

Legal Consequences

Purpose: To learn about the legal consequences of non-compliance with GMPs.

Group Size: Unlimited.

Level of Physical Activity: Low

Props: Attached case studies, or create more of your own.

Instructions: You are to read the attached cases and decide which legal consequence could have been applied to that case.

1. Divide participants into groups of 2-3.
2. Direct participants to read the cases in their book.
3. State that the stories should take about 15 minutes to read.
4. State, after reading the cases, the group is to decide which legal consequences

could have taken place.

5. Ask the group's help to list on a flip chart all the possible legal consequences.

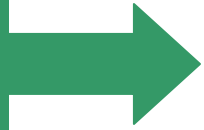
- Warning Letters
- Observation of Violation of cGMPs – 483
- Untitled Letter
- Recall
- Seizure
- Injunction
- Consent Decree
- Criminal Prosecution

6. Direct the class to begin reading the case studies.

7. Announce when 10 minutes have elapsed.

Debrief:

- Using the round robin format, ask each group to share with the class their expected legal consequences.



Note: The correct answer is less important than the class begins to see a connection between actions in a company and the legal consequences.

Case Studies

Alpha Pharmaceutical

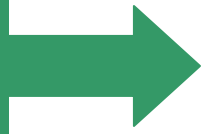
Alpha Pharmaceutical is a contract packaging operation in the Southeast. They do a large volume of their work with mid-size manufacturers who have a need for greater capacity. Alpha Pharmaceutical is very good at quick changeover, and documents its production operations very well. As Alpha Pharmaceutical works for many companies, the FDA visits their manufacturing facilities regularly. The FDA reviews the facility for cGMP compliance for each new client. On two previous general GMP inspections, the FDA made unofficial comments about the casual attitude toward head covers. The FDA commented that in some areas operators had hair sticking out from underneath the head cover.

Beta Pharmaceutical

Beta Pharmaceutical is located in the Southeast.

They are a small vitamin manufacturer. Historically, they operated outside the reach of the FDA because they sold their products to a very small group of acquaintances all within their home state.

When some customers moved out of state, they continued to order vitamins. At that point, the FDA has jurisdiction over an operation. Taking advantage of the opportunity, the FDA conducted a routine cGMP Inspection. During the inspection, it was discovered that their documentation was not in compliance. Specific observations noted were, missing data, pencil data entries, and the use of white out.



Charlie Clinic

Charlie Clinic is an animal health care clinic in the Midwest. The Clinic frequently purchases drug products in bulk and repackages them for farmers. Because most farmers are accustomed to administering drug products to the farm animals, the Clinic did not consistently provide written directions for intended use as is required by cGMP Regulations. The Clinic repackages product without written directions. Upon a routine cGMP inspection, the FDA discovered the lack of directions for intended use. This causes a serious health concern for the animals, specifically, misuse, or under- or over-dosing.

Delta Pharmaceutical Company

Delta Pharmaceutical Company is located in the Midwest. Delta Pharmaceutical Company is a small

manufacturer of an Anti-hemophilic Factor for humans. Several patient complaints cited a specific lot of product produced pyrogenic reactions including chills, fever, and headache. When the firm received the complaints they initiated a thorough investigation, and discovered pyrogenic material in some vials.

Echo Company

Echo Company located in the Southeast. Echo is a small pharmaceutical packaging operation. Echo packaged material in bottles labeled as O-21. O-21 was a birth control tablet. Upon discovery that Echo Company was packaging drug products, the FDA conducted a routine cGMP Inspection of their operation. The FDA discovered that the product being packaged was counterfeit O-21.

Five Corporation

Five Corporation is a small medical gas producer located on the East Coast. Five Corporation's volume is very high. Five Corporation produces only one product. Their product is used in surgery and some dental procedures to "knock out" patients. One lot of product received by a dentist had a carbon dioxide label on the cylinder and an oxygen tag on the valve.

Ghost Inc.

Ghost Inc. is a mid-sized, but continually growing, drug product manufacturer located in the US. Among their many products, they manufacture and package a sterile broad-spectrum antibiotic used to treat infections. This product is sold in large volumes to hospitals and physicians. One lot was packaged with product that had been stored in warehouse conditions

that exceeded the parameters approved for that product. Upon subsequent laboratory testing the data revealed that the product was sub-potent. The result of sub-potency in antibiotic means that the patient's medical condition may not improve quickly, if at all.

Tango Corporation

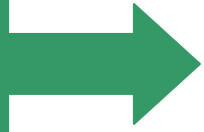
Tango Corporation is a manufacturer of anti-inflammatory drugs located in Spain. Tango uses a compounding center located in the United States for its manufacturing operation. The product of concern was used to treat arthritis. Tango began the distribution of its drug product before receiving an approved New Drug Application from the FDA.

Mango Services

Mango Services is a small sterile diagnostic tissue manufacturer located in the US. Their product volume is very small. After a GMP Inspection by the FDA, significant GMP deficiencies throughout the facility were noted. Of most concern to the FDA was the absence of validation data for the sterilization process.

India Pharmaceutical

India Pharmaceutical is a mid-sized drug manufacturer located in the US. Although they manufacture numerous sterile injectable drug products, their volume is low. Their products were packaged in ready-to-use syringes. Laboratory analysis revealed that some syringes may contain microbiological contamination. The effect of this contamination on patients would have been high



fever, chills, and nausea. Poor gowning and poor sterile room procedures caused this.