

## **Good Manufacturing Practices for All Sizes**

No matter what size your company is, complying with the Cosmetic Good Manufacturing Practice Guidelines can be a daunting experience. Hopefully, with some helpful hints from someone who has gone from a small home business to a growing manufacturing facility, you will be inspired to go the extra mile to get into compliance with the FDA's guidelines. Change is often resisted, but if you really intend on making your company grow, now is the time to put in the extra effort. I am going to focus mainly on Quality Control measures that can bring your company from kitchen chemists to name brand. The entire list of measures can be found at <http://www.cfsan.fda.gov/~dms/cos-gmp.html>.

### **Incoming QC**

The Quality Control of your incoming ingredients and products is one of the most critical steps to making your company profitable. There are dozens of reasons that you should QC check everything coming in. You could easily have made a mistake when you placed your order, the company you order from could have made a mistake, or the ingredient might have a natural variation, and natural ingredients can easily have something go wrong with them and you want to catch it when the ingredient arrives. For instance, I know of a company that orders large quantities of the dried herb calendula. They received their order but did not need it right away so they did not open it. A few weeks later they opened the container and the calendula was crawling with bugs. Because they did not QC check it upon arrival, the company that sold them the ingredient would not refund or reship the ingredient because there was no evidence as to whether it happened from the point of shipment or after it was received.

Incoming documentation can save your company from disasters down the road. In order to properly QC incoming ingredients you should keep an Incoming QC Log. In it you should include: name of the ingredient, supplier, order date, received date, received by, QC checked by, approved or rejected, lot number from supplier and/or lot number you assign it, description of the appearance, texture and smell. You should detail any variation. For instance sometimes Grapeseed Oil comes in slightly green and other times it is bright green. You should write this down so that if your finished product turns out to have a change in color you will know what caused the variation. You can print bright colored stickers on your computer in order to put a QC Label onto every bottle, box or drum of ingredient. Also, a small sample of every incoming ingredient or finished product should be taken and labeled. That sample should be held in your facility for at least three years. It can be used if there is a problem down the road to isolate the issue or as a standard to check for your next order.

### **Standardize Formulations**

When I cook at my house every meal is slightly different because I don't use recipes. I just add a dash of this and a splash of whatever I have around the house. That works for cooking food but should never be the method you use to formulate your products. You want your product to be duplicable, so that it is consistent every time. You also want the ability to have your employees confidently making the products. Always think ahead to when you need to use a private label manufacturer to make and fill your products. A standardized formula is required in order to correctly label your product in descending order. Your formula should include the methodology used, which are simply the steps and procedures used in detail.

In order to standardize your formula you need to choose the method you are going to use for measurements. Either everything needs to be measured by volume or weight. You can't use the scale for some ingredients and a tablespoon for others. How can you accurately label your products if they are not all using the same standard of measurement? A conversion table can be found at [http://www.essentialwholesale.com/Weights\\_and\\_Measurements.pdf](http://www.essentialwholesale.com/Weights_and_Measurements.pdf)

### **Lot Logs and Lot Batch Samples**

I hate paperwork as much or more than the next person. But detailed logs are absolutely required if you are going to be in this business. A Lot Log should include: the date the product is made, date it's packaged, who made the product, who QC checked the product (not the one who made it), who packaged the product, what it was packaged into (all sizes), who pulled the Lot Batch Sample, and of course the name of the product and batch size. The ideal situation would be if you printed a copy of each formula when it was made and also detailed the Lot Number of the ingredients that were used. You must always pull a small sample of the product. It should be labeled and stored for at least three years.

### **Cleanliness is Vital**

Not only does your work space need to be spotless, but the equipment that you use must be sanitized at all times. A full list of the guidelines can be found online at the FDA site <http://www.cfsan.fda.gov/~dms/cos-gmp.html>. I don't know if you are working out of your kitchen, garage, a separate work space or a full fledged FDA registered facility. But you should take as many of the guidelines as you can and put them into place. Most importantly you must have clean walls, floors, and ceilings that are smooth and can be kept easily clean. You must be certain that nothing can drip from your ceiling, duct work or cabinets into your products or cleaned utensils and equipment. Your area must be well lit and ventilated. All of the utensils and equipment should be stainless steel or the appropriate design. They must be able to be completely sanitized between each use. For instance you should use a stainless steel spoon and not a wooden or rubber spatula, because the latter cannot be thoroughly sanitized between uses. Your utensils and equipment should be cleaned after and before every use. It is important that you clean everything with alcohol right before you use it, even if you think it is clean.

You and all of your employees should wear hairnets, gloves and coverings like lab coats at all times when you are in contact with supplies, equipment, finished goods or packaging. Food and drink should not be consumed anywhere near your manufacturing area.

Raw materials, packaging, finished good and bulk bases should be stored and handled carefully. You must have everything clearly labeled with the name of the product and the lot number. All containers should be tightly closed at all times. All containers should not be stored directly on the floor. You should make certain that you are storing your ingredients and products in an area that does not expose them to excessive heat or cold, sunlight or moisture. A product improperly stored will cause it to age prematurely, oxidize and go bad too quickly.

### **Standard Operating Procedures aka SOP's**

Don't run and hide from this one. It sounds more frightening than it is. If you create SOP's now you will save yourself an abundance of time and headaches in the long run. SOP's simply put into writing, with great detail, all of the steps of every and any given job within your company. The most important ones to start with have to do with the manufacturing of your products. Simply write down step by itty bitty step what you do in sequential order. This will

save you hours and hours of training and insure that your employees are doing everything exactly like you expect it to do be done. The SOP for manufacturing should include written instructions for: formulation, cleaning and sanitizing, what should be worn, QC checked ingredients, accuracy of measuring, samples taken, logs maintained, heating, cooling, mixing, transferring, filling procedures and any tests done on the product. Spending time on this now, before you grow any more, is well worth the effort. As you grow and expand, continuously add more SOP's.

### **Labeling**

All of your finished goods must be appropriately labeled. It must list the name of the product, and accurate standard and metric measurements. The statement "Warning--The safety of this product has not been determined" if the product has not been tested for stability and safety, must be shown. Your label must also include the name and address of your company, not just website or email address and directions for the safe use of the product. Most importantly it must not make any claims that would cause it to be considered an OTC drug. Do not make the mistake of making your product appear to be an Over the Counter Drug without clinical trials, as this can lead to costly fines. You cannot claim SPF value, healing properties or anything that alters the skin or health. It is absolutely critical that all labels comply with the FDA regulations. All ingredient lists should be in descending order and using INCI names. That means if you use ingredients that are known by their trade names, then you are required to list them out. For example, the preservative Phenonip, whose INCI name is: phenoxyethanol, methylparaben, butylparaben, ethylparaben and propylparaben. Listing Phenonip alone would be inaccurate.

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