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"Multi vendor compliance services can be used by scientists across the disciplines"

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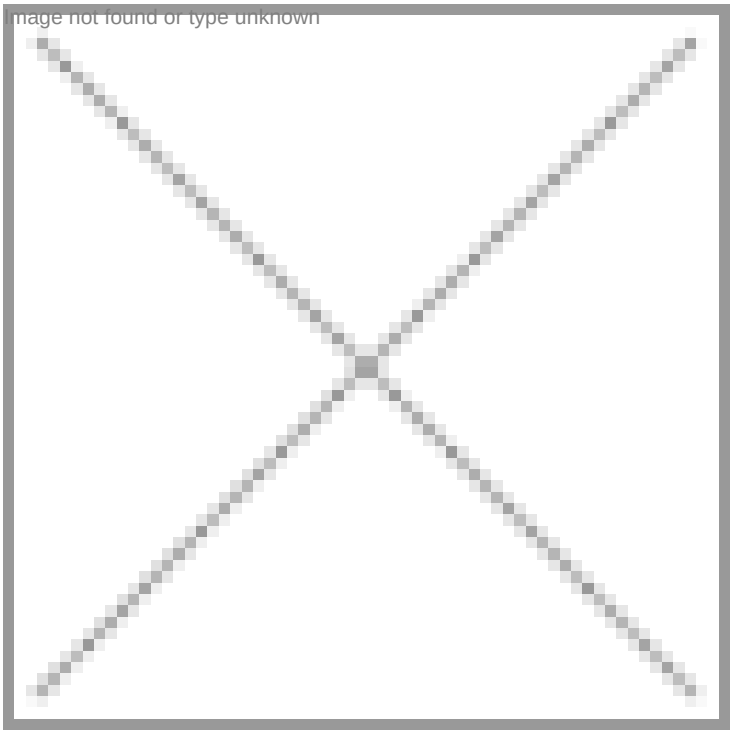


"Multi vendor compliance services can be used by scientists across the disciplines"

Dr Ludwig Huber, validation and compliance expert, Agilent Technologies.

Dr Ludwig Huber has published over 70 papers on validation and compliance and 21 CER Part 11 and authored many books. In an exclusive interview, he speaks about the role of lab compliance in the times to come. Excerpts:

How crucial will be the role of laboratory compliance in the life sciences/pharma arena in the future?

Laboratory compliance has always been necessary. It is crucial for service companies developing and manufacturing products that are marketed in the US and Europe. If a company is developing a drug and wants to tap the international market, then it does not have an alternative. It has to comply with the international regulations.

It is interesting to look at the origin of these regulations - where did they really come from? They always came at a point when the industry was having a problem with drug safety or drug development. For example, the Good Manufacturing Practice (GMP) was developed in the early Sixties and was filed as a rule when there was a problem with drug development. The Good Laboratory Practice (GLP) was developed in the US in the late Seventies when the Food and Drug Authority (FDA) identified some problems in the developmental stage of drugs. So whenever there has been a problem, the regulators come up with new regulations.

It has been observed that the regulated area is more focused on pure drug development. Hence there has been a shift from strictly manufacturing and late stage development to the early development stage now. As the FDA would like to have documented evidence that all the tests have been well developed under control, now compliance will become more important because of the increased use of electronic records. Worldwide, compliance is increasing and it has also been a part of the FDA regulated industry.

Can you elaborate on the multi vendor compliance service that was recently launched by Agilent Technologies? How has been the response till date?

Going a little back, around the 1990s, we realized after extensive interaction with the pharma industry that there was a need to validate or qualify the instrumentation/equipment used in the industry due to the compliance regulations. That was the starting point when we developed a qualification protocol and services for our own products. Later on, the pharma companies were keen to have a globally applicable uniform compliance protocol, which is independent of the brand of the instrument. And this is what our multi vendor compliance program offers. This is applicable to the products of different vendors on a worldwide basis.

The multi vendor compliance service is a platform, which can be used by scientists across the disciplines like pharma, biotechnology and life sciences. In addition there are similar compliance requirements in other industries too like the food industry and environment testing laboratories. In all these sectors the requirements are related to qualifying the equipment, revalidating the computers and software. But its usage is highest by the pharma industry.

This service has just been launched for the first time across the world including India. The response has been very good because it fills a requirement, which has come up many times in the industry and people are very happy about it.

How do you view the compliance market?

Compliance has been predominated by the research and the pharma industry. So the way the pharma industry is growing, the compliance market is also growing. There is definitely a high rate of growth expected in the compliance industry in the times to come.

