Somerset
Therapeutics Private Limited
(Formerly Known as Somerset Therapeutics Limited)

A . Aseptic Product Bulk Compounding and Autoclave Area Supervisor

Position: Aseptic Product Bulk Compounding and Autoclave Area Supervisor
Location: Nelamangala, Bangalore

Department: Manufacturing / Production
Reports to: Aseptic Manufacturing Manager / Operations Manager

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Position Overview:

The Aseptic Product Bulk Compounding and Autoclave Area Supervisor is responsible for overseeing the bulk compounding and autoclave sterilization processes within an aseptic manufacturing environment. This includes supervising all three shifts of production operations, ensuring adherence to aseptic techniques, and maintaining strict compliance with GMP and regulatory standards. The supervisor will manage the preparation of solutions and suspensions, oversee the cleaning and sterilization processes (CIP/SIP), and ensure aseptic filtration and bulk sterilization are conducted accurately and safely. The role requires a strong technical knowledge of compounding, sterilization, and aseptic practices, as well as the ability to lead a team across shifts to meet production and quality goals.

Key Responsibilities:

1. Bulk Compounding Process Management:

- Oversee the preparation of aseptic bulk solutions and suspensions in compliance with standard operating procedures (SOPs) and GMP regulations.
- Ensure accurate weighing, mixing, and formulation of ingredients for aseptic compounding.
- Monitor and control the bulk compounding equipment (e.g., mixing tanks, filtration systems, etc.), ensuring they are operating within established parameters.
- Verify that all critical processes (e.g., pH, viscosity, concentration) are properly controlled and documented during compounding.
- Ensure aseptic technique is strictly followed throughout the entire compounding process to prevent contamination.

2. Autoclave and Sterilization Process Oversight:

- Supervise the autoclave sterilization process for bulk containers, equipment, and supplies, ensuring compliance with sterilization cycles (time, temperature, pressure).

- Oversee the implementation of **CIP (Cleaning in Place)** and **SIP (Sterilization in Place)** protocols for compounding equipment, pipelines, and vessels.
- Ensure proper documentation of sterilization cycles, including temperature and pressure logs, to meet regulatory requirements and internal quality standards.
- Work closely with the maintenance team to ensure autoclave equipment is properly calibrated, maintained, and regularly serviced.

3. Shift Operations & Team Supervision:

- Supervise the daily operations of the bulk compounding and autoclave areas across all three shifts to ensure continuous, efficient, and safe operations.
- Ensure that staffing levels are appropriate for each shift and work with human resources to schedule production teams accordingly.
- Train, guide, and provide leadership to compounding technicians, operators, and other team members to ensure adherence to aseptic techniques and best practices.
- Monitor employee performance, provide feedback, and assist in the development of team members.

4. Process Improvement and Efficiency:

- Identify and implement improvements in the bulk compounding and autoclave sterilization processes to enhance efficiency, reduce cycle times, and improve product quality.
- Collaborate with the engineering team to troubleshoot and resolve issues with equipment, facilities, or processes.
- Propose and lead initiatives for continuous improvement, ensuring that best practices are shared across shifts and teams.

5. Reporting & Communication:

- Maintain accurate and detailed reports of production activities, including compounding yields, sterilization parameters, and any deviations or issues encountered.
- Communicate production status, issues, and improvement initiatives to management and cross-functional teams.
- Ensure clear and consistent communication between shifts to ensure smooth transitions and alignment on production goals.

Qualifications:

Education & Experience:

- Bachelor’s degree in Pharmaceutical Sciences, Chemical Engineering, Life Sciences, or a related field (or equivalent experience).

- 7+ years of experience in aseptic manufacturing, with a focus on bulk compounding and sterilization processes, ideally in a regulated industry (pharmaceuticals, biotechnology, or medical devices).
- At least 2 years of experience in a supervisory role, overseeing production staff in a GMP-compliant environment.

