Linh Tran

MANUFACTURING SPECIALIST

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Summary

Manufacturing specialist with 6 years in GMP biologics and oral-solid-dose plants, owning batch records, SOP updates and deviation work for a 2,000-liter suite. Combines technical writing with data analysis in Microsoft Excel and SAP ERP to find yield losses and close CAPAs on time. Trains operators and prepares the floor for FDA and ISO audits.

Skills

- GMP
- Technical Writing
- Data Analysis
- SAP ERP
- Microsoft Excel
- CAPA
- ISO 9001
- Troubleshooting
- Attention to Detail
- Leadership

Experience

Manufacturing Specialist 05/2024 - Present

Triangle BioProcess Morrisville, NC

Contract manufacturer of monoclonal antibodies for clinical and commercial programs.

- Author and revise 40+ SOPs and master batch records a year, using technical writing that operators follow on the floor.
- Investigate process deviations and own CAPAs, closing **95%** within the 30-day target since taking the role.
- Analyze titer and yield data across 60 batches in Microsoft Excel, finding a hold-step loss worth 4% yield.
- Train 25 operators on GMP documentation and gowning, with zero FDA 483 observations in the 2025 inspection.

Senior Manufacturing Associate 05/2022 - 04/2024

Triangle BioProcess Morrisville, NC

Upstream and downstream operations on a 2,000-liter single-use train.

- Operated 2,000-liter bioreactors, harvest skids and chromatography systems across 45 GMP batches.
- Reviewed executed batch records for 3 shifts, cutting QA correction requests by 40% in a year.
- Coordinated equipment changeovers with maintenance and validation, keeping the suite on its production schedule.

Manufacturing Associate II 06/2020 - 04/2022

Cape Fear Pharmaceuticals Wilson, NC

Generic tablet and capsule manufacturer with 3 packaging lines.

- Ran granulation, compression and coating equipment to SOPs, completing 220 batches with right-first-time records.
- Recorded material use and batch status in SAP ERP, keeping inventory variances under 0.5%.
- Troubleshot tablet press weight variation with maintenance, cutting rejected tablets 18% on one product line.
- Supported ISO 9001 internal audits by pulling records and correcting 12 minor findings.

Education

Bachelor of Science 05/2020

North Carolina State University Raleigh, NC

Biological Sciences

Certificates

Certified Pharmaceutical GMP Professional (CPGP)

ASQ

09/2023

BioWork Certificate

Wake Technical Community College

08/2020