From Eye to Insight

Leica Microsystems is a world leader in microscopes and scientific instruments with a history marked by unparalleled innovation on its way to becoming a global enterprise.
Its historically close cooperation with the scientific community is the key to Leica Microsystems' tradition of innovation, which draws on users' ideas and creates solutions tailored to their requirements. At the global level, Leica Microsystems is organized in three divisions, all of which are among the leaders in their respective fields: the Life Science Division, Industry Division, and Medical Division.
Leica Microsystems has six manufacturing facilities in five countries, with sales and service organizations in 20 countries. The company is headquartered in Wetzlar, Germany.

For our R&D team in Heerbrugg, Switzerland we are looking for a personality as

Manager Verification & Validation Lab (f/m)

Key Responsibilities:

- Definition of the strategy and planning of all V&V activities
- Responsible for the definition and improvement of test processes, techniques, tools and laboratory management
- Improvement and extension of automated duration testing
- Definition, improvement and implementation of SOPs
- Verification and validation planning, execution and reporting according the applicable standards, directives and regulations for medical devices
- Participation in review meetings of requirements, specification, design and finally verification and validation reports
- Coach, motivate and engage with direct reports to drive Verification and Validation to the next level by having a motivated and high performing, winning team
- Planning of the team resources across all projects according schedules and all other lab topics.
- Responsible for the test area, equipment park and test infrastructure
- Responsible for the on-time delivery of the R&D part for the Device History File (main lead is with RA/QA) plus user documentation (IFU)
- Support with production issues and customer complaints plus proposals for product improvement and cost savings
- Support of the production during design transfer in NPI projects including the Outgoing Inspection planning and reporting

Key Requirements:

- Bachelor or Master in Mechanical or Medical Engineering
- Minimum 7 years of experience in the area of Verification, Requirement Management and Traceability, out of that in minimum 5 years in the field of Medical Devices.
- Minimum 5 years of technical experience in team management and / or management of complex projects

- Experience in Risk management for Medical Devices
- Familiar with regulated (medical) environment (FDA/GMP, QSR, IVDD, ISO 13485), and Laboratory- and Test automation
- Experience in Quality Engineering is appreciated
- Further education in QSR requirements and Project Management is appreciated
- Strong written and verbal German and English communication skills
- Ability to create a V&V Strategy for Medical by understanding risks, strengths, weaknesses, opportunities and threats and translates this into actionable plans
- Proven leadership skills with the ability to take the lead in a team, manage by influence and also function as a team player

Are you interested to work independently in a team orientated environment, do you want to go new ways and solve innovative issues?
Thomas Gläser is looking forward to your application to thomas.glaeser@leica-microsystems.com or apply online at:
https://danaher.taleo.net/careersection/external/jobdetail.ftl?job=RES000079