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GMP compliance for inspections, sampling and testing of packaging components in pharmaceuticals

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Good Manufacturing Practices dictates that every packaging material either product contact or non product contact, has to be inspected, sampled and tested to be in compliance with the regulations and to protect the consumer health. The Federal Food, Drug, and Cosmetic Act mandates the need for adequate information related to packaging materials. Section 501(a)(3) of the Act states that a drug is deemed to be adulterated “if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health. Current good manufacturing practice (CGMP) requirements for the control of drug product containers and closures are included in 21 CFR Parts 210 and 211 and reference packaging materials such as bottles, blisters, shippers, resins, caps, liners, ampules, vials, labels etc. Hence, both drug manufacturers and packaging material suppliers are equally responsible for providing assurance on Quality and Integrity of the packaged drug product to consumers.

This session provides a overview of all the criteria and guidelines governing inspecting, sampling and testing of packaging materials for pharmaceutical manufacturers and suppliers

Biography

Sarma R Donepudi is a Scientific and Technical professional with vast experience in cGMP, GDP, GLP, HACCP, IS14001, Quality Assurance, Environmental Research, SOP and Technical writing and Instrumental techniques, applicable to microbial and chemical quality evaluations in Pharmaceutical, Food and Environmental industries. Sarma also has specialized and trained several quality assurance professional on the nuances of packaging component testing, GMP, GCP, GLP, Technical Writing and packaging validation applicable to pharmaceutical, natural health products, cosmetics and medical device industries. Sarma holds two Master degrees in Science for reputed Indian Institute of Technology, India and Post Masters degree from Andhra University, India. He authored around 20 technical publications in the fields of environmental microbiology, chemistry, health and toxicology in journals of repute and serving on the editorial board of South Asian Health Chronicle. He is the president and consultant at SCITECHSOLUTIONS INC., a reputed scientific consulting firm based in Ontario, Canada. Sarma has lectured at several pharmaceutical and food conferences and instructed at private careers colleges in Toronto, Canada.

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