

# SETTING UP YOUR GRANULES PHARMACY



A step-by-step  
guide to success  
in practice

# INTRODUCTION

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The transition from being an acupuncture student to being a professional acupuncturist means learning to do many things for yourself on a smaller scale and from a different perspective. While prescribing herbal medicine is a key part of any professional training program, the back-end management of inventory, quality control, pricing, and dispensing may not have been an explicit part of your education.

This workbook is the first in a series designed to set you up for success in managing your pharmacy, helping you maximize your efficiency and productivity within your space and budget.

Follow this step-by-step guide [and watch our companion video(s)] with useful tips, links to templates, and recommendations built from the real experience of new entrepreneurs.

The workbook is designed to be viewed digitally, with hyperlinks to templates of key resources. Or you can print it off and fill it in with pen and ink. We encourage you to use this guide in a way that works best for you.

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# 1 step

## MAKE YOUR BUSINESS PLAN

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Having a clear plan from the start is the best way to be successful as an entrepreneur. Most acupuncturists and Chinese herbalists are sole proprietors, so designing your medicinal operation to grow alongside your practice is the best way to avoid unnecessary expenses, product loss, or liability concerns.

**Let's get started by answering a few questions.**



[Access an online document to record your choices.](#)

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What patient demographic(s) do you want to serve?

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In what conditions do you want to specialize?

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What types of herbal products will best serve the needs of those patients?

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What base formulas typically treat conditions of that type?

## Planning Your Inventory

Based on utilization of OCOM's medicinary, here is a list of our 50 most frequently prescribed single herbs and formulas.

**Check all the single HERBS that you listed in the table above.**



**[Access an online form to record your choices.](#)**

- |   |  |  |  |
|---|--|--|--|
| <input type="radio"/> 1. Bai Shao             | <input type="radio"/> 14. Huang Qin        | <input type="radio"/> 27. Xiang Fu     | <input type="radio"/> 40. Ju Hua       |
| <input type="radio"/> 2. Fu Ling              | <input type="radio"/> 15. Huang Qi         | <input type="radio"/> 28. Zhi Mu       | <input type="radio"/> 41. Bai Zhu      |
| <input type="radio"/> 3. Gui Zhi              | <input type="radio"/> 16. Ze Xie           | <input type="radio"/> 29. Chi Shao     | <input type="radio"/> 42. Jie Geng     |
| <input type="radio"/> 4. Mu Dan Pi            | <input type="radio"/> 17. Tao Ren          | <input type="radio"/> 30. Huang Bai    | <input type="radio"/> 43. Rou Gui      |
| <input type="radio"/> 5. Dang Gui             | <input type="radio"/> 18. Chuan Xiong      | <input type="radio"/> 31. Zhi Shi      | <input type="radio"/> 44. Zhi Ke       |
| <input type="radio"/> 6. Da Zao               | <input type="radio"/> 19. Chen Pi          | <input type="radio"/> 32. Dan Shen     | <input type="radio"/> 45. Bai He       |
| <input type="radio"/> 7. Chai Hu              | <input type="radio"/> 20. Dang Shen        | <input type="radio"/> 33. Fang Feng    | <input type="radio"/> 46. Bo He        |
| <input type="radio"/> 8. Fu Zi (pure steamed) | <input type="radio"/> 21. Bai Zhu          | <input type="radio"/> 34. Gou Qi Zi    | <input type="radio"/> 47. Cang Zhu     |
| <input type="radio"/> 9. Bai Shao (Chao)      | <input type="radio"/> 22. Da Huang (shu)   | <input type="radio"/> 35. Hou Po       | <input type="radio"/> 48. Ge Gen       |
| <input type="radio"/> 10. Zhi Gan Cao         | <input type="radio"/> 23. Sheng Di         | <input type="radio"/> 36. Mai Men Dong | <input type="radio"/> 49. Hong Hua     |
| <input type="radio"/> 11. Ban Xia (Jiang)     | <input type="radio"/> 24. Shu Di           | <input type="radio"/> 37. Suan Zao Ren | <input type="radio"/> 50. Mu Li (Duan) |
| <input type="radio"/> 12. Fu Shen             | <input type="radio"/> 25. Shan Yao         | <input type="radio"/> 38. Du Zhong     |  |
| <input type="radio"/> 13. Gan Cao             | <input type="radio"/> 26. Ren Shen (White) | <input type="radio"/> 39. Huai Niu Xi  |  |

