

POSITION TITLE: BFS (Blow-Fill-Seal) Operator Level I	DEPARTMENT: Production
REPORTS TO: Production Supervisor	FLSA DESIGNATION: Non-Exempt
DATE WRITTEN/REVISED:	HR APPROVAL/DATE: QA APPROVAL/DATE:

JOB SUMMARY:

Level I BFS Operators are operators that have been qualified on specific operations and specific BFS Lines at Unipharma. The position requires familiarization with the underlying engineering and scientific principles on which BFS technology and aseptic processing are based.

Level I BFS Operators are responsible for specific operations and BFS Line equipment on which they are trained and qualified. These responsibilities include achieving and maintaining qualification for Aseptic Operations and may also include setting up adjusting and running BFS equipment and downstream equipment within the cleanroom, CIP, SIP, and area cleaning. Level I BFS Operators routinely perform pre- and post-operational checks, operate BFS and downstream equipment for production, perform cleaning of equipment and areas, and document work performed per SOPs and Batch Documentation requirements.

DUTIES AND RESPONSIBILITIES:

Level I BFS Operators may be assigned to specific tasks within the following general range of duties and responsibilities based on the specific training and qualifications they have achieved. Training of Level I BFS Operators is performed with the goal of qualifying each operator in all of the specific duties and responsibilities applicable to each individual BFS Line, on a line-by-line basis. Following this strategy, Operators become fully qualified for every Operator responsibility on individual lines, and may successively be trained on operating every line.

- BFS Operators must achieve and maintain Aseptic Operations Qualification. BFS Operators may be disqualified based on routine testing of hand and gowning samples taken by QA or based on observed behavior such as not following SOPs. Failure to achieve or maintain Aseptic Operations Qualification may result in termination (such as during probationary periods or under the Progressive Discipline), transfer, reduction in pay, etc.
- BFS Operators follow Batch Record instructions that specify processing parameters to be utilized, in-process sampling and testing, etc. BFS document the work performed as specified in the Batch Record.
- During production filling of containers, BFS Operators are responsible for monitoring the operation of the equipment, processing parameters utilized, and the product produced.
- Based on monitoring activities and feedback from downstream manufacturing staff and On-Line QC, the BFS Operator makes adjustments as required or specified in Batch Records, performs clearance of machine jams, troubleshoots minor production problems, and makes minor adjustments for processing parameters, fill volume, etc.
- At the completion of each run the BFS Operator discontinues the downstream feeding of product when the last product determined to be acceptable has been produced, and shuts down the line or prepares for lot change as directed in Batch Records and required by the Production Schedule.

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- BFS Operators perform filter integrity tests, initiate Clean-in-Place(CIP) and Sterilize-in-Place (SIP) processes, confirm satisfactory completion and recording of CIP and SIP processes, perform line clearance, equipment and area cleaning, post status and in-process product/lot number labeling, coordinate delivery of bulk product and resin. and complete all associated documentation as specified in Batch Records and SOPs.
- BFS Operators maintain BFS Lines in a clean and orderly state. Performs minor and spot cleaning as required.
- Provides QA Support for Audits and Inspections.
- Verifies documentation and reports for accuracy.
- Comply with all aspects of quality management systems, cGMP policies, documentation and record keeping in accordance with industry and FDA standards. Enforce safety and sanitation regulations.

SUPPORTIVE FUNCTIONS

In addition to performance of the essential functions, this position may be required to perform a combination of the following supportive functions, with the percentage of time performing each function to be solely determined by the manager based upon the particular requirements of the plant:

- Team member for problem solving of BFS related quality issues.
- Responsible for participation in internal plant audits.
- Participates in cross-training in Manufacturing areas of responsibility.
- May be responsible as member of Emergency Response Team under the Emergency Response Plan.
- Promotes safe operating and working procedures.
- Provides support for process improvement teams and capital projects.

SPECIFIC JOB KNOWLEDGE, SKILLS AND ABILITIES

The individual must possess the following knowledge, skills and abilities and be able to explain and demonstrate that he or she can perform the essential functions of the job, with or without reasonable accommodation, using some other combination of knowledge, skills, and abilities:

- Must have legible handwriting, and the ability to perform accurate documentation.
- Must be able to count accurately, and have good basic math skills such as adding, subtracting, multiplying, and dividing.
- Must be organized, capable of following instructions, and have the ability to coordinate multiple activities simultaneously.
- Must be able to work in a methodical and organized fashion and maintain mental focus to ensure efficient and accurate completion of individual tasks.
- Must be mechanically oriented and understand the function and operation of common tools and the operation of PLCs and graphical user interfaces on equipment.
- Must be familiar with functions of equipment systems that operate utilizing multiple utilities such as compressed air, electrical supply, vacuum, steam, chilled water, etc.
- Must have basic computer skills including data entry.

PHYSICAL DEMANDS

- Must be flexible in terms of working hours to meet requirements of position.
- Must be able to fit and wear respiratory, hearing, gowning and other personal protection as required for entry and work in Unipharma facilities.
- Must be able to sit, walk, and/or stand for a minimum of 12 hours per day.
- Must be able to speak clearly on the telephone.
- Ability to sit at a desk and work on a computer as needed
- Must be able to exert well-paced ability in limited space and to reach other locations of the plant on a timely basis.
- Vision occurs continuously with the most common visual functions being those of near and color vision and depth perception.
- Must be able to bend, stoop, squat and stretch to fulfill production and cleaning tasks.
- Must be able to lift up to 50 pounds.

TRAINING

The BFS Level I Operator must be trained on the following specific SOPs before performing GMP related documentation or plant related tasks:

SOP	Title
0.100	SOP on SOP's
0.101	Document Control
0.102	Change Control
0.103	Training Program, Qualification, and Development (Includes cGMPs)
0.104	Good Documentation Guidelines

The BFS Level I Operator must be trained on specific SOPs and documentation before performing documentation or other tasks relevant to each procedure. Relevant SOPs are found in the following sections.

Section	Title
~ Section 0 -	General ~
~ Section 4 -	Manufacturing - Administration ~
~ Section 8 -	Manufacturing- Blow Fill Seal ~
~ Section 11 -	Safety ~

QUALIFICATION STANDARDS

Education:

Associate Degree preferred; High School Diploma required.

Experience:

Two years of experience in Food/OTC or other FDA Regulated production environment preferred.
Two years of experience in an Aseptic Processing production environment preferred.

Grooming:

All employees must maintain a neat, clean and well-groomed appearance per Unipharma standards.

This job description is not an exclusive or exhaustive list of all job functions that an employee in this position may be asked to perform from time to time.

Relevant position titles:

Aseptic Filling Operator
Aseptic Manufacturing Operator
Aseptic Manufacturing Technician
Pharmaceutical Manufacturing Operator
Pharmaceutical Manufacturing Technician
Filling Operator
Manufacturing Operator
Manufacturing Technician
Production Operator