Technical Skills:

- Strong understanding of **aseptic compounding**, including solution and suspension preparation techniques.
- In-depth knowledge of **CIP (Cleaning in Place)** and **SIP (Sterilization in Place)** processes.
- Familiarity with aseptic filtration techniques, bulk sterilization methods, and equipment used in aseptic manufacturing.
- Experience with autoclave sterilization cycles, parameters, and validation.
- Familiarity with regulatory requirements (FDA, EMA) and industry standards for aseptic processing.
- Strong problem-solving abilities, with a focus on troubleshooting equipment, processes, and operational challenges.
- Ability to drive a culture of continuous improvement, safety, and quality.

Physical Requirements:

- Ability to stand or sit for extended periods.
- Ability to lift and move materials (up to 25 kgs).
- Comfortable working in aseptic cleanroom environments with strict hygiene and PPE requirements.

Working Conditions:

- This position requires oversight of operations in an aseptic manufacturing environment with controlled conditions.
- The role involves supervising operations across all three shifts (morning, evening, and night) on a rotating or fixed schedule.
- Will be required to work across all three shifts (morning, evening, and night) on a rotating basis to ensure 24/7 operations

B . Aseptic Filling Line Supervisor/Assistant Manager

Position Title: Aseptic Filling Line Supervisor/Assistant Manager

Location: Nelamangala, Bangalore

Reports to: Production Manager / Operations Manager

Department: Manufacturing/Production

Position Overview:

The Aseptic Filling Line Supervisor/Manager is responsible for overseeing the daily operations of the aseptic filling process for sterile injectable or ophthalmic products. This includes managing the production team, allocating tasks, tracking day-to-day activities, and ensuring compliance with regulatory standards such as FDA guidelines and cGMP (current Good Manufacturing Practices). The supervisor/manager will also work closely with cross-functional teams, including Quality Assurance (QA), Quality Control (QC), Microbiology, and Engineering to ensure product quality, equipment performance, and a sterile production environment. Additionally, this role involves leading investigations of deviations, implementing CAPA (Corrective and Preventive Actions), and ensuring FDA readiness for inspections.

Key Responsibilities:

1. Daily Operations & Work Allocation:

- **Work Allocation**: Assign and prioritize tasks to operators and other production staff based on production schedules, resources, and customer demands.
- **Day-to-Day Activity Tracking**: Monitor daily production activities on the aseptic filling line, ensuring efficient workflow and minimal downtime. Track production metrics, such as yield, cycle time, and uptime.
- **Shift Supervision**: Supervise daily operations across multiple shifts, ensuring that filling operations are performed in accordance with production goals, quality standards, and regulatory requirements.

2. Compliance and Regulatory Readiness:

- **FDA Readiness**: Maintain a state of continuous compliance with FDA regulations (21 CFR Part 210/211) and ensure the aseptic filling process is always inspection-ready. Prepare for internal and external audits by ensuring all procedures, documentation, and systems are fully aligned with regulatory expectations.
- **Aseptic Techniques**: Ensure all aseptic filling practices, including gowning, sanitization, and equipment handling, meet strict sterility protocols to prevent contamination.

- **Documentation**: Oversee proper completion of batch records, SOPs, logs, and production reports. Ensure timely and accurate reporting in compliance with GMP documentation standards.

3. Cross-Functional Collaboration:

- **Work with QA and QC**: Collaborate with the Quality Assurance (QA) team to ensure that all processes, materials, and finished products meet regulatory and internal quality standards. Facilitate inspections, audits, and non-conformance investigations.
- **Support from Engineering**: Coordinate with the Engineering team for troubleshooting, maintenance, and calibration of filling equipment and utilities. Ensure any equipment downtime or failures are addressed immediately to prevent production delays.

4. Investigation and Review:

- **Root Cause Analysis**: Lead investigations of any process deviations, non-conformances, or product quality issues, identifying root causes and determining corrective actions. Collaborate with QA, QC, and other departments to resolve issues and implement improvements.
- **Deviations & CAPA**: Oversee the investigation and implementation of Corrective and Preventive Actions (CAPA) for any identified deviations. Ensure CAPAs are tracked, implemented, and followed up to completion.
- **Documentation & Reporting**: Ensure that all investigation reports, CAPA actions, and resolution documents are completed and properly documented. Maintain clear records for regulatory audits and inspections.

