Clinic Profiles: GMPs in the Clinical Setting

Joanna Helms, RH (AHG), a 6th generation Floridian, has been in clinical herbal practice for 15 years, and is the founder of Mama Jo's Sunshine Herbals in Indian Harbour Beach. Joanna has authored and teaches a Fundamentals of Herbalism course annually, and presents workshops and lectures throughout east central Florida. She is also a co-founder of the Herbal Wisdom Society, a local herb club. In her spare time, Joanna enjoys gardening, being in nature, and is an advocate for the native flora of Florida.

Mama Jo's Sunshine Herbals, Indian Harbour Beach, Florida

We exist in a 2200 square foot facility in a beachside community on the East Coast of Florida. Mama Jo's is a unique, family run medicinal herb retail store, a clinical practice, a professional/community dispensary, and an education center. We offer a variety of bulk herbs, essential oils, hand-made products and custom formulation

What kind and how many different herbal products do you make?

We make over 200 herbal products for sale in our retail area, as well as hundreds of other products for use in our clinical practice only. Our herbal product creations consist of a variety of choices for the retail customers: capsules, herbal tea blends, tinctures/extracts, salves, syrups, reductions, oil infusions, culinary blends, pickled garlic, soaps, lotions, toners, serums, herbal bush baths, bath salt soaks, aromatherapy sprays, an animal line of herbal products, as well as an expectant mother and baby line of herbal support products. The clinical practice products encompass herbs in an individualized form: single

Mama Jo's crew in the apothecary

tinctures, powders, concentrate powders, and bulk herbs. This allows freedom to create specific formulas for clients in any desired or preferred form. Additionally, we offer specialty products for "clinical practice only": herbal pessaries, syrups, suppositories, and roughly 50 different tinctures blends & 100 individual tinctures.

Do you market and label these products as "Dietary Supplements"?

At the store, in class, and in clinical practice, I refer to vitamins as dietary supplements. I prefer to call herbal products by their traditional terms: capsule, tea, tincture, powder, salve, etc., I explain that I am an herbalist that uses herbs in a whole form. The products are made according to our historical tradition; therefore, we choose to call them herbal products, not supplements.

Do you include health claims on your products?

Absolutely not! Our clients and customers are educated on the use of our products either by consultation, conversation, or classes.

Do you maintain claim substantiation files for your products?

No, as stated above, we utilize traditional Materia Medica of herb usage or consumption. We provide a list of valuable resources for individuals to educate themselves. We also share valuable book titles and authors for a basic home library. We support being an active advocate of personal health.

Do you sell finished products to customers/clients directly?

Yes, we sell completed products to customers and clients directly.

Do you conduct a personal consultation before selling every product to a customer/client?

We sell our handmade products from the retail store area directly to our customers without a consultation. Custom formulas are for clinical practice clients and are created only after a private consultation. We also offer several products for private practice clients that are not available through retail.

How are custom blends labeled?

Custom blend labels indicate the herbs contained in the formula, the client name, date made, an expiration date (if necessary) and the name, address, and phone number of the business.

What steps have you taken in terms of addressing GMP (Good Manufacturing Practice) requirements for the products you manufacture?

We have created a GMP document that addresses and conforms to all required regulatory statutes. We have a complete BPR (Batch Production Record) Master Manufacturing Manual that coincides with our GMP booklet and have established a working system for GMP compliance.

Do you conduct GMP assessments of finished products, such as bulk herbs and tinctures that you use when custom blending?

We utilize organoleptics for testing and microscopy when

Joanna in the dispensary

needed. We keep samples of all products made for two years, with the documentation needed for trace ability.

What methods do you utilize to identify the bulk herbs you sell and make products from?
Organoleptic (Appearances: plant form, color, odor, flavor, and extraneous matter found) and microscopy procedures are used. If wild crafting, a botanical press of the herb is saved with the sample.

Did you write SOP's (Standard Operating Procedures)? If yes, for what procedures?
Yes, we have SOP's as a part of our GMPs. They define procedures for manufacturing operations, holding area and distribution, and product complaints. We originated other SOP's for the Master Manufacturing Manual: tea blending, grinding powders, tincture making / straining and salve making. We are in the process of writing a SOP manual to complement our entire GMP manual and additional booklets.

What guidance did you have and find most useful?
Faith fueled the passion to actively pursue any information available to better understand the possible regulation heading the herbalists' way. Roy Upton has been a true asset for all herbalists facing GMP compliance and I am grateful for his drive to bring forth true data for the survival of herbalism in health care. The AHG provides the platform for us to learn and share such valuable data with our community; I found AHG members and friends as a valuable resource, Thank you! I discovered that the support from my family, friends and colleagues, provided the foundation to grow and move through this process with grace.

What was the easiest GMP type practice for you to incorporate?
Once I surrendered and went within, it was clear. Our existing process at Mama Jo's made the GMP transition smooth. We needed to create clear, concise data from our grounded history. Organoleptics is the most fun; I love tasting, smelling, observing, and personally interacting with the plants. I have utilized organoleptics for 15 years. I feel blessed to have the procedure as part of my original training.

What was the most difficult GMP type of practice for you to incorporate?
The most challenging aspect of the GMP process was the QC (Quality Control) responsibilities during the initial implementation of GMP procedures. It took patience to observe the life force of the GMP; yet, revisions allowed flexibility, and six months later we all adapted successfully.

