# Job Advertisement

- Position: Regulatory and Quality Affairs Manager for Medical Devices
- Division: European Medical Systems Division
- Company: FUJIFILM Europe GmbH
- Date: 20th February 2019

FUJIFILM is a globally operating technology group. Committed to continuous innovation FUJIFILM brings leading-edge products to a broad spectrum of industries including imaging, medical, graphic arts, consumer electronic, optical and biopharmaceutical products based on its vast portfolio of digital, optical, fine chemical and thin film coating technologies.

FUJIFILM Europe GmbH is the regional headquarter company of the FUJIFILM group based in Düsseldorf and represents the aforesaid business divisions throughout Europe and in some cases throughout EMEA. FUJIFILM Europe operates through local and international branches and subsidiaries.

For our European Medical Systems Division located at FUJIFILM's European Headquarters in Düsseldorf we are looking for a

**Regulatory and Quality Affairs Manager for Medical Devices (m/f/div)**.

This position will support FUJIFILM´s medical business in the area of X-ray, IT, IVD and Endoscopy medical devices.

## Organization

The European X-Ray (EX) department, with its HQ position at FUJIFILM Europe GmbH in Düsseldorf, is responsible to carry out sales strategies and service operations for diagnostic imaging in Europe.
Our products and technologies are proven in clinical applications, and are constantly being refined to make the work of health professionals more effective and efficient. The portfolio includes picture archiving and communication systems (PACS), digital radiography, digital mammography, computed radiography, X-ray films, dry imagers, clinical chemical analyzers and ultrasound systems and continues to grow.
Fujifilm is a pioneer in diagnostic imaging, and for decades has been a reliable partner for hospitals and doctors.

## Your tasks and responsibilities include:

This position is intended to lead and oversee the FUJIFILM European Medical Systems division's Regulatory, Quality and Compliance program. This position is intended to partner with all internal and external stakeholders to ensure that a fully compliant and efficient Regulatory, Quality and Compliance program is developed, deployed and maintained.

- Develop, deploy, maintain and oversee a fully compliant and efficient company-wide Quality Management System at FUJIFILM European Medical Systems Division, all FUJIFILM European entities and dealers.
- Develop, deploy, maintain and oversee the following fully compliant and efficient company-wide programs at FUJIFILM European Medical Systems Division, all FUJIFILM European entities and dealers:
    - Regulatory Affairs program
    - Corporate Compliance program

- Represent the Regulatory and Quality Affairs function and provide regulatory and Quality guidance and strategy to our parent companies and give European wide regulatory and Quality affairs support for FUJIFILM entities and dealers
- As the Medical Devices Regulations (MDR) Project leader in European Medical Systems Division, ensure FUJIFILM Medical Systems Division, entities and dealers are compliant with MDR.
- Act as medical regulatory and Quality affairs representative for European (but especially to German) Competent Authorities, external partners and in-house functions
- Act as Safety Officer for medical devices and organizing incident reporting and execution of Field Safety Corrective Action (FSCA) for FUJIFILM
- Keep strong relationships with Industry associations and organizations
- Report to FUJIFILM worldwide headquarters and Senior Management level of European Medical Systems division.

**What we expect from you:**

- Bachelor of Science Degree.
- 10 or more years of executive leadership experience, building, leading and maintaining a Global Regulatory, Quality and Compliance program in the medical device industry.
- Deep knowledge of European Medical Device Directive and Medical Device Regulations and international standard requirements (ISO 13485/ISO9001, ISO 14971, IEC 62304, FDA regulations and guide lines).
- Comprehensive knowledge of European international premarket and post-market regulatory requirements.
- Strong knowledge of Corporate Compliance laws and regulations
- Excellent leadership, communication, collaboration, team work and interpersonal skills.
- Superb ability to effectively communicate with staff members and business partners at all levels of the organization (both internal and external).
- Excellent talent assessment skills.
- Strong ability to multi-task and to meet business deadlines.
- Excellent organizational skills with an ability to think proactively and prioritize/deploy work.
- Organization and planning skills.
- Project management, presentation, communication, negotiation and interpersonal skills.
- Written and conversational fluency in professional English is required. Proficiency in German is favorable.
- Team spirit and cross-cultural awareness.

Enjoying working professionally in international teams is one of your strengths. We offer you an exciting, challenging position with highly international work, an attractive compensation package and the social benefits of an international company.

If you are interested in joining our European Medical team, please send your application (including education and qualification certificates) until 8th March preferably by e-mail to: Ms. Silja Bischoff (silja.bischoff@fujifilm.com).