## 21st Century Herbal Pharmacy: from Kitchen Medicine to cGMP

## presented by Sheila M. Devitt, Certified Herbalist for the American Herbalist Guild Annual Symposium 2015

- I. The Herbalist as Pharmacist
  - A. Botany & Pharmacognosy
    - 1. Organoleptics
    - 2. Water vs. Alcohol Solubility: will this herb make a better tea or tincture?
    - 3. Infusions & Decoctions: will these herbs combine well in a tea?
  - B. History of Apothecary Guilds
    - 1. filling your own prescriptions: an ethical dilemma?
  - C.Working Across Contemporary Disciplines: NDs, LAcs, MDs, etc.
- II. Meeting Regulations
  - A. 21CFR111: rules to live by
  - B. Start with Documentation
    - a. Inventory Lists: what herbs do you stock?
      - 1. Bulk dry herbs; tinctures; concentrated extract powders; topical ingredients, etc.
    - b. What's in a name? Latin, Common, TCM, Ayurveda, etc.
      - 1. Specify plant species & variety, plant part
    - c. Ordering & Receiving Raw Materials: quality testing, receive-date, opened-on labels
    - d. Cleaning Check Lists: daily, weekly, monthly, quarterly
      - 1. inspect your fire extinguisher
  - C. Define your Standard Operating Procedures
    - a. Work Orders/Prescriptions: templates
      - 1. Dosing Instructions, # Re-fills
    - b. Master Manufacturing Records, Batch Production Records
      - 1. Batch #s (manufactured-on date)
    - c. Dispensary Daily Log; Work Flow Chart; Work Order Archives
    - d. Dress Code: are you wearing your PPE?
  - D. Test you Standard Operating Procedures
    - a. Returned Product Form
    - b. Adverse Event Form
    - c. Re-call Procedure Drill
- III. Herbalists Finding the Middle Ground: Optimism!
  - A. Commercial Kitchen Dispensary
    - 1. one-year/ three-year/ five-year business plan
  - B. Co-operative Power: Stronger Together
    - 1. the 8 Co-operative Values
  - C. Making the Most of the AHG Chapter Network 1. an herbalist in every community
- IV. Made with Love
  - A. Energetics & Spirit Medicine

## Resources

**Co-operative Business Organizations** http://coopindex.coop

## **American Herbalist Guild Resources**

**BioNetwork webinar 2015** 

2013 Symposium cGMP pre-symposium intensive

JAHG vol. 11 - 2 GMPs: A Practical Guide JAHG vol 11 - 1 Herbal Products GMPs 101 JAHG vol.10 - 1 Clinic Profiles: GMPs in the Clinical Setting JAHG vol 9 - 2 Clinical Profiles

2009 Symposium FDA Good Manufacturing Practices (GMPs) and Community Herbalists, Roy Upton Herbal Adulterations: The Good, the Bad, and the Ugly, Roy Upton

2006 Symposium Herbal Pharmacopoeias and the Evolution of American Herbal Medicine, Roy Upton Maximizing Herb Safety, Roy Upton

2004 Symposium Herbal Toxicology, Roy Upton Powdered Extracts, Standardization, Tinctures, Teas, and Dose, Christopher Hobbs

2003 Symposium Medicine Making for Herbalists, Mitch Coven Phytopharmacy: The Chemistry, Pharmacology, Toxicology, and Clinical Applications of Herbs, Part 1 & 2, Chris Hobbs Review of Medicinal Plant Chemistry, Part 1 & 2, Jillian Stansbury

2002 Symposium Botany for Herbalists, Part 1 & 2, 7Song Establishing an Herbal Apothecary, Mitch Coven From Microscopy to Clinical Studies on Herbs, Norman Farnsworth The Art of Western Herbal Formulation, Mitch Coven

2001 Symposium Starting an Apothecary for a Home Practice, Kathleen Maier The Quality and Safety of Chinese Herbs, Roy Upton

2000 Symposium Clinical Formulating & Dosing, Chanchal Cabrera Notes Part 1 - 3 Herbal Pharmacology, Amanda McQuade Crawford Notes