5. Continuous Improvement:

- **Process Optimization**: Work closely with production and engineering teams to continuously improve the aseptic filling process, focusing on reducing downtime, increasing yield, improving efficiency, and enhancing product quality.
- **Training & Development**: Oversee the training and development of operators and technicians on aseptic techniques, equipment handling, GMP compliance, and safety protocols. Ensure team members are updated on any new procedures, guidelines, or technologies.

6. Safety & Compliance:

- **Safety Oversight**: Ensure that all team members follow safety protocols and wear the appropriate PPE (personal protective equipment) when working in cleanrooms or with aseptic equipment. Promote a safety-first culture.
- **Environmental Monitoring**: Collaborate with the environmental monitoring team to ensure that the aseptic environment remains within required specifications (e.g., particulate and microbial levels). Oversee corrective actions for any out-of-spec conditions.
- **GMP and SOP Adherence**: Ensure that all team members comply with GMP regulations, internal SOPs, and other relevant standards for sterile manufacturing.

Qualifications:

- **Education**:
    - Bachelor's degree in a relevant field (e.g., Life Sciences, Pharmaceutical Sciences, Engineering) or equivalent experience. Advanced degrees preferred (e.g., Master's, or Certification in Pharmaceutical Manufacturing).
- **Experience**:
    - 10+ years of experience in sterile manufacturing, including at least 2 years in a supervisory or managerial role in aseptic filling or sterile injectable production.
    - Experience in managing aseptic filling lines, equipment, and cross-functional teams within a regulated environment.
    - Strong understanding of FDA regulations (21 CFR Part 210, 211), GMP, and aseptic processing.
    - Proficient in manufacturing systems, data analysis, and inventory management systems (e.g., SAP).
    - Experience with environmental monitoring equipment and other validation technologies used in sterile manufacturing.
- **Working Condition:**

  Will be required to work across all three shifts (morning, evening, and night) on a rotating basis to ensure 24/7 operations

C. Sterile Bulk Compounding Operator

Position: Sterile Bulk Compounding Operator
Location: Nelamangala, Bangalore
Department: Manufacturing / Production
Reports to: Production Supervisor / Manufacturing Manager

Position Overview:

The Sterile Bulk Compounding Operator is responsible for the preparation and compounding of sterile bulk solutions in a regulated, aseptic manufacturing environment. This role requires a strong understanding of bulk compounding techniques, as well as knowledge of **CIP (Cleaning in Place)** and **SIP (Sterilization in Place)** processes. The operator will be responsible for operating and maintaining compounding equipment, ensuring product sterility, and performing tasks in compliance with Good Manufacturing Practices (GMP) and regulatory requirements. This position involves working in collaboration with cleaning crews, ensuring the proper maintenance of equipment logs, and following strict documentation practices across all shifts (morning, evening, and night).

Key Responsibilities:

1. Bulk Compounding:

- Operate compounding equipment to prepare sterile bulk solutions and suspensions as per formulation instructions and SOPs.
- Measure, weigh, and mix raw materials accurately to ensure the correct formulation of sterile products.
- Monitor the compounding process, ensuring that product parameters (e.g., pH, viscosity, concentration) are within specification.
- Ensure aseptic techniques are followed throughout the compounding process to prevent contamination and maintain product integrity.

2. CIP (Cleaning in Place) and SIP (Sterilization in Place):

- Perform **CIP (Cleaning in Place)** and **SIP (Sterilization in Place)** procedures to ensure that all compounding equipment, vessels, and lines are cleaned and sterilized before and after each use.
- Follow established SOPs for cleaning and sterilization, ensuring compliance with GMP and regulatory requirements.
- Verify that all CIP/SIP parameters (e.g., temperature, time) are met during each cycle.
- Maintain accurate records of CIP/SIP activities and ensure that equipment is properly prepared for the next batch.

3. Filtration Process:

- Operate and maintain aseptic filtration systems, ensuring that bulk solutions are filtered through sterile, sterilizing-grade filters as per standard operating procedures.
- Monitor the filtration process to ensure the removal of particulates and microbial contamination.
- Perform regular checks on filtration integrity and document results according to regulatory and internal requirements.

