

Buğra ELVER

Sterile Production Manager

✉ elverbugra@gmail.com ☎ +90 5377794645 📍 Tekirdag, TURKEY 🔗 [linkedin.com/in/bugra-elver](https://www.linkedin.com/in/bugra-elver)

Summary

Sterile Production Manager with 10+ years of experience in aseptic pharmaceutical manufacturing, cleanroom operations (Grade A/B), lyophilization and EU GMP compliance. Proven track record in leading multi-shift sterile manufacturing operations with workforces of up to 150 employees, managing investment budgets and supporting successful regulatory inspections.

Professional Experience

Sterile Production Manager, Haver Farma

07/2022 – Present
Tekirdag, TURKEY

- Managed 3-shift sterile manufacturing, visual inspection and packaging operations for ampoules, vials, lyophilized products and IV solutions, leading a workforce of approximately 150 employees including supervisors, specialists and operators.
- Led production readiness activities for a successful EU GMP inspection, ensuring audit preparedness of manufacturing areas and documentation.
- Prepared and monitored manufacturing, investment, and new machine budgets to optimize costs.
- Led the manufacturing phase of the SAP-PP project, defining production workflows for SAP consultants and guiding the key user specialist.
- Set and monitored department KPIs and production targets periodically to improve operational efficiency.

Sterile Production Assistant Manager, AIS Pharma

04/2021 – 07/2022
Tekirdag, TURKEY

- Managed 3-shift sterile manufacturing and packaging operations for ampoules, vials, pre-filled syringes, and BFS lines, while tracking department KPIs and leading a team of supervisors, specialists, and operators.
- Actively led cleanroom plant tours and defended manufacturing documentation during the facility's first successful EU GMP audit, working with the Production Manager.
- Used QDMS to review and approve SOPs, change controls, manufacturing deviations, and CAPA processes.

Sterile Production Supervisor, MS Pharma

05/2020 – 03/2021
Tekirdag, TURKEY

- Supervised sterile manufacturing lines (for ampoules, vials, and IV serums) for a multinational pharmaceutical company, while expanding technical expertise into visual inspection and primary/secondary packaging operations.
- Managed production schedules and team assignments for specialists and operators within a 3-shift system, ensuring cleanroom compliance.
- Investigated line-specific deviations using QDMS and participated in root-cause analysis within cross-functional teams to resolve production line issues.
- Participated in risk analysis teams as the sole representative of the production department to evaluate and improve process safety.

Lyophilization & Sterile Production Supervisor, AIS Pharma

10/2016 – 04/2020
Tekirdag, TURKEY

- Created and developed lyophilization recipes through trial runs for a newly established facility, executing registration batches and coordinating the scale-up to commercial production.
- Supervised sterile filling lines (for ampoules, vials, and pre-filled syringes) and lyophilization processes, ensuring compliance with cGMP and aseptic regulations.
- Coordinated daily cleanroom activities (especially critical Grade A/B) and personnel gowning & aseptic behavior qualifications.
- Actively contributed to media fill runs and process validation protocols.
- Collaborated with Quality Assurance teams within CAPA groups to investigate manufacturing deviations and implement corrective actions.
- Participated in the validation and qualification protocols of sterile equipment, autoclaves, and freeze-dryers on the production floor.

Production Supervisor, Gozum Milk

07/2015 – 10/2016
Tekirdag, TURKEY

- Managed daily production operations. Led the blue-collar team to meet quality and production output targets.
- Ensured strict compliance with hygiene, sanitation, and food safety standards on the production floor.

Education

Bachelor of Science in Food Engineering, Ondokuz Mayıs University

09/2009 – 01/2014
Samsun, TURKEY

Skills

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|-----------------------------------|----------------------------------|
| • Aseptic & Sterile Manufacturing | • Lyophilization / Freeze-Drying |
| • cGMP / GMP Compliance | • Root Cause Analysis (RCA) |
| • Budgeting & Cost Optimization | • SAP-PP |
| • QMex & QDMS | • Microsoft Office |

Languages

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| • Turkish | • English |
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Training & Certificates

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| • Aseptic Area and General GMP | • Filter Validation Training (Sartorius) |
| • Effective Leadership | • Situational Leadership |
| • Improving Interpersonal Communication | • Lighthouse LMS Express 8 |
| • Coaching Training | • Leadership Approaches Training |
| • Recognition and Feedback Training | |