Interview: Ansie Savrda – Managing Director, ERS, South Africa

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Ansie Savrda of ERS (pty) ltd, highlights the important role that ERS plays in helping pharmaceutical companies to efficiently navigate South Africa and Africa's regulatory environment through the company's broad portfolio of regulatory advisory services.

As an introduction, what were your initial aspirations starting ERS?

There is a continuous progression in the market and the need for consultancy has therefore increased. Competition in the consultancy field is limited, as consultants have different focus areas and demand continuously increases. My experience includes product development and pre-clinical research, and the need for internationally experienced regulators was evident to me. Fortunately, from the beginning of my career I had opportunities and exposure to international markets. ERS' aspiration is to guide and assist companies in broadening their scope, while being compliant to the various applicable regulations and guidelines. In the same sense, we also aim to guide the requirements for product development in the sense of addressing the required data portfolios, compliant with the requirements of various regulatory authorities.

What does your service portfolio look like today?

We play an important role in allopathic, complementary medicines and medical devices for various markets by offering a wide range of pharmaceutical services. These services include international

regulatory intelligence used by companies for strategic decisions. A detailed portfolio of services are detailed on the website: www.execregulate.com . ERS work with International Consultants based in the EU, providing support in many applicable areas.

In this highly knowledge-intensive industry, how do you go about attracting and retaining the best talent available?

ERS started with personnel whom I've previously managed, not always directly, but which were in my divisions. Interviewing candidates is a science in itself, as you're aware. Select colleagues that fit the type of company and who are able to be trained in a multi-focused arena. Knowledge building is relatively easy if the candidate is academic in nature, fits the company type and most of all has a positive attitude. I appreciate the professionalism, ethics and dedication of my colleagues.

Based on your deep expertise of the South African & African markets, what are the most fundamental regulatory considerations that companies need to take into account? Furthermore how would you compare the regulatory scheme in South Africa to more mature markets?

South Africa (SA) is known to be a highly competitive market. Companies considering investing in the SA Pharma market need a niche area of focus. Strong purpose is important to succeed.

The regulatory component should not be underestimated, the local requirements are on par with developed markets for instance, Regulatory Authorities such as the EMA. The CTD (Common Technical Document) and its requirements, has been employed by the Medicines Control Council since 2010. Module 1, which addresses the regional requirements, of the ZA CTD is complex and has more requirements than for instance Europe's EMA CTD's. To prevent delays during the registration (licensing) process of a product, it's imperative to submit a high quality dossier.

The South African Regulatory Authority, the Medicines Control Council, is in a process of revamping and updating its organisation. Industry is supporting the process and we trust that we will have a highly efficient authority in the near future.

Looking back at training and development, what do you think are some of the most relevant topics in terms of the pharmaceutical industry?

If one is afforded exposure to various areas of the Pharma Industry in various markets, it's a huge benefit. Opportunities need to be grabbed even if it means inconvenience. A mind-set of continuous development and keeping up to date with International benchmarks, supports career growth. Understanding business objectives are beneficial and post-graduation courses in this area

are valuable. Self-study of local and international, guidelines and publications, should not be under estimated. Lastly but not least, soft skills and ethics are hugely valuable.

What is ERS' future direction?

Our goal is to support the evolution of companies to go to market, in the most efficient and fluid manner possible!

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