EuroSciCon

EuroScicon Conference on

Applied Science, Biofuels & Petroleum Engineering

November 12-13, 2018
Athens, Greece

Int J Appl Sci Res Rev 2018, Volume: 5
DOI: 10.21767/2394-9988-C1-003

GXP/GMP AND ITS CONSEQUENCES FOR DOCUMENTATION AND INFORMATION TECHNOLOGY SYSTEMS

Eleonora Babayants
Galaxy Consulting, USA

Documentation is a critical tool for ensuring GxP/GMP compliance. This is what GMP states about document control: each manufacturer shall establish and maintain procedures to control all documents that are required. In the regulated environment which must be GxP/GMP compliant, document control is the cornerstone of the quality system. It is so important that if an external audit identifies deficiencies in the document control system, the entire organization can be shut down. There are also GMP requirements for information technology. For a drug to be produced in a GxP/GMP compliant manner, some specific information technology practices must be followed. Computer systems involved in the development, manufacture, and sale of regulated product must meet certain requirements. Change control within quality management systems (QMS) and information technology (IT) systems is a formal process used to ensure that changes to a product or system are introduced in a controlled and coordinated manner. In the regulated industries, manufactures are required to use a change control procedure. In this presentation, I will discuss the connection between GxP/GMP and document control. I will describe details of document control procedures and the role of quality assurance in the documentation systems. I will review GMP requirements for information technology and how computer systems including documentation management systems must meet GxP/GMP requirements. I will also review change control procedure and how it should be used in GxP/GMP environment.

eleonora@galaxyconsulting.net