

Miriam Joshi

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SUMMARY

Associate Engineer with four years of progressive experience supporting regulated **biopharmaceutical manufacturing**, process equipment, clean utilities, maintenance, and reliability programs. Bachelor's trained chemical engineer with hands on experience across **Mammalian Cell Culture**, Protein Purification, CIP, SIP, Production Services, and non GMP utility systems. Diagnoses field equipment and control issues through trend review, instrument history, maintenance records, and operator observations, then coordinates practical corrective action. Experienced with Maximo asset records, job plans, spare parts, safety information, preventive maintenance, **condition based maintenance**, deviation investigations, commissioning, and qualification support. Collaborates with Manufacturing, Quality Assurance, Validation, **Process Engineering**, Maintenance, and Utilities teams while communicating risks, findings, and proposed resolutions clearly. Supports startup, shutdown, off hours operations, and regulated documentation with steady attention to safety, quality, schedule, and reliability.

EXPERIENCE

Associate Engineer, Biopharmaceutical Manufacturing

July 2024 - Present

Northstar Bioprocess Solutions

Madison, Wisconsin

Supports commercial biologics operations through daily engineering coverage for cell culture, purification, CIP, SIP, and clean utility systems. Owns field troubleshooting, asset data quality, reliability reviews, deviation work, startup support, and qualification documentation while coordinating technical decisions with senior engineers and cross functional partners.

- Supported cell culture, purification, **CIP**, SIP, and clean utility equipment during commercial **manufacturing operations**.
- Diagnosed skid pressure instability using control trends, instrument history, and maintenance records, stabilizing performance before campaign start.
- Updated Maximo hierarchies, job plans, **spare parts**, safety details, and **preventive maintenance** tasks for process assets.
- Reviewed vibration, temperature, and work order history, adding condition based review points for rotating equipment.
- Supported design reviews, construction walkdowns, startup, commissioning, and qualification for modified clean utility distribution systems.
- Led scoped **deviation investigations**, documenting evidence, conclusions, risks, and proposed actions for **Quality Assurance** and Validation.

Engineering Associate, Biopharmaceutical Manufacturing

October 2022 - June 2024

Lakeview BioManufacturing

Milwaukee, Wisconsin

Supported process and **reliability engineering** across upstream and downstream manufacturing, Production Services, non GMP Utilities, and controlled bioprocess systems. Worked with technicians, automation partners, Manufacturing, Quality Assurance, Validation, Process Engineering, and Utilities teams on troubleshooting, maintenance planning, commissioning, qualification, and shutdown readiness.

- Supported upstream and downstream equipment across **Production Services**, **non GMP Utilities**, and controlled bioprocess systems.
- Investigated equipment alarms with technicians and automation partners, isolating instrumentation and mechanical causes through trend review.
- Prepared **maintenance data** summaries and recommendations, helping lead engineers prioritize shutdown work against production schedules.
- Revised preventive maintenance tasks and spare parts information after equipment history reviews, clarifying planner requirements.
- Contributed to **commissioning** and qualification through walkdowns, punch list follow up, turnover records, and protocol support.
- Coordinated issue resolution across Manufacturing, Quality Assurance, Validation, Utilities, and **Process Engineering** partners.

PROJECTS

Clean Utility Distribution Modification 📅 2024

Supported a modified clean utility distribution system from design review through walkdowns, startup, commissioning, and qualification documentation. Field coordination kept technical issues visible and supported controlled handoff into operations.

Rotating Equipment Reliability Review 📅 2023

Reviewed vibration, temperature, and work order history for rotating assets, then helped add condition based review points. Maintenance teams gained clearer timing for intervention during planned operating windows.

LEADERSHIP & AWARDS

- Recognized by engineering and maintenance peers for clear field troubleshooting and practical issue resolution during manufacturing support.
- Selected to lead scoped deviation investigations involving abnormal equipment conditions, evidence review, technical conclusions, and partner communication.

EDUCATION

Bachelor's Degree in Chemical Engineering

2022

University of Wisconsin Madison GPA: 0

Madison, Wisconsin

Coursework: Process design, thermodynamics, fluid mechanics, biochemical engineering

CERTIFICATIONS

- Engineer in Training (EIT), Wisconsin 📅 2022
- Good Manufacturing Practice Training 📅 2022

TECHNICAL SKILLS

- **Bioprocess Systems:** Mammalian Cell Culture, Protein Purification, Production Services
- **Utility Systems:** Clean Utilities, CIP, SIP, non GMP Utilities
- **Asset Management:** Maximo, equipment hierarchies, asset records
- **Maintenance Planning:** Job plans, preventive maintenance, spare parts
- **Reliability Methods:** Condition based maintenance, predictive maintenance, work order history
- **Data Analysis:** Control trends, instrument history, vibration data
- **Project Delivery:** Design reviews, construction walkdowns, startup
- **Commissioning Support:** Commissioning, turnover documentation, punch lists
- **Qualification Support:** Qualification protocols, qualification documentation, validated conditions
- **Quality Systems:** Deviation investigations, abnormal conditions, technical conclusions
- **Manufacturing Operations:** Commercial manufacturing, clinical manufacturing, shutdown execution
- **Technical Collaboration:** Manufacturing, Quality Assurance, Validation

SKILLS

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|---------------------------|-------------------------------|----------------------------|-----------------|
| • Mammalian Cell Culture | • Reliability Engineering | • Predictive Maintenance | • Qualification |
| • Protein Purification | • Maximo | • Data Analytics | • CIP |
| • Clean Utilities | • Preventive Maintenance | • Deviation Investigations | • SIP |
| • Process Troubleshooting | • Condition Based Maintenance | • Commissioning | |

PROFESSIONAL AFFILIATIONS

- Cross Functional Biopharmaceutical Engineering Collaboration with Manufacturing, Quality Assurance, Validation, Maintenance, and Utilities teams.
- Wisconsin Engineering Community participation through Engineer in Training development and regulated manufacturing practice.

LANGUAGES

- English (Native)
- Hindi (Proficient)

ADDITIONAL INFORMATION

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

REFERENCES

AVAILABLE ON REQUEST