SOFTWARECPR

RAFFAELE CALIRI

EXPERIENCE

- Over 33 years of medical device software project management, development and quality assurance
- Management of multi-national software development and testing groups
- Experience with software based In Vitro Diagnostic devices and clinical information systems
- Software Development and Validation Planning
- Software development process for compliance with ICE62304, FDA GPSV and other international standards
- Development of software development procedures and support templates compliant with IEC62304 and FDA guidances
- Software technical design reviews
- Software hazard analysis and risk management for IVD devices
- Requirements capture management, and traceability
- Architecture and implementation of real-time multi-tasking systems
- User Interface Design and Implementation
- Software projects localization, including far eastern languages using ideograms
- Software testing and validation planning, defects and changes management
- Experienced in performing and developing Tool Validation

CREDENTIALS

- SoftwareCPR course on Efficient Use of Medical Device Software Standards for Safety and Regulatory Compliance, Burlington, MA 2008
- AAMI's course on Software Validation Requirements and Industry Practice, Washington DC, 2006
- IBC, Amsterdam, Panelist in Workshop on Validation of Manufacturing & Quality System Software, 1997
- SER, Bruxelles, Panelist in Workshop on Software Evolution and Reuse, 1995
- Formerly International Director of Software for Instrumentation Laboratory
- Software Program Manager for several medical device projects.
- Responsible for software project transfer between different geographical locations
- Teacher for EEC classes on computer, software
- Speaks fluent Italian, English and adequate French
- Formerly member of IEEE Computer Society and IEEE Engineering Management Society
- Politecnico di Milano, Degree in Electronic Engineering, 1976