Clinical Affairs Associate (Medical Device Manufacturer)

Salary Range: £25,000 to £32,000 Location: Harrietsham, Kent

Full or Part Time Opportunity

This is a full or part-time role with a preferred working schedule of at least 30 hours per week within standard office hours (8:30 AM to 5:00 PM). However, there is some flexibility to consider slightly fewer hours for the right candidate. Once settled into the role, there will be an opportunity for hybrid working, with the arrangement tailored to align with the agreed hours. As a guide, full-time staff have the equivalent of up to two days per week working from home.

Interviews

The job advert closes on **12th February 2025**, with 1st stage telephone interviews during the week commencing **17th February 2025** and 2nd stage face-to-face interviews during the week commencing **24th February 2025**.

The Story:

Established in 1976, Bedfont is an award-winning medical technology company based in Harrietsham, Kent. Its breath analysis medical devices are exported globally thanks to its network of carefully selected distributors.

The Challenge:

Healthcare is evolving and the market for breath analysis monitors is expanding. Bedfont are looking for hard-working, like-minded, and passionate individuals to join the Bedfont Family to help achieve its goal of innovating healthcare worldwide.

The Benefits:

- 25 days paid holiday plus bank holidays
- Private medical insurance
- Subsidised health checks
- Annual optical allowance
- Pension scheme
- Bonus scheme
- Hybrid working
- Employee Assistance Programme (EAP)
- Rewards app
- Referral bonus
- Charity days
- Home office setup allowance
- Social events
- Well-being warriors
- Well-being garden and room
- Cycle to work scheme
- Employee awards
- Free on-site parking
- Training & development opportunities
- Free uniform
- Subsidised Celler8 device
- Subsidised kids club
- Time in service annual leave bonus
- Enhanced Maternity and Paternity Pay

Your Mission:

As the Clinical Affairs Associate you will coordinate key clinical and regulatory activities, including clinical evaluation, Post-Market Surveillance (PMS), Post-Market Clinical Follow-Up (PMCF), and risk management for medical devices. You'll work closely with the small Clinical & Medical Affairs team, contributing to the successful development, market introduction and maintenance of safe and effective medical devices. You will also assist with grant applications to secure funding for clinical research and development.

Our family, innovating health, for yours.

Bedfont® Scientific Ltd.
Station Yard, Station Road, Harrietsham, Kent, ME17 1JA, England. Tel: +44(0)1622 851122 Fax: +44(0)1622 854860 Email: ask@bedfont.com

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Roles and Responsibilities:

Clinical Evaluation:

- Help coordinate and maintain clinical evaluation plans and reports with the appointed consultancy, ensuring compliance with company procedures and regulatory standards.

Post-Market Surveillance (PMS):

- Assist in gathering and analysing clinical data to support device safety, update risk management files, and identify potential improvements.

Post-Market Clinical Follow-Up (PMCF):

- Contribute to PMCF studies, including preparing plans, managing data collection, and creating reports to ensure compliance with regulations.

Risk Management:

- Collaborate with the risk management team including periodic risk reviews to integrate clinical data into the risk management file (RMF).
- Assist in evaluating risks associated with clinical studies and post-market data to support device safety.

Biocompatibility:

- Assist in coordinating biocompatibility testing and assessments with the appointed consultancy to ensure the device materials are safe for human use.
- Support the development of biocompatibility documentation, including test plans, reports, and regulatory submissions, ensuring compliance with ISO 10993 and related standards.

SOP Development and Updates

- Help update and maintain Standard Operating Procedure's (SOPs) for clinical activities, ensuring they align with current regulations and best practices.

Grant Application Support

- Assist with identifying funding opportunities and preparing grant applications for clinical research and development.

Qualifications:

A bachelor's degree in Biomedical Science, life sciences, another related field or equivalent experience would be preferred. A qualification in medical writing and/or technical writing is preferred, but not essential. The following experience would also be advantageous:

- Previous experience in medical and technical writing.
- Previous experience in supporting PMS, PCMF, risk management, and clinical evaluation activities.
- Familiarity with regulatory requirements and guidance documents for medical devices, such as FDA regulations (e.g., 510(k), PMA) and international standards (e.g., ISO 13485, EU MDR, MEDDEV 2.7/1, ISO14155, MDCG).

Preferred Skills:

- **Strong Communication Skills:** Ability to convey information clearly, both in writing and verbally, to team members and consultants.
- **Attention to Detail:** Meticulous in reviewing data, documentation, and regulatory requirements.
- **Organisational Skills:** Capable of managing multiple tasks, projects, and timelines effectively.
- **Adaptability:** Thrives in a fast-paced environment with shifting priorities.
- **Regulatory Compliance Awareness:** Understanding of global regulatory landscapes, including EU, US, and international standards.
- **Self-Motivation:** Works independently with minimal supervision to meet goals.

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In addition, employees may be required to undertake other duties as may reasonably be required of them. In these circumstances training will be given where it is considered.

Bedfont® Scientific Ltd. does not and will not discriminate in the recruitment or managing of staff on the basis of race, colour, religion, gender, age, disability, marital status, sexual orientation and more. We are an equal opportunity employer and Bedfont® regards every employee as a member of the Bedfont® family and is committed to providing a fair, safe, diverse and welcoming atmosphere. Our application process has been designed so that everyone is able to demonstrate their skills and how they meet the criteria required for the job advertised. All successful candidates will be subject to a digital ID and DBS check. If you are interested in applying for this role, please visit https://www.bedfont.com/careers to apply.

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