational compilers that are able to compile dossiers in terms of the administrative and electronic formatting requirements to the correct standards. Our administrative staff work hand-in-hand with the technical/regulatory experts to ensure that the client receives the most value for a comprehensive service at a competitive rate. MRA Consultants has been proactive in terms of technological advancements and we were one of the first consulting companies in South Africa to get an electronic system implemented for eCTD submissions.. We started our implementation in 2010, before the eCTD pilot was implemented as a mechanism for the submission of regulated product information. So we are truly at the forefront of the developments and very much in tune with the international standards of data management.

Another success factor is our client-driven focus, as we are not driving other interests such as acting as marketing authorization holders. We keep our focus on our clients' regulatory and compliance needs and make sure they are aware of the latest developments. That is why we attend conferences in South Africa and overseas in order stay on top of the latest trends in the industry. Also, in the health products space, there are many borderline products where we need to

be able to give strategic advice on how to manage the risks in the registration process as new regulations and guidelines are implemented.

We also deal with acquisition intelligence: when companies acquire another company, we assist them in many different aspects. For example, we help them see what their regulatory prospects are, what has been managed well, what needs attention, where there is a need for further investments going forward to make sure that the product portfolio is sound from a compliance perspective. There are many cases where product classifications are rather ambiguous and where the changes in regulations and compliance standards require that the company focus resources on new and previously unregulated products. We help make the determination where products fit from a compliance and legislation perspective as well as assisting with strategic planning on phasing products into regulatory project workflows. We have a very broad experience base with many years of regulatory experience in different fields, which has helped us to give the right advice.

In terms of the client portfolio, which segments will serve as the key growth drivers for the company moving forward?

Our main sector is predominantly pharmaceuticals because the legacy is there. There is a lot of maintenance work, in addition to new work, but the emerging workload will probably come from complementary medicines and medical devices. Although not currently the focus of our efforts, we customize training packages that are specifically tailored to the needs of individual companies' regulatory or executive teams. Furthermore, we are partnering with the Foundation for Professional Development (FPD), which is a higher education department accredited training institute specifically focused on healthcare, with training for primary healthcare nurses, doctors, and other practitioners. We also run periodic training programmes in the industry, especially for software and electronic compliance issues, for anybody that wishes to attend, as opposed to the tailor-made packages I mentioned earlier.

What are the biggest pitfalls that companies have experienced when it comes to regulatory compliance in South Africa?

We have a considerable challenge as an industry in that our regulatory and compliance information is still predominantly paper-based. It is a huge burden because digitization can take time and if it is not done well, poses a risk due to the potential loss of data. We are seeing companies struggle with the management of regulatory information from multiple mergers and acquisitions that have also often lead to incomplete data transfer/on-boarding. We assist companies in the transition from legacy dossiers to CTD, with the June 2016 deadline looming for all industry players. The emerging

medical devices regulations and guidelines as well as the recently implemented complementary medicines portfolios, which companies need to manage and get ahead of, also pose a significant challenge to the industry. Many companies have not yet changed their focus and investment strategy from marketing to the implementation of compliance systems which places a considerable strain on the quality management and regulatory teams within these organisations. Not that businesses are alone in this challenge – the Medicines Control Council (MCC) is also trying to improve their systems and evaluation timelines.

Considering the newly emerging requirements for the medical devices industry in South Africa, how can we expect the regulatory environment to evolve in this sector?

The medical devices industry is vast and if market data is to be believed, this together with the complementary medicines and the pharmaceutical sector is conservatively estimated to be worth more than 10 billion Rand. Sources from both the complementary medicines and medical devices industries have been quoted to say that their industries are worth between 3 – 6 billion rand per annum – if you consider this, it means that half of this health products industry is currently still unregulated/starting with the processes related to regulation. The importance of embarking on the regulation of medical devices and in-vitro diagnostics cannot be underestimated from a public health and safety concern. The mechanisms on how best to manage the implementation process, in the light of the vast scope of products that fall into this classification, have been debated since before 2008. We have arrived at a framework and approval process for companies and products that is very different from the traditional MCC regulatory approval processes for pharmaceutical products. Instead, it will be driven through a combination of frameworks related to the various legislations related to healthcare products, national standards and ISO compliance which results in an accreditation system. This is going to be an extremely interesting phase for us as we are entering into a new and unique regulatory space with a soon-to-be new regulator, with regulations that we've never had to meet as an industry. As regulatory consultants, we are looking forward to familiarizing ourselves with the new systems, which will largely pursue a technology and engineering-focused approval process.

What factors have ultimately motivated you to maintain such a longstanding tenure in this industry?

It is by far the most comprehensive insight you will ever have into a product. Nowhere will you achieve as much insight into a product as in regulatory affairs. We have to put together the summary of evidence that shows that the product should be allowed onto the market, based on its quality of manufacturing and controls, its intended use and related safety concerns. We have the

responsibility to ensure that what comes from all the regions of the world meets our South African regulatory requirements. The evidence and the information we get in regulatory affairs is absolutely fascinating. Regulatory affairs (RA) is the department in the company which markets the company to the regulator – RA gives assurance to the regulator that the company is able to fulfill its mandate of maintaining compliance systems and striving to continuously improve itself and its products.

Looking forward the next three to five years, what are your ambitions for the company and the industry?

I hope that in five years' time we will have put our paper legacy behind us. We are predominantly a paperless office but all of our outputs to the MCC and other regulators in Africa are still paper-based. From my perspective, the industry can stand to wholly benefit from transitioning to a fully electronic submission era. Internationally, medical device legislations are moving into the same data exchange packages and regulatory products submission platforms as pharmaceuticals, biological and complementary medicines. Within the coming years, I hope that the industry will have transitioned at least 80% of its activities to electronic document management systems. Also at that point, the country will have hopefully established some form of a post-graduate degree and vocational accreditation programme for regulatory professionals to ensure the sustainable development of this practice.

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