SOFTWARECPR

MOLLY RAY

EXPERIENCE

- Prepared successful FDA premarket submissions for blood establishment computer software, software applications used in donor infectious disease testing instruments, hemodialysis machines, and extracorporeal blood circuit for hemodialysers.
- 4 years FDA experience as a CBER Consumer Safety Officer performing regulatory and scientific reviews of ~20 510(k) submissions for Blood Establishment Computer Software
- Developed the FDA CBER Draft Guidance for FDA Reviews: Premarket Notification Submissions for Automated Testing Instruments used in Blood Establishments and participated in the development of the CBER Reviewer Guidance for Premarket Notification Submissions for Blood Establishment Computer software.
- FDA CBER representative to the CDRH Specialty Task Group that evaluates voluntary software consensus standards for potential recognition by FDA
- Several FDA presentations including one to the FDA Blood Products Advisory Committee on device classification of blood establishment computer software
- FDA Compliance Officer for the Veterans Administration (VA) for blood establishment computer software development and the quality system.
- Deputy Project Manager for a joint VA/DoD project for the development of blood establishment computer software
- Senior Director for Biomedical Information Technology Quality and Regulatory Management for the ARC responsible for quality assurance activities for software development, submissions of 510(k)s, MDRs, establishment registration and device listing
- Functional Executive responsible for Continuous Process Improvements for the ARC IT department
- Conducted audits of potential suppliers for blood establishment computer software
- 23 years supervisory experience in blood establishments
- Responsible for converting two facilities from manual blood banking to computerized systems
- Director of centralized transfusion service for multiple hospitals including development of the Quality System.Prepared facilities for regulatory inspections by the State of Virginia, FDA, CAP, JCAHO, CLIA, and AABB

CREDENTIALS

- B.S. in General Science, Radford College, 1970
- B.S. in Medical Technology, Medical College of Virginia, 1973
- Specialty in Immunohematology, MCV, 1975
- Certified Software Quality Engineer, American Society of Quality
- Past AABB and CAP assessor of blood establishments for compliance with the AABB standards
- Author of book chapter on selection of blood establishment computer software published by AABB, *Information Technology in Transfusion Medicine*
- Special Contribution Award, Department of Veterans Affairs for contributions to the first Department of Defense (DoD) and VHA information sharing system
- Certificate of Appreciation, DoD, for providing training on the QSIT
- Time Off Award, CDRH, for participation in the Software Specialty Task Group
- Time Off Award, CBER, for professionalism in the execution of the 510(k) review process
- Scientific Achievement Award Regulatory Scientist, FDA, for executing a team-based product and regulatory review program for computer systems
- On-the-Spot Award, FDA, in recognition of work in review and policy development in a new regulatory area, software used in blood banking and for work done to reduce the number of overdue submissions
- Member of AABB, ASQ, and ASCP
- Outstanding Rating Certificate, VA, for making significant contribution to the mission of the Department of Veterans Affairs by substantially exceeding performance for the rating period
- Contribution Award, VA, for a unique contribution to the mission of the VA
- Three Suggestion Awards, Veterans Administration, in recognition of noteworthy contributions to the improvement of the operations resulting from adopted suggestions