Pharma Regulatory Conclave 2023: The Unique Inaugural Program Taking Bold Steps!

The Inaugural Regulatory Program of Eminence Business Media, Pharma Regulatory Conclave 2023 set a very high benchmark for conferences based off learning and rejuvenation. The program was designed with a unique framework with one day virtual day program on 30th June and a two-day in-person conference at Hilton Resort, North Goa on July 5th - 6th. With the unique theme on the Day 2, “Patrao”, having dedicated Q/A rounds after every session, case study solving exercises, within the quaint locality in Goa amidst the monsoon, this regulatory program took a very distinctive and bold step by not only addressing current challenges of the pharma regulatory industry but also acknowledging the unaddressed yet crucial focus of emerging markets.

The virtual day was designed to give theoretical understanding to the delegates about the various required regulatory processes like Regulatory Intelligence, Dossier Filings and GDUFA III guidelines delivered by Mr Prafulla Nandi from Cadila Pharma, Ms Minoo Biju from Piramal Pharma Solutions and Mr Adam Freeman from exFDA Consultants. The program also included a very interesting panel discussion of international experts from regulatory bodies of USA, South Africa, and Latin America. Mr. Larry Stevens from USFDA, Ms Emtia Perold from SAPHARA and Mr Ivan Calderón from COFEPRIS shared their experience and gave insights about the practicality of having a common dossier for emerging markets. Pharma Industry veterans like Dr Udaykumar Rakibe from PharmaMantraTM and Dr Sanjit Singh Lamba from Biocuris Pharma were also a part of the discussion and presented the Indian Pharma perspective with their standing within the global market.

The unique design of the program facilitated Eminence Business Media’s commitment to delivering excellence by learning. The virtual program was corroborated with the in-person conference with a unique case study solving exercise which focused on emerging markets regulatory requirements. The session was designed by Mr. Rajeev Mathur from Sun Pharma and was facilitated by Mr. Udaykumar Rakibe and Mr. Rahul Jain at the in-person conference. Delegates and attendees were working in groups and solving the case study for over a week to present their solutions with the groups on Day 2 of the conference. The group exercise was fruitful with unique frameworks being presented by the delegates as a solution to the cases.

The two day in-person conference further thoroughly discussed topics like regulatory requirements of complex generics, drug approvals in ICH countries, life cycle management of a drug, post approval changes, among others. Experts like Mr. Rahul Gupta from USV, Ms Meenakshi Jain from Sandoz, Ms Adity Sen Pal from Indoco Remedies and Ms Vandana Singh from Biocon delivered the crucial topics and interacted with the audience by accommodating their questions. Mr Arani Chatterjee from Cadila Pharma and Mr Praveen Cherukupalli from Innovare Labs discussed the clinical trial regulatory requirements and the nitrosamine requirements which are the pain points for the industry. The in-person conference also witnessed a panel discussion on the ever-evolving challenges of regulatory affairs moderated by

Dr Sanjit Singh Lamba. The expert consisted of panel members like Dr Mayur Parmar from Govt of Gujarat, Dr Venkat R Naidu from Dr. Reddy's Laboratories, Ms Adity Sen Pal, and Mr Rahul Gupta.

Having understood the unique requirements of the regulatory professionals to clarify their doubts and addresses their questions, the program accommodated a panel of experts namely, Mr Prafulla Nandi, Mr Arani Chatterjee and Mr Praveen Cherukupalli to solely address the queries of the delegates and attendees. The in-person conference also had sessions catering to gap mitigation between regulatory and other departments by having a dedicated session on soft skills delivered by Mr Sushil Barkur. Further, the rejuvenating activity of the program was also designed with the underline learning of importance of working in collaboration focusing more on regulatory professionals being facilitators than inspectors.

Eminence Business Media plans to announce the dates for the fourth edition of the Computer Software Assurance in 2024, so stay tuned for updates on their LinkedIn page and event website.