

CLINICAL AFFAIRS SPECIALIST

Posted on 28 augusti, 2025

Company Name Breas Medical AB

Location Stockholm/Skåne/Göteborg

Job Description

At Breas Medical, we improve the quality of life for respiratory patients worldwide. Our mission: innovation, quality, and customer focus.

Are you a solution-driven professional who thrive when working independently, meets deadlines, and has a keen eye for detail? If clinical affairs and regulatory compliance excite you, join our mission to make a real difference for patients.

We are currently expanding our market presence and we're looking for a **Clinical Affairs Specialist** to strengthen our clinical and regulatory activities. You will manage and update documentation for Clinical Evaluation, Post Market Surveillance (PMS), and Post Market Clinical Follow-Up (PMCF) in line with applicable MDSAP and US regulations.

Key responsibilities include conducting literature reviews, collecting and structuring data, retrieving vigilance information, and updating State of the Art reports. You will also perform clinical activities such as customer surveys to generate necessary data.

Main Responsibilities

- Lead clinical evaluations and post-market activities
- Compile and analyze clinical and regulatory data
- Ensure compliance with applicable MDSAP and US regulations
- Collaborate cross-functionally to support product safety and performance

To be successful in this job, we believe that you have:

- Experience from clinical/medical affairs positions within the Medtech industry, including hands-on experience of writing clinical evaluations and PSUR for minimum Class II devices
- Good understanding of Design Control in accordance with ISO 13485 and risk management in accordance with ISO 14971 and the implications on clinical evaluation and PMS requirements
- PhD or Master's degree in relevant field

On a personal level you enjoy working independently; initiating, planning, and completing tasks within set timelines. You have a strong attention to details, but still the approach to getting things done. You can also work in close cooperation with internal resources and external partners when needed.

Be Part of a Mission That Makes a Difference

At Breas, you'll be part of a dedicated global clinical team with deep expertise in ventilation, airway clearance, and sleep solutions. We work across borders and disciplines to develop products that make a real difference in the lives of patients. Here, your work will directly support innovation and patient safety in a company where quality and compassion go hand in hand.

To apply

In this recruitment Breas is collaborating with Moveup Consulting.

For questions regarding the position, please contact Recruitment Consultant Tom Bergqvist +46 733 87 27 22.

Please send your CV to tom.bergqvist@moveup.se

By submitting your application, you also give your consent to storing your personal information, including a CV & Cover letter, and that we have the right to share this information with third parties (our client). You can withdraw your consent at any time.

We look forward to hearing from you.

Om företag

When you can't breathe, nothing else matters. That's why a career at Breas Medical matters.

Breas Medical is a global company headquartered in Sweden, with over 30 years of expertise in ventilation, airway clearance and sleep solutions. We are passionate experts dedicated to respiratory care, with unwavering focus on the patient and the caregiver, delivering high quality and reliable products. We respond to your changing needs with agility, and while growing globally, we take customer care personally. Our solutions cover a broad range of devices, consumables, service solutions, educational & training programs, and comprehensive connectivity capabilities to improve the quality of life of patients, from hospital to home.

Breas Medical employs over 300 people globally. Our solutions reach 50 countries around the world,

and we manufacture our product in four countries, China, UK, Sweden, and the US.

Find out more about Breas:

<https://educationbybreas.com>

<https://breas.com>

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