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"European and US expectations differ in validation of sterilization process"

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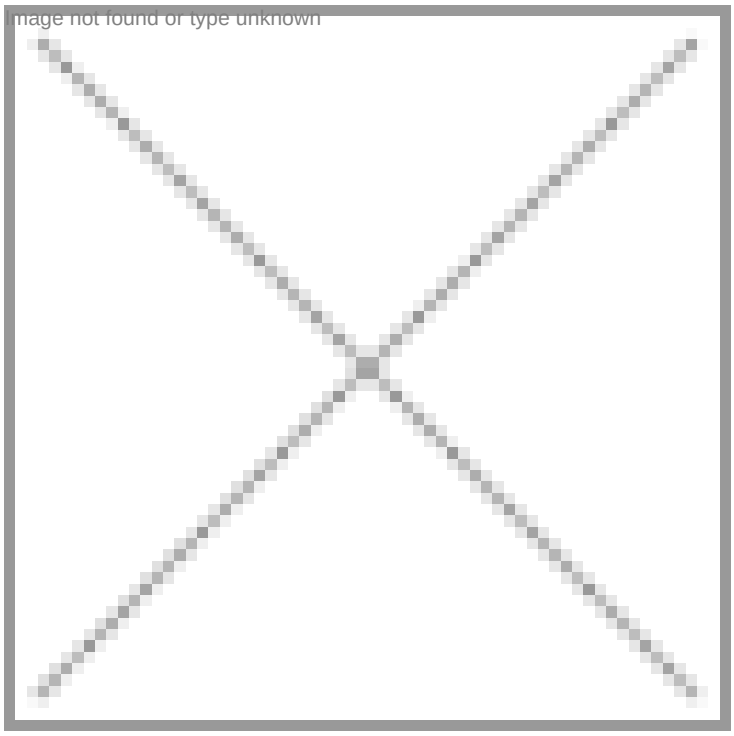

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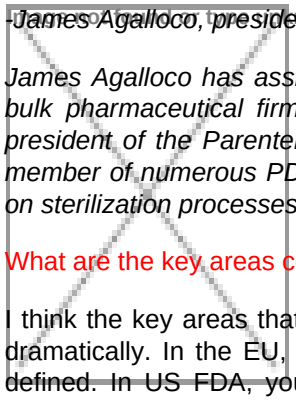

-James Agalloco, president of Agalloco & Associates

James Agalloco has assisted more than 100 pharmaceutical, biotechnology, medical device, equipment manufacturers and bulk pharmaceutical firms in a range of validation, automation and compliance areas in the last 15 years. Jim, a past president of the Parenteral Drug Association, has over 33 years of industrial experience. He has served as chairman and member of numerous PDA committees and remains active on several committees. He was in India to share his perspective on sterilization processes and systems validation.

What are the key areas companies should look at when talking about validation of sterilization process systems?

I think the key areas that we have to address are the European and US expectations that differ from each other somewhat dramatically. In the EU, there is a great deal of emphasis on physical measurements and the requirements are very well defined. In US FDA, you have much broader perspective and the focus is more on microbiological issues and physical directives are much less important. There are many prescriptive requirements you find in Europe.

As noted earlier, the regulators in the US require microbiological data. Sterilization is mainly to kill harmful microorganisms, which according to me, is core and that is what the sterilization process is all about. In the European sense, it is much more related to physical data and have a greater number of constraints on temperature measurements, pressure measurements

and other measurements that we get from instrumentation as a proof of vital efficacy. There is a disconnect. So the emphasis should be on what we emphasize and how to approach.

How will it effect the Indian companies as most of them export their range of products to European countries as well as to the US?

It has its effect on everyone. In a global sense, you try to comply with differing expectations with different emphasis. You don't want to make different things, for the same purpose and the same thing in different ways, with different modules, in terms of lot of products and documentations. The documentation packages have to be addressed. For different needs, you don't want to prepare two reports, for the same thing.

Is the US FDA looking at streamlining this process for the benefit of the industry?

There is an idea going on for harmonization of the entire process. The one area, which has not been harmonized so far, is sterilization process systems. There is a little consensus on what we have to do on sterilization process. The European and US regulations are different. Further there is a major gap between what the firms do and what the inspectors require. We have different views on the same thing.

Is there any agency active in harmonizing the processes related to sterilization systems?

In the real sense, there is no organization or agency, which is actively working for harmonization of the entire process. The real harmonization should come from the industry. The industry should become the leader and rest will become followers. The harmonization will come out by doing more, rather than by doing what is correct. Harmonization is not what is acceptable to one or the other but it is doing things in an acceptable manner for all. At present, we don't see that.

Where do Indian companies stand as far as validation of sterilization process is concerned?

I don't think they lack much in any of areas at this point in time. I am quite impressed with the companies that I have interacted with. Certainly they know and are aware of the expectations and requirements of the regulatory agencies from the European Union and US FDA. However, it is hard to say where they are. Even the American companies do not know where they are. The game is harder to play every year. These products are critical. The FDA is changing the focus to these products and also raising the bar all the time. I feel Indian companies already have world-class facilities and are having the tougher job of meeting requirements of both the EU and the US.

What are your suggestions for Indian companies that are looking at both the markets (the European Union and the US)?

Simplify. Do things in a common way as much as possible. Take advantage of what is agreeable in common ground and participate as much as possible in shaping up issues on harmonization.