**Check the FORMULAS that you listed in the table above.**



**[Access an online form to record your choices.](#)**

- |  |  |
|--|--|
| <input type="radio"/> 1. Chai Hu Shu Gan San   | <input type="radio"/> 16. Bai Hu Tang                      |
| <input type="radio"/> 2. Dang Gue Bu Xue Tang  | <input type="radio"/> 17. Ban Xia Bai Zhu Tian Ma Tang     |
| <input type="radio"/> 3. Er Chen Tang          | <input type="radio"/> 18. Ban Xia Xie Xin Tang             |
| <input type="radio"/> 4. Er Miao San           | <input type="radio"/> 19. Bu Yang Huan Wu Tang             |
| <input type="radio"/> 5. Gan Mai Da Zao Tang   | <input type="radio"/> 20. Cang Er Zi San                   |
| <input type="radio"/> 6. Gui Zhi Tang          | <input type="radio"/> 21. Chuan Xiong Cha Tiao San         |
| <input type="radio"/> 7. Ling Gui Zhu Gan Tang | <input type="radio"/> 22. Ge Gen Huang Lian Juang Qin Tang |
| <input type="radio"/> 8. Si Jun Zi Tang        | <input type="radio"/> 23. Gui Pi Tang                      |
| <input type="radio"/> 9. Si Ni San             | <input type="radio"/> 24. Huang Lian Jie Du Tang           |
| <input type="radio"/> 10. Si Wu Tang           | <input type="radio"/> 25. Jing Gui Shen Qi Wan             |
| <input type="radio"/> 11. Suan Zao Ren Tang    | <input type="radio"/> 26. Li Zhong Wan                     |
| <input type="radio"/> 12. Xiao Jian Zhong Tang | <input type="radio"/> 27. Liu Wei Di Huang Wan             |
| <input type="radio"/> 13. Xiao Yao San         | <input type="radio"/> 28. Sheng Mai San                    |
| <input type="radio"/> 14. Xue Fu Zhu Yu Tang   | <input type="radio"/> 29. Yu Nu Juan                       |
| <input type="radio"/> 15. Yu Ping Feng San     |  |

# DETERMINE YOUR START-UP COSTS

Once you have determined the types of patients you would like to serve, areas of specialization, and the types of common formulas that would serve them well, it's time to start thinking about the start-up costs involved in building your perfect herbal pharmacy.

Start-up costs include not only the cost of inventory, but all of the equipment required to compound, dispense, and label your inventory. See below for a sample of how to determine your pharmacy's start-up costs.



A digital version is [linked here](#), which you can copy and edit.

*To determine costs for formulas, build a table including:*

<b>Formula Name</b>	<b>Quantity</b>	<b>Cost</b>	<b>Total Cost</b>
Hint! Consider your list of formulas above, or grouping initial purchases by areas of clinical focus such as women's health.	Hint! For frequently prescribed formulas, consider buying in larger bottles for price breaks.	This is your cost, not the cost to the customer.	

*To determine costs for single herbs, build a table including:*

<b>Single Herb Name</b>	<b>Quantity</b>	<b>Cost</b>	<b>Total Cost</b>
Hint! Consider your list of herbs above, and which herbs you like to modify with, based on a focus such as women's health.	Hint! If buying many formulas, only buy the singles that allow you to make key modifications.	This is your cost, not the cost to the customer.	

*To determine costs for equipment, build a table including:*

<b>Equipment</b>	<b>Quantity</b>	<b>Cost</b>	<b>Total Cost</b>
Hint! This should include fixed costs (e.g. printer, scales), as well as rotating inventory such as spoons and bags for dispensing.	Buy what you need to begin and replenish based on actual dispensing volume.	Include these costs in your mark-up for formulas.	

## Setting Your Prices

There are a number of factors that influence the retail cost of a prescription. In retail, the industry standard is that the wholesale costs should never exceed more than 30 percent of your retail price.

As a formula, this means that your retail cost = cost of materials/.30

If the granule prescription of 100 grams of Gui Pi Tang costs \$16.60, then the retail price should be \$55.30. However this mark-up does not reflect an absolute 70 percent profit. You also have to consider fixed and labor costs.

