Global quality experts call for strengthening quality culture & leveraging technological advancements at IPA's 9th Global Pharmaceutical Quality Summit 2024

Mumbai, 28 June 2023: Indian Pharmaceutical Alliance (IPA) today successfully concluded the 9th edition of the Global Pharmaceutical Quality Summit 2024. The theme for the Summit was, **'Advances in Manufacturing and Quality – Patient Centricity'**. The two-day Summit brought together industry leaders, global regulators, quality experts, and stakeholders to foster knowledge exchange and deliberate on areas of importance in shaping the pharmaceutical landscape in India.

The summit witnessed **16 sessions and 45 speakers** from around the globe including senior officials from the Government of India, USFDA, MHRA and IGBA**.** Sudarshan Jain, Secretary General, IPA, began with the welcome address, followed by opening remarks from Nilesh Gupta, Chair, Quality Committee, IPA and MD, Lupin and Patrizia Cavazzoni, Director, CDER, USFDA; special remarks by Rajeev Raghuvanshi, Drug Controller General of India, Government of India. Arunish Chawla, Secretary, Department of Pharmaceuticals, Government of India delivered the keynote address.

Day 1 of the summit set the stage for the Summit and pharmaceutical industry's future by focusing on strategic priorities, quality management, and technological advancements. The Summit featured the release of the **IPA Best Practices Guideline on Good Engineering Practices and Process Analytical Tools**. The sessions reviewed the industry's current landscape and future planning, emphasizing robust quality frameworks. This was followed by deliberations on the transformative role of AI in enhancing pharmaceutical quality and operations, and the importance of cybersecurity in protecting digital infrastructure and strategies to minimize cross-contamination, crucial for maintaining high production standards. The day concluded with insights into future data and documentation imperatives, highlighting meticulous record-keeping and data management for compliance and quality.

Day 2 of the Summit began with opening remarks from Sarah McMullen, Country Director, USFDA. This was followed by a session on regulatory reforms by Chandrasekhar Ranga, Joint Drugs Controller, Government of India, and Susana Almeida, Secretary General, International Generics & Biosimilar Association (IGBA); and on talent acquisition strategies, and skilling institutes for quality manufacturing by Global CHROs and Manufacturing Heads. The highlight of the day featured insightful panel discussions on charting the next decade of pharma quality and operations and the biopharma opportunity which saw leaders from leading pharma companies. The Summit concluded with closing remarks from Nilesh Gupta, emphasizing continuous improvement and building on the culture of quality for the sector.

Mr Sudarshan Jain, Secretary General, Indian Pharmaceutical Alliance, said, "The Summit has indeed grown from strength to strength since its inception in 2016. This year's theme, 'Advances in Manufacturing and Quality with focus on Patient Centricity,' highlighted the unwavering commitment of the industry to enhance the culture of quality in the pharmaceutical sector, always prioritizing patient welfare. Quality remains fundamental to our industry, and the Indian Pharma Industry continues to strive to become a global benchmark in quality. Our focus is on reimagining the future of manufacturing and quality through leveraging technological advancements, seizing the digital future of pharma quality operations, and adopting a shift in mindset. The insights and collaborations will significantly advance quality in the pharmaceutical industry."

Rajeev Raghuvanshi, Drug Controller General of India, Government of India, said, “Changing the culture is a slow process, but the journey has started well, and we are moving in the right direction. One of the most impactful initiatives is the risk-based inspections, where we inspected about 400 manufacturing units, closing more than 36% for non-compliance. This has significantly improved perceptions and realities on the ground. The first group of industries with more than 250 crores of turnover will soon come under the compliance purview of the revised Schedule M, ensuring higher standards and better quality. Additionally, we are enhancing internal processes, including the transfer of 207 officers to raise a culture of quality and integrity. Our ongoing efforts aim to bring consistency and efficiency to the regulatory framework."

Arunish Chawla - Secretary, Department of Pharmaceuticals, Government of India, said, “Quality is of paramount focus - standing on three essential pillars: market, patient, and neighbour. Market quality commands a premium and builds reputation, which is our best defence against malpractices. Patient quality is driven by robust regulatory systems, and India is progressing rapidly on this front. Our mission going forward is to make quality the center of policy framework. We've upgraded Schedule M of the Drug and Cosmetic Rules, surpassing WHO GMP standards in some areas. With the audits starting in July 2024, we aim to produce world-class products, as emphasized by the Prime Minister's vision of 'Zero defect and Zero effect.' Quality requires investment, and we support medium and small plants through reform initiatives. The integrity of the Indian industry relies on every player's adherence to the highest standards. When one fails, it affects the entire industry. Therefore, we must collectively uphold quality to protect our reputation and ensure excellence in every aspect."

About IPA:

IPA represents 23 research-based national pharmaceutical companies. Collectively, IPA companies account for over 85 percent of the private sector investment in pharmaceutical research and development. They contribute more than 80 per cent of the country’s exports of drugs and pharmaceuticals and service over 64 percent of the domestic market.

For more information, visit https://www.ipa-india.org/

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