Interview with Michael Schultz, Director of Sales Middle East & Asia Pacific, Lorenz Life Science Group

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In 2010, South Africa officially joined the BRICS grouping. The Indian and Russian work environments are familiar to you, considering your significant experience in these countries. How would you compare South Africa with its BRIC counterparts in terms of its regulatory environment?

It has been eight months since I first came to South Africa to assess the market potential. Initially, the South African authorities had some fairly aggressive initiatives regarding the adoption of some application standards – namely for the registration of pharmaceutical drugs – which most of Europe, North America and Japan are currently using. These applications are called eCTD (Electronic Common Technical Document) – or electronic submission. The government wanted to be up and running, willing to adopt these standards last year.

Nevertheless, considering the industry's feedback towards this radically new system and other regions experience in adopting this whole new process, South Africa took the decision to progress in a smoother and slower way. It is understandable that the industry cannot just switch over to any new kind of application over night. As a result, the country has adopted another format, the CTD, which is the first step before going to the eCTD. This format is also proving to be a challenge for industry, as people have to be trained again, because the application standards are different from what companies are used to.

South Africa is moving to the right direction. When comparing India with South Africa, India is further behind in terms of adopting worldwide standards for internal applications. On the other hand, most of the Indian industry markets their products outside of India, in Europe and North America. The Indian industry has been quick in integrating and implementing software solutions such as ours to meet the requirements for marketing their products outside of India.

What is LORENZ's approach in the South African market?

As a software vendor, we always try to be at the forefront. We have to change and develop our software to meet the local requirements. We are always interested in understanding our environment and try to stay on top of what is happening in the country, so that we acquire more customers. As we already work with customers in South Africa, it is my responsibility that our development team stays on top of the changes happening in South Africa.

This approach is similar in other regions. For instance, we have a Japanese version of our product. Also when the American, Canadian or the European environment changes, we need to change our offer. It is not an easy task. And as more regions continue to adapt the CTD and eCTD, we need to be ready to meet the new requirements. It is an ongoing process and the industry expects a certain adaptability and reactivity from software vendors like LORENZ.

We are not a large Microsoft-type company, but rather a German family –owned business. We are very focused on providing software and services specifically for the regulatory market. As we have been in this business for more than twenty years, LORENZ has a lot of knowledge in this area, especially when it comes to electronic applications. This is in fact how LORENZ started. The company was developing software for the German regulatory agency, for which we helped develop one of the first electronic formats for electronic applications. LORENZ has always been at the forefront of this electronic submission development.

However, if you look at the current application process worldwide, over 90% of the applications are still done in paper; it is a small percentage of companies that are in the electronic sphere. This is why we need to develop our software to also meet these formats. We cannot advance products too fast, because we would leave a lot of the market behind.

Our products are able to adhere to all formats, and there will always be new formats coming out. For instance, the US authorities are already considering a new format to replace the eCTD called the Regulated Product Submission (RPS). It will only be another format which you can publish into, but it takes the eCTD and adds more requirements and information to the application structure. At the moment, the eCTD accommodates only Pharmaceuticals and Biotech applications, meaning

that if you are a medical device company or cosmetics or anything else, you cannot use the eCTD format to submit your application.

The RPS combines all applications to one application structure. The RPS will be tested next fall, in one year from now. We already have our core product to the point that we can publish into that format. The RPS was supposed to be tested this year already, but this has now been delayed until 2012.. This new format will eventually replace the eCTD in Europe, in Canada, as well as here in South Africa – although it will take more time.

LORENZ has been operating in South Africa since the beginning of a partnership with Amitacel CC last year and you now also work with MRA Regulatory Consultants in this market. What is LORENZ's marketing strategy in South Africa?

Amitacel CC is our sales and development partner. MRA Regulatory Consultants were actually our first customer here, and have since become our local training partner. Now, for every new customer that comes on board, we do not have to send resources down from Germany. MRA Regulatory Consultants can take care of the training. The next step is to set up or establish our local IT support in the country, as for the moment we are still sending one of our consultants to South Africa to install the software. We are in the process of identifying an IT partner to help provide local support to the South African industry.

We have been good at supporting all our customers worldwide from one of our main support centres in the US, Germany, India and Japan. For instance, the first couple of customers we had from India were supported out of Germany. As we have now grown our customer base considerably there, this model no longer works, due to the time difference, the cultural barriers, and the importance of local knowledge. Therefore we ended up setting up an office in Chennai in 2009 to support our Indian customers.

How receptive is this market towards LORENZ's solutions? Do customers come to you or do you have to convince them about LORENZ's added value?

South African companies are slowly showing their interest in making their processes more efficient using software to submit their dossiers. Before, they used to do everything manually, from the print out to the correction of the document. Paper submissions are a lot of work, therefore moving to an electronic environment offers great savings – customers only need to print out the final application; they are able to do more in less time by using software. Once the word gets around about how our customers are becoming more efficient and how their resources are being better utilized, this business will definitely pick up even more so.

Nonetheless, a lot of companies are still apprehensive about buying software. South Africa was supposed to go to eCTD by November 2010. At that moment, the industry was panicking. I was down here every month for the first seven months. All of a sudden, the Medicine Control Council (MCC) decided not to go for the eCTD and has since introduced the CTD format.

As a result, the interest did not die, but clearly things did slow down. There is still a lot of interest though, although it is not as hectic as the first seven months were.

What are LORENZ's comparative advantages in South Africa?

Our software architecture is very different, and this allows us to be compliant to so many different standards – all with the same software. However, this is often difficult to communicate if someone is more interested in their immediate needs, rather than long-term compliance. Therefore, it really comes down to the user friendliness of the product and its support. If you talk to all our customers worldwide and ask them about the quality of our services and the way we support both our products and our customers, I do not think any other vendor can match that.

We pride ourselves in customer support. We work nights and weekends when a company is doing its first eCTD for its major products. For example, we had one company in Denmark submitting a major application into both the US FDA and the EMEA at the same time. They wanted to publish both applications within one week. We had people on site, and others on stand-by in the office. We did not have any problems, but they needed from us that assurance that if something went wrong, we would be reactive.

When submitting an application, you have a timeline to respect. Delaying approvals by months represents a lot of money; it impacts the bottom-line. A lot of companies have started to realize how important the regulatory team is to pharmaceutical companies. If they are not given the proper tools to have their applications submitted and approved within the right time frames, it really impacts the company's business.

This is where LORENZ stands out.

Through the tools and applications provided to its customers, LORENZ aims at fostering their independence as well as empowering them. In this context, is it possible to establish long term business relationships with them or would you say that you work more on a tender basis?

We train our customers on the software and a lot of companies ultimately choose to do everything themselves. They have specialists, what we call power users, who may at some point even know the software better than some of our own consultants!

For instance, Health Canada is an authority which uses our software for reviewing applications and their eCTDs. They now have over 500 reviewers trained on the software. We did not train all these people, but we trained twenty of their power users in the beginning, who then trained all their people internally. We got them to the point where they were certified on our products to train others.

One of the recommendations from Mr Pillay today – at the IGPA – to solve the different issues faced by the country and improve access to medicines is to reduce the timeline and fees for the registration of drugs. With this encouraging speech from a representative of the SA health authorities, does the future look brighter for the industry in that respect, and if the timeline is reduced, what impact would it have on your business?

To reduce the approval time is something they need to work on internally. Certainly, technology can support them in doing so.

I see a lot of frustration from the South African pharmaceutical industry side, as their products sit in the approval process for years. I had never come across that kind of timeline before. Having a new medicine registered can take over four years in South Africa. Canada, on average, would approve a product in eight to nine months. The US FDA and the EMA are also close to meeting these same timelines.

Reducing the approval time to less than a year would really boost a lot of companies financially, which means that they could ultimately employ more people, expand their activities, invest, which would have a positive impact on the national economy in the end.

Not all of the European authorities require the eCTD yet, but some authorities have indicated that they would review applications/submissions quicker if they were submitted in an electronic format such as eCTD. Something along these lines might also happen in South Africa.

What are the objectives you have set for the South African operations for the five next years?

In the line of what we have done in India, with the set up of a Lorenz affiliate, we might even have to set up a LORENZ affiliate here to support our growing customer base and to support that base. Until then, we will continue to work with our current partners and continue to build up this market, similarly to what we have done in the US and in India before the creation of a local affiliate.

And since many pharmaceutical companies use South Africa to eventually market their products in the African continent, we could accompany them in that process.

As a final message, what are the tips you would give to our international audience looking at South Africa and ready to invest in this market?

I enjoy working here. The people that I have met so far in South Africa are keen on learning.

We are keen on providing the people here with information that helps them learn more about what they should expect when adopting the CTD/eCTD, and if we do not have the answers to their questions, we will put them in contact with people who do.

We consider ourselves fairly knowledgeable in our area but we cannot pretend to know everything. This is where our experience and networks count. We put on a user conference every year – userBridge – with customers attending from all over the world, from both industry and government authorities. As a result, we have a very strong relationship with both of these groups, a relationship that we believe no other vendor has. This helps LORENZ stand out around the world as a leader in this particular market.
With that in mind, I think the best advice I could give is to have patience – over time the market here will develop and you should be well prepared beforehand to take advantage of that.

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