

Haven Warren

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SUMMARY

Quality specialist with four years of experience in regulated biological collection and laboratory support environments. Performs final **quality assurance** review, **shipment release**, record assessment, investigations, corrective action follow up, training control, internal audits, and audit readiness activities. Applies cGMP, FDA, CLIA, COLA, OSHA, HSE, SOP, **Quality Management System**, data integrity, and confidentiality requirements in daily decisions. Maintains **Learning Management System** records, schedules new hire and recurring training, verifies controlled materials, and tracks qualification gaps. Uses TrackWise for nonconformity investigations, corrective action documentation, effectiveness checks, and closure. Communicates clearly with operations and quality leaders while resolving deficiencies, protecting donor information, supporting customer service, and keeping regulated processes inspection ready.

EXPERIENCE

Quality Specialist

May 2024 - Present

Sierra Biologics Collection Center

Sacramento, CA

Owns quality oversight for regulated biological product collection and shipment operations. Reviews records, releases shipments, manages TrackWise investigations, maintains training data, conducts audits, and supports operational decisions that protect compliance, donors, personnel, and customers.

- Released biological product shipments after reviewing records against **customer specifications** and quality requirements.
- Investigated record deficiencies and documented **corrective action** needs using controlled quality system workflows.
- Managed TrackWise **investigations** through root cause review, corrective action, effectiveness checks, and closure.
- Maintained **Learning Management System** data for new hire, annual, and **remedial training** requirements.
- Conducted **internal audits** against SOP, cGMP, FDA, OSHA, CLIA, and COLA requirements.
- Prepared objective evidence for audits while protecting confidential donor and personnel information.

Quality and Training Coordinator

March 2023 - April 2024

Pacific Donor Health Services

Elk Grove, CA

Coordinated regulated training and quality documentation across donor service operations. Maintained Learning Management System accuracy, translated recurring findings into retraining, supported investigations, and helped supervisors sustain compliant service delivery.

- Coordinated onboarding, annual qualification, and **remedial training** with current controlled materials.
- Administered **Learning Management System** records and prepared compliance reports for quality **leadership**.
- Reviewed quality **records**, identified **nonconformities**, and organized evidence for corrective action investigations.
- Converted recurring process findings into targeted retraining with center supervisors.
- Facilitated quality and safety discussions covering audit findings, HSE expectations, and improvement actions.
- Managed overlapping training, documentation, and follow up deadlines while protecting **confidentiality**.

Quality Operations Assistant

October 2022 - February 2023

Capital Valley Clinical Services

Davis, CA

Supported quality operations within a regulated clinical services environment. Reviewed controlled records, logged deviations, maintained employee qualification files, assembled audit evidence, and applied documented procedures supporting safe, consistent operations.

- Reviewed controlled **records** for required fields, signatures, dates, and supporting documentation before approval.
- Logged process deviations with supporting facts for investigation and **corrective action** documentation.
- Maintained employee training files and completion trackers, then escalated qualification gaps.
- Assembled internal audit records and traced document versions for objective evidence.
- Applied **OSHA**, **HSE**, confidentiality, and controlled document practices during daily operations.
- Built practical skill with **Quality Management System** workflows and root cause **problem solving**.

PROJECTS

Training Data Integrity Review 📅 2024

Reviewed Learning Management System records, identified qualification gaps, and organized follow up supporting accurate training status reporting.

Audit Evidence Readiness Program 📅 2023

Organized controlled records, document versions, and objective evidence into a clearer audit support process for quality leadership.

LEADERSHIP & AWARDS

- Recognized by quality leadership for dependable TrackWise investigation follow up and clear corrective action documentation.

- Selected to support audit readiness through organized evidence review, confidentiality practices, and timely quality communication.

EDUCATION

Bachelor of Science in Biological Sciences
California State University, Sacramento GPA: 4.0
Coursework: Biology, Microbiology, Immunology, Laboratory Methods

2022
Sacramento, CA

CERTIFICATIONS

- Good Manufacturing Practice Fundamentals Certificate 📅 2023
- OSHA General Industry Safety Certificate 📅 2024

TECHNICAL SKILLS

- **Quality Systems:** Quality Management Systems, SOPs, TrackWise
- **Regulatory Compliance:** cGMP, FDA, CLIA
- **Laboratory Standards:** COLA, biological collection, laboratory support
- **Safety Standards:** OSHA, HSE, workplace safety
- **Corrective Actions:** CAPA, root cause analysis, effectiveness checks
- **Audit Activities:** Internal audits, external audits, audit evidence
- **Training Systems:** Learning Management Systems, new hire training, remedial training
- **Documentation Control:** Controlled records, document versions, data integrity
- **Shipment Quality:** Final QA review, shipment release, customer specifications
- **Investigation Records:** Nonconformity investigations, deviations, TrackWise reports

SKILLS

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|------------------------------|--------|-------------------|-------------------------------|
| • Quality Assurance | • CLIA | • SOP Compliance | • Shipment QA Release |
| • Quality Management Systems | • COLA | • TrackWise | • Learning Management Systems |
| • cGMP | • OSHA | • CAPA | • Data Integrity |
| • FDA Compliance | • HSE | • Internal Audits | |

PROFESSIONAL AFFILIATIONS

- Quality operations contributor supporting regulated biological collection and laboratory service standards.
- Training coordination partner for supervisors managing qualification, retraining, and compliance documentation.

LANGUAGES

- English (Native)
- Spanish (Intermediate)

ADDITIONAL INFORMATION

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

REFERENCES

AVAILABLE ON REQUEST