

CAREERS IN SOFMEDICA

SofMedica is dedicated to providing thousands of patients with innovative medical technologies, aiming to ensure progress for the benefit of as many patients as possible by **creating a bridge between the latest and most innovative medical technologies, patients and healthcare professionals.**

We are a Company that is driven by our values: Passion, Synergy, Change. These values guide our actions every day and describe how we will achieve our vision.

Quality & Regulatory Affairs Specialist, Romania

Required skills and experience

- University degree in the medical, scientific or engineering field;
- Solid medical knowledge;
- Good knowledge of national and EU medical devices regulations;
- Minimum 3 years experience in regulatory affairs and quality management system;
- Well organized and meticulous;
- Analytical skills;
- Computer literate: at least Microsoft Office (Word, Excel, Outlook);
- Good understanding of performing the above quality & regulatory tasks;
- Proactive approach and excellent communication skills (written and verbal);
- Fluent English and Romanian.

Key responsibilities for this position include, but are not limited to:

- Documents management update process (e.g. CE, DoC, ISO, IFUs, labeling);
- Management of the updated versions of approved marketing materials;
- Performing necessary activities related to Quality management systems processes (e.g. nonconformities, corrective actions etc.);
- Preparing regulatory documents necessary for participation in tenders;
- Handling complaints from customers.

Terms

This is a full time position. SofMedica Group is an equal opportunity employer committed to workforce diversity

The offer

- Opportunity to work in one of the most innovative healthcare companies in South Eastern Europe, with high standards in our work environment and ethics;
- Opportunity to work in a dynamic and fast-evolving market;
- Opportunities for training and professional development in Romania and abroad;
- Our Company is offering a competitive compensation and benefits package extending to medical coverage, wellness, and transport.