You should consider fixed costs and labor when determining how to charge for an herbal prescription or any hand-made product for sale in your practice. Examples of fixed costs are your space rental, utilities costs, and premises insurance. To determine fixed costs:

Total fixed monthly costs/operating hours per month = cost per hour

Finally, you need to make sure you value your labor in compounding the formulas! The value of your personal labor should include consideration of the cost of your education (and its repayment), market rates for reimbursement and treatment costs, malpractice insurance, and continuing education.



**A digital version of the formulas and considerations is [linked here](#), which you can copy and edit to reflect your personal practice.**



## CREATE SYSTEMS

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### Identifying a Quality Source for Your Products

When identifying the right supplier for you, there are a few key considerations. Many vendors may sell the same products, but are regional distributors, so first identify who serves your local area. You may need to identify multiple suppliers to fulfill your herbal, equipment, and acupuncture needs.

When contacting a potential supplier for the first time, questions you should be sure to ask include:

- What products do you sell?
- Where are the herbs sourced?
- Where are the herbs manufactured?
- What quality assurance programs does the supplier have in place?
- Can the supplier provide certificates of analysis (COA)?
- What type of sourcing methodology does the supplier have in place?



[Click here](#) for a comprehensive list of questions you'll want to ask of potential suppliers.

### Establishing Good Compounding Practices

An herbal pharmacy is subject to [FDA](#) and [OSHA](#) regulations, which should all be taken into account when setting up policies and procedures in your clinic. It should follow “Good manufacturing practices,” a set of guidelines that requires herbal supplement labels to include all information required by state and federal law, such as the presence of any major food allergens. OSHA guidelines govern workplace safety generally, including infectious disease control and sanitation.

It is ideal to gather into one manual your business’ standard-operating-procedures (SOP) in case of any inspection or audit. This manual can consist of a number of different policy statements, checklists, and detailed procedures for maintaining clinic operations. Key areas to include are sanitation, record keeping, and various audits.

For example, in the area of sanitation, you will want to include procedures for keeping herbal products:

- Out of direct sunlight
- In a dry environment
- Under temperature control



[Click here](#) for a sanitation checklist.

In the area of quality control and audits, you will want to include procedures for:

- Dates and labels
- Stock rotation
- Periodic audit and cleaning of storage areas



[Click here](#) for a **dispensing procedures checklist**.

Another critical area of pharmacy management is documentation. The adage goes, “If you did not document it, it did not happen.” Any patient prescribed an herbal formula should have an accompanying chart note that indicates the following:

- Patient’s name, date of consultation, date of birth
- Patient’s comorbidities
- Chinese medicine pattern diagnosis
- Diagnostic information: tongue, pulse, vital signs (if available), temperature
- Patient symptoms
- Herbal treatment strategy (e.g. clear heat and resolve phlegm)
- Current medications: including prescriptions, over-the-counter products, herbs, and supplements
- Known allergies
- Herbal medicine ingredients and dosage
- Date prescribed
- PARQ counseling
  - Declaration of alcohol in a liquid formula, if present;
  - Recommendations for use;
  - Possible side-effects; and
  - Point of contact for the herbal compounder, if different from the practitioner.



[Click here](#) for a **chart note template**.

When you dispense a formula to a patient, it should be accompanied by a document or a label that includes:

- Patient’s name
- Declaration of ingredients, including inactive
- Declaration of potential allergens
- Declaration of alcohol in a liquid, if present
- Herbal prescription name
- Dosage form and strength
- Preparation date and dispensing date (if different)
- Control number or lot number
- Assigned beyond use date or expiration date, if relevant
- Name and address of the practitioner

- What it's used for in Chinese medicine terms (e.g. clear heat, resolve damp-phlegm in the lung, etc.)
  - Herbalists do not treat diseases. This should be communicated consistently and labeled accordingly as a treatment of symptoms.



[Click here](#) for a patient information sheet template.

Finally, it is important to be prepared for the case of an adverse event or patient complaint. This means both tracking subjective complaints, reported reactions to herbal medicines, and the disposal of any herbs that may have been damaged due to a defective batch or lot.

Any patient who reports a complaint or adverse event should have their case documented in their chart and for annual safety audit purposes.



[Click here](#) for a patient complaint form to document recalls and adverse reactions.

## Tracking Your Inventory

From your very first order, to the day your practice is up and running, it is important to keep track of your inventory. Unless you have an electronic health record (EHR) system that includes a pharmacy module or independent pharmacy management program, you will have to manually keep track of your inventory.