4. Documentation & Record-Keeping:

- Complete batch records, equipment logs, and other documentation accurately and promptly.
- Maintain detailed logs of all manufacturing activities, including compounding, filtration, CIP/SIP cycles, and equipment maintenance.
- Ensure that all documentation is in compliance with GMP standards and that records are fully traceable and complete.
- Ensure that any deviations, non-conformances, or discrepancies are properly documented and reported in a timely manner.

5. Maintenance and Equipment Handling:

- Assist in the setup, breakdown, and sanitization of equipment, ensuring that all parts and equipment are in working order.
- Work closely with the cleaning crew to ensure that cleaning and sanitization tasks are performed according to schedule and GMP guidelines.
- Ensure that equipment is correctly stored and that proper calibration and maintenance procedures are followed.

6. Safety, Quality, and Compliance:

- Adhere to all safety and GMP guidelines to ensure the integrity of the sterile manufacturing environment.
- Follow strict aseptic techniques, ensuring that the environment and products remain contamination-free.
- Ensure compliance with regulatory requirements (FDA) and internal SOPs for all activities.
- Report any safety hazards, equipment malfunctions, or procedural deviations immediately to the supervisor or quality team.

7. Shift Operations & Team Collaboration:

- Work in a three-shift rotation (morning, evening, and night shifts) to ensure continuous production operations.
- Communicate effectively with team members across shifts to ensure smooth handover of operations and alignment on production goals.
- Collaborate with other departments, including Quality Assurance, Maintenance, and the Cleaning Crew, to ensure that all processes and procedures are followed seamlessly.

Qualifications:

Education & Experience:

- Bachelor's degree or equivalent in Pharmaceutical Sciences, Life Sciences, Engineering or a related field (preferred).
- 3+ years of experience in a sterile manufacturing environment, preferably in bulk compounding or aseptic processing.
- Familiarity with **CIP (Cleaning in Place)** and **SIP (Sterilization in Place)** processes.
- Knowledge of sterile filtration techniques, bulk manufacturing, and aseptic practices.

Technical Skills:

- Understanding of aseptic processing, bulk compounding, and sterile techniques.
- Experience with filtration systems and maintaining aseptic conditions during compounding.
- Proficiency in completing batch records, logbooks, and documentation in compliance with GMP.
- Familiarity with regulatory standards such as FDA, GMP, and ISO.

Physical Requirements:

- Ability to lift up to 25 kg and carry materials.
- Ability to stand or sit for extended periods.
- Comfortable working in a cleanroom environment with strict gowning and aseptic procedures.

Additional Skills:

- Strong attention to detail and ability to follow SOPs accurately.
- Excellent communication skills for effective collaboration with colleagues across shifts.
- Ability to work independently and as part of a team in a fast-paced environment.

Working Conditions:

- This role requires working in sterile manufacturing environment with controlled conditions.
- The position requires working in a three-shift rotation (morning, evening, and night shifts) to ensure continuous production coverage.
- Use of personal protective equipment (PPE) is required, including gloves, gowns, and face masks.

D. Aseptic Product Manufacturing Line Manager

Position: Aseptic Product Manufacturing Line Manager
Location: Nelamangala, Bangalore
Department: Manufacturing / Production
Reports to: Operations In-charge

Position Overview:

The Aseptic Product Manufacturing Line Manager is responsible for managing all aspects of aseptic manufacturing operations across three shifts, ensuring the safe, efficient, and compliant production of bulk products. This position involves supervising Assistant Managers and Supervisors, overseeing daily manufacturing activities, driving performance improvements, managing investigations, and ensuring all production and quality systems (including Trackwise and SAP) are utilized effectively. The Line Manager will ensure that all products meet regulatory and quality standards while continuously optimizing the manufacturing processes.

