



XAVIER
HEALTH

MedCon 2014 Combinations Product Working Session



Inspiring Collaboration Leading Innovation Making a Difference



Faculty

Thinh Nguyen

John Barlow Weiner

Suzanne O'Shea

Kathleen O'Sullivan

Francis Blacha

Steve Binion



Agenda

Overview of Case Study Process

Case Study 1 – BestDeviceCo PreFill Delivery System

Case Study 2 – Acme Corporation Factor XYZ

Case Study 3 – Acme Corporation Slickiness Product

Session Wrap Up

Audience Q&A

Closing comments from FDA OCP



Case Study 1 – BestDeviceCo Pre-Filled Delivery System

BestDeviceCo manufactures various pre-fillable delivery system components that combine a primary packaging (container closure system) function with injection delivery of drugs or biologics, following final assembly after filling. BestDeviceCo is considering different ways to market its container closure/delivery system and the GMP obligations that apply to participants in each of the scenarios as it works with other manufacturers including Pharmco, PharmDesign, FillerCo, and Drugs-R-US to bring products to market.

Case Study 2 – Acme Corporation Factor XYZ

Acme Corporation is a manufacturer of drug products with an established quality system that is in compliance with the cGMP regulations set forth in 21 CFR Part 210/211. Acme Corp. is planning to launch a new product, Factor XYZ, a protein that needs to be injected for the treatment of chronic fatigue syndrome. The formulation is provided in a prefilled syringe for self-injection by the patient or a care giver. The syringe acts in part as a primary container/closure system. Quality systems to meet specific CGMP requirements for containers and closures per § 211.84 are in place at the facility.

Case Study 3 – Acme Corporation Slickiness product

Acme Corporation is a manufacturer of PMA-approved implantable cardiac pacemakers. These products are intended to produce a periodic electrical pulse to stimulate the heart. The device is a substitute for the heart's intrinsic pacing system to correct intermittent and continuous cardiac rhythm disorders.

A researcher at Acme Corporation has developed a new substance, code named Slickiness, which will not combine with blood, much like oil and water do not combine. The researcher has proposed that if Slickiness is administered to patients intravenously, it will not mix with the patient's blood, but will tend to accumulate along the walls of the patient's blood vessels. The pressure of the patient's blood traveling through the vessels will maintain Slickiness' position along the vessel walls. The lining of Slickiness along the patient's vessels will prevent plaque from attaching to the vessel walls, thus keeping the vessels open for blood flow.

It has been proposed to add delivery device functionality to existing Acme pacemakers, so that the new product will both correct cardiac rhythm disorders and provide a continuous flow of Slickiness to prevent plaque accumulation on vessel walls. The new product would be indicated for patients with both cardiac rhythm disorders and excessive plaque build-up on coronary vessels.



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