Jayce Rowe

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SUMMARY

Engineering leader with 14 years supporting **regulated manufacturing**, biologics **sterile fill** operations, capital programs, and technical governance. Leads aseptic processing design, **contamination control strategy**, barrier technology, **equipment and facility interfaces**, GMP readiness, validation integration, and CQV activities across complex manufacturing environments. Guides quality, EHS, operations, MS&T, validation teams, suppliers, and engineering partners through technical decisions, risk resolution, qualification, and startup. Experience includes engineering standards, governance for capital programs, facility upgrades, capacity expansion, lifecycle planning, technology deployment, cleanroom systems, sterile equipment, and manufacturing reliability. Builds trust through clear reviews, practical risk management, and thoughtful mentoring. Brings a steady, collaborative approach that connects engineering decisions with compliance, operational readiness, patient focused quality, and reliable production outcomes.

EXPERIENCE

Senior Engineering Manager, Sterile Manufacturing

March 2021 - Present

Evergreen BioManufacturing

Durham, NC

Leads sterile manufacturing engineering initiatives for biologics fill finish upgrades, technology improvements, equipment interfaces, GMP readiness, qualification, startup, lifecycle planning, and technical team development.

- Led **aseptic processing** reviews for facility upgrades, clarifying equipment interfaces before startup activities.
- Established **contamination control** practices that strengthened **GMP readiness** across sterile manufacturing improvement programs.
- Coordinated quality, validation, operations, suppliers, and **engineering partners** through qualification and startup decisions.
- Mentored engineers on regulated manufacturing documentation, technical judgment, and practical project execution.
- Evaluated lifecycle requirements and **operational impacts**, informing capital planning decisions for **facility investments**.
- Guided risk reviews for technology improvements, helping teams resolve issues before production readiness milestones.

Engineering Manager, Sterile Systems

June 2017 - February 2021

Pinnacle Pharmaceutical Systems

Boston, MA

Managed engineering programs for cleanroom systems, sterile equipment, facility modifications, validation planning, vendor reviews, reliability improvements, and manufacturing issue resolution in regulated production environments.

- Managed cleanroom and sterile equipment projects that improved reliability across regulated production environments.
- Provided technical input for **qualification planning**, strengthening **validation** readiness before manufacturing implementation.
- Reviewed vendor documentation and **equipment proposals** against regulated production requirements and lifecycle needs.
- Standardized technical review workflows, giving **engineering** teams clearer decisions and faster issue escalation.
- Partnered with manufacturing teams to resolve process and equipment issues affecting production continuity.
- Guided **facility modifications** and **maintenance strategies** through practical engineering and operational assessments.

PROJECTS

Biologics Fill Finish Readiness Program 2024

A late readiness review surfaced competing equipment and validation concerns. Coordinated engineering inputs across facility interfaces, GMP readiness, qualification planning, and startup preparation, creating a clearer path for sterile manufacturing execution.

Contamination Control Governance Framework 2022

A recurring review question revealed inconsistent contamination control decisions. Built a practical governance approach connecting aseptic processing, cleanroom conditions, equipment interfaces, and cross functional risk discussions.

LEADERSHIP & AWARDS

- Recognized by engineering leadership for sustained contributions to biologics sterile manufacturing readiness and technical governance.
- Selected to mentor engineers supporting regulated manufacturing projects, documentation quality, and technical decision making.
- Earned cross functional recognition for constructive risk resolution during qualification and startup activities.

EDUCATION

Bachelor's Degree in Chemical Engineering

2012

North Carolina State University GPA: 4.0

Raleigh, NC

Coursework: *Chemical process design, Bioprocess engineering, Manufacturing systems, Process safety*

CERTIFICATIONS

- Certified Pharmaceutical GMP Professional 2024
- GMP Readiness and Validation Integration 2024

TECHNICAL SKILLS

- **Sterile Manufacturing:** Sterile fill finish, Aseptic processing, Sterile filtration
- **Barrier Technologies:** Isolators, RABS, Barrier systems
- **GMP Standards:** GMP, EU GMP Annex 1, GMP readiness
- **Cleanroom Systems:** Cleanrooms, Classified areas, Environmental monitoring
- **Validation Delivery:** CQV, Qualification planning, Validation integration
- **Contamination Control:** Contamination control strategy, Aseptic controls, Microbial control
- **Facility Engineering:** Facility interfaces, Facility modifications, Manufacturing facilities
- **Capital Programs:** Capital projects, Capacity expansion, Lifecycle improvements
- **Engineering Governance:** Engineering standards, Technical governance, Design reviews
- **Risk Management:** Technical risk reviews, Risk assessment, Issue resolution
- **Equipment Systems:** Sterile equipment, Equipment interfaces, Equipment proposals
- **Project Readiness:** GMP readiness, Startup readiness, Operational readiness

SKILLS

- Sterile Fill Finish
- GMP
- EU GMP Annex 1
- Aseptic Processing
- CQV
- Risk Management
- Isolators
- RABS
- Cleanroom Environments
- Sterile Filtration
- Environmental Monitoring
- GMP Readiness
- Validation Integration
- Capital Projects
- Technical Leadership

PROFESSIONAL AFFILIATIONS

- Professional participation in pharmaceutical engineering discussions focused on GMP readiness, sterile manufacturing, and validation integration.
- Collaborates with quality, EHS, operations, MS&T, validation teams, suppliers, and engineering partners on regulated delivery.

LANGUAGES

- English (Native)
- Spanish (Intermediate)

ADDITIONAL INFORMATION

Work Status : Authorized to work in United States. No sponsorship required.

REFERENCES

AVAILABLE ON REQUEST