SOFTWARECPR

SANDY HEDBERG

EXPERIENCE

Over 14 years of software quality assurance and regulatory affairs experience

5 years of clinical research, including protocol creation, monitoring and evaluation of data

Over 25 years of blood and plasma establishment experience

Software validation for medical device 510 (k) software submissions for blood establishment software and other medical devices containing software

Over 14 years experience in constructing FDA compliant quality systems for both start up and established companies

Successfully managed large projects including a major SOP rewrite project for a large corporation

CAPA experience including Complaint Handling, Medical Device (MDR) reporting, and root cause analysis

Constructed MDR program

Constructed quality systems training as it relates to blood establishment software

Software hazard analysis and risk management including conformance to standards

Compliance and quality assessments, including supplier audits

Constructed process validation program

Validation project management

Equipment calibration and validation for blood and plasma establishments

CREDENTIALS

- B.S. in medical technology with specialty in blood banking; MT(ASCP) SBB
- Developed first BECS 510(k) cleared by the FDA
- Speaker at AABB Annual Meeting
- Author or co-author on a number of Transfusion articles
- Former member of ABRA/PPTA Information Systems Committee
- Former member of PTAG (plasma technical advisory group) for ICCBBA
- Represented Information Data Management on Health Industry Manufacture's Association software task force