qmedics UNIQUE MEDICAL SOLUTIONS

We encourage and support new ideas and are always seeking to improve the quality of patients' lifes.

Qmedics AG is a privately held, independent Swiss medical technology company founded in 2008. We develop and manufacture stents, stent systems and balloon dilatation catheters. Our portfolio offers standard and customized products, solutions, and technologies. With our passion for life, we focus on innovation and enhancement of endovascular implants.

Are you our new experienced professional with passion in validation to support our growing Quality Affairs Team?

Validation Engineer 100%

Your Responsibilities

The Validation Engineer Job Description includes writing/executing qualification and validation documents on equipment, instruments, processes, and handle validation deliverables for projects.
Utilizing the lifecycle approach, the successful candidate will ensure activities are performed in accordance with the Site Validation Master Plan, project specific validation plans, and applicable SOP's.
The position is also responsible for the analysis of data, completion of validation plans, protocols, and reports. Specific duties include validation of equipment, Medical device systems and processes.
Develops validation master plans, schedules, protocols, and reports for systems that may be complex in nature, to support clinical and commercial manufacturing.
Coordinates Activities with Validation, Development, Manufacturing, Engineering, Quality, and other groups on validation projects to ensure validation projects are carried out on time and on budget.

Your Qualifications

- Must have a Master's degree in Engineering with five years of practical experience or Bachelor's degree in Engineering or relevant technical discipline with seven years of practical medical device experience.
- Five or more years of general Verification & Validation experience of which two or more years of V&V experience working on regulated medical device industry.
- Excellent knowledge of validation principles including commissioning, IQ/OQ/PQs related to equipment and facilities as well as ability to design and setup test benches.
- Familiarity with a statistical software tool is a plus and / or experience in engineering tools and software languages (Visual Basic, SQL, Labview).
- Good interpersonal skills and the ability to work well in an international team environment.
- Excellent technical writing, communication, and organizational skill.
- Must have extended knowledge on all ISO, GMP, and other International regulations.
- Working knowledge of Product and Process development, Risk Management, Design Validation and Regulatory Systems.
- Experience with balloon catheters & stent systems is a plus.

You will find a challenging position in a motivated expert team. Qmedics AG is a growing innovative company with the ambition to make a substantial contribution to a world where everyone enjoys life without limitations.

We look forward to receiving your application at HR@qmedics.ch to the attention of our HR Manager Mrs. Monica Baumann. Please note, that we do not work with recruitment agencies to fill this vacancy. Only direct applications will be considered.