

Luigi Schiavello

Personal data

📅 09 January 1987

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giposi



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Profile

I am a Biomedical Engineer with over 9 years' experience in quality, regulatory and validation and verification (over 8 years in medical devices).

I worked in dialysis field (bloodlines, dialyzers, ultrafilter, cartridge), on Cells recovery machine (following transition from RUO to IVD) and a project as coordination on Automatic Cell Selection based on Cluster machine learning (following the IEC 62304). In all company following ISO 13485 standard.

As Regulatory Affairs Spec. I developed experience in knee/hip implantable prostheses (MDR class III, IIA and IIB) in particular Technical Files and Risk Analysis (ISO 14971:2012) preparation and management, Validation and Declaration of conformity preparation, Registration in EU (CE mark) and extra CE countries, Standards applicability management, Magnetic resonance standards,

I have experience also in Barcode scanner and mobile rugged phone, in particular: Safety Certification (CB, UL, CSA, CTIA 1725), Electromagnetic compatibility test, Cyber Security, Bluetooth qualification, WIFI technology test, radio certification for network approval (PTCRB and GCF) and North America Carrier Certification.

I'm very able to develop VBA macro for Excel with form (i.e I realized a database JASON based on artificial intelligence to store, find Certificates, Request of purchase and activities) and code Python code. I performed a code analysis to reverse engineering.

Starting from June 2019 I'm a professional recognized AIS Sommelier.

Professional Experience

QUA & REGULATORY ENGINEER- DATALOGIC | JUNE 2019 - PRESENT

- Responsible of Technical Files of handheld scanner (CE mark, FCC Registration in extra EU country)
- Representative in internal Core Team for handheld scanner and rugged mobile phone
- Manage Certification renewal Budget (different Country, CE mark, FCC et al.)
- Develop internal database (VBA excel) JASON based on (artificial intelligence) to store, find Certificates, Request of purchase and activities Develop and manage internal Declaration of conformity vba and Latex tool
- Reviewer of EMC report. Radiated emission, Conducted emission and immunity for CE part (ETSI standard, EN 55032, EN 55035, EN 61000) and FCC (FCC 15)
- Safety Certification (CB, UL, CSA, CTIA 1725),
- Bluetooth qualification and Wifi Tester
- Radio certification for network approval (PTCRB and GCF) and North America Carrier Certification.

REGULATORY AFFAIRS SPECIALIST - SAMO | JULY 2016 – JUNE 2019

- Technical Files and Risk Analysis (ISO 14971:2012) preparation and management as owner (MDR class III, IIB, IIA, I). Knee and hip implantable prostheses
- Declaration of conformity preparation
- Responsible of registration in EU and extra EU country

- Owner of Notification Body rapport (for Technical File) with 9 Audit from Notification Body and 2 from Italian Minister of Health
- Standards applicability management - Experience in orthopedics prostheses (ISO 14630, ISO 21534, ISO 21535), ISO 13485, Magnetic resonance standards, MDR
- Label concept (following MDR) and realization using Bartender tool
- Developer and management internal certification database (Access)

VERIFICATION AND VALIDATION ENGINEER - MENARINI SILICON BIOSYSTEM | MAY 2014-JULY 2016

- Analysis design, creation and testing of SDS and SRS Requirements, design and implementation of protocols following ISO 62304
- Concept of test verification and validation (use cases, usability, risk management, hardware and mechanical component, electric security design and control)
- Manage Anomaly Reviews, Validation plan, Verification plan following Quality system ISO 13485
- Coordinate a team to develop Automatic Cell Selection based on Cluster machine learning (artificial intelligence) basing on an internal and external survey
- Medical Imaging following IEC 62304-
- Experience in RUO machine, IVD machine, high-resolution microscope images, microscopy, data analysis.

