Anastasiya Rylova

Contact

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Education

B.S., Information Technology Software Engineering
UNIVERSITY OF PHOENIX, DALLAS, TX (Jan 2016)

A.S., Liberal Arts and Applied Mathematics
BUTTLER COMMUNITY COLLEGE, WICHITA, KS (Jan 2010)

Additional Skills

- Thorough understanding of Current Good Manufacturing Practices (cGMP)
- CAPA management
- Process Improvement
- Quality Systems Implementation
- Regulatory Inspection Experience (European, FDA, etc.)
- Analysis and Problem Resolution Leadership and Coaching
- Effective Communication (written and verbal)
- Project Managment
- Technical Documentation

Profile

Over 15 years of experience working within the FDA and EMA regulated pharmaceutical industry, specializing in plasma-based services. Experience in hosting regulatory inspections, client and corporate audits, and conducting internal audits. Extensive background with manufacturing, analytical, problem-solving and facility qualification activities as well as various plasma collection equipment, Blood Establishment Computer systems (BECS), and software validation processes. Recognized on multiple occasions for outstanding performance and commitment to quality, clients, and exceptional teamwork.

Professional Experience

SOFTWARE VALIDATION SPECIALIST
GRIFOLS – Seattle, WA **MAR 2020 – Present**

- Demonstrated and supported continuous improvement and growth mindset.
- Established and implemented departmental policies, goals, objectives and procedures in conjunction with other departments and team members.
- Collaborated with departmental leaders to establish organizational goals, strategic plans and objectives.
- Mentored center staff and leadership teams on use of the new Blood Establishment Computer systems (BECS).
- Assisted with employee recruitment and interviews.
- Support centers with the audit process (audit preparation, post audit responses, assistance during the audit, etc.)
- Development and composition of the Standard Operation Procedures (SOPs), Center Notifications, and Corporate Directives.
- Resolved testing problems by modifying testing methods and revising test objectives and standards.
- Developed validation master plans, process flow diagrams, test cases and standard operating procedures.
- Conducted audits of validation or performance qualification processes to comply with regulatory requirements.
- Prepared detailed reports based on results of validation and qualification tests, compliance documentation and reviews of procedures and protocols.
- Analyzed validation test data to determine whether systems and processes had met validation criteria and to identify root causes of production problems.
- Recommended resolution of identified deviations from established product and process standards.
- Participated in internal and external training programs to maintain knowledge of validation principles, industry trends and novel technologies.
- Directed protocol creation and testing.

- Communicated with regulatory agencies regarding compliance documentation and validation results.
- Conducted validation and qualification tests of new and existing processes, equipment and software in accordance with internal protocols and external standards.
- Coordinated implementation and scheduling of validation testing with affected departments and personnel.
- Reviewed quality documentation necessary for regulatory submissions and inspections.

TRAVELING CENTER QUALITY MANAGER **NOV 2016 – MAR 2020**
GRIFOLS – Remote

- Instructed staff in quality control and analytical procedures.
- Analyzed quality process within the center and provided feedback to production management and staff.
- Reviewed and updated standard operating procedures.
- Identified quality problems and areas for improvement and recommended solutions.
- Communicated quality control information to all relevant organizational departments.
- Generated and maintained quality control operated budgets.
- Monitored performance of quality control systems to ensure effectiveness and efficiency.
- Collaborate with Center Managers to ensure product quality, donor suitability and donor safety.
- Direct and monitor processes and ensure that centers are compliant with all applicable state, federal, and company-designated regulations.
- Oversight of all aspects of internal and external audits including hosting, documentation, review of and preparation of the responses.
- Continuously assess, promote, and improve the effectiveness of the quality systems in the donor center through recognition of trends, investigation of failures in the procedure execution, conduct employee observation and review of center documents.
- Responsible for the personnel functions of the Quality Associates; including direction, assignment of work, hiring, development and training, disciplinary actions, termination, maintenance of all personnel records, management of work schedule and delegation/follow-up of tasks.
- Work in collaboration with the Center Manager to develop the staff's knowledge of their job functions and how their performance relates to the end product and patients.
- Recommended employees for promotion and performed corrective actions to reduce misconduct.

