MENARINI
silicon biosystems

Verification & Validation Engineer (REF_2103_ENG_VV)

Location: Castel Maggiore, Bologna, Italy

JOB DESCRIPTION

The resource will be involved, as part of Verification and Validation (V&V) team in the development of In Vitro Diagnostics (IVD) and For Research Use Only (RUO) products.

MAIN ACTIVITIES AND RESPONSIBILITIES

- Critical review of product specifications to assess requirements testability at Hardware, Software and System level.
- Define test strategies for Verification and Validation of applications, workflows and high technology products for IVD market
- Test Plan, Test execution and Test Reports editing needed for delivery of the IVD products
- Documentation according to ISO 13485 and FDA QSR 820 requirements
- Management of internal and external resources for test design, execution and related documentation
- Design Change management: requirements impact analysis and regression test definition

JOB REQUIREMENTS

- Master Degree in Electronic/Mechanical/Biomedical Engineering or Physics is required
- Experience of 3-5 years in V&V area in IVD or Medical Devices development
- Excellent written and verbal communication skills in English are needed
- Ability to interact and communicate with people from all areas and level of business, both verbally and written form
- Ability to create and give presentations and updates to team members on an international project
- Aptitude for problem solving
- Product Development Methodologies – V Model Waterfall, Agile
- ISO13485 & FDA 21CFR820 Medical Device QMS, DHF/DMR Documentation
- Design Control in compliance to CFR 820.
- ISO 14971 Medical Device Risks Management
- IEC 62304 Medical device software — Software life cycle processes
- Project Management and Scheduling
- Availability to national and international business trips

Menarini Silicon Biosystems S.p.A. is committed to equal opportunity in the terms and conditions of employment for job applicants without regard to race, colour, religion, sex, sexual orientation, age, gender identity or gender expression, national origin. Please, deliver your CV to employment-eng@siliconbiosystems.com and specifying into object field: "REF_2103_ENG_VV ".

Please be informed that by sending us emails at the above address you are consenting to: (i) the processing of the personal data submitted in your correspondence in line with Privacy Laws and with our Privacy Policy, which is available at www.siliconbiosystems.com/privacy; (ii) the transfer of your personal data outside the EEA.