

# **GMP Training Systems, Inc.**

*Creators of the GMP Ready-to-Use Training System™*

## **GMP Training: Keep it Fresh by Making it Real**

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GMP regulations require that we conduct GMP training on an ongoing basis. One of the biggest challenges in GMP training is keeping the training FRESH. It's a topic that tends to change with glacial slowness. Keeping the trainees interested can be difficult if you are teaching the same things over and over.

Here's a Tip on keeping your GMP training FRESH. Look for stories in the news. The first half of this year has given us several cases that one can use in your compliance training. Here are some examples you can use now. Details on these cases can be found on FDA's website – [www.FDA.gov](http://www.FDA.gov)

After each case, we've suggested one way it can be used in a GXP training situation.

### **May 2009 – Eat drugs for breakfast?**

FDA issued a Warning Letter to General Mills for making claims on the label for Cheerios® that it lowers cholesterol. FDA says that this claim classifies Cheerios® as a drug.

***GMP Tip** – Discuss label claims and other copy on labels and packaging materials. Discuss what constitutes misbranding.*

### **May 2009 – Bad news travels fast**

A Proctor and Gamble plant in Puerto Rico got a Warning Letter from FDA. Within days, the San Francisco Chronicle published an article about the Warning Letter and included excerpts from the FDA. This news in the major media travels fast and wide and can certainly impact sales of other products and reflect negatively on a company's image and reputation.

***GMP Tip** – Discuss the impact of this Warning Letter on Proctor and Gamble. Discuss whether the cost of prevention would have been lower than the costs of correction.*

### **April 2009 – Salmonella tainted alfalfa sprouts**

The FDA and the Centers for Disease Control and Prevention (CDC) recommended that consumers not eat raw alfalfa sprouts, including sprout blends containing alfalfa sprouts, until further notice because the

product has been linked to *Salmonella* serotype Saintpaul contamination.

**GMP Tip** – *Discuss the criticality of keeping things clean.*

#### **April 2009 – Salmonella tainted pistachios**

Setton Pistachio of Terra Bella, Inc. is recalling all lots of roasted in-shell pistachios and roasted shelled pistachios that were produced from nuts harvested in 2008 and some pistachios from the 2007 crop that were processed on the same equipment as the 2008 crop. The firm also is recalling those raw shelled pistachios from the 2008 crop (and some from the 2007 crop that were also processed on the same equipment as the 2008 crop) that are not subsequently roasted prior to retail sale.

**GMP Tip** – *Discuss the importance of cleanliness and establishing and following Standard Operating Procedures.*

#### **April 2009 – Destroy your inventory**

Under a Consent Decree obtained by FDA, a permanent injunction has barred Neilgen Pharmaceuticals, Inc. and its parent company, Advent Pharmaceuticals, Inc., from manufacturing and distributing any unapproved, adulterated, or misbranded drugs. They are

also ordered to destroy their existing drug supply.

**GMP Tip** – *Discuss the impact of this action on the future of these companies and their employees.*

#### **March 2009 – President Obama speaks out**

“No parent should have to worry that their child is going to get sick from their lunch. Just as no family should have to worry that the medicines they buy will cause them harm. Protecting the safety of our food and drugs is one of the most fundamental responsibilities government has and it is a responsibility that I intend to uphold in the months and years to come. The FDA has been underfunded and understaffed in recent years, leaving the agency with the resources to inspect just 7,000 of our 150,000 food processing plants and warehouses each year. That means roughly 95% of them go uninspected. That is a hazard to public health. It is unacceptable. And it will change.”

**GMP Tip** – *This is the “Writing on the Wall.” The Obama administration’s proposed budget includes a 19% increase for FDA. Expect a bigger and more assertive FDA.*

### **March 2009 – Go to Jail – Go Directly to Jail**

Both the Plant Manager and Director of Quality Control for AM2PAT Inc. were sentenced to 54 months in prison for shipping improperly labeled syringes linked to hundreds of bacterial infections and several deaths. Syringes containing saline and heparin were labeled "sterile" and shipped before any sterility tests were performed. Records were changed to give the impression that the tests were done.

***GMP Tip*** – Use this example to reinforce that FDA's regulations are federal law. Breaking the law can land you in jail.

### **March 2009 – Stop manufacturing and distribution**

The FDA announced that Del Rey Tortilleria Inc., Chicago, Ill., its president, and two general managers have entered into a consent decree of permanent injunction that prevents Del Rey Tortilleria from manufacturing and distributing soft-shell flour tortillas until the company obtains FDA approval.

During FDA inspections, the agency found several violations including cleaning chemicals stored improperly, unsuitable containers used for food processing, and other unsanitary conditions inside the Illinois plant. According to the

complaint, flour tortillas manufactured by Del Rey Tortilleria were associated with several outbreaks of gastrointestinal illness in school children, resulting in a product recall by the company.

***GMP Tip*** – Use this example to reinforce that the health and well being of our customers in the FDA regulated industries is of primary importance and is the reason for the regulations.

### **February 2009 – Systems problems can cause continuing issues**

Cardinal Health 303 Inc. agreed to an amended Consent Decree with FDA to correct violations of cGMP requirements in the company's infusion pumps. In 2007 Cardinal 303 signed a Consent Decree in which they agreed to cease manufacturing, processing, or distributing the Alaris SE line of infusion pumps until the company corrected deviations from the Quality System regulations. Cardinal 303 is still in the process of making these corrections. In FDA inspections since then, FDA investigators found similar QSR deviations relating to another line of Cardinal 303's infusion pumps.

***GMP Tip*** – Many problems are system problems. Treating a problem as an individual or fleeting event may "fix" the immediate issue, but if the system isn't improved and

*optimized, similar problems will continue to occur.*

**February 2009 – Knock Knock. Who’s there? The FBI**

The FBI is “fully involved” in helping the Food and Drug Administration’s inquiry into the Peanut Corp. of America’s Blakely, Ga. plant. The outbreak of salmonella has led to one of the nation’s biggest food recalls

and spurred a spate of lawsuits from victims claiming millions of dollars in damages. Politicians are calling for criminal charges, and the government is working on an investigation.

***GMP Tip*** – *Use this example to demonstrate how things can get out of control if the primary focus is on making profits at the expense of customer safety.*

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