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"Cleaning validation has a long-term benefit"

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Destin LeBlanc, expert in pharmaceutical and medical device cleaning validation

Destin LeBlanc regularly trains FDA investigators on cleaning validation issues. He has spent more than 25 years in the field of pharmaceutical cleaning validation, and has written and lectured internationally on cleaning validation, both as part of technical symposia as well as on-site company training. He holds nine patents and has authored numerous articles including a book on cleaning validation. During his first visit to India recently to share his experiences with key personnel of the pharmaceutical industry on "Cleaning Validation", he spoke to BioSpectrum. Excerpts of the interview:

You have interacted with the pharmaceutical industry in India. Where do you think these companies stand in the area of cleaning validation?

This is my first visit to India. Having said that, the Indian players are in touch with me over e-mail. They are exposed to the global scenario. They have the same kind of questions and concerns that were usually being asked by the players where I teach in Europe and the US. It seems the same level of interest exists among the players of India and players from the west.

What do you feel the Indian companies should focus on?

Some changes have occurred in India in the recent past. They are on patent laws and changes in the regulatory system. With

these, India is now more a part of the international community. And it is going to be a level playing field in one sense. Considering this, there should be more interaction, inter change, cooperation with the group. This is going to be a positive for the Indian pharmaceutical industry. Now there are going to be more relationships with the multinationals and large pharmaceuticals in terms of being suppliers of APIs and products. India has an edge as a low cost producer over Europe and the US. But still quality is a concern. The best way to do this is to organize training sessions on issues related to cleaning validation. The focus should be on the most important, relevant things on priority basis, which add significant values and really improve the quality of the product. Attention should be given on proper utilization of the limited resources.

What is the relevance of cleaning validation in the process of receiving US FDA approval?

In terms of getting US FDA approval, the way cleaning validation works for the drug products is that if you have an NDA (new drug application), you can get the approval without having the cleaning validation completed. But you can't sell it or introduce it in the market until the cleaning validation is completed. So it is critical for a company to get into the market and take it to the patient. It helps the company in terms of making profits and also the patient in terms of receiving a quality product. Besides cleaning validation, there are a lot of other processes like manufacturing process, bioequivalence studies which are essential for getting the US FDA approval.

What inputs are the Indian companies looking at on cleaning validation?

I think they are aware of all the issues in cleaning validation. We have to do sampling and other things while doing cleaning validation. But one of the things is a sort of balancing those and trying to set all the things together. You can't spend a lot of time on doing this and ignore the rest. You have to balance the efforts of both by sitting together for the overall progress. You can't select an analytical message without considering how to do the sampling. This ultimately has to be done in a consensus manner.

What are the benefits a company can reap by adopting cleaning validation?

I must say that cleaning validation can reduce the cost. By doing cleaning validation properly and deciding it properly and talking about it in advance, you can do it more efficiently. So you can do it and do justice to your job. By that you are not wasting resources and can spend time properly without compromising on quality. Cleaning validation shouldn't be part of something that is necessary to save money.

Hopefully it is going to save money in long term because it is going to prevent problems, recalls, contamination issues and lose. But it is difficult to quantify in terms of resources and financial terms. However, definitely it will have a long-term benefit for the companies.

Narayan Kulkarni