

Autumn French

Quality Systems Analyst

☎ (732) 555-6418 ✉ autumn.french@example.com

🌐 linkedin.com/example/autumnfrench 📍 New Brunswick, NJ 08901

STRENGTHS

- 📁 **Document Control**
Managed review, approval, issuance, and retirement records, and became a dependable resource when teams needed status clarity.
- ✅ **Audit Readiness**
Prepared traceable evidence for audit requests, and careful follow through helped process owners respond with confidence.
- ♥ **Data Integrity**
Spotted documentation gaps in records and workflows, then routed concerns clearly so corrective action could begin.
- 🔍 **Investigation Support**
Built clear event chronologies from source records, giving reviewers a practical story they could verify and close.
- 👥 **Cross Functional Coordination**
Connected manufacturing, quality, and technical partners around approved actions, keeping work moving when priorities shifted.

SKILLS

cGMP Data Integrity
Change Control Audit readiness
Document control
Quality Assurance Quality Control
Investigations
Records management
Risk escalation SOP revision
Project closure
Process optimization
Time management
Written communication

SUMMARY

Quality Systems Analyst with three years supporting cGMP regulated manufacturing through document control, records management, Data Integrity, Change Control, investigations, audit readiness, and process improvement. Administers **controlled document lifecycles**, revises **Standard Operating Procedures**, maintains traceable quality records, and supports site **quality systems** in fast paced production settings. Serves as a **quality system superuser**, resolves workflow questions, identifies potential quality risks, and escalates material concerns with sound judgment. Coordinates actions across manufacturing, quality, and technical stakeholders, helping align site procedures with broader organizational requirements. Brings a biology background, ASQ quality training, clear written and verbal communication, dependable follow through, and practical time management. Ready to contribute thoughtful quality system execution, reliable documentation, and steady operational support within a regulated manufacturing environment.

EXPERIENCE

Quality Systems Analyst

Meridian Biologics Manufacturing 📅 July 2025 - Present 📍 New Brunswick, New Jersey

Supports manufacturing and quality functions through controlled documentation, site quality system administration, audit preparation, Change Control, **Data Integrity** review, and improvement assignments. Serves as a **site superuser** while coordinating closure activities across production, quality, and technical teams.

- Administered **controlled document lifecycles** through review, approval, issuance, periodic review, and retirement under cGMP controls.
- Resolved quality system workflow questions by correcting metadata practices and escalating system or compliance concerns.
- Retrieved traceable records for audits, coordinated process owner responses, and tracked assigned actions through closure.
- Reviewed **Change Control** packages, confirming impact assessments, implementation evidence, and closure documentation before quality review.
- Evaluated **Data Integrity risks** in records and workflows, escalating potential compliance concerns for corrective follow up.
- Led **quality improvement** assignments that aligned site procedures with broader quality expectations without disrupting production schedules.

Quality Assurance Associate

Garden State Life Sciences 📅 October 2023 - June 2025 📍 Somerset, New Jersey

Executed **Quality Assurance** activities for cGMP manufacturing, with responsibility for batch records, controlled procedures, investigations, Change Control, Data Integrity, and **audit support**. Partnered with manufacturing personnel and subject matter experts to convert approved changes into usable, compliant documentation.

- Reviewed batch records and **controlled documents** for completeness, consistency, and adherence to approved procedures.
- Drafted **Standard Operating Procedures** with subject matter experts, translating approved process changes into clear instructions.
- Assembled investigation records, documented event chronology, and tracked approved actions through documented completion.
- Supported equipment, process, and documentation Change Controls by maintaining evidence and confirming implementation steps.
- Identified documentation gaps under **Data Integrity** principles and routed discrepancies for timely correction.
- Balanced audit requests, document revisions, **investigations**, and routine quality work within a high paced manufacturing setting.

LANGUAGES



MY CAREER



- Quality Systems Analyst at Meridian Biologics Manufacturing (1.2 Years)
- Quality Assurance Associate at Garden State Life Sciences (1.7 Years)

PROJECTS

- Site Document Lifecycle Optimization** 📅 2025
- Improved document workflow practices across manufacturing and quality teams by standardizing review routing, metadata checks, approval evidence, and retirement records. Work supported clearer ownership, stronger traceability, and smoother audit preparation.
- Manufacturing Investigation Records Review** 📅 2024
- Supported investigation documentation by organizing event records, clarifying chronology, coordinating factual input, and tracking approved actions. Work helped quality reviewers locate complete evidence and maintain reliable closure records.

LEADERSHIP & AWARDS

- ASQ Certified Quality Improvement Associate, earned 2025, recognizing applied quality improvement knowledge.
- Quality Systems Improvement Recognition, received 2025 for dependable document control and closure support.
- Manufacturing Quality Contribution Award, received 2024 for clear investigation and procedure documentation.

EDUCATION

Bachelor's Degree in Biology
Rutgers University 🎓 GPA: 0 📅 2023 📍 New Brunswick, New Jersey
Coursework: Cell biology, microbiology, genetics, biochemistry

CERTIFICATIONS

- ASQ Certified Quality Improvement Associate 📅 2025
- cGMP for Manufacturing Professionals, Rutgers Continuing Studies 📅 2024

TECHNICAL SKILLS

- **Quality Systems:** Document control, Records management, Quality Assurance
- **Regulated Manufacturing:** cGMP, cGxP, Manufacturing quality
- **Data Integrity:** ALCOA principles, Traceability, Record review
- **Controlled Documents:** Standard Operating Procedures, Work instructions, Periodic review
- **Change Control:** Impact assessment, Implementation evidence, Closure packages
- **Audit Support:** Audit readiness, Evidence retrieval, Response tracking
- **Investigation Support:** Event chronology, Root cause review, Corrective actions
- **Quality Risk:** Risk identification, Escalation, Compliance review
- **Quality Records:** Batch records, Controlled records, Approval records
- **Process Improvement:** Workflow optimization, Procedure alignment, Project closure
- **Communication Tools:** Written communication, Verbal communication, Stakeholder coordination
- **Manufacturing Operations:** Production support, Operational continuity, Off shift support

PROFESSIONAL AFFILIATIONS

- ASQ, quality improvement professional affiliation supporting continued development in quality systems.
- Rutgers Life Sciences Community, biology alumni connection grounded in regulated science and manufacturing interests.

ADDITIONAL INFORMATION

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

REFERENCES

AVAILABLE ON REQUEST