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Quality issues cannot be addressed holistically unless we make the product more patient-centric: Dr Rajeev Singh Raghuvanshi, DCGI

12 July 2023 | News | By Bhagwati Prasad

Dr Rajeev Singh Raghuvanshi, Drugs Controller General of India spoke at iPHEX in Hyderabad

At the 9th International Pharmaceutical Exhibition (iPHEX) held recently in Hyderabad, Dr Rajeev Singh Raghuvanshi, the Drugs Controller General of India (DCGI) stated, “Pharma, besides being a regulated industry, is also a knowledge-driven industry. If we put the purpose before the individual and follow a knowledge-based approach rather than focusing only on profitability, most of the quality issues and aberrations will get resolved”. The three-day iPHEX commenced on July 5 and was organised by the Pharmaceuticals Export Promotion Council of India (Pharmexcil) with support from the Union Ministry of Commerce.

“Today, the cost is offset by the quality towards increasing profitability. Unless quality is taken as the basic ingredient of the product, the issues around regulatory compliances cannot be taken care of”, added Dr Raghuvanshi.

Citing an example, he said that the number of filings and approvals in the nutraceutical domain from the CDSCO has nosedived and has become zero over the past ten years. These days, nobody applies to the national drug regulator - the Central Drugs Standard Control Organisation (CDSCO) for a nutraceutical product. Similarly, applications to the national food regulator, the Food Safety and Standards Authority of India (FSSAI) have soared because the regulation is a bit lenient as compared to that in the CDSCO. Besides this, the review process in FSSAI is much more forgiving than what is done in the CDSCO.

“Despite the prescriber being a doctor and consumer or patient being the same, manufacturers have made a shift and changed the regulators to make some good profit. The product seems to be being made for the regulator and not the patient. Quality issues cannot be addressed holistically unless we shift the mindset in this country that the product has to be patient-centric. Regulators are here to facilitate the industry. Aberrations which have happened and will happen are a minor part of the entire dynamics, if all stakeholders take the responsibility of quality and patient centricity,” Dr Raghuvanshi concluded.

While echoing similar views on the sidelines of the event, Dr Veer Raju Pilla, Vice President, Regulatory Affairs, Quagen Pharma said, “Quality issues in medicines can be taken care of when we follow quality by design (QbD) principles. QbD ensures building the quality into the medicinal product rather than testing at the end. Testing only evaluates the product based on the list or criteria of the tests prescribed. When you are following QbD principles, the reference product is analysed, evaluation is done about what characteristics you want to build into the product, controls on the various components of the product and the control strategy adopted is also ensured.”

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