



Leica Microsystems (Schweiz) AG is part of the international Leica Microsystems group, a world leading company for microscopy and laboratory technology. Since 2005, we are part of the successful American Danaher Group. At our Swiss location in Heerbrugg, we are developing and marketing surgical microscopes for medical applications, as well as, stereo and digital microscopes. The consistent development of innovative products makes Leica Microsystems a successful, globally active company in a leading market position.

To support our local RA&QA Team, we are looking for you!

## Quality Assurance Engineer (m/f)

You are responsible for:

- Quality assurance during design, development, verification, and validation, as well as, design changes of Leica Microsystems Surgical Operating Microscopes and Accessories;
- Verifying new product development and design changes to ensure compliance to ISO 13485, FDA 21 CFR Part 820 and other international regulatory requirements. You will actively participate in such projects representing both quality assurance and the customer;
- Supporting the RA/QA Manager and Project Leaders during internal and external audits;
- Performing design transfer reviews at our contract manufacturer in Singapore;
- Organizing training sessions on Quality System Regulations related to Design Control;
- Supporting, or where appropriate, taking leadership on CAPA for product quality issues.

Your Profile is:

- Bachelor's degree (BA/BS) from four-year college or university in science, engineering or equivalent;
- Minimum 2-3 years proven QMS, QA and/or RA and/or R&D experience with medical electrical devices in an FDA-regulated industry, or equivalent combination of education and experience;
- International experience in problem solving, complaint handling or equivalent, ideally from a R&D or RA/QA environment;
- Knowledge of US and EU medical device regulatory requirements;
- Fluent in English (mandatory) and preferably German also.

Interested ladies and gentlemen, who are willing to work flexibly and independently in a team-oriented matrix organization, please click here:

<https://danaher.taleo.net/careersection/external/jobdetail.ftl?job=REG000022>