

Pharma discusses FDA suggestion on Quality by Design

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Mumbai: At the recently held, DIA IT Life Sciences Summit 2012, a host of current topics were discussed at length among senior members of the pharma, CRO and IT communities. The event was the very first DIA India conference with the theme of Information Technology in Life Sciences.

Various topics including whether pharma is leveraging the opportunities provided by IT, methods to bridge the drug discovery and development chain through IT, enabling integrated clinical enterprise pharma compliance, and social media, were discussed and allowed the audience to actively engage in thought provoking discussions.

One of the discussion also focused on the need for Quality by Design in drug discovery and development. The US FDA had made an announcement asking for generic drug manufacturers to implement Quality by Design (QbD) into their Abbreviated New Drug Applications (ANDA) by 2013.

One of the panelists, Mr K K Bhagchandani, director, Asia Pacific operations, Advanced Chemistry Development (ACD Labs)Variables, said," QbD is all about systematically designing methods which are robust. Variables in an experiment such as chromatography column, mobile phase etc need to be designed accordingly A mathematical approach can be adopted to design a strategy for multivariate analysis, where more than one dynamic entity is at play. "

The move is said to help pharma companies reduce the number of hit-and-trial methods, thus saving precious time as well as money. Speaking about the impact that it will have on operations, Mr Bhagchandani said, "There are various software that are already present, that can be used to for complex method development in pharma. What the US FDA decision will do is, make pharma companies plan their the processes with more detail, such that they will be able to explain the importance of choosing each process and experiment, making the drug discovery process accountable."

Through the two days of this conference, the attendees heard about latest developments, case studies and solutions from Life Science industry experts. Sessions featured expert presentations on the latest trends and technology advances that are

reshaping the life sciences industry. The next IT life sciences summit will be held in July 2013 in Bangalore.