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DIA's conference focuses on global regulatory changes, challenges

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With a view to tap the challenges faced by the Indian pharma industry due to the change in the regulatory policies, a three-day conference was organised by the DIA on 'Global regulatory changes: Quest for optimisation'. The event that started from May 7 to 9 focussed on the challenges that the industry is facing globally due to regulatory changes and how to deal with it.

The event was attended not only by people within the industry but also by the regulators from India and the US FDA. They shared their expectations and future plans that they have from the industry. The event focussed on the challenges faced by Indian pharma manufacturers while supplying drugs to domestic and global markets. Each session was planned with presentation on challenges faced by the industry and the regulatory authorities.

In keynote address, Dr Sadhna Joglekar, VP, medical and clinical research, GSK spoke about the need for a different patent line. She said that in the near future speciality sectors like oncology and vaccine is going to grow. It is estimated that the vaccine industry is slated to grow around 47 per cent in the coming year. She also spoke about the challenges in the emerging biosimilar market. "In biosimilars we cannot operate like in generic market since its different thus for biosimilars we need to have operations that should be different in nature from that of generics," She said.

Giving a short and brisk update on pharmacovigilance, Dr Surinder Singh, DCGI said that having a proper pharmacovigilance programme is very important for detection, assessment, understanding and prevention of adverse drug reaction. The need for it arises more since global market for medicines is growing due to ageing population and increasing number of diseases. He informed that soon his office will be starting a quarterly publication from July 1st that will contain information on ADR and it would be circulated in all medical colleges.

The first session was on the challenges during product development. Albinus D'sa, deputy country director (India), US FDA who was also chairing the session gave a detailed information on the advantages of the new regulatory path as a result of implementation of ICH Q8, Q9 and Q10 for product design and quality. He said that a strong quality system needs to exist for robust development of the industry and to do so the industry needs to adept it according to the changing times and new regulatory developments.

Speaking about the challenges faced by the industry during drug product development Nitin Dharmadhikari, scientist, Sun Pharma expressed that the Indian pharma industry should work along with government of India and ensure adopting the regulatory changes as an when it happens. Referring to PWC report he said that companies that follow the PAT and ICH Q8, Q9 and Q10 are ahead of the other companies in the

competition.

Further, Premnath Shenoy, director, regulatory affairs, AstraZeneca while speaking on the regulatory challenges during product development for global market said that there is a need for knowledge sharing with regulatory officers so that the whole process can be easy. The next session was on compliance challenges and it focused on topics like cGMP challenges in pre-approval inspections, use of PAT as analytical tool for risk mitigation to ensure product consistency and on regulators perspective in meeting compliance challenges etc.

All of the members present in the conference were of the view that good regulatory policy is the need of the hour and both the government and the industry should work and collaborate with each other to attain it.