Key Responsibilities:

1. Operational Leadership:

- Manage all aspects of aseptic product manufacturing across three shifts, ensuring continuous, 24/7 operations.
- Supervise and provide leadership to Assistant Managers, Supervisors, and production staff to achieve production targets, maintain quality standards, and drive operational efficiency.
- Oversee daily manufacturing processes for bulk products, including sterile preparation, filling, and packaging, ensuring adherence to standard operating procedures (SOPs), Good Manufacturing Practices (GMP), and regulatory requirements.
- Ensure efficient scheduling and staffing for all shifts to maintain operational continuity.

2. Compliance & Quality Oversight:

- Ensure that manufacturing activities comply with all relevant GMP, FDA, and other regulatory guidelines, including environmental and aseptic control practices.
- Oversee the documentation and completion of batch records, investigation reports, and other required documentation to ensure compliance with regulatory standards and internal quality systems.
- Lead investigations of deviations, non-conformances, and quality-related issues, and drive corrective and preventive actions (CAPA).
- Work closely with the Quality Assurance team to ensure that all quality systems, including the Trackwise system for CAPA management and investigation tracking, are fully utilized and up-to-date.

3. Process Optimization & Continuous Improvement:

- Collaborate with engineering and technical teams to drive improvements in manufacturing processes, reduce downtime, and enhance productivity.
- Lead root cause analysis for manufacturing issues, identify opportunities for process improvements, and implement solutions to minimize production bottlenecks.
- Drive continuous improvement initiatives using Lean, Six Sigma, or other methodologies to improve production efficiency, quality, and reduce operational costs.

4. Systems Management:

- Ensure effective use of manufacturing and quality management systems, including **Trackwise** for tracking investigations, CAPA, and deviations, and **SAP** for production scheduling, material management, and inventory tracking.
- Oversee and ensure accurate recording of batch data, production parameters, and other critical manufacturing information in SAP and other production systems.
- Track and report on key performance indicators (KPIs) such as yield, cycle time, downtime, and other operational metrics.

5. Team Leadership & Development:

- Lead, mentor, and develop a team of Assistant Managers, Supervisors, and frontline operators to ensure a high level of performance and engagement.
- Provide training and guidance on aseptic processes, safety protocols, and GMP standards to ensure continuous professional development and adherence to best practices.
- Conduct regular performance reviews, provide feedback, and manage personnel issues, promoting a positive and collaborative team environment.

6. Health, Safety & Environmental Compliance:

- Ensure compliance with all safety regulations and environmental standards, and foster a culture of safety across all shifts.
- Promote and enforce the use of proper personal protective equipment (PPE) and aseptic techniques to maintain product integrity and safety.
- Monitor work environments and practices for potential safety hazards and implement corrective actions where needed.

7. Communication & Reporting:

- Provide regular updates and reports on manufacturing performance, investigations, deviations, and CAPA status to senior management.
- Foster strong communication across all shifts, ensuring that the team is aligned with production goals, quality expectations, and any changes in processes or schedules.
- Address and resolve operational issues or challenges, keeping management and other departments informed.

Qualifications:

Education & Experience:

- Bachelor's/Master's degree in Engineering, Life Sciences, Pharmaceutical Sciences, or a related field (or equivalent experience).
- 15+ years of experience in aseptic manufacturing, with at least 5+ years in a supervisory or management role.
- Strong understanding of GMP, aseptic manufacturing processes, and quality systems.

Technical Skills:

- Proficiency in **SAP** (Systems, Applications, and Products) for production scheduling, materials management, and reporting.
- Experience using **Trackwise** for managing investigations, CAPA, and deviations.
- Strong understanding of aseptic processing equipment and sterilization technologies.

Leadership & Interpersonal Skills:

- Proven leadership skills with experience managing cross-functional teams and driving performance across shifts.
- Excellent communication, coaching, and team-building skills.
- Ability to work under pressure and handle multiple tasks simultaneously.
- Strong problem-solving skills and the ability to make data-driven decisions.

Regulatory & Compliance Knowledge:

- In-depth knowledge of FDA, GMP, and other relevant regulatory guidelines for aseptic manufacturing.
- Understanding of environmental monitoring, sterility assurance, and aseptic techniques.