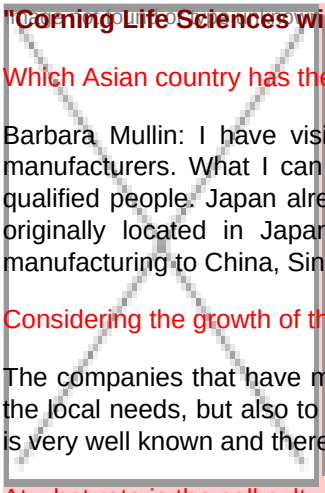
India has a GNP deadline whereby all laboratories must comply with national regulations and guidelines. What are the essential steps needed and how can Agilent help in this area?

The first step in this direction is to understand what compliance really means and build up the expertise. The best way to learn quickly is to go to those companies/organizations, which have experience in compliancy issues, which are working with US FDA and European agencies. It is mainly a training and learning exercise and then, of course, the next step would be to do an Asian analysis, to see what is already in place. Hence the requirements should be identified first, and then a gap analysis should be done after which comes the implementation plan on how to plug those gaps.

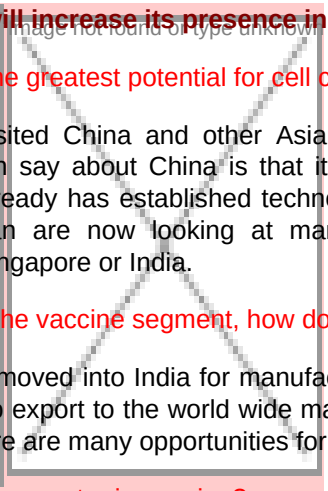
Agilent had helped a lot of international companies in the area of compliance by giving seminars and we have organized many such seminars in India too. Now probably we will extend this service to the service companies serving the local markets as well.

Rolly Dureha

"Corning Life Sciences will increase its presence in India"



Barbara Mullin, sales and marketing manager - Japan, Korea and India regions, Corning Life Sciences



Lydia A Kenton, business manager - cells platform, Corning Life Sciences.

Which Asian country has the greatest potential for cell culture products?

Barbara Mullin: I have visited China and other Asian countries like Korea and Japan. In China, I visited some of the manufacturers. What I can say about China is that it is very efficient for in-country manufacturing, with bright and highly qualified people. Japan already has established technology for manufacturing, but has higher costs. Hence, the companies originally located in Japan are now looking at manufacturing outside the country. Some may relocate a portion of manufacturing to China, Singapore or India.

Considering the growth of the vaccine segment, how do you see the opportunity for cell culture in India?

The companies that have moved into India for manufacturing vaccines have set up state-of-the-art facilities to meet not only the local needs, but also to export to the world wide market. They have a qualified and skilled work force. The Corning brand is very well known and there are many opportunities for growth.

At what rate is the cell culture sector is growing?

In India the projected growth rate is extremely good. The growth rate is a factor of two different areas. We look at growth rate for our own products and the growth rate for the actual market. Some published market studies project a 25 percent annual growth rate for the life sciences market. Is it really going to happen? We don't know. Economics and time will tell. For Corning brand products, we do not discuss projected growth rates, but we do feel that the India region will provide the opportunity to significantly increase Corning Life Sciences sales.

How do you see the competition? Who are the leaders in this space?

There are three to four other manufacturers that we consider to be competitors, selling similar products. As a policy of the company, we do not disclose the names of our competitors.

What are your future plans for India?

Corning Incorporated, a world leader in specialty glass, has a 150-year tradition of innovation. Corning International has a business entity in India with a broad spectrum of business activities such as automotive environmental products, optical fiber, optical cable, and ophthalmic products, but the focus until recently was not on life sciences. That has changed in the last few years as the life sciences and biotechnology market in India has grown. Since mid 2004, we have had direct sales presence in India for life sciences. We have strengthened our field force by adding additional dedicated personnel for life sciences. We feel that countrywide distribution is the key factor for successful growth. Hence, we believe in having a multi-centric distribution network. Corning India is planning to establish a warehouse in Delhi. It will be operational by mid 2006. This warehouse will stock the most frequently ordered products and will shorten the order placement cycle for customers. In 2005, Corning Life Sciences offered for the first time, a web based scientific seminar series on topics from cell culture to microarrays. These seminars were given by Corning's technical marketing and applications team. The seminars were very well attended by customers worldwide, including customers located in India.

What new technologies is Corning planning to launch in India?

We have several new technologies of interest. We will launch a range of patented products for drug discovery, cell culture and high throughput screening in 2006. Recently, we introduced the Corning CellBIND Surface family of products. These products are particularly useful for vaccine producers and have generated a high level of interest from Indian companies.

Narayan Kulkarni