UNIVERSITY PHARMACY
CUSTOM COMPOUNDING SPECIALISTS

TOLL FREE: (888) 768-7414
Phone: (801) 582-7624 / Fax: (801) 582-7633
1320 East 2nd South, Salt Lake City, UT 84102
www.universitypharmacy.com

Compounding Taskforce

Tuesday, February 11, 2014
7:00 – 8:30 AM

Pharmacy Conference Room, Intermountain Supply Chain Center

Minutes

7:00- Introduction
7:05- Angela Whitney

- Resident will begin in March and will try to arrange hospital training for inspectors
- Trip can help facilitate with DOPL

7:10- Evan Vickers

- Controlled Substances
  - 2 scripts on 1 prescription- taking out, so it will now be valid
- Pharmacy Mac Pricing Bill
  - Trying for committee on Friday
- Physician Dispensing Bill
  - 3 Groups can currently dispense and new bill will address other groups
    - Dermatology
    - Oncology
    - Latisse

7:20- Trip Hoffman

- Review of Minutes/Update
  - Update on USP 795 & 797 Checklist
    - Possible talk with Ray Walker for disclaimer
  - New report on compliance (77%)

7:30- Jim Ruble

- 503a and 503b

- 353a is 503a the numbering is off
- Compliance policy guide rescinded through FDA
- 503a is for traditional compounders
    - They are making an FDA advisory committee made up of about 12 members.
        - Defining and making lists of bulk substances
        - Compounding formulary (positive/negative list)
        - Jurisdiction- who is to watch and regulate- state vs federal.
            - >5% of prescription volume is going out of state
            - State is responsible with Memorandum of understanding.
            - If no Memorandum of Understanding then it is the FDA.

7:40- Jim Ruble

- Pharmacist/Prescriber relationship for excess compounding
    - Not allowed to compound excess for multiple prescribers on same compound. Maybe if it is done for a clinic setting.
- Compounding defined
    - Three drafts on Guidance outlines

7:40- Jim Ruble

- 503b
    - Nine Components on the label
        - Main one is the contact information for consumer to file a complaint for ADR for manufacturing compounders
    - Register through FDA is voluntary
    - Quality Control and Quality Assurance

8:00- Trip Hoffman

- "For Office Use"
    - Not for sterile products
        - Trip sent an email with change to allow for sterile preparations, language and rules to be set forth by the Board of Pharmacy.

8:25- Trip Hoffman

- USP 1079
    - Protocol that shipping methods work
        - Calling 1-2 patients/week

    - Temperature control sensors being utilized

8:30- Trip Hoffman

- Simple Compounding
    - Simple compounding should still follow USP 795; however a pharmacy could easily create policy and procedures for certain simple compounds such as Magic Mouthwash.

8:35- Trip Hoffman

- Sending random products from all employees to be tested for potency & 1 random product/month, different type each month.
- Quality Assurance (SOP Process)
    - There is a check list for compounders to look at pH, color, odor, etc. to analyze if compound is made correctly.
    - Eagle Analytical, Dynalab, ARL. Would like to make a list of companies for Quality Control, but being sure not to endorse certain companies.

8:50- Trip Hoffman

- Speaker at UPhA Meeting in St. George about 503a and 503b
    - Send an email to Jim Ruble and see if he would like to, or possibly set up a booth.

-Next Meeting: Tuesday May 20th @7am