Tracking batch and lot numbers, quantity of herbs on hand, and the volume of purchasing over time can assist you in mitigating product loss, refining your inventory to best serve your patients, and identifying trends in your practice. It is also the foundation of annual audit.



[Click here](#) for an Inventory tracking sheet.

# 3 step

## DEVELOP A DISPENSING STRATEGY

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### Choosing formulas versus single herbs in your inventory

In a space where the storage and dispensing areas may be limited, it is important to consider how to make the most of your inventory. One strategy is to prioritize stocking your core formulas rather than all the single herbs that are required to make those formulas. This has two benefits to you as a provider — decreasing compounding time and decreasing your labor costs.

Another reason to consider prescribing formulas is that, in granule form, they may have been cooked together and contain the synergistic properties of that process. Given the nature of formula modification, it may be possible to create a wide variety of common modifications from a handful of foundation formulas.

Based on the earlier section of the workbook, if you were to carry all 50 of the most commonly prescribed singles, you could fill all 50 of the most commonly prescribed formulas, simply by adding 15 additional singles. However, that would require shelf space for storing a minimum of 65 different bottles of granules.

Answer the following questions to help determine what is the right balance for you.



[Click here](#) for a fillable version of reflection questions.

Since my initial inventory purchase, is there anything I have not used?

Since my initial inventory purchase, is there anything I used more frequently?

When I look at my herbal inventory, is it over-crowded? Where could I simplify?

When I look at my herbal inventory, is it empty? Where could I expand?

Since my first reflection exercise, have any demographic characteristics of my patient's changed?

## Combining extracted formulas with singles

In the end, most medicinaries that use granules will have some combination of base formulas and single herb granules. Yet, many of our herbal references refer to bulk dosing as the classical and modern standard.

**Assuming that most granules are formulated as a 5:1 concentration, the simplest way to convert bulk to granule dosages is by dividing the standard formula or single herb dose by five.** This would apply to the total dose for a single formula, as well as for all the single herbs in a modification or compounded by using singles.

Some EHR systems have features that allow you to query your inventory for percentages of known formulas. If you do not have such a tool, then a manual calculator can help you convert any formula listed in bulk dosages to a combination of single or formula in granule dosage.



[Click here](#) to link to a dosing calculator.

## Reflecting on Patterns in Your Practice

Once you have been in practice for several months (or several years!), it is worth looking over the patterns in your prescribing habits to see if you can set new goals for growth of your practice. This begins with a process of reflection on your experience as an entrepreneur and envisioning your future.

Perhaps there are seasonal opportunities to pre-stock useful formulas, such as cold and flu season, around the onset of spring allergies or in anticipation of holiday-related food stagnation. Looking forward, reflect on the following questions to consider how to strategically expand your inventory.



[Click here](#) to link to fillable version of reflection questions.

Do certain clinical patterns occur annually on a seasonal basis?

Looking at inventory that did not move, is there anything you could do toward patient education to let them know you treat conditions appropriate to those formulas or herbs?



## EXPAND YOUR PRODUCT LINE

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### Setting Goals for Your Practice

Chinese herbal medicine is just one of the many tools in the toolbox of a licensed acupuncturist. An acupuncturist does not need to prescribe herbs and manage a pharmacy as part of a long term business plan. Yet, OCOM graduate surveys show a positive correlation between having an active herbal practice and the success of their practice.

It is important to make time to work on building your clientele, including patient information campaigns that may help you reach new patients and deepen your impact on their wellbeing. It can also mean investing in strategies to keep you connected as a resource for patients who may need additional services.

As you move from your first year in practice and begin to imagine where you may be in five years, envision where you want to grow. You can then work backwards to generate all the steps and resources it will take to get you there.



[Click here to link to a fillable version of reflection questions.](#)

In five years, what do you want your practice look like? In terms of those you serve? In terms of what you offer?

Do you belong to any business referral, provider referral or other networks? If yes, how could you bring Chinese herbal medicine into that conversation?

If you could do one community education activity in the next year to reach a new audience, what would it be? How would you bring Chinese herbal medicine into the conversation with that audience?

Have you invested in new technologies such, as social media platforms or an EHR that sync with an online newsletter? How do they allow you to share your vision for patient education?

