



P.E.P. Aseptic

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Quality Assurance

How do you ensure the quality of your preparations if you cannot test every one that you make? This same question has confronted many manufacturers in the past, as history gives us the story of a general just before World War II. On visiting an ammunition plant, he asked the plant manager, "How do I know that a bullet is good?" The manager replied quite seriously, "You shoot it!" The general retorted, "If you shoot it, you then don't have the bullet, and you can't shoot every bullet to make sure that they are all of the highest quality."

I think many compounding pharmacists can identify with that WWII general, and are similarly perplexed as to what to do when considering quality control testing of their preparations.

Fortunately for us, the general found an answer to his question. Simply stated, he validated the process and procedures to make the bullet and then he chose a sampling plan to check a random number of the bullets to make sure that the process was still working as required. It seems to me, that as compounding pharmacists, we should adopt this same methodology to ensure that the preparations we provide have the highest quality. We need to:

1. View our pharmacy in light of the processes we use to make compounded preparations. We have processes for:
 - a. capsules
 - b. topical creams
 - c. troches
 - d. sterile preparations, etc.

2. Clearly document, via Standard Operating Procedures (SOPs), the process in its most general manner.
3. Adapt the SOP to a specific compounded preparation that is representative of the process. For example: a BiEst capsule for capsule making, or testosterone in PCCA Lipoderm[®] for a topical cream.
4. Test that preparation to validate that your process is correct. You now have tested not only that specific preparation, but you have shown that your process is valid.
5. Pick an interval for a repeat of the test. Our skip-lot testing protocol is an excellent model for this exercise (see *IJPC* Vol. 10 No. 4 July/August 2006).

The utility of this "Process Validation" model for quality assurance allows you to decide the level at which you want to define your processes. For example, if you make capsules using several distinct processes, validate and skip-lot test each of them. The methodology also works for both sterile and non-sterile compounding.

Finally and most importantly, test your preparations for quality. Only by testing can we validate the processes that we use to prepare compounded medications and silence our detractors.

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