Quality Associate II **APR 2013 – NOV 2016**
GRIFOLS – Dallas, TX

- Independent level of quality inspection and control – responsible for center compliance with quality standards and regulations.
- Notified supervisors and other personnel of production problems.
- Recommended necessary corrective actions, based on inspection results.

- Monitored production operations and equipment to ensure conformance to specifications, making necessary process and assembly adjustments.
- Ensure that Standard Operating Procedures (SOPs) are properly interpreted, implemented in a timely fashion, and that the staff performs according to all SOPs.
- Continuously assess, promote, and improve the effectiveness of the quality systems in the donor center through recognition of trends, investigation of failures in the procedure execution, conduct employee observation and review of center documents.
- Document, investigate, and perform root cause analysis for deviations and customer complaints, specifically in how they relate to the safety of the donor and the quality of the product.
- Interpret and implement processes, regulations and SOPs for quality control and overall regulatory compliance, making independent decisions and modifications as required.
- Produced reports regarding nonconformance of products and processes, daily production quality, root cause analyses and quality trends.
- Set performance goals for staff members and helped teams meet important deadlines.
- Mentored employees in complex issue resolution and drafted scripts for addressing common challenges.

Phlebotomist **DEC 2011 – APR 2012**
GRIFOLS – Dallas, TX

- Trained personnel in phlebotomy techniques and laboratory processes.
- Collected whole blood samples at specific time intervals for tests.
- Drew blood from veins by vacuum tube, and butterfly venipuncture methods using appropriate collection procedures.
- Education of the donors on the plasma collection processes.
- Monitored donors during and after procedures to ensure health, safety, comfort and possible signs of adverse reactions.
- Calibrated and maintained plasma collection equipment.
- Reviewed donor vital signs and medical history to determine eligibility.

AREA SUPERVISOR **OCT 2007 – DEC 2011**
OCTAPHARMA PLASMA INC. – Wichita, KS

- Notified employees of policy and procedure changes to promote overall compliance.
- Supervisor of all areas of plasma donation center including medical screening, donor floor phlebotomy, and sample collection.
- Chosen as a subject matter expert to travel and train employees from 25 newly acquired centers.
- Assisted Quality in observation and documentation of deviations on the Donor Floor.
- Ensure that maintenance and repairs on all plasmapheresis machines are completed.
- Ordering of inventory.
- Supervised the medical screening and processing laboratory areas, including managing schedules and delegation of responsibility.

- Assisted in the hiring and training of management and operational staff members for newly acquired donor center facilities.
- Took newly hired staff through a rigorous training regimen in preparation for multiple internal audits to conclude with zero 483 FDA and successful AGES audits.
- Recognized as a designated trainer and utilized by the company to travel and train a multitude of individuals at both the center and corporate level.
- Measured vital signs and handled blood test results, meeting company and FDA regulated standards.
- Coordinated requirements by increasing or decreasing personnel and overtime to meet changing conditions.
- Delegated tasks to team members according to individual strengths.
- Resolved escalated complaints and answered questions regarding policies and procedures.

Center Supervisor **JAN 2007 – OCT2007**
ZLB Plasma Services

- Inspected work environment for health and safety hazards and reported findings to manager.
- Organized workflow tasks to prevent downtime and production gaps.
- Tracked company inventory and noted item shortages for future product orders.
- Coordinated employee schedules according to availability and approved shift changes.
- Communicated employee, customer and workplace needs to managers.
- Taught company procedures to new employees and increased progress by identifying areas of weakness.
- Conducted employee evaluations and documented overall progress.
- Drafted and monitored employee scheduling to support effective resource allocation.
- Trained employees in job-specific tasks and evaluated continuing education needs to improve team performance.
- Supervised direct reports and enforced adherence to established procedures and deadlines.
- Implemented and enforced corporate and departmental policies and service standards.
- Monitored daily operations and evaluated performance to proactively approach backlogs.

REFERENCES

References can be provided upon request.