### Developing Your Brand Identity

Once you have established a practice and are focusing on your long term goals, you can develop a brand identity that goes far beyond a logo and a website. Your brand identity is the culmination of all the elements of style and service that represent the vision for your long-term practice and should always send a consistent message.

Contract manufacturing, or OEM (original equipment manufacturing), service is one way to leverage third party services by creating your own line of products. Some manufacturers, such as KPC, work directly with practitioners who want to create a

custom formula under your own brand. Through these services, manufacturers can support practitioners by providing customized high-quality single herb and herb formulas directly to you, creating value for your brand and with your patients.



[Click here](#) to link to a fillable version of reflection questions.

## RESOURCES

### **Good herbal dispensing guidelines from the American Herbal Products Association (AHPA):**

[http://www.ahpa.org/Portals/0/PDFs/Policies/Guidance-Documents/AHPA\\_Good\\_Herbal\\_Compounding\\_Dispensing\\_Practices.pdf](http://www.ahpa.org/Portals/0/PDFs/Policies/Guidance-Documents/AHPA_Good_Herbal_Compounding_Dispensing_Practices.pdf)

### **Current Good Manufacturing (cGMP) Regulations from the FDA:**

<https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations>

### **Q and A on cGMP:**

<https://www.fda.gov/drugs/pharmaceutical-quality-resources/qa-cgmps>

### **Link to entire folder of worksheet and document templates**

[https://drive.google.com/drive/folders/1q7Fv4iqTV8cKSp-D\\_zlBJ9Ox2UGeWmzD?usp=sharing](https://drive.google.com/drive/folders/1q7Fv4iqTV8cKSp-D_zlBJ9Ox2UGeWmzD?usp=sharing)

## GLOSSARY

**Aflatoxin** - a highly-toxic mold that can cause severe liver damage. Suppliers needs to test and eliminate any compromised herbs from its production processes;

**Aristolochic Acid** - this acid is believed to have links to cancer, acute fibrosis and Belgian Chinese Herbs Nephropathy (CHN), a serious condition

**Current Good Manufacturing Process cGMP**, an FDA protocol, provides manufacturers with systems that assure proper design, monitoring and control of manufacturing processes and facilities.

**Convention on International Trade in Endangered Species (CITIES)** - an organization that ensures that trade in plant and animal species does not endanger their survival.

**Certificate of Analysis (CoA)** - indicates the test results for each batch of its herbs. Companies who routinely test each batch of their product, not merely a “blanket” CoA for a product item or formula, and will not have a problem providing you

with copies of their CoA's (Certificates of Analysis) for you to review. A reputable manufacturer should be able to provide you with this data within a reasonable timeframe.

**Halal Certification** - ensures that raw materials and their sources, preparation, processing, sanitation and equipment conform to Islamic consumable food rules.

**ISO** - International Organization for Standardization is an international body responsible for promoting and creating proprietary industrial and commercial standards. There are numerous ISO standards that apply to herbal product production as well as herbal cultivation. ISO 9001 standardizes manufacturer's stages of operations and endures regular quality audits of the process. ISO 17025 standardizes laboratory techniques for measurements of herbal products. ISO 22000 increases food and herb safety through continuous monitoring of hazardous substances.

**Kosher Certification** - signifies all equipment and raw materials used conform to Jewish dietary laws.

**Macroscopic Identification** - pharmacognosy and other visual inspection of medicinal plants to identify species and also plant characteristics that may correlate to plant medicinal qualities. This usually happens as part of the sourcing process.

**Microscopic Identification** - minimum testing standards of all raw materials

**Original equipment manufacturer (OEM)** - produce herbal products based your specification and needs.

**OSHA** is the Occupational Safety and Health Administration created by the US Congress to ensure safe and healthy working conditions for working people. For an acupuncturist and herbalist, OSHA sets and enforces standards in the medical office and provides **training**, outreach, **education** and assistance to health care employers and employees.

**standard-operating-procedures (SOP)** - A set of step-by-step instructions compiled to help workers carry out routine operations. The aim in creating an SOP is efficiency, quality assurance and uniformity of production, while reducing miscommunication and failure to comply with regulations.

**USDA NOP** - USDA's National Organic Program ensures that raw materials, production processes, and facilities all meet USDA regulations for organic processing. It confirms that no chemicals or artificial additives were used during processing.