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Need for a neutral platform where people, science and regulations connect

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The Parenteral Drug Association (PDA) is the leading global provider of science and technology, regulatory information and education for the pharmaceutical and biopharmaceutical community. A nonprofit organization, it acts as an interface by providing and developing scientifically sound, practical technical information and resources to advance science and regulation through the expertise. The PDA has over 9500 members worldwide with dedicated chapters in Japan, Korea, Australia and other countries. Indian manufacturers such as Zydus, Hospira, DRL are members of PDA.
Early last month, two sessions were held in Mumbai and Hyderabad to spread the word about PDA's activities and its plans for Indian manufacturers. The PDA India chapter seeks to be the voice-of-industry and bridge the gaps between the industry needs and the regulatory expectations in the geography. Both the events included representatives from some of the top pharma companies in India. In an email interaction with BioSpectrum, **Mr. Richard Johnson**, President PDA talks about how the organisation can make a difference for Indian Pharma manufacturers in the regulatory processes, about the PDA Biotechnology Advisory Board and more.

How does the PDA plan to help Indian companies with streamlining the regulatory process?

The Parenteral Drug Association has been associated with interfacing with science technology and regulations for over 60 years in the world. The PDA Biotechnology Advisory Board (BioAB) establishes the strategic direction and provides oversight for PDA's biopharmaceutical scientific and technical activities through the development of guidelines, technical reports, and technical bulletins and recommendations of other activities such as conferences or training courses. Through its sister Advisory Boards, RAQAB and SAB, interacts with regulatory authorities by participating in the development of consensus responses to regulatory draft and final guidance and directives.

What have been the activities by the PDA in India, prior to this event.

PDA is a member based organization, that has been in existence since 1946. There have been members from India for many

years. In the last 3 years we have been working to establish a firm core of supporters and volunteers to assure that a PDA India Chapter will be sustainable. India is recognized as an important player in the global pharmaceutical community, and PDA wants to support this community.

Will the PDA interact with just parenteral drug manufacturers or those involved in the manufacture of API, biologics etc as well?

The Parenteral Drug Association is a forum that offers interaction opportunities for all of the industry and its allied services from API, biologics and formulations alike. The recent technical reports reflect this holistic approach, for example PDA Technical Report No. 60 (TR 60), "Process Validation: A Lifecycle Approach" is as much relevant to API manufacturing as it is to Biologics or formulations. Another initiative, running for some time now is the "Paradigm Change in Manufacturing Operations" (PCMO) which has wide range of industry and regulatory professionals contributing their expertise.

What was the response to both the events in Mumbai and Hyderabad? What was the main take away for PDA in terms of the Indian Pharma industry?

The PDA Inaugural convention, which was held in Hyderabad on June 04th was attended by 70+ Industry professionals and followed by the Convention at Mumbai on June 06th which saw the attendance of around 70+ professionals. The Convention at Hyderabad saw the presence of the Director General of the Food Drug Administration from Andhra Pradesh while the Mumbai Event was a kind of first with the presence of the US FDA Office from Mumbai and Delhi.
There is an enormous need for a neutral platform where people, science and regulations connect. The geographical spread and the industry segments present in India makes this task further challenging and PDA India Chapter understands the huge expectation and responsibility, that rests unaddressed.