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US FDA to hold drug quality management training programmes for Indian pharma companies

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In collaboration with the Indian Drug Manufacturers Association

The US Food and Drug Administration (FDA) is scheduled to conduct training programmes for pharma companies in India for capacity building in areas of drug quality management in collaboration with the Indian Drug Manufacturers Association (IDMA).

IDMA will cover subjects like quality management maturity, control of cross contamination in shared facilities, designing of bioequivalence studies and adoption of Industry 4.0 digitisation initiatives. IDMA members were requested to provide basic details in the survey provided by the USFDA to help identify the gaps in audit readiness, list of topics for the training programmes like filing of Drug Master File (DMF) and Abbreviated New Drug Application (ANDA) .

A DMF is a submission to the FDA that may be used to provide confidential information about facilities, processes or articles used in the manufacturing, processing, packaging and storing of one or more medicinal products. ANDA contains data which is submitted to the FDA for the review and potential approval of a generic drug product.

“The USFDA is transparent for their ANDA programme or product review. Therefore, IDMA members should be in touch with the agency for review updates so that upfront information can be obtained,” stated an official associated with the development.

Various quality initiatives have been undertaken by the IDMA over the past two decades such as quality excellence award, annual pharmaceutical analysts convention (PAC), seminars conducted in collaboration with the Department of Pharmaceuticals (DoP) across the country and advanced programme in pharmaceutical quality management (APPQM), the MBA style international education programme offered by the IDMA in collaboration with NSF, UK.

Launched in 2018, the APPQM programme is aimed at helping quality control heads of Indian pharma companies enhance audit-readiness and implement compliance in areas of good manufacturing practices (GMP), quality assurance, documentation, data integrity and quality management system (QMS). The programme encompasses ICH, WHO and the US FDA requirements and best industry practices.

The NSF has trained regulators from regulatory agencies including those in the EU and USA. With offices in Delhi, NSF has an excellent understanding of the Indian pharma industry, gained over the last 30 years. NSF International UK (previously David Begg Associates) is a global leader in education for the pharma industry.

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