Working Conditions:

- This role requires oversight of operations in an aseptic manufacturing environment with controlled conditions.
- Will be required to work across all three shifts (morning, evening, and night) on a rotating basis to ensure 24/7 operations.

E. Sterile Injectable Manufacturing Operator

Position Title: Sterile Injectable Manufacturing Operator

Location: Nelamangala, Bengaluru

Reports to: Production Supervisor/Manager

Department: Manufacturing/Production

Position Overview:

The Sterile Injectable Manufacturing Operator is responsible for operating and maintaining equipment used in the production of sterile injectable pharmaceutical products, ensuring compliance with Good Manufacturing Practices (GMP), safety guidelines, and regulatory requirements. This role involves various tasks related to the preparation, filling and sealing of sterile injectable products within a cleanroom environment.

Key Responsibilities:

1. **Production Operations**:
    - Operate and monitor equipment used in the manufacturing of sterile injectable products, such as filling lines, vial capping machines, and autoclaves.
    - Perform aseptic techniques and ensure sterility in all operations.
    - Assist with the preparation and formulation of injectable products as per batch records and Standard Operating Procedures (SOPs).
    - Perform in-process checks and monitor the quality of products during manufacturing processes.
    - Ensure that all manufacturing processes meet safety, quality, and regulatory standards.
2. **Cleaning and Sterilization**:
    - Conduct cleaning and sanitization of equipment, tools, and the manufacturing environment following GMP and SOP requirements.
    - Ensure the proper sterilization of equipment used in production (e.g., autoclaves, sterilizers).
    - Maintain cleanliness and organization within the cleanroom environment to prevent contamination.
3. **Documentation and Record Keeping**:
    - Accurately document all activities, production processes, and test results in batch records, logbooks, and other required documents.
    - Ensure compliance with all GMP and regulatory documentation practices.
    - Report any deviations or non-conformance events in a timely manner and assist with investigations.

4. **Safety and Compliance**:
    - Adhere to all safety guidelines, SOPs, and company policies, ensuring safe operation of manufacturing equipment.
    - Participate in safety audits and environmental monitoring programs.
    - Maintain a high standard of personal hygiene and follow gowning procedures within controlled environments.
5. **Quality Assurance and Control**:
    - Collaborate with Quality Assurance (QA) and Quality Control (QC) teams to ensure product quality.
    - Conduct in-process testing, inspections, and measurements to verify product specifications are met.
    - Assist with product sampling and preparation for final release testing.
6. **Continuous Improvement**:
    - Participate in process improvement initiatives to enhance efficiency and reduce manufacturing risks.
    - Provide feedback on process issues and equipment malfunctions to supervisors and engineers.
    - Participate in training and development programs to continuously improve technical skills and knowledge.
    - Experience with aseptic processing, sterile fill/finish, or cGMP manufacturing is a plus.

- **Skills**:
    - Strong understanding of GMP guidelines and FDA regulations.
    - Ability to operate and troubleshoot basic manufacturing equipment.
    - Familiarity with cleanroom protocols and aseptic techniques.
    - Good attention to detail, record-keeping, and documentation skills.
    - Ability to work effectively in a team-oriented environment.
    - Preparation of protocols, SOP's and training of subordinates.
    - Familiarity with aseptic filling machines and processes (e.g., vial filling, syringe filling, capping, and sealing).
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- **Physical Requirements**:
    - Ability to stand for extended periods, lift moderate weights (up to 25-30 lbs), and work in a cleanroom environment with required PPE (Personal Protective Equipment).
    - Manual dexterity for tasks such as operating machinery and assembling equipment.

Qualifications:

- **Education**:
  - Bachelor's degree/Diploma in a relevant field (e.g., Life Sciences, Pharmaceutical Sciences, Engineering).
- **Experience**:
  - 3 – 8 years of experience in sterile manufacturing.
  - Experience in operating aseptic filling lines including sealing machine.
  - Strong understanding of FDA regulations (21 CFR Part 210, 211), GMP, and aseptic processing.
- **Working Condition:**

  Will be required to work across all three shifts (morning, evening, and night) on a rotating basis to ensure 24/7 operations