

# REGULATORY AFFAIRS SPECIALIST

*Posted on 18 december, 2023*

**Company Name** Carasent

**Location** Göteborg

**Job Description**

## About the Role:

Are you excited about making a meaningful impact on patient care through improved documentation and regulatory compliance? Do you thrive in a dynamic and innovative environment? If so, Carasent invites you to join our growing Compliance team as a Regulatory Affairs Specialist in Gothenburg.

You will play a vital role in securing all our technical documentation and making sure we are compliant with all external regulations. As an integral part of the Compliance team, you're contributing to the improvement of our quality and regulatory efforts. The RA Specialist will be the point of contact in all regulatory matters for our cutting-edge medical software solutions.

## Key Responsibilities:

- Collaborate with cross-functional teams to ensure compliance with regulatory requirements in the development and maintenance of Carasent's medical software solutions
- Support the creation and maintenance of technical documentation, submissions, and product registrations
- Conduct regulatory assessments and provide guidance on the impact of new regulations on product development
- Interface with regulatory agencies to facilitate efficient and successful product registrations
- Influence and optimize QA/RA processes, implementing changes in collaboration with the rest Compliance team
- Educate and collaborate with colleagues across the organization to ensure understanding and adherence to regulatory requirements.

## Requirements:

- Proven experience in Regulatory Affairs or SW Development
- Familiarity with software development processes and the regulatory requirements associated with software in a medical context.
- Excellent communication and interpersonal skills to effectively collaborate with internal teams and external regulatory agencies.

## Desirable:

- Knowledge of, or interest in, information security and its standards (ISO 27001)

## Why Carasent?

- Joining us means immersing yourself in a blend of start-up dynamism and established brand strength. You'll be part of a journey that fuels professional and personal growth, supported by a culture of inclusion, teamwork and humbleness.
- Enjoy the flexibility of a Hybrid Office: We champion the balance between in-person connections and remote work, fostering an environment that respects collaboration and individual well-being.
- Unite in Fun and Learning: Expect many engaging activities – from trivia nights to workshops, festive celebrations, and team activities – fostering an environment where collaboration flourishes.
- A Constantly Evolving Journey: We're a fast-paced, growth-oriented SaaS enterprise, constantly striving for progress. To flourish in this role, perseverance, strategic thinking, and a deep belief in the power of teamwork are essential.

## Application:

This recruitment is managed by our recruitment partner, Moveup Consulting AB. To apply, please send your CV to Fredrick Asare at [fredrick.asare@moveup.se](mailto:fredrick.asare@moveup.se)

If you have questions regarding Carasent or this open position, please contact Fredrick Asare at +46 733 440 900 or [fredrick.asare@moveup.se](mailto:fredrick.asare@moveup.se)

As part of our recruitment process, we do background checks for the final candidate. *By submitting your application, you also consent to us storing your personal data, including CV & cover letter and that*

*we have the right to share this information with third parties (our client). You can revoke the consent whenever you want*

## **Om företag**

### **About Carasent:**

*The health tech group Carasent shares the mission to enhance efficiency and quality within the healthcare industry. The group provides expertise and technological solutions that streamline administrative processes while offering access to crucial data, equipping customers with the right tools to tackle present and future challenges. The current product portfolio includes electronic health record systems and value-adding services. The core products Webdoc, Metodika, Medrave, HPI, Ad Curis, and Ad Opus, each hold a prominent position in its target market. Carasent is publicly listed on the Oslo Stock Exchange and headquartered in Gothenburg. Sweden.*