CONSULTING - VERIFICATION AND VALIDATION- ALTEN/GAMBRO (BAXTER)| SEPTEMBER 2011 – MAY 2014

- Software and System tester
- Requirements analysis, Risk analysis review
- Conception, design and implementation of protocols, test verification and validation of instrumentation for hemodialysis (use cases, usability, risk management, hardware and mechanical component, electric security design and control)
- Experience haemodialysis field

CONSULTING - ALTEN – MAGNETI MARELLI | PROJECTY (1 MOUNTH)

- Using Matlab Simulink tool I'm responsible to target CAR centraline variables

CONSULTING - AJILE | PROJECTY (3 MOUNTHS)

- I perform a reverse engineering code analysis and documentation on the security part of JMG Cranes MC580 (Crane)

POST-DEGREE FOLLOW| CHEMICAL ENGINEERING, INDUSTRIAL CHEMISTRY AND MATERIALS DEP.TO UNIVERSITY OF PISA – MARCH 2011 – SEPTEMBER 2011

- Biomaterials, drug delivery, mass transport, development of polymeric membranes and nano-particle for drug delivery. I'm responsible on simulation on drugdelivery (Using Ansys or similar)

EDUCATION

MASTER'S DEGREE BIOMEDICAL ENGINEERING | FEBRUARY 2011| UNIVERSITY OF PISA (110/110)

BECALOR DEGREE BIOMEDICAL ENGINEERING | DECEMBER 2008| UNIVERSITY OF PISA (98/110)

CERTIFICATES – TRAINING

- MDR (2017/745) (KIWA Idea) 06/12/2018 – Bologna
- Risk Analysis for Medical Device: ISO 14971:2012 (KIWA Cermet) 08/06/2017 – Bologna
- CERTIFICATION requirements engineer– REQB 21-23/11/2013 - REQB
- CERTIFICATION software tester ISTQB (foundation) 06-09/03/2012 - ISTQB
- **Enabling to be an engineer “Abilitazione alla Professione di Ingegnere”2012- UN. OF PISA**

Scientific activities

- PODIUM presentation: Experimental and Computational Study of the Dual Drug Release from Polymeric Stent Coatings. M. Gagliardi, L. Schiavello, C. Cristallini. 24rd European Society for Biomaterials 2011 (ESB2011) in Dublin from September 4th to September 8th
- Strass project: study on speed skating and short track. Part1: Review and technique description, Students of Biomedical Engineering (L.Schiavello), F. Di Puccio, L.Mattei. Congresso Nazionale Bioingegneria (Pisa, 3-5 luglio 2008).
- Project: study on speed skating and short track. Part3: Modelling and simulation Students of Biomedical Engineering (L.Schiavello), F. Di Puccio, L.Mattei. Congresso Nazionale Bioingegneria (Pisa, 3-5 luglio 2008).

SKILLS

SOFT SKILLS

- Problem Solving
- Work under stress (with exp date)
- Work hard in autonomy for objective (passionate, proactive, precise, sunny, accurate)
- Team building (working and motivate the team with focused topic)

TECHNICAL SKILLS

- Requirement Analysis
- Cluster machine learning (artificial intelligence)
- Technical Files Preparation (in particular Risk Analysis)
- Budget preparation, Registration in extra EU country,
- CE mark, Validation following standard
- Project Management, Notify Bodies
- Finite elements analysis

COMPUTER SKILLS

- Office Base / Office Advanced (Access, Macro Excel, Power Point). Automate test, Database, Declaration of conformities
- Windows (Xp, Seven, 10)
- Linux (Ubuntu, Debian)
- Programming (C++, VBA, **Python**). Code decoding and analysis
- Matlab / Ansys (university experience and work experience)

LANGUAGES

Italian: Mother tongue language; **English:** Fluent written and median fluent spoken, **French:** school learning

FREE TIME

I read science fiction (I. Asimov) detective fiction books, look Thrillers, science. I watch fiction moviesI play Volleyball and Beach Volleyball. AIS Professional Sommelier – 3 levels course completed