Are there any GMP requirements you felt were important but impossible to do as a small business?
There are many requirements that do not compute well from a large-scale, big business manufacturer, to a small-scale community manufacturer. We refer to this as the scalability factor and wrote our manual accordingly. We believe all requirements are met without any compromise of quality.

Have you been inspected? If yes, by whom and what were the results of that inspection?
We have annual inspections by the Florida Department

Mama Jo's dispensary

of Agriculture and Consumer Services Division of Food Safety. They have conducted inspections for the past 12 years. Mama Jo's completed all GMP documentation by June 2010. The FDA-trained, Florida State Agricultural Department head, came to our store December 2010. He arrived with our County inspector; their dual inspection lasted four hours on-site. The inspection was thorough, and covered every aspect of our GMP manual. Overall the inspection went well. We passed with an unexpected compliment from the FDA-trained inspector. He stated that he had not come across a system like ours in the state of Florida, and he felt we are ahead of the regulation by 3-5 years. A slight sigh of relief, although our next project is improving labeling. He commented on the labels being a main focus in the next few years.

Can you estimate the increased cost of doing business because of GMP compliance requirements?
The process of compiling the documentation has been costly. It takes double the amount of labor to make products, additional hours for QC inspections, and additional equipment was purchased (commercial grade); as well as the space needed for designated processing increased the cost of general overhead by a third. Currently it is difficult to give an estimated cost. I will have a better idea after a full year, but the overall cost was extensive.

Bastyr University Dispensary Kenmore, Washington

What kind and how many different herbal products do you make?
Bastyr Dispensary is the Dispensary for the Bastyr Center for Natural Health, the teaching clinic of Bastyr University. Our primary purpose is to provide nutritional and botanical medicines for patients of our Clinical Faculty and their student interns. We carry a large inventory of vitamin and herbal supplements from outside vendors. Before a vendor's product/s can be brought into our inventory, we ask them to complete our Quality Assurance Questionnaire and to provide us with certain documents, such as examples of Certificates of Analysis and Standard Operating Procedures. The vendor is then reviewed by the University's Formulary Review Committee, whose members then decide whether the vendor meets our standards.
We compound liquid herbal tinctures, teas, creams, and flower essences per physician prescription. These compounded products are unique to the individual for whom they are prescribed.

Do you market and label these products as "dietary supplements"?
Vitamin and herbal supplements may have a prescription label applied if they were prescribed by a provider licensed by Washington State. Many of the same items may be purchased without a prescription label simply as 'dietary supplements' in our retail section. Compounded products are considered prescription products and are not sold as dietary supplements.

Do you include health claims on your product labels?
We do not. We include pertinent prescription information regarding compounded ingredients, how to take, refills, prescribing physician name, etc.

Do you maintain claims substantiation files for your products?
We do not. We maintain record of prescriptions as per Washington State Law.

Do you sell finished products to customers/patients directly?
We sell sealed products purchased from vendors directly to customers/patients. We sell compounded products directly to patients as per prescription protocol.

Do you do a personal consultation before selling every product to a customer/patient?
We do not counsel customer/patient either on sealed products or on compounded products. We respect that any such conversation is solely between physician and patient.

Do you custom formulations for customers/patients?
Our compounded products would fall under the phrase 'custom formulations.' We compound products according to physician instructions for individual patients.

How are custom blends labeled?
Any compounded product will have the following information: Bastyr Dispensary contact information, patient name, current date, type of compounded product (cream, tea, etc), actual ingredient ratio/recipe, treatment instructions, refill number(s), physician issuing prescription, dispensary staff initials.

What steps have you taken in terms of addressing GMP issues for the products you manufacture?
We no longer break any seal of a product to dispense smaller amounts as in bulk dispensing. We carry sealed product to ensure customer safety and product viability (ie. acidophilus capsules). We no longer blend our own Bastyr University teas for bulk dispensing. We have Western Herbs in Index, WA, blend our bulk teas, using our proprietary ratios. This again ensures product consistency and a higher degree of safety in production.

Do you conduct any GMP assessment of any of the finished products you use, such as bulk herbs and tinctures that you may use when custom-blending?
Not applicable. The practitioner selects compound ingredients and ultimately determines the efficacy of the prescription for the patient.

What methods do you utilize to identify the bulk herbs you sell and make product from?
We collect Certificates of Analysis. We also log all bulk products upon initial use with date, lot number, vendor, and staff initials.

Did you write SOP's? If yes, for what procedures?
Yes. We wrote and continue to update SOP's for all compounding practices. These are used for staff consistency, for staff review, and for staff and student training.

What guidance did you have and find most useful?
None for writing SOP's, aside from common sense and the goal of safe compounding methodology.

What was the easiest GMP type practice for you to incorporate?
Paper trail recordkeeping to log new lots for compounded product ingredients.

What was the most difficult GMP type practice for you to incorporate?
Searching dispensary database for a specific product should there be a recall issue.

Are there any GMP requirements you felt were important but impossible to do as a small business?
Testing each unique compounded prescription.

Have you been inspected? If yes, by whom and what were the results of that inspection?
No. Bastyr Dispensary was visited by a FDA agent in 2003. They purchased the nutritional supplement Niacinol by Tyler from our retail section. They shared they would be testing ingredient accuracy, etc.