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Q: Please tell us about your clients and activities in India? What are the opportunities that exist in India?

Being in confidential agreements with our clients, we cannot reveal the names but they are among the prominent names here. Companies approach us for resolving their issues with the FDA. Since clients seek remedies from us, we basically have expertise in rescue and remediation. Generally those who have been served warning letters, higher level of enforcement activity approach us. We try to help them in making amends to their existing processes and documentation habits.
If the market forces would have moved to Tanzania, everybody has been there but that is not the case. India continues to be in focus and that is why people talk about it. There are more than 200 USFDA (United States Food and Drug Administration) approved manufacturing set ups in India. However, next focus is China and that can prove competitive for India to deal with. Although big opportunity lies in the biologics, these pose a great challenge too. We have a great team that is working in the area. Also, I think biosimilars are complex and it is not going to be easy for the FDA to accept these.

Q: With growing challenges in quality control and compliance, how mature is the Indian industry and its regulatory system?

There have been few controversies but it is hard to say that the loopholes exist across the whole industry. Lot of the key inspections happen and there are just few headlines. Therefore, it is not exactly true that all the companies are the same. It is on company to company basis. Two years ago we had just one client here in India and today we have five. It is inappropriate to brand entire community or paint all with one brush. Today 42 percent of finished products and 80 percent of active drug ingredients (API) are coming from China and India. It is the regulator's job to find issues and things that can be potentially risky if entering their country. It is wrong to label India as bad while the FDA inspectors who are tasked to do their job, find any issues in few cases. India is still being talked about positively.

Q: In the backdrop of few examples where Indian companies were fined by USFDA, How could they ignore the basic quality parameters?

It depends on the commitment of the founders and the people involved. Since the things have got complex and the standard operating procedures (SOPs) followed by the workers might not be really understood by them. In such cases, they do their routine work without much interest. Then the day FDA inspectors arrive, there is panicking and inability to provide satisfactory replies. Enough training and discipline is required on that front.

Q: How do you look at the differences between Indian regulatory body and USFDA?

I don't see much differences though FDA is a huge organization with 12, 000 employees. There is a group called 'Office of Generic drugs' at FDA that is responsible for technical checks of the products and have final say on approvals. Meanwhile, Compliance department too has its opinion on facilities visits and inspections. So it is difficult for companies sometimes. I know regulatory offices change their structure and companies have to keep adjusting to new environments. Although FDA has huge experience in industry and GMP (36 years), in principle it has not changed much. Mostly inspectional changes happen. Before 10-12 years, the focus was more on validation and companies used to receive warning letters mostly on that. Hence, we can see that only the focus changes but not the basic regulations.

Q: Are the Indian companies responding positively to upgradation in compliance measures or it is just under pressure?

There is a discourse that industries across the globe hold same standards. But actually that is not the case. To quote an example, I remember a meeting with an Indian company's CEO in 2009 who was agitated about the FDA regulations. "We make products for Japan, Korean markets, but FDA calls us wrong. How can we be wrong?," he had asked. I remember telling him that he had to change his attitude as it is not the question of right or wrong. The regulatory authorities hold the rule book. For the product coming to US, one has to follow the rules there if one is interested in doing business there.

I agree that it becomes difficult for businesses to operate in varying set ups across globe but then adopting to change is important. I have seen Japan coming up with new facilities spending time over cleanliness but not bothering about the documentation. Different regulators have different focal points. It is a challenge for the large companies that work across boundaries get audited by the different regulators.

Q: You have had experiences with the Chinese companies besides US and India. What do you think about this market?

I think Chinese are still not much open yet. The documentation is still in Chinese as compared to India which I think benefitted from the English language due to British. Only if they recognize English, they can make great strides. It is interesting that the Chinese companies in US and their representatives with I have spoken to talked about the bad name created by the influx of 'Made in China' consumer products to US. That earned the reputation of being junk there. It has a stigma that refuses to go even after assurances of quality on other good products. Therefore, they are reluctant to come over because of image issues and thus don't want to enter the market with the Chinese names. To overcome that, they as a solution, are now partnering with the US companies and the brands that are already recognized there.

Q: Have there been any changes or increase in standards for quality compliance? Has it transformed over the period of time?

The basic regulations haven't fundamentally changed since 1978. So, it is interesting that you asked this question. Probably what have changed are the expectations of the regulators from the companies. A lot many times two big companies using different technologies merge and then face issues. Also, there is pressure on the industries to grow. That puts the companies in difficult conditions. In case of generic companies in particular, by definition, when you make low cost drugs, profitability is narrow. The main focus is on the cost cutting and we have seen many a times that it hampers the quality control.

Companies design their quality assurance and other functions themselves. When served letters, the organizations have to generate response within 15 days and all of a sudden people in QA/QC stop everything and work only to respond to FDA. They change procedures, documentation ways and the entire extra information to make changes in equipment revalidation. The list is long as there is lot of pressure on companies. The task gets bigger and response is confusing. The scenario could be better salvaged if the attention be provided to details at earlier stages.