Centurion University of Technology and Management

BOLANGIR

Workshop on

GMP and cGMP Considerations in Pharmaceutical Industry

Date: 03-02-2020

No. of Students and/or Faculty Participated: **12**

Resource Person

Dr. G.V. Ramana

Assistant Professor

School of Agriculture & BIO-Engineering

CUTM, Paralakhemundi

Objective:

- To provide knowledge on GMP 's and elucidating their impact on production quality. To introduce the concept of quality standards in terms of ISO-9000 and quality audit. To enlighten the issues in relevance to Hazard analysis and critical points.

About the session

cGMP refers to the Current Good Manufacturing Practice regulations enforced by the US Food and Drug Administration (FDA). cGMP provides for systems that assure proper design, monitoring, and control of manufacturing processes and facilities. Adherence to the cGMP regulations assures the identity, strength, quality, and purity of drug products by requiring that manufacturers of medications adequately control manufacturing operations. This includes establishing strong quality management systems, obtaining appropriate quality raw materials, establishing robust operating procedures, detecting and investigating product quality deviations, and maintaining reliable testing laboratories. This formal system of controls at a pharmaceutical company, if adequately put into practice, helps to prevent instances of contamination, mix-ups, deviations, failures, and errors. This assures that drug products meet their quality standards.

FDA ensures the quality of drug products by carefully monitoring drug manufacturers' compliance with its Current Good Manufacturing Practice (CGMP) regulations. The CGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and

packing of a drug product. The regulations make sure that a product is safe for use, and that it has the ingredients and strength it claims to have.

The approval process for new and generic drug marketing applications includes a review of the manufacturer's compliance with the CGMPs. FDA assessors and investigators determine whether the firm has the necessary facilities, equipment, and ability to manufacture the drug it intends to market.

The webinar highlights the necessity of GMPs. They will know how to maintain the quality through the audits and allow them to maintain homogenous quality throughout the production line.

List of Participants

CENTURION UNIVERSITY OF TECHNOLOGY AND MANAGEMENT, ODISHA

WORKSHOP

ON

GMP & cGMP considerations in Pharmaceutical Industry

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ATTENDANCE SHEET

Sl. No.	Name	Full Signature
1	Dr. A.M. Mohanty	
2	Dr. Dillip Kumar Panigrahi	
3	Dr. Krishanu Ganguly	
4	Dr. Mukundjee Pandey	
5	Dr. Ramesh Ch. Mohanty	
6	Abhisek Sahu	
7	Dr. Amulya RatnaBehera	
8	Dr. Ashirbad Nanda	
9	Ayushi Pradhan	
10	Bikash Ranjan Jena	
11	Biswajit Samantaray	
12	Dr. Chandan Das	

Prof. KVD Prakash
Dean - IIE & HRD

Dr. Prasanta Ku. Mohanty
Dean Academic