

Five Things You Need to Know about the GMPs

By Michael Tousey and Carol Brennon

1. If it isn't written down, it didn't happen.

There's an old saying in many regulatory and quality departments: "If it isn't written down, it didn't happen." That is because during an FDA inspection, companies must be able to demonstrate GMP compliance. One of the most critical ways this is accomplished is by providing written proof that your company actually does what the regulations and your procedures say. Make sure all cleaning, training, and procedural activities are documented properly.

2. Many pest-control programs are inadequate.

Your company has a pest-control program—but will it stand up to scrutiny? This is one of the areas many companies receive an inspection observation for, and the reason is that their programs are inadequate. A comprehensive pest-control program carried out by a qualified pest-control company, documented completely and accurately, is the way to go. This is not an area to try to save money by delegating it to the company janitor or hiring a nonprofessional company. Get your pest control program in good order.

3. Your employees must be trained and qualified.

GMPs require that all employees be trained and qualified to perform their duties. So, how will your employees stack up when their training records are examined during an FDA inspection? Your employees must be trained for each task they perform. Who trains them? Who qualifies that the training was effective and the employees are now trained and ready to perform their duties? How is the trainer qualified? Yes, these are all questions you may be asked during an inspection. Be ready to answer them and provide procedures for how these activities are performed and documented. Don't stop there! Focus on the quality of your employees, too. Build pride into your process and allow the operators to grow along with quality and productivity.

4. Written procedures should match what your employees and processes do.

For many companies, it would be easy to make the statement that if they only did what was written in the standard operating procedures (SOPs), the process would not be successful. How many times do your operators say their SOPs don't work? Once is too many! Procedures must match what is being done or there is a problem, not just from the FDA investigator's perspective, but because your company is not functioning optimally. Your procedures and processes must accurately reflect actual practices, while adhering to regulatory requirements.

5. Audits are not just for accountants and the IRS.

If there is one message to deliver, it is that we are all part of the quality team, all of the time. Did you know that FDA requires companies to conduct self audits? It is important that your company has an internal audit program to determine your compliance to regulatory requirements, as well as adherence to your own company specifications and procedures. This does not mean you must create a new department in your company, though. You may use the service of an auditing company—just



All cleaning, training, and procedural activities should be documented as a means of demonstrating compliance with the GMPs. Photo courtesy of Bergstrom Nutrition.

make sure that you have carefully created your audit policies that state the expectations of your audit program.

With the requirements of the new dietary supplement GMP ruling, companies are being motivated to take action now. The first step is to complete a GAP assessment audit. A GAP assessment determines where your company is now and where it needs to be. Step two is to create and execute a plan for compliance. The final step is being active and prepared for an FDA inspection. You do not have to do this by yourself with your own staff; you can hire outside help.

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