

## Medical Writer

Salary Range: £36,000 - £42,000 DOE

Location: Harrietsham, Kent

### 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 healthcare
- Optical allowance
- Pension scheme
- Bonus scheme
- Hybrid Working
- Employee Assistance Program
- Rewards App
- Social events
- Well-being warriors
- Bike-to-work scheme
- Employee awards
- Free on-site parking
- Training & Development Opportunities
- Uniform

### Your Mission:

The Medical Writer will be part of the growing Clinical department at Bedfont. The Medical Writer specialises in medical devices and plays a crucial role in creating compelling and accurate content to support development, regulatory approval, and marketing.

Working closely with cross-functional teams, including Research & Development, Quality Assurance & Regulatory Affairs, and Marketing, the Medical Writer translates complex scientific and technical information into clear and engaging content tailored to various audiences, including healthcare professionals, regulatory agencies, and consumers.

### Roles and Responsibilities:

- Collaborate with cross-functional teams to understand product specifications, clinical data, and regulatory requirements for medical devices.
- Write and edit a variety of scientific and technical documents, including clinical study reports, regulatory submissions, product manuals, and marketing materials.
- Prepare clear, concise, and scientifically sound clinical documentation, including, but not limited to, Clinical Evaluation Plans (CEPs) and reports and Post Market Clinical Follow-Up (PMCF) plans and reports in accordance with medical device regulatory requirements and industry best practices.
- Help manage clinical evaluation processes to include developing detailed plans for conducting clinical evaluations, outlining objectives, methodologies, data sources and timelines.
- Conduct comprehensive Systematic Literature Reviews (SLRs) to gather relevant clinical data on similar medical devices, treatments, or technologies, and identify and review clinical studies, trials, and reports related to the medical device under evaluation.
- Interpret clinical evidence in the context of applicable regulations, standards, and guidelines (e.g., MEDDEV 2.7/1, MDR, FDA guidance).

### Bedfont<sup>®</sup> Scientific Ltd.

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- Collect and analyse clinical data, including safety and performance information, adverse events, and patient outcomes to support clinical evaluations and post market surveillance activities.
- Evaluate the clinical significance of findings and their relevance to the intended use and risk profile of the device to support ongoing clinical evaluation processes, post market surveillance activities, post market clinical follow-up activities, and risk analysis activities including benefit/risk analysis.
- Conduct literature reviews and research to stay abreast of industry trends, competitor products, and emerging technologies.
- Write and review educational marketing material to ensure consistency and compliance to current claims of medical devices we manufacture.
- Assist in the development and maintenance of document templates and standard operating procedures.
- Participate in internal and external meetings, providing insights and recommendations on medical writing-related matters.
- Support continuous improvement initiatives to enhance the efficiency and quality of medical writing processes.

### Qualifications and Experience:

A degree in a scientific or medical discipline is preferred however relevant equivalent medical writing qualifications and experience will be considered.

### Valuable Expertise:

- In-depth knowledge and understanding of performing systematic literature reviews (SLRs)
- Familiar with PICO framework search strategies
- Familiar with using literature search databases such as Embase and Pubmed
- Experience in writing clinical evaluation documentation to MEDDEV 2.7/1
- Previous experience in medical writing, preferably within the medical device industry
- Previous experience in Post Market Surveillance activities (PMS) and Post Market Clinical Follow-up activities (PMCF)
- 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).

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<sup>®</sup> 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<sup>®</sup> regards every employee as a member of the Bedfont<sup>®</sup> 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. If you are interested in applying for this role, please visit <https://www.bedfont.com/careers> to apply.

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