

# Sila Bounmark

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## Objective: Manufacturing processing operator

### Qualifications and Job Duties

- More than 16 years of experience working in cGMP production facility. Experienced in fully gownned cleanroom operations, weighing, formulation, labeling, packaging, aseptic filling, and cleaning according to ISO guidelines and company policies.
- Familiar with equipment setup, operation and research and development entailing changeover of products produced in small scale into large scale pharmaceutical product operations.
- Performed proper documentation practices in a cGMP environment and compliance to controlled assay worksheets, Laboratory Information Management System (LIMS).
- Provided communication to project management and manufacturing groups regarding test results. Demonstrated ability to communicate effectively to scientists, management and staff.
- Familiarity with cGMP standards of practice. Demonstrated safe work and safe lab practices including personal protective equipment, knowledge of chemical industry safety practices, safe chemical storage, and interpretation of chemical safety data sheets (SDS), shipment practices, and standards set by EPA guidelines.
- Technical support for team of development scientists.
- Perform all duties involving validation and statistical analysis of new experimental, change control and ANDA drugs.
- Have input on the development of new cleaning procedures and equipments.
- Perform all trials and analytical testing of small scale production per formulation protocol proficient on equipment and process of finished dosage, involving tableting, blending and coating.
- Make adjustment to the formula and equipment necessary during the development process.

### Experience

#### Sandoz Inc. Production Technician ATO III

JUNE 1999-FEBRUARY 2016

#### Summary of Qualifications

- Supported regulatory affairs by assembling quality assurance methodology, data, protocols, and validation reports for the purpose of filing ANDA's, NDA's, and other FDA required annual submissions.
- Responsible for writing protocols and SOPs, equipment qualifications, new method training and transfer, performing laboratory investigations, reviewing notebooks and raw data and complying with cGMPs, GLPs, current ICH and USP reference guidances, and general safety guidelines.
- Pre-formulation and stability R&D pharmaceutical testing experience in dissolution, product purity, content uniformity, related compounds, blend uniformity, residual solvents, identification by Karl Fischer titration, water content.
- Mastered skills needed for large-scale bulk production.
- Performed final review for documentation error on all equipment log and batch records
- Ensure that usage of chemicals is recorded in warehouse inventory system.
- Performed equipment cleaning according to FDA standards.
- Enjoy working with other.
- Always willing to learn and understand the importance of exact documentation.

- Always compliant to current health,safety,and environment standards.
- Assembled precision mechanical components in clean room environment using engineering drawing,written procedure and standard work specification.
- Tested and repaired circuits and PC boards with soldering.
- Measured products with different tools including calipers,micrometer and CMM machine.
- Technical coordinator providing technical and product support,project management,process analysis,trouble shotting,consulting and group training.
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### **Storage Technology Corporation**

#### **CNC Machinist III**

**March 1992-June 1997**

- Operated CNC machining operations to cut, trim, and slot wafers with actuators and flex circuits to create magnetic recording heads that are used for tape drives.
- Utilized machines for lapping and grinding the modules in order to create contours.
- Assembled and wired tape reel DFT machines for NGD, sycorax, and caliban heads using CAD schematics.
- Completed pole, resistance, and failure tests as well as contamination inspections on NGD and servo writer heads.
- Team Coodinater.

### **Education**

**Westminster High School GRADUATED 1991**