IPA-PHARMEXCIL

Technical Conference 2017

28th Jan. 2017

Ahmedabad

"Quality Metrics- Future need of the Pharmaceutical Industry for marketing drug products in the U.S. market"

Venue

Hotel Hyatt Regency

Usmanpura, Asharam Road

Ahmedabad

----------Organized Jointly By----------

The Indian Pharmaceutical Association (IPA)

Industrial Pharmacy Division

In association with

IPA-Gujrat State Branch,

Food & Drug Control Administration (FDCA), Gandhinagar,

&

Pharmaceutical Export Promotion Council of India (Pharmexcil)

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USFDA Guidance on Quality Metrics

Quality metrics are used throughout the drugs and biologics industry to monitor quality control systems and processes and drive continuous improvement efforts in drug manufacturing. These metrics can also be useful to FDA: to help develop compliance and inspection policies and practices, such as risk-based inspection scheduling of drug manufacturers; to improve the Agency's ability to predict, and therefore, possibly mitigate, future drug shortages; and to encourage the pharmaceutical industry to implement state-of-the-art, innovative quality management systems for pharmaceutical manufacturing. This revised draft guidance includes an explanation of how the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) intend to utilize submitted data and quality metrics to help ensure that their policies and practices continue to support continuous improvement and innovation in the pharmaceutical manufacturing industry. In order to achieve these goals, FDA is initiating a quality metrics reporting programme. As described in this guidance, FDA is initiating a voluntary reporting phase of the FDA quality metrics reporting programme. In the voluntary reporting phase of the program, FDA expects to learn more about a limited set of quality metrics, associated analytics, and improve the FDA quality metrics reporting program.

Background Information

The goal of FDA is to provide drug products with high and consistent quality. Quality Metrics are introduced because product recalls are increasing despite elaborate QC/QA monitoring by most companies. QM's are expected to check the consistency of processes and quality of the marketed drug products. FDA intends that lot acceptance rate, product quality complaint rate invalidated out of specification rate and annual product review (APR) or product quality review (PQR) in time rate be calculated. The optional metrics are CAPA effectiveness and calculation of Cp and Pp

Objectives of Seminar

The participants will learn to improve their practice and reporting of Quality Metrics to USFDA. Small to medium scale entrepreneurs and academicians are expected to understand the requirements of Quality Metrics and voluntarily start the practice of Quality Metrics.

The comments and suggestions regarding this draft document will be submitted to USFDA, which will be useful for Indian industry.

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Time	Title	Speaker
08:30 to 9:30	Registration	
9:30 to 10:15	Inauguration	
10:15 to 11:00	Meaningful quality metrics for sustainable compliance	**Mr. S.M.Mudda** (Exec.Director Technical Operations) M/s Micro Labs Ltd. Banglore
11:00 to 11:45	Product Quality Review	**Mr. Sanjay Kumar Jain** (VP-Quality) M/s Amneal Pharma Ahmedabad
11:45 to 12:30	Quality Metrics- A tool to evaluate our quality system	**Mr. Sanjay Kapadia.** President - Corporate Quality Assurance, M/s Ipca Laboratories Ltd, Mumbai
12:30 to 13:30	**Lunch Break and Networking**	
13:30 to 14:15	Data Integrity : An overriding factor for Quality Metrics.	**Mr. Vijay Kshirsagar** Director TRAC Pharma Consulting, Mumbai,
14:15 to 15:00	Calculation of Quality Metrics	**Dr. M.C.Gohel** Research Director & Professor Anand Pharmacy College, Anand
15:00 to 15:45	Review of Pharmaceutical Quality Systems including KPI	**Mr. Shailesh Patel** Head- Quality & Regulatory Affairs- Cadila Pharmaceutical Ltd Ahmedabad
15:45 to 16:15	**Tea/Coffee Break**	
16:15 to 17:00	Panel Discussion/Question-Answers	Speakers and Panel Members

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Company/Institute : ……

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IPA/Pharmexcil Member : ☐ Yes / ☐ No Membership No……

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Please send your remittance by Cheque/DD in favour of
"Indian Pharmaceutical Association Gujrat State"

Amount Rs…….

Issuing Bank……..

Delegate Signature ……

Contact for Registration & Sponsoring the event

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Registration Details: **(in INR)**

Registration Categories	Registration Fees
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Student/Research Scholar	1000