

Verification & Validation Biologist (REF 2103 BIO 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

- Prepares biological samples from different origins (e.g. blood, forensic and FFPE)
- Develops and performs cell-based assays for verification and validation activities
- Collaborates with engineering units including R&D, technical support and manufacturing groups
- Develops conference materials, application notes and scientific papers
- Critical review of product specifications to assess requirements testability
- Define test strategies for the 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
- Design Change management: requirements impact analysis and regression test definition

JOB REQUIREMENTS

- PhD in sciences or equivalent acquired by professional experience
- Master's Degree in Biology or Biotechnology
- At least 5 years of experience in science field with proven experiences in cell culture, cell-based assay development, immunofluorescence staining, microscopy and image-based technologies, flow cytometry, immunomagnetic cell enrichment and sorting
- Experience in using CellSearch® system is a plus
- Experience in V&V area and/or in IVD/Medical Devices development is a plus
- Good skills in planning and execution of research projects
- Fluent English (written and spoken)
- 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
- Teamwork and problem solving
- ISO13485 & FDA 21CFR820 Medical Device
- Availability to national and international business trips

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