BOARD OF REGENTS STATE OF IOWA

REGENT MERIT SYSTEM

Class Title: Pharmacy Manufacturing Technician II Class Code: 3382

Pay Grade: 409

GENERAL CLASS DESCRIPTION:

Under the direct supervision of a Pharmacy Manufacturing Technician III, a Pharmacy Manufacturing Technician Supervisor, or other designated Professional staff, performs the technical activities necessary to manufacture various types of pharmaceutical dosage forms used in human or veterinary clinical research studies.

CHARACTERISTIC DUTIES AND RESPONSIBILITIES:

- Acquires and delivers raw materials and supplies to be used in the manufacture of the drug products.
- 2. Handles and keeps records of raw materials including hazardous/regulated chemicals(i.e. toxic, potent and/or carcinogenic chemicals, Schedule I to V controlled substances and alcohols).
- 3. Weighs, mixes, blends, dries, filters, assembles, cleans, inspects, labels, and packages the final product.
- 4. Utilizes aseptic technique in horizontal and vertical flow hoods to prepare sterile products, including schedule I, II, III, IV, & V controlled substances and cytotoxic compounds.
- 5. Prepares solid dosage products, including schedule I, II, III, IV, & V controlled substances and cytotoxic compounds.
- 6. Documents all aspects of the manufacturing process as required in the manufacturing record.

The tasks listed under the heading of Characteristic Duties and Responsibilities are examples of the variety and general nature of duties performed by employees in positions allocated in the class. The list is descriptive only and should be used for no other purpose. It is not intended that any position include every duty listed nor is it intended that related duties cannot be required.

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7. Sets up, operates, cleans and maintains a variety of complex and expensive equipment associated with the manufacturing of pharmaceutical dosage forms. This equipment includes but is not limited to the following;

Autoclaves, lyophilizers, microfiltration systems, ampule sealers, filling/packaging systems, component washers, specialized milling/grinding/mixing apparatus, encapsulation/tablet compaction fluid bed/granulation/drying/pan systems. coating and computerized labeling systems.

8. Performs processes involved in the inspection, labeling, and final packaging of various pharmaceutical dosage forms. These processes include but are not limited to the following;

Visual/mechanical examination of the finished product for contamination, content, appearance, and proper fill.

Setup, operate, clean, and maintain all equipment used in the inspection process (i.e. dessicators, light inspection stations, etc.).

Preparation and production of labeling materials. Setup, operate, clean, and maintain a variety of computerized and non-computerized labeling equipment. Documentation of all labels produced as required by the manufacturing batch record and cGMP's.

Packaging of finished product for shipping and preparation of all necessary documentation as directed.

Documentation of all labels produced/dispensed as required by the manufacturing batch record.

- 9. Assists in the training of Pharmaceutical Manufacturing Technician I's and train hourly temporary laboratory assistants.
- 10. Maintains orderliness and cleanliness of all assigned work areas.

KNOWLEDGE, SKILLS, AND ABILITIES:

- 1. Knowledge of the metric system.
- 2. Knowledge of drug and drug/food manufacturing nomenclature.

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3. Knowledge and understanding of Standard Operating Procedures and Federal Current Good Manufacturing Processes as they relate to a food/drug regulated industry.

- 4. Ability to assemble/disassemble pharmaceutical manufacturing, packaging, & labeling equipment.
- 5. Ability to operate various equipment including computers, calculators, and pharmaceutical manufacturing and packaging equipment.
- 6. Ability to work safely and willingness to comply with special safety and health precautions.
- 7. Ability to maintain effective working relationships.
- 8. Ability to sit or stand for an entire shift as required.
- 9. Ability to perform simple mathematical calculations.
- 10. Ability to interpret and follow written and oral instructions.
- 11. Ability to perform work under direct observation.
- 12. Ability to use software relevant to job duties (i.e. word processing, spreadsheets, database, email, specialized environmental systems control software and equipment operating/data collection software).
- 13. Ability to train temporary laboratory assistants.
- 14. Ability to demonstrate proper safety procedures for manufacturing equipment and production areas.
- 15. Ability to learn and demonstrate proper safety procedures for handling raw materials including hazardous/regulated chemicals (i.e toxic, potent and/or carcinogenic chemicals, Schedule I to V controlled substances [regulated by State and Federal DEA], and alcohols [regulated by Federal ATF]).

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MINIMUM ELIGIBILITY REQUIREMENTS:

High school graduate or equivalent and;

Two years experience as a Pharmacy Manufacturing Technician I or; Two years experience in a directly related position in the food/pharmaceutical/medical device industry or; A combination of related post high school education and related industrial experience equal to two years.

REVISION EFFECTIVE: January 16, 2002

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