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"The level of compliance is increasing"

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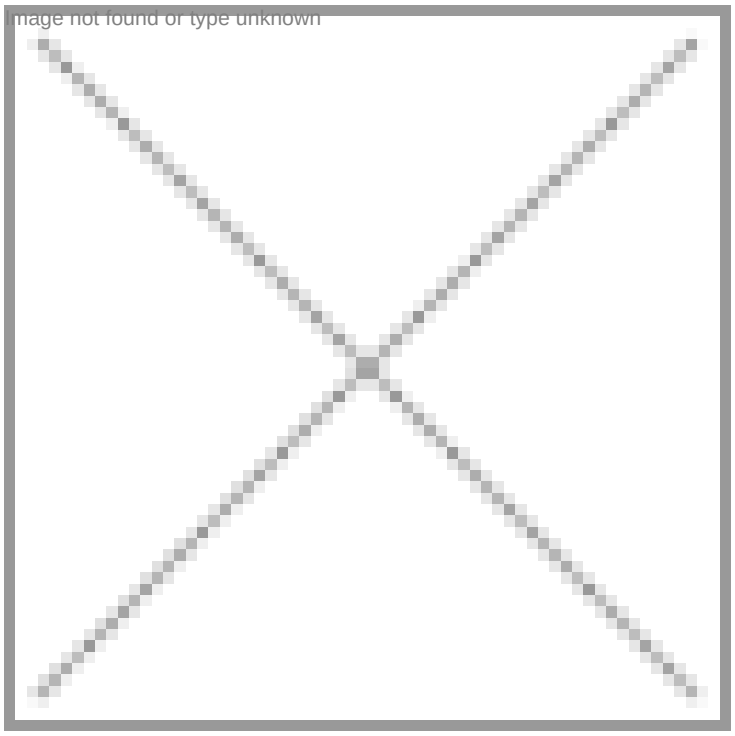

"The level of compliance is increasing"

-Dr Ludwig Huber, Compliance Fellow, Agilent Technologies, LSCA

Dr Ludwig Huber, a Compliance Fellow at Agilent Technologies, has published more than 70 papers on validation and compliance and 21 CFR Part 11 and has been visiting India since the 1990s to participate in seminars on validation and compliance and to meet customers. Besides authoring books on the topic, Dr Huber has been a review member of PDA's task forces on "21 CFR Part 11" and "Validation of Laboratory Data Acquisition Systems", and of the GAMP special interest group on Laboratory Equipment. Currently, Dr Huber is on the scientific advisory board of the European Compliance Academy and a member of IVT's task force on network infrastructure qualification. Dr Huber spoke to BioSpectrum on issues related to validation and compliance during his visit to India. Excerpts of the interview:

What were the missing links during the early 1990s related to compliance?

There was very little emphasis on compliance then. It's knowledge space. They didn't know how to do it. And they couldn't afford to hire consultants from the US and Europe. Then there was very little expertise here in India on compliance. Things have changed now. There are a lot of books available in India from local authors and also from abroad. Journals and articles too are available on compliance and validation. There is now a high level education on these issues.

What are your observations on validation and compliance in the early 1990s and now?

The level of compliance and expectations is much more increasing. Earlier there was a lot of demand about information, but it is strange to know that not much implementation has taken place. The level of compliance now is on higher side if we look at Indian multinationals like Ranbaxy, Wockhardt, Cipla and Sun Pharma and subsidiaries of global companies like Johnson & Johnson, Sanofi Aventis. Now I don't find in anyway a significant difference between European countries and India. And it can't be because of as long as the companies look at exports, they have to comply with the regulations of the countries to which they are going to export.

What was the driving force for the companies to look for compliance?

The driving force was to be the ability to export to the US, Australia and European countries. The companies have recognized that those who are not satisfying the compliant issue of high standards will not be successful. They realized that they cannot sell APIs, intermediaries, finished products in the regulated markets and also cannot do research activities. Compliance and marketing go hand in hand. Even regulatory issue is a driving factor for companies to have compliance systems in place.

How many Indian companies do you think are in compliance with validation and compliance systems?

It's very difficult to answer this. I can't give the exact number. However, I feel at least 200 companies have complied with. And there will be many more. All I can say is that every company exporting to the US and Europe have no other choice. They are doing it actively.

Do you feel Indian companies still have gaps in compliance?

I think the gap is more so in electronic recording. This is the most recent revelation. The Indian customers are keen to have more information on it during my visit to India.

How is the outlook for validation and compliance in India?

Not only in terms of compliance and validation, the overall outlook is excellent. If you look at the market in India, initially the industry started manufacturing APIs, generic drugs. Now the market is penetrating into the research and development space and also in the area of contract research, clinical research and manufacturing. The whole market is expanding from manufacturing to early chain of value development. In terms of compliance and validation, there is big difference between the international and local companies, i.e. companies focusing on the local market and companies that are exporting to the US, Europe, Australia and Japan. I don't expect much from the companies targeting the Indian market as the compliance level with these companies is quite low and they don't have the necessary instrumentation to keep up this requirement. However, there is an initiative from the Indian government called Schedule M, which is a mandate that everyone selling in India or exporting has to comply with this regulation.

Narayan Kulkarni