Turkey Jobs Expertini®

Senior RA Specialist

Apply Now

Company: CooperCompanies

Location: Turkey

Category: other-general

JOB TITLE : Senior Regulatory Affairs Specialist

LOCATION: Remote/Hybrid

WORKING HOURS : 37.5 Hours, Monday to Friday

A brighter future awaits you

At CooperVision, we are proud to be the global leader in contact lenses. At our innovative sites worldwide, we manufacture and distribute contact lenses to some of the biggest names in optics. We're all about creating brighter futures for our customers, our wearers and our people.

What can you expect from us as an employer? Well, we like to look at things a little differently. We call it bringing a refreshing perspective. And for every one of us who works here, it means our opinion really counts, we get to share our ideas, and we get to make an impact.

We're big on belonging. Because being part of something great is what makes our company the best it can be. And we value diversity, because you can see a whole lot more when you have different perspectives. We're an ambitious company. And to help us achieve our goals, we'll give you all you need to achieve yours.

What will you be doing:

As a Senior Regulatory Affairs Specialist, you will be expected to l provide Regulatory support and direction to products from concept to launch. You will also be required to follow the regulatory strategy for assigned corporate projects including providing assists in creating, developing, and implementing global regulatory affairs procedures for marketed products and

to ensure company's regulatory compliance status.

The Senior Regulatory Affairs Specialist fulfils some of the responsibilities of the Person Responsible for Regulatory Compliance, per Article 15 (3) of the MDR, in a shared capacity.

Essential responsibilities:

Registration Activity

Prepares, compiles, and submits regulatory documents for the registration of current and new products in assigned markets.

Maintains submission documents, and agile databases in an accurate, complete and timely manner to ensure prompt and accurate access to company regulatory information.

Monitors pending submissions to ensure timely approvals. Communicates to management any identified delays that may impact business expectations.

Monitors approved registrations in respect to expiry and ensures management is aware of action required to renew in a timely manner to ensure no disruption in product distribution.

Interacts with Regulatory Affairs personnel at regulatory agencies, consultants, contract manufacturers, and distributors to ensure requirements are understood and submissions are complete and accurate to avoid any potential delays in approval.

Monitoring Registration Requirements within Region

Works with in-country representatives, contractors or perform independent research to determine regulatory requirements for product registrations in responsible regions

Maintains up-to-date knowledge of regional and national regulations, guidelines, and advisory documents required for marketing CooperVision products in a specified region.

Communicates applicable regulatory requirements to CooperVision Regulatory Affairs management and business partners.

Analyses impact and communicates to management changes in regulations or requirements that have been identified.

Compilation of Technical Documentation

Authors STED and GSPR documents and compiles Notified Body submissions in line with CooperVisionTechnical documentation procedures for MDD and or MDR.

Supports RA Management with Notified Body requests for information.

Support to CooperVision Processes
Represents the perspective of regulatory affairs to the company.

Interprets general business objectives and effectively present information to manager and regions.

Reviews and approves product labelling. Initiates IFUs and other required product labelling in line with relevant UK, EU, ACE & MENA requirements.

Supports “Own Brand” and “Private label “ customers and liaises with EU Competent Authorities and other Ministries of health as necessary

Provides input to Regulatory Affairs Impact Documents (RAIDS) from aUK EU, ACE & MENA perspective.

Undertakes other administrative tasks to support CE marking and regional registrations.

Responsible for exhibiting professional behaviour with internal and external business associates that reflects positively on CooperVision, The individual conveys a trustworthy, credible, and reliable image at all times.

Act as a resource to the regions on quality issues and propose changes to minimise risks and enhance quality, reliability, safety and productivity.

Act as spokesperson, when appropriate, regarding CooperVision practices, public policy, business interests; arrange for technical explanations from internal or external experts.

Support RA compliance activities as necessary in assigned regions

PRRC
Ensures that, per Article 15 (3) of the MDR: the technical documentation and the EU declaration of conformity are drawn up and kept up-to-date; the post-market surveillance obligations are complied with in accordance with Article 10(10) of the MDR; the reporting obligations referred to in Articles 87 to 91 of the MDR are fulfilled;

in the case of investigational devices, the statement referred to in Section 4.1 of Chapter II of Annex XV of the MDR is issued.

This individual has autonomy to perform the duties of Person Responsible for Regulatory Compliance (PRRC) under the EU MDR. This individual shall suffer no disadvantage within the organization in relation to proper fulfilment of his or her duties in lieu of article 15 of the EU MDR.

What are we looking for?

3-6 years of medical device regulatory experience.

Experience of working within UAE, Turkey, India, Iran, Jordan & neighbouring countries.
We would also consider a candidate who is based in these geographical locations.

Technical writing experience. Has experience evaluating manufacturing changes for impact on global regulatory affairs submissions.

Medical device industry experience including strong working knowledge and experience with MDD and MDR.

Ability to operate in a business driven model providing quick, salient analysis and concrete action plans emphasis on understanding and anticipating business needs and interests and devising proactive approaches/responses.

Must have the ability to build relationships and influence decision makers.

Comprehension of industry developments and changes in the political environment.

Extensive network-building and contact experience.

Capability to interact effectively and credibly at senior levels.

Experience in electronic document management systems

Strong IT skills, problem solving ability, analytical and communication skills.

Education:
Bachelor’s degree in a scientific or technical discipline and working knowledge of medical device regulations.

In addition, you’ll have experience in:
Understanding of ISO 13485 requirements and EU medical device regulations.

Ability to read and understand technical material.

Computer literate, with intermediate skill in the use of Word, Excel and Outlook, and some knowledge of relational database systems, . Agile Project Management system.

Ability to work effectively either alone or as part of a team. Managing time effectively and completing tasks on time with general supervision.

Experienced at reviewing and approving product labelling.

Able to work effectively in multinational/multicultural environments.

Flexibility to work across the UK sites

What we offer

You'll receive competitive compensation and a fantastic benefits package including; 25 days holiday, pension scheme, healthcare cover, life assurance, access to our Wellness Platform to support you in mental health and wellbeing, a discounted contact lens scheme and much more!

Apply Now

Cross References and Citations:

1. Senior RA Specialist Seouljobs Jobs Turkey Seouljobs ↗

2. Senior RA Specialist Searchamericanjobs Jobs Turkey Searchamericanjobs ↗

3. Senior RA Specialist AdminjobsJobs Turkey Adminjobs↗

4. Senior RA Specialist MaintenancejobsJobs Turkey Maintenancejobs↗

5. Senior RA Specialist Healthybird Jobs Turkey Healthybird ↗

6. Senior RA Specialist Researchjobs Jobs Turkey Researchjobs ↗

7. Senior RA Specialist ElectricianjobsJobs Turkey Electricianjobs↗

8. Senior RA Specialist Mediajobs Jobs Turkey Mediajobs↗

9. Senior RA Specialist Omanjobs Jobs Turkey Omanjobs↗

10. Senior RA Specialist Muscatjobs Jobs Turkey Muscatjobs ↗

11. **Senior RA Specialist Chilejobs Jobs Turkey Chilejobs ↗**
12. **Senior RA Specialist Searchukjobs Jobs Turkey Searchukjobs ↗**
13. **Senior RA Specialist Finddriverjobs Jobs Turkey Finddriverjobs ↗**
14. **Senior RA Specialist JobscareerscentralJobs Turkey Jobscareerscentral ↗**
15. **Senior RA Specialist CopenhagenjobsJobs Turkey Copenhagenjobs ↗**
16. **Senior RA Specialist Teachingassistantjobs Jobs Turkey Teachingassistantjobs ↗**
17. **Senior RA Specialist Searcheuropeanjobs Jobs Turkey Searcheuropeanjobs ↗**
18. **Senior RA Specialist Pinkcollarjobs Jobs Turkey Pinkcollarjobs ↗**
19. **Senior ra specialist Jobs Turkey ↗**
20. **AMP Version of Senior ra specialist ↗**
21. **Senior ra specialist Turkey Jobs ↗**
22. **Senior ra specialist Jobs Turkey ↗**
23. **Senior ra specialist Job Search ↗**
24. **Senior ra specialist Search ↗**
25. **Senior ra specialist Find Jobs ↗**