Written by Matt Fiore Sunday, 09 August 2009 00:00

Before I fling immature epithets at the world of alternative medicine, I need to give a brief overview of the regulations imposed on those who make *real* medicine. The medicines that do everything from saving lives to preventing gas. In America, these regulations are known as "Current Good Manufacturing Practices", or cGMPs for short. The best way to illustrate the thoroughness and complexity of these regulations is to use a narrative. The narrative won't even scratch the surface, but it will give you a general idea:

Let's say a company wants to make a new drug. What are some of the things it must it do? For one, it must develop scientific tests that prove the finished product is free of contamination, identify the ingredients, and that confirm the amount of drug present in each pill. The tests must also prove the testing equipment is clean, the chemist's prep work is accurate, and the equipment is working consistently as each sample is run. The company must also develop a method to track the product as it degrades over time. This "stability study" must identify and quantify all new chemicals that are formed as the product ages. (It is also used to show that the active ingredient has not dropped too far below the amount claimed on the label. If it does, the company is in danger of false advertising.) The degradation products must be proven safe for consumption as well. Every batch of drug that goes out the door will be checked using these methods. A portion of every batch is kept in the warehouse and is periodically monitored for purity and safety.

When the manufacturer finally gets down to the business of manufacturing, it builds a plant according to strict health, safety, and environmental regulations and orders the raw chemical materials from a distributor. These materials are also tested for purity, identity, and freshness. Every piece of equipment in the plant must be cleaned, inspected, and calibrated on a regular basis. As the drug is being created, a sample of the mixture is sent to the lab to ensure the everything is going according to plan. The finished product may not be legally shipped until it is approved by a trained team of professional biologists and chemists. Rejection by the nerds usually means the destruction of the batch and the loss of thousands of dollars. Every step is recorded and checked by at least one supervisor.

The data from the chemical tests are usually sent directly to computer systems that timestamp and permanently save every single test so ugly results cannot be ignored. The mathematical equations that are hardwired into the system are checked for accuracy before manufacture even begins. In spite of this, the final results are confirmed with hand calculations after every test just to be sure.

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As you can imagine, cGMPs result in a stack of paperwork that is several inches thick. Sadly, some unfortunate men and women are assigned the task of rechecking it all one last time. Every typo and minor error must be explained in writing by the perpetrator and corrected using specific rules to avoid confusion or fraud. Major errors or failed tests result in a long and torturous investigation that can invalidate everything that has been done up to this point and can restart the entire process from square one.

It is important to understand cGMP for two reasons. First, people need to appreciate how much effort goes into drug development and drug safety. (cGMP regulations even apply to common drugs like aspirin!) Second, I want homeopathy to stand in stark contrast to *real* science.

Two weeks ago, I started a new job at a fairly large pharmaceutical company. This is my third chemist position since getting my BS in chemistry so am quite familiar with cGMPs However, the FDA requires that I relearn everything from scratch and document my training as it progresses. As part of my retraining, I had to read a pair of testing techniques from a reference book called the European Pharmacopoeia, a compendium of official lab tests. Pharmacopeias are written by experts for experts and are supposed to be the gold standard for proper laboratory procedure. While looking for the index, I accidentally stumbled across a chapter entitled "Methods of Preparation of Homeopathic Stocks and Potentisation".

As skeptics know, homeopathy is a quack art that involves two steps: First, you prepare a "mother tincture" solution which may or may not have medicinal value. Second, you dilute the tincture over and over and over again. By the time the homeopath is done, not even a single molecule of the active ingredient remains. I was stunned to find this subject in a reference book of such high renown. It is akin to finding a chapter on voodoo in the latest edition of *Gray's Anatomy* 

is not just bad chemistry, it is chemistry's evil, worthless, ignorant, bastard twin with a funny comb over.

A quick scan of the chapter revealed several recipes for mother tinctures, all written in accurate scientific language. Some even included valid scientific tests that one could use to prove the mother tinctures were prepared correctly. Unsurprisingly, the chapter does not suggest performing the same tests *after* the dilution is complete.

Buried amongst scientific language, I found this description of the dilution process:

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1 part of the stock plus 99 parts of the vehicle; they may be designated as 'C' or 'CH' (centesimal)

The number of potentisation steps defines the degree of dilution; for example, 'C3', '3 CH', or '3C' means 3 centesimal potentisation

It concludes by saying that if greater dilutions are desired, one need only repeat the process. Nowhere does it mention that the most popular homeopathic dilution is 30C. Like Alfred Hitchcock, the editors of the *European Pharmacopoeia* pan the camera away just before the true horror begins. 30C is

the strength of the original mother tincture.

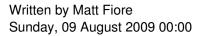
Even more disturbing, I found this definition:

for the purpose of dosage forms for homeopathic use, 'active substances' are considered to be 'dilutions...of homeopathic stocks"

In other words, the *European Pharmacopoeia* has decided to change the definition of "active substance" to "dilution of an active substance" just so homeopaths could worm their way past the protocols that prevent drug companies from ripping off the consumer. Thanks to this implicit endorsement from an official source, homeopaths can get away with fraud that would literally bankrupt "evil" pharmaceutical giants like Johnson & Johnson or Merck.

I encourage all of my European friends to contact the editors and authors, the <u>EDQM</u>, and give them a severe and logical verbal beating.

I'll close with a philosophical homeopathy quote from the *European Pharmacopoeia*:



the test for uniformity of content is normally not appropriate

How Zen. Let us all ponder the uniformity of nothingness.

Matt Fiore is a chemist and law student living in Philadelphia, PA.