

IPA releases QF focused on Investigation of Non-conformities at IPF 2019

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IPF 2019 started on a very somber note and with the sudden demise of Mr. D G Shah, Secretary General, IPA, the event lacked luster unlike the other previous events.

In the last four years, the QF focused on several priority areas, namely, Data Reliability, Best Practices & Metrics, Culture & Capability, Investigations, etc. and released a comprehensive set of Data Reliability Guideline in February 2017 and Process Validation Guideline and Good Documentation Practice Guideline in Feb 2018.

The senior managers nominated to study the best practices and frame the guidelines were: S V Gopalakrishnan, Shirish Belapure and Arunava Ghosh from Cadila Healthcare; Sanjay Gorana, Gopi Reddy and Rachel Princess from Cipla; K V Raghu and Sairam Philkana from Dr. Reddy's; Pradeep Chakravarty, Alok Ghosh and Indrajit Bose from Lupin; Sanjay Deshmukh, Jila Breeze and Jigar Marfatia from Sun and Jayendra Tripathi, Rakesh Sheth and Sweetie Shah from Torrent. They were assisted in this task by Vivek Arora and Jyoti Saini of McKinsey. The QF has been benchmarked with the existing regulatory guidance from the USFDA and other regulatory bodies such as UKMHRA, WHO etc.

The 2-day event saw participation of delegates from various top-notch pharmaceutical companies. Apart from the presentations from regulatory bodies such as MHRA, EMA, USFDA India Office and CDSCO, this time the event also mentioned about creating an academy to impart entry level training for quality culture. In a session moderated by Mr. Rahul Guha, Partner and Director, Boston Consulting Group, India a spokesperson of Dr. Reddy's Labs mentioned "We have six levels of intermediate process. We interviewed 300+ students for a 30-student batch. We kept into account factors such as job-readiness, willing to sacrifice for a year etc," when asked about what criteria was taken into account for the selection.

"Since Lupin already has a program, we had some experience in the selection. We received 110 applications and from that we selected 30. We took into account 10+2, ITI etc," said a spokesperson from Lupin. While a spokesperson from Cipla said that "As the academy is based in Goa, we had a Goa-focused approach. We considered lower economic strata and as we

were not paying stipend for 3 months, we also took that into account.” Soft-skills training was also suggested during the conversation.

A session on Disruptive Technologies in Pharma Operations by Mr. Parag Patel, Disruptive Technologies for Pharma Operations Globally, McKinsey and Company was very interesting. He mentioned that by 2020, there will be 21 billion connected devices in IoT. Mr. Parag also mentioned some case studies of companies such as Pfizer, Merck, Amgen adopting to technologies and about paradigm shifts driving pharmaceutical operations in the industry.

The most talked about session of the event was again the CEO panel which saw participation from companies such as Lupin, Dr. Reddy’s Laboratories, Cadila Healthcare and Cipla. The session saw some very candid responses from the MDs and CEOs. All of them showed optimism for the upcoming years.