

# Singota Solutions

JD149

**Job title:** Production Operator  
**Department:** Production  
**Location:** Bloomington, IN  
**Position Type:** Full-time, 40 hours/week, non-exempt

## **General Description:**

Production operators actively participate in all the manufacturing operations for the company including:

- Sampling/Dispensing
- Drug product formulation
- Aseptic filling
- Finished dose labeling/kitting/packaging

### **General:**

1. Must be able to work within the FDA regulated environment per 21CFR 210/211 requirements and those established by internal policy and standard operating procedures
2. Computer experience necessary. Proficiency with Microsoft Office (Outlook, Excel, Word).
3. Experience using equipment HMIs, as well as ERP or inventory systems desired
4. Attention to detail and good organization skills mandatory
5. Participate in and fully support process improvement initiatives
6. Ability to work in both collaborative and independent work situations and environments.
7. Must strictly adhere to all safety requirements, including wearing proper PPE (personal protection equipment) while performing operations, i.e. respirator, safety glasses, gloves, etc.
8. Job requires gowning to work in cleanroom environments
9. Perform cleaning/disinfecting/sanitization of cleanrooms
10. Assist in process investigations, writing of deviations, and implementation of CAPAs to continuously improve operations
11. Ability to stand for a minimum of 4 hours
12. Must have good documentation practices with clear, legible handwriting
13. Provide recommendations and implement solutions to resolve equipment and/or process problems in a timely manner
14. Comply with quality and safety management systems including requirements for documentation, training, system use, SOPs, processes and procedures
15. General support required of a company where everyone is expected to perform multiple tasks both inside and outside their department to meet the needs of the business

### **Sampling/Dispensing:**

1. Pulling client material from warehouse for sampling and dispensing operations; putting client material away after operations complete
2. Sampling and dispensing client material from parent containers into smaller child containers
3. Working with hazardous and non-hazardous materials in a controlled environment and performing operations for short and long periods of time
4. Keeping sampling/dispensing suites clean and stocked with supplies

### **Formulation:**

1. Precision weighing and measuring of buffers, excipients, API, etc.
2. Ability to use basic lab instruments, such as; pH meter, conductivity meter, pipets
3. Ability to use basic manufacturing equipment, such as; biosafety cabinets, mixers, pumps, filter testers

### **Aseptic Filling:**

1. Install machine change parts and load recipes on fill machine
2. Staging/loading of components and preparation of fill path
3. Perform cleaning and VPHP decontamination of isolators
4. Assist with environmental monitoring

**Finishing (Labeling and Kitting):**

1. Label and package filled drug product and/or pharmaceutical components per written specifications, SOP's, job aids and batch records
2. Inspect product and printed materials for defects
3. Responsible for reconciliation of all controlled printed materials and product
4. Setup and operation of labeling and packaging equipment and systems
5. Preparation and use of precision measuring instruments

**Skills and Physical Activity Requirements:**

1. Excellent work ethic and attention to detail
2. Requires repetitive hand, wrist, arm motions
3. Hand eye coordination and manual dexterity with small components
4. Use of small tools and laboratory/production equipment
5. Clear, legible handwriting
6. Able to comprehend and execute complex written instructions  
Must be able to lift, push, or pull up to 50 pounds

**Education and Work Experience Requirements:**

1. High school diploma with minimum 4 years industry experience  
or
2. Associates Degree in an Engineering or Science discipline with minimum 1 year industry experience  
Or
3. Bachelors Degree in an Engineering or Science discipline

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