

Turkey Jobs Expertini®

Senior Regulatory Affairs Specialist

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Company: Stryker

Location: Kayseri

Category: other-general

Are you interested in working for a global company where you can work across functions and on a wide-variety of projects? As a member of Stryker's RA/QA team, that is exactly what you will do! Here, we provide our RA/QA team the opportunity to learn new things, as well as endless growth opportunities! If you are interested in working at one of the World's Best Workplaces, apply now !

Need another reason to apply? Here are 10 reasons to join our Regulatory Affairs/Quality Assurance team:

We are currently seeking a Senior Regulatory Affairs Specialist to join our Medical Division to be based at our offices in Kayseri, Türkiye.

Who we want:

Self-directed initiators People who take ownership of their work and need no prompting to drive productivity, change, and outcomes.

Strategic thinkers People who enjoy analyzing data or trends for the purposes of planning, forecasting, advising, budgeting, reporting, or sales opportunities.

Collaborative partners People who build and leverage cross-functional relationships to bring together ideas, data and insights to drive continuous improvement in functions.

Dedicated achievers. People who thrive in a fast-paced environment and will stop at nothing to ensure a project is complete and meets regulations and expectations.

Goal-oriented developers. Keeping the customer and requirements squarely in focus,

people who deliver safe and robust solutions.

What you will do:

As the Senior Regulatory Affairs Specialist, you will enable and maintain global market access for new and innovative medical devices within Stryker's Acute Care portfolio. You will be the regulatory affairs lead on new product development teams, analyze the impact of medical device modifications, support regulatory aspects of the quality management system, and interpret emerging regulatory intelligence. You will enable global market access in Türkiye and liaise with global Stryker teams to execute registrations in other global markets in accordance with health authority requirements. You will lead throughout the business as the regulatory affairs subject matter expert for all devices manufactured in Kayseri, Türkiye.

Provides regulatory input and technical guidance on global regulatory requirements to product development teams

Leads in the development of regulatory strategy and updates strategy based upon regulatory changes

Determines requirements (local, national, international) and options for regulatory submission, approval pathways, and compliance activities

Prepares and submits regulatory submissions according to applicable regulatory requirements and guidelines

Evaluates device modifications and takes appropriate action to ensure global product compliance.

Identifies the need for new regulatory procedures, SOPs, and participates in development and implementation

Helps train stakeholders on current and new regulatory requirements to ensure organization-wide compliance

Assesses regulatory intelligence to assist in the development of local, regional, and global regulatory strategies

What you need:

A Bachelor's Degree (B.S or B.A) is required.

A minimum of 2 years of Regulatory Affairs experience.

Türkiye regulatory submission experience required.

Fluent Turkish and English language proficiency required.

Ability to understand and explain detailed regulatory compliance requirements and/or issues.

Ability to comply with constantly changing regulatory procedures and prioritize work effectively.

Ability to analyze and resolve non-routine regulatory issues using independent judgment.

Excellent analytical and writing skills.

Excellent interpersonal, written, and oral communication skills.

Effective organizational skills.

Advanced PC skills with proficiency in Microsoft office Suite, including Word and Excel.

About Stryker Stryker is a global leader in medical technologies and, together with its customers, is driven to make healthcare better. The company offers innovative products and services in MedSurg, Neurotechnology, Orthopaedics and Spine that help improve patient and healthcare outcomes. Alongside its customers around the world, Stryker impacts more than 130 million patients annually. More information is available at

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