ADRIENNE M. GOSSMAN, MHA, CQA (ASQ)

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Professional Summary:

Amply experienced, compliance oriented, and results driven quality assurance professional with a diverse skill set, including strong communication skills, leadership, and project management, seeking a position of responsibility with a progressive organization in the healthcare or biotech industries

Professional Qualifications:

- Familiar with Pharmacovigilance and Human Resource Management Practices
- Knowledge of AABB Standards, CMS guidelines, Food and Drug Administration (FDA), European Union (EU), International Organization for Standardization (ISO), clinical research regulations for Investigative New Drugs (INDs), and NCQA and Joint Commission core measures for accreditation
- Extensive experience with Good Manufacturing Practices (GMPs), Good Laboratory Practices (GLPs), Good Clinical Practices (GCPs), and Good Tissue Practices (GTPs)
- Solid understanding of Clinical Laboratory Improvement Amendments (CLIA)
- Skilled in root cause and data analysis and Failure Mode and Effects Analysis (FMEA) and statistical process control (SPC)
- Trained in Six Sigma and LEAN Principles
- Knowledge of Occupational Safety and Health Administration (OSHA) requirements, including blood borne pathogens
- Familiar with medical terminology, electronic medical records, and the Health Insurance Portability and Accountability Act (HIPAA)
- Trained in revenue cycle analysis, including balance sheets and profits/losses

Professional Experience

August 2016- Present
Sr Quality Assurance Auditor, University of Miami, Life Alliance, Dept of Surgery
Miami, FL

- Coordinate, host, and respond to external inspections (CMS, UNOS, AOPO, FDA)
- Perform internal audits and supplier audits to ensure compliance with regulations and control points
- Review organ donor records to ensure completeness, timeliness, and accuracy
  - Response time
  - Documentation
  - Equipment Maintenance
  - Patient serology testing, biopsies, and cultures
  - Organ Donation Process
- Analyze data points
- Review processes to improve efficiency, reduce waste, & identify opportunities for improvement
- Track & trend data; Prepare and present data reports to organizational leadership
- Classify potential organ donor referrals for national data reporting
- Participate in cross-functional root cause analyses
- Collaborate with operations and medical staff on process improvement initiatives
- Develop and review organizational procedures
- Team Lead for the Internal Compliance Committee
- Member, Strategic Planning Committee

September 2014 – August 2016
Quality Assurance Manager, KEDPlasma, LLC
Mobile, AL

- Manage the Quality Management System (QMS) throughout the facility to ensure regulatory compliance and customer satisfaction
- Ensure equipment calibrations, validations, and maintenance (IQ, OQ, PQ) are accurate & timely for optimal operation
- Evaluate product integrity and client eligibility through review of client physical exam documentation and plasma collection records
- Prevent unsuitable product release with oversight of client test results and disposition of plasma products

Skills Summary

- Staff & Operations Management
- Problem Solving & Performance Improvement
- Gap Analysis
- Procedure & Training Development & Implementation
- Procedure & Software Usability Testing
- Microsoft Office: Word, Excel, PowerPoint, Visio, Access
- QMS Software: QPulse, eProgesa, DMS, Master Control, SmartSolve, NextGen, SAP, MiniTab, Tableau
- Relationship Building
- Written/Oral Communication
- Training & Motivation
- Detail Oriented

Education:

Franklin University, Columbus, OH
Master of Healthcare Administration

The Ohio State University, Columbus, OH
Bachelor of Arts, Biological Sciences

Certifications:

Certified Quality Auditor (CQA),
American Society for Quality (ASQ)

Awards

Commitment to Compliance, 2008

Red Ribbon for Quality and Regulatory Excellence, 2012

Volunteerism

The Ohio State University Wexner Medical Center Nursery (boarder babies)

Nationwide Children's Hospital- Child Life Services (patient comfort)

American Society for Quality (ASQ) - Section 801 Conference Committee

Columbus Blue Jackets Foundation- Fundraising

Professional Experience - Cont'd

- Review & approve documentation for distribution of suitable injectable plasma products
- Manage implementation of regulated documents to ensure current versions are utilized
- Review employee training against corporate training matrix to ensure completeness
- Perform staff observations to ensure compliance with procedures and regulations
- Monitor supply inventory for "first in, first out" (FIFO); ensure segregation and appropriate management of defective supplies
- Coordinate, host, and respond to internal and external inspections
- Submit Biological Product Deviation Reports to the Center for Biologics Evaluation and Research (CBER)
- Develop and implement corrective and preventative actions (CAPA)
- Collaborate with the facility medical director on process improvement & patient safety initiatives
- Address compliance questions from medical staff
- Review and address:
  - Adverse events
  - Key performance indicators for compliance
  - Production and budget metrics
- Maintain FDA licensure and CLIA and PPTA certifications
- Manage employee schedules, timecards, and performance reviews; Develop skills of personnel through coaching and mentorship

August 2007- September 2014
Quality Assurance Associate III, American Red Cross Biomedical Services,
Columbus, OH

- Perform the monthly analysis of key performance indicators for presentation to the CEO
- Function as QA lead for meetings/projects to identify undesirable trends, opportunities for standardization and process improvement, and monitor change for effectiveness
- Investigate risk & determine disposition of non-conforming blood products
- Perform internal audits and coordinate, host and respond to external inspections
- Maintain FDA licensure and AABB accreditations
- Review inspection reports received by other Red Cross facilities to determine risk and take appropriate action in local facilities
- Oversee high-risk deviations: participate in root cause analysis meetings to develop or approve cost-effective Corrective Action Plans (CAPs)
- Oversee communication to vendors for defective supplies
- Develop and review new procedures for blood manufacturing
- Develop and execute usability test plans for new procedures and training documents
- Communicate procedural changes for new processes and software to the field
- Notify FDA regarding product recall, process suspensions, and non-compliant staff
- Review and approve incoming supplies and promotional literature
- Train/mentor new Quality Assurance staff on daily responsibilities
- Educate new Red Cross personnel on current GMPs, quality principles, and regulatory requirements
- QA Director Designee; Served as Interim Quality Director in May 2013

November 2006- August 2007
Sr. Microbiology Technician, Smiths Medical, ASD
Dublin, OH

- Prepare and distribute certificates of conformance to customers
- Develop microbiology department documents
- Review Device History Records for completeness & accuracy
- Management of daily laboratory operations
- Maintain daily communication with contract sterilizers
- Conduct supplier audits at contract sterilizers
- Prepare products for Limulus Amebocyte Lysate (LAL) testing
- Review & approve:
  - Contract sterilization reports based on product specifications
  - In-house sterilization test results (LAL indicators)
  - Environmental testing results based on data analysis
- Interim Microbiology Manager, January-February 2007