

VINCETTA M. SHORTINO

vinni2758@gmail.com

816-547-4241

Professional Skills

Quality Systems for Medical Device Industry, FDA Regulation adherence, ISO 13485, EU MDR / MDD, and GMP Guidelines, Project Management, Product Recalls, Field Actions, Post-Market Surveillance (PMS / PSUR), Complaint Handling, eMDR and 806 Reporting, Internal and External Audit Support, SOP Development, Process Improvement, Global Cross-functional Collaboration, Data Analysis, PowerPoint Presentations. Applications such as; SharePoint, Windchill, PowerBI, Microsoft Office Suite, TEAMS and SAP. Participated in Kaizen for process improvement. Completed Business Excellence Class and a Project Management course for continuous learning and goal achievement. Medical Device Training – Rika Plasma Donation System.

Relevant Work Experience

TERUMO BLOOD CELL TECHNOLOGIES – Lakewood, CO -Field Action Specialist – Mar 2018 – Present

- Lead end-to-end product field action and recall management, including safety alerts, corrections, and regulatory reporting
- Partner with SMEs, Regulatory Affairs, Medical Safety, and Quality leadership to conduct investigations, risk assessments, and CAPA initiation
- Coordinate /collaborate cross-functional stakeholders across global teams to ensure timely execution of compliance activities
- Prepare and submit FDA, Health Canada, and support EU regulatory filings, including follow-up reports and compliance tracking
- Author and review customer-facing communications related to product safety and recall activity
- Perform quality review of recall documentation to ensure accuracy and regulatory compliance
- Generate and analyze KPI metrics and management review reports using PowerBI and internal systems
- Extract and manage product distribution data to support traceability and customer notification processes
- Contribute to process improvement initiatives (Kaizen), identify pain points, provide gap analysis, revise SOPs/WINS and forms
- Support internal and external audits, ensure readiness and document preparation for successful outcomes
- Complete Post-Market Surveillance Reports (PSURs) for field action activities to track product performance through lifecycle

DOHMEN LIFE SCIENCE SERVICES - Wheat Ridge, CO - Quality Assurance Specialist – Jan 2011 – Feb 2018

- Led QA activities for medical device clients, ensuring FDA compliance and regulatory reporting accuracy
- Managed complaint handling and investigation workflows, including data collection, analysis, and documentation
- Submitted eMDR reports and adverse event filings to the FDA on behalf of multiple clients
- Served as team lead on remediation projects, improving compliance processes and documentation quality
- Maintained and updated quality systems databases to ensure data integrity and audit readiness

CONSULTANT (KELLY SCIENTIFIC) – COVIDIAN - Boulder, CO - Regulatory Affairs Associate – 06/10 - 01/11

- Reported to Manager of Regulatory Affairs
- Performed QC review of all product IFUs, manuals, and packaging labels for new template design in re-branding project

TALECRIS PLASMA RESOURCES - Provo, UT – Quality Supervisor - 10/08 - 05/10

- Traveled to four centers within the company to assist in remediations for FDA audit preps
- Worked with team members to review donor files and logbooks to identify gaps
- Assisted with internal audit preparation for FDA audits
- Worked closely with nursing staff and employees to screen donors for eligibility
- Received soft goods and supplies, completed and reviewed inventory documentation
- Performed shipment of all frozen plasma product and signed off on paperwork
- Performed daily calibration checks for all equipment used in the process of plasma donation
- Performed QC review of all donor files post donation to ensure accuracy on all documented content and GMP
- Maintained a 2% error rate within the facility on all documentation

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BIOLIFE PLASMA SERVICES – Independence, MO-Center Supervisor - 01/07 - 02/08

- Supervised 25+ employees and managed donor floor and employees
- Trained in all areas of operation: Donor Eligibility/Screening - Vitals – Phlebotomy - Lab
- Received soft goods and supplies, completed and reviewed inventory documentation
- Handled all donor and employee complaints/concerns
- Assisted in process improvement of donor intake to increase efficiency
- Performed daily calibration checks for all equipment used in the process of plasma donation
- QC Review of all donor files post donation to ensure accuracy on all documented content
- Assisted in employee interviews, performance reviews, write ups and mediations
- Achieved company goal KPIs and the reduction of employee deviations
- Opened/Closed facility

Education – Bachelor of Fine Arts, Kansas City Art Institute — Graduated May 2003 GPA: 3.8

Certified Massage Therapist – Colorado School of Healing Arts – Graduated May 1992

(Massage Therapy Instructor – Heritage School of Massage Therapy - MT Level 1 – Anatomy)