SOFTWARECPR

ANNETTE HILLRING

EXPERIENCE

- Over twenty years regulatory affairs and compliance experience in the medical and in vitro diagnostic devices industry
- Extensive experience in FDA regulatory submissions (510(k), PMA, IDE)
- Expert in software driven device submissions
- Expert in design control, complaint handling and MDR reporting
- Provided regulatory support and defined requirements for numerous new product development projects to facilitate compliance and effective submission strategies
- FDA Quality System Regulation, Design Control, Complaint Handling and MDR Reporting, Submissions, and General Regulatory Requirements training
- Facilitated numerous FDA inspections and ISO certification audits
- Extensive experience as a company FDA liaison and negotiations
- Expert in responses to FDA 483 observations and warning letters
- Extensive experience in the review and approval of labeling and promotional materials
- Experienced in acquisition and OEM due diligence for regulatory, compliance and liability status
- Represented Johnson & Johnson on HIMA (AdvaMed) Software Task Force and other software driven medical device industry/FDA initiatives

CREDENTIALS

- Lead instructor for AAMI GMP/QSR and Design Control courses
- Instructor for AAMI Software Validation and Process Validation courses
- Frequent speaker on software design controls, FDA software submissions, and other regulatory requirements at numerous trade association meeting
- Member, AAMI/FDA Software Hazard Management Working Group
- FDA expert witness
- Regulatory affairs consultant for the medical and in vitro diagnostic devices industry since 1998
- Director, Regulatory Affairs, Critikon, Inc., a Johnson & Johnson Company, Class II and III electronic and sterile cardiovascular and general hospital devices
- Director, Regulatory Affairs, InterVascular, Inc. (Datascope Corporation), Class II and III implantable cardiovascular devices
- Regulatory Affairs Specialist, Coburn Optical Industries, Inc. (Bausch & Lomb), Class II and III ophthalmic implantable and laser devices
- Regulatory Affairs Certified (RAC)
- Member, RAPS, ASQ, AAMI, ACRP
- University of South Florida, Tampa, FL
  BA, cum laude, Biology, 1977
  BA, cum laude, Science Education, 1978
  BA, Microbiology, 1979