

Luisa Rancapan

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SUMMARY

Aseptic Production Technician with 5+ years in cGMP manufacturing, including sterile vial and syringe filling at Sanofi since 2024. Aseptic gown qualified. Experienced in Grade A isolator filling, media fills, filler set-up and changeover, VHP isolator decontamination, Grade A-D cleanroom sanitization, and batch record reconciliation under Good Documentation Practices (GDP).

SKILLS

Aseptic and cleanroom: Aseptic technique and gowning qualification; Grade A isolator operations; media fills; VHP setup; cleanroom sanitization (Grade A-D); environmental monitoring (EM) support; water sampling

Production: Vial and syringe filling; filler assembly, set-up and changeover; capping, sealing, labeling, packaging and palletizing; visual inspection; HMI monitoring; E-beam radiation operations; freeze dryer (lyophilization) operations

Quality and systems: cGMP; GDP; batch record reconciliation; qualification/validation support; deviation investigation support; SAP; LIMS (STARLIMS, LabWare)

WORK EXPERIENCE

Sanofi

Jan 2024 – Present

Systems: SAP, STARLIMS, LabWare LIMS

Aseptic Production Technician · Swiftwater, PA

May 2025 – Present

- Carry out manufacturing activities for bulk vial products, including vial filling in an isolator using aseptic technique
- Take part in media fills (aseptic process simulations)
- Set up VHP decontamination of the isolator before production runs
- Monitor the filling line HMI and help resolve line issues
- Perform visual inspection of filled vials and water sampling; support environmental monitoring (EM)
- Reconcile batch records and keep documentation GDP-compliant
- Perform aseptic gowning and support cleanroom sanitization

Aseptic Production Technician · Ridgefield, NJ

Jan 2024 – May 2025

- Filled bulk syringe products, covering all manufacturing activities on the line
- Prepared for production: batch records, component staging, and sterilization of cleanrooms and isolators using aseptic technique
- Assembled and disassembled filler machines using aseptic technique
- Monitored the HMI and identified and resolved syringe filling malfunctions
- Worked in an E-beam radiation environment under its safety and operating protocols
- Inspected finished syringes, logged defects in Code Nest Reports, and rejected syringes with gross defects
- Collected samples for the microbiology and chemistry labs and reconciled batch records
- Labeled and palletized finished syringes for transfer to the warehouse
- Took part in qualification/validation activities and assisted with deviation investigations and inspections

Aseptic Cleanroom Technician

Jul 2022 – Jan 2024

ACM/Minaris, Allendale, NJ

- Prepared sanitizing agents and sanitized Grade A-D manufacturing rooms using aseptic technique and sterile wipe-folding methods
- Sanitized manufacturing equipment and transported material supplies using aseptic technique
- Trained new team members on SOPs
- Maintained batch records following Good Documentation Practices

Pharmaceutical Manufacturing Technician

Jun 2021 – Jul 2022

Collagen Matrix, Allendale, NJ

- Assisted in manufacturing collagen-based wound care products according to batch records
- Prepared and formulated solutions, processed them in freeze dryers, and shaped them into wound care products
- Operated, monitored and sanitized production equipment; monitored data loggers; assisted with calibration
- Recorded production data, kept detailed manufacturing logs, and reconciled batch records
- Visually inspected product and pulled rejects