GARRETT R. WINTER
+1 (401) 935-8217 wintergarrett@gmail.com

SUMMARY:

Proven self-starter with 5 years of commercial and clinical cGMP manufacturing experience. Extensive manufacturing and engineering expertise from Amgen with 7,000+ hours between purification and upstream. Regulatory, project management, and continuous improvement experience from Vertex.

PROFESSIONAL EXPERIENCE:

Vertex Pharmaceuticals - Boston, MA

Senior Specialist, Manufacturing Technical Operations | Feb 2025 - Present

- Investigated and closed 120+ major and minor deviations supporting phase 3 clinical trials of Vertex's novel T1D cell therapy and supporting commercial production of the Casgevy gene-editing therapy.
- Identified, authored, and executed 30+ CAPAs and process improvements driving improved compliance and operational efficiency with successful proven effectiveness checks.
- Performed impact assessments leveraging extensive process data trending and characterization.
- Trained and mentored 4 new investigators while developing onboarding tools, including a centralized contacts database and role-specific operational dashboards.
- Delivered critical harvest-day issue resolution by completing full investigations, documentation, and approvals within 24 hours during time-sensitive manufacturing events.
- Modernized deviation and operations workflows by developing automated Smartsheet systems for triage tracking, meeting minutes, and investigation management.
- Created Power BI dashboards to trend deviation root causes, record rejection drivers, and investigation cycle times, enabling data-driven decision making across operations.

Amgen - West Greenwich, RI (4 years)

Associate II, Manufacturing Upstream Cell Culture | Jul 2024 - Feb 2025 (8 months)

- Executed AR30 single-use upstream operations including thaw, inoculation, daily sampling, and harvest using depth filtration, ATF, and flocculation methods.
- Trained and mentored 3 upstream and cross-functional manufacturing operators.
- Routinely provided DeltaV automation expertise for process troubleshooting.
- Led internal AI development projects by building custom Microsoft Copilot models using OPL and BLOT knowledge repositories, reducing time to determine manufacturing path forward.
- Conducted real-time process monitoring using PI Vision, SIMCA, and Spotfire to identify trends, support investigations, and maintain state of control.

Associate I, Manufacturing Downstream Purification | Sep 2021 - Jul 2024 (3 years)

- Accumulated 5,000+ hours of hands-on downstream experience across ProA, CEX, AEX, HIC, chromatography, viral inactivation, viral filtration, TFF, UF/DF, and final fill operations.
- Supported 4 successful new product introductions (NPIs), actively contributing to tech transfer, critical operations, issue resolution, and process optimization.
- Participated in C&Q of TFF and ProA skids for major capacity expansion projects.
- Delivered $3,100,000 in annual cost savings by leading a buffer batching optimization initiative involving datamining, process analysis, and cross-functional collaboration.

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- Certified SME trainer for 35 downstream operations; trained and mentored 5 new operators.
- Developed Smartsheet dashboards to standardize production turnover, reducing administrative burden and improving shift-to-shift communication.
- Built Tableau visualizations for deviation trends, record closure metrics, and scrap analysis; designed EBR closure tracker that reduced average closure time by 39%.
- Cross-trained by completing two 1-month temporary work assignments in processing engineering.
- Supported process engineering projects including test plan execution, C&Q, and NPI readiness.
- Resolved critical punch-list items using manufacturing insight and process knowledge.
- Led engineering improvement projects generating $122K in realized site cost savings.

Associate I, Manufacturing Solution Prep | Jul 2021 - Sep 2021 (3 months)

- Gained core experience in MES, DeltaV, LIMS, SOP management, and cGMP fundamentals.
- Supported commercial-scale single-use solution prep for cGMP manufacturing operations.

Millstone Medical Outsourcing - Fall River, MA (3 months)

Engineering Intern | Jun 2020 - Aug 2020

- Designed and tested custom PCBs featuring microcontroller and MOSFET-based control for high-voltage cleanroom airflow systems.

CORE SKILLS:

Bioprocessing: Upstream Cell Culture, Protein Purification, Chromatography (ProA, CEX, AEX, HIC), Viral Filtration, Depth Filtration, Tangential flow filtration, ultrafiltration/diafiltration, Single-Use Systems
Operations: cGMP Compliance, CAPA, Deviation Investigation, Root Cause Analysis, Lean Six Sigma
Software: DeltaV, OSI PI, SIMCA, Spotfire, Tableau, Power BI, Smartsheet, MES, Veeva, TrackWise
Leadership: SME Trainer, Cross-Functional Collaboration, Project Management, Process Optimization
Digital & Analytics: Data Visualization, Automation Tools, Leadership.

EDUCATION:

B.S., Chemical Engineering - University of Rhode Island, May 2021
Medical Lab Science, Biotechnology Specialty - University of Rhode Island, May 2016

CERTIFICATIONS:

Lean Six Sigma Yellow Belt - Amgen, 2024
Advanced Chromatography - URI PDI, 2024
Cell Harvest - URI PDI, 2024
Advanced Filtration - URI PDI, 2023
Advanced Cell Culture